SUBMISSION

Consultation Regulation Impact Statement:

Managing the risks of respirable crystalline silica at work

Instructions

To complete this online submission:

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- Use the saved version to enter your responses under each question below. These questions are from the Consultation Regulation Impact Statement on managing the risks of respirable crystalline silica at work.
- Once you have completed your submission, save it and upload it using the upload your submission link on the Engage submission form.

Submissions will be accepted until **11.59 pm on 15 August 2022.**

Additional documentation

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Questionnaire

(Consultation RIS questions)

Statement of the problem (Chapter 2)

2.1 Do you agree with the identified problem? Has the entirety of the problem been identified? Please provide evidence to support your position.

I do not have an opinion.

2.2 Do you have further information, analysis or data that will help measure the impact of the problem identified?

Consider confirming the intent is to exclude dusts, other than RCS, that have similar hazards. E.g. Coal dust in a coal port, or power station (as opposed to a mine that is generally subject to other legislation).

Consider if the following states any useful information:

https://oem.bmj.com/content/79/5/319

https://www.safequarry.com/hotTopics/2021_nepsi_protocol_rcs.pdf

Consider identifying cases by completing a retrospective data analysis, of data collected for other reasons as stated in the following.

Monash Centre for Occupational and Environmental Health School of Public Health & Preventive Medicine Faculty of Medicine, Nursing and Health Sciences Monash University, 2016, Review of Respiratory Component of Coal Mine Workers' Health Scheme.

Why is Government action needed? (Chapter 3)

3.1 Do you agree with the case for government intervention? Please provide evidence to support your position.

I do not have an opinion.

3.2 Do you agree with the objectives of government intervention? Please provide evidence to support your position.

Consider stating "minimise so far as is reasonably practicable" instead of "reduce" to be generally consistent with the model legislation etc.

What policy options are being considered? (Chapter 4)

4.1 Do these options address the problem? Please provide evidence to support your position.

I do not have an opinion in general.

4.3: Consider including the statics of chronic deaths relative to immediate deaths in the awareness, e.g. https://www.whlgni.org.uk/the-scale-of-the-problem

4.4: Consider confirming the intent to state roadheaders relative to generic definitions, and/or other similar machinery e.g. continuous miners, and/or excavator with cutting attachment etc.

4.2 Are there any other non-regulatory or regulatory options you think should be considered to address the problem?

Consider completing "Targeted Assessment Program" similar in principle to the NSW Department of Planning and Environment, NSW Resources Regulator, though with increased: frequency, and scope, with "enforceable undertakings" [Work Health and Safety Bill 2011 (Not applicable) s 216] for non-conformances.

Consider stating that the WES is the maximum acceptable, and stating a specific obligation to minimise the WES so far as is reasonably practicable.

I am apprehensive to duplicate statements in general, and particularly in legislation.

Consider if any relevant lessons from the Inquiry into the re-identification of Coal Workers' Pneumoconiosis in Queensland e.g. publishing dust exposure, and mobile lung screening etc.

What is the likely impact of each option? (Chapter 6)

6.1 Is the cost modelling methodology appropriate to estimate the costs to industry and governments (Appendix D)? Please provide evidence to support your position.

Table 23: Consider stating existing cases to facilitate comparison.

Option.	Net Present Costs ($M).	Required number of silicosis cases prevented to breakeven (unitless).	Minimum Cases Currently (unitless).
Option 2.	6.08.	1.49	100.

Alternatively consider stating in the introduction, the maximum cases for any of the options required to breakeven of 48, is less than the actual minimum cases of 100, if(?) each option prevents the breakeven quantity of cases, all of the options provide a net positive benefit to the community.

Consider qualitatively/quantifying the number of cases prevented by each option.

Consider discussing the tolerability of the current RCS risk.

E.g. A minimum of 100 cases/year according to Figure 1.

The average mortality rate is 28 % according to Table 22.

I.e. The direct deaths due to RCS is a minimum of 28/year.

A coarse estimate of the “SEG” is 1 453 000 according to Table 5.

I.e. The likelihood of death due to RCS in the SEG is 7×10^{-7}/year.

A “broadly acceptable” level of risk is generally a maximum of 1×10^{-6} according to the following:

https://www.hse.gov.uk/managing/theory/r2p2.htm

I.e. The current risk is broadly acceptable, and hence consider stating justification for the proposed controls, including demonstrating that the proposed options’ incurred values are not “gross disproportion” to the risk reduction.

Also cost may be interpreted to include GST according to the following judgement, consider confirming that this was the intent.

Cityrose Trading Pty Ltd v Booth & Anor [2013] VSC 504.

6.2 Are the estimates of the number of businesses covered by each of the regulatory and non-regulatory options accurate? Please provide evidence to support your position.

I do not have an opinion.

6.3 Are there other factors that should be considered in the assessment of the effectiveness of each option (Section 6.5)? Please provide evidence to support your position.

I do not have an opinion.

6.4 Are the cost and other estimates (including worker wage assumptions) listed in Appendix D accurate and appropriate? If not, please provide additional data to support a more accurate estimate of costs.

I do not have an opinion.

6.5 Do you have further information regarding the costs to the public health system for silicosis and silica related diseases?

Considering the stated “high degree of uncertainty”, consider providing a sensitivity analysis. E.g. The effect to the recommendations if the values are say +/- 100 %.

I do not have facts, though according to my general experience, I propose that the cases will be the minimum due to not being: detected, and/or reported.

I observe that the failure to detect similar disease was identified during the Inquiry into the re-identification of Coal Workers’ Pneumoconiosis in Queensland (Monash 2016).

Monash Centre for Occupational and Environmental Health School of Public Health & Preventive Medicine Faculty of Medicine, Nursing and Health Sciences Monash University, 2016, Review of Respiratory Component of Coal Mine Workers’ Health Scheme.

Discussion of options (Chapter 7)

7.1 Which option or combination of the options presented is most likely to address the identified problem? Please provide evidence to support your position.

I do not have an opinion.

7.2 Are there any significant barriers to implementation of the options presented? What are those barriers? Is there a cost associated with them? How could they be overcome?

I do not have an opinion.

Other comment

Do you have anything further you would like to add as part of this process?

I do not have an opinion.

European Network for Silica (NEPSI)

Respirable Crystalline Silica Monitoring Protocol

June 2021

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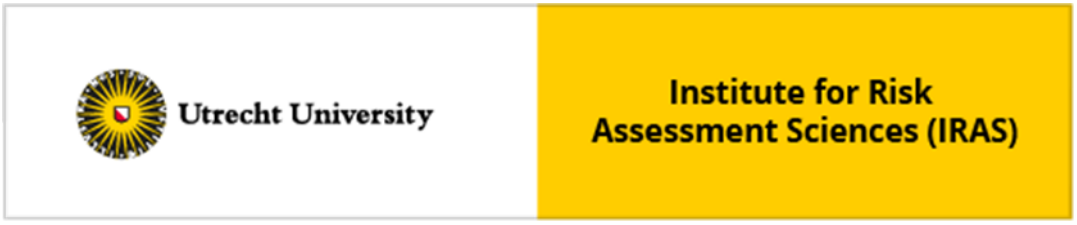

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Contents

Chapter 1 Context

On 25 October 2006 the NEPSI signatories[1] (European Network for Silica) signed an 'Agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products containing it', further referred to in this document as the NEPSI agreement (https://www.nepsi.eu/agreement). Dust exposure monitoring is one of the elements of this agreement, and a dust monitoring protocol was included as Annex 2 of the 2006 NEPSI agreement.

The recent debate on the new European Binding Occupational Exposure Limit has highlighted the need to further discuss monitoring of the exposure to respirable crystalline silica (RCS) within the NEPSI industrial sectors. The signatories of the NEPSI agreement have expressed the need for a NEPSI harmonised methodology to monitor the exposure to RCS among their members. The existing Annex 2 on Dust Monitoring within the NEPSI Agreement was considered to be too general and more specific and updated guidance for a common methodology to monitor respirable crystalline silica at their workplaces was needed.

On 26 February 2019 the newly established NEPSI roadmap was launched by the signatories of the NEPSI agreement. Several projects within the roadmap were defined, one of them being the 'Development of a NEPSI standardized RCS measurement methodology'.

For this purpose, the NEPSI partners commissioned in 2019 the Institute for Risk Assessment Sciences (IRAS) of Utrecht University in cooperation with the Netherlands Expertise Centre for Occupational Respiratory Disorders (NECORD) to prepare such a common basic methodology, which would enable the NEPSI partners to collect RCS exposure data in a harmonised way.

At the start of the project an inventory was made of existing sampling programs and/or protocols among all 18 NEPSI signatories by a short questionnaire via E-mail ('Does your organization have a dust monitoring program and/or a written protocol on sector level to perform representative exposure measurements of respirable dust and its crystalline silica content?'). Fifteen sectors (83%) responded to this inventory. Of the respondents four sectors (27%) indicated that a dust monitoring program at sector level existed. The other 11 sectors (73%) did not have a common protocol at sector level, however, within several of the sectors dust monitoring programs had been implemented at individual members (company) level.

Sectors that had monitoring protocols available (either at sector or at company level) were interviewed in more detail. In total, seven interviews were held with sector and/or company representatives: CEMBUREAU (sector), EXCA (sector), EUROMINES (one company), FEVE (2 companies), Glass Fibre Europe (one company), Glass for Europe (one company). In addition, detailed information was already available from IMA-Europe, since both IRAS and NECORD have been involved in the IMA Dust Monitoring Programme since 2006.

A standardized interview protocol was used with the following core items:

- What are the main aims of the dust monitoring program or protocol?
- What is the year of implementation of this program or protocol?
- What are the potentially exposed groups of workers covered by the program?

[1] Employers: ASTA Worldwide (engineered stones); BIBM (Precast Concrete), CAEF (Foundry), CEEMET (Metal, Engineering and Technology-Based Industries), CEMBUREAU (Cement), CERAME-UNIE (Ceramics), ECSPA (calcium silicate), EMO (Mortar), ERMCO (Ready-mixed concrete), EUROMINES (Mining), EUROROC (Natural Stones), EURIMA (Insulation Mineral Wool), EXCA (Expanded Clay), FEVE (Container Glass), Glass for Europe (Flat Glass), Glass Fibre Europe (Glass Fibre), IMA-Europe (Industrial Minerals), UEPG (Aggregates)
Trade Union: IndustriALL European Trade Union

- What were the sampling strategy and sampling methodology being used?
- What is described for data management (data handling, storage & confidentiality)?
- What are the main elements that should be covered in the new NEPSI harmonized protocol?

The results of this survey were presented and discussed during a NEPSI Technical Committee Meeting in Brussels on 3 December 2019. In addition, a short complementary two-question survey was held by E-mail among the participants just prior to the meeting:

- What are the most important reasons for your organization to have a NEPSI standardized RCS measurement methodology?
- From the perspective of your sector, what main elements need to be covered by the standardized protocol to meet these goals within your organization?

During the meeting an open discussion was held on the goals of the common NEPSI RCS Monitoring Protocol, and the particular guidance needed for specific elements. All respondents mentioned compliance testing with Occupational Exposure Limit Values (OELVs) as their first need of the protocol. In addition, the need to lower exposure levels and being able to compare exposure levels between members were seen as important.

The current RCS protocol has been developed with the input of NEPSI partners as described above and will answer the following questions:

- Why collect measurement data on dust and RCS? (Chapter 2 Objectives)
- What measurement strategy should be followed? (Chapter 3 Measurement Strategy)
- How should the monitoring take place? (Chapter 4 Metrology)
- How should measurement results be used and what format could be used to store and handle measurement data? (Chapter 5 Data management)
- What tools exist for statistical evaluation of measurement data? (Chapter 6 Statistical evaluation)

Although NEPSI partners have a mutual goal for a common RCS monitoring protocol, it is important to realize that the exact obligations for each sector or company may vary due to national legislation and or specific sector/company policies. The new protocol should therefore be seen as guidance on the basic principles of RCS monitoring, but at the same time it does allow for flexibility on many aspects to be able to comply with other existing obligations.

Chapter 2 Objectives

The main objective of this monitoring protocol is to provide a harmonized methodology to measure exposure to respirable crystalline silica (RCS) of workers employed at member companies of the NEPSI signatories.

The project aims to provide a common basic methodology to help those sectors who do not have a standardized monitoring methodology in place and enable these sectors to collect RCS exposure data in a harmonized and representative way. Guidance is provided on measurement strategy, appropriate sampling and analytical methods, and data management.

The implementation of the protocol is not mandatory, but should be considered as guidance for the development of a dust and quartz monitoring programme within all NEPSI partners.

Chapter 3 Measurement strategy

This chapter will focus on all aspects of the measurement strategy. More technical aspects (pumps, dust fraction, sampling heads, sampling flow, filters, analytical methods for RCS and blanks) will be covered in Chapter 4 Metrology.

Some companies will make use of external contractors for sampling and analysis of the samples. Annex 1 provides an instruction sheet for external contractors which summarizes relevant items of measurement strategy, practical sampling instructions end sampling- and analytical methods. All aspects are described in more detail in the following chapters.

Testing of Compliance with Occupational Exposure Limit Values (OELVs) was identified by the NEPSI partners as the main aim of this protocol. In Europe, the technical standard EN-689 "Workplace exposure – Measurement of exposure by inhalation to chemical agents – Strategy for testing compliance with occupational exposure limit values" provides guidance on how to evaluate exposure measurement data in relation to an OELV, and was recently updated in 2018.

It should be kept in mind, that the approach outlined in EN-689 is not a mandatory approach, but should be seen as mere guidance. EN-689 was therefore used as the starting point of this protocol.

In this chapter the following topics will be covered:

- Similar Exposure Groups (SEGs)
- Type of sampling (personal sampling versus static sampling)
- Sampling duration
- Number of samples needed
- Number of workers per SEG to be sampled and number of samples per worker
- Periodicity of sampling

Similar Exposure Groups (SEGs)

As it will not be feasible to sample each individual worker in a company, all workers have to be classified into groups of workers with an assumed similar exposure, so-called Similar Exposure Groups (SEGs). Those SEGs are defined before the actual sampling takes place and will form the sampling frame from which workers to be sampled should be chosen at random. SEGs need to be defined based on the exposure profile of the workers, in this case their RCS exposure profile:

- Similar location or phase within the production process
- Similar tasks and work patterns
- Similar exposure profile (frequency and duration of tasks with RCS exposure)
- Similar exposure conditions (operational conditions, control measures)

As the sectors within NEPSI have distinctly different production processes, it is not possible to define one standardized set of job functions or SEGs for all NEPSI partners as part of this protocol. The list of SEGs will be specific for each industrial sector although some job functions like for instance maintenance/engineering and transport workers might appear in multiple sectors. For some sectors it might even be difficult to define a list of SEGs that will be applicable for all member companies within that specific sector. However, if comparison of exposure data between companies is desirable within a sector, it is highly recommended to use a standardized list of SEGs, which at company level could even be subdivided

for local purposes. An example of the SEG definition from one of the NEPSI sectors (IMA Europe) has been included in Annex 2.

The analysis of the production process will define which SEGs will potentially be exposed to RCS. It is recommended to take RCS measurements in each of these SEGs and not to limit measurements to the highest exposed SEGs. After the initial sampling campaign it is possible to differentiate follow-up based on the exposure concentrations and variability of exposure, and put more focus on highest exposed SEGs and less on SEGs with RCS exposures well below the OELV (see also 'Periodicity' below).

The main advantage of using the concept of SEGs as the basis of a measurement strategy is that only a selection of the workers within a SEG need to be measured. If the exposure of a representative selection of workers is below the OELV, it is considered that all workers within a SEG will be in compliance with the OELV. As SEGs are defined *a priori* (before the start of the measurements), it is important to evaluate homogeneity of exposure within a SEG after the measurement results have become available and if necessary redefine the SEG. 'Representative sampling' within a SEG (choosing a random worker on a random working day) is preferred over 'worst-case sampling' (selecting the assumed worst sampling conditions or select a worker with the potentially highest exposed tasks during the day of sampling). First, the EN-689 and comparable standards do consider random sampling necessary for statistical evaluation of measurement data. Statistical evaluation will not be informative with worst-case sampling strategies. Second, worst-case sampling will limit the possibilities of comparing measurement data with other companies or between sectors.

Most workers will be part of just one SEG during a working day (all tasks performed during a sampling day will be part of the regular tasks of that specific SEG). In many sectors, however, a small proportion workers may perform multiple tasks over a shift, that have been assigned to more than one SEG. If so, a multi-skilled job function can be included in the list of SEGs to cover workers for which none of the *a priori* SEGs will fully apply. Measurements should be assigned to a multi-skilled job function when for instance less than 50% of a worker's working time belongs to just one SEG.

Type of sampling (personal sampling versus static sampling)

The main goal of the monitoring will be to get a valid and unbiased estimate of workers' exposure within a SEG. This will require personal sampling, using samplers or personal sampling pumps with sampling heads positioned in the workers' breathing zone. Static sampling (with a sampler or a pump and a sampling head at a certain location within the workplace during the entire sampling time) will hardly ever provide a valid estimate of workers' exposure. Often the worker's activity is the main source of exposure (for instance emptying a bag or sweeping a floor) and static sampling will in that case likely underestimate the worker's exposure, as there will be no optimal (close enough to the breathing zone) position for the static sampler. When however the static sampler is close to the source of exposure, but the workers spend most of the time in a control room the static measurement will result in overestimated exposure concentrations. Therefore in this protocol, personal monitoring is required.

Sampling duration

The OELV for RCS is set as an 8-hour time weighted average (8-hr TWA). No Short Term Exposure Limit (STEL) has been set for RCS. Full-shift sampling is therefore required to evaluate compliance with the OELV. It is recommended to aim for 6-8 hours of sampling. If shifts of workers are different from regular 8-hour shifts (e.g. 12 hour shifts) it is recommended to sample for at least 75% of the duration of the shift. For measurements with shorter sampling duration the sampling result will not represent a full work shift of a

worker within a SEG. Measurements of shorter duration can be useful for other purposes, for instance to study the sources of high exposures within a SEG. Task-based sampling or real-time sampling can help identifying the sources of exposure and provide valuable information for risk mitigation measures. However, these types of measurement are not part of the NEPSI RCS monitoring protocol. Within this protocol, full shift sampling is required.

Number of samples needed

Within a SEG, RCS exposure will vary considerably from day to day, as process conditions, activities and tasks performed, environmental conditions, etc. will not be constant from day to day. The average 8-h TWA exposure estimate for a SEG will therefore be more precise and more stable when samples are being collected over multiple days. Importantly, compliance with an 8-h TWA OELV can never be evaluated based on one sample within a group. To be in line with the EN-689 guidance a minimum of three samples should be collected for basic compliance testing with the OELV. Preferably up to six samples per SEG collected over multiple days would be needed for statistical evaluation (see Chapter 6). Also, when comparing exposure levels between SEGs within a company, or when comparing SEGs between different companies within a sector, measurements of multiple workers on multiple days per SEG are needed for meaningful comparisons.

Number of workers per SEG and number of samples per worker

Within each SEG, RCS exposure will slightly vary from worker to worker and for each worker from day to day. To evaluate exposure and check compliance with an OELV, it is vital to take into account the variability of exposure. It is therefore important to take some multiple measurements over several days from the same workers, whenever possible. In addition, if we have multiple measurements from workers in a SEG, it will be possible to better evaluate day-to-day variability in exposure and to evaluate (a-posteriori) the similarity of workers' average exposures within a pre-defined SEG. Of course, the possibilities for repeated sampling will largely depend on the total number of samples being taken in each SEG and the number of workers in a SEG. To provide some guidance:

- When taking only the minimum 3 samples per SEG:
    - Sample on multiple days
    - Sample multiple workers
- When taking up to 6 samples per SEG:
    - try to collect repeated samples per individual, e.g.:
        - 4 workers sampled just once and 1 repeated sample for an additional worker
        - 3 workers, each measured two times
        - 2 workers, each measured two times and two additional workers sampled once
        - avoid sampling one person six times or six people once

Periodicity of sampling

Situations vary over time, e.g. changes in production process, changes in production volumes, the probability of process disturbances with aging equipment, and hygiene policies. Therefore, RCS sampling cannot be limited to just one sampling campaign and exposure needs to be re-evaluated regularly. If exposure levels exceed the OELV, control measures need to be taken to reduce the workers' RCS exposure. After risk mitigation measures have been put in place, new measurements need to be taken to evaluate the

effectiveness of the control measures and to define a new RCS exposure level for the SEG. If RCS exposure within a SEG is below the OELV (based on the evaluation according to EN-689), the main goal of repeated sampling is to ensure that RCS exposure has not changed, or to detect changes in exposure in time. The periodicity of the sampling can depend on the exposure level, sampling more often in SEGs with exposure closer to the OELV, and fewer sampling in SEGs who are under control and well below the OELV. It is recommended to follow the scheme as mentioned in EN-689:

- Geometric mean exposure of a SEG above 50% of the OELV: sample every 12 months
- Geometric mean exposure of a SEG between 25-50% of the OELV: sample every 18 months
- Geometric mean exposure of a SEG between 10-25% of the OELV: sample every 24 months
- Geometric mean exposure of a SEG below 10% of the OELV: sample every 36 months

The above scheme is relevant if the initial evaluation is based on six samples. If the initial evaluation is based on less than six samples (preliminary testing phase according to EN-689), at least three additional samples need to be taken after one year. If process conditions have not been changed, these results can be pooled with the earlier ones in order to test compliance and to determine the period for the next reassessment. In case significant modifications in the workplace have occurred (e.g. change in process, significant change in process volumes, implementation of control methods), all previous sampling results will no longer be relevant for compliance testing. In such cases, start again with the basic characterization and evaluation.

Outliers

Exposure levels can vary considerably from day to day. As exposure within a SEG will follow a lognormal distribution, incidental high exposure levels can happen when several determinants of high exposure occur on a given day (e.g. excessive cleaning with compressed air). In principle, therefore, all available measurements should be part of the statistical evaluation, even high values. Only if there are clear indications of tampering with the measurement or if technical failure is apparent, outliers should be deleted.

Summary of basic elements of the measurement strategy:

	Recommendations (Dos)	Discouragements (Don'ts)
Similar Exposure Groups (SEGs)	- Classify your workforce into groups with assumed similar exposure - Preferably use a standardized set of job functions or SEGs within each sector to be able to compare exposure data across companies - Sample all SEGs with potential RCS exposure - Sample a representative selection of workers within each group on multiple days (random sampling)	- Worst-case sampling within a SEG as this will hamper both compliance testing according to EN-689 and will not allow comparisons exposure data across companies within a sector
Type of sampling	- Personal sampling	- Static sampling
Sampling duration	- Full-shift sampling (6-8 hour sampling) - If longer than an 8-hour shift, sample at least 75% of the duration of the shift	- Task-based sampling or real-time sampling (useful for identifying sources of exposure but not part of this protocol)

Number of samples	- A minimum of 3 samples per SEG - Preferably 6 samples per SEG	- Less than 3 samples per SEG
Number of workers per SEG & number of samples per worker	- Sample multiple workers over multiple days - Try to collect repeated samples per individual for each job title	- Take all samples within a SEG on one single day
Periodicity of sampling	- Re-evaluate after major changes in production process or implementation of control measures - Re-evaluate SEG exposures from time to time to detect relevant changes in exposure - Periodicity of sampling depends on exposure level within a SEG	- Limit RCS sampling to just one sampling campaign

Chapter 4 Metrology

Dust fraction

Dust that can be inhaled by humans can have a wide range of particle sizes. Bigger particles will be deposited in the nose, mouth or upper airways. Smaller particles can reach the alveoli of the lungs. For dust measurements in occupational settings different dust fractions are distinguished, most importantly the inhalable dust fraction (all dust particles that can be inhaled) and the respirable dust fraction (smaller dust particles that can reach the alveoli) (see Figure 1). For health effects of respirable crystalline silica only small particles that can reach the alveoli are relevant. Respirable dust consists of particles that are generally smaller than 10 µm, with a 50% cut-off aerodynamic diameter (d_{50}) of 4.00 µm. More information can be found in EN-481 "Workplace atmospheres – Size fraction definitions for measurement of airborne particles" (CEN 1993). When sampling for respirable crystalline silica it is important to use sampling equipment that measure the respirable dust fraction.

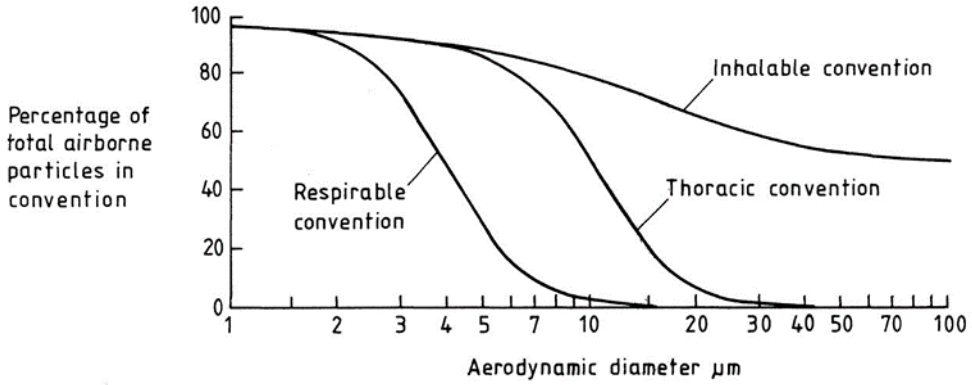


Figure 1. Inhalable, thoracic and respirable conventions as percentage of total airborne particles (CEN 1993)

General guidance for the measurement of respirable crystalline silica can be found in the international standard ISO 24095 (ISO 2009), which is currently being revised.

Choice of equipment

The choice of sampling equipment must be conform the international standard ISO 13137 (ISO 2013). The equipment either consists of a pump connected with a respirable dust sampling head or an integrated respirable dust sampler. The sampling takes place on a filter or in a foam. The performance of a large variety of samplers have been assessed in several experimental and field studies (Lidén 1993; Baron 1998; Görner et al. 2001; Lee et al. 2010; Verpaele and Jouret 2013; Stacey et al. 2016).

Examples of current respirable dust samplers are:

- FSP-10 high flow cyclone uses a 37 mm filter holder using a flow rate of 10 l/min, with a filter as the sample collection material
- CIP 10-R using a flow rate of 10 l/min, with polyurethane foam sponge as the sample collection material
- GS-3 using a flow rate of 2.75 l/min, with a filter as the sample collection material
- Respicon particle sampler using a flow rate of 3.11 l/min, with multiple filters as the sample collection material
- Dorr-Oliver 10mm nylon cyclone connected to a personal sampling pump using a flow rate of 1.7 l/min, with a filter as the sample collection material

- Higgins-Dewell cyclone connected to a personal sampling pump using a flow rate of 2.2 l/min, with a filter as the sample collection material
- IOM dual sampler includes a foam disc insert simultaneously collects respirable and inhalable dust using a flow rate of 2 l/min

For the cyclone sampling equipment the sample collection materials (filters) are placed in filter cassette. Examples are:

- Polyvinyl chloride (PVC) membrane filter, 25 or 37mm diameter, 5 µm pore size
- Silver membrane filter, 25mm diameter, 0.45µm pore size (cannot be used for FTIR analysis)
- Mixed cellulose ester (MCE) membrane filter, 25 or 37mm diameter, 0.8 µm pore size

Glass fibre filters should never be used for RCS sampling.

Currently two different analytical techniques can be used to determine the crystalline silica content of the collected dust: Fourier Transform Infrared spectroscopy (FTIR) and X-ray diffraction (XRD). FTIR is reported to have a lower detection limit than XRD and the samples require different handling procedures, but both methods are recommended and described in international standards and published methods (ISO 2009; ISO 2015a; ISO 2015b; ISO 2018; HSE 2005; NIOSH 2003a, 2003b). Cristobalite will require XRD analysis. Recent analysis of a large database of RCS measurements showed that no practical difference existed between laboratories using either XRD or FTIR methods (Harper et al. 2014).

The actual choice of sampling equipment and analytical method will be largely determined by the expected respirable dust concentration and its crystalline silica content. With a relatively high respirable dust concentration and high crystalline silica content a low volume pump with a traditional cyclone in combination with XRD analysis of the collected dust on the filter might be the choice of preference. However, when the respirable dust concentrations are expected to be low and have low crystalline silica content, a high volume sampler and FTIR analysis will be needed in order to collect informative concentrations above the limit of detection.

In the following scheme some guidance is being provided:

LoD

XRD 5-20 µg

8h 2 l/min (1.8-2.2) Higgins Dewell, Dorr-Oliver, IOM					
% RCS	RCS ug/filter				
20%	19	38	96	192	960
10%	10	19	48	96	480
5%	5	10	24	48	240
1%	1	2	5	10	48
	0.1	0.2	0.5	1	5
	resp dust (mg/m3)				

8h 2.75-3.11 l/min GS-3, Respicon					
% RCS	RCS ug/filter				
20%	29	58	144	288	1440
10%	14	29	72	144	720
5%	7	14	36	72	360
1%	1	3	7	14	72
	0.1	0.2	0.5	1	5
	resp dust (mg/m3)				

8h 10 l/min FSP-10, CIP10-R					
% RCS	RCS ug/filter				
20%	96	192	202	960	4800
10%	48	96	101	480	2400
5%	24	48	50	240	1200
1%	5	10	10	48	240
	0.1	0.2	0.5	1	5
	resp dust (mg/m3)				

LoD

FTIR 1-5 µg

8h 2 l/min (1.8-2.2) Higgins Dewell, Dorr-Oliver, IOM					
% RCS	RCS ug/filter				
20%	19	38	96	192	960
10%	10	19	48	96	480
5%	5	10	24	48	240
1%	1	2	5	10	48
	0.1	0.2	0.5	1	5
	resp dust (mg/m3)				

8h 2.75-3.11 l/min GS-3, Respicon					
% RCS	RCS ug/filter				
20%	29	58	144	288	1440
10%	14	29	72	144	720
5%	7	14	36	72	360
1%	1	3	7	14	72
	0.1	0.2	0.5	1	5
	resp dust (mg/m3)				

8h 10 l/min FSP-10, CIP10-R					
% RCS	RCS ug/filter				
20%	96	192	202	960	4800
10%	48	96	101	480	2400
5%	24	48	50	240	1200
1%	5	10	10	48	240
	0.1	0.2	0.5	1	5
	resp dust (mg/m3)				

For example when based on prior knowledge (or indicative measurements) the lowest expected respirable dust concentration will be 0.2 mg/m^3 and the percentage of respirable crystalline silica will be at least 5% a combination of a high volume sampler like FSP-10 and CIP10-R and XRD as analytical method will suffice, while when using FTIR, also more traditional sampling with low volume cyclones like Higgins-Dewell and Dorr-Oliver would also result in informative measurements. However, when in the same situation the percentage of respirable crystalline silica would be just 1% only FTIR and high volume cyclones (FSP-10, CIP10-R) would work.

Procedure

A calibrated analytical balance with a resolution of (at least) 0.1 mg for foam collection medium and (at least) 0.01 mg for a filter will be needed. The collection mediums should be conditioned in the weighing room for at least 12 hours before pre-weighing.

The collection equipment should have been thoroughly cleaned, conditioned and weighed. Before the actual sampling will be started make sure the pump batteries have been fully recharged so that it will be functional during an entire work shift. Calibrate the sampling pump according to manufacturer's instructions and the requirements for the used sampler. Load the collection medium (filter or foam whether or not in a cassette) in the sampler and connect to the sampling pump. Set and record the sampling flow rate before starting. Switch on the pump and record the start time. Place sampling equipment in the breathing zone of the worker (no more than 30 cm from the mouth) and record the actual place on the body.

During sampling, record all the important information (see sampling form in Annex 3) and, if the equipment allows it, check the sampling flow rate. During the sampling period record activities conducted, dust control measures in use, personal protective equipment used, etc.

At the end of the shift, remove the sampling equipment from the worker, check sampling equipment (pump, tubing and collection equipment connections) and measure the pump flow rate (over the loaded sampler). Consequently switch off the pump. Record the sampling end time. Remove the sampler from the sampling equipment. Take the collection equipment to the laboratory for the re-weighing procedure. If sampling has been carried out under humid conditions foams or filters should be placed in an oven at 50-60 °C for at least 4 hours. Consequently the foams in their cups or filters (cassettes) should be left next to the analytical balance for at least 12 hours before re-weighing. After re-weighing, the foams and filters should be analyzed for RCS by either FTIR or XRD. The analytes to be measured are at least quartz (also called α-quartz or free silica) and if relevant considering the production process, cristobalite or tridymite.

Field blanks

During each measurement day at least one field blank should be collected. Field blanks should follow the entire procedure, except active monitoring. Information on field blanks should be entered in the collection sheet as they will be used to estimate limits of detection for respirable dust and correct all samples for these field blanks. Furthermore, it is advised to send the field blanks for respirable crystalline silica analyses together with the regular samples. More detailed information on field blanks can be found in Annex 4.

Chapter 5 Data management

For the management of RCS exposure data, two phases needs to be distinguished. First, the phase of actual data collection at the time of the measurements. Second, the processing and storage of data for further evaluation and documentation.

Data recording during the measurements

During the measurement it is important to collect and document all relevant information for further processing of the information, but also for correct interpretation of the measurement results.

The following information is essential for calculation of the exposure concentrations:

- Start time of the sampling [hh:mm]
- Stop time of the sampling [hh:mm]
    - **D:** Sampling duration (stop time minus start time) [minutes]
- Flow-rate of the pump at start of sampling [litres/minute]
- Flow-rate of the pump at the end of sampling [litres/minute]
    - **F:** Mean flow-rate ((start flow + end flow)/2)) [litres/minute]
- Weight of filter or foam before sampling [mg]
- Weight of filter or foam after sampling [mg]
    - **W:** Weight gain (post-weight minus pre-weight) [mg]
- **RCS:** Result of RCS analysis (mass RCS) [mg]

With this information respirable dust and RCS exposure concentrations can be calculated as follows:

- **T:** Total flow rate = (D [min] x F [l/min])/1000 [m^3]
- **Dust concentration** = W [mg] / T [m^3] [mg/m^3]
- **RCS concentration** = RCS [mg] / T [m^3] [mg/m^3]

Additional essential data to be recorded during sampling for tracking and identification of the measurement:

- Date of sampling
- Shift (day, morning, afternoon, night, weekend)
- Technician taking care of the sampling (name or code)
- Company and site (name or code)
- Job function or SEG (name or code)
- Worker being sampled (name or code)
- Pump (type and serial ID)
- Sampling head (type and number ID)
- Filter or foam (type and number ID)
- Technique for RCS analysis (XRD or FTIR)

Finally, contextual information may be recorded during the measurement to enable interpretation of the measurement results, e.g.:

- Use of respiratory protection during the sampling period
- Process disturbances on the day of measurement (if relevant)
- Specific tasks with high exposure potential carried out by the worker and duration of these tasks (e.g. cleaning activities)
- Process characteristics (are process conditions representative or does it significantly deviate from other days and if so, how)
- Control measures in place and/or correct use of these control measures by the worker (if relevant)
- Working behaviour of the worker during the measurement (normal or deviant from normal procedures)

As part of this protocol a sampling form has been developed (Annex 3). All items above appear on this form.

Data handling and storage after the measurements

For data storage a data collection sheet (a spreadsheet in MS-Excel©) has been developed as part of this protocol. In this data collection sheet all essential and contextual information for the measurements can be entered. Exposure concentrations will be automatically calculated when entering the basic sampling information (start time, stop time, flow, filter weight & RCS analysis). In addition, all other relevant information for a measurement can be entered. Each record in the collection sheet will represent one measurement. In Annex 4 a more detailed instruction can be found for all items in the data collection sheet

Main purpose of the data collection sheet is a structured and uniformed storage of all RCS measurements. In addition, using the filter option in MS-Excel, specific data can be selected for entering into tools for statistical evaluation of the data (see Chapter 6).

When using the data collection sheet for entering and storing RCS exposure data, it will open the option of pooling and/or sharing data. Pooling of data can also be relevant within a company that has multiple sites. Importantly, data sharing is not a goal of this protocol. However, if in the future there might be a wish or need to pool or share data (between companies within a sector, or even between sectors within NEPSI), the use of this standardized data collection sheet will facilitate this.

Confidentiality

Confidentiality of information is relevant within the framework of the EU General Data Protection Regulation (EU-GDPR). In addition, confidentiality will be needed whenever data from multiple sites or companies will be pooled or shared. For this reason it is recommended to use codes instead of names for the following items in the collection sheet:

- Worker names (Worker ID)
- Technician names (Technician ID)
- Country names (Country code)
- Sector names (Sector code)
- Company names (Company code)
- Site names (Site code)

Part of the coding (country codes, sector codes) is specified for this protocol and can be found in Annex 4 and the Collection sheet. Coding of company and site names, worker IDs & technician IDs should be done at the level of each individual company. Importantly, coding will have to be harmonized between companies or sectors whenever measurement data will be shared.

Chapter 6 Statistical evaluation

Statistical evaluation conform EN-689 could be performed using an MS-Excel© tool developed by a concerted action of several National Occupational Hygiene Societies: BWStat (Geens et al 2005). In the text below guidance is provided for the statistical evaluation using EN-689 & BWStat.

Basic statistics

Occupational exposure measurements will almost always show a skewed distribution, with lower exposure concentrations more likely than higher exposure concentration. This is called a lognormal distribution (see Figure 2 below).

The arithmetic mean (AM) is the sum of all sampling results divided by the total number of samples. In the case of lognormal distributed data, the distribution of the measurement data can be described by just the geometric mean (GM) and the geometric standard deviation (GSD). The geometric mean (GM) is equal to the median of the distribution (50th percentile) and will always be lower than the arithmetic mean in case of a lognormal distribution. The geometric standard deviation (GSD) represents the variability of the measurement data. It is estimated by taking the exponential of the standard deviation of the logarithms of the measurement results. A GSD of 1 would imply no variability at all (all measurements taken from multiple days from multiple workers resulted in the same concentration). Analyses of a large database has indicated that on average a GSD of ~2.30 is to be expected for a group of workers with the same job in a location (Kromhout et al. 1995).

Occupational exposure measurement results can thus be described by just presenting the geometric mean (GM) and geometric standard deviation (GSD). Importantly, this needs to be done for each Similar Exposure Group (SEG).

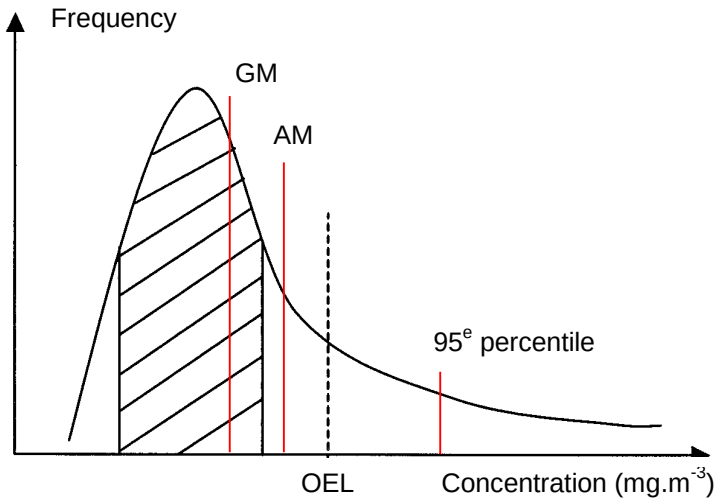


Figure 2 Lognormally distributed exposure measurements (as an example of the shape of a lognormal distribution).

Compliance in EN-689

To test compliance with an Occupational Exposure Limit value (OELV), you will have to show that exposure for a group of workers (SEG) is below the OELV. If you have one measurement result above the OELV, it will be an easy decision: non-compliance.

If all measurement results are below the OELV, this does not always imply that you will be in compliance with the OELV. Suppose the OELV is 0.1 mg/m^3 and you have a few measurement results that are close to this limit (e.g. 0.09 and 0.099 mg/m^3), how confident could you be that the observed SEG will be in compliance with the OELV? In this case, the probability that the next measurement result will exceed the OELV will be relatively high and you cannot be confident that this SEG is in compliance with the OELV. The question is how certain do you need to be and how can you consequently decide that the SEG will be in compliance with the OELV?

As an employer you need to be 95% certain that the SEG's exposure is below the OELV. For this purpose you can calculate the 95th percentile of the distribution (see Figure 2). In addition, you need to estimate the 95th percentile with a required amount of certainty (70% certainty). In other words you will have to estimate the Upper Tolerance Limit (UTL) of the distribution (the so-called $UTL_{95,70\%}$).

Although the statistical procedure to estimate the UTL is quite complex, the good news is that several free-of-charge tools are available on the Internet that will estimate the UTL. One of these tools is BWStat. The tool can be found on the website of the Belgian Society for Occupational Hygiene Society (BSOH): www.bsoh.be. The BWStat tool will be explained in this protocol. The collection sheet for data storage supports importation of measurement results into BWStat for statistical evaluation.

EN-689 compliance testing

Compliance testing can be performed as a preliminary test and as a formal statistical evaluation.

Preliminary test (if you have less than six exposure measurements)

The preliminary test requires three, four or five measurements. You will be in compliance with the OELV if:

- the three measurement results are all below 10% of the OELV. If any of the three samples is above 10% but below the OELV, no decision can be made and more samples are needed.
- the four measurements results are all below 15% of the OELV. If any of the four samples is above 15% but below the OELV, no decision can be made and more samples are needed.
- the five measurements results are all below 20% of the OELV. If any of the five samples is above 20% but below the OELV, no decision can be made and more samples are needed.

If one of the samples in the preliminary test is above the OELV, you will be in non-compliance with the OELV.

Statistical testing (if you have six or more exposure measurements)

As explained before (see Chapter 3) preferably six measurements over multiple days per SEG should be collected for statistical evaluation. If you have six or more measurement results you can estimate the Upper Tolerance Limit (UTL) of the distribution ($UTL_{95,70\%}$) and compare this value with the OELV:

- If for a SEG the $UTL_{95,70\%}$ is below the OELV, you will be in compliance with the OELV
- If for a SEG the $UTL_{95,70\%}$ is above the OELV, you will be in non-compliance with the OELV

If there is a situation of non-compliance in any of the SEGs, control measures need to be taken to further reduce RCS exposure. For potential control measures, please refer to the NEPSI Good Practice Guide (https://guide.nepsi.eu/).

Treatment of samples below the limit of detection

If one or more of the exposure measurements are below the limit of detection of the measurement procedure (LOD), these values need to be treated in a way which will not result in a biased evaluation of the exposure. There are several ways this can be done, but within the NEPSI RCS protocol we have chosen to use the 'Regression on Order Statistics (ROS)' method. In this method all samples below the LOD will be substituted by new values, based on the distribution of samples above the LOD. More detailed information on this method can be found in EN-689.

Importantly, a proper statistical evaluation can only be done if there are enough measurements available above the LOD. As a rule of thumb at least three measurements within a SEG must be above the LOD. If too many samples in a sampling campaign are below the LOD, it is strongly advised to consider more sensitive sampling methods (high volume samplers) and/or more sensitive analytical techniques (FTIR) (see Chapter 4). According to EN-482 (CEN, 2021) a method should at least be able to sample in the full range of 10% to 200% of the OELV.

Example compliance testing using BWStat

In this example we will use two sets of measurement results for two SEGs:

For Similar Exposure Group 1 (SEG1), the following six quartz measurement results are available:

- 0.014 mg/m^3
- 0.031 mg/m^3
- 0.017 mg/m^3
- 0.009 mg/m^3
- 0.052 mg/m^3
- 0.013 mg/m^3

For Similar Exposure Group 2 (SEG2), the following six quartz measurement results are available:

- 0.040 mg/m^3
- 0.008 mg/m^3
- 0.052 mg/m^3
- 0.011 mg/m^3
- 0.025 mg/m^3
- 0.073 mg/m^3

The actual statistical evaluation using BWStat can be performed as follows and requires seven steps.

STEP 1: Check if all information in the NEPSI RCS collection sheet is entered in the right format:

- Check if all information on LOD is available. In the worksheet 'LOD & Field blanks' the orange box in column L-O must be filled for the analytes that need statistical analysis
- Check if the information on field blanks is of good quality and if you want to use this blank information to correct your individual samples (for detailed information why this is necessary see Annex 4). If so, select 'yes' in field F3 in the worksheet 'LOD & Field blanks'
- Check if the information in the worksheet 'Collection sheet is complete', especially information on dust weight en -concentration, weight and concentration of analytes (quartz, cristobalite and/or tridymite), date, worker ID, and job function. If any of this information is missing, further statistical analysis is not possible.

STEP 2: Open the BWStat tool and enter the basic information

- Go to: https://www.bsoh.be/?q=nl/bwstat
- Enter the substance name (in this example respirable quartz)
- Enter the measurement unit (in this case mg/m^3)
- Enter the occupational exposure limit (in this example 0.1 mg/m^3, which is the current European OELV)

STEP 3: Select the data to be analysed in the NEPSI RCS collection sheet

- Go to one of the yellow coloured worksheets. In this example we want to analyse the data for respirable quartz. All relevant data from the collection sheet will appear in this worksheet:
    - Job function (SEG)
    - Type of measurement
    - Concentration respirable quartz (mg/m^3)
    - Worker ID
    - Date
    - Information if the quartz result is above (TRUE) or below (FALSE) the detection limit
- Select the job function (SEG) that needs to be analysed, in this example we select the data for Similar Exposure Group 1 or Test SEG1. This how the data appear in the spreadsheet.:

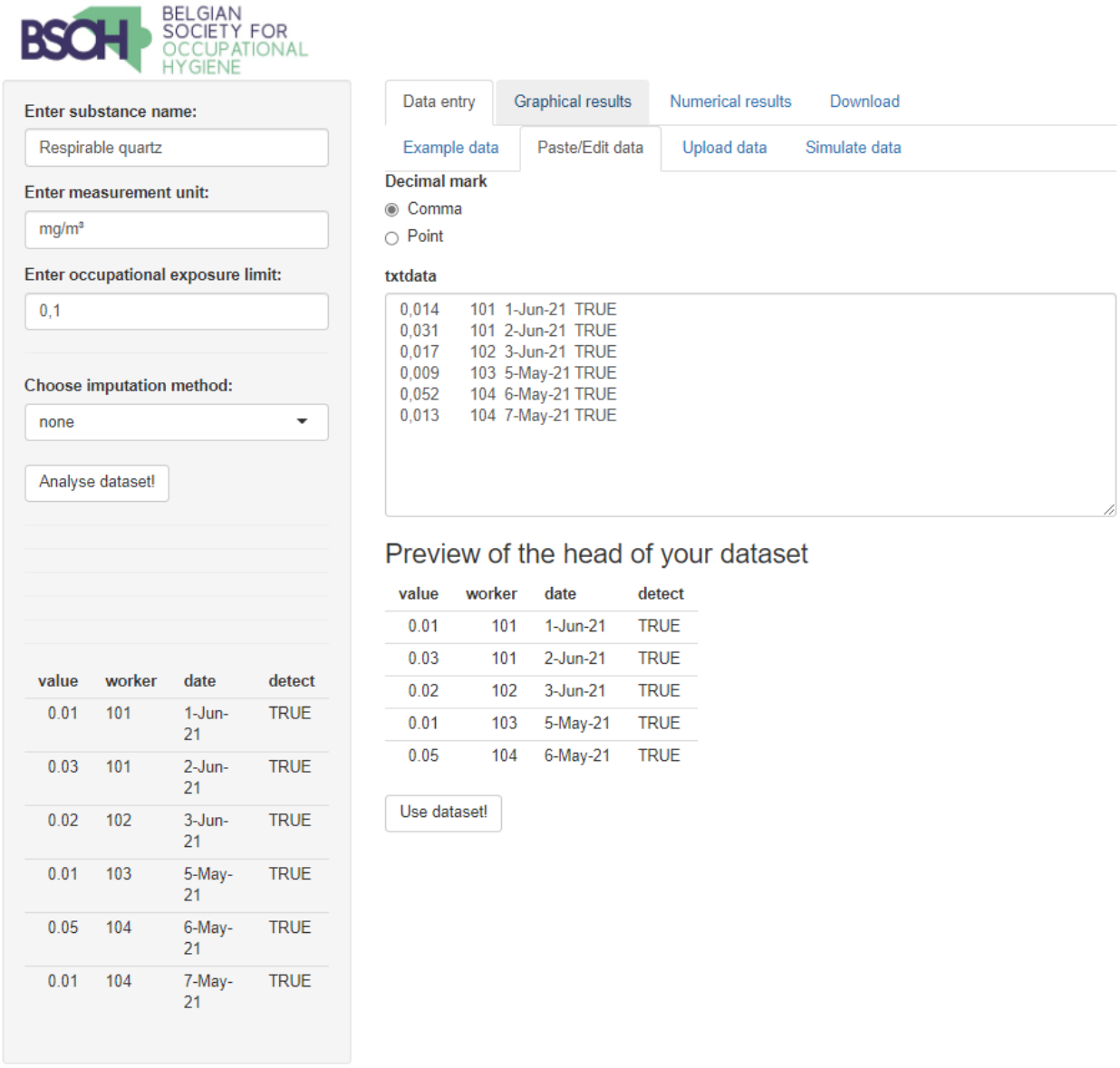
	A	B	C	D	E	F	G	H
1	Job function (SEG)	Type of Measurement	Concentration respirable quartz (mg/m3)	Worker ID	Date	Quartz above (TRUE) OR below (FALSE) the limit of detection		QUARTZ
2	Test SEG 1	Full-shift personal	0,014	101	1-Jun-21	TRUE		
3	Test SEG 1	Full-shift personal	0,031	101	2-Jun-21	TRUE		
4	Test SEG 1	Full-shift personal	0,017	102	3-Jun-21	TRUE		
5	Test SEG 1	Full-shift personal	0,009	103	5-May-21	TRUE		
6	Test SEG 1	Full-shift personal	0,052	104	6-May-21	TRUE		
7	Test SEG 1	Full-shift personal	0,013	104	7-May-21	TRUE		

- Make sure only full-shift personal measurements are analysed. If not, select in column B only the full-shift personal measurements. Other type of measurements cannot be used for compliance testing
- If relevant, make further selections for this SEG and select the period or dates to be analysed. Make sure that you end up with at least six samples for statistical analysis
- Select the data from the yellow marked columns. In our example this part of the collection sheet should be selected and copied:

0,014	101	1-Jun-21	TRUE
0,031	101	2-Jun-21	TRUE
0,017	102	3-Jun-21	TRUE
0,009	103	5-May-21	TRUE
0,052	104	6-May-21	TRUE
0,013	104	7-May-21	TRUE

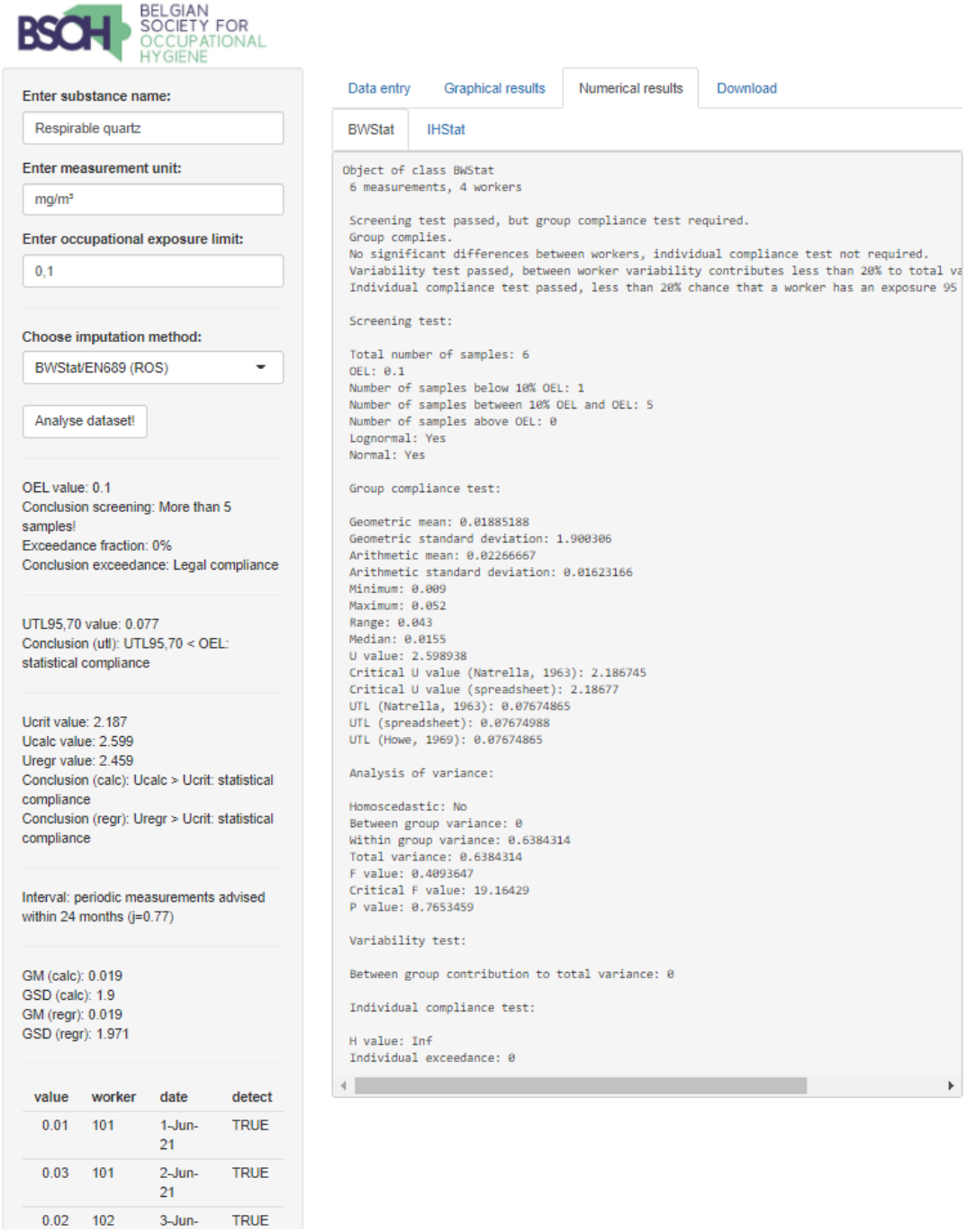
STEP 4: Copy the selected data in the BWStat tool

- Go back to the BWStat webpage
- Select Past/Edit data
- Select Comma or Point for indication of decimals (default is Comma but it may depend on your version of Excel
- In the txtdata box delete all data currently in the tool
- Copy your data in this box
- Check the box 'Use dataset!' (this is an essential step and performs the actual selection of data to be analysed)
- The selected data will appear in BWStat as follows:



STEP 5: Start the analysis

- First, choose the imputation method to be used for samples below the limit of detection. Always select 'BWStat/EN689 (ROS)'. Within this method all samples below the limit of detection will be substituted by new values, based on the distribution of samples above the limit of detection by 'Regression on Order Statistics (ROS)'. More detailed information on this method can be found in EN-689.
- Check the box 'Analyse dataset!'
- Click on Numerical results
- This will appear in BWStat as follows:



- All data you will need for the evaluation of compliance with the OELV is available on this page

STEP 6: Select the information you need on from the "Numerical results" page

- You will need the following information to be added to summary page in the collection sheet. For each item a screenshot is taken where to find the information:
  - Number of quartz samples
  - Number of quartz samples above the OELV

```
Screening test:

Total number of samples: 6
OEL: 0.1
Number of samples below 10% OEL: 1
Number of samples between 10% OEL and OEL: 5
Number of samples above OEL: 0
Lognormal: Yes
Normal: Yes
```

  - Arithmetic mean respirable quartz (AM) [mg/m^3]
  - Geometric mean respirable quarts (GM) [mg/m^3]
  - Geometric standard deviation (GSD)

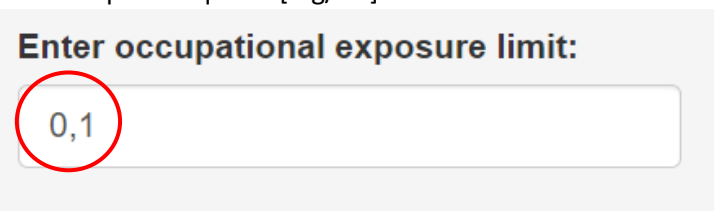
```
Group compliance test:

Geometric mean: 0.01885188
Geometric standard deviation: 1.900306
Arithmetic mean: 0.02266667
Arithmetic standard deviation: 0.01623166
Minimum: 0.009
Maximum: 0.052
Range: 0.043
Median: 0.0155
```

  - $UTL_{95,70\%}$ respirable quartz [mg/m^3]

```
UTL95,70 value: 0.077
Conclusion (utl): UTL95,70 < OEL:
statistical compliance
```

  - OELV respirable quartz [mg/m^3]



STEP 7: Enter this information into the red coloured worksheet 'SEG list' and make decision on compliance or non-compliance based on BWStat parameters

This will appear in the in the worksheet "SEG list" as follows:

	A	B	K	L	M	N	O	P	Q	R
1	**Summary from statistical evaluation in BWStat (6 or more san**									
2			**Quartz exposure**							
3	**List SEG's**	Number of workers in this SEG	Number of quartz samples	Number of quartz samples above the OELV	Arithmetic mean respirable quartz (AM) [mg/m3]	Geometric mean respirable quartz (GM) [mg/m3]	Geometric Standard Deviation respirable quartz (GSD)	UTL95,70% respirable quartz [mg/m3]	OELV respirable quartz [mg/m3]	Respirable quartz compliant with OELV?
4	Test SEG 1		6	0	0,023	0,019	1,90	0,077	0,100	yes
5	Test SEG 2								0,100	

- More detailed information on the decision on compliance or non-compliance can be found as a comment in cell R3, and elsewhere in this protocol:
    - Non-compliant if:
        - one or more samples above the OELV
        - or UTL95,70% above the OELV
    - Compliant if:
        - all samples <OELV
        - and UTL95,70% below the OELV

Second example

In case we also analyse the second example as mentioned in the beginning of this chapter we will get the results below:

For Similar Exposure Group 2 (SEG2), the following six quartz measurement results are available:

- 0.040 mg/m^3
- 0.008 mg/m^3
- 0.052 mg/m^3
- 0.011 mg/m^3
- 0.025 mg/m^3
- 0.073 mg/m^3

	A	B	K	L	M	N	O	P	Q	R
1	**Summary from statistical evaluation in BWStat (6 or more san**									
2			**Quartz exposure**							
3	**List SEG's**	Number of workers in this SEG	Number of quartz samples	Number of quartz samples above the OELV	Arithmetic mean respirable quartz (AM) [mg/m3]	Geometric mean respirable quartz (GM) [mg/m3]	Geometric Standard Deviation respirable quartz (GSD)	UTL95,70% respirable quartz [mg/m3]	OELV respirable quartz [mg/m3]	Respirable quartz compliant with OELV?
4	Test SEG 1		6	0	0,023	0,019	1,90	0,077	0,100	yes
5	Test SEG 2		6	0	0,035	0,026	2,41	0,180	0,100	no

In the second example the SEG is non-compliant with the OELV, despite none of the actual samples exceeded the OELV. However, the exposure variability is high and therefore the Upper Tolarance Limit ($UTL_{95\%,70\%}$) is above the OELV.

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Glossary

AM	Arithmetic Mean
APF	Assigned Protection Factor (for respiratory protective devices)
BWStat	MS-Excel tool for evaluation of exposure data & compliance with the OELV
EU-GDPR	EU General Data Protection Regulation
FTIR	Fourier Transform Infrared Spectroscopy
GM	Geometric Mean
GSD	Geometric Standard Deviation
MCE	Mixed Cellulose Ester (filter)
NEPSI	European Network for Silica
OEL/OELV	Occupational Exposure Limit (Value)
PVC	PolyVinyl Chloride (filter
RCS	Respirable Crystalline Silica
ROS	Regression on Order Statistics
SEG	Similar Exposure Group
STEL	Short Term Exposure Limit
TWA	Time Weighted Average
UTL	Upper Tolerance Limit
XRD	X-ray diffraction

Annexes

Annex 1 Instructions and minimal requirements for external contractors

This sheet summarizes relevant items in case sampling and/or analysis is subcontracted to external parties. It will cover four items: (1) sampling- and analytical methods, (2) measurement strategy, (3) practical sampling instructions, and (4) data handling.

Sampling- and analytical methods

Sampling method	- Measurement of respirable dust conform the International standard ISO 13137 (2013). More guidance can be found in Chapter 4 of the protocol. - The choice of sampling method will depend national and/or company regulations, but also on the expected respirable dust concentration and its crystalline silica content. Guidance can be found in Chapter 4 of the protocol.
Dust weighing	- A calibrated analytical balance with a resolution of (at least) 0.1 mg for foam collection medium and (at least) 0.01 mg for a filter will be needed; - Both pre- and post-weight of filters should be documented, not weight difference only.
RCS analytical method	- Analysis of respirable crystalline silica conform the international standards and published methods. More guidance can be found in Chapter 4 of the protocol; - The choice of analytical method (Fourier Transform Infrared spectroscopy (FTIR) and X-ray diffraction (XRD)) will depend on the expected respirable dust concentration and its crystalline silica content. Guidance can be found in Chapter 4 of the protocol; - Analytical limit of detection for RCS should be specified; - External laboratories should be certified for RCS analyses.

Measurement strategy

Similar Exposure Groups (SEGs)	- Workforce should be classified into groups with assumed similar exposure (SEGs); - Sample all SEGs with potential RCS exposure; - Sample a representative selection of workers within each group on multiple days (random sampling).
Type of sampling	- Personal sampling only
Sampling duration	- Full-shift sampling (6-8 hour sampling); - If longer than an 8-hour shift, sample at least 75% of the duration of the shift.
Number of samples	- A minimum of 3 samples per SEG; - Preferably 6 samples per SEG
Number of workers per SEG & number of samples per worker	- Sample multiple workers over multiple days; - Try to collect repeated samples per individual for each job title

Practical sampling instructions

Flow measurement	- Record the sampling flow rate both at the start and at the end of sampling; - Measure the flow rate over the loaded sampler.
Field blanks	- During each measurement day at least one field blank should be collected. See Annex 3 of the protocol for detailed instructions on field blanks.

Data handling

Sampling form	- Make use of the sampling form in Annex 2 of the protocol and record for each sample all items as mentioned on the form.
Collection sheet	- Summarize and deliver all data in the format of the Collection sheet. Detailed instructions can be found in Annex 2 of the protocol; - Enter in the text fields all relevant information important for interpretation of the data.
Summary	- Evaluate all exposure data per SEG according to EN-689. Guidance can be found in Chapter 6 of the Protocol.

Annex 2 Example of SEG definition from one of the NEPSI sectors

Below the Similar Exposure Group as has been defined within the IMA Dust Monitoring Project within the NEPSI sector IMA-Europe

General category	Example of tasks/activities description
1. Quarry operator (outdoor)	Works in quarry Load dumper using an excavator Feed the crusher in quarry Transport raw materials to the unloading places using a dumper or wheel loader
2. Crusher operator (indoor)	Feed the crusher in plant Control of crusher in plant
3. Wet process operator	Supervise the process in a control room Sampling and control of sieve
4. Dry process operator	Supervise the process in a control room Sampling and control of screen or sieve
5. Miller operator	Supervise the process near the mill
6. Bagging operator	Supervise automatic bagging machines and bulk loading into 25/50kg bags Add bag to semi-automatic bagging machine Fill powder bags and cover pallets with plastic films Handle bags on pallets Stock the product in the storage building
7. Transport/bulk loading	Fill the hopper with end product using a wheel loader Supervise the conveyor belt feeding ship/train/truck Load goods in lorries and organize the storage operation
8. Foreman/plant management staff	General office work Supervise and organize plant activities Control of process and product
9. Maintenance	Control of plates in the crusher, new sieves, dust sealing, checking and cleaning inside enclosures In charge of mechanical and electrical maintenance in plant/office/quarry
10. Multi-skilled	The multi-skilled operator is an operator who does several job functions, none of which amounting to or exceeding 50 % of his working time.
11. Laboratory workers	Samples collection in the plant, analysis & quality control of the samples.
12. Research and Development	Development of new products in a pilot plant Running tests on an installation for technology or product improvement Applications of products on laboratory scale.
13. Plastification	Manufacture of prepared body from clay.

Annex 3 Sampling form (print on both sides)

NEPSI Sampling form for respirable crystalline silica (front side)					
General project information:					
Company					
Site					
Project coordinator					
Sampling method:					
Type of sampler					
Sample collection material					
Pump (type and ID)					
General sampling information:					
Date of sampling					
Weather conditions	Temperature(°C): Humidity(%): Wind speed(m/s):				
Technician ID					
Sample ID					
Type of measurement	full-shift personal sampling				
Department/sample location					
Job function (SEG)					
Worker ID					
Shift (circle the relevant shift)	Day/morning/afternoon/evening/night/weekend				
Shift length (hrs)					
Sampling details:					
Start of sampling			End of sampling		
Filter weight (mg)			Filter weight (mg)		
Flow at start (l/min or rpm*)			Flow at end (l/min or rpm*)		
Start time (hr:min)			Start time (hr:min)		
Clock time on pump (min)			Clock time on pump (min)		
Quartz analytical information:					
Further analysis needed			O yes O no		
Lab ID/name					
Analytical technique			O XRD O FT-IR		

* Flow of a CIP-10 is checked by measuring rotational speed in rounds per minute (rpm)

NEPSI Sampling form for respirable crystalline silica (back side)												
Tasks during sampling with relevance for the interpretation of sampling results												
		Control measures relevant for this sample (within the occupational hygiene strategy)										
Time (hr:min)	Short description of workers activity (type and place of work)	Duration of the task (min)	Enclosure of source	Local Exhaust Ventilation (LEV)	Area ventilation	Isolation/segregation of workers from the source	Increase distance from the source	Reduction of exposure time	Change in working methods	Maintenance & housekeeping	Education & training	Respiratory protective equipment (RPE)
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no

When checked 'yes' on any of the above control measures, specify below the relevant details of the control measures (e.g. which type of RPE was used):

Annex 4 Data Collection Sheet instructions

When collecting dust sampling results as part of the NEPSI monitoring protocol, each participating company should use the collection sheet. In this instruction you will find all the information you will need when using the collection sheet.

The collection sheet and these instructions for using the collection sheet are linked to the NEPSI Respirable Crystalline Silica Monitoring Protocol. For details on procedures and background information please refer to that protocol.

The MS-excel file has in total 16 worksheets:

- Two grey colour tabbed works sheets
  - LOD & Field blanks
  - Collection sheet
- One red colour tabbed work sheet
  - SEG list
- Nine green colour tabbed work sheets
  - Analytical technique
  - RPE
  - Sample collection material
  - Samplers
  - Countries
  - NEPSI sectors
  - Shifts
  - Type of measurements
  - YesNo
- Four yellow colour tabbed work sheets

The green colour tabbed worksheets contain the drop-down lists for the variables in the collection sheets . Some of them don't need to be edited (Countries, NEPSI sectors, Shifts, Type of measurents & YesNo). Other drop-down lists can be modified and allow 'User defined' elements in the list. Below per variable instructions will be given when and how to make changes, if applicable.

The red colour tabbed worksheet is the list of Similar Exposed Groups (SEGs) for your NEPSI sector of company. In the protocol you can find information what a SEG is. Very likely, the definition of SEGs need to be done only once and the SEG list can be used in all subsequent sampling campaigns. The worksheet 'SEG list' can also be used for entering the results of the statistical evaluation using BWStat (see chapter 6 of the protocol).

The two grey colour tabbed worksheets must be filled with sampling information and need to be used in each sampling campaign.

First there are some general instructions, followed by more detailed instructions for each of the worksheets. Please read these instructions carefully when first using the collection sheet and keep these instructions as reference document afterwards.

General instructions

1. First define your SEGs (for instructions see the NEPSI Respirable Silica Monitoring Protocol) and enter the SEG names in column A of the worksheet 'SEG list'. Once entered here, the correct SEG names will show up in the collection sheet. Importantly, the worksheet 'SEG list' need to be filled with this information before entering the measurement data in the collection sheet.

2. Second, start with the worksheet 'LOD & Field blanks'. Information on analytical limits of detection and results of field blanks are important for proper interpretation and handling of the data. See the detailed instructions below for this particular worksheet. All cells to be filled out are marked with a yellow colour. White cells mostly contain a formula and most of these cells have a write protection. Importantly, do not enter data from field blanks in the regular collection sheet. Instead, enter this information in the worksheet 'LOD & Field blanks'.

3. Third, start entering information for each sample taken in the worksheet 'Collection sheet'. There is one line for each sample. See the detailed instructions below for this particular worksheet. All cells to be filled out are marked with a yellow colour. White cells mostly contain a formula and most of these cells have a write protection. Again, do not enter data from field blanks in the regular collection sheet.

4. Fourth, once all sampling information has been entered in the worksheets 'LOD & Field blanks' and 'Collection sheet', data is ready for statistical evaluation using BWStat. All information needed for input into BWStat is summarized into the four yellow worksheets, one for each type of analyte (dust, quartz, cristobalite, and tridymite). Most companies will only use the worksheets for dust and quartz, but in case cristobalite and/or tridymite will be relevant separate analysis can be done for these analytes as well. The yellow worksheets put all information in the exact format for analysis in BWStat. More detailed instruction for using these worksheets can be found in chapter 6 of this protocol. Output of BWStat can be entered in the worksheet 'SEG list', as is also explained in more detail in chapter 6.

Instructions worksheet 'LOD & Field blanks'

The following information should be entered in this worksheet:

1. Choose in cell F3 yes or no if all samples should be corrected for the available field blanks. The default option in the worksheet is 'no'. We recommend to choose 'yes'. If you do, the numbers in line 54 will be used to correct all the samples entered in the collection sheet. For instance, if the mean weight difference of all field blanks will be 0,01 mg, the filter weight of all samples in the collection sheet will be subtracted with 0,01 mg. Importantly, first evaluate the information on field blanks before changing this option into 'yes'. Make sure that the information on field blanks is correct, as it will influence the final concentrations for respirable dust and respirable RCS of each individual sample.

2. Enter in lines 8-10 the analytical limits of detection for weighing procedures and analytes. Again, this is important information as it will detect which samples in the collection sheet will be below or above the limit of detection. If needed, check with your (external) laboratory what the precision of the balance is, which type of analytical procedures have been used (FTIR or XRD), and what the exact limit of detection is for each relevant analyte (quartz, cristobalite, tridymite).

6	INFORMATION ON THE ANALYTICAL LIMIT OF DETECTION:					
7			Dust	Quartz	Cristobalite	Tridymite
8	Balance (mg)					
9	FTIR (mg)					
10	XRD (mg)					

3. Enter in lines 18-50 all relevant information on field blanks. See detailed instructions below what a field blank is and the exact procedures for field blanks. For each field blank, the following information should be entered:

    a. Date of the field blank
    b. Sample ID of the field blank
    c. Short free text for additional information or a short remark, if applicable
    d. Pre-weight of the filter
    e. Post-weight of the filter
    f. If relevant, the analytical results of the analytes (quartz, cristobalite and/or tridymite) if the field blank was sent to the laboratory for further analysis. **IMPORTANTLY**, if the analytical result of quartz, cristobalite or tridymite is below the limit of detection, **enter zero** in these cells. If you would enter the analytical limit of detection in these cells, all samples in the worksheet 'Collection sheet' will be corrected with this value and there will be an overcorrection of the actual samples.

13	FIELD BLANKS						ANALYSIS OF FIELD BLANKS		
14	For information on field blanks see instruction								
15									
16	Date	Field blank ID		Pre-weight (mg)	Post-weight (mg)	Amount (mg)	Quartz (mg)	Cristobalite (mg)	Tridymite (mg)
17	1-Dec-20	sample ID	additional info	2,000	2,200		0,001	0,002	0,003
18									
19									
20									

Please do not enter information in the orange box in this worksheet. It automatically selects the relevant information needed for statistical evaluation in BWStat. Based on this information all actual measurements in the worksheet 'Collection sheet' will be identified as being below or above the limit of detection. More detailed information can be found in chapter 6 of this protocol.

L	M	N	O
Input parameters LOD for calculations with BWStat			
Summary LOD for each analyte	mg		
Dust (mg)			
Quartz (mg)			
Cristobalite (mg)			
Tridymite (mg)			

What is a field blank?

A field blank is a filter handled in exactly the same way as a normal sample, **except** for the actual sampling itself.

Why do we need field blanks?

Information on the analytical limits of detection is only part of the information needed to calculate the limit of detection (LOD) for a dust sampling method. Irregularities in other steps of the sampling are not incorporated in the analytical limit of detection, for instance:

- Pollution of the filters when sampling heads are not properly cleaned after previous sampling, resulting in extra dust on the filters
- When removing filters out of the sampling head, slight damage of the filters might occur resulting in a small decrease in filter weight

When collecting and reporting field blanks in the excel sheet we will be able to detect problems **during sampling**, if any.

How many field blanks should be taken:

- During each measurement day at least one field blank should be collected
- When dust samples are further analysed in the lab at least 20% of all available (gravimetric) field blanks should be analysed for the relevant analytes for your company (quartz, cristobalite, etc), with a minimum of 1 per campaign. When taking 10 field banks within a sampling campaign, 2 field blanks should be analysed for each analyte.

Handling field blanks when also using weighing blanks in the lab

Some companies also use weighing blanks in their lab to account for differences in weighing conditions during pre- and post-weighing of the filters. Apparently, there has been some confusion how to handle field blanks when samples are also corrected for weighing blanks in the lab.

THE GOLDEN RULE IS AS FOLLOWS: FIELD BLANKS SHOULD BE TREATED AS ANY OTHER REGULAR SAMPLE.

Thus: if you use weighing blanks to correct your regular samples, also correct your field blanks in exactly the same way. The best thing to do is not to identify field blanks for the weighing personnel to avoid any confusion.

Working procedure for field blanks:

- Pre-weigh filter as other filters
- Put the filter in the sampling head as other filters
- Take the field blank with you to the field as other samples. Distribute the pumps and samples to the workers in a dust free environment on the production site, for instance an office room or coffee break room. Handling samples and field blanks on the actual dusty working environment may cause pollution on the samples before the actual sampling starts.
- Unpack the field blank in the field as other samples (if relevant). Do not connect the field blank to a running pump (no active sampling) and do not leave the field blank unpacked in the field during the sampling day (no passive sampling). After unpacking the field blank immediately treat the field blank as a sample which was just returned from the actual sampling (pack as other samples).
- Transport the field blank back to the lab in exactly the same way as all other samples
- Post-weigh filter as other filters (after reconditioning like all other samples)

- Enter all information in the collection sheet ‘LOD and field blanks’
- Select field blanks for further analyses
- Send the filter of the field blank to the lab with all other filters to be analysed
- Enter the results of the analyses in the collection sheet ‘LOD and field blanks’
    - Fill in the date of the field blank
    - Enter the sample ID for future identification and tracking
    - Add additional information if necessary (free text)
    - Enter pre- and post-weight of the filter. Make sure you receive actual weight information of the field blanks from the analytical laboratory or contractor in order to make any calculations on the LOD. Some laboratories only report a field blank as being below the limit of detection, without specifying information on pre- and post-filter weight. Such limited information is insufficient for estimating LOD.

When all information had been entered in the worksheet ‘LOD & Field blanks’ the information is summarized in lines 52-53:

- The limit of detection (LOD) is the lowest concentration of the analyte that can be reliably detected and distinguished from zero. It is calculated as the mean of the blanks + three times the standard deviation of the blanks. For dust this information will be used to identify which samples in the worksheet ‘Collection sheet’ are below or above the limit of detection (for RCS this will be done based on the analytical limit of detection in lines 9 and 10 of this worksheet.
- Blank correction: the mean value of all field blanks. This information will be used to correct all individual samples in the worksheet ‘Collection Sheet’. Make sure that all field blank information is correct, as this will impact all individual sampling results.

52	Limif of Detection (LOD)							
53	Blank correction				0,000	0,000	0,000	0,000

Instructions worksheet ‘Collection sheet’

General remark

One of the goals of the collection sheet is to record data for future use and optional to pool data from multiple sites and/or companies. Some of the information that is required in the collection sheet does not change within one campaign but still needs to be filled in for each individual sample (e.g. NEPSI sector, Country, Company, Site, and probably also Sampler, Sample collection material). In case data from multiple campaigns within a site, from multiple sites or even multiple companies need to be pooled, this information will be important contextual information of the data that needs to be available. Without this information, pooling of data will be hampered significantly.

NEPSI sector

Your NEPSI sector can be chosen from the drop-down menu. The drop-down list is defined in the green colour tabbed worksheet ‘NEPSI sector’. As all the NEPSI sectors have been listed here, there won’t be a need for editing this drop-down list. In column B a country code will appear as soon as you have chosen a country.

Country

The country can be chosen from the drop-down menu. All European sectors have been predefined in the green colour tabbed worksheet 'Countries'. As all European countries been listed here, there won't be a need for editing this drop-down list. In column D a country code will appear as soon as you have chosen a country.

Company and Site

For further identification of the samples, you can add the name (or a code) for a specific company and/or a specific site within a company. This can be entered as number or free text.

Sampler

In this column specify which type of sampler has been used, using the drop down menu. The drop-down list is defined in the green colour tabbed worksheet 'Samplers'. If your sampler is not specified in the drop-down menu, please go to the green colour tabbed worksheet 'Samplers' and change one of the 'User Defined' options in the name of your sampler. This is then added to the drop-down list as used by the Collection sheet.

Sample collection material

In this column specify which type of filter has been used, using the drop down menu. The drop-down list is defined in the green colour tabbed worksheet 'Sample collection material'. If your filter/foam is not specified in the drop-down menu, please go to the green colour tabbed worksheet 'Sample collection material' and change one of the 'User Defined' options in the name of your filter/foam. This is then added to the drop-down list as used by the Collection sheet.

Date

Enter the date for each sample using day – month – year format.

Technician ID

For reasons of traceability you may want to add the name (or code) of the technician involved in taking the sample.

Sample ID

Each sample should be given a unique sample ID. This sample ID can be used during the actual sampling and for identification of the sample for the laboratory.

Type of measurement

Only full-shift personal measurements will be relevant within the framework of the NEPSI RCS monitoring protocol. This can be chosen from the drop-down menu. There are two other options in the drop-down menu, in case some static or task-based sampling has been done and you want to document all samples within a campaign in the same collection sheet. Importantly, compliance testing conform EN-689 is only valid for personal samples and can be analyseD with BWStat.

Sample location

Is a free text field for more specific information on the exact department or location of the sampling, if needed.

Job Function (SEG)

In this column the job function or Similar Exposure Group (SEG) of the worker should be entered for the main task performed during the sampling. The name of the job function or SEG can be chosen from the drop-down menu. Importantly, each NEPSI sector needs to define their own SEGs. Once you have defined your SEGs, please go to the red colour tabbed worksheet 'SEG-list' and change the 'User Defined' options in the name of your SEGs. This is then added to the drop-down list as used by the Collection sheet. The worksheet 'SEG list' should therefore be filled before entering measurement data in the Collection sheet.

Worker ID

It is important that each worker participating in the sampling program is given a *UNIQUE WORKER CODE!!* A unique worker code will only be assigned to one and only one individual. Not only during one sampling campaign, but it has to be retained during the follow-up of all other campaigns. The same worker code has to be assigned to the same worker and not to any other worker. Worker codes should also be different between sites.

A personal registration number in the staff register of the company is a good example of such a unique worker code (if personal registration numbers are not reused when workers leave the company).

So it is very important that we can distinguish worker A and worker B, not only during one specific campaign, but we also need to be sure that worker B is the same worker B in all campaigns of that particular company even when a worker moves from site A to site B.

If unique worker codes have been assigned, the opportunities for the statistical analyses of the data will strongly increase.

Shift

Enter the relevant shift using the drop down menu: day, morning, afternoon, evening, night. The options in the drop-down list have been defined in the worksheet 'Shifts'. In general, there will be no need to modify this drop-down list, but it is possible when needed.

Shift length (hours)

For each sample the total regular shift length should be entered (do not enter the actual sampling time in this column!). So if a regular working day is 8 hours, please enter '8' in this column. If continental shift patterns are relevant for your site (3 x 12 hours or 4 x 12 hours), please enter '12' in this column.

Filter Weight before sampling (mg)

In this column enter the pre-weight of the filter. Make sure the weighing procedure is followed as described in the Protocol.

Filter Weight after sampling (mg)

In this column enter the post-weight of the filter. Make sure the weighing procedure is followed as described in the Protocol.

Weight collected dust (mg)

The weight collected dust will be calculated automatically. In case the laboratory does not report pre- and post-weight of the filter, but only weight difference, the calculation can be overruled by entering the reported weight difference in the column ('weight collected dust (mg)'). However, if pre- and post-weight of filters is available it is strongly advised to enter this more detailed information, as this will increase the possibilities for quality checks en control.

Weight collected dust corrected for blanks(mg)

If you choose the option to correct all samples for the field blanks in the worksheet 'LOD & Field blanks', the corrected weight collected dust will be calculated automatically (by subtracting the mean result of all field blanks from the sample weight).

Measured Flow rate at start sampling

In this column note down the measured flow rate in litres/minute at the start of the sampling. In case of a CIP10, note down the flow rate in litres/minute that correspond to the reading in rounds per minute (rpm).

Measured Flow rate at end sampling

In this column note down the measured flow rate in litres/minute at the end of the sampling. In case of a CIP10, note down the flow rate in litres/minute that correspond to the reading in rounds per minute (rpm).

Average Flow rate

The average flow rate during the sampling day will be calculated automatically. Please make sure that you enter the actual flow rate for each sample. The best practice for checking and estimating flow rate may differ, dependent on the sampler being used. Follow the best practice for your type of sampling equipment. In principle the calculation in the collection sheet can be overruled by entering a value in this column. However, it is strongly advised to enter the more detailed information and use the calculation option, as this will increase the possibilities for quality checks and control.

Sampling time on

In this column enter the exact time when the sampling was started using the time format, for instance 8:20 hours (do not type just 8 when you mean 8:00)

Sampling time off

In this column enter the exact time when the sampling was stopped using the time format, for instance 16:20 hours (do not type just 16 when you mean 16:00)

Sampling duration time (min)

The sampling duration will be calculated automatically. In principle the calculation in the collection sheet can be overruled by entering a value in the cell. However, it is strongly advised to enter the more detailed information and use the calculation option, as this will increase the possibilities for quality checks and control. If the sampling on a worker is stopped during lunch time you could choose for the option to enter the total sampling time here (sum of the sampling times before and after lunch break). However, it is preferred to continue sampling during lunch break (with the worker still carrying the pump in the lunch break area).

Sampled Volume (l)

The sampled volume will be calculated automatically. In principle the calculation in the collection sheet can be overruled by entering a value in the cell. However, it is strongly advised to enter the more detailed information and use the calculation option, as this will increase the possibilities for quality checks and control.

Calculated dust concentration (mg/m^3)

The time weighted average (TWA) dust concentration will be calculated automatically. In principle the calculation in the collection sheet can be overruled by entering a value in the cell. However, it is strongly advised to enter the more detailed information and use the calculation option, as this will increase the possibilities for quality checks and control.

8-hour TWA dust concentration (mg/m^3)

The 8-hour time weighted average dust concentration will be calculated automatically, by using the regular shift length. If a regular shift will be very different from a regular 8-hour shift, the 8-hour TWA dust concentration will be different from the calculated dust concentration. For instance, if your workers normally work on 12-hour shifts, the 8-hour TWA dust concentration will be higher, as the OELV has been set for an 8-hour exposure. If all your workers only work on regular 8-hour shifts, both concentrations will be the same.

Analyses

When samples are sent to the lab for further analysis, enter the relevant information in the appropriate columns:

- Quartz
- Cristobalite
- Tridymite

Quartz, Cristobalite or Tridymite Technique

In this columns enter the type of lab analyses, using the drop down menu. The drop-down list is defined in the green colour tabbed worksheet 'Analytical technique'. If your sampler is not specified in the drop-down menu, please go to the green colour tabbed worksheet 'Analytical technique' and change the 'User Defined' option in the name of your analysis. This is then added to the drop-down list as used by the Collection sheet.

Weight Quartz, Cristobalite or Tridymite (mg)

In this column enter the results of the lab analyses in milligrams. It is important that lab results below the analytical limit of the detection (LOD) are clearly marked in this column, preferably by entering the analytical limit of detection. When entering the analytical the analytical limit of detection in this field, samples will be treated in the statistical analysis as being below the LOD.

Weight collected dust corrected for blanks(mg)

If you choose the option to correct all samples for the field blanks in the worksheet 'LOD & Field blanks', the corrected weight collected RCS will be calculated automatically (by subtracting the mean result of all field blanks from the sample weight.

Concentration Quartz, Cristobalite or Tridymite (mg/m^3)

The time weighted average (TWA) concentration of the analytes will be calculated automatically. In principle the calculation in the collection sheet can be overruled by entering a value in the cell. However, it is strongly advised to enter the more detailed information and use the calculation option, as this will increase the possibilities for quality checks and control.

Percentage Quartz, Cristobalite or Tridymite (%)

The percentage of analyte in the dust will be calculated automatically.

8-hour TWA concentration Quartz, Cristobalite or Tridymite (mg/m^3)

The 8-hour time weighted average analyte concentration will be calculated automatically, by using the regular shift length. If a regular shift will be very different from a regular 8-hour shift, the 8-hour TWA dust concentration will be different from the calculated dust concentration. For instance, if your workers normally work on 12-hour shifts, the 8-hour TWA dust concentration will be higher, as the OELV has been set for an 8-hour exposure. If all your workers only work on regular 8-hour shifts, both concentrations will be the same.

Information on relevant tasks during sampling (free text)

Here you can summarize relevant information from the back of the sampling form in case specific tasks or activities have been performed that will be important for proper interpretation of the sampling result.

Respiratory protection worn during specific tasks

Select yes or no if the worker used respiratory protection during a specific task during the day of sampling. If so, further specify in the previous free text cell for which tasks this was relevant. As respiratory protection was only used during part of the day, no correction is possible of the measured exposure concentration, as they will reflect the mean exposure during the entire shift, and respiratory protection was only used during specific parts of the day.

Respiratory protection worn during the entire shift

Select yes or no if the worker used respiratory protection during the entire day of sampling. If so, it is possible to correct the measured concentration using the Assigned Protection Factor connected to the specific respiratory protection device that was used.

Type of respiratory protection worn and Assigned Protection Factor (APF)

In this column specify which type of respiratory protection that was used, using the drop down menu. The drop-down list is defined in the green colour tabbed worksheet ‘RPE’. If your type of respiratory protection is not specified in the drop-down menu, please go to the green colour tabbed worksheet ‘RPE’ and change one of the ‘User Defined’ options in the name of your type of respiratory protective device. This is then added to the drop-down list as used by the Collection sheet.

The protection factor varies per type of respirator. In the worksheet ‘RPE’ the commonly used protection factor for each type of respirator has already been added, based on the ‘Assigned Protection Factor (APF)’ (the protection to be expected in actual field conditions). This protection factor is automatically added in the collection sheet if a respirator is selected. For the option Supplied Air Respirator no APF has been entered yet, as this largely depends on the exact type being used, and should be entered by the user. In case you enter a new type of respirator in one of the two ‘User Defined’ options in column A of this worksheet, you also should add the APF in column B.

Corrected concentrations (dust, quartz, cristobalite, tridymite)

If the respiratory protection was worn during the entire shift, the corrected concentrations for respirable dust, quartz, cristobalite and tridymite will be calculated by dividing the concentration with the Assigned Protection Factor (APF) for the selected type of respiratory protection. This is only done, however, if the option ‘yes’ was selected in the column ‘Respiratory protection worn during the entire shift’. If not, no corrected concentrations will be calculated. If respiratory protection was only worn during specific tasks during the sampling day, it would be totally incorrect to correct a full-shift average concentration, as the protection factor was only relevant for the duration of that specific task.

Summarized information on control measures (free text)

Here you can summarize relevant information from the back of the sampling form with regard to the control measures in place that will be important for proper interpretation of the sampling result.

General comments (free text)

Here you can add any other information that will be important for proper interpretation of the sampling result, for instance if any process disturbance took place during the sampling day, specific process characteristics, etcetera.

HSE
Health & Safety Executive

Reducing risks, protecting people

HSE's decision-making process

HSEBOOKS

Reducing risks, protecting people

HSE's decision-making process

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Contents

Preface

We are pleased to present the document *Reducing risks, protecting people* revised in the light of comments on the discussion document.

The Health and Safety Executive (HSE) published the original discussion document *Reducing risks, protecting people* in May 1999. It set out how the statutory bodies responsible for the administration of the Health and Safety at Work Act 1974[1] ('the HSW Act') approached those decisions about the management of risk that are required of them under the Act. For the Health and Safety Commission (HSC) these include making arrangements to secure the health, safety and welfare of people at work, and the health and safety of the public, in the way undertakings are conducted – including proposing new laws and standards, conducting research and providing information and advice. HSE advises and assists HSC in its functions, including the preparation of draft regulations and Approved Codes of Practice. It has some specific statutory responsibilities of its own, notably for the enforcement of health and safety law, the licensing of nuclear power stations and dealing with a variety of safety case regimes etc. Local authorities also have statutory responsibilities for enforcement of health and safety law, mainly in the distribution, retail, office, leisure and catering sectors.

A major purpose of the document was to set out an overall framework for decision taking by HSE which would ensure consistency and coherence across the full range of risks falling within the scope of the Health and Safety at Work Act. This framework was based on the method which HSE applies to the control of risk at nuclear power stations, originally published in 1988 as *The tolerability of risks from nuclear power stations (TOR)*.[2]

Events since the publication of the discussion document have reinforced the need to publish a description of HSE's decision-making process. Over recent years, public concern over such matters as Bovine Spongiform Encephalopathy (BSE), railway safety and food safety has intensified the call for openness about how decisions are taken on the regulation of risks. The public is also more aware that, given few activities are without any risk, there must be a balance between the health and safety measures introduced to eliminate or control risks, and the costs arising or benefits forgone when the measures are introduced. Hence the recent lively debate about where that balance lies.

Not surprisingly, there was great interest in the discussion document. It was widely distributed both in print and electronically in a portable format. We received over 150 responses, many of them representing consolidated replies from a number of interested parties, and around 10 000 hits on the Internet site. We thank all those who have responded. Your comments have proved invaluable and the new version has taken them into account.

In fact most of the comments received were generally favourable. The concept of a single document explaining HSE's decision-making process was welcomed, as was the extension

of TOR beyond the nuclear industry. Moreover, the decision-making framework was accepted as being universally applicable, and no area was identified where the proposed criteria on tolerability would create difficulties. The majority of respondents also found that good practice had been given the right emphasis and supported the principles for conducting cost benefit analysis.

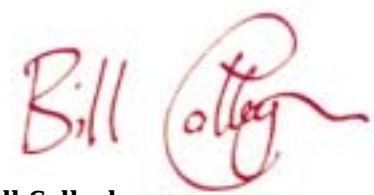
Nevertheless, the consultation has highlighted some points which could benefit from clarification. One of these relates to the status of the document. We would like to emphasise that the document is aimed at explaining the decision-making process in HSE rather than providing guidance to individual duty-holders on what they need to do. Such guidance is available in other documents and particularly *Management of health and safety at work regulations 1999. Approved Code of Practice and Guidance*.[3] The consultation process has shown that many duty holders, and others involved in occupational health and safety, would like to emulate HSE's approach to devising the control regime that should be put in place for addressing hazards at work. As the new document says, we welcome this as long as those who want to emulate the regulator recognise the different context in which HSE applies the framework and take this into account when applying our process to their own decisions. We have amended the text to make this distinction clearer.

We have also taken the opportunity to dispel any perception that we were moving away from a risk-based approach. The new version emphasises the role of risk assessment, both quantitative and qualitative, in the decision-making process and expands on the role of good practice in determining the control measures that must be put in place for addressing hazards. We also make clear that the philosophy and approach set out in the document operate within, and not as an alternative to, the principles of good regulation published by the Better Regulation Task Force.

In presenting this latest document we recognise there will be scope for further development and refinement. We shall revise it as necessary so that it remains a document attuned to current needs.

Improving health and safety requires attention to the assessment and management of risk. For this to be achieved, we need to raise public understanding of the issues involved and of our own understanding of the concerns of society and the values people employ when they consider matters of risk. Prompting a more informed public debate on how to handle risk is an essential part of this and we hope that publication of this document will help to stimulate this debate. We will certainly play our part in doing so.

Finally, we would like to thank all those, both in HSE and outside, who have contributed to the redrafting of this document.



Bill Callaghan
Chair
Health and Safety Commission

Timothy Walker
Director General
Health and Safety Executive

Introduction

This document is aimed primarily at stakeholders who want to know more about HSE's philosophy for securing the health, safety and welfare of persons at work and for protecting others against risks to health and safety arising from work activities, and the procedures, protocols and criteria underpinning the philosophy. It sets out the basis and criteria by which HSE, in complying with its functions, decides upon the degree and form of regulatory control that it believes should be put in place for addressing occupational hazards. It considers the way scientific evidence (or the lack of it) and uncertainties are taken into account and how the balance is struck between the benefits of adopting a measure to avoid or control the risks, and its disadvantages.

It is in three parts and has four appendices, as follows:

Part 1

- Sets out the aims of the document, namely the need to:
  - open to scrutiny HSE's approach to the regulation and management of risk, and the philosophy underpinning it;
  - make transparent the factors that inform our decisions on how risks should be regulated and managed, for example how account is taken of the scientific knowledge of the risks concerned, the technology available for controlling them, the resource implications of adopting the decisions, public attitudes towards the risks and the benefits they engender and show how these shape the form and content that our regulations and guidance take;
  - help reassure the public that risks to people from work activities are properly addressed, taking due account of the benefits of the activities giving rise to the risk. In particular to satisfy the public that industry, in taking advantage of technological advances and in responding to economic pressures, will not be allowed to impose intolerable risks on people;
  - let other regulators, whose responsibilities may overlap with those of HSC/E, know the basis for the management of health and safety risks from work activities and thereby help to promote consistency of decision-making amongst regulators. In this instance, consistency does not mean uniformity, it means the particular application of a coherent philosophy in a way suitable to the particular context.

- Mentions some of the difficulties inherent in meeting the above aims, particularly those involved in taking account of ethical, social, economic and scientific considerations and the preference values of society at large.

- Introduces the concept of tolerability which is central to the document. This concept (explained in greater detail in Part 3) refers to a willingness to live with a risk so as to secure certain benefits.

- Points out that the proper regulation of risks requires that both the individual risks and societal concerns engendered by a hazard must be addressed.

Part 2

- Reviews some of the developments that have influenced our approach to decision-making since the HSW Act was enacted. The developments examined include advances in knowledge on how people view risks; changes in the regulatory environment and on the industrial scene; and shifts in the values, preferences and expectations of our society.

- Describes the principles of good regulation that have evolved in adapting our approach to take account of the developments; namely:
  - the targeting of action: focusing on the most serious risks or where the hazards are less well controlled;
  - consistency: adopting a similar approach in similar circumstances to achieve similar ends;
  - proportionality: requiring action that is commensurate to the risks;
  - transparency: being open on how decisions are arrived at and what are their implications; and
  - accountability: making clear, for all to see, who is accountable when things go wrong.

- Notes some of the above developments which have been particularly important, ie:
  - the need for the meaning of risk to encompass more than physical harm by taking into account other factors such as ethical, economic and social considerations;
  - the recognition that, because the system for informing and reaching decisions is iterative, it is often very difficult to put a demarcation line between risk assessment and risk management;
  - a discussion by the Courts of the meaning of 'risk' in the HSW Act which implies that approaches for managing risks must ensure that anything in an undertaking presenting the possibility of danger (or what conceptually is regarded as a hazard) has to be properly addressed.

Part 3

- Describes the six stage iterative system adopted by HSE for reaching decisions on how risks should be regulated and managed, namely:
  - deciding whether the issue is primarily one for HSC/E;
  - defining and characterising the issue;

- ✦ examining the options available for addressing the issue, and their merits;
- ✦ adopting a particular course of action for addressing the issue efficiently and in good time, informed by the knowledge gained going through the six stage iterative system and by the expectation that as far as possible the course of action will be supported by stakeholders;
- ✦ implementing the decisions;
- ✦ evaluating the effectiveness of actions taken and revising the decisions and their implementation if necessary.

- Sets out the framework, known as the Tolerability of Risk (TOR),[2] for reaching decisions on whether risks from an activity or process are unacceptable, tolerable or broadly acceptable and its application in practice. In this context, 'tolerable' does not mean 'acceptable'. It refers instead to a willingness by society as a whole to live with a risk so as to secure certain benefits in the confidence that the risk is one that is worth taking and that it is being properly controlled. However, it does not imply that the risk will be acceptable to everyone, ie that everyone would agree without reservation to take the risk or have it imposed on them.

- The framework makes clear that:
  - ✦ both the level of individual risks and the societal concerns engendered by the activity or process must be taken into account when deciding whether a risk is unacceptable, tolerable or broadly acceptable;
  - ✦ the decision-making process and criteria adopted are such that action taken is inherently precautionary;
  - ✦ moreover, HSE starts from the position that, for every hazard, the law requires that:
    - – a suitable and sufficient risk assessment must be undertaken to determine the measures needed to ensure that risks from the hazard are adequately controlled;
    - – suitable controls must be in place to address all significant hazards, and
  - ✦ HSE also starts with the expectation that:
    - – those controls, at a minimum, must achieve the standards of relevant good practice precautions, irrespective of specific risk estimates;
    - – where there is no relevant good practice, or the existing good practice is considered by HSE to be insufficient or inadequate, the decision as to what control measures are suitable will generally be informed by further risk assessment;
    - – there are some risks from certain activities, processes or practice which are not tolerable whatever the benefits, i.e. they are unacceptable. Any activity, process or practice giving rise to risks falling in that region would be ruled out unless the activity, process etc can be modified to reduce the degree of risk so that it becomes tolerable;
    - – as control measures are introduced, the residual risks may fall so low that additional measures to reduce them further are likely to be grossly disproportionate to the risk reduction achieved, though the control measures should still be monitored in case the risks change over time;
  - ✦ HSE has proposed numerical criteria for informing decisions on the tolerability of risks only for very limited categories of risk, for example, those entailing fatalities either individually or in multiple fatality accidents.

Appendix 1

Sets out some of the conventions adopted for undertaking risk assessment. It points out that:

- more often than not, a risk assessment is done in relation to a hypothetical person (a hypothetical type of individual who is deliberately assumed to have some fixed relation to the hazard under consideration);
- the procedures adopted for handling uncertainty are in line with the precautionary principle and ensure that a lack of certainty is not a reason for not taking preventive action.

Appendix 2

Sets out:

- the architecture of health and safety law;
- the constraints that must be taken into account when introducing health and safety legislation;
- the procedures adopted for identifying the hierarchy of options for new regulatory measures.

Appendix 3

Examines some issues relevant to assessing risk reduction options, including:

- the implication of case law on 'reasonable practicability';
- the protocols and procedures adopted for conducting a cost benefit analysis and for ensuring consistency when comparing costs against benefits.

Appendix 4

Gives some statistics for comparing risks from different hazards.

Part 1

Overview of risk and risk management issues

Purpose of this document

1 Work activities give rise to many hazards which present risks to workers and the public. The HSC/E are responsible for regulating such risks. The aim of this document is to explain the basis for HSE's decisions regarding the degree and form of regulatory control of risk from occupational hazards, and in particular to:

- open to scrutiny our approach (eg when advising the HSC) to the assessment, management and regulation of risk and the philosophy underpinning it;
- make transparent the factors that inform our decisions on risks and show how these shape the form and content of our regulations and guidance. For example, how account is taken of the scientific knowledge of the risks concerned, the technology available for controlling them, public attitudes towards the risks, the benefits engendered by allowing the processes, events etc giving rise to the risk to take place;
- help reassure the public that risks to people from work activities are properly addressed, taking due account of the benefits of the activities giving rise to the risks. In particular to satisfy the public that industry, in taking advantage of technological advances and in responding to economic pressures, will not be allowed to impose intolerable risks on people;
- let other regulators, whose responsibilities may overlap with those of HSC/E, know the basis for the management of health and safety risks arising from work activities and thereby help to promote consistency of decision-making amongst regulators.

2 The central purpose throughout has, therefore, been on opening up our decision-making process rather than providing guidance to duty holders. The document is thus aimed at showing how our approach to the assessment and management of risk shapes the form and content of our regulations and guidance, and informs our compliance activities. The difference in emphasis is important. For example, as we point out in paragraphs 80-81 the boundaries that HSE applies in assessing and regulating risks are generally much broader than those we would expect duty holders to undertake in complying with the relevant statutory provisions.

Hazard and risk

Hazard and risk are used interchangeably in everyday vocabulary. Nevertheless, it has proved useful to HSE to make a conceptual distinction between a 'hazard' and a 'risk'

by describing a hazard as the potential for harm arising from an intrinsic property or disposition of something to cause detriment, and risk as the chance that someone or something that is valued will be adversely affected in a stipulated way by the hazard. HSE – as far as the health, safety and welfare of people is concerned – frequently makes use of the above conceptual distinction in its guidance by requiring that hazards be identified, the risks they give rise to are assessed and appropriate control measures introduced to address the risks. This reflects the fact that in most cases it makes sense to take account of the circumstances in which people and management systems interact with a hazard.

It is often possible to regard any hazard as having more remote causes which themselves represent the 'true hazard'. For example, when considering the risk of explosion from the storage of a flammable substance, it can be argued that it is not the storage per se which is the hazard but the intrinsic properties of the substance stored. Nevertheless, it makes sense to consider the storage as the basis for the estimation of risk since this approach will be the most productive one in identifying the practical control measures necessary for managing the risks, such as not storing the substance in the first place, using less of it or a safer substance, or if there is no alternative to storing the substance, using better means of storing it.

The term 'hazard' is absent in the HSW Act.[1] However, the Courts have ruled that as, far as section 3 of the Act is concerned, 'risk' means 'possibility of danger' rather than 'actual danger' (see paragraphs 41-42). Conceptually, HSE will therefore regard anything presenting the 'possibility of danger' as a 'hazard'. Moreover, since in any given workplace there would be a large number of hazards which duty holders could address, requiring duty holders formally to address them all would place an excessive and largely useless burden on them. So as not to impose unnecessary burdens on duty-holders, HSE will not expect them to take account of hazards other than those which are a reasonably foreseeable cause of harm, taking account of reasonably foreseeable events and behaviour. Whether a reasonably foreseeable, but unlikely, event – such as an earthquake – should be considered depends on the consequences for health and safety of such an event.

Why the need to explain decisions on the management of risk?

3 The risk of suffering harm is an inescapable aspect of living. Nevertheless, there has been tremendous progress in improving many aspects of the quality of our lives. We now live longer than at any time in history; products for use at home and at work are safer and more reliable than ever before. Although accidents at work still occur, the trend averaged over the years has been downwards and we have recently published our targets for reducing these further.[4]

4 This progress in the quality of our lives is readily acknowledged but, paradoxically, it has been accompanied by an increased expectation for a society free of involuntary risks. The

rapid technological developments of recent years have introduced new hazards but also enhanced the scope for controlling existing hazards. Though people accept that we should continue to take advantage of advances in science and technology, this is moderated by expectations that:

- those responsible for the hazards should ensure that adequate measures are taken to protect people from the harmful consequences that may arise from such hazards;

- the State should be proactive in ensuring that its arrangements for securing the protection of people from risks are adequate and up to date as distinct from reacting to events, and that those arrangements should address, as necessary, the concerns the hazards give rise to.

5 Such expectations are complemented in a free market economy by an underlying presumption that industry should be able to take advantage of new technologies, unfettered by undue State intervention.

6 It was such conflicting pressures that led the Government, in an initiative supported by all parties in the political spectrum, to undertake in the early seventies a fundamental review, under the Chairmanship of the late Lord Robens, of the way occupational risks are regulated and managed.[5] The result is that risks to health and safety arising from workplace activity in Great Britain are regulated through a single legal framework – the relevant statutory provisions which include the HSW Act – and by a single set of institutions – the Health and Safety Commission (HSC) and the Health and Safety Executive (HSE), (see the second paragraph of the Preface).

7 A fundamental principle underpinning the HSW Act is that those who create risks from work activity are responsible for protecting workers and the public from the consequences. Thus, the HSW Act places specific responsibilities on employers, the self-employed, employees, designers, manufacturers, importers, suppliers and people in charge of premises. Associated legislation places additional duties on owners, occupiers, licensees and managers.

8 Regulations have also been introduced clarifying these duties, requiring people such as employers and the self-employed to assess risks and to base their control measures on the results of the assessments. Where hazards entailing severe consequences are involved, the trend in recent years has been to amplify the duties for generic risk assessments to require the production of safety cases. These require duty holders to write down and submit to HSE the measures they have in place, or intend to introduce, to meet their legal obligations and ensure safe and healthy systems of work and the proper management of health and safety. This enables duty holders to demonstrate that they understand the hazards associated with work activities and how to control them.

9 In short, since 1974 the trend for managing risk at work has been to merge and centralise the authorities responsible for occupational health and safety and to clarify responsibilities in criminal law for managing risks in particular circumstances through the establishment of regulatory regimes whereby broad general duties are explicitly put on those who are best placed to do something about preventing or controlling the risks. The broad duties are supplemented by specific regulations. Many of these regulations place absolute duties

on duty holders. Others, however, like the broad general duties are qualified by expressions such as 'so far as is reasonably practicable' (SFAIRP) in order to avoid the imposition of duties that no one can fulfil – because absolute safety cannot be guaranteed – and in order to ensure that preventive and protective actions are commensurate with the risks. It is useful to note that SFAIRP is not the only qualification. There are other similar qualifications such as 'as low as reasonably practicable' (ALARP); 'as low as reasonably achievable' (ALARA).

10 The general approach is to set out the objectives to be achieved and to give considerable choice to duty holders as to the measures they should put in place to meet these objectives. However, this is not universal. As explained later in this document, there are circumstances where the enabling powers of the HSW Act have been used to enshrine in regulations specific measures for ensuring that the risks from certain hazards are properly controlled – extending in certain circumstances to proscriptions or to the establishment of a licensing or permissioning regime for certain activities.

11 A similar trend towards centralisation of regulatory authorities and the adoption of non-prescriptive regimes is found in other areas, eg the environment.

12 For a non-prescriptive regime to work, duty holders must have a clear understanding of what they must do to comply with their legal obligations. It is therefore not surprising that HSE, as the regulator responsible for implementing the law on health and safety, is being pressed with increasing frequency for explanations of how risk issues are addressed, both in general and in particular circumstances, so that the risks are regarded as tolerable. In this context 'tolerable' does not mean 'acceptable'. It refers instead to a willingness by society as a whole to live with a risk so as to secure certain benefits and in the confidence that the risk is one that is worth taking and that it is being properly controlled. However, it does not imply that the risk will be acceptable to everyone, ie that everyone would agree without reservation to take the risk or have it imposed on them.

13 Providing such an exposition of the risk decision-making process is not an easy task. The process is inherently complex, with a variety of inputs. It has to be workable whilst allowing the use of judgement by the regulator and flexibility for duty holders. At the same time, it must reflect the values of society at large on what risks are unacceptable, tolerable or broadly acceptable. Any informed discussion quickly raises ethical, social, economic and scientific considerations, for example:

- whether certain hazards should be entertained at all;
- how to maximise benefits to society through taking account of advances in scientific knowledge and technology while ensuring that undue burdens with adverse economic and social impact or consequences are not imposed on the regulated;
- how to achieve the necessary trade-offs between benefits to society and ensuring that individuals are adequately protected;
- the need to avoid the imposition of unnecessary restrictions on the freedom of the individual.

14 The reform of the law relating to health and safety at work, set in train by the HSW Act itself, has proceeded over the past 25 years or so by taking such considerations into account. The approach has evolved – and is still evolving – through the formulation of regulations, Approved Codes of Practice and guidance spanning an enormous variety of industrial activity (see Appendix 2 for a fuller discussion of these regulatory tools). The evolution has taken place under many influences which need to be reviewed in order to set the approach in its full context. This review is the subject of Part 2 following, which leads on to a description in Part 3 of the approach to regulation designed to ensure that risks that are taken are tolerable in the sense already described.

Part 2

Review of developments that have influenced our decision-making approach

Developments and influences

15 The Robens Committee's diagnosis of the issues at stake when regulating for health and safety still holds good, namely that:

- health, safety and welfare at work could not be ensured by an ever-expanding body of legal regulations enforced by an ever-increasing army of inspectors;
- primary responsibility for ensuring health and safety should lie with those who create risks and those who work with them;
- the law should provide a statement of principles and definitions of duties of general application, with regulations setting more specific goals and standards.

16 Though the above diagnosis still underpins our approach for reaching decisions on the management and regulation of risks, the approach has also evolved to take into account developments that have arisen over the past 25 years. There is nowadays a better understanding of how people view risks. Changes have also taken place in the regulatory environment and on the industrial scene. Finally, within a generation, there have been some marked shifts in the preferences, values and expectations of our society. This review examines some of these developments – particularly those which have influenced the decision-making process and criteria described in Part 3.

Advances in knowledge on how people view risks

17 How people view risks and apply value judgements is perhaps the most challenging factor to take into account when developing an approach to the regulation of risk – not least because these views and value judgements are not static but change according to circumstances. Recent studies have shown that as mankind has evolved to cope with the dangers and uncertainty of life, we have all been provided with inbuilt mechanisms for dealing with risk – mechanisms that reflect our personal preferences and the values of the society in which we live.

18 We all recognise that, as an inescapable fact of life, we are surrounded by hazards – all with a potential to give rise to unwanted consequences. Less apparent is that whatever we do, however we occupy our time or even if we 'do nothing', we are taking some kind of risk. Even at home there are myriad risks – we could get hurt, for example, in a house fire

or when doing DIY jobs. If we did something else, we would be taking other kinds of risks. Some of the risks we face may be from naturally occurring hazards while others may arise from our lifestyle and are risks we take willingly to secure some wanted benefits, eg flying to go on holiday.

19 Moreover, everyday, consciously or unconsciously, we all view hazards and evaluate their risks to determine which ones we choose to notice, ignore or perhaps do something about. We may take the consequences of some risks for granted and, for others, consider that our own chances of being harmed may be either more or less than the average, depending on the apparent degree of control we have for taking or limiting the risks, eg whether we are more nimble, younger, have better sight and so on.

20 In short, the way we all treat risks depends on our perception of how they relate to us and things we value. It is only fairly recently that social scientists have examined in detail what factors affect people's perception of risk. They have found that there is a wide range of factors. Particularly important for man-made hazards are 'how well the process (giving rise to the hazard) is understood, how equitably the danger is distributed and how well individuals can control their exposure and whether risk is assumed voluntarily'.[6]

21 Other studies on perception of risk have led to a theory which considers that it may be simplistic to believe that it will be possible to derive a quantifiable physical reality that most people will agree represents the 'true' risk from a hazard. This theory argues that the concept of risk is strongly shaped by human minds and cultures. Though it may include the prospect of physical harm, it may include other factors as well, such as ethical and social considerations, and even the degree of trust in the ability of those creating the risk (or in the regulator) in ensuring that adequate preventive and protective measures are in place for controlling the risks. The logical conclusion drawn from the theory is that it is human judgement and values that determine which factors should be defined in terms of risk and actually made subject to analysis.[7,8,9,10]

22 The theory has been used to explain why, for many new hazards, high quality risk assessments by leaders in the field often fail to reassure people. Even using all available data and best science and technology, many risk assessments cannot be undertaken without making a number of assumptions such as the relative values of risks and benefits or even the scope of the study. Parties who do not share the judgmental values implicit in those assumptions may well see the outcome of the exercise as invalid, illegitimate or even not pertinent to the problem – as exemplified by the controversy surrounding the proposal to dispose of the Brent Spar oil platform in the middle of the ocean.

23 Social scientists have also proposed another theory for explaining why risks that are minor in quantitative terms at times produce massive reactions while major risks are often ignored.[11] Their social amplification of risk model suggests that the impact of a particular risk begins with the initial victims and diffuses outward to society at large. In that process, public response to the risk can be amplified or attenuated depending on how the reporting of the risk interacts with psychological, social, cultural, and institutional processes.

24 For example, awareness of the risk of air travel following an airline crash can be amplified by a large volume of information, scientific experts challenging one another, dramatisation

of the issue and use by the media of value-laden terminology and images. This perception can then be further amplified or attenuated depending on the effects of such media exposure on the community and society as a whole.

25 These and other studies have established that hazards give rise to concerns which can be put into two broad categories:

- **Individual concerns** or how individuals see the risk from a particular hazard affecting them and things they value personally. This is not surprising since one of the most important questions for individuals incurring a risk is how it affects them, their family and things they value. Though they may be prepared to engage voluntarily in activities that often involve high risks, as a rule they are far less tolerant of risks imposed on them and over which they have little control, unless they consider the risks as negligible. Moreover, though they may be willing to live with a risk that they do not regard as negligible, if it secures them or society certain benefits, they would want such risks to be kept low and clearly controlled.

- **Societal concerns** or the risks or threats from hazards which impact on society and which, if realised, could have adverse repercussions for the institutions responsible for putting in place the provisions and arrangements for protecting people, eg Parliament or the Government of the day. This type of concern is often associated with hazards that give rise to risks which, were they to materialise, could provoke a socio-political response, eg risk of events causing widespread or large scale detriment or the occurrence of multiple fatalities in a single event. Typical examples relate to nuclear power generation, railway travel, or the genetic modification of organisms. Societal concerns due to the occurrence of multiple fatalities in a single event is known as **societal risk**. Societal risk is therefore a subset of societal concerns.

26 Hazards giving rise to societal concerns share a number of common features. They often give rise to risks which could cause multiple fatalities; where it is difficult for people to estimate intuitively the actual threat; where exposure involves vulnerable groups, eg children; where the risks and benefits tend to be unevenly distributed – for example between groups of people with the result that some people bear more of the risks and others less, or through time so that less risk may be borne now and more by some future generation. People are more averse to those risks and in such cases are therefore more likely to insist on stringent Government regulation. The opposite is true for hazards that are familiar, often taken voluntarily for a benefit, and individual in their impact. These do not as a rule give rise to societal concerns. Nevertheless, activities giving rise to such hazards (for example, Bungee jumping) are often regulated to ensure that people are not needlessly put at risk.

27 In addition to the direct societal concerns about the impact of the hazards on those affected, there is also, and importantly, a concern that, in the wake of an event giving rise to such concerns, confidence in the provisions and arrangements in place for protecting people against risks to health and safety, and the institutions responsible for setting out and enforcing these provisions and arrangements, would be undermined, however remote was the chance of the event happening in the first place. The result would be a consequential loss of trust by the public not only in the duty holders with the primary responsibility for

reducing the risk, but also in the regulator and Government – even if current provisions and arrangements were very good. Consideration of how regulation should approach hazards of this kind to safeguard against such undesirable outcomes is intensely political and usually described on a case-by-case basis. A prime consideration is the amount of resources (time, money, etc) that should be devoted to introduce measures to control the hazard, relative to the total detriment suffered by society in the event of the hazard being realised.

Changes in the regulatory environment

28 We explore below some of the marked changes that have taken place in the regulatory environment since Robens.

The internationalisation of regulation

29 The regulation of risk is nowadays increasingly being undertaken at European or international level in the form of legally binding instruments on Member States – such as directives, treaties and conventions adopted in the wake of the creation of new global markets and new technologies. For some of the new risks, like those arising as a result of the release of genetically modified organisms, action will clearly have to be taken at international level to have any effect. Moreover, in other areas the technology is moving so fast that de facto international standards or practices are evolving all the time, eg in ensuring the safe use of computerised systems for controlling plant and machinery. Regulators, industry and pressure groups in many countries are calling for such technologies to be regulated at international level as the only effective way to prescribe appropriate standards.

30 The pressure towards the internationalisation of regulation requires innovative forms of regulatory co-operation which must take into account a host of other factors such as agreements for regulatory harmonisation, mutual recognition of standards and removal of barriers to trade – such co-operation is essential since the legal instruments used for that purpose (eg directives) take precedence over national legislation.

Increased complexity in the regulation of risk

31 Throughout the long history of legislation introduced to eliminate or minimise risks, the first areas to be regulated have always been the most obvious, often requiring little scientific insight for identifying the problem and possible solutions. For example, it was not difficult to realise that controlling airborne dust would reduce the risk of silicosis in miners and that making it mandatory to guard moving parts of machinery would prevent workers from being killed or maimed. In short, dramatic progress towards tackling such problems could be (and was) made without unduly taxing existing scientific knowledge or the state of available technology.

32 However, as the most obvious risks have been tackled, new and less visible hazards have emerged and gained prominence. Typical examples include those arising from technologies such as biotechnology, and processes emitting gases which contribute to global warming

and ozone depletion. One frequent characteristic of these new hazards is that it can be very difficult to define precisely the risks they may give rise to, even when scientific knowledge is pushed to the limit. The processes that may give rise to risks are only partially understood with the result that regulatory decisions must frequently be based on limited data and considerable scientific and technological uncertainties. The control measures required by regulation should reflect the nature of the uncertainties and err on the side of health and safety.

33 Moreover, whereas in the past, agreement about the action necessary could usually be reached on the basis of the degree of risk posed by a particular hazard as assessed by applying theories from natural sciences, engineering, logic and mathematics, this is no longer the case. This approach is no longer sufficient to counter the growing demand that regulation of some risks should take account of the quality (or attributes) of the hazard as distinct from objective assessment of the quantity of risk.

34 It has become a matter of course to request, for example, that taking into account undesirable consequences should include consideration of matters such as distributional or economic equity or ethical considerations[12,13,14] or, for those occupational risks that are often accompanied by secondary environmental risks, whether it is morally right to adopt policies without considering their effects on natural phenomena like the survival of species and the maintenance of ecosystems.[15] In short, the evaluation and management of hazards are evolving to include values that cannot readily be verified by traditional scientific methods. Techniques being produced for taking these values into account are at an early stage of development.

35 This has led to disagreements about the role that risk assessment should play in the regulation of risk – complicating matters still further. It has become a recent fashion by some to campaign against the use of risk assessment in the decision-making process, particularly for risks with widespread consequences. Many of the criticisms voiced about the role of risk assessments are based on mistaken beliefs about how such assessments are undertaken and applied. For example, it is often argued that an approach based on assessment of the risks:

- often underestimates the true impact of a problem overall. For example, a risk assessment is always undertaken for a specific purpose and with a specific population in mind and may therefore ignore risks to another population;
- is used capriciously to legitimise decisions, for example, to allow an unpopular development in one area but not in another;
- can be misused to present a particular problem as being primarily one of risk and could thereby undermine the adoption of a precautionary approach based on anticipating and averting harm;
- is inadequate since it often reduces the characteristics of what is in many instances a complex issue to a single number and is therefore weak in taking into account societal concerns or other important factors such as the degree of trust between regulators and their stakeholders (see paragraph 21).

36 However, the counter view – which we hold – is that there is overwhelming evidence that, properly used, the results of a risk assessment often provide an essential ingredient in reaching decisions on the management of hazards. Depending on the issue, the results of a risk assessment may be expressed in qualitative or quantitative terms, or both. The proper use of risk assessment also requires inter alia that:

- the risk problem is properly framed;
- the nature and limitations of the risk assessment are clearly set out and understood; and
- the results of the risk assessment are used to inform rather than to dictate decisions and are only one of the many factors taken into account in reaching a decision.

Clarification by the Courts on the meaning of risk

37 Arguments on the meaning that duty holders should attach to the concepts of 'hazard' and 'risk' when complying with their legal duties to ensure the health, safety and welfare may have contributed to the disagreements on the role that risk assessment should play in the decision-making process.

38 The concepts of hazard and risk are enshrined in our everyday vocabulary. When people say that they are prepared to take a risk they mean that in taking a particular decision they are willing to incur a chance of adverse consequences happening in the expectation of a probable benefit (ie a positive consequence). Intrinsic in that definition is that 'risk' should reflect both the likelihood that some form of harm may occur and a measure of the consequence. In everyday life though, we are more likely to pay attention to one than the other.

Regina vs Board of Trustees of the Science Museum, 1993

In the above judgement, the Court of Appeal ruled that as far as the use of risk in the HSW Act, section 3 was concerned, this should be interpreted as conveying the 'idea of a possibility of danger'.

'The starting point must be the ordinary meaning of the language of section 3(1). In our judgment the interpretation of the prosecution fits in best with the language of section 3(1). In the context the word 'risks' conveys the idea of the possibility of danger. Indeed, a degree of verbal manipulation is needed to introduce the idea of actual danger which the defendants put forward. The ordinary meaning of the word 'risks' therefore supports the prosecution's interpretation and there is nothing in the language of section 3 or indeed in the context of the Act, which supports a narrowing down of the ordinary meaning. On the contrary the preventive aim of sections 3, 20, 21 and 22 reinforces the construction put forward by the prosecution and adopted by the judge. The adoption of the restrictive interpretations argued for by the defence would make enforcement of section 3(1) and to some extent also of sections 20, 21 and 22 more difficult and would in our judgment result in a substantial emasculation of an essential part of the Act of 1974. The interpretation which renders those statutory provisions effective in their role of protecting public health and safety is to be preferred.

We have not lost sight of the defence submission that we ought to concentrate on the word 'exposed' rather than 'risks' in section 3(1). If the word 'risks' has the meaning which we consider it has, the point disappears. In that event exposure to a possibility of danger is sufficient. The word 'exposed' simply makes clear that the section is concerned with persons potentially affected by the risk… But the word 'exposed' cannot change the meaning of 'risks' from a possibility of danger to actual danger. On the principal points in this case the argument for the defence is really a red herring.'[16]

39 Nevertheless, it has proved useful to HSE to make a conceptual distinction between a hazard and a risk by describing a hazard as the potential for harm arising from an intrinsic property or disposition of something to cause detriment, and risk as the chance that someone or something that is valued will be adversely affected in a stipulated way by the hazard. HSE – as far as the health, safety and welfare of people is concerned – frequently makes use of the above conceptual distinction in its guidance by requiring that hazards be identified, the risks they give rise to are assessed and appropriate control measures introduced to address the risks. This reflects the fact that in most cases it makes sense to take account of the circumstances in which people and management systems interact with the hazard.

40 However, depending on the situation and degree of knowledge, the relative importance of likelihood and consequence in determining control measures may vary. HSE, for example, might attach a different weighting to the likelihood that harm will occur from the weighting attached to the consequences. In some circumstances, particularly where the consequences are particular serious or knowledge of the likelihood is very uncertain, we may choose to concentrate solely on the consequences so that, in effect, we are concerned only with the hazard.

41 However, the use of the latter approach by HSE has been challenged by some – perhaps because the HSW Act[1] makes reference to 'risks' but not 'hazards'. In that respect, a clarification by the Courts on the meaning of 'risks' in the context of the HSW Act is very relevant. The Court of Appeal in Regina vs Board of Trustees of the Science Museum, 1993,[16] ruled that, as far as the use of 'risks' in the HSW Act,1 section 3 was concerned, this word should be interpreted as conveying 'the idea of a possibility of danger'. We would interpret the use of 'risk' in other sections of the Act in the same way.

42 *The implication of this interpretation is that successful management of risk in the workplace must satisfy the premise that anything present in an undertaking which 'presents the possibility of danger' is properly addressed.* Conceptually, HSE will regard anything presenting the possibility of danger as a 'hazard'. As we shall see later, the processes and criteria described in Part 3, which include the use of risk assessment to determine the required control measures, meet this important condition. For example, they ensure that for hazards surmised to have consequences that may be irreversible and deleterious, there is an overriding need to introduce control measures to address the hazards. This is true when, or perhaps especially when, there is considerable uncertainty about the nature of the hazards and the likelihood of them causing harm.

Changes on the industrial scene

Changes in patterns of employment

43 The regulatory environment now has to cope with the increasing trend in industry and elsewhere to outsource work and hence risks, with changes in patterns of employment and with the fragmentation of large companies into autonomous organisations working closely together. For example, there have been dramatic increases in self-employment and home-working; small and medium size firms are now a major force in creating jobs. Moreover, many monolithic organisations have become a series of separate companies, eg the railways now operate as separate companies with different responsibilities for operating the track, the rolling stock and the networks.

Polarisation of approaches between large and small firms

44 Some of these changes have blurred legal responsibilities for occupational health and safety, traditionally placed on those who create the risks or on those best situated to take steps to control the risks. In certain industries it is often no longer easy to determine who may be in such a position. Though case law has in many instances clarified the situation, the fact remains that for many sectors the above factors make it more difficult to co-ordinate the adoption of measures for controlling risks. Many more players are involved, some with little access to expertise. There has in consequence been a growing demand by small firms for a reversion to prescriptive regulation, running counter to the self-regulatory approach – a demand resisted by large firms because they do not face the same problems and are comfortable with the self-regulatory approach. This has resulted in greater emphasis being placed on the need for clarity of the status and content of the guidance element of the architecture of regulation (see Appendix 2).

Changes in the preferences, values and expectations of society

45 The preferences, values and expectations of society have never been static. Current shifts are linked in part to:

- the rapid rise in information technology which nowadays plays an important role in shaping perceptions by making it easier for people to have information on the risks that may affect them and the society (or indeed the planet) in which they live. This explosion in information technology has, for example, resulted in greater awareness of issues such as the Chernobyl accident, the toll of asbestos-related deaths, and the threats to the ozone layer. Unfortunately information about risks is frequently passed on in isolated bits by the mass media and without any critical examination or peer review – often resulting in the public getting confused or in some risks being amplified while others are attenuated;

- the increased pace in exploiting advances in scientific and technological knowledge, which has led to an increased focus on technological risks;

- greater affluence in society. The majority of people in industrialised countries no longer have to struggle at subsistence level. As a consequence, the acceptance of industrial activity to gain increased standards of living is no longer as readily given as when the fight against hunger and poverty overshadowed everything else.

46 These shifts in preferences and values result in:

A growing perception that risks imposed on people should be justified

47 There is a growing propensity to scrutinise benefits brought about by industrial activity against potential undesirable side effects such as the risk of being maimed or killed or of environmental pollution. This is particularly true for risks:

- which could lead to catastrophic consequences;

- where the consequences may be irreversible, eg the release of genetically modified organisms;

- which lead to inequalities because they affect some people more than others, such as those arising from the siting of a chemical plant or a waste disposal facility;

- which could pose a threat to future generations, such as toxic waste.

48 This has already resulted in industry having less discretion on matters on which they previously had considerable freedom to decide which course of action to adopt, eg plans for modifying their plant within their own boundaries, what raw materials and processes they should use, or how the waste generated (or the plant itself at the end of its useful life) should be disposed of.

An increasing reliance by the public on regulators that they trust

49 A heightened perception of risk has been accompanied by a recognition that modern society has evolved in such a way that it is virtually no longer possible for many of its individual members to:

- avoid risks that they would have preferred not to incur. For example, a person who does not want to travel by car or plane may find their employment or promotion opportunities severely restricted. A person wanting to avoid processed food because of their fear of additives would be able to do so only at great expense or by having a restricted way of life;

- assess for themselves the risks posed by many of the newer hazards arising from industrialisation. This often may be because the risk is not immediately obvious, eg the risks from new hazardous substances which do not cause immediate acute

effects and for which there might be long delays between first exposure and the manifestation of undesirable symptoms. People must rely instead on the opinion of experts. However, the trust placed in expert opinion as a source of reassurance is being continually eroded, particularly for those issues where the mass media seek to expose controversies surrounding such opinions or where the experts have had to frequently reassess the risks arising from certain hazards to take account of new knowledge etc.

50 The net result is that, increasingly, people are having to rely on authoritative bodies such as HSC/E as a source of reassurance about the arrangements in place for protecting people and the impartiality of those arrangements. These bodies for their part are acutely aware that they would not be able to provide reassurance unless they are trusted and that trust will not be bestowed but will have to be earned.

51 This is far from easy. There is often considerable pressure on regulators (and industry) to act quickly and decisively in a climate heavily influenced by perceptions of harm often based on graphic imagery. Regulating slavishly on such occasions is not the answer. Regulating to address concerns, which with hindsight turn out to be no more than transitory shifts in value preferences, carries heavy penalties.

Calls for greater openness and involvement in the decision-making processes

52 Perhaps the most dramatic shift in value preferences of society has been the pressure on regulators for greater clarity and explanation of their approaches to the regulation of risk. This is reflected in the broadly stated principles of good regulation published by the Better Regulation Task Force.[17] These require:

- the targeting of action: focusing on the most serious risks or where the hazards need greater controls;
- consistency: adopting a similar approach in similar circumstances to achieve similar ends;
- proportionality: requiring action that is commensurate to the risks;
- transparency: being open on how decisions were arrived at and what their implications are; and
- accountability: making clear, for all to see, who are accountable when things go wrong.

53 This need for clarity and explanation is entirely consistent with the Robens Committee's conclusion that real progress on health and safety is not possible without the agreement of those affected and the co-operation and commitment of those playing a role in implementing decisions.

54 Though all the developments described in this part have influenced our approach, the following have been particularly important:

- the need for the meaning of 'risk' to encompass more than physical harm by taking into account other factors such as ethical, economic and social considerations (paragraphs 17-27);

- clarification by the Courts on the meaning of 'risk' in the HSW Act which implies that approaches for managing risks must ensure that hazards present are properly addressed (paragraphs 37-42); and

- the need to explain how we apply the principles at paragraph 52 above.

55 The rest of this document sets out how we have taken these developments on board, building on our previous approach.

Part 3

Approach to reaching decisions on risk

System for informing and reaching decisions

56 In this part we build upon the developments described in the review in Part 2 to explain the approach that HSE adopts for reaching decisions on the degree and form of regulatory control of risk from occupational hazards. This includes both the system used for informing and reaching decisions and the criteria and philosophy adopted for deciding on what risks are unacceptable, tolerable or broadly acceptable.

57 Many systems have been developed for informing and reaching decisions, and some particularly pertinent to health and safety have been described.[18] The stages below characterise the system, governed by the principles set out in paragraph 52, that has evolved in HSE in the course of undertaking its own statutory responsibilities and in advising and assisting HSC, for example in implementing policies on modernising health and safety legislation.

58 The stages are:

- Stage 1: Deciding whether the issue is primarily one for HSC/E;
- Stage 2: Defining and characterising the issue;
- Stage 3: Examining the options available for addressing the issue, and their merits;
- Stage 4: Adopting a particular course of action for addressing the issue efficiently and in good time, informed by the findings of the second and third points above and in the expectation that as far as possible it will be supported by stakeholders;
- Stage 5: Implementing the decisions;
- Stage 6: Evaluating the effectiveness of actions taken and revisiting the decisions and their implementation if necessary.

59 However, it is worth emphasising four points. First, though the stages as listed above give the impression that they are distinct and independent of each other, in practice the boundaries between them are not clear-cut. We usually gather valuable information or perspectives while progressing from one stage to another, often requiring early stages of the process to be revisited. In short we find that going through the stages is an iterative process.

60 Secondly, we involve stakeholders at all stages in the above process with the aim of reaching a wider consensus. However, we are conscious that HSC must take, or propose to

Ministers, final decisions where consensus is not possible, for example, because different stakeholders hold opposite views based on deep-rooted beliefs.

61 Thirdly, as a corollary to the first point, how we proceed through the above stages will not be found in a single document because the process is reflected, for example, in the way we assist HSC and its Advisory Committees to go about their business, the research we commission to better understand the issue, the consultative documents that we publish, the responses to such consultation, and discussions that take place with our stakeholders, both formal and informal.

62 Finally, the system describes our current arrangements but some caution is necessary for those looking for their universal application in our past, present and future decisions. Because the system was developed over time, previous regulatory decisions may not be in full accord with them. Moreover, there are often many constraints which prevent the system from being applied fully. For example, as explained in Appendix 2, most health and safety at work legislation originates from the EC in the form of directives and their transposition may require, for example, regulations where otherwise we would use an Approved Code of Practice. Furthermore, the arrangements are also applied proportionately and with discretion. There may be times when the need to act quickly may circumvent some of the stages, and there may not be any need to go through all the stages if information and knowledge from past decisions can be transposed to inform new decisions.

63 We examine, in further detail below, what is involved at each stage.

Stage 1: Deciding whether the issue is one for HSC/E

64 The scope of the HSW Act is very wide and it will usually be self-evident that an issue or subject of concern is primarily one of occupational health, safety and welfare. These issues or subjects of concern can arise through many ways. The most important are:

- intelligence on new hazards for example from new technologies, or inadequacies in existing arrangements to cope with change, for example, in the pattern of employment;
- pressure of events and experience in terms of statistics of accidents and ill health and reports of investigations into particular incidents;
- public perceptions that there is a problem to be addressed;
- feedback that existing arrangements are not fit for purpose, for example in imposing unnecessary burdens on duty holders;
- political moves in Europe or internationally to which we have to respond.

65 It must always be borne in mind that the objectives of the HSW Act include not only the securing of the health, safety and welfare of people at work but also the protection of people not at work against risks to their health and safety arising out of work activities. The wide scope of the Act, together with its wide-ranging enabling powers to make regulations, often result in pressure on HSC/E to take the lead in protecting the public, because of the workability and effectiveness of the arrangements that can be put in place under health and safety legislation and/or its enforcement. Moreover, similar pressure may arise from the practical consideration that other institutions with relevant powers may not exist within the Government machine.

66 Such considerations have arisen particularly in the case of activities with minimal involvement of employees but with the potential to cause harm to the public and where the relevance of health and safety 'at work' legislation may not be obvious. Typical examples include golf courses, horse-riding establishments and pop concerts.

67 The wide scope of the HSW Act and its considerable enabling powers to make regulations have resulted in two other effects. Firstly, many of its provisions and regulations made under the Act overlap with other legislation which is the responsibility of other Government Departments. As a general rule, HSC/E wish to avoid duplication with other enforcing authorities and, where policy areas overlap, there are often demarcation agreements between HSE and other Departments on respective responsibilities covering many areas of potential risks to the public. In many areas of overlap, agreement has been reached that HSE should not attempt generally to enforce the requirements of sections 2 and 3 of the HSW Act, because public safety will be adequately guaranteed by the enforcement of the other legislation covering the risk in question.

68 Secondly, pressure on HSC/E is at times targeted at issues where health, safety and welfare is not a prime consideration but might be seen as a means of objecting to inequity between those who reap the benefits and those who are put at a detriment of some sort that may include a health and safety component, eg the loss of a visual amenity in the vicinity of a scenic spot or a fall in property values as a result of allowing a major installation, such as an airport, to be developed. In these circumstances, we may advise HSC:

- that public debate and discussion on the distribution and balancing of the benefits and detriments involved should take place in a wider context, and that it would therefore be better for the issue to be addressed and/or regulated through a more appropriate avenue in the political and democratic system; or

- to consider the issue but only with respect to the matters which are within its powers to consider ie the health, safety and welfare aspects entailed in the particular context. That is, to look at the appropriateness of the measures in place to protect workers and the public from the risks arising from the activity but leave wider aspects – such as whether the activity should be entertained in the first place – to be considered by the political and democratic system as per the first point above. For example, HSE has made it clear that in its consideration of the tolerability of risks from nuclear power stations, it has limited its analysis to the consideration of the safeguards that

should be in place and the way they should be exercised, and has left it for Parliament to weigh the benefits of nuclear power against the risks entailed.[2,19]

69 A quite different issue arises when a European directive is enacted under Article 137, the health and safety article of the EC Treaty. It is not always the case that matters covered by an Article 137 directive are interpreted as health and safety matters in Great Britain. Such a question arose when we had to advise HSC on whether the enabling powers of the HSW Act should be used to introduce regulations to implement an EC health and safety directive on working time. We (and HSC) were not convinced that all elements of the directive (eg paid annual leave) were primarily occupational health, safety and welfare issue and agreement was reached with Ministers that the enabling powers of the HSW Act should not be used to implement them.

70 In short, if an issue ends up being regulated under health and safety legislation, it should always be the result of careful consideration of all the factors involved, such as those described above.

Stage 2: Defining and characterising the issue

Defining the issue

71 In this stage we consider how the issue can be framed or described in terms of problems to be tackled and the means for tackling them.

72 For example, the rate of replacement of older rolling stock on the railways is an issue with two quite different dimensions:

- transport policy, regarding the public's willingness to use the system; and
- public safety policy, regarding the safety benefits of modern rolling stock.

The issue could be framed either way, giving rise to quite different problems to be tackled by different arms of the Government regulatory machine.

73 In framing an issue we shall therefore pay particular attention to whether:

- the action to be taken can be efficiently delivered by HSC/E acting within their powers and arrangements as discussed in paragraphs 64-70 above; and
- society at large will regard as valid the whole process that was adopted for reaching the decision on the most appropriate course of action for addressing the issue. This is because, as we have already seen, the way an issue is framed can have a considerable influence on judgements about whether risk is actually the crux of the issue and, if so, the effectiveness of the measures that should be put in place for addressing the risk.

74 Areas of particular contention arise when there is a divergence between public perceptions that there is an issue to be addressed and objective analysis of the associated problems in health and safety terms. There may then be a need for iteration between this stage and the first stage described earlier (paragraphs 64-70). We sometimes issue discussion documents as a means of seeking convergence towards a workable option.

Characterising the issue in terms of risk

75 The framing of the issue may point to it being one where a decision on proportionality of action requires information on the risks. In such cases, we need to characterise the risk quantitatively and qualitatively, to describe how it arises and how it impacts on those affected and society at large. Such information is needed in order to inform later consideration of options for risk reduction.

76 We usually undertake an assessment of the risks to achieve this. Assessing risks involves identifying the hazards associated with the risk issue, ie what in a particular situation could cause harm or damage, and then assessing the likelihood that harm will actually be experienced by a specified population and what the consequences would be.

77 The process of gathering and refining information on risks is underpinned by a great deal of research and the engagement of expertise both within and outside HSE. The systems devoted to establishing sound information and intelligence on risk account for around 25% of HSE's total resources notwithstanding the intelligence gathered by inspectors as part of day-to-day inspection/investigation activities. External expertise is engaged through research, often carried out collaboratively, and through the system of HSC Advisory Committees. The science underpinning HSC/E policies and practices is extensively exposed to the normal scientific process of peer review. There is, in addition, provision in our research commissioning arrangements for ideas generated independently to be considered for funding in order to bring fresh perspectives to bear. All told, the arrangements in place for incorporating science into the characterisation of risk require much deliberative activity between HSE and the science community at large.

78 We would be interested in assessing at this stage the individual risks and then identifying the associated societal concerns generated by the hazards and other issues such as whether a hazard should be entertained at all or should be regulated in particular way. But the extent to which each of these issues is considered in our assessment will depend on the nature and attributes of the hazard as well as the context of our intervention.

79 For example, many hazards in the workplace are well known, familiar, easy for people to gauge the actual threat they give rise to, have no stigma attached to them and would not cause society any significant concern if realised. We are likely in those cases to pay more attention to the level of residual individual risks after measures have been introduced rather than the societal concerns (if any) that they might engender. On the other hand, gauging the extent of the societal concerns caused by a hazard is likely to be a major consideration when considering whether regulations should be introduced for addressing a hazard that is new, unfamiliar and where its realisation would generate a socio-political response.

80 Moreover, in our role as a regulator and with powers of discretion, the assessment of risk that we undertake – for example when we propose options to the HSC for draft regulations – may, according to circumstances, be much broader than the one that we would generally expect a duty holder to undertake in complying with their duty to assess risks, for example, as required under the Management of Health and Safety at Work Regulations 1999.[3] The risk assessment performed under those Regulations would be confined in scope to the conduct of the undertaking and would usually concentrate on:

- looking at the prospect of harm to individuals and in some cases to society but, as far as the latter is concerned, limited to the extent to which HSC/E has stated in regulations, guidance etc how this should be undertaken;
- identifying, in the light of good practice, what needs to be done to comply with the law.

81 On the other hand, the assessments we carry out (at a much earlier stage):

- more often than not, have to probe in depth in order to develop standards of good practice for future application. In this way, good practice established by HSE is based on the risk assessment by HSE, and compliance with that good practice implicitly conforms to a risk-based approach to control;
- could go beyond the confines of the undertaking and look at the impact of our proposed action on society;
- would not necessarily be limited to the identification of control measures but could cover any matter which could be the subject of health and safety regulations as specified in section 15 of, and Schedule 3 to, the HSW Act;
- would in scope cover both individual risks and societal concerns as already mentioned at paragraphs 78-79 above (see also Appendix 3, paragraph 7).

82 Thus, we use a risk assessment essentially as a tool to inform our decisions by assisting in our understanding of the nature and degree of risk and for extrapolating, from available data, our experience of harm, or for representing a large amount of scientific information and judgement as an estimate of the risks. The policy process then couples the scientifically-based judgements about risks with policy considerations about the approach to their control. The latter (sometimes separately described as risk evaluation) includes such considerations as the relative weightings to be attached to likelihood and consequence as discussed in paragraphs 38-40, and the way that public perceptions of the risk should be taken into account.

83 For example, the risk assessment may show that the risks are such that individuals may not be unduly concerned because of the familiarity of the risks etc (see paragraph 79) and/or that the expectation of harm to any one individual is low. Nevertheless, the activity giving rise to the risks may need to be regulated further because of the numbers of people individually affected, and other possible detriments. For example, regulations have been introduced to make the wearing of hard hats compulsory on construction sites.

84 The proper characterisation of the risk is important to the effective application of the preferred risk control hierarchy promoted by HSC/E and the EU. The hierarchy actually covers controls on hazards as well as the resulting risks. At the top of the hierarchy, and consistent with the general duty to secure health and safety, is the consideration of measures or alternatives that will avoid the hazard in the first place. This might involve substitution or the adoption of processes that conform with principles aimed at ensuring that a design is inherently safer. Lower down the hierarchy is the consideration of measures that will reduce the risks, given that there are no viable alternatives to accepting the hazard.

85 An implicit presumption underlying the hierarchy is that it is not the case that any activity can be pursued simply because measures are available to control the risks it entails. This would be particularly true for activities where there are considerable uncertainties in the estimates of the risks attached to them. Indeed, in line with our earlier discussion on the meaning of risk at paragraphs 37-42, the regulation of health and safety is replete with examples where the potential severity of the consequences, rather than the probability of them occurring, is the dominant consideration. This is particularly true for hazards where there is considerable uncertainty on the nature and scale of the risks they give rise to, eg the release of genetically modified organisms. We therefore need to look at uncertainty in more detail.

Inherently safer design

Adoption of the principles of inherently safer design is particularly important where the consequences of plant or system failure are high. HSE will press for the incorporation of inherently safer design features, where these are possible, to reduce the reliance on engineered safety systems or operational procedures, to control risk.

For example, the concept of 'defence in depth', redundancy, diversity and segregation, the provision of multiple barriers and other good practices, as set out in HSE's safety assessment principles for nuclear plant[20], are fundamental to ensuring safety. These apply against a requirement to: firstly, avoid the hazard and maintain safe conditions through inherent and, where appropriate, passive design features; and, secondly, to minimise the sensitivity of the plant to potential faults as far as can be reasonably be achieved, by ensuring the plant response to a fault is as near the top of a hierarchy of: (i) produces no operational response or a move to a safer condition; (ii) passive or engineered safeguards, continuously available, make the plant safe; (iii) active engineered safeguards, brought into service in response to the fault, render the plant safe.

The RBMK type of reactor used at Chernobyl, for example, would not be licensed by HSE's Nuclear Installations Inspectorate for operation in Great Britain. The design of this type of reactor does not satisfy HSE's requirements because, under certain conditions, a change in the condition of the water coolant in the reactor core from liquid to steam could lead to a significant increase in the rate of nuclear fission. Such a change in coolant condition could occur either as a result of a mismatch between the rates of heat generation in the core and heat removal by the coolant, or as a result of a fall in coolant pressure. The increase in nuclear fission would exacerbate the situation, as the resulting rise in reactor power would increase the mismatch between the rates of heat generation and removal, leading to a runaway nuclear reaction. This

inherently unsafe aspect of the design was one of the main factors that led to the infamous accident at Chernobyl in 1986.

Handling uncertainty

86 The process of assessing risks needs to take account of the possibility of uncertainty. For example the science underpinning the assessment may be complex, ambiguous or incomplete and/or the necessary data may not be available.

87 We must first distinguish between uncertainty and ignorance. The latter refers to a lack of awareness of factors influencing the issue. This is a well-recognised weakness in risk assessment – that the identification of hazards may be incomplete. The measures needed to counteract ignorance are a wide engagement of different disciplines and communities of interest in the characterisation of the issue. Paragraph 77 describes the very broad base of expertise called into play by HSE in undertaking that task. A further measure is to practise openness to the greatest degree possible so that thinking can be exposed to alternative views at an early stage. This is a principal requirement in the guidelines issued by the Office of Science and Technology.[21]

88 Uncertainty itself is a state of knowledge in which, although the factors influencing the issue are identified, the likelihood of any adverse effects or the effects themselves cannot be precisely described. Uncertainty has many manifestations and they affect the approach to its handling. In summary:

- **Knowledge uncertainty** – This arises when knowledge is represented by data based on sparse statistics or subject to random errors in experiments. There are established techniques for representing this kind of uncertainty, for example confidence limits. The effect on a risk assessment is estimated by sensitivity analysis. This provides information relating to the importance of different sources of uncertainty which can then be used to prioritise further research and action, which is the only feasible way to address the uncertainty, though in some cases research may not be technically possible or cost-effective.

- **Modelling uncertainty** – This concerns the validity of the way chosen to represent in mathematical terms, or in an analogue fashion, the process giving rise to the risks. An example is the growth of a crack in the wall of a pressure vessel. The model would postulate the way the growth rate is affected by factors such as the material properties and the stress history to which the vessel is exposed in service. The model will provide prediction of failure in terms of time and the nature of the failure. It will inform intervention strategies such as the material specification, in-service monitoring and mitigation measures. All these factors may be modelled in many ways with the assumptions for each one open to question. The rigour of the peer review process and openness to alternative hypotheses are the main safeguards. However, the most intractable problems arise when it is not practical or physically possible to subject the alternative hypotheses to rigorous testing. In such cases, the exercise of expert judgement is paramount and confidence depends on the procedures adopted for selection of the experts and the management of bias (or appearance of bias).

- **Limited predictability or unpredictability** – There are limits to the predictability of phenomena when the outcomes are very sensitive to the assumed initial conditions. Systems that begin in the same nominal state do not end up in the same final state. Any inaccuracy in determining the actual initial state will limit our ability to predict the future and in some cases the system behaviour will become unpredictable.

Precaution in the face of uncertainty

89 However, our risk assessment and risk management procedures have a number of safeguards to ensure that our approach is inherently precautionary and in line with the precautionary principle. Included though not defined in the EC Treaty, the precautionary principle has been defined, for example, by the United Nations Conference on the Environment and Development (UNCED) in 1992 as: ***'where there are threats of serious or irreversible environmental damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent degradation.'***

90 Thus, the precautionary principle describes the philosophy that should be adopted for addressing hazards subject to high scientific uncertainty, and rules out lack of scientific certainty as a reason for not taking preventive action. Although originally formulated in the context of environmental protection, particularly in connection with 'global' environmental issues (eg climate change, ozone depletion), the precautionary principle has been applied more widely.

91 Our policy is that the precautionary principle should be invoked where:

- there is good reason, based on empirical evidence or plausible causal hypothesis, to believe that serious harm might occur, even if the likelihood of harm is remote; and

- the scientific information gathered at this stage of consequences and likelihood reveals such uncertainty that it is impossible to evaluate the conjectured outcomes with sufficient confidence to move to the next stages of the risk assessment process.

92 Good reason to believe that serious harm might occur could be demonstrated by showing that an activity, product or situation is similar to others which are known to carry a substantial adverse risk; or by adducing a sound theoretical explanation (tested as necessary by peer review) as to how harm might be caused.

An example of a qualitative assessment of risks

Crowd Safety at Pinner Fair

Estimates of risk are often qualitative rather than quantitative, and are frequently based on systematic observation. An example is the assessment of crowd safety risks at an annual fair in Pinner on the north-west outskirts of London.

Pinner Fair was established by Royal Charter in 1337. Each year it attracts about 50 000 people to the central streets of Pinner, where the restricted space contrasts with the increasing size and complexity of modern fairground rides.

In a study in 1993 by HSE, observation of the setting up, running and dismantling of the fair, together with an analysis of the safety management, formed the basis for hazard identification and risk assessment. The hazards included overcrowding during the fair and dismantling rides while crowds were still present. Comparisons were made with standards in codes of practice and guidance, and with good practice for comparable events. Opinions voiced by local residents, the local authority and the police were also taken into account. It was shown that straightforward changes in the organisation and layout of the fair could eliminate some hazards and substantially reduce the risks from others. To prioritise the improvements needed the risks were ranked qualitatively using a five point scale from 'very low' to 'very high'.

The findings of the risk assessment were discussed with interested parties, including the local authority, the emergency services and the Showmen's Guild of Great Britain, who decided to adopt a series of measures to improve crowd safety. HSE evaluated the effectiveness of the action taken in a follow up study in 1994 when significant improvements were already apparent.

Further information: Fairgrounds and amusement parks: guidance on safe practice.[22]

93 Though the precautionary principle is invoked for hazards where, because of the uncertainty involved, it is not possible to apply the conventional techniques of risk assessment to assess the risks involved whatever the circumstances, it is possible in practice, to use such techniques for operationalising the principle. Uncertainty is overcome by constructing credible scenarios on how the hazards could be realised and thereby making assumptions about consequences and likelihood. The credible scenarios can range from a 'most likely' worst case to a 'worst case possible' depending on the degree of uncertainty. For example, by assuming that exposure to a putative carcinogenic chemical will cause cancer the chemical becomes subject to a very stringent control regime. Though such risk assessments made on scenarios are inevitably narrower in scope than a full blown risk assessment, this may not be a serious limitation if the scenarios are carefully chosen to reflect what could happen in reality.

Quantitative risk assessment

As indicated in a previous example, estimates of the likelihood that a hazard will be realised are often qualitative rather than quantitative, and in general duty holders under occupational health and safety legislation adopt authoritative good practice to address the significant hazards arising from their work activities.

Some sectors of industry, however, have used the tool of quantitative risk assessment (QRA) as part of their consideration of the safety of plant and operations. QRA is a powerful tool in showing the relationship between different subsystems and the dependencies within the overall system. QRA is frequently used to estimate the risk from plant, as designed and operated. However, care needs to be taken to avoid numerous pitfalls that can trap the unwary. For example, in estimating the likelihood of an event by looking back at historical accident or incident data, care needs to be taken in selecting:

- *the accident/incident sample – too small a sample or too narrow a scope can mislead; too wide a scope may result in the inclusion of accidents/incidents that developed differently from the event in question;*

- *the time period – too short a period may lead to the omission of representative accidents/incidents; too long a period may again result in the inclusion of accidents/incidents that developed differently from the event in question. Whatever time period is chosen, the assumption of a constant relationship between accident/incidents and time needs to be questioned in the light of changes in technology and in public expectations;*

- *the statistical method – historical accident/incident data may not include the cause, and selective use of data and/or choice of model can result in numerical figures that do not properly reflect actual history.*

The process of undertaking a QRA can lead to a better understanding of the important features contributing to risk and weaknesses in the systems as well as allowing a numerical estimate of the residual risk to be derived. The quality of the modelling and the data will affect the robustness of the numerical estimate, and the uncertainties in it must always be borne in mind when using the estimate in risk management decisions. The use of numerical estimates of risk by themselves can, for several reasons including those above, be misleading and lead to decisions which do not meet adequate levels of safety. In general, qualitative learning and numerical risk estimates from QRA should be combined with other information from engineering and operational analyses in making an overall decision.

94 In addition to invoking the precautionary principle as above there are many other ways in which our approach is inherently precautionary. For example our risk assessment procedures:

- do not take 'absence of evidence of risk' as 'evidence of absence of risk', although they recognise that persistent absence of evidence of risk, notwithstanding appropriate and thorough efforts to find it, may be indicative;

- require that the effects of the assumptions made to cover gaps in knowledge be tested through recognised methods, eg sensitivity analysis;

- build safety factors into the assessment process where appropriate, eg in assessing toxic substances, safety factors are used depending on the quality of data, severity of effect, and whether data from animals or *in vitro* experiments are being extrapolated to humans;

- attach more weight to consequences where a hazard has attributes which makes it likely that it will give rise to societal concerns, such as the potential to affect future generations, or the potential for severe detriment, eg a major explosion in a built-up area;

- make use of comparative risk assessment for novel hazards that bear a similarity with existing hazards, requiring a stringent control regime for reducing risks to tolerable levels.

95 All the above show that assessing risks is far from being a straightforward exercise. At times the risk assessment will be a simple process based on observation and judgement, while at the other extreme it can also require the use of complex techniques such as quantified risk assessment. In practice it cannot be carried out without adopting certain conventions or protocols. We examine some of these at Appendix 1.

Stage 3: Examining the options available and their merits

Identifying options

96 Once the problem has been characterised we then identify the options available for managing the risks. These can range from doing nothing to introducing measures (whether non-regulatory or regulatory) to get rid of the cause of the problem altogether, or to reduce it to one which people are prepared to live with so as to secure certain benefits and in the confidence that the risk is one that is worth taking and that it is being properly controlled.

97 The courses of action available are similarly many and varied, for example:

- providing more information and guidance to duty holders to enable them to fulfil their responsibilities;
- publicity campaigns to create awareness, for example the 'Good Health is Good Business' campaign and the publicity given to the poor maintenance of domestic gas heating installations;
- engaging the assistance of intermediaries in the health and safety system (eg safety representatives, consultants);
- stronger enforcement of existing legal provisions;
- exerting pressure for heavier penalties on transgressors;
- developing the line to be taken in negotiation of European directives to reflect the issue as it manifests itself in Great Britain;
- targeting action on those who should be controlling the risks;
- improving the available knowledge base through research; and
- proposing new measures that are commensurate with the risks to be addressed, eg new law.

98 For example, the following illustrates some of the options that are available for preventing or controlling exposure to a particular substance:

- banning the use of the substance altogether;
- requiring the use of technology to prevent the substance being released into the workplace or the environment;
- introducing new law, eg licensing regimes to limit the exposure of people to the substance while ensuring that they use best practice to prevent accidental exposure to the substance;
- educating/informing the public on the steps they can take to prevent exposure (eg on the need to service gas appliances to prevent carbon monoxide poisoning); or
- doing nothing because the substance does not pose a significant risk at the level at which it is present.

Adopting decisions: setting occupational exposure limits

Occupational exposure limits (OELs) are important risk management tools that regulate the extent of personal exposure (via inhalation) to substances hazardous to health. The procedures for setting OELs illustrate the involvement of the stakeholders in consensus decision-making in an area where risk assessment is complex and where account has to be taken of uncertainty and socio-economic factors. The procedures also illustrate the use of dose as a necessary surrogate for risk and the importance of openness.

Under the framework in the Control of Substances Hazardous to Health Regulations (COSHH), there are two types of OEL – an occupational exposure standard (OES) and a maximum exposure limit (MEL). Both are expressed as airborne concentrations of a hazardous substance averaged over a period of time.

An OES is set at a level at which, based on current scientific knowledge, it is judged that there is minimal risk to the health of the workforce if exposed via inhalation to the substance day after day. MELs are normally set for substances which may cause health effects such as cancer or occupational asthma where it is not possible to identify reliably a threshold of exposure on which to base an OES. MELs are also set for substances for which 'safe' thresholds may be identifiable, but control to these levels is not reasonably practicable.

OESs and MELs are set on the recommendations of the HSC's Advisory Committee on Toxic Substances (ACTS) and its Working Group on the Assessment of Toxic Chemicals (WATCH). The role of WATCH is to consider all the scientific evidence; the role of ACTS is more to take into account socio-economic factors in balancing risks to health against the cost and effort of reducing exposure. Both groups comprise appropriate representatives of the stakeholders, eg employers and employees, together with scientific experts.

The process starts in WATCH which decides for each substance whether an OES can be established, and if so at what level it should be set, using assessment or uncertainty factors to reflect, eg the quality of the data, the nature of the toxic effect and the need to extrapolate from animal data to effects on people. If, however, WATCH decides that a MEL is appropriate, consideration of the level passes to ACTS. ACTS makes recommendations on the basis of the level that can be achieved by application of good occupational hygiene practice, taking into account socio-economic factors (in practice WATCH or ACTS may recommend separate levels for 8 hour time-weighted average and 15 minute reference periods). If the recommendations are endorsed by the Commission, proposals are published for public consultation, together with criteria documents summarising for each substance the toxic effects, typical exposure levels, measurement levels and the basis for the proposed exposure limit – including for a MEL, a cost benefit assessment.

After public consultation the Commission may approve a new OES or a new MEL.

Further information: Health and Safety Executive guidance booklets EH40, Occupational exposure limits[23] *and EH64,* Summary criteria for occupational exposure limits, *both published annually.*[24]

Fairhurst S, *'The uncertainty factor in the setting of occupational exposure standards'.*[25]

99 We can often build on our experience to identify options that are likely to work in certain circumstances. For example, we identify at Appendix 2 the options that should be considered when introducing new regulations or guidance and the order in which they should be examined.

100 In looking at options, we would be particularly interested in examining:

- **possible good practice** for addressing the hazards identified, and evaluating whether it is relevant and sufficient. If specific good practice is not available we would also examine the merits of good practice that applies in comparable circumstances if we believe that this is directly transferable or can be suitably modified to address the hazard;

- **possible constraints attached to a particular option**; for example whether the option is technically feasible; or whether there are legal constraints on its adoption. As shown in Appendix 2, the general principle is that the option adopted will improve or at least maintain standards of health, safety and welfare;

- **any adverse consequences associated with a particular option**. Very often adopting an option for reducing one particular risk of concern may create or increase another type of risk. For example: banning a particular solvent may increase the use of a more hazardous one; reducing airborne concentration of substances in the workplace by exhaust ventilation may increase risk in the community or vice versa. Therefore for each option having adverse consequences we examine the trade-off between reducing the target risk and the increase in other risks. Appendix 3 gives an indication of how far and how deeply this exercise is carried out;

- **how much uncertainty is attached to the issue under consideration** and as a consequence **the precautionary approach** that should be adopted to ensure that decisions reached are in line with the precautionary principle (see paragraphs 89-94). As we shall see later, though HSE adopts a framework (see paragraph 121-127) for reaching decisions which intrinsically ensures that the treatment of uncertainty is biased towards health and safety to take account of uncertainty, this bias reflects a proper judgement of the degree of caution needed in the circumstances of the decision. The framework achieves this by ensuring that, as the degree of uncertainty increases, and depending on certain other characteristics attached to a particular hazard (eg whether the risk, if realised, could result in consequences that are irreversible or could detrimentally affect future generations), there is an increasing shift towards requiring more stringent measures to mitigate the risks. Moreover, in cases where the benefits cannot justify the risks, the framework requires that consideration is given to banning the activity, process or practice giving rise to the hazard;

- **how far certain options should be constrained** so that the problem remains within the boundaries that we have set in Stage one. For example, when considering options for improving health and safety on the railways and in particular whether a railway operator should introduce investments, we cannot consider the question whether the resources could be better spent on the National Health Service as this would be an issue for the Government to address;

- **how far the options succeed in improving (or at least maintaining) standards** in line with section 1(2) of the HSW Act. Though there is a duty on the HSC to adopt this principle when proposing the modernising of legislation predating the HSW Act, the same principle permeates HSC/E's policies and approach to the regulation and management of risks;

- **the costs and benefits** attached to each option by looking at what is required to implement each option and the degree of risk reduction it is likely to achieve. Since this is one of the factors taken into account to inform decisions (the next stage in the process), it is examined in greater detail below;

- **what is the most appropriate regulatory instrument** in the range available to HSC/E (see Appendix 2) for achieving its objectives for managing the risks in question.

Assessment of risk reduction action

101 We sometimes need to carry out formal analyses of costs and risk reduction to help with judgements on the benefits of each option and the costs involved in reducing the risks. These analyses may be of varying sophistication and complexity, and might in some cases include a cost benefit analysis (CBA). CBA is often a useful tool for judging the balance between the benefits of each option and the costs incurred in implementing it. CBA aims to express all relevant costs and benefits in a common currency, usually money. This in principle requires the explicit valuation of the benefit of reducing the risk. However, such a valuation may not always be possible or practicable – in these circumstances we rely on qualitative estimates. And, in any case, we apply common sense when reviewing the results. Moreover, explicit valuations may not always be necessary because:

- as we shall see later, most safety provision for day to day hazards is in terms of the adoption of good practice or the voluntary pursuit of best practice, taking advantage of technological advances; and

- it may be possible to compare the difference in costs from switching from one option to another against the gains so achieved in terms of avoidance of harm.

102 Nevertheless, we do carry out explicit valuations in support of policy proposals that would require duty holders to make major investments in safety measures, or when introducing new regulations.

103 When an option produces the benefit of preventing fatalities, this requires putting a monetary value on achieving a reduction in the risk of death. For example, for the purpose of conducting CBAs, we currently take as a benchmark that the value for preventing a fatality (VPF) is about £1 000 000 (2001 figure). As is made clear in Appendix 3, VPF is **not** the value that society, or the courts, might put on the life of a real person or the compensation appropriate to its loss. This figure derives from the value used by the Department of Transport, Local Government and the Regions (DTLR) for the appraisal of new road schemes. However, we regard higher values as being appropriate for risks for which people appear to have a high aversion (the practical use of the VPF is discussed in Appendix 3).

104 There will of course be many options where potential benefits are not concerned with a reduction in the risk of death, for example avoiding deafness or dermatitis or a major injury. Very often in these cases, we place monetary values on the risk reduction by comparing how society rates the risks of harms such as a major injury relative to the risk of death. In addition, there may be non-monetary benefits of a regulatory option such as improvement in the sense of well-being or security. There may also be potential benefits in terms of not having to take measures, such as food bans, evacuations etc, which otherwise would be needed to reduce the effects on health and safety following an incident.

105 Expected costs for an option may also be non-monetary as well as monetary. Typical examples of monetary costs include those associated with the development and application of technology, training, clean-up etc. Non-monetary costs include loss of things that people value, such as convenience or a reduction in choice for consumers and businesses, for example if a product or process is banned.

106 We give further information on our approach for appraising options at Appendix 3, including the use of the results of CBA for assessing the cost-effectiveness of the options identified. However, as will be clear from the next stage, cost-benefit analysis is only one of a number of factors that are taken into account in deciding whether to pursue any particular course of action.

107 This approach means that the cost for preventing a fatality (CPF) of a particular measure adopted might reasonably be very different from the value of preventing a fatality (VPF) used for the purpose of conducting a cost-benefit analysis (see Appendix 3 for a fuller discussion).

108 Eventually we reach a point where we have to make a judgement about whether enough information has been collected and analysed to enable us to proceed to the next stage. This

avoids us falling into a mode known as 'paralysis by analysis' where the need for additional information is used as an excuse to avoid or postpone the adoption of a decision.

Stage 4: Adopting decisions

109 This is the stage where we review all the information gathered in the previous stage with a view to selecting the most appropriate option for managing the risks. The key to success depends to a large extent on ensuring as far as possible that interested parties are content with the process for reaching decisions and, hopefully, also with the decisions themselves. They will have to be satisfied, for example, about:

- the way uncertainty has been addressed, the plausibility of the assumptions made; and
- how other relevant factors such as economic, technological and political considerations have been integrated in the decision-making process.

110 Meeting these conditions is not always easy to achieve, particularly when parties have opposing opinions based on differences in fundamental values or confine themselves to a single issue. Nevertheless, we tackle the first condition by:

- finding out and focusing on the uncertainties that matter;
- explaining why a particular method was chosen, in preference to others, for estimating the risks; and finally
- being open on the science, assumptions and other critical inputs that have contributed to the value or judgement obtained from the risk assessment exercise.

111 Addressing the second condition above (ie how economic, technological and political considerations have been integrated in the decision-making process) is more difficult. Success lies in adopting decisions which most accurately reflect the ethical and value preferences of society at large on what risks are unacceptable, tolerable or broadly acceptable, and how far we have been successful in involving stakeholders in the decision-making process. At times, to take account of uncertainty and the need to adopt a precautionary approach, this might require focusing more on the consequences of harm occurring from a hazard than on the likelihood that the hazard will be realised (see paragraphs 37-42).

The importance of societal concerns: Adventure activities

The regulatory controls put in place on adventure activities (eg certain caving, watersport or climbing activities) show how societal factors can sometimes dominate considerations of individual risk and cost benefit.

In 1993 four young people lost their lives in a canoeing tragedy at Lyme Bay. At the request of Ministers, the Health and Safety Commission published a consultative

document (CD) seeking views on proposed new regulations to license commercial providers of certain adventure activities. The proposed controls took the form of a statutory licensing system even though (as the CD noted):

- *the historic risk of fatalities was low;*
- *formal licensing systems are normally reserved for activities which, if not properly managed, would pose high risks to large numbers of people (eg manufacture and storage of explosives, operation of nuclear installations, or certain work with asbestos).*

Public consultation confirmed the desire for new controls along the lines proposed – a reflection of societal concerns. Such concerns might perhaps be summarised in the view that society expects a very high standard of care of organisations which provide activities that aim to develop young people by enabling them to experience a sense of achievement in overcoming challenges they would not otherwise meet. The Adventure Activities Licensing Regulations came into force in April 1996.[26]

Note: Although made under the Activity Centres (Young Persons' Safety) Act 1995,[27] *the requirements of the 1996 Regulations are enforceable as if they were relevant statutory provisions under the Health and Safety at Work etc Act 1974,*[1] *and the licensing authority has to report annually to the Health and Safety Commission.*

112 We shall examine in more detail later how the criteria that we have developed on the tolerability of risks address these issues.

Stage 5: Implementing the decisions

113 When we have reached a decision on the degree to which a risk should be controlled, we have to decide how the decision can be implemented in practice using the regulatory tools at our disposal, eg recommending new legislation, inviting new guidance or taking enforcement action (see Appendix 2 for a fuller discussion of this process). As explained in paragraphs 7-8, the responsibility for measures for controlling a risk will usually fall on the person who creates it or who is in a position to do something about preventing or minimising it.

114 When constructing the regulatory tool we apply, our approach:

- is exposed to the checks and balances inherent in HSC's arrangements for dealing with occupational health and safety matters, thus ensuring fundamental principles (eg the strategy and targets set out in the 'Revitalising Health and Safety' programme agreed by the Government and HSC) are not compromised and that societal concerns are taken into account properly;
- involves consulting our stakeholders, and requires communicating effectively the outcome to stakeholders;
- takes place in the context of legal requirements which include the Management of

health and safety at work Regulations (MHSWR)[3,28,29] and so requires those who have to introduce measures for managing risks to:

- enlist the co-operation and involvement of those affected and those able to assist, such as safety representatives, by pointing out that this is crucial for the proper management of health and safety. For example, the involvement of safety representatives in health and safety management can help duty holders considerably to fulfil their legal obligations and achieve high standards of health and safety. Moreover, employers are unlikely to achieve the proper control of risks in their workplace without the help of their employees;
- introduce procedures that foster a culture disposing everyone involved to give of their best. For example, in the workplace this may mean getting a commitment, at every level of the organisation, to adopt high health and safety standards and work to them. It also calls for the establishment of well-considered and articulated safety policies where responsibilities are properly defined and allocated and organisational arrangements set out to ensure control and promote co-operation, communication and competence;
- have a plan for taking action by looking ahead and setting priorities for ensuring that risks requiring most attention are tackled first, based on the risk assessment which they are legally required to undertake under the MHSWR[30] and other specific legislation;
- set up a system for monitoring and evaluating progress, eg by identifying potential indicators for evaluating how far the control measures introduced have been successful in addressing the problem;
- comply with well-established principles on the hierarchy of measures for the prevention of risks, e.g. eliminating risks, combating the risk at source, generally applying sound engineering practice such as inherently safer design and applying collective protective measures rather than individual protective measures;

- takes account that employees also have duties imposed on them (eg by virtue of section 7 of the HSW Act[1] and Regulation 14 of MHSWR[30]) to:
  - take reasonable care of their own health and safety and of other persons who may be affected by the employees' acts or omissions at work;
  - cooperate with their employers as necessary to enable the latter to comply with their statutory health and safety responsibilities.

Stage 6: Evaluating the effectiveness of action taken

115 Finally, our process for ensuring that risks are properly managed would not be complete without procedures to review our decisions after a suitable interval to establish:

- whether the actions taken to ensure that the risks are adequately controlled resulted in what was intended;

- whether decisions previously reached need to be modified and, if so, how; for example, because levels of protection that were considered at the time to be good

practice may no longer be regarded as such as a result of new knowledge, advances in technology or changes in the level of societal concerns;

- how appropriate was the information gathered in the first two stages of the decision-making process to assist decisions for action, eg the methodologies used for the risk assessment and the cost benefit analysis (if prepared), or the assumptions made;

- whether improved knowledge and data would have helped to reach better decisions;

- what lessons could be learned to guide future regulatory decisions, improve the decision-making process and create greater trust between regulators, operators and those affected by, or having an interest in, the risk problem.

116 We regard such evaluations as an ongoing process which we need to plan carefully to ensure, for example, that we can tap the data that we have encouraged risk managers to obtain by suggesting they set up a system for monitoring and evaluating progress (paragraph 114). Since there might be some time before the full impact of risk reduction measures can be monitored, we might first focus on the extent of our success in getting risk managers to introduce appropriate measures before concentrating on the success of the decisions as a whole.

117 The importance of the evaluation stage should not be underestimated. For example, we shall see later that the criteria we adopt for deciding the degree to which risk should be controlled rely heavily on good practice being adopted or alternatively the introduction of measures achieving a similar or better level of protection. Evaluation provides a good opportunity to assess whether such 'established standards of good practice' are out of date. New developments such as better knowledge of the risks involved and advances in technology may indicate that a higher standard would be more appropriate to control the risk.

Criteria for reaching decisions

118 Though all six stages of the decision management system just described are important, getting Stage 4 right (the one concerned with reaching decisions) is crucial. Achieving this will not only help to reach decisions that are likely to be supported and implemented but, because of the iterative process inherent in the health and safety management system, it will also help to get the other stages right as well. Getting it right depends to a large extent on the criteria adopted for deciding whether a risk is unacceptable, tolerable or broadly acceptable. It is, therefore, not surprising that a lot of effort has been spent in developing such criteria.

119 Research analysing the criteria used by regulators in the health, safety and environmental field has shown that, in general, the criteria can be classified according to three 'pure' criteria. Regulators have either used these 'pure' criteria on their own or have used them as building blocks to create new criteria. They are:

- an **equity-based** criterion, which starts with the premise that all individuals have unconditional rights to certain levels of protection. This leads to standards, applicable to all, held to be usually acceptable in normal life, or which refer to some other premise held to establish an expectation of protection. In practice, this often converts into fixing a limit to represent the maximum level of risk above which no individual can be exposed. If the risk estimate derived from the risk assessment is above the limit and further control measures cannot be introduced to reduce the risk, the risk is held to be unacceptable whatever the benefits;

- a **utility-based** criterion which applies to the comparison between the incremental benefits of the measures to prevent the risk of injury or detriment, and the cost of the measures. In other words, the utility-based criterion compares in monetary terms the relevant benefits (eg statistical lives saved, life-years extended) obtained by the adoption of a particular risk prevention measure with the net cost of introducing it, and requires that a particular balance be struck between the two. This balance can be deliberately skewed towards benefits by ensuring that there is gross disproportion between the costs and the benefits;

- a **technology-based** criterion which essentially reflects the idea that a satisfactory level of risk prevention is attained when 'state of the art' control measures (technological, managerial, organisational) are employed to control risks whatever the circumstances.

120 Though there are many circumstances where these criteria work well on their own, their universal application has been found wanting. For example, it has been argued that:

- an equity-based criterion may often, in practice, require taking decisions on worst case scenarios bearing little resemblance to reality. In such cases, the decisions reached are inevitably based on procedures which systematically overestimate risks, causing undue alarm and despondency among the public or resulting in benefits achieved at disproportionate costs;

- a utility-based criterion tends to ignore that there are ethical and other considerations than just achieving a balance between costs and benefits. For example, some people believe that certain hazards should not be entertained at all because they are morally unacceptable. At the other extreme, utility-based criteria do not impose an upper bound on risk, whereas we believe that there are risks that society regards as unacceptable because they entail too high a likelihood that harm will actually occur to those exposed or the consequences are too extreme, however small the likelihood of the risk being realised, to countenance exposure to the hazard;

- technology-based criteria often ignore the balance between costs and benefits. They would, for example, require wood furniture manufacturers to adopt the state-of-the-art technology developed for keeping, clinically clean, factories, manufacturing medicines – hardly a realistic proposition.

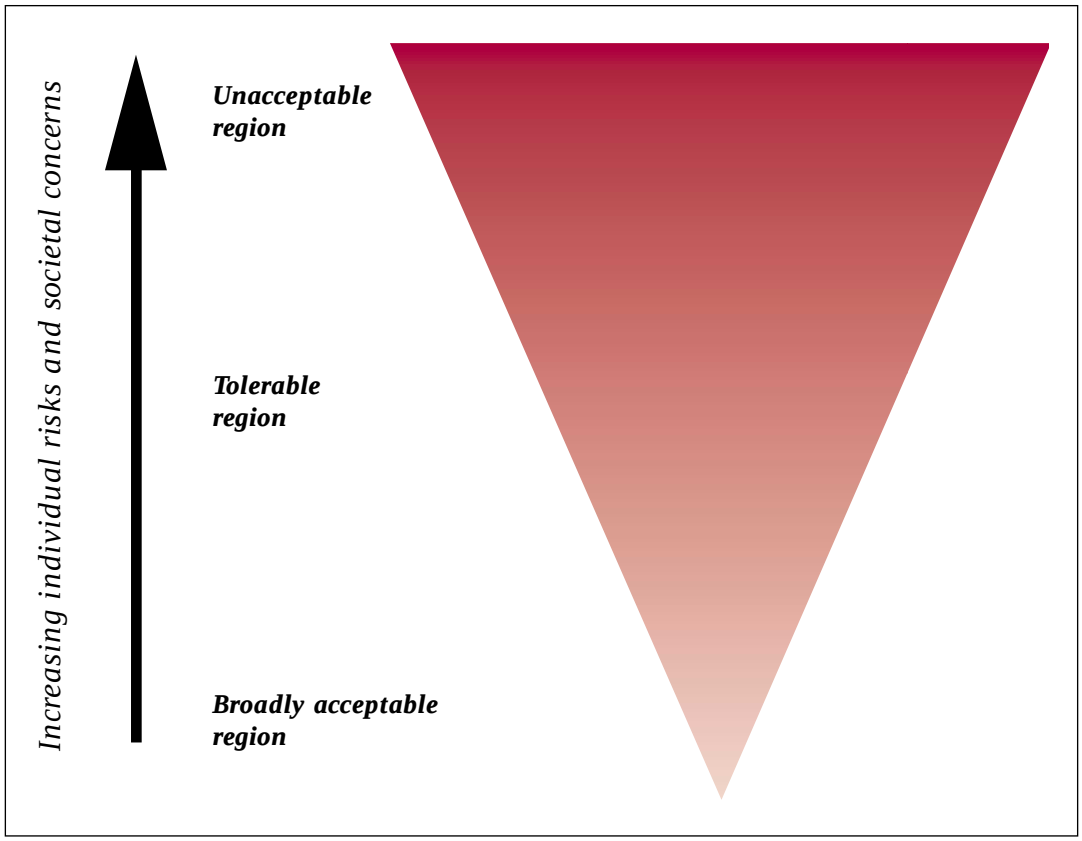
121 However, as already mentioned above, there is of course no reason why the above three pure criteria should be regarded as mutually exclusive. Indeed, the criteria that HSE has

adopted in the form of a framework, known as the tolerability of risk (TOR), accommodate all three criteria. The strength of the framework lies in:

- its ability to capitalise on the advantages of each of the above 'pure criteria' whilst avoiding their disadvantages; and

- the fact that the main tests that are applied under it for reaching decisions on what action needs to be taken are very similar to those people apply in everyday life. As already mentioned, in everyday life there are some risks that people choose to ignore and others that they are not prepared to entertain. But there are also many risks that people are prepared to take by operating a trade-off between the benefits of taking the risks and the precautions we all have to take to mitigate their undesirable effects.

Figure 1: HSE framework for the tolerability of risk



122 The framework is illustrated in Figure 1. The triangle represents increasing level of 'risk' for a particular hazardous activity (measured by the individual risk and societal concerns it engenders) as we move from the bottom of the triangle towards the top. The dark zone at the top represents an unacceptable region. For practical purposes, a particular risk falling into that region is regarded as unacceptable whatever the level of benefits associated with the activity. Any activity or practice giving rise to risks falling in that region would, as a matter of principle, be ruled out unless the activity or practice can be modified to reduce the degree of risk so that it falls in one of the regions below, or there are exceptional reasons for the activity or practice to be retained.

123 The light zone at the bottom, on the other hand, represents a broadly acceptable region. Risks falling into this region are generally regarded as insignificant and adequately controlled. We, as regulators, would not usually require further action to reduce risks unless reasonably practicable measures are available. The levels of risk characterising this region are comparable to those that people regard as insignificant or trivial in their daily lives. They are typical of the risk from activities that are inherently not very hazardous or from hazardous activities that can be, and are, readily controlled to produce very low risks. Nonetheless, we would take into account that duty holders must reduce risks wherever it is reasonably practicable to do so or where the law so requires it.

124 The zone between the unacceptable and broadly acceptable regions is the tolerable region. Risks in that region are typical of the risks from activities that people are prepared to tolerate in order to secure benefits, in the expectation that:

- the nature and level of the risks are properly assessed and the results used properly to determine control measures. The assessment of the risks needs to be based on the best available scientific evidence and, where evidence is lacking, on the best available scientific advice;
- the residual risks are not unduly high and kept as low as reasonably practicable (the ALARP principle – see Appendix 3); and
- the risks are periodically reviewed to ensure that they still meet the ALARP criteria, for example, by ascertaining whether further or new control measures need to be introduced to take into account changes over time, such as new knowledge about the risk or the availability of new techniques for reducing or eliminating risks.

125 Benefits for which people generally tolerate risks typically include employment, lower cost of production, personal convenience or the maintenance of general social infrastructure such as the production of electricity or the maintenance of food or water supplies.

126 As such the framework can be seen as essentially applying an equity-based criterion for risks falling in the upper region, while a utility-based criterion predominates for risks falling in the middle and lower regions and technology-based criteria complement the other criteria in all three regions.

127 It must be stressed that Figure 1 is a conceptual model. Moreover, the factors and processes that ultimately decide whether a risk is unacceptable, tolerable or broadly acceptable are dynamic in nature and are sometimes governed by the particular circumstances, time and environment in which the activity giving rise to the risk takes place. For example, standards change, public expectations change with time, what is unacceptable in one society may be tolerable in another, and what is tolerable may differ in peace or war. Nevertheless, the protocols, procedures and criteria described in this document should ensure that in practice, risks are controlled to such a degree that the residual risk is driven down the tolerable range so that it falls either in the broadly acceptable region or is near the bottom of the tolerable region, in keeping with the duty to ensure health, safety and welfare so far as is reasonable practicable.

Tolerability limits

128 The TOR framework just described can in principle be applied to all hazards. When determining reasonably practicable measures for any particular hazard, whether the option we have chosen to control the risk is good enough or not depends in part on where the boundaries are set between the unacceptable, tolerable or broadly acceptable regions in Figure 1. As will be clear from earlier discussions, the choice will be the outcome of much deliberation and negotiation in the course of policy development, reflecting the value preferences of stakeholders and the practicability of possible solutions.

Tolerability limits for risks entailing fatalities

In practice the actual fatality rate for workers in even the most hazardous industries is normally well below the upper limit of a risk of death to any individual of 1 in 1000 per annum for workers and of 1 in 10 000 per annum for the public who have a risk imposed on them 'in the wider interest of society' (see paragraphs 131-132).

For example, in 1999/00 the annual fatality rates for agriculture, hunting, forestry and fishing (but not sea fishing); construction; and mining and quarrying (including offshore oil and gas) were 1 in 12 984, 1 in 21 438, and 1 in 14 564 respectively. In traditionally less hazardous industries the annual risk of death for workers is lower still; for example in the service sector in 1999/00 it was 1 in 388 565.

Similarly the actual risk of death per annum for the public from work activities is usually very much lower than the figure of 1 in 10 000. For example, during the period 1994/5-1998/9 the annual risk of death to the public from the use of gas (fire, explosion or carbon monoxide poisoning), averaged over the entire population of Great Britain, was 1 in 1 510 000 – in other words below the limit of what is often regarded as broadly acceptable. Gas incidents, however, continue to give rise to societal concern, particularly where the incidents occur because unscrupulous landlords seek to avoid the cost of simple safety checks on their gas heating systems and so put those who rent the accommodation (often young people) at greater risk. In effect such societal concerns override averaged numerical considerations. HSE has responded by firm enforcement action where appropriate, and by targeted publicity emphasising the importance of annual safety checks on gas appliances.

Further Information: Appendix 4 gives other examples of the magnitude of different risks. Further information is available in Health and Safety Statistics *published annually by the Health and Safety Commission.*

129 As a result what is unacceptable, tolerable or broadly acceptable in specific circumstances is often spelled out or implied in legislation, ACOPs, guidance, etc or reflected in what constitutes good practice ie there is no need to set explicit TOR boundaries. However, HSE on the basis of its wealth of experience accumulated over the years in engaging its stakeholders subscribes as a matter of policy to the following indicative criteria, as to where these boundaries lie, for risks in a limited category, namely those entailing the risk of individual or multiple deaths. We must also stress that these criteria are merely

guidelines to be interpreted with commonsense and are not intended to be rigid benchmarks to be complied with in all circumstances. They may, for example, need to be adapted to take account of societal concerns or preferences.

Example of good practice enshrined in law

Substances hazardous to health and genetically modified micro-organisms

Some basic principles of good occupational hygiene practice are enshrined in the Control of Substances Hazardous to Health Regulations (COSHH). Control of exposure to substances hazardous to health, for example, must be achieved by:

- *prevention (eg by avoiding use altogether, or by substituting a less hazardous substance), or where this is not reasonably practicable;*
- *control measures (eg engineering controls such as containment or local exhaust ventilation), or where this is not reasonably practicable;*
- *personal protective equipment.*

Sometimes application of good practice is made a specific requirement in law. For example, in setting down standards of human health and environmental safety the Genetically Modified Organisms (Contained Use) Regulations 2000[31] require application of 'the general principles of good microbiological practice and of good occupational safety and hygiene' (14 well accepted principles are then listed). Societal concerns over the risks from genetically modified micro-organisms are reflected in a high standard of control and, in the developing area of micro-biological safety, a legal requirement which demands application of accepted good practice in step with evolving scientific knowledge and technological developments.*

**These Regulations implement Directive 90/219/EEC, as amended, on the contained use of genetically modified micro-organisms, which includes the same wording.*

Boundary between the 'broadly acceptable' and 'tolerable' regions for risk entailing fatalities

130 HSE believes that an individual risk of death of one in a million per annum for both workers and the public corresponds to a very low level of risk and should be used as a guideline for the boundary between the broadly acceptable and tolerable regions. As is very apparent from Tables 1-4 at Appendix 4, we live in an environment of appreciable risks of various kinds which contribute to a background level of risk – typically a risk of death of one in a hundred per year averaged over a lifetime. A residual risk of one in a million per year is extremely small when compared to this background level of risk. Indeed many activities which people are prepared to accept in their daily lives for the benefits they bring, for example, using gas and electricity, or engaging in air travel, entail or exceed such levels of residual risk.

131 Moreover, many of the activities entailing such a low level of residual risk also bring benefits that contribute to lowering the background level of risks. For example, though electricity kills

a number of people every year and entails an individual risk of death in the region of one in a million per annum, it also saves many more lives, eg by providing homes with light and heat, operating lifts, life support machines and through a myriad of other uses. Indeed, it is the combined effect of many activities involving such low levels of residual risks that contributes to the wealth of the nation and leads to improvements in health and longevity.

Boundary between the 'tolerable' and 'unacceptable' regions for risk entailing fatalities

132 We do not have, for this boundary, a criterion for individual risk as widely applicable as the one mentioned above for the boundary between the broadly acceptable and tolerable regions. This is because risks may be unacceptable on grounds of a high level of risk to an exposed individual or because of the repercussions of an activity or event on wider society. Indeed, it would be quite unusual for high levels of individual risk not to engender societal concerns, on equity grounds, for example, as we have already argued. The converse is not, however, true – society can be seized by hazards that pose, on average, quite low levels of risk to any individual but could impact unfairly on vulnerable groups, such as the young or the elderly or particularly susceptible individuals. Furthermore, exposure to an activity may result in a low level of average risk to any one individual but the totality of such risks across the affected population would not be acceptable as judged by the socio-political response to a particular event such as a railway disaster. Nevertheless, in our document on the tolerability of risks in nuclear power stations, we suggested that an individual risk of death of one in a thousand per annum should on its own represent the dividing line between what could be just tolerable for any substantial category of workers for any large part of a working life, and what is unacceptable for any but fairly exceptional groups. For members of the public who have a risk imposed on them 'in the wider interest of society' this limit is judged to be an order of magnitude lower – at 1 in 10 000 per annum.

133 However, these limits rarely bite. As we have already pointed out, hazards that give rise to such levels of individual risks also give rise to societal concerns and the latter often play a far greater role in deciding whether a risk is unacceptable or not. Secondly, these limits were derived for activities most difficult to control and reflect agreements reached at international level. In practice most industries in the UK do much better than that.

Risks giving rise to societal concerns

134 Developing criteria on tolerability of risks for hazards giving rise to societal concerns is difficult. Hazards giving rise to such concerns often involve a wide range of events with a range of possible outcomes. The summing or integration of such risks, or their mutual comparison, may call for the attribution of weighting factors for which, at present, no generally agreed values exist as, for example, the death of a child as opposed to an elderly person, dying from a dreaded cause, eg cancer, or the fear of affecting future generations in an irreversible way.

135 Nevertheless, HSE has adopted the criteria below (some of which are currently under review) for addressing societal concerns arising when there is a risk of multiple fatalities occurring in one single event. These were developed through the use of so-called FN-curves

(obtained by plotting the frequency at which such events might kill N or more people, against N). The technique provides a useful means of comparing the impact profiles of man-made accidents with the equivalent profiles for natural disasters with which society has to live. The method is not without its drawbacks but in the absence of much else it has proved a helpful tool if used sensibly.[32] Moreover, the criteria are based on an examination of the levels of risk that society was prepared to tolerate from a major accident affecting the population surrounding the industrial installations at Canvey Island on the Thames. Reports on the risk from the installations at Canvey Island were discussed in Parliament, and (after improvements) the risk was deemed by Ministers to be just tolerable. The limit was subsequently endorsed by the HSC's Advisory Committee on Dangerous Substances in the context of major hazards transport.[33] These criteria are, however, directly applicable only to risks from major industrial installations and may not be valid for very different types of risk such as flooding from a burst dam or crushing from crowds in sports stadia.

136 Thus, where societal concerns arise because of the risk of multiple fatalities occurring in one event from a single major industrial activity*, HSE proposes the following basic criterion for the limit of tolerability, particularly for accidents where there is some choice whether to accept the hazard or not, eg the risk of such an event happening from a major chemical site or complex continuing to operate next to a housing estate. In such circumstances, HSE proposes that the risk of an accident causing the death of 50 people or more in a single event should be regarded as intolerable if the frequency is estimated to be more than one in five thousand per annum. See reference 32 for a discussion of techniques available for extrapolating this criterion to other numbers of casualties and their frequency.

* Here a single major industrial activity means an industrial activity from which risk is assessed as a whole, such as all chemical manufacturing and storage units within the control of one company in one location or within a site boundary, a cross-country pipeline, or a railway line along which dangerous goods are transported.

137 A different situation arises altogether when giving advice to planning authorities in connection with proposed developments in the vicinity of major hazard chemical plants. Since the developments have not yet received planning permission, not allowing them because of the putative societal risks to which would-be occupants would have been exposed by living next to a chemical plant, is relatively inexpensive when compared to the costs entailed in requiring existing developments with similar risks to introduce remedial measures. HSE's criteria for advising against a development because of the societal risks that it may engender are based in the first instance on the level of individual risk per year calculated for a hypothetical person (see Appendix 1) receiving a dangerous dose, or worse, together with certain characteristics of the development.

Occupational exposure limits for substances hazardous to health and the TOR framework

In a previous example we explained that occupational exposure limits (OELs) determine the extent of exposure (by inhalation) of people at work to substances hazardous to health; an OEL can be of two types – an occupational exposure standard (OES) or a maximum exposure limit (MEL).

In principle an OEL ought to be set using data on all the effects on health produced by the substance at different levels of occupational exposure. In practice, however, absence of data and lack of a clear understanding of the biological processes involved means it can be difficult to relate occupational exposure over time to a probability of

specific harm, particularly for chronic effects such as cancer, occupational asthma or dermatitis. (One exception is chrysotile asbestos, for which the relationship between the risk of death from lung cancer and occupational exposure has been estimated.) Alternative approaches are, therefore, normally adopted. Nevertheless, the general TOR framework (Figure 1) still applies, and illustrates the application of the different types of OEL, the role of legislation in sometimes setting out what is intolerable, and the use of good practice in setting limits.

The conventional approach is to decide whether or not the hazardous properties of the substance have a threshold, and if so to seek to derive from the available data an overall no observed adverse effect level (NOAEL). Using suitable assessment or uncertainty factors (see Example Box on page 37) the NOAEL is then translated into an OES – a level of exposure at which, based on current scientific knowledge, it is judged that there is minimal risk to the health of the workforce. An OES is, however, only set if the level can be met by the application of good practice, and foreseeable excursions above this level are not associated with serious health effects.

In contrast, MELs are normally set for substances for which it is judged that there is no identifiable threshold of exposure and the health effects produced are of serious concern. (A MEL may also be set for substances for which it may be possible to identify a 'no-effect' level, but control to the corresponding exposure level is not reasonably practicable.) A MEL is set at the level which is reasonably practicable to achieve for the work activity where control of exposure is most difficult.

Under the Control of Substances Hazardous to Health Regulations (COSHH), exposure must not exceed the MEL and must be reduced to a level which is as low as is reasonably practicable below the MEL in accordance with good practice. In effect, MELs are at the boundary between the unacceptable and tolerable regions of exposure (Figure 1); exposure above the MEL is deemed intolerable.

On the other hand, control of exposure to an OES represents a level of risk that is close to or even within the broadly acceptable region. The permitted excursions are in the tolerable region provided exposure is restored to the OES as soon as is reasonable practicable (as required by COSHH).

Note: however, that whilst MELs and OESs fit within the framework of Figure 1, the levels at which they are set do not correspond with the numerical limits of risk in paragraphs 129-131. (OELs are, of course, set substance by substance; they do not usually relate to end points of death; and they are not expressed in terms of probability of harm.)

Further Information: The role of occupational exposure limits in the control of workplace exposure to chemicals.[34]

138 Thus in the case of most housing developments, for example, HSE advises against granting planning permission for any significant development where individual risk of death for the hypothetical person is more than 10 in a million per year, and does not advise against granting planning permission on safety grounds for developments where such individual risk is less than 1 in a million per year. (Somewhat different criteria are applied to sensitive

developments where those exposed to the risk are more vulnerable, e.g. schools, hospitals or old people's homes, or to industrial or leisure developments, reflecting the different characteristics of the hypothetical person used to assess individual risk).

139 Cases of proposed housing development where the individual risk of death per annum is between 1 and 10 in a million per year are scrutinised more closely, taking into account a more detailed assessment of the individual risk, the area of the development, the number of people involved, their vulnerability and how long they are exposed to the risk. Further information is available on the risk criteria presently applied by HSE in land use planning, including the criteria applied for different categories of development, for developments in the vicinity of major chemical plants, and for development of new plants.[35]

Applying the (generalised) TOR framework

140 Our general thrust in applying the framework is aimed at ensuring that our approach for addressing hazards is inherently precautionary and leads to control regimes that improve or at least maintain standards, while retaining the principles of proportionality, consistency, etc as mentioned in paragraph 52.

141 Thus when we apply the framework to policy formulation, regulatory development and enforcement activities, we:

- take into account that societal concerns are often absent for a wide range of hazards, for example, this is often the case for those hazards that are familiar or where the risks they give rise to are generally accepted as being well controlled. As we have pointed out in paragraph 26, hazards giving rise to societal concerns have a number of well known features and such concerns are often absent for many routinely encountered occupational hazards. This means that when determining where the hazard falls on the TOR triangle (as described in paragraph 122) we can, as a general rule, for most occupational hazards, focus on the individual risks (generally assessed in relation to a hypothetical person using conventional risk assessment techniques – see Appendix 1). We would weigh up the extent (if any) to which societal concerns are taken into account according to the degree that they are pertinent to the circumstances under consideration;

- decide, from the information gathered in going through the decision-making process, how precautionary our approach will be when determining where the individual risk and societal concerns ie on the TOR geometry;

- concentrate on ensuring that duty holders must have in place suitable controls to address all significant hazards arising from their undertakings;

- start with the expectation that those controls should, as a minimum, implement authoritative good practice precautions (or achieve similar standards of prevention/protection), irrespective of specific risk estimates.

142 In this context we would:

- regard a hazard as significant unless past experience, or going through the decision-making process described earlier, shows the risk from it to be extremely low or negligible when compared to the background level of risk to which people are exposed, and the hazard does not give rise to societal concerns;

- consider as authoritative sources of relevant good practice those enshrined in prescriptive legislation, Approved Codes of Practice and guidance produced by Government. We would also consider including as other sources of good practice, standards produced by Standards-making organisations (eg BS, CEN, CENELEC, ISO, IEC, ICRP) and guidance agreed by a body representing an industrial or occupational sector (eg trade federation, professional institution, sports governing body). Such considerations would take into account that HSE is a repository of information concerning good engineering, managerial and organisational practice, and would also include an assessment of the extent to which these sources had gained general acceptance within the safety movement.

143 The next stage is to distil from the information gathered at Stages 2 (characterising the problem) and 3 (examining options and their merits) on individual risks and societal concerns and, by applying the tests at Appendix 3 and the criteria in paragraphs 118-139 above, decide whether adoption of authoritative good practice precautions is an adequate response to the hazards. Our experience suggests that in most cases adopting good practice ensures that the risks are effectively controlled.

144 One consequence of linking the required control regime to relevant good practice (or measures affording similar levels of protection) is that the control measures so derived apply regardless of the length of exposure. In most circumstances, we would expect control measures to be in place at all times. For example, if good practice requires that accidental contact with the moving parts of a machine should be prevented through the fitting of a guard, the guard will need to be in place, however short the period the machine is being used.

145 There will be, however, cases where existing good practice:

- was not identified as an option at Stage 3. This will be particularly true for hazards that are new or not well studied, or where the circumstances in which people interface with the hazard are untypical or exceptional;

- is found to result in inadequate control of risks.

146 In these circumstances we have to examine (again by adopting the procedure set out at paragraph 58 above) whether any of the other options identified at Stages 2 and 3 would reduce the risks to the degree HSE considers appropriate. If one is found we would advocate its adoption. However, as we go through this iterative process of examining options, there will be occasions when we may find that no option is available for reducing the risks to a tolerable level. This will be the case for risks from activities:

- that are so high and their control inherently so difficult that it is not possible to find reasonable control measures that one could feel confident would work in practice; or

- where it is not possible to allay the societal concerns about the risk. For example, though experts may regard available control measures as adequate for controlling a particular risk, that view may not be shared by society as a whole, as established through existing democratic processes and regulatory mechanisms, either because the majority of people believe that the measures will not always be observed or that they have doubts that the risks should be entertained at all.

Intolerable risks: I

There are relatively few examples in health and safety legislation of processes or activities that have been banned because the risks they entail are so high and their control inherently so difficult that it is not possible to find any control measure that one could feel confident would work in practice (paragraph 146(i)).

The examples below are historical and reflect judgements on the risks from two particularly hazardous substances. The bans, however, have been continued into modern legislation because the risks are still real and, notwithstanding modern control measures, the judgement of the Health and Safety Commission (confirmed in public consultation) remains that, in the light of accepted good practice in using alternatives, the effort required to control the risk would be disproportionate.

The manufacture and use for any purpose of 2-naphthylamine and its salts was banned under the Carcinogenic Substances Regulations 1967[36] because its combination of physical (sublimation) and chemical (potent carcinogen) properties means that control of exposure is very difficult and the potential ill-health effects severe. The ban was continued under an EC Directive now implemented by the Control of Substances Hazardous to Health Regulations 1999 (COSHH).[37]

The Control of Lead at Work Regulations 1998 (CLAW)[38] continue a prohibition on the use of certain glazes in pottery manufacture first introduced more than 40 years ago. The requirement bans any glaze unless it is 'leadless' or 'low solubility' (terms which are defined).

Historically the use in pottery manufacture of glazes containing raw lead compounds resulted in unacceptably high levels of lead poisoning. The problem was resolved by the development of glazes containing reduced amounts of lead, or by 'fritting' the lead compounds (ie fusing and quenching to form a glass, and then granulating) to produce glazes with much reduced lead bioavailability. Adoption of these glazes became accepted good practice and their use was made a legal requirement.

Levels of exposure of workers to lead in the pottery industry are now relatively low, and there are very few cases where workers have to be suspended from work with lead because their blood lead levels are above prescribed limits.

Intolerable risks: II

Presently there are very few examples in health and safety at work legislation of processes or activities that have been banned outright on the basis of societal concerns (paragraph 146(ii)). One concerns the employment of young people (under 18 years) in certain work activities where there is potential for exposure to high levels of lead.

The Control of Lead at Work Regulations 1998 (CLAW)[36] rationalise and continue certain historical restrictions on the employment of young persons and women of reproductive capacity in specific activities where there is potential for high exposure to lead. Historically these restrictions were imposed mainly on the basis of ethical considerations. The provisions of CLAW expressly provide for a high level of protection for women of reproductive capacity, as the foetus is now known to be at greater risk from exposure to lead than adults. Nevertheless, public consultation on CLAW when still in draft form confirmed that there were continuing societal concerns over the employment of youngsters in such work activities, and the Regulations expressly ban the employment of young persons, as well as women of reproductive capacity, in a list of specified activities involving work in lead smelting and refining, and in lead-acid battery manufacture.

147 We would conclude in such circumstances that we are dealing with activities located in the upper, 'unacceptable' region of the framework. In our experience, activities or processes where the above conditions apply are relatively rare. There may be several reasons for this. First, as noted above, advances in technology mean that most risks can now be controlled. Secondly, we are aware that as regulators we can often allay societal concerns by giving reassurance that risks are being properly controlled through the introduction of progressively more stringent regulatory instruments, such as the use of guidance, ACOPs, or prescriptive legislation, culminating if necessary in the introduction of process regulations such as notification or licensing systems (see Appendix 2).

148 Nevertheless, in situations where Intolerable risks I and II are found to apply, we shall give consideration to banning these activities or processes. For existing risks where banning would be an incomplete solution because the hazard is already widespread, remedial action of some kind has to be undertaken – removal of asbestos prior to demolition of buildings is a case in point.

149 We must stress that we use the above criteria and framework flexibly and with commonsense. For example, addressing certain hazards from existing situations may require that certain activities be undertaken which would fall into the intolerable region for a short period of time, eg when the emergency services are engaged in saving life. Our decision-making process provides the necessary flexibility. Thus in the above example of the emergency services, as we go through the iterative stages of the decision-making process, we should be able to gauge the best option overall for ensuring that measures are introduced so that health and safety standards are not compromised.

Appendix 1

Some of the conventions adopted for undertaking risk assessments

Actual and hypothetical persons

1 Though a risk assessment can be done (and is sometimes done) to assess the risk to an actual person – ie the risk to an individual taking full account of the nature, extent and circumstances in which the exposure arises – there are three problems which limit the usefulness of such an approach for managing risks generally. First, the implications of the case law mentioned in paragraph 41, means that we do not need to wait for people to be actually exposed to a hazard before taking decisions about whether the risk they entail should be incurred at all or the degree to which it should be controlled. Secondly, the approach could be very resource intensive. Exposure to most hazards is seldom confined to one person. It would be necessary to carry out a risk assessment for each person exposed since individuals are affected by risk differently depending, amongst other things, on their physical make up, abilities, age, and the circumstances giving rise to their exposure. Thirdly, it would be very difficult to extract and distil useful information from all the individual assessments.

2 In practice therefore, assessment of the risks to an actual person has rather limited uses such as checking whether a generic measure introduced is suitable for a particular person. What is done instead is to perform the assessment in relation to an hypothetical person. An hypothetical person describes an individual who is in some fixed relation to the hazard, eg the person most exposed to it, or a person living at some fixed point or with some assumed pattern of life. For example, occupational exposure to chemicals, entailing adverse consequences after repeated exposure for long periods, is often controlled by considering the exposure of an hypothetical person who is in good health and works exactly forty hours a week.

3 To ensure that all significant risks for a particular hazard are adequately covered, there will usually have to be a number of hypothetical persons constructed. For example, for each population exposed to the hazard, there will usually be an hypothetical person specifically constructed for determining the control measures necessary to protect that population.

4 Relating assessments to an hypothetical person has several advantages. Persons actually exposed to the risks can compare their own circumstances to those associated with the measures deemed necessary to control the risks found for the hypothetical person, and decide whether they or their family incur a greater or lesser risk and therefore whether the measures in place are adequate in their circumstances. Furthermore, those who have a duty to assess risk and introduce appropriate measures can also reach similar conclusions in respect of those they have to protect. Moreover, the approach allows all relevant factors to be taken into account in the assessment of the risks, for example, human factors where relevant.

5 In addition the concept of hypothetical person has the considerable advantage that it allows the risk of a certain process, activity, situation etc to be assessed meaningfully and independently of

the exposure of persons actually exposed to the risks. This is because in applying the concept, it is assumed that exposure to the hazard is for the time period that was fixed when the credible scenario for the exposure of the hypothetical person was agreed upon.

6 Accordingly, its use:

- limits claims that, in particular circumstances, it is not necessary to introduce control measures for addressing a hazard entailing a significant probability of adverse consequences because the exposure to persons exposed to the hazard is actually low as they interface with the hazard for a short time. Attempts to justify such a claim could be made if, for example, persons interfacing with the hazard were periodically dismissed and replaced with others, thereby ensuring that exposure of any person to the hazard is short;

- deals elegantly with the phenomenon that exposure to many hazards is not uniform but comes in peaks and troughs. This, if present, must be factored in when determining the exposure of any exposed population by creating as necessary one or more hypothetical person to take this into account. For example, the period of exposure of the hypothetical person could be time-weighted and/or more than one hypothetical person could be constructed to deal with the various attributes of the exposure to the hazard.

- helps to improve (or at least maintain) standards by encouraging risks to be assessed (and therefore controlled) in an integrated manner by taking account of the way people interface with the hazard giving rise to the risk. A particular hazard might pose a risk of immediate traumatic injury and/or long-term health effects and affect the various population exposed differently, (eg pregnant women as opposed to male workers). A particular work activity might give rise to a number of hazards which could occur at different stages of the activity. Hazards might arise as a direct consequence of the work activity or incidentally to it (eg traffic at road works). The same hazard may be found in the different locations of a duty-holder's undertaking (eg hazards occurring on the railway system). There will usually be a need for more than one hypothetical person to be constructed to capture all these factors when assessing risks.

Hypothetical persons in the assessment of risk from nuclear plants

The procedures for assessing risks from nuclear plants illustrate how careful use of the concept of 'hypothetical persons' can reduce uncertainty and increase confidence in the outcome of the assessment.

When establishing the radiation risk to those outside a nuclear site three different hypothetical persons are used to ensure that the control measures built into the plant and incorporated in its operational procedures cater both for normal operation and for all reasonably foreseeable faults and accidents. To ensure that any calculations do not underestimate the risk, these hypothetical persons are assumed to have lifestyles that would result in the highest realistically conceivable doses from exposure to:

- *direct radiation from normal operation of the plant itself;*

- *routine emissions to air, water, etc;*

- *direct radiation and intakes of radioactivity in the event of a fault or accident.*

The definition of each hypothetical person would have to be justified in the light of the nature and environment of the plant. For the points above respective examples might be:

- *a child present continuously in the nearest dwelling to the site*
- *someone whose diet includes regular consumption of the greatest plausible quantity of a locally produced food likely to be most affected by the maximum allowable discharges from the plant (see note);*
- *someone who remains at the position of highest dose for the duration of a release of radioactive material occurring in weather conditions that resulted in the greatest exposure.*

Further information: Health and Safety Executive Safety assessment principles for nuclear plants.[39]

Note: In England and Wales discharges to the environment are regulated by the Environment Agency (in Scotland the Scottish Environment Protection Agency); food safety is the responsibility of the Food Standards Agency.

7 Our approach is to provide a 'full picture' of the risks generated by a hazard by creating enough hypothetical persons to enable control measures to be put in place to protect all those exposed from all the undesirable consequences of the hazard, taking account of the different populations exposed and the circumstances of their exposure (see paragraph 3). This technique has the merit of preventing risk being underestimated by making clear whether a generic assessment of the risks on its own is adequate, or whether it should be supplemented by other assessments pertaining to:

- particular groups of persons interacting with the hazard in a certain way or who are particularly vulnerable to it;
- a slice of time;
- particular locations.

8 In practice, when assessing compliance, it will also be necessary to check whether actual persons exposed to the risks fall within the profile of the hypothetical person(s) adopted for the assessment of the risk. If the preventive measures adopted for controlling risks to the hypothetical person are found not to be adequate to protect actual persons, more stringent measures may need to be introduced.

Standards

9 The results of assessments done in relation to hypothetical persons are also used for the

adoption of standards. Standards can be regarded as generic control measures that must be applied to eliminate or reduce the risks for a particular hazard. The scope of the standard is set by specifying the circumstances in which the hazards give rise to the risk. One feature of using standards is that once adopted they may be regarded as applying to the hazard rather than to the risk in the sense that they are applied to control risks whatever the circumstances, for example, however short the actual exposure to the hazard.

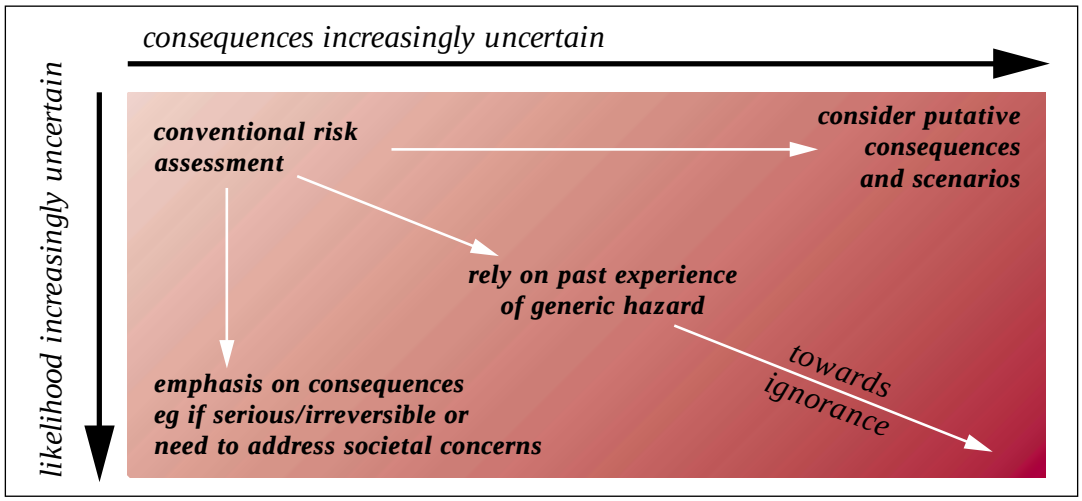
Procedures for handling uncertainty

10 The procedures adopted for handling uncertainty are illustrated in Figure 2. The vertical axis represents increasing uncertainty in the likelihood that the harmful consequences of a particular event will be realised, while the horizontal axis represents increasing uncertainty in the consequences attached to the particular event.

11 At the upper left hand corner, a risk assessment can be undertaken with assumptions whose robustness can be tested by a variety of methods. However, as one moves along the axes increasingly assumptions are made that are precautionary in nature and which cannot be tested.

12 For example, at the bottom of the vertical axis where there is a high degree of uncertainty about likelihood, it is assumed that the event will be realised by focusing solely on the consequences, while on the far right of the horizontal axis, where there is a high degree of uncertainty surrounding the consequences, putative consequences are deliberately assigned to the hazard.

Figure 2: Procedures for tackling uncertainty when assessing risks



13 It is also worth noting that though more information frequently leads to a decrease in uncertainty, it does not necessarily change the probability of an event. For example, though frequent inspections of a critical component may reduce the uncertainty regarding the probability of the component failing within a period of time, the inspections do not reduce the probability of the component failing unless action is taken to remedy the situation.

Appendix 2

Identifying and considering options for new regulations, Approved Codes of Practice and guidance

1 When considering a specific risk problem, HSC/E are often confronted with the question as to how they should use the powers conferred on them by the HSW Act to clarify how duty holders should comply with their legal duties under the Act, or to extend those duties in particular cases. In these circumstances, in our role in advising HSC, we need to decide whether the new measure is really necessary and, if it is, what form this should take so that the decisions reached take due account of the framework in Part 3 of this document, the architecture of our health and safety law, and the fact that there may be constraints in pursuing certain options. How we tackle this question is explored below.

Architecture of health and safety law

2 The HSW Act puts a range of regulatory instruments at HSC's disposal in its role as guardian of occupational health, safety and welfare. These include making proposals to the Secretary of State for new legislation, and issuing Approved Codes of Practice (ACOPs) and guidance. The Act also allows for modernising health and safety law according to a particular architecture. Our policy is to ensure that regulations, like the Act itself, should, so far as possible, express general duties, principles and goals with subordinate detail set out in ACOPs and guidance. As such the architecture is designed to keep the need for intervention by the regulator to a minimum.

3 The architecture takes the following form:

- **the general duties** on employers, self-employed persons and others in the HSW Act. They amount to a statutory (criminal law) enactment of common law duties of care. They are comprehensive in coverage – of people, places, activities and other sources of hazard. They are qualified by 'so far as is reasonably practicable' (SFAIRP). An exception is Section 7, under which employees have a duty to 'take reasonable care' of their own and others health and safety;

- **regulations**, some of which clarify particular aspects of the general duties and are mandatory; others may introduce particular requirements for specific hazards, sectors etc. They do not add to the scope of the general duties, but regulations may impose a higher standard of duty ('practicable' or absolute requirements). Of special mention is the Management of Health and Safety at Work Regulations 1999 (MHSWR).[32] These require employers and self-employed people to assess the risks in their undertakings so as to identify the measures they need to have in place to comply with their duties under health and safety law. As such, the assessment provisions of

MHSWR permeate all other workplace health and safety legislation including the general duties in the HSW Act;

- **ACOPs**, which clarify particular aspects of the general duties and regulations, and are HSC's way of spelling out their implications. ACOPs have a special guidance status. If employers are prosecuted for a breach of health and safety law, and it is proved that they have not followed the relevant provisions of the Approved Code of Practice, a court can find them at fault unless they can show that they have complied with the law in some other way. Accordingly, the HSC agreed in 1996, following consultation, that it would limit the use of guidance having the status of an ACOP to cases where four conditions were met. These are when:
  - there is clear evidence of a significant or widespread problem;
  - the overall approach being taken to an area of risk is by amplifying general duties in the HSW Act or preparing goal-setting regulations (see paragraph 4);
  - there is a strong presumption in favour of a particular method or particular methods that can be amplified in an ACOP in support of the general duties or goal setting regulations to give authoritative practical guidance;
  - the alternative is likely to be more prescriptive regulation;

- **guidance**, which is not law but gives advice on measures available and what is good practice.

4 Regulations broadly take three forms:

- **'process' regulations** concerned with what has to be done to manage the control of risks. These include requirements to assess risks, set out management approaches, draw up safety cases, notify hazards, keep records etc. and may include some form of permissioning, eg licensing. Many of the requirements are derived directly from what is implicit in the general duties, eg the need to assess risks. They deal with matters where there is a need to demonstrate that risk is subject to careful, explicit control;

- **goal-setting regulations** which set out the objectives to be achieved but leave considerable freedom on how these objectives are to be met. Goals or targets to be met in such regulations are often qualified by 'reasonable practicability' and thus demand from both regulator and duty holders some matching of response to risk and of cost to benefit;

- **standard-setting regulations** which prescribe what constitutes an appropriate response to a hazard.

5 These forms are not mutually exclusive, ie a set of regulations could contain all three.

Constraints

6 The regulation of health and safety risks from work activities is subject to certain constraints, some voluntary and others which we must take into account. In the latter

category we would include:

- the fact that most health and safety legislation these days originates from the European Union, mainly in the form of European Community directives (some legislation may originate in International Conventions). Once adopted, the UK has to transpose the provisions of the directive into national legislation. Though the framework described in Part 3 of this document will be most useful to inform the line that should be taken in negotiation of directives, compromises reached during the negotiations may result in measures for managing risks which do not fit completely in either the framework or the above architecture. If the enabling provisions of the HSW Act (as is often the case) are subsequently used to implement the directives into UK law, these 'misfits' will inevitably be reflected in the implementing legislation;

- the need, when modernising legislation preceding the HSW Act, to maintain or improve standards of health, safety and welfare.

7 Voluntary constraints include:

- adhering to the general principle that standards of health, safety and welfare should be maintained, even when this is not mandatory, for example, when replacing legislation or guidance introduced after the Act;

- ensuring that, wherever possible, regulatory measures adopted domestically fit as far as possible with the architecture described above.

Hierarchy of options

8 Based on our wealth of experience in applying the framework and while taking account of the above constraints, the following procedure has evolved for identifying options most likely to work for new regulatory measures and the order in which they should be considered:

- reliance on the general duties and the Management of Health and Safety at Work Regulations. These would be judged as sufficient unless:
  - past experience shows enforcement of the above duties does not succeed;
  - there is a high level of uncertainty about what is required;
  - EC Directives (or International Conventions) require more specific or different legislation to be introduced domestically;
  - societal concerns require that some explicit form of action is needed (politically or to allay public fears).

- use of guidance. This may help to deal with some of the above, but could be insufficient if:
  - EC Directives (or International Conventions) require more;
  - the need to address societal concerns requires more;
  - the current compliance record suggests guidance will not be effective, or will leave

too large a gap between average and poor compliance;
- statutory regulation is required to ensure a level playing field for the risk creators;
- the general view of stakeholders is that guidance alone leaves too much discretion to duty holders and/or HSW Act inspectors, eg in interpreting 'reasonable practicability' and measures necessary to reduce risk 'as low as reasonably practicable' (ALARP).

- ACOPs. These may help to overcome some of the above, whilst still allowing scope for alternative, equally good, ways of controlling hazards and reducing risks. They would be considered particularly effective if:
  - there is rapidly developing technology offering new ways of achieving good practice;
  - there is high diversity of circumstance best dealt with by allowing different approaches;
  - the industry is highly organised, homogeneous and capable of a fair degree of self-regulation;
  - the ACOP can be used, in effect, to define reasonable practicability (or other legal standard, as appropriate) and hence prevent over-response by industry, over-enthusiasm by enforcers and over-selling by intermediaries – and the converse (under-response etc).

- But an ACOP is likely to be regarded as insufficient if:
  - the hazard requires an absolute and/or prescribed duty to deal with it;
  - EC Directives (or International Conventions) allow no alternative approaches;
  - there is not a sufficiently strong statutory 'peg' on which to hang requirements in an ACOP (since ACOPs are not to be used to introduce higher duties by the back door);
  - the need to address societal concerns requires more.

- goal-setting regulations. These may help to amplify general duties in ways which overcome most of the above. But these may still be insufficient if:
  - EC Directives (or International Conventions) require specificity or prescription;
  - HSC has decided that adequate control of the risk from a particular hazard requires that specific standards have to be met;
  - a 'level playing field' requires duty holders to do the same thing as well as to achieve the same results;
  - uncertainty needs to be reduced to the minimum (including allowing minimum discretion to the regulator);
  - the need to address societal concerns requires more, such as the introduction of process regulations.

- specific or prescriptive regulations. These may be justified to:
  - deal with manifest hazards and/or those hazards entailing high risks or societal concerns;
  - deal with new hazards so as to ensure consistency of action;
  - secure a step-change in behaviour in known areas of bad practice (including changes that will reduce the 'spread' of performance and bring bad performers up to generally acceptable levels);

- define and eliminate uncertainty by providing a generic assessment of risk and a suitable response which can help cut costs;
- secure standardisation and fair competition;
- meet the requirements of EC Directives (or International Conventions);
- allay worker and public concern by transparent measures and accountability;
- cut down duty holders and/or inspectorial discretion;
- ban a specific activity or process in line with the criteria adopted for stage four of the decision-making process.

9 If specific or prescriptive legislation needs to be introduced then process regulations will generally be used as a last resort because they tend to be resource intensive. Nevertheless, this course of action will be adopted if process regulations are found to be the best way of ensuring that adequate measures are put in place for controlling the particular hazard under consideration. Such regulations could require (in ascending order of stringency) the notification of the hazard; the drawing up of safety cases for demonstrating that the risks from the hazard are adequately controlled; or establishing a licensing system that stipulates specific conditions for ensuring health and safety.

Appendix 3

Some issues relevant to assessing risk reduction options

1 When deciding how to regulate hazards and their concomitant risks, HSE can consider a broader range of factors than those which the HSW Act and its relevant statutory provisions require duty-holders to take into account when they manage risks at work (see paragraphs 80-95). However, HSE must operate within the framework provided by the HSW Act and the existing case law – it cannot propose a regulatory regime which places requirements on duty-holders to reduce risks at work which does not fit within this legal framework. The framework though is very wide.

2 The enabling powers of the Act to make regulations (section 15) and the subject matter that may be covered in regulations (see Schedule 3) are very broad in scope. Health and safety legislation made under the Act may be absolute or qualified by expressions such as 'practicable' or 'reasonable practicability'. The latter expressions provide duty holders with a defence against a duty. They are therefore used for instances where HSC/E would like duty holders to have such a defence, for example when the lack of the qualification would result in bad law by imposing duties that cannot be fulfilled because absolute safety cannot be guaranteed. Paragraphs 3-9 are a discussion of the implications of case law when regulating through the imposition of duties qualified by the concept of 'reasonable practicability'. Paragraphs 10-22 discuss the factors taken into account by HSE when comparing risks and costs in the context of undertaking a cost benefit analysis before regulating.

Implications of case law on 'reasonable practicability'

3 Because, ultimately, it is a matter for the courts to decide whether or not duty-holders have complied with such duties, considerable attention must be paid to how the courts have interpreted the above qualification. Case law on duties qualified by 'so far as is reasonably practicable' (SFAIRP) makes it clear that the courts will look at all relevant circumstances, on a case by case basis, when reaching decisions on the appropriateness of action taken by duty-holders in meeting this qualification.

4 Of particular importance in the interpretation of SFAIRP is *Edwards v. The National Coal Board (1949)*.[40] This case established that a computation must be made in which the quantum of risk is placed on one scale and the sacrifice, whether in money, time or trouble, involved in the measures necessary to avert the risk is placed in the other; and that, if it be shown that there is a gross disproportion between them, the risk being insignificant in relation to the sacrifice, the person upon whom the duty is laid discharges the burden of proving that compliance was not reasonably practicable.

5 In seeking to apply this case law, when regulating or producing guidance on compliance with duties qualified by all injunctions embodying the concept of 'reasonable practicability' such as SFAIRP, ALARP (as low as reasonably practicable), ALARA (as low as reasonably achievable), HSE believes that such duties have not been complied with if the regime introduced by duty holders to control risks fails the above 'gross disproportion' test. Moreover, HSE believes that in making this compliance assessment, the starting point for determining whether risk has been reduced as low as reasonably practicable, should be the present situation in the duty holder's undertaking. However, in certain circumstances, it will not be possible to assess options in this way. In such situations, the starting point should be an option which is known to be reasonably practicable (such as one which represents existing good practice). Any other options should be considered against that starting point, to determine whether further risk reduction measures are reasonably practicable.

Risks taken into account in regulating

6 HSE would not normally impose duties on duty-holders which required them to consider risks other than those which:

- arise out of reasonably foreseeable events and behaviour. For example, the risk of a well designed, properly built and well maintained building collapsing would not be regarded as a reasonably foreseeable event (unless signs such as subsidence, cracked walls or falling roof tiles suggest otherwise). This is because the risks were considered and taken care of by the building designers, contractors and maintenance engineers and the building is unlikely to collapse unless it is affected by an external event such as a severe earthquake, itself very unlikely. In contrast, the risk of a building collapse during its demolition would be regarded as reasonably foreseeable. However, in some circumstances, we would consider very unlikely risks (ie 'foreseeable' but not 'reasonably foreseeable') because of the extent of the consequences should those risks be realised. For example, it would be proper to consider the effects of a severe earthquake in the case of major hazard industries because it could trigger an even greater catastrophic event;

- are under the control of the duty-holder. This is in line with the regulatory structure provided by the HSW Act, which for example requires employers to ensure the health and safety of their employees and members of the public who may be affected by the conduct of the employers' undertakings. When determining what is reasonably practicable, HSE will take into account that the risks which an employer needs to consider are limited to those present in the conduct of his undertaking and which he is in a position to eliminate or control.
  ✦ For example, a railway operator would not need to consider whether increasing their fares would put more people at greater or less risk overall because they suspect that some people might be inclined to choose to travel by inherently less safe modes of transport (eg using their own motor cars). What determines such choices is very complex and depends on many elements. Though the operators might be able to control one of those elements (the price of their fares), they have no way of

controlling the other elements. Nor for the same reasons would they in practice be able to reach a view on the impact of their proposed fare increases on the level of risk overall. On the other hand it would be quite proper for Government (as opposed to HSC/E) to consider such matters;

- are not trivial or arising from routine activities associated with life in general, unless the work activity compounds those risks, or there is evidence of significant relevance to the particular work activity.

7 In regulating and assessing risks, HSC/E considers both individual risks and societal concerns, including societal risks. Therefore, where hazards give rise to societal concerns, HSC/E may require duty holders to take these into account. Duty holders action on societal concern is limited to instituting the measures set out by HSC/E in the control regimes which are required by regulations enacted to address the hazard concerned, and in associated guidance.

8 Within these constraints, HSE when regulating attaches great importance to risks being assessed in an integrated manner as described at Appendix 1, paragraph 7. Here again, HSE's approach in deciding the control regime that duty holders should adopt would initially be to require the introduction of generic control measures to eliminate or control the risk for the full range of hypothetical persons identified at the risk assessment stage. However, if these are not sufficient to control the risk, HSE will consider whether it is appropriate to require control measures specifically tailored for risks which may occur at particular locations or in a slice of time, or for particular groups.

9 If, due to unusual circumstances, some actual persons exposed to the risks fall outside the profile adopted for the hypothetical person(s) used for assessing the risks (see Appendix 1, paragraphs 3-8), then HSE will expect that the control measures adopted for protecting the hypothetical person(s) are modified by the duty holder to ensure that the actual persons are protected. For example, control measures may need to be adapted to cater for people with disabilities such as colour blindness, if the need to distinguish between colours is a health and safety requirement, or if the employees lack a particular skill that the hypothetical person is assumed to have, such as the ability to read or understand instructions.

Use of cost benefit analysis in the decision-making process

10 As discussed in paragraphs 101-108 cost benefit analysis (CBA) offers a framework, widely used in Government, for comparing the benefits of reducing risks against the costs incurred for a particular option for managing risks. HSE uses CBA to informs its decisions when regulating and managing risks. It does this by expressing all relevant costs and benefits in a common currency – usually money. It is normally undertaken for options falling within the tolerable region in Figure 1. In practice, a CBA cannot be done without the adoption of certain technical conventions. Those used generally by Government have been published in guidance from HM Treasury.[41]

11 The Treasury rules are meant to cater for a wide range of circumstances and as such are inevitably broad brush. We examine below in more detail (but still in general terms) the policy rules that we consider particularly relevant for assessing the relationship between the cost and benefits of occupational health and safety measures.

Valuation of benefits

12 A suitable and sufficient assessment of cost and risk can often be done without the explicit valuation of the benefits, on the basis of common sense judgements while, in other situations, the benefits of reducing risk will need to be valued explicitly. The latter is far from easy because the health and safety of people and their societal concerns are not things that are bought and sold, and yet a monetary value has to be attributed to matters such as the prevention of death, personal injury, pain, grief and suffering.

13 Where the benefit is the prevention of death, the current convention used by HSE, when conducting a CBA is to adopt a benchmark value of about £1 000 000 (2001 prices) for the value of preventing a fatality (VPF).* This is the VPF adopted by the Department of Transport, Local Government and the Regions for the appraisal of road safety measures. It may well be the case that individuals' willingness to pay for risk reduction – measured in aggregate by the VPF – will vary, depending on the particular hazardous situation. Thus, the particular hazard context will need to be borne in mind when a VPF figure is adopted. Currently, HSE takes the view that it is only in the case where death is caused by cancer that people are prepared to pay a premium for the benefit of preventing a fatality and has accordingly adopted a VPF twice that of the roads benchmark figure. Research is planned to assess the validity of this approach.

* VPF is often misunderstood to mean that a value is being placed on a life. This is not the case. It is simply another way of saying what people are prepared to pay to secure a certain averaged risk reduction. A VPF of £1 000 000 corresponds to a reduction in risk of one in a hundred thousand being worth about £10 to an average individual. VPF therefore, is not to be confused with the value society, or the courts, might put on the life of a real person or the compensation appropriate to its loss.

14 Moreover, it is also important to note that when HSC/E regulate, VPF is not the only factor in balancing costs against risks since a CBA informs, but does not determine, the decisions on measures that should be adopted to control the risk. As already explained, the final decision may take into account wider political and equity considerations as to whether costs are grossly disproportionate to benefits.

15 Once a decision has been adopted on the control regime that should be introduced to control the risk, the cost of the measures required can be assessed to derive a value for the 'cost of preventing a fatality' (CPF), by dividing the total final cost by the (putative) total fatalities prevented. Comparison of CPF with VPF may well reveal a difference between the two values.

Discounting of costs and benefits

16 When preparing formal CBAs, it is customary to discount future costs and benefits to reflect the fact that people, on balance, prefer to have benefits now and pay for them later. Thus they value a benefit in the present more highly than the same benefit received some

time in the future. Similarly, a health and safety measure paid for in the present is considered more costly than if it is paid for at some future date. Conventional economic theory is that such preferences are reflected in the rate of interest paid by borrowers or to savers for capital.

17 For most public policy applications, a real rate of return of 6% a year is used currently to discount costs and benefits. This assumes that all monetary costs and benefits are expressed in real terms (constant prices). The value that individuals place on safety benefits tends to increase as living standards improve, so the future values applied to such benefits should be uprated to allow for the impact on well-being of expected growth in average real income. On the basis of past trends and Treasury guidance, HSE regards an uprating factor of 4% a year as appropriate on the benefits side of the comparison.

18 However, when costs and benefits accrue far into the future, the assumptions underlying these discounting conventions may need to be re-examined. Special considerations may be needed for specific cases.

Costs taken into account in regulating

19 HSE adopts the following principles when it make judgements about costs in assessing possible regulatory options:

- the costs to be considered are those which are incurred unavoidably by duty-holders as a result of instituting a health and safety measure. In other words the costs that should be considered are only those which are necessary and sufficient to implement the measures to reduce risk. Where duty holders incur additional costs for other reasons, these should not be counted. So, for example, extra costs incurred by the duty holders adopting 'deluxe' measures where 'standard' ones would serve just as well should be excluded;

- for any particular measure, it will be proper to include the cost of installation, operation, maintenance and the costs due to any consequent productivity losses resulting directly from the introduction of the measure. In general, these should be estimated on the basis of the value of the economic resources involved. This will usually be the same as the financial costs to the duty-holder, but there may be cases where alternative estimation procedures are necessary.

- monetary gains accrued from the introduction of a health and safety measure should be offset against the costs. This is because measures for managing risk often have the effect of reducing costs. Typical examples are the reduction of losses (eg damage to property, lost production) resulting from decrease in accidents or incidence of ill health, and savings made from any productivity gains resulting directly from the introduction of the measure. However, costs should be offset only against those productivity savings which can actually be realised, ie unit cost reductions. The following should not be offset:
  - potential savings/gains, which may depend upon the state of the market, such as

the profits which would result from selling on the increased production made possible through improved productivity;

- gains which would accrue from an improved commercial reputation;
- indirect savings such as those resulting from reduced insurance premiums* or civil damages.
- the ability of the duty holder to afford a control measure is not a legitimate factor in the assessment of costs. This ensures that duty holders are presented with a level playing field.

* In some cases, insurance companies may link reduced premiums directly with the introduction of health and safety measures, in which case the reduction should be used to offset costs.

Comparison of risk against costs

20 In comparing cost against risks HSE, when regulating, will be governed by the principles that:

- there should be a transparent bias on the side of health and safety. For duty holders, the test of 'gross disproportion' implies that, at least, there is a need to err on the side of safety in the computation of health and safety costs and benefits. HSE adopts the same approach when comparing costs and benefits and moreover, the extent of the bias (ie the relationship between action and risk) has to be argued in the light of all the circumstances applying to the case and the precautionary approach that these circumstances warrant (see paragraphs 89-94);

- whenever possible, standards, should be improved or at least maintained.

21 In practice, as noted in paragraphs 140-141, HSE when regulating will consider that normally risk reduction action can be taken using good practice as a baseline – the working assumption being that the appropriate balance between costs and risks was struck when the good practice was formally adopted and the good practice then adopted is not out of date. However, there will be cases where some form of computation between costs and risks will form part of the decision-making process. Typical examples include major investments in safety measures where good practice is not established.

22 Moreover, HSE may decide that certain hazards would be best regulated through a safety case regime requiring an explicit demonstration in the safety case that control measures introduced conform with the ALARP principle. Though HSE expects that this requirement can often be met by just showing that the control measures adopted represent good practice there will, nevertheless, be certain occasions where HSE will expect duty holders to show (not necessarily by a full cost benefit analysis) the comparisons made between the costs of introducing particular options and the risk reduction thereby achieved.

Appendix 4

Some statistics for comparing risks from different hazards

1 Comparing the degree and probability of the various risks we run is not an easy task. Different kinds of risks have to be compared in different ways. Some kinds of risk, such as being killed by lightning or in a road accident or by some other violent cause, are borne by large numbers of people or even by all of us all the time, so it is reasonable to give the chance per million per annum, even though some of us would have a better chance than others.

2 However, some kinds of risk need to be compared in a way that takes account of the extent to which the risk is being run. For example, to compare the risks of death from travelling by air, road or rail we need to express it as a proportion of the number of kilometres or the number of journeys travelled.

3 Estimating the annual chance of certain major events occurring also presents difficulties. In Great Britain, estimates of this kind can sometimes be based on direct or historical experience. We know for example how many major fires occur each year and we can expect the same trend to continue, more or less. Sometimes, however, these estimates represent no more than a complex set of expert judgements based on a variety of factors such as the known rate of failure of engineering components. Some others, such as estimating the chance of an aircraft crash represent a scaling down of world experience. As a result, all of them are subject to large margins of error, particularly in translating the probability of accidents occurring in developing countries to more industrialised ones. Moreover, some statistics will be overstated, eg those that depend on engineering judgement because of the caution and pessimism that it is customary to build into such estimates. Others will be understated because, for many hazards, they compare only the chance of immediate death, ignoring that the hazards also carry with them a risk of injury or ill health or of delayed death.

4 Notwithstanding these important reservations, the tables below give some idea of how the different risks we run compare with each other in size and probability.

Examples of large numbers taken from everyday life

- 2 litre bottles of water in a 3 metre-deep, 50 by 20 metre swimming pool (1 500 000).
- Grains in a 500 gram bag of sugar (1 000 000).
- Teaspoons (5 millilitres) of water in a standard bath (0.5 cubic meters) (100 000).

Examples of low probability taken from everyday life

- The probability that the temperature below 500 metres in Great Britain will fall below a certain minimum value in a certain month, based on measurements from 1875 to 1990 (Tornado and Storm Research Organisation, 1996). For example:
  - On any day in September, a minimum temperature of -6 C or lower has occurred on a total of five occasions in five separate years (1942, 1948, 1974, 1975, and 1979), representing an annual probability of 1 in 23.

- The probability of a high-scoring draw at a football match. The statistics reported below are based on data from 10,148 matches from all English League Divisions, for the four seasons in the period 1990-95.
  - A 3-3 draw occurred 118 times, representing a probability of about 1 in 100.
  - A 4-4 draw occurred 11 times, representing a probability of about 1 in 1 000.
  - A 5-5 draw occurred only once, representing a probability of about 1 in 10 000.

- The probability of winning the National Lottery is reported by Camelot in terms of a single lottery ticket matching the main numbers and/or the bonus ball:
  - Match 6 of 6 main numbers (winning the jackpot): 1 in 14 000 000.
  - Match 5 of 6 main numbers and the bonus ball: 1 in 2 300 000.

Average annual risk of death/injury from various causes:

Table 1: Annual risk of death for various United Kingdom age groups based on deaths in 1999 (Annual Abstract of Statistics, 2001/Health Statistics Quarterly – Summer 2001).

Population group	Risk as annual experience	Risk as annual experience per million
Entire population	1 in 97	10 309
Men aged 65-74	1 in 36	27 777
Women aged 65-74	1 in 51	19 607
Men aged 35-44	1 in 637	1 569
Women aged 35-44	1 in 988	1 012
Boys aged 5-14	1 in 6 907	145
Girls aged 5-14	1 in 8 696	115

Table 2: Annual risk of death for various causes averaged over the entire population.

Cause of death	Annual risk	Basis of risk and source
Cancer	1 in 387	England and Wales 1999 (1)
Injury and poisoning	1 in 3 137	UK 1999 (1)
All types of accidents and all other external causes	1 in 4 064	UK 1999 (1)
All forms of road accident	1 in 16 800	UK 1999 (1)
Lung cancer caused by radon in dwellings	1 in 29 000	England 1996 (2)
Gas incident (fire, explosion or carbon monoxide poisoning)	1 in 1 510 000	GB 1994/95-1998/99 (3)
Lightning	1 in 18 700 000	England and Wales 1995-99(4)

(1) Annual Abstracts of Statistics (2001)
(2) National Radiological Protection Board (1996)
(3) Health and Safety Executive (2000)
(4) Office of National Statistics (2001)

Table 3: Annual risk of death from industrial accidents to employees for various industry sectors (Health and Safety Commission, 2001).

Industry sector	Annual risk	Annual risk per million	Basis of risk and source
Fatalities to employees	1 in 125 000	8	GB 1996/97 to 2000/01*
Fatalities to the self-employed	1 in 50 000	20	GB 1996/97 to 2000/01*
Mining and quarrying of energy producing materials	1 in 9 200	109	GB 1996/97 to 2000/01*
Construction	1 in 17 000	59	GB 1996/97 to 2000/01*
Extractive and utility supply industries	1 in 20 000	50	GB 1996/97 to 2000/01*
Agriculture, hunting, forestry and fishing (not sea fishing)	1 in 17 200	58	GB 1996/97 to 2000/01*
Manufacture of basic metals and fabricated metal products	1 in 34 000	29	GB 1996/97 to 2000/01*
Manufacturing industry	1 in 77 000	13	GB 1996/97 to 2000/01*
Manufacture of electrical and optical equipment	1 in 500 000	2	GB 1996/97 to 2000/01*
Service industry	1 in 333 000	3	GB 1996/97 to 2000/01*

**Health and Safety Commission, Health & Safety Statistics (1996/97, 1997/98, 1998/99 & 1999/2000) published by HSE Books. Figures used for 2000/2001 are provisional.*

Table 4: Average annual risk of injury as a consequence of an activity.

Type of accident	Risk	Basis of risk and source
Fairground accidents	1 in 2 326 000 rides	UK 1996/7-1999/00 (1)
Road accidents	1 in 1 432 000 kilometres travelled	GB 1995/99 (2)
Rail travel accidents	1 in 1 533 000 passenger journeys	GB 1996/97-1999/00 (3)
Burn or scald in the home	1 in 610	UK 1995-99 (4)

(1) Tilson and Butler (2001)
(2) Department of Environment, Transport and the Regions – Transport Statistics (2000)
(3) Health and Safety Executive (2001)
(4) Department of Trade and Industry and Office of National Statistics (2001)

Table 5: Average annual risk of death as a consequence of an activity.

Activity associated with death	Risk	Basis of risk and source
Maternal death in pregnancy (direct or indirect causes)	1 in 8 200 maternities	UK 1994-96 (1)
Surgical anaesthesia	1 in 185 000 operations	GB 1987 (2)
Scuba diving	1 in 200 000 dives	UK 2000/01 (3)
Fairground rides	1 in 834 000 000 rides	UK 1989/90-2000/01 (4)
Rock climbing	1 in 320 000 climbs	England and Wales 1995-2000 (5)
Canoeing	1 in 750 000 outings	UK 1996-99 (6)
Hang-gliding	1 in 116 000 flights	England and Wales 1997-2000 (7)
Rail travel accidents	1 in 43 000 000 passenger journeys	GB 1996/97-1999/00 (8)
Aircraft accidents	1 in 125 000 000 passenger journeys	UK 1991-2000 (9)

(1) NHS Executive (1998)
(2) Lunn and Devlin (1987)
(3) Based on assumption of 3 million dives per year. British Sub-Aqua Club (2001)
(4) Based on estimated 1 billion rides per year. Tilson and Butler (2001)
(5) Based on the assumption that there is a total of 45,000 climbers making an average of 20 climbs per year each. Mountain Rescue Council (2001)
(6) Based on the assumption that there are 100,000 whitewater canoeists making an average of 30 outings per year each. Drownings in the UK, RoSPA (1999)
(7) Based on the assumption that each member makes an average of 50 flights per year. British Hang-gliding and Paragliding Association (2001)
(8) Health and Safety Executive (2001)
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While every effort has been made to ensure the accuracy of the references listed in this publication, their future availability cannot be guaranteed

Glossary of acronyms

ACOP	Approved Code of Practice
ACTS	Advisory Committee on Toxic Substances
ALARA	As Low as Reasonably Achievable
ALARP	As Low as Reasonably Practicable
CBA	Cost Benefit Analysis
CD	Consultative Document
CEN	Comité Européen de Normalisation
CENELEC	Comité Européen de Normalisation Electrotechnique
CLAW	Control of Lead at Work Regulations
COSHH	Control of Substances Hazardous to Health Regulations
CPF	Cost of Preventing a Fatality
EC	European Communities
EU	European Union
HSC	Health and Safety Commission
HSE	Health and Safety Executive
the HSW Act	The Health and Safety at Work etc Act
ICRP	International Commission on Radiological Protection
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
MEL	Maximum Exposure Limit
MHSWR	Management of Health and Safety at Work Regulations
NOAEL	No Observed Adverse Effect Level
OEL	Occupational Exposure Limit
OES	Occupational Exposure Standard
QRA	Quantitative Risk Assessment
RBMK	Reactor Bolshoi Mozjnoct Kanali
SFAIRP	So Far as is Reasonably Practicable
TOR	Tolerability of Risk
VPF	Value for Preventing a Fatality
WATCH	Working Group on the Assessment of Toxic Chemicals

"Reducing Risks, Protecting People": Index

(Figures in italics refer to boxed examples)

Index to Regulations

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Parliamentary Committees

Inquiry into the re-identification of Coal Workers' Pneumoconiosis in Queensland - Interim Report

Report No. 1, 55th Parliament
Coal Workers' Pneumoconiosis Select Committee
March 2017

Coal Workers' Pneumoconiosis Select Committee

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Deputy Chair	Hon Lawrence Springborg MP, Member for Southern Downs
Members	Mr Jason Costigan MP, Member for Whitsunday
	Mr Craig Crawford MP, Member for Barron River
	Mr Joseph (Joe) Kelly MP, Member for Greenslopes
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Contents

Abbreviations

BMA	BHP Billiton Mitsubishi Alliance
CFMEU	Construction, Forestry, Mining and Energy Union
CMDLDs	Coal Mine Dust Lung Diseases
CMHSA	*Coal Mining Safety and Health Act 1999* (CMSHA)
CMSHR	Coal Mining Safety and Health Regulation 2001
CMWHS	Coal Mine Workers' Health Scheme
COPD	Chronic Obstructive Pulmonary Disease
CWP	Coal Workers' Pneumoconiosis
DNRM	Queensland Department of Natural Resources and Mines
HSU	Health Surveillance Unit, DNRM
ILO	International Labour Organisation
MSHA	Mine Safety and Health Administration (US)
Monash Review	Monash Centre for Occupational and Environmental Health, *Review of Respiratory Component of the Coal Mine Workers' Health Scheme*, 2016
NIOSH	National Institute for Occupational Safety and Health (US)
NSW	New South Wales
OEL	Occupational Exposure Limit
SIMTARS	Safety in Mines Testing and Research Station, DNRM

Foreword

On behalf of the Coal Workers' Pneumoconiosis Select Committee, we present this interim report on the committee's inquiry into the re-identification of Coal Workers' Pneumoconiosis in Queensland.

We commend this report to the House.

Jo-Ann Miller MP

Chair

Hon Lawrence Springborg MP

Deputy Chair

1. Introduction

The Coal Workers' Pneumoconiosis (CWP) Select Committee was established by the Queensland Parliament on 15 September 2016 to conduct an inquiry and report on the re-emergence of CWP amongst coal mine workers in Queensland. The committee is to report to the Legislative Assembly by 12 April 2017.

Until recently, the entire coal industry laboured under the illusion that CWP had been eradicated in Queensland. In April 1984, the Queensland Coal Board published a report by Rathus and Abrahams highlighting 75 cases or suspected cases of CWP.[1] In the intervening years, there were no cases of CWP reported, with the incidence of the disease appearing to all but vanish. During this period, those tasked with monitoring the health of Queensland coal workers were not actively looking for the disease, and in many cases were insufficiently informed and ill-equipped to enable its diagnosis.

> *I had the naïve belief that there was in fact some form of long-term health maintenance and monitoring of the mine worker, but obviously … this was not the case.*[2]

Tragically, miners' concerns over their respiratory health were raised and met with denial, as worker Mr Stuart McConnell testified:

> *The attitude towards [CWP] was that it was eradicated to the point where you would go to the doctor and try to talk to the doctor about what you are coughing up and they would say, 'Don't worry about that.' In my opinion, if you are not looking for something there is no way you are going to find it. I could take you out into the scrub and say, 'Let's go looking for ants.' If you are looking up in the air, you are never going to find them. You have to get your head down in the grass and actually look for them, and that has not been happening. It had not happened for the 20 years plus that I was in the mines.*[3]

Clearly, CWP was never eradiated in Queensland. It did not "re-emerge" in 2015 but was merely re-identified, after more than 30 years of responsible Queensland authorities failing to look for it or properly identify it.

As at March 2017, 20 Queenslanders had been diagnosed with this insidious and entirely preventable disease, with more likely to follow.

Queensland coal miners diagnosed with CWP, giving evidence at the public hearing in Mackay on 25 November 2016.

1 E.M. Rathus & E.W. Abrahams, *Report on the Queensland Coal Board Coal Miners' Health Scheme: chest x-ray and emphysema check survey of colliery employees in Queensland*, The Queensland Coal Board, May 1984, p 6.

2 Dr Ewen McPhee, Nominated Medical Advisor and former President, Rural Doctors Association of Australia, public hearing transcript, Emerald, 15 November 2016, p 5.

3 Mr Stuart Connell, private capacity, public hearing transcript, Moranbah, 22 November 2016, p 2.

2. Inquiry Terms of Reference

In undertaking the inquiry, the committee was asked to consider the following terms of reference:

a. the legislative and other regulatory arrangements of government and industry which have existed in Queensland to eliminate and prevent CWP;

b. whether these arrangements were adequate, and have been adequately and effectively maintained over time;

c. the roles of government departments and agencies, mine operators, nominated medical advisers, radiologists, industry safety and health representatives and unions representing coal mine workers in these arrangements;

d. the study into CWP undertaken by Monash University and the findings of the Senate Select Committee on Health (Fifth Interim Report) and other relevant reports and studies;

e. the efficacy and efficiency of adopting methodologies and processes for coal mine dust measurement and mitigation, including monitoring regimes, engineering measures, personal protective equipment, statutory requirements, and mine policies and practices, including practices in jurisdictions with similar coal mining industries; and

f. other matters the committee determines are relevant, including other respiratory diseases associated with underground mining.

3. Committee inquiry process

To date, the committee has received 44 submissions. However, as a result of recent hearings which canvassed the health risks of coal dust to workers in Queensland's ports and power stations, this number is set to increase, with a new round of submissions being received.

The committee has held 27 public and 15 private (in-camera) hearings and one departmental briefing. Over the course of these hearings, the committee has taken evidence from 190 witnesses.

The committee held 13 of these public hearings in Brisbane, during which it has taken evidence from government departments and agencies, medical specialists, occupational safety and health professionals, union representatives, academics, mining engineers, mine operators, retired and former coal miners, and coal mine workers presently employed in the industry. The committee also heard testimony from a number of the individuals who have been diagnosed with CWP, and their families.

Most of these witnesses came willingly to give evidence to the committee. However, the committee has been required to compel the attendance of some witnesses under summons, including officers of Queensland's largest coal mine operator, BHP Billiton Mitsubishi Alliance (BMA).

The committee's 14 regional public hearings were held in regional centres and mining towns including:

- Ipswich
- Mackay
- Rockhampton
- Collinsville
- Moranbah
- Dysart
- Middlemount
- Tieri
- Blackwater, and
- Emerald.

In order for the committee to hear from current miners, these hearings were timed to coincide with the conclusion of either a day shift or night shift. Consequently, the hearings took place from 6.00am in the morning or until 9.00pm at night. The committee was overwhelmed by the numbers of miners who attended and wanted to speak about their own experiences. Every miner had a story about the high levels of dust that they are exposed to as a result of their job. Most miners described health assessments and surveillance that were significantly lacking.

Public Hearing held at Middlemount on 24 November 2016

In November 2016, the committee visited Carborough Downs underground mine, located 20 kilometres east of Moranbah, and held talks with mine management on the operation of a longwall mine and the approach that Vale Australia had taken to dust management and worker health following the diagnosis of CWP in three of its workers.

In December 2016, the committee visited Grasstree Mine, located 25 kilometres south-west of Middlemount, and went underground to view a longwall in operation. During the site visit the committee held discussions with a large number of Anglo American senior executives and technical experts about the measures that Anglo has undertaken to mitigate and control dust at its Queensland mines.

In February 2017, the Chair and the Deputy Chair travelled to the United States to investigate how the United States (US) regulates its coal mining industry and identifies and manages Coal Workers' Pneumoconiosis (CWP) and other Coal Mine Dust Lung Diseases (CMDLDs). The US is now recognised internationally as the world's best practice jurisdiction in relation to dust regulation and health surveillance of coal workers. The delegation conducted site visits and held meetings at the following locations:

- National Institute for Occupational Safety and Health (NIOSH): Centre for Dust Control Research in Pittsburgh
- Mine Safety and Health Administration (MSHA): Dust Division in Pittsburgh
- NIOSH: Division of Respiratory Disease Studies in Morgantown
- Black Lung Clinic: Northwestern Medicine, Northwestern University in Chicago, and
- Black Lung Centre of Excellence: University of Illinois in Chicago.

Also in February 2017, the committee met with representatives from Coal Services Pty Ltd and the New South Wales (NSW) Resources Regulator to discuss the collaborative model approach taken in NSW in relation to the monitoring and management of coal dust exposure and worker health, and workers' compensation for coal industry workers.

In March 2017, the committee engaged in site visits at Wiggins Island Coal Export Terminal at the Port of Gladstone and Dalrymple Bay Coal Terminal at the Port of Hay Point, south of Mackay.

In March 2017, the committee also conducted a site visit to the Department of Natural Resources and Mines' (DNRM) Safety in Mines Testing and Research Station (SIMTARS) at Redbank.

During the course of the inquiry the committee has to date issued over 60 summonses to obtain information in regard to dust monitoring records and the health surveillance of coal workers in Queensland. This process has generated in excess of 10,000 documents.

4. Evidence to date

Since 2015, 20 current and former coal mine workers in Queensland have been diagnosed with CWP or "black lung" disease. In summary:

- 19 have been formally "confirmed" through the DNRM process, with the 20th case currently pending confirmation
- two cases are described as "complex", presenting with multiple conditions
- 17 involve miners who were actively working in the Queensland coal industry at the time of their diagnosis, and three were retired or former coal miners at the time of diagnosis
- current ages range from 38 to 73, with an average age of 56
- one involves an aboveground coal mine worker with no underground experience
- four have substantial overseas coal mine experience (UK and USA)
- two have worked in NSW coal mines, as well as in Queensland
- two have worked in the Ipswich coal fields, and
- all worked in Bowen Basin coal fields at some point in their careers.[4]

The committee considers that the overwhelming weight of evidence gathered to date suggests it is likely that many more Queensland miners and former miners will be diagnosed with CWP or related CMDLDs as a result of what has been a catastrophic failure of the regulatory and health surveillance systems intended to ensure the protection of coal industry workers.

By the end of 2016, experts advised:

> *…the CWP cases being identified now are a small indicator of what is to come. This will be an epidemic. The Australian coal mining industry as a whole, will see many more cases of this totally preventable disease in the very near future.*[5]

As at March 2017, the committee understands that 28 claims have been made with workers' compensation insurers in regard to CWP, with more claims lodged in relation to other respiratory conditions that may be related or co-occurring. As the world's leading expert on CWP, Dr Robert Cohen, told the committee:

> *When you identify something that is unusual, that could affect other people, it means that you do not just care for that one person; you immediately investigate the circumstances surrounding that case so that you can see if there are other cases or what was the causes of that. That should have triggered some major alarm bells at that time… What we all suspected was that it was just overlooked and now it has been rediscovered. Those are all examples of alarm bells that could have been rung and people could have answered that alarm and just started doing exactly what we are doing now, but we could have done it a decade ago.*[6]

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4 Department of Natural Resources and Mines, submission 35, p 7.

5 Dr Brian Plush, submission 15, p 1.

6 Dr Robert Cohen, Director of Occupational Lung Disease, Division of Pulmonary and Critical Care Medicine, Feinberg School of Medicine, Northwestern University, public hearing transcript, Brisbane, 15 March 2017, p 41.

CWP is a type of pneumoconiosis, or fibrotic lung disease, solely caused by the inhalation of coal mine dust.[7] There is a spectrum of lung diseases that are classified as pneumoconiosis:

- asbestosis, cause by the inhalation of asbestos dust particles
- silicosis, caused by the inhalation of silica dust particles, and
- CWP, caused by the inhalation of fine coal dust particles.[8]

In addition, there are a range of CMDLDs, related to CWP, that can be directly attributed to coal mine dust exposure but that are commonly not identified as arising from a coal mine worker's occupation. These include:

- emphysema
- chronic bronchitis, and
- Chronic Obstructive Pulmonary Disease (COPD).[9]

There are distinct features of early-stage CWP that contribute to what the committee discovered was a widespread and general belief that the disease had been eradicated in the Queensland coal mining industry:

- there is a long latency period before symptoms appear
- symptoms of the disease are highly variable and may be masked by features of other respiratory diseases, such as emphysema, chronic bronchitis and fibrosis (all of which are CMDLDs), and
- the disease requires experience and expertise among medical professionals to be accurately identified.

The evidence suggests that until the re-identification of CWP in 2015, the entire coal mining industry in Queensland (and NSW) seemed to believe that CWP had been eradicated in Australia, with the last cases in Queensland in the 1980s. This view was accepted by the DNRM, Queensland Health, the Department of Industrial Relations, coal mine operators, the Queensland Resources Council, trade unions, and coal workers. This is particularly concerning given the continuing high rates of CWP diagnoses in the United States over the same period.[10] However, it seems that all stakeholders accepted at face-value that the Coal Mine Workers' Health Scheme had not identified any cases of CWP in Queensland since 1984, and therefore, that it must have been eradicated here.

Clearly, CWP was never eradiated in Queensland. It did not "re-emerge" in 2015 but was merely re-identified, after more than 30 years of responsible Queensland's authorities failing to look for it or properly identify it.

The Monash *Review of Respiratory Component of the Coal Mine Workers' Health Scheme* (Monash Review) in 2016 found a general belief held by most stakeholders that, as there had been no new cases of CWP for many years, the disease had been eradicated in Queensland.[11]

The committee noted this general belief has influenced the development of government policy and regulatory frameworks, workplace health and safety policies and standards at mine sites, and the way medical professionals conducted their medical examinations and made diagnostic decisions. Evidence received at public hearings and in submissions from a range of stakeholders attested to this.[12]

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7 The Thoracic Society of Australia and New Zealand, submission 6, p 2.

8 Australian Institute of Occupational Hygienists Inc., submission 14, p 4; CFMEU Mining & Energy Division, submission 27, p 5.

9 Dr Robert Cohen, public hearing transcript, Brisbane, 15 March 2017, p 8.

10 Dr Robert Cohen, public hearing transcript, Brisbane, 15 March 2017, p 3.

11 Monash Centre for Occupational and Environmental Health, *Review of Respiratory Component of the Coal Mine Workers' Health Scheme*, 2016, p 19.

12 See for example: Public briefing transcript, Brisbane, 14 October 2016; Public hearing transcript, Mackay, 26 November 2016, p 23; Queensland Resources Council, submission 18.

There is no cure for CWP, and treatment consists of managing the symptoms.[13] However, a number of submissions to this inquiry noted that CWP is a completely preventable disease, which can be avoided by removing or limiting exposure to coal dust.[14] The risk of developing CWP is directly related to the magnitude and duration of exposure to coal mine dust.[15] When detected early, the progression of the disease can be halted by the removal of the worker from further exposure to coal mine dust.[16]

The evidence so far suggests that there has been a massive systemic failure across the entirety of the regulatory and health systems intended to protect coal industry workers. Prior to the re-identification of CWP in 2015, there was an absolute failure by the DNRM, its Mine Inspectorate, SIMTARS and its Health Surveillance Unit (HSU) to properly regulate air-borne dust and to look for or identify CWP or CMDLD. The evidence suggests that Queensland Health, WorkCover and self-insurers have played a role in this failure.

As identified in the Monash Review, there were serious shortcomings in the practices of health professionals charged with monitoring the health of coal workers in regard to the diagnosis, notification and treatment of respiratory disease. These professionals include Nominated Medical Advisors and examining medical officers (doctors engaged by mine operators to conduct health assessments under the Coal Mine Workers' Health Scheme), radiographers, radiologists, and thoracic specialists.

Mine operators have also contributed to this failure through inadequate attention to dust mitigation and suppression, poor dust monitoring, and inadequate health surveillance.

The increasing casualisation of the mining workforce has also intensified the vulnerability of coal mine workers. Workers report they are less likely to report or complain about excessive dust levels and are more likely to ignore respiratory symptoms for fear an adverse health assessment would put their employment at risk.[17]

The committee notes that following the diagnoses of coal miners with CWP in 2015, the CFMEU Mining and Energy Division commenced an industry-wide campaign to draw attention to black lung disease and the risk it poses to coal mine workers. Were it not for the efforts of the CFMEU in this regard, it is most unlikely all the current cases of CWP would have been discovered.

4.1 Department of Natural Resources and Mines

The evidence suggests that the DNRM did not administer the *Coal Mining Safety and Health Act 1999* (CMSHA) and the Coal Mining Safety and Health Regulation 2001 (CMSHR) to protect the safety and health of persons at mines with respect to respirable coal mine dust. DNRM did not have or adequately maintain dust records for coal mines. Coal mines were not, until recently, required to report dust monitoring results or exceedances to the inspectorate or the Commissioner for Mine Safety and Health. There was no central repository of data about dust exposures in Queensland coal mines.

No mine operator has ever been prosecuted for breaching the regulatory dust exposure limit or failing to ensure risk to workers arising from dust exposure was kept to an acceptable level. The use of other enforcement powers such as Directives issued by the mining inspectorate has been inconsistent and often takes many months to achieve compliance.

The Mines Inspectorate did not, in any systematic and co-ordinated manner, monitor the activities of mine operators in relation to respirable dust. Their focus was primarily on other mine hazards, with limited regard given to the dangers of respirable dust prior to the re-identification of CWP.

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13 CFMEU Mining & Energy Division, Submission 27, p 6.

14 See: CFMEU Mining & Energy Division, submission 27, p 6; AMA Queensland, submission 23, p 1; Australian Institute of Occupational Hygienists Inc., submission 14, p 2.

15 The Thoracic Society of Australia and New Zealand, submission no 6, p 2.

16 The Thoracic Society of Australia and New Zealand, submission no 6, p 3.

17 CFMEU Mining & Energy Division, submission no. 27, p 23; Public hearing transcript, Moranbah, 23 November 2016, p 15; Private hearing transcript, Moranbah, 22 November 2016.

SIMTARS, while a world leader in mine safety research, has not conducted any research on respirable dust or its mitigation. This is in stark contrast to the long-standing and extensive research in this area undertaken by the MSHA in the United States. Despite several senior officers of SIMTARS and DNRM visiting MSHA and NIOSH in the US over the past 10 years, it seems none of this research or knowledge was brought back to Queensland to be shared amongst regulators and mine operators.

SIMTARS dust monitoring is provided on a fee-for-service basis. The committee is concerned there may be inherent conflicts in the body charged with training and research functions providing commercial dust monitoring services to industry with no authority to report or act upon discovered breaches of regulatory standards.

The committee was deeply disturbed by the evidence uncovered in relation to the HSU. From its establishment, the HSU failed to undertake any actual health surveillance. It served as nothing more than a storage unit for miners' chest X-ray and health records.

> *Mr KELLY: … Was it your perception when you were sending things off to the department that there was going to be another level of vigilance in terms of reviewing the X-rays or other tests that may have been done?*
>
> *Dr McPhee: I think it was probably naïve of me to think that would be the case. When the title of the department was the Health Surveillance Unit, I thought that there would be some attempt to provide health surveillance because this is an insidious disease. The mechanisms that we have to diagnose it are not particularly reliable. Both spirometry and chest X-ray are really blunt instruments. This is a disease that evolves over time and, as I mentioned before, we often only may see this miner once in their career. I had the naïve belief that there was in fact some form of long-term health maintenance and monitoring of the mine worker, but obviously from my own reading this was not the case.*[18]

Even data entry and basic administration was hopelessly under-resourced to the point where at times, the HSU was staffed by only one part-time administration officer at the lowest classification level available.[19] As the Commissioner for Mine Safety and Health, Mrs Kate du Preez, attested:

> *… to my understanding, the HSU was only a storage facility in the past … at no time did they ever assess any of the documentation or the medicals that came to them. Their whole role was to ensure that it was stored and that the people's confidentiality was maintained.*[20]

Overwhelmed with health assessment records during the mining boom, the committee heard that many health records of the HSU were "…stored in a janitor's cupboard next to the female toilets",[21] and in shipping containers at the DNRM site at Redbank. Environmental conditions meant that when efforts were finally made to retrieve and review those records, many were destroyed or unreadable.[22]

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18 Dr Ewen McPhee, public hearing transcript, Emerald, 15 November 2016, p 5.

19 DNRM reported in response to a question taken on notice that the HSU operated with one full-time equivalent (FTE) employee in 2005 and less than three FTE staff up until 2010. See: DNRM, Response to Question taken on Notice No 8 asked on 30 November 2016, Brisbane, p 15.

20 Mrs Kate du Preez, Commissioner for Mine Safety and Health, Public hearing transcript, Brisbane, 2 November 2016, p 6.

21 Dr David Smith, Occupational Physician, DNRM, public hearing transcript, Brisbane, 30 November 2016, p 21.

22 Former HSU occupational physician Dr David Smith testified that "… the x-rays were subjected to high temperatures and terrible storage conditions". See: Public hearing transcript, Brisbane, 30 November 2016, p 15.

Shipping containers which housed the records of the HSU, SIMTARS Redbank site, 14 March 2017

Additionally, DNRM appointed an occupational physician to oversee the HSU on only a part-time basis. No senior executive of DNRM ever reviewed the performance of the occupational physician or discussed with him what work he was expected to do to ensure the HSU functioned as it should have.[23]

The committee discovered that efforts to improve the efficiency and purpose of the HSU, following a review in 2002 and again during development of a proposed regulatory impact statement on mine safety in 2013, became indefinitely delayed due to:

- the prioritisation of other perceived higher and more immediate risks, and
- lack of agreement among tripartite advisory committees.

Only one of 19 recommendations in the 2002 review of the HSU was ever implemented.

Many of these recommendations sought to address concerns with the HSU that were very similar to those dealt with in the Monash Review 13 years later.

The committee has been appalled by the level of disregard for its work demonstrated by some senior officers of DNRM. Despite repeated assurances from DNRM that it would work expeditiously to assist the committee in any way possible, the committee has been met with resistance and obstruction by some officers of DNRM. Documents requested have not been produced, requiring the issue of a summons. Key departmental witnesses, vital to understanding the system failure at HSU were not advised they would be required to give evidence; were then produced only under threat of summons; and were not properly prepared by DNRM prior to their appearances before the committee. Frequently senior officers have been unprepared and unable to answer important questions relevant to the committee's inquiry and where answers were given, often the officers were argumentative and resistant to acknowledging the wide-ranging failures of their department. This appears to be a reflection of a culture and attitude that has built up over 30 years.

4.2 Workers' Compensation

Despite the widespread belief that Queensland had not had a case of CWP for 30 years until 2015, the committee discovered that WorkCover approved a claim for CWP in 2006. That worker was diagnosed

[23] Dr David Smith, public hearing transcript, Brisbane, 30 November 2016, pp 18-19.

with CWP in a Queensland public hospital in 2004. The Medical Assessment Tribunal confirmed the diagnosis in 2007.

Neither WorkCover nor Q-Comp (as it then was) alerted DRNM to the diagnosis. Queensland Health did not treat the diagnosis as a sentinel event or undertake any investigation as to how a disease previously thought to have been eradicated had re-emerged.

It is evident that no information sharing occurred between the Queensland Health, DNRM and WorkCover. As Dr Cohen told the committee:

> *This is another example of why these data systems need to talk to each other. Hospital discharge data systems, death certificate data systems, compensation data systems and surveillance data systems need to be coordinated.*[24]

The committee has also heard from current CWP sufferers, including Mr Steve Mellor, that the diagnosis comes with massive financial and emotional impacts that are only exacerbated by the impersonal and bureaucratic approach of workers' compensation insurers.

> *CHAIR: How are you living in terms of money?*
>
> *Mr Mellor: My father recently passed away so I have had a small inheritance that I have been living off…To then be advised by WorkCover that you have been assessed as having a zero per cent permanent impairment and offered a lump sum of zero dollars is offensive and humiliating. I cannot help wondering, if the system is not changed, how many other employees of contractors will be tossed to the scrapheap with me.*[25]

It is apparent that the current workers' compensation scheme needs modification to ensure current and former coal workers effected by respiratory symptoms are supported and encouraged to seek appropriate diagnosis and treatment, and that those diagnosed with CWP or CMDLD have easy access to comprehensive support, assistance, and treatment.

4.3 Queensland Health

The committee heard evidence from Queensland Health that CWP was not a primary concern of that department.

> *Queensland Health has not had responsibility for occupational health and safety since 1988 when it was transferred to the then Division of Workplace Health and Safety within the department of industrial relations. As such, we do not hold any records in relation to this. Legislative and other regulatory arrangements for occupational health and safety are now the responsibility of other agencies.*
>
> *When we are looking specifically at Queensland Health's role in the management of coalmine workers with pneumoconiosis, miners may be reviewed in a specialist outpatient setting or require hospitalisation for the treatment of symptomatic coalmine workers' lung disease. Miners with simple coal workers' pneumoconiosis would not be expected to have any symptoms that would require hospitalisation, and it would be expected that only those with more advanced disease would require inpatient treatment.*[26]

This simplistic understanding of CWP and its effects on the health and well-being of coal workers (and complete absence of recognition of other CMDLD) is typical of the level of knowledge demonstrated across the health system until very recently. While Queensland Health was working within the bounds of its regulatory framework at the time, if the 2004 case of CWP that was diagnosed in the public health system had been treated as a notifiable disease, it could have been recognised as a sentinel event and

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24 Dr Robert Cohen, public hearing transcript, Brisbane, 15 March 2017, p 42.

25 Mr Steve Mellor, private capacity, public hearing transcript, Brisbane, 15 March 2017, p 44.

26 Ms Sophie Dwyer, Executive Director, Health Protection Branch, Prevention Division, Queensland Health, Public briefing transcript, Brisbane, 14 October 2016, p 33.

referred to the Chief Health Officer, and action taken 11 years before its positive re-identification in 2015.

The committee considers that CWP and CMDLDs should be classified as notifiable diseases, ensuring they are brought to the attention of the Chief Health Officer. Further, there is currently no clinical pathway for CWP or CMDLD that ensures sufferers get access to proper treatment and referral, including pulmonary rehabilitation. It is critical that Queensland Health develop this in the future.[27]

4.4 Medical Professionals

The committee strongly supports the findings of the Monash Review. It is likely that all the recommendations of that report will be adopted or encompassed within the recommendations of the committee.

The committee heard evidence from a very large number of miners who had lost faith in the medical professionals who were tasked to monitor and protect their health. In evidence, the committee has heard that:

- some medical professionals undertaking CMWHS medicals did not live in or near a mining town and had no clear understanding of the occupational groups employed in a mine or the work done by mine workers
- most medical professionals undertaking CMWHS medicals did not take complete occupational histories
- the scheme is predominantly focussed upon fitness for work assessments rather than true health screening and surveillance
- despite the recommendations of the Monash Review regarding the need for x-rays to be performed by appropriately trained staff to a suitable standard of quality,[28] approximately 20 per cent of chest x-rays taken for the CMWHS medicals are still of poor quality and cannot be read or interpreted[29]
- chest x-rays that indicated signs of CWP were not correctly read
- coal mine workers were confirmed fit for work and continued to work underground for years after chest x-rays showed CWP[30]
- coal mine workers were not informed of the outcomes of their medicals
- specialist medical professionals gave conflicting and confusing diagnoses and information, and
- mine operators were not informed of workers' adverse health assessments due to privacy concerns.

4.5 Mine Operators

Evidence provided to this committee suggests a large difference in management and approaches between mine operators in relation to their commitment to dust mitigation and to the health of their workforce. The re-identification of CWP triggered responses ranging from quick acknowledgement and action to blame-shifting and avoidance.

While many aspects of the current risk-based regulatory framework are effective, self-regulation as a model is not without problems. The committee has heard in regard to dust monitoring:

> *Dust sampling is undertaken by the companies. It is not an independent process. When you put the fox in charge of the hen house, eventually it fails.*[31]

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27 Dr Robert Cohen, public hearing transcript, Brisbane, 15 March 2017, p 20.

28 Monash Centre for Occupational and Environmental Health, *Review of Respiratory Component of the Coal Mine Workers' Health Scheme*, 2016, p 12.

29 Public hearing transcript, Brisbane, 15 March 2017.

30 Public hearing transcript, Mackay, 25 November 2016.

31 Mr Jason Hill, Industry Safety and Health Representative, CFMEU Mining & Energy Division, public hearing transcript, Ipswich, 4 November 2016, p 31.

The evidence suggests a number of mine operators have not complied with their statutory responsibilities to protect the safety and health of workers from the hazard of respirable coal mine dust. Examples include:

- regular and gross exceedances of the regulated dust limits
- limited provision of PPE in high dust environments
- limited base-line dust monitoring
- limited use or availability of dust suppression mechanisms
- poor systems for responding to dust exceedances, and a
- lack of diligence by mine operators in meeting their obligations under the CMWHS.

5. Emerging issues

It is the committee's intention to report as soon as possible to the Queensland Parliament. However, by December 2016, 17 cases of CWP had been confirmed in Queensland and the issue of CWP was much larger and more complex than was understood when the Parliament established the committee's Terms of Reference. There are currently 19 confirmed cases of CWP in Queensland but the committee is aware of more miners who may soon have their diagnoses finalised. The evidence suggests many more cases are out there but are yet to be identified.

During the course of this inquiry it has become apparent that CWP is not a disease that effects only underground coal mine workers. One case of CWP in an above-ground coal worker has been confirmed in Queensland, and the evidence suggests that more cases of CWP will be found in this occupational cohort.

The committee has heard evidence which raises concerns about all workers who are exposed to coal dust, including port terminal workers, rail workers, and coal-fired power station workers. These occupational cohorts were not initially considered as part of this inquiry – however, where there is coal there is coal dust; and where there is coal dust, there is the potential for CMDLD.

Throughout the inquiry, mine workers also raised their concerns about silica. The committee heard testimony about the debilitating effects of silicosis on mining workers and the lack of support and medical help these sufferers receive. Dr Cohen gave evidence that:

> *Silica is probably more dangerous than coalmine dust. We talked about the toxicities earlier. Quarriers, tunnelers, metal miners—anyone who is disturbing the earth's crust and drilling through rock is at risk for quartz and silica exposure.*
>
> *There should be industrial hygiene monitoring of the exposure levels. We just lowered our exposure level to silica from 0.1 milligram per metre cubed to 50 micrograms or 0.05 milligrams per metre cubed because of the horrendous diseases that occur from silica. Aside from the diseases we have already talked about for coalmine dust, silica is actually a lung carcinogen. It is an International Agency for Research on Cancer, IRAC, class 1 human carcinogen. It causes renal disease and causes other autoimmune diseases like rheumatoid arthritis and other things.* [32]

6. Recommendations

The committee expects to make significant and wide-ranging recommendations in relation to the public administrative framework for protecting the health and welfare of coal workers in Queensland.

[32] Mr Greg Dalliston, Industry Safety and Health Representative, CFMEU Mining & Energy Division, public hearing transcript, Brisbane, 15 March 2017, p 31.

The committee may recommend changes, including in the following areas:

- the Occupational Exposure Limit (OEL) for respirable coal mine dust
- the regulation of atmospheric dust monitoring
- the frequency and extent of atmospheric dust monitoring inspections
- the workplaces at which atmospheric dust monitoring must be undertaken
- the use of real time personal dust monitors
- the current Coal Mine Workers' Health Scheme
- the providers of radiographic imaging and spirometry under the Health Scheme
- the arrangements for ensuring coal workers' chest x-rays are properly read and classified according to the International Labour Organisation (ILO) system for Classification of Radiographs by properly qualified and approved B-Readers
- the cost and scope of health assessments for retired or former coal workers
- the workers' compensation scheme as it applies to long latency respiratory diseases
- the regulatory environment, and
- the implementation of a new regulatory environment.

7. Conclusion

7.1 Extension to reporting date

Over a six month period the committee's inquiry has generated a significant amount of public interest and has produced a significant amount of evidence. The committee has heard evidence from 190 witnesses and has held 42 public and in-camera hearings. It has received 44 submissions and obtained over 10,000 documents under summons.

In light of the evidence received, the committee intends to make significant and wide-ranging recommendations in relation to the public administrative framework for protecting the health and welfare of coal workers in Queensland. This will include the administration of the CMSHA and the CMSHR; the *Mining and Quarrying Safety and Health Act 1999* and Regulation; the *Workers' Compensation and Rehabilitation Act 2003* and Regulation; the *Public Health Act 2005* and Regulation; and consequential amendments to a range of other legislation.

To provide the committee with the time needed to undertake the task at hand the committee has resolved to seek an extension to its reporting date until 29 May 2017 for the committee's first report.

7.2 Extension to the terms of reference

A number of issues have emerged during the course of this inquiry that had not been envisaged at the establishment of this select committee. These include:

- respirable dust exposure for coal port workers
- respirable dust exposure for coal rail workers
- respirable dust exposure for coal-fired power station workers, and
- respirable dust exposure for other workers.

The committee requests that:

- the parliament amends the terms of reference of the Select Committee to allow inquiry into these important issues and that the committee report the findings of this inquiry to the Legislative Assembly by 29 September 2017
- the Coal Workers' Pneumoconiosis Select Committee be extended to monitor and review the implementation of recommendations made by the CWP in its reports, including the development of a draft Bill for the consideration of the Assembly, and
- the committee continues in existence until the Assembly dissolves or otherwise orders, despite reports by the committee.

Statement of Reservation

Statement of Reservation

Inquiry into the re-identification of Coal Worker's Pneumoconiosis in Queensland – Interim Report

There has been broad support across party lines during the conduct of this inquiry. All committee members have shown a willingness to conduct the inquiry according to the current terms of reference with the objective of establishing processes that prevent pneumoconiosis, provide ongoing health screening for those engaged in coal mining, detect the disease in people currently in or retired from coal mining, provide ongoing high standards of health care for those affected and provide appropriate compensation.

This problem spans three decades and all parties involved share some responsibility for the current situation including employers, government departments, health care professionals and unions.

The work of the committee has built on and added substantially to work done by a Federal Senate inquiry and the Monash Review.

The interim report is fair, balanced and no doubt discomforting for some people. That discomfort does not compare to the suffering of people affected by CWP or their families.

We support the committee expanding its terms of reference to inquire into coal port worker, coal rail workers and coal fired power plant workers and dust issues for workers in all industries. We also support the role of the committee being maintained to monitor and review the implementation of recommendations made by the committee.

The Minister, Dr Anthony Lynham has shown leadership on this very difficult issue. As a medical doctor, he understands what this condition means for people and their families. The Minister has already taken action to deal with this terrible disease, action that has received support of employers, unions, academics and medical professionals. No doubt the Minister, like many others are awaiting the outcome of the report to determine what further action can be taken to deal with this disease including administrative, regulatory and legislative changes.

We do not support the committee taking on the role of drafting legislation. we believe, if the opportunity is granted by the house, the committee should focus

on investigating the matters referred to in the extended terms of reference as well as monitoring and reviewing any other recommendations. The Minister is fully capable of drafting any required legislation and may have already taken steps in the right direction based on recommendations gathered from other inquiries.

We fully support the right of any member of this house to bring a Private Member's Bill and no doubt all involved as committee members would be fully capable of this task, however, we believe the Minister is most appropriately placed to enact all administrative, regulatory and legislative actions to deal with this terrible disease.

While we have made a statement of reservation about one aspect of the interim report, we wish to make it clear to all people who work in the mining industry and their families, particularly those diagnosed with this disease, that all members of the committee and secretariat are committed to getting this situation resolved. The majority of employer representatives, union officials and members, public servants, academics and health professionals have showed a similar commitment, although as noted in the report some people have for a range of reasons been less than cooperative. We trust this interim report will play an important part in preventing this disease and supporting the people affected.

Joe Kelly

Member for Greenslopes

Craig Crawford

Member for Barron River

Date: 21 March 2017

Review of Respiratory Component of the Coal Mine Workers' Health Scheme for the Queensland Department of Natural Resources and Mines

Final Report

Monash Centre for Occupational and Environmental Health

School of Public Health & Preventive Medicine

Faculty of Medicine, Nursing and Health Sciences

Monash University

In collaboration with

School of Public Health

University of Illinois at Chicago

12th July 2016

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Erratum (30 August 2016)

On page 68 of the original version of this report, it was stated that Safe Work Australia (SWA) found 237 accepted WC claims for respiratory diseases such as silicosis and pneumoconiosis (due to coal dust, asbestos, silica or other causes) and this included 3 WC claims for CWP, two from NSW and the other from WA. Since this report was released, SWA has notified the review team that the numbers they supplied had some small errors. The correct figures are 236 accepted WC claims for respiratory diseases such as silicosis and pneumoconiosis (due to coal dust or other causes). The one WA CWP claim was a coding error, so this claim has been removed from the total. In addition, the two remaining CWP claims were from Victoria, not NSW. These corrections have been made on page 68.

TABLE OF CONTENTS

List of Figures

List of Tables

List of Appendices

Overview

Background

As of December 2015, when this review was being developed, six confirmed cases of coal workers' pneumoconiosis (CWP) had been identified by the Queensland Department of Natural Resources and Mines (DNRM) over a period of about seven months among coal miners in Queensland. An additional case was later notified in May 2016, making a total of seven confirmed CWP cases which could be included in this review. An 8th case was reported on 28 June 2016, but it was too late for any further details to be included in this final report.

Prior to this, the Queensland Coal Mine Workers' Health Scheme had not identified any new cases for many years and CWP was thought to have been eradicated in Queensland. Following the discovery of the initial cases, a review of the design and operation of the respiratory component of the scheme was commissioned by DNRM. A review team from Monash University and the University of Illinois at Chicago was engaged to conduct the review. This multidisciplinary review team included expertise in occupational medicine, respiratory medicine, occupational hygiene, epidemiology, radiology and respiratory science.

The aims of the review were to:

A Determine whether the respiratory component of the health assessment performed under the Queensland Coal Mine Workers' Health Scheme is adequately designed and implemented, to most effectively detect the early stages of coal mine dust lung disease (CMDLD) among Queensland coal mine workers, estimating the extent and providing feedback and, if not,

B Recommend necessary changes to correct deficiencies identified under Aim A, recommend measures to follow up cases that may have been missed as a result of these deficiencies, and identify what additional capacity is needed in Queensland to improve this scheme.

In undertaking this review, the review team accessed and reviewed data and documents from a wide range of sources, including the content of the health assessment form, the information kit given to Nominated Medical Advisers (NMAs), a sample of completed health assessment forms, a sample of spirograms, a sample of chest x-rays (CXRs) and associated radiologists' reports collected under the scheme. We examined the qualifications and geographical spread of the listed NMAs and surveyed them about their spirometry equipment, its calibration, and the technician training. We visited underground and open-cut mines and a coal handling and preparation plant (CHPP) in Queensland and spoke to DNRM, employer and Construction Forestry Mining and Electrical Union (CFMEU) stakeholders. We reviewed relevant literature and spoke to individuals involved in other similar schemes in Australia and overseas and identified other potential sources of information on CWP.

The following aspects of the scheme were identified for inclusion in the review:

1. Purpose of the respiratory component of the current scheme
2. The overall process of the current scheme
3. The scheme health assessments of the confirmed CWP cases
4. The Coal Mine Workers' Health Scheme health assessment form
5. Risk from dust exposure for the purpose of a CXR
6. Nominated Medical Advisers
7. CXR quality and reading
8. Spirometry quality and reading
9. Health assessment form data handling and storage
10. Interstate and overseas health surveillance schemes for coal miners
11. Queensland medical capacity
12. Other sources of data about the extent of CWP
13. Research framework for a survey of CMDLD prevalence among coal miners

Main findings and recommendations

This chapter outlines the main findings relating to limitations of the scheme and recommendations to make improvements, as well as documenting the relevant chapter of the review for each. We have included some supplementary detail, to correct the deficiencies identified with the current Coal Mine Workers' Health Scheme. These findings and recommendations are drawn from chapters 4-15 of this report, which contain further supporting evidence and discussion relating to these limitations and recommendations.

Chapter 4: Purpose of the respiratory component of the current scheme

- After discussion with stakeholders and reviewing the relevant documentation, it is clear that the focus of the respiratory component of the scheme is on fitness for work rather than the detection and management of early CMDLD.
- The respiratory component of the scheme is not being used for group health surveillance to monitor trends in CMDLD, and this is compounded by the exclusion of former and retired coal miners from the scheme.

Recommendation 1

The main purpose of the respiratory component of the scheme should explicitly focus on the early detection of CMDLD among current and former coal mine workers.

1.1. The purpose of the respiratory component of the scheme should be clearly stated as being to:
   - 1.1.1. Provide mandatory respiratory health screening to detect early CMDLD in coal mine workers.
   - 1.1.2. Offer participation in the scheme to former coal mine workers.
   - 1.1.3. Ensure appropriate referral for follow-up, diagnosis and management, including appropriate reductions in further exposure to dust, for coal mine workers with respiratory abnormalities indicating CMDLD.
   - 1.1.4. Collect, analyse and report group surveillance data to monitor trends in CMDLD, and to inform Government, industry and trade union reviews of dust exposure levels and occupational exposure limits for coal mines.

1.2. The purpose of the scheme should be clarified to employers, coal mine workers, doctors and other stakeholders. The roles and responsibilities of the stakeholders (the DNRM, employers unions and mine workers) under the scheme should be defined.

1.3. An information pack about CMDLD and how these conditions are identified and diagnosed should be developed for workers.

Chapter 5: Overall process of the current scheme

There are clear deficiencies with several processes and components of the current scheme, such as: the registration and training of NMAs; the role of Examining Medical Officers (EMOs); decisions about who is "at risk from dust exposure" and thus requires a CXR; the reading and reporting of CXRs; the conduct of spirometry; and the processing of health assessment forms by the DNRM, and these are expanded upon in other sections of the review.

Other notable limitations of the current scheme's overall process include:

- The lack of a clear follow up and clinical referral pathway for investigation, diagnosis and management of coal mine workers and former coal miners with respiratory abnormalities consistent with CMDLD detected during scheme health assessments.
- The lack of clear process to advise mines to review dust exposure levels if respiratory abnormalities are identified.
- The absence of an established mechanism whereby a diagnosis of CMDLD identified under the scheme is formally reported to DNRM.
- The potential for preclinical changes in respiratory health over serial assessments to be overlooked as previous health records are not readily available to NMAs.

Recommendation 2
Clinical guidelines for follow-up investigation and referral to an appropriately trained respiratory or other relevant specialist of suspected CMDLD cases identified among current and former coal miner workers should be developed and incorporated into the scheme.

Recommendation 3
DNRM should require the reporting of detected cases of CWP and other CMDLDs in current and former coal miners identified by the scheme.

Chapter 6: Confirmed CWP cases

We examined the Health Scheme records for the confirmed CWP cases to identify where the scheme had failed to identify and/or act on early respiratory abnormalities indicative of CMDLD.

- There was poor documentation and inconsistent follow-up of abnormal results which were not always recognised by the NMAs, and workers with indications of early CMDLD were still deemed fit to work underground with no restrictions on further coal mine dust exposure.
- Where abnormal spirometry results were thought suggestive of chronic obstructive airways disease, this was attributed to tobacco smoking rather than coal mine dust exposure.
- CXRs referral slips were often not specified as being for coal mine worker screening purposes and the CXRs were not reported using the International Labour Organization (ILO) classification and, for at least two cases, early CXR changes were not identified.

Chapter 7: Heath assessment form

We reviewed the content and design of the respiratory component of the seven page health assessment form and assessed the completeness of a sample of 91 submitted forms.

- The current form lacks a comprehensive respiratory medical history and respiratory symptom questionnaire.
- There is no specific section where information from respiratory medical history and symptoms, respiratory physical examination, spirometry and CXRs are consolidated.
- An earlier version of the health assessment form included a CXR reporting section consistent with the ILO classification, but this was removed many years ago.

- There is no specific section where the final conclusion about the presence or absence of CMDLD is recorded, and if present, the implications for mitigating further coal mine dust exposure.
- Section 1 (the employer's section) was poorly completed, with generic similar exposure groups (SEGs) provided in only a few health assessment forms and company SEGs not provided in any of the forms examined.

Recommendation 4

There should be a separate respiratory section of the health assessment form which includes all respiratory components, including the radiology report using the ILO format and the spirogram tracings and results.

Recommendation 5

The form should include a comprehensive respiratory medical history and respiratory symptom questionnaire.

The new health assessment form should include:

5.1 A detailed respiratory symptom questionnaire and past medical history.

5.2 Revised and expanded questions about smoking history to better identify current/former/never smokers and cumulative smoking exposure (pack-years).

5.3 Occupational history which allows identification of job categories or industries where high coal dust and/or mixed dust exposure is likely to occur.

5.4 A specific reference to the absence or presence of symptoms/signs and CXR or spirometry changes consistent with CMDLD, the follow-up required and frequency of subsequent health assessments.

5.5 Determination of any restrictions on work capacity for individuals with CMDLD, including ability to use respiratory protective equipment (RPE).

<u>Chapter 8: Risk from dust exposure for the purposes of requiring a surveillance CXR</u>

We visited an underground and an open-cut coal mine and a CHPP, and interviewed mine company and Union representatives to understand the development and application of SEGs. While the review team recognises that SEGs have an important role to play in dust monitoring and control and in risk assessment, their use in informing decisions about whether a CXR is required for mine workers was the focus for this review.

- The criteria to determine jobs "at risk from dust exposure" and thus which coal mine workers should have a CXR are not explicit in the Regulations, and the DNRM do not specify which generic SEG categories fulfil these conditions.
- "At risk from dust exposure" is meant to be applied to workers in underground coal mines, open-cut coal mines and CHPPs, but this criterion is most clearly recognised and applied to workers in underground mines.
- The SEGs approach does not adequately account for mobile workers, for example contractors employed in a range of jobs across various mines, who can transition between different SEGs and lower and higher dust exposure jobs.
- The current SEG does not consider dust exposure from previous jobs in other SEGs, which are important to consider when considering the risk of CMDLD.
- While useful for coal dust exposure monitoring and control, the SEGs approach is too complex and has not been used extensively to decide which individual mine workers require a CXR.

Recommendation 6

The criteria to determine workers "at risk from dust exposure" should be based on past and current employment in underground coal mines and designated work categories in open-cut coal mines and CHPPs.

6.1 The criteria to determine job categories "at risk from dust exposure" should be standardized across the Queensland coal mining industry.

6.2 All job categories involving underground work in underground mines, and designated jobs in open-cut mines (e.g. blasting, drilling, rock screening) and CHPPs (e.g. some production and laboratory workers) should require a CXR.

6.3 For workers currently not involved in such jobs, but who have had significant dust exposure in past jobs, the approved medical practitioner undertaking the health assessment should decide whether a CXR is required, and whether the frequency should be more often than five years, based on discussion with the mine worker, including a full occupational history of exposure to coal dust. This is particularly important for former mine workers.

6.4 The criteria to determine dust exposure job categories should be reviewed and/or revised regularly to reflect changes in level of risk, for example due to changes in coal mining technology.

Chapter 9: NMA registration and training

We examined the qualifications and geographical coverage of NMAs currently listed with DNRM, and reviewed the information kit provided to newly-registered NMAs.

- There are too many NMAs performing health assessments to allow for adequate initial training, maintenance of skills, and quality control. Performing enough assessments to maintain skills is a potential problem with so many listed NMAs.
- There is inadequate formal initial and continuing training for NMAs regarding purpose of the scheme and the criteria used to diagnose CMDLD.
- EMOs have no formal recognition under the current scheme but they often perform health assessments, nominally under the supervision of an NMA. This results in an even larger pool of medical providers and further impacts quality control.

Recommendation 7

There should be a much smaller pool of approved doctors undertaking the respiratory component of health assessments under the scheme, taking into account geographical considerations and other workforce needs.

Recommendation 8

Doctors should undergo a formal training program, including visits to mine sites, prior to being approved by the DNRM, to ensure they reach a suitable standard of competence and have the necessary experience to undertake respiratory health assessments under the scheme.

8.1 The minimum qualifications and experience for doctors who are to undertake respiratory health assessments under the scheme should be established.

8.2 While doctors seeking to be appointed to perform respiratory health assessments should have already reached a certain level of competence in the necessary knowledge and skills set out below, a formal induction and ongoing training and audit program for these doctors should be developed to ensure initial and ongoing competence for the specific requirements of the early detection of CMDLD:

8.2.1 Information about the primary purpose of the respiratory component of the scheme, in particular health protection, prevention and early detection of CMDLD and the importance of undertaking such assessments in an independent way.
8.2.2 Information about the spectrum of diseases included in CMDLD.
8.2.3 Information about coal and silica dust exposure, and other respiratory hazards associated with the Queensland coal mining industry.
8.2.4 A visit to a coal mine(s), with a focus on inspecting jobs deemed "at risk from dust exposure".
8.2.5 Conduct and interpretation of quality spirometry.
8.2.6 Instruction in how to consider coal dust exposure for the purposes of deciding which miners require a CXR.
8.2.7 Instruction in the ILO CXR classification of pneumoconiosis to enable them to interpret such reports from the radiologists.
8.2.8 Instructions about how to complete each section of the respiratory component of the modified health assessment form.
8.2.9 Clinical guidelines for follow-up and appropriate referral of CMDLD cases or other respiratory abnormalities.
8.2.10 Instructions to explain the outcome of health assessments, including follow-up with treating doctors and specialists and workplace restrictions on dust exposure for those with indications of CMDLD.

8.3 An experienced Medical Officer should be responsible for the ongoing training and audit of doctors approved to undertake respiratory health assessments under the scheme.

Recommendation 9

The approval of doctors to undertake the respiratory health assessments for the early detection of CMDLD under the scheme should become the sole responsibility of the DNRM.

Recommendation 10

Doctors approved to undertake respiratory health assessments should have a different designation from 'NMA', which should reflect their specific responsibility for respiratory health assessments under the new scheme.

Chapter 10: Chest x-ray review

A sample of 258 digital CXRs from coal miners with at least 10 years of experience in coal mine work was assessed independently by two B-Readers.

- Twenty percent of the CXRs had quality issues, which could affect the accurate detection of the small opacities characteristic of pneumoconiosis.
- The quality issues include poor positioning cutting off portions of the chest, covering up the chest with the scapula or shoulder blades, poor contrast and excessive edge enhancement.
- The quality issues noted above may result in false positive classifications for pneumoconiosis.
- Of the 248 classifiable CXRs reviewed, 18 were considered to have opacities consistent with simple pneumoconiosis.

- Review of the original radiology reports for the 18 positive cases found only two which identified abnormalities consistent with pneumoconiosis, 13 were reported as no abnormalities, and three reports were missing.
- Follow up by the NMA was not done in the two cases where the original radiologist had identified changes on the CXR.

Recommendation 11

Chest x-rays should be performed by appropriately trained staff to a suitable standard of quality and performed and interpreted according to the current ILO classification by radiologists and other medical specialists classifying CXRs for the scheme.

11.1 Require additional training in the use of the ILO classification for radiologists or respiratory physicians classifying CXRs for the Coal Mine Workers' Health Scheme.

11.2 Develop a program to evaluate those radiologists or respiratory physicians who seek to classify CXRs for pneumoconiosis to demonstrate adequate performance. Examples of programs that provide such an evaluation are the US NIOSH B-Reader and the Asian Air Pneumo programs.

11.3 In order to maintain the highest quality, ILO classifications of CXRs for the DNRM should be performed by a selected group of medical practitioners, separate from the clinical interpretation provided by the local radiologist.

11.4 Due to variability in reading CXRs, utilise a protocol involving at least two independent classifications to confirm agreement about the presence or absence of radiological features of pneumoconiosis, similar to the protocol used in this study.

11.5 Provide guidelines to radiology clinics performing CXRs for the Coal Mine Workers' Health Scheme detailing the appropriate qualification of personnel, imaging equipment and software, image acquisition, documentation, image display, and quality control systems. An example of such a guideline to be found at http://www.cdc.gov/niosh/docs/2011-198/

11.6 Develop ongoing clinical audit of CXRs and classifications to ensure quality.

11.7 Provide appropriate feedback to coal mine workers so that they have access to the information in the radiologist and NMA reports.

11.8 Improve the acquisition and archiving of digital CXRs by Queensland DNRM to facilitate disease surveillance efforts.

Chapter 11: Spirometry review

We audited spirometry equipment and training using an online survey which was completed by around one-third (74) of NMAs on the current Health Surveillance Unit (HSU) list. We also assessed the quality and reading of a sample of 256 spirometry tests completed under the current scheme.

a. Spirometry equipment and training:
   - Less than 50% of spirometry currently performed is undertaken by sufficiently trained and experienced staff.
   - Overall, quality control and quality assurance of spirometry testing is inadequate for more than 50% of sites.

b. Spirometry quality and interpretation:

- Forty percent of spirograms reviewed could not be interpreted as they were not performed to American Thoracic Society/European Respiratory Society (ATS/ERS) standards.
- Only 43% (110/256) of the spirometry results evaluated had been accurately interpreted and reported by NMAs.
- Of the 30 spirograms assessed as abnormal by the reviewers, only two had been accurately identified in the NMA reports.

Recommendation 12

Spirometry should be conducted by appropriately trained staff and performed and interpreted according to current ATS/ERS standards.

12.1 Spirometry should be conducted at respiratory laboratories accredited by Thoracic Society of Australia and New Zealand (TSANZ) or similar bodies and for other medical facilities seeking to undertake spirograms under the scheme, accreditation specific to spirometry should be required.

12.2 Spirometry scientists or technicians who conduct tests for the new scheme should undergo initial training and participate in periodic refresher courses provided by an approved organisation.

12.3 Spirometry testing must take part in a quality control program consistent with current ATS/ERS standards and the quality of spirometry tests should be audited regularly as part of the overall auditing within the scheme.

Chapter 12: Health assessment form data handling and storage

We reviewed DNRM's data handling and storage procedures, including accessibility of previous health assessments.

- The transfer of health assessments between the DNRM and NMAs by ordinary mail is inefficient, and the use of hard copy forms and test results is outmoded compared with modern electronic data entry and storage methods.
- The HSU performs an administrative check of the health assessment forms for missing information, but there is no medical review or audit of the collected health data.
- The storage of health records as both scanned and hard copy across a number of sites hampers access to previous records by DNRM staff and NMAs.
- There is a large backlog of about 100,000 health assessments still awaiting entry into the DNRM database, which further hampers accessibility of these records. However, steps are in place to process health assessments for underground coal mine workers by the end of 2016, and to clear the remaining backlog by the following year.

Recommendation 13

DNRM should transition to an electronic system of data entry and storage, whereby doctors undertaking these respiratory assessments enter the data for their assessment and can access previously collected data for the mine worker and to facilitate auditing.

13.1 DNRM should institute electronic data entry and data storage, with suitable consent and security arrangements and the facility to link all records for individual mine workers, and enable access to previous records by doctors undertaking the respiratory health assessments.

13.2 A regular audit function of the collected medical information should be introduced to monitor quality with regular feedback to the doctors performing respiratory health assessments under the scheme.

Recommendation 14
All coal mine workers, including contractors, subcontractors and labour hire employees, who meet the revised criteria for being "at risk from dust exposure" should be registered in the DNRM database on entry into the industry for the purposes of ongoing medical surveillance.

Recommendation 15
DNRM should conduct ongoing individual and group surveillance of health data collected under the scheme, to detect early CMDLD and analyse trends to disseminate to employers, unions and coal mine workers.

Recommendation 16
Coal mine workers should have exit respiratory health assessments regardless of whether they leave the industry due to ill-health, retirement or other reasons.

16.1 Due to the latent period for developing CMDLD, health surveillance under the scheme should include current and former coal mine workers, including retirees, as this would provide a more accurate depiction of industry-wide disease trends.

Recommendation 17
An implementation group, including representatives of stakeholders and relevant medical bodies, should be established to ensure that the necessary changes to correct the identified deficiencies with the respiratory component of the current scheme are implemented in a timely manner.

Recommendation 18
There should be a further review of the revised respiratory component of the scheme within 3 years to ensure that it is designed and performing according to best practice.

Chapter 13: Interstate and overseas health surveillance schemes for miners

We reviewed health surveillance systems for mine workers in other Australian states and overseas, to determine components which could be incorporated to improve Queensland's current scheme. The following points were common to the surveillance programs:

- The objectives and purpose of the scheme, in particular identification and monitoring of respiratory disease, are explicit.
- There are designated high dust exposure jobs and a clearly stated frequency of health assessments and CXRs for workers in these (and other lower risk) job categories.
- Health assessments, including spirometry and CXR interpretation and reporting are administered by trained medical and nursing staff.
- Data collection is electronic to facilitate data collation, analysis and reporting of group surveillance data.
- Medical staff are required to explain the outcome of (adverse) health assessments to workers, with suggested referral pathways to treating doctors and specialists.

Chapter 14: Queensland medical capacity

We identified the specialist medical expertise and resources currently available in Queensland to contribute to the performance of high quality health assessments for the early detection of CMDLD.

- There are three relevant Australian specialist medical organisations (Royal Australian and New Zealand College of Radiologists, Thoracic Society of Australia and New Zealand and the Australasian Faculty of Occupational and Environmental Medicine of the Royal Australasian College of Physicians) with the interest and capacity to assist with health assessments under an improved scheme, however this expertise has not been adequately harnessed.
- While some training and up-skilling is needed due to limited recent experience with CMDLD, these organisations can contribute to training, accreditation of CXR and spirometry testing and clinical audit, development of clinical guidelines, and nominating members to provide specialist opinion to miners with suspected CMDLD.

Chapter 15: Other sources of data about the extent of CWP

We identified routinely collected health data to gauge the extent of CWP among Queensland coal miners, from Queensland hospital records and workers' national and state-based compensation data.

- Four probable and seven possible CWP cases in older, probably retired coal mine workers were identified by Queensland Health after cross-checking public hospital records from the last 20 years with Queensland Coal Mine Workers' Health Scheme records.
- Six accepted workers' compensation (WC) claims for CWP were found through a search of the Queensland compensation database from 2005/06 to current, including four accepted claims in 2015/16. There are also a further 6 cases pending.
- These data sources have limitations and do not provide accurate information about the prevalence of CWP or other CMDLD.

Chapter 16: Research framework for a survey of CMDLD prevalence among coal miners

The current review was not intended to provide an estimate of CWP or other CMDLD among Queensland coal miner workers and the information from existing data sources are also incomplete. Therefore, the extent of CMDLD in current and retired Queensland coal miners remains unknown. As a result, the review team designed a research framework which could better estimate the prevalence of CMDLD in Queensland coal miners.

Overall conclusions

This review of the respiratory component of the Coal Mine Workers' Health Scheme has revealed major system failures at virtually all levels of the design and operation of the respiratory component of the current health assessment scheme, but has also identified ways to modify the current scheme to make it more effective in undertaking medical screening for CMDLD in the future.

The measures identified in the review to address the system failures include:

- A more clearly articulated purpose of the scheme.
- A smaller number of doctors approved by the DNRM to undertake respiratory health assessments under the scheme.
- A greater focus on the credentials and experience of these doctors.
- Introducing initial and ongoing training about CMDLD for doctors seeking approval to undertake respiratory health assessments under the scheme.
- Developing clinical guidelines to inform diagnosis and management of CMDLD identified through the scheme.
- More standardised and consistently applied criteria to determine workers "at risk from dust exposure" for deciding which coal mine workers require a CXR.
- A more complete and better designed respiratory component of the health assessment form with data collected online and better access to the findings from the worker's previous health assessments.
- Better standard of CXR referral, interpretation and reporting using the ILO criteria.
- Better standards of spirometry testing and interpretation.
- A process of clinical audit of collected health data, including spirometry and CXR.
- Greater accessibility of previous job history and health assessment records to inform subsequent assessments of coal mine workers, resulting in a greater ability to monitor changes in respiratory health at an individual level over time.
- Inclusion of former mine workers, including retired mine workers, in whom CMDLD is most likely to be seen.
- The development of robust industry-wide health surveillance data to assist in informing coal mine dust exposure control measures, including review of occupational exposure levels.
- A research framework to provide more robust estimates of the prevalence of CMDLD in Queensland coal mine workers.

These (and other) deficiencies with the respiratory component of the current scheme itself have been confounded by the widespread belief that CWP had been eliminated in Queensland and is of historical interest only leading to complacency about the risks of CMDLD. Where there is a lack of belief that CMDLD can occur among coal mine workers, then it is no surprise that there is a lack of rigour applied to detect such diseases.

Therefore, a major overhaul of the design and operation of the respiratory component of the current Coal Mine Workers' Health Scheme is necessary. As previous attempts by the DNRM to improve aspects of the respiratory component of the scheme did not result in required changes, it will be important for an oversight group to be formed to drive the implementation of the recommendations of this review and in a timely manner.

It is also important to acknowledge the loss of confidence among coal mine workers (and their families) in the scheme's ability to effectively monitor their respiratory health, especially since the recently diagnosed CWP cases have been identified. Understandably, this has resulted in uncertainty about the validity of clearances received about their respiratory health after previous respiratory health assessments. The review team encourages all workers who are concerned about their respiratory health to consult their local doctor in the first instance. Where a CXR or spirogram examined in this report suggests the possible presence of CMDLD, the authors will inform DNRM of the finding so that the appropriate medical practitioner(s) can be informed.

More broadly, the findings of this review, the failures identified and the recommendations to improve the scheme have implications beyond the coal mining industry in Queensland. The coal mining industry in other Australian states, and other industries where (hazardous) respirable dust exposure, such as silica, occurs should also take note of our findings. Respiratory surveillance for their workers should be assessed and, where existing health assessment schemes are in place, these should be reviewed to ensure that their design, implementation and audit are best practice.

The review team would like to conclude by restating that medical screening and surveillance is not a substitute for effective dust control, which should be the first line of action in protecting coal mine workers from CMDLD. This is particularly important since this group of diseases can progress even after dust exposure has ceased. Regular respiratory health assessments are an adjunct to dust control and can inform preventive programs, but only if such medical screening is effectively designed, implemented and monitored.

1. Introduction

1.1 Background

Coal Mine Dust Lung Disease[1] (CMDLD) comprises a group of occupational lung diseases that result from the cumulative inhalation of respirable coal mine dust. Coal mine dust includes: carbon, quartz and silicates, and it is thought that interactions between these dusts leads to a range of pathological changes in the lungs which result in CMDLD.[2]

Coal miners are at risk of developing these diseases, which include the classic fibrotic lung diseases of CWP, mixed dust pneumoconiosis and silicosis, as well as chronic bronchitis, emphysema and diffuse dust-related fibrosis. Progressive massive fibrosis (PMF) is also on the spectrum CMDLD, and is the most severe form of CWP. Early detection of each of these diseases is based on different diagnostic criteria and testing. For example, CXRs primarily detect the small opacities of early CWP, while spirometry can identify early declines in lung function and better assists in the early diagnosis of chronic obstructive pulmonary disease (specifically emphysema), than CXR.

Detection of small opacities, especially those indicative of early lung disease requires careful examination of a high quality CXR. There are established guidelines to read CXRs for changes indicative of CWP, published by the International Labour Organization (ILO). The use of the ILO guidelines results in systematic and reproducible CXR reading so that screening and surveillance can be carried out.[3]

All Queensland coal mine workers are required under the *Coal Mining Safety and Health Act 1999* (Queensland), and Part 6 of Division 2 of the *Coal Mining Safety and Health Regulation 2001*, to undergo a Coal Mine Workers' Health Scheme (the scheme) medical assessment prior to the start of their employment at a coal mine, and then at least once every five years during their employment. The scheme commenced in 1983 when all current coal miners were required to participate in a one-off CXR survey, although participation was voluntary for retired miners. This study revealed cases of pneumoconiosis and other respiratory abnormalities,[4] and prompted the second Health Order.

Under the second of the Health Orders issued, all new entrants to the coal mining industry were required to undergo CXR and lung function tests to satisfy a pre-employment medical standard. A further Order was issued by the Queensland Coal Board in 1993 that provided for both pre-employment and ongoing health surveillance periodically every five years. In addition, a CXR was required only when the employer advised that the coal mine worker was "at risk from dust exposure".

The focus on respiratory diseases continued after the Queensland Coal Board was abolished in 1997, and at least until the Coal Mining Safety and Health Regulation (2001) came into force. Although the current Regulations stipulate periodic monitoring of workers' level of risk, this relates broadly to the variety of hazards encountered in coal mines.

The parts of the current health assessment relevant to the early detection of CMDLD include a medical history, physical examination, spirometry to assess lung function and a posterior-anterior CXR.

Health assessment under the scheme is the responsibility of NMAs, who are required to complete a "Report on Health Assessment" (the report) at the completion of the assessment. The actual health assessment may be performed by the NMA or an EMO, however only the NMA may complete and sign off on the report. The report is provided to the coal mine worker and the employer, and the full health assessment form, CXR films and CXR reports are also forwarded to HSU at DNRM.

As of December 2015, when this review was proposed, six confirmed cases of CWP had been identified within seven months among coal miners in Queensland, and an additional case was notified in May 2016. An 8th case was reported on 28 June 2016, but this case was identified too late for further details to be included in this review. Prior to this, no new cases had been identified despite the ongoing coal miners' health assessment scheme, and CWP was thought to have been eradicated decades ago. A review of the design and operation of the respiratory component of the scheme was therefore commissioned.

1.2 Coal mining in Queensland

There were 54 coal mines in Queensland in 2013-2014, including 41 open-cut and 13 underground mines.[5] In addition there were 31 coal handling and preparation plants (CHPPs), some of which serve multiple mines. According to data from the DNRM, there were approximately 5,000 underground coal miners in Queensland at the end of 2015. Table 1 presents the number of miners in each mine, and which mines are regarded as "gassy". Gassy mines are dewatered to expedite gas extraction, for example of methane, leading to drier and more friable coal, and hence likely higher dust levels.

Table 1: Estimated number of mine workers in Queensland underground mines, in 2015 (Data source: DNRM)

Mine	No. of miners	Gassy Mine?	Operational Status
Aquila	0	No	Non-operational (care and maintenance)
Broadmeadow	683	Yes	Operating Long Wall
Carborough	314	Yes	Operating Long Wall
Cook	362	No	Redevelopment - Long Wall not yet operating
Crinum	223	No	Non-operational (care and maintenance)
Eagle Downs	5	No	New development (care and maintenance)
Ensham	209	No	Operating Place Change
Grasstree	639	Yes	Operating Long Wall
Grosvenor	249	Yes	New development - Long Wall not yet operating
Kestrel	536	No	Operating Long Wall
Moranbah North	649	Yes	Operating Long Wall
Newlands	109	No	Operating Long Wall
North Goonyella	275	Yes	Operating Long Wall
Oaky No 1	248	Yes	Operating Long Wall
Oaky North	386	Yes	Operating Long Wall
Total	**4,887**		

The vast majority of Queensland coal is coking coal or thermal coal. These are classified as bituminous coals and typically contain between 76–90% fixed carbon, that is, high rank coal types. All of the underground mines in Queensland are bituminous coal mines mines.[6] Currently, there are no anthracite coal mines in Queensland, though three are considered semi-anthracite, one of which is currently on 'care and maintenance. All three of these mines are/were operated as open-cut mines. There is also an anthracite deposit in Nebo West, but the DNRM advised that there are no current plans to mine it.

In general, Queensland underground coal mines are thought to contain less than 5% silica, provided the mining horizon is within the seam, which can vary. On the other hand high silica exposure can occur with mining processes that involve driving drifts through stone, mining through rock intrusions, drilling or bolting into a stone roof during development and secondary support activities. Open cut mines remove overburden (overlying soil and rock) before reaching the coal seams, and there is a potential for silica exposure during this process.

Most Queensland underground coal mines are operating longwall mining. Longwall mining is thought to give rise to four times as much dust as continuous mining,[7] particularly when production rates (machine speeds) are high.[7, 8] In addition, bi-directional cutting can result in increased exposure to coal mine dust.[7]

1.3 Trends in coal workers' pneumoconiosis

The rates of fatalities and injuries among coal miners have diminished markedly in the USA[1] and UK[9] since the 1970s, however workers in the coal mining industry are more likely to suffer chronic lung disease than comparable non-mining heavy industry.[10] Using the USA as an example, data on occupational illnesses are substantially underreported in coal mining[11] (and other industries[12]), and hinders a targeted public health and industrial hygiene response.

CWP re-emerged in the USA in the late 1990s, though the occurrence of the disease was expected to continue to decline after the institution of modern dust control Regulations. The USA National Institute for Occupational Safety and Health (NIOSH) had reported a decline in prevalence of CWP from 6.5% in the 1970s to a low of 2.1% in the 1990s. However, CWP prevalence subsequently increased to 3.2% in the first decade of the 21st century. The rate of progressive massive fibrosis (PMF) in certain coal mining states in the USA has also recently increased to levels observed prior to the introduction of modern dust controls.[13] In addition, exposure to silica and silicates, e.g. from cutting rock beyond the coal seam and roof-bolting, has been implicated as a factor in rapidly progressive disease.[14]

High rates of CWP have been measured elsewhere. For example, coal miners in Chinese state-owned coal mines who commenced work in the 1970s had cumulative rates of CWP of between 4 to 17%.[2] In Colombia, the prevalence of CWP was recently reported as 36%.[2] A 1984 prevalence survey of CMDLD in Queensland identified 75 cases of pneumoconiosis or suspected pneumoconiosis among 7,784 current and 123 retired employees. [15]

Since the 1990s, Australia has had very few reported cases of CWP.[16] A 24-year mortality surveillance study[17] revealed that out of over 1,000 pneumoconiosis-related fatalities in Australia between 1979 and 2002, CWP accounted for fewer than 100 fatalities, with the largest decline occurring between 1988 and 1996. There were fewer than 5 WC claims per million employees for pneumoconioses (excluding asbestosis) from 2000-01 to 2007-08 and no claims from 2008-09 to 2010-11.[18]

This contrasts with the situation in the USA, where there has been little change since the late 1970s (See Figure 1). Joy et al[19] compared the differences observed between USA and Australian mines and miners, although most of the data were from New South Wales, not Queensland. They concluded that the much lower prevalence of CWP (defined as an ILO category of 1/0 or greater) among Australian miners was due to less exposure to quartz, and perhaps the thicker coal seams, larger numbers of employees (implying bigger operations with more investment for environmental monitoring and dust control), and more effective use of respiratory protection. This was despite occupational exposure limits for coal dust in Australia not keeping pace with reductions in such limits overseas (see section 1.4).

The recent cases of CWP identified in Queensland indicate that more recent information on prevalence and/or incidence of CWP is required and a research framework for this is included in chapter 16 of this report.

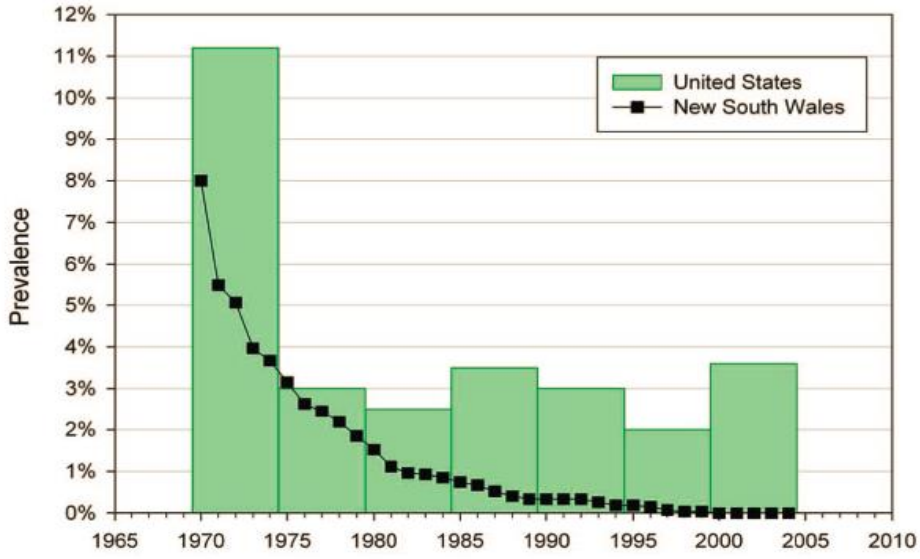


Figure 1: Prevalence of pneumoconiosis, ILO category 1/0 or greater among US underground coal miners and New South Wales[1] coal industry employees, by year [19]

[1]. Equivalent data from Queensland were not provided in this paper but CWP rates in Queensland were thought to be similar to those in NSW

1.4 Exposure limits and risk of pneumoconiosis

The current Australian workplace exposure standard for coal dust is 3 mg/m^3, and for crystalline silica which may also cause silicosis, another type of pulmonary fibrosis, the exposure limit is 0.1 mg/m^3.[20] Other countries have lower occupational exposure limits (OELs) for coal dust than does Australia.

Exposure limits for coal dust are measured as mean air concentrations over 8 hours (i.e. an 8-hour time weighted average (TWA)). If the shift is normally 12 hours for 5 days (i.e. longer than 40 hour per week) the mean exposure must be compared to a proportionally reduced limit (e.g. 8/12). This is because for coal dust and silica, increased risk is associated with cumulative exposure rather than exposure intensity. Consideration of extended shifts is discussed in Appendix C of a Queensland Government report 2010.[6]

The USA Mine Safety and Health Administration (MSHA) requires mine operators "to use the continuous personal dust monitor to monitor the exposures of underground coal miners in occupations exposed to the highest respirable coal mine dust concentrations".[21] Samples must be taken over the whole of a shift during normal production.

Number of samples is a critical issue to demonstrate compliance with exposure limits. This is also discussed in the above Appendix.[6] Exposure measurements typically show lognormal distribution with a tail at the high end of the exposure distribution. This means that if few samples are taken, they are likely to fall at the lower end of the distribution.[22]

More information on exposure limits and risk including a list of the available international exposure limits for coal dust and silica are provided in Appendix 1.

2. Aims of the review

A. To determine whether the respiratory component of the health assessment performed under the Queensland Coal Mine Workers' Health Scheme, is adequately designed and implemented to most effectively detect the early stages of coal mine dust lung diseases in Queensland coal mine workers, estimating the extent and providing feedback and, if not,

B. To recommend necessary changes to correct deficiencies identified under Aim A, recommend measures to follow up cases that may have been missed as a result of these deficiencies, and identify what additional capacity is needed in Queensland to improve this scheme.

The full scope of the review is included in Appendix 2.

3. Ethics approval and data security

Ethics approval for the review was granted by Monash University Human Research Ethics Committee, and the Institutional Review Board of the University of Illinois at Chicago.

The DNRM accessed and extracted data for the review from their Coal Mine Workers' Health Scheme records. Data were de-identified, copied and provided in electronic format, except for analogue CXR films which were provided in hard copy. De-identification included removal of the name, address, telephone number, day and month of birth (but not year of birth) for each worker.

The de-identified data were sent to Monash University via secure file transfer, and stored on a password-protected server. Access was limited to the review team. CXR data were sent to Professor Cohen by secure file transfer and courier, from Monash University and the DNRM.

4. Purpose of the respiratory component of the current scheme

The original coal mine workers' medical assessment scheme was put in place in response to a concern about pneumoconiosis and other respiratory abnormalities (see chapter 1.1). The current NMA information kit does not however clearly state that the purpose of the scheme includes early detection of CMDLD.

A 2010 report of a dust self-assessment survey of coal mines[6] acknowledged the "general confusion around the requirements for, and the content of health surveillance for Queensland coal mine workers." There was a lack of awareness about the purpose of the respiratory component of the scheme, in particular when spirometry and CXRs were required.

While historically, early detection of CWP and other CMDLD in individual miners has been a focus of the respiratory component of the scheme, the current emphasis is on fitness for work. Different parts of the respiratory component of the current scheme are embedded within the assessments of other body systems, and so there is potential for the integration of all of the respiratory health information and important patterns of early lung changes to be overlooked.

CMDLD may develop after some years of exposure to coal dust even if exposure stops. The dust remains in the lungs and CMDLD may only become apparent some years later.[9] The scheme is designed to assess current coal mine workers, so once workers retire or move to another industry, they are lost to the scheme. Cases of CMDLD that develop among former mine workers are unlikely to be identified. This omission further reduces the effectiveness of the scheme as a group surveillance program.

The main purposes of the respiratory component of the scheme, with respect to CMDLD, should be more clearly stated as being to:

1. Provide respiratory health screening to detect early CMDLD in coal mine workers.
2. Ensure appropriate referral for follow-up, diagnosis and management, including appropriate reductions in further exposure to dust, for coal mine workers with respiratory abnormalities.
3. Collect, analyse and report group surveillance data to monitor trends in CMDLD, and to inform Government, industry and trade union reviews of dust exposure levels and occupational exposure limits for coal mines.

The review team would like to emphasise that medical surveillance of CMDLD is only useful for secondary prevention and identifying where there may have been previous excessive exposure. Because of the long latency in the development of CMDLD, it is not a substitute for primary prevention, which should be in the form of coal mine dust monitoring and control.

5. Overall process of the current scheme

Having considered the purpose of the respiratory component and identified the lack of a focus on the early detection of CMDLD, the review team assessed the scheme's processes.

The information in this chapter is summarized from the Coal Mine Workers' Health Scheme – Information for Newly Appointed Nominated Medical Advisers (version 8, 24/02/15), which includes relevant sections of the Coal Mining Safety and Health Regulation (2001) (CMSHR). The flow chart in figure 2 depicts the overall process of the current scheme.

Current situation

The process and procedures of the Coal Mine Workers' Health Scheme begin when a potential, current or previous coal miner applies for work with an employer, which could be a coal mine operator or a contractor (step 1).

As specified under section 46 of the CMSHR, employers must ensure prospective coal mine workers undergo health assessments with their NMA prior to employment. Employers are expected to complete section 1 of the coal mine workers' health assessment form before workers attend NMA appointments (step 2). Section 1 is meant to inform the NMA about the potential hazards of the coal miner's proposed job and importantly should specify whether the worker is "at risk from dust exposure" and therefore requires a CXR.

In some instances however, companies advertise for workers, especially contractors and subcontractors with a current fit for work health assessment. As the miner's job category and location(s) will be unclear, section 1 about the relevant SEG and other potential hazards associated with the job cannot be completed.

The coal mine worker is required to complete section 2 of the health assessment form, to provide details about work history and past and current medical history (including respiratory symptoms) prior to attending their NMA appointment (step 3).

Section 3 of the form consists of the clinical findings, including the spirometry and CXR results (if a CXR was performed), and is completed by either the NMA or an EMO after s/he has reviewed sections 1 and 2 (step 4). Under section 46 of the CMSHR, health assessments can be carried out by an EMO other than the NMA, although assessments must be undertaken under the supervision of an NMA.

EMOs are not authorized to complete section 4 of the report. Instead, partially completed health assessments should be forwarded by the EMO to the NMA, who is meant to review sections 1 to 3 prior to completing section 4 and issuing the report to the employer and coal mine worker (step 5). The report essentially summarizes the health assessment and outlines a worker's fitness for work, including any restrictions. NMAs are expected to provide an explanation of the outcome of the medical examination to the worker and "where practical" secure the worker's signature on the report. It is also the NMA's role to specify the nature and duration of restrictions imposed on a worker's fitness and any required review. However, the instructions do not relate explicitly to CMDLD or other respiratory abnormalities.

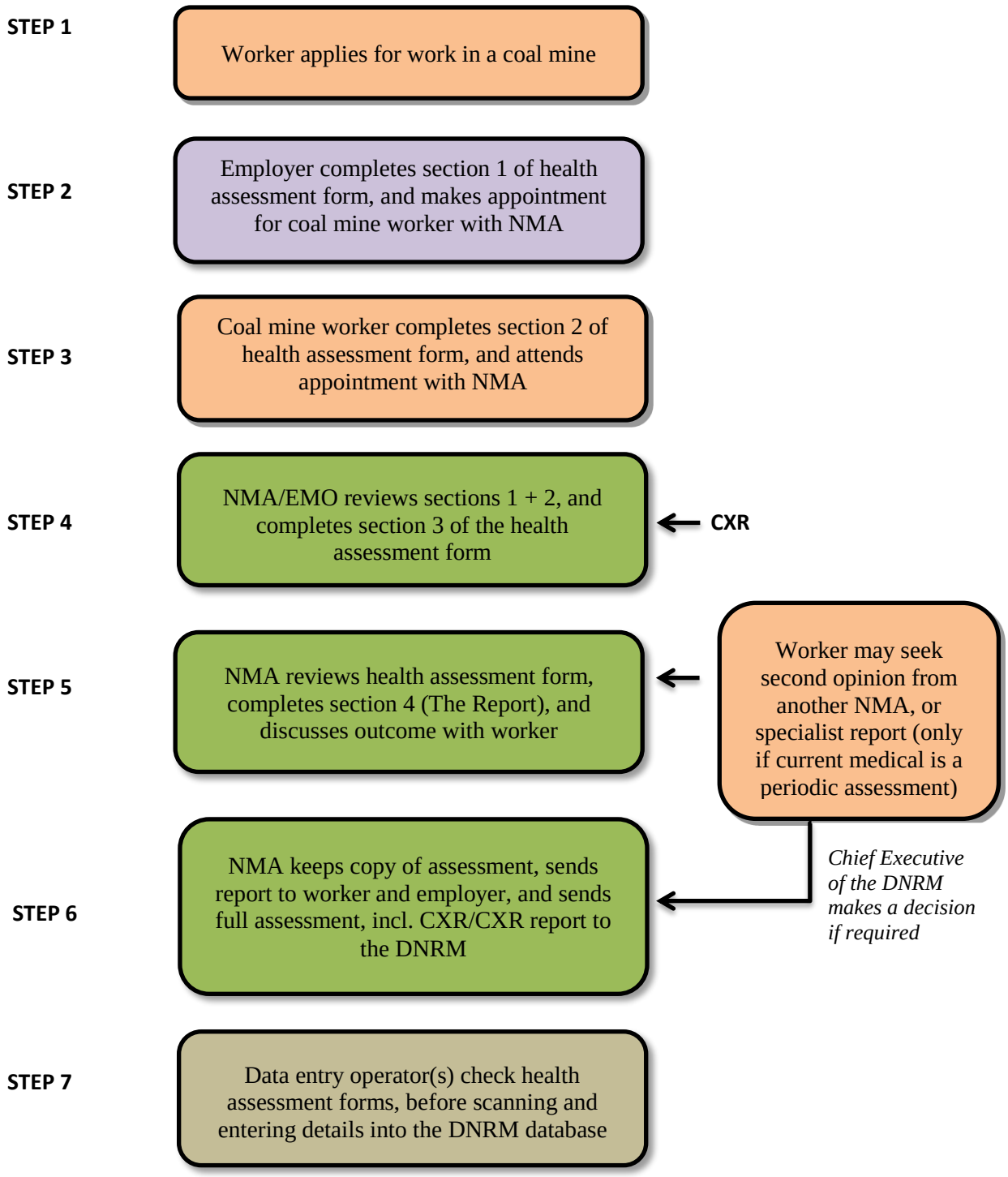


Figure 2: Flow chart of the process of the current Coal Mine Workers' Health Scheme

If the report indicates that a coal mine worker is unable to perform in their usual role without creating an unacceptable level of risk, the worker has a right under section 48 of the CMSHR to request an opportunity for a second opinion from another NMA or relevant specialist, although only if the medical is a periodic health assessment (step 5a). The original NMA is then expected to review their initial report in light of the findings in the second doctor's report and issue another report. Where differences between the reports are unresolved, the worker or employer notifies the chief executive of the DNRM, who will appoint a medical specialist to make a final decision based on a review of the conflicting reports and, if necessary, arrange a further assessment of the worker.

The health assessment records collected under the scheme are the property of the DNRM. NMAs are required to keep a copy of the health assessment data and completed forms and to send a copy of the full assessment, including original CXR films and reports (or copies of CD/DVD) and spirograms to HSU at DNRM (step 6).

Data entry operators in the HSU check health assessments for completeness, before entering the data into the DNRM database (step 7).

Section 46 of the CMSHR states that employers must ensure coal mine workers undergo health assessments periodically as decided by the NMA, but at least every 5 years.

Limitations

As found in our review of the purpose of the scheme in the previous section, the overall assessment process, including the respiratory component, is also aimed at establishing current fitness for work rather than the early detection and management of CMDLD.

There is no clear referral pathway for follow up of respiratory abnormalities detected during the health assessments, nor criteria for further investigation, diagnosis or management of CMDLD in instances where abnormal lung function (spirometry), CXR or other respiratory abnormalities are identified. Clinical guidelines for follow-up of respiratory abnormalities are needed, including involvement of a respiratory physician and/or other specialist with expertise in occupational lung disease, and determination of appropriate workplace restrictions aimed at preventing or reducing dust exposure. It is also important that the results of health assessments are explained to the workers, especially where abnormalities suggestive of CMDLD are detected.

A diagnosis of CMDLD may be made by a respiratory physician or other medical specialist after referral from the NMA, but this may require further investigations, such as a CT scan. However, there are currently no agreed standardised diagnostic criteria within the scheme for the various diseases within CMDLD and no established process in the Regulations by which coal mine workers found to have such disease is formally reported to the DNRM when identified under the scheme.

The SEG approach in section 1 of the form, which is currently required to determine whether a miner needs a CXR, does not account for contractors, subcontractors or labour-hire workers who may not be based at a specified mine or employed for a specific role. CXRs are not being undertaken by all coal mine workers who work underground,[6] but there is also the potential for duplication of health assessments and CXRs. In addition to the scheme assessments, we understand from stakeholders that many employers arrange their own pre-employment and periodic health assessments.

Under the current process, information from previous assessments is not promptly available to NMAs. Miners may have very small opacities and acceptable lung function at any one

assessment and be viewed as fit for work. However, comparison across serial medical assessments is more likely to show the development of small, preclinical changes and declines in lung function. The current scheme also has no requirement for any follow-up health assessments focusing on the respiratory health of coal miners previously in a position "at risk from dust exposure" once they leave such a position. In addition, there is no mention of exit health assessments or on-going follow-up of coal mine workers who retire or leave the industry.

The current process does not prevent the submission of incomplete health assessments, as this is performed manually. An electronic system of data entry to a centralised secure database would reduce workload for HSU by removing step 7. Lack of completion of steps e.g. step 2 could be programed to prevent the submission of incomplete forms. Such a system would also enable the findings from previous health assessments to be accessed by NMAs directly from the DNRM data and compared with the current assessment, including in instances where a worker's previous health assessments have been completed by different NMAs.

The review of the health assessments at DNRM is purely administrative and involves no medical review or audit, and the DNRM database is currently not being utilised for group surveillance.

There is also no explicit process by which DNRM can ensure that the scheme as implemented remains fit for purpose as the industry changes, i.e. that it continues to meet its intended aims.

In order to utilise data from the respiratory component of the scheme for evaluation and monitoring of industry-wide trends, the necessary data fields should be identified and the database interrogated regularly for overall reporting purposes. If a case of CMDLD is identified, the DNRM Occupational Physician should be able to contact the employer's NMA to discuss and implement action to reduce exposure and try to prevent other cases occurring. However, under the current regulations, these discussions can only proceed with the consent of the individual worker.

6. Confirmed CWP cases

Having reviewed the purpose and processes of the scheme, we examined health records for the confirmed CWP cases to identify where the scheme had failed to identify and/or act on early respiratory abnormalities indicative of CMDLD. We received de-identified data of the seven individuals with confirmed CWP (as of May 2016), including a majority of completed health assessment forms and CXR reports, from the DNRM. The spirometry printouts performed under the scheme were not available, however lung function results were reported in the records.

The respiratory component of the health assessment forms was reviewed and the overall deficiencies are summarised below. The details of the individual cases are not included, to preserve confidentiality.

The review team was not provided with additional medical information gathered outside the scheme, so we were not always able to assess what prompted the (re-)assessments or investigations that led to the diagnosis of CWP in these cases.

Limitations

For most cases, there were abnormalities identified (respiratory symptoms, spirometry or CXR) during one or more of their health assessments. However, there was a lack of documentation and inconsistent processes about follow-up or referral when abnormal results were found. Furthermore, there were cases where workers were still reported as being fit to work underground with no recommendation for restrictions for respiratory conditions, e.g. to avoid exposure to dust.

Health assessments are required to be completed periodically at least every five years. Some earlier review appointments were organised to re-assess previously identified respiratory problems, but these were sometimes scheduled less frequently than the NMA indicated. In some cases, health assessments were conducted more frequently, but the reasons for this were not always made clear on the health assessment forms. This may be explained, in part, by the worker changing employer and requiring a new health assessment. This can result in more frequent CXRs than desirable.

The majority of the abnormal spirometry results found that the health assessments were considered to be suggestive of chronic obstructive airways disease, but these were often attributed to tobacco smoking rather than coal dust exposure. In addition, decline in lung function tests over serial health assessments were not taken into account by NMAs.

CXRs were not reported according to the ILO classification (see chapter 1.1), although for two cases where abnormalities on CXR were noted, the terminology used by the radiologist was consistent with this classification.

In some cases, diagnosis of CWP was made many years after retirement, this highlights another limitation of the current scheme, which is its exclusion of retired (and former) coal miners and lack of ongoing health surveillance for these groups.

7. Health assessment form

We reviewed the content and design of the respiratory component of the health assessment form (Appendix 3), which includes information about the worker's medical history, respiratory symptoms, job history and information provided by the employer about "at risk from dust exposure". We also assessed the completeness of a convenience sample of 91 forms, and explored possible reasons for incompleteness and/or poor quality.

7.1 Content and design

Current situation

The scheme's health assessment form is a seven page paper-based document. It is divided into four sections for completion by the employer, worker, EMO and NMA, respectively.

The employer's section consists of free text boxes to record the employer and mine name, the coal worker's position (including generic and company SEG) and six "yes/no" questions about exposure to various hazards.

The coal mine worker's section consists of over 40 questions grouped under five separate headings, including "yes/no" tick box options for a range of medical conditions and free text entry for the work history.

The EMO's section consists of over 50 questions grouped under eighteen separate headings, including "yes/no", "abnormal/normal", "absent/present" tick box options for medical history and clinical findings for the respiratory and other major body systems, and space for additional comments.

The NMA's section (section 4 – the report), consists of similar fields as the employer's section, the EMO's examination details and five tick box options to record the coal mine worker's fitness for duty and restrictions.

Limitations

The current structure of the health assessment form has the respiratory component scattered among the numerous questions and physical findings related to other body systems, which reduces the focus on the respiratory system.

The form is also lengthy, and could be shortened by the use of tick boxes, e.g. for previous occupational history provide a list of jobs (such as in Table 2), and duration of employment. This would allow rapid identification of jobs associated with development of CMDLD.

There are insufficient questions about previous respiratory conditions such as asthma, bronchitis, emphysema, tuberculosis, pneumoconiosis, lung surgery, lung infections, and allergies. The form does not have a complete respiratory symptom questionnaire, which should be a standard for health surveillance of workers exposed to hazardous substances that affect the lungs.

The 1995 National Occupational Health and Safety Commission (now Safe Work Australia) guidelines include a respiratory questionnaire and both the NSW and (previous) WA health assessment forms for mining employees include expanded respiratory sections, compared with

the Queensland form. The six-page health assessment form used in the WA scheme focussed almost entirely on work history, respiratory symptoms, spirometry and CXR results.

The current Coal Mine Workers' Health Scheme assessment form has several ambiguously-phrased questions, e.g. Question 2.4e "Abnormal shortness of breath or wheezing?" asks about two symptoms in one question. The smoking history is also poorly worded, e.g. "Do you currently smoke, or have you ever smoked?", and doesn't allow for the differentiation of current and former smokers.

There are also several duplicate questions: Question 1a, "Dust exposure (x-ray needed?)" corresponds with questions 3.12, and question 1b, "underground work" corresponds with a question in the report (section 4), "Is the assessment for underground work?"

The lack of "N/A" tick box options also increase the likelihood of errors, as well as inconsistent interpretation and responses during form completion.

There is also no specific reference in section 4 to the absence or presence of symptoms/signs, or to spirometry or CXR changes consistent with CMDLD, or to the follow-up required and frequency of subsequent health assessment in section 4.

Prior to 2001, the ILO classification of each CXR was provided on the form, so that the frequency with which categories other than 0/0 were reported could be used as an early warning of CXR changes, and which could also be used for health monitoring.

During the review, the DNRM advised that NMAs have been issued with an amended form (dated 01/05/16) that includes additional instructions about: the category of coal mine workers who require a CXR; qualifications for individuals conducting spirometry and CXRs; and the standards for interpreting/reporting these tests including the use of the ILO classification.

7.2 Completion and quality

Current situation

The respiratory component of the current health assessment form was compared with the fields included in a sample of 91 records extracted from the DNRM database.

In general, this sample from the DNRM database captured most of the respiratory component. However, a number of important questions were often omitted, including:

- Section 2.2 - work history;
- Section 2.3 - health-related history, in particular whether a previous medical had been completed under the scheme and date of the last examination;
- Section 2.4 - past medical history, in particular asthma, bronchitis or other lung diseases and abnormal shortness of breath or wheezing;
- Section 3.12 - quality of CXR film and whether it was attached to the report;
- Section 3.18 - fitness for duty in relation to working under various conditions such as underground, in dusty conditions and while wearing RPE;
- Section 4 - NMA explained restriction or additional assessment for the worker.

In addition, other past medical history from section 2, such as tightness of chest and allergic reaction or reaction to chemicals or dust, are relevant to the respiratory system and therefore should be included in the DNRM database.

The information contained in the sample of 91 health assessment forms was also assessed for completeness and quality. Completeness was ascertained by the proportion of dataset fields that required an entry that were provided, for example worker's date of birth. Quality was determined by the proportion of fields that were internally consistent, for example the consistency of entries for duplicate questions.

Full quantitative results from the review of completeness and quality are presented in Appendix 4.

We found that the medical information was largely complete. However, some fields were consistently incomplete or poorly completed.

Limitations

The employer's section of the form was poorly completed. This may in part be due to workers being required to complete a health assessment prior to being employed. This is problematic in that the job may be unknown, particularly where contractors are involved, and so the appropriate decision about whether a CXR is needed cannot be made.

The SEG to which the coal worker's position was allocated was a required field from November 2010. The generic SEG was only provided in a minority (4/21) of medicals and company SEGs were not completed in any of the health assessments. Some employers reported that section 1 is usually completed by a human resources staff member or their NMA, in which case they are provided with a list of SEGs. In other companies, this is the role of the line manager. This creates a potential for miscommunication, as NMAs (or labour hire companies) may not consider themselves as the "employer" for the purposes of completing section one.

Other important fields that were poorly completed were questions about dust exposure and whether the assessment was for working underground.

Some of these questions overlapped or were duplicated. Question 1a, "Dust exposure (x-ray needed?)" corresponded with questions 3.12 "CXR undertaken". Although "y" was entered for question 3.12 in all 91 medicals, over one-third (38%) of entries for question 1a did not correspond, and had either "N" entered or were left blank. Question 1b, "underground work" corresponded with a question in the report (section 4), "Is the assessment for underground work?" Almost one-third (27%) of the responses in section 4 did not correspond with the responses for question 1b.

Another field from section 1 that was poorly completed was the name of the mine. Although all 91 medicals had this field completed, approximately one-third (36%) had quality limitations, with either "Unknown" or "Various mines" entered for this field. It is possible that the term "Unknown" is because these were workers seeking employment and "Various" was used where the worker is a contractor or labour hire employee.

The remaining notable quality issues related to the EMO's details in section 4, for which surnames alone were entered for fifty-seven out of fifty-nine medicals, and details of restrictions on work activities in section 4, from which it was not apparent whether the restrictions were required for CMDLD, as it is the current practice not to include any medical information in section 4.

In some cases the free text boxes throughout the form had been completed in illegible handwriting.

Targeted auditing, which could be conducted in several ways, would reduce the poor completion of the forms. For example, an audit of the first batch of health assessment forms completed by new NMA, and a random sample of assessment forms completed by more experienced NMAs. For example, with the (recently ceased) WA system, approvals to undertake mining employees health surveillance was revoked if an unacceptable number of poor quality forms were submitted.

8. Risk from dust exposure requiring a surveillance CXR

Current situation

When a coal mine worker is sent for a health assessment under the current scheme, the employer must specify whether the worker is "at risk from dust exposure" in section 1 of the assessment form. This indicates that a CXR is required as part of the miner's health assessment.

In order to better understand the criteria used to determine coal mine workers "at risk from dust exposure", the review team visited an open-cut and an underground coal mine and a CHPP in Queensland. We had further discussions with health and safety representatives from 11 companies (including 3 labour-hire contractors), and with representatives from the CFMEU.

Who currently gets a CXR?

A recent survey[23] revealed that although all coal mines conduct health surveillance, only 83% of underground mines include CXRs as part of the periodic coal mine workers' health assessments. The majority of open-cut miners were considered not "at risk from dust exposure", however, from a convenience sample of 5,997 DNRM health assessment records, about half of the CXRs were performed for open-cut miners (though the majority, 41 of 54 mines in Queensland, are open-cut).

In discussions, some mine companies identified open-cut jobs such as drilling and blasting, overburden drilling, rock screening and exploration drilling as "at risk from dust exposure", mainly due to exposure from silica rather than coal dust.

Completion of SEGS on the health assessment form

In order to help with the decision about whether a miner is in a dust-exposed job, employers have been required, since November 2010, to specify the relevant SEG in Section 1. Employers may use the DNRM generic SEGs or company SEGs. It is important that the specified SEG accurately reflects the likely dust exposure. Otherwise those who require a CXR may not receive one and those who do not require a CXR may have one unnecessarily.

In the sample of 91 completed health assessment forms examined (discussed in chapter 7.2), 21 were completed after 2010, i.e. when the SEGs were introduced. For these 21, we found that:

1. Generic SEGs were poorly completed, having been provided in only four forms
2. Company SEGs were not completed in any of the forms, so the review team was unable to identify any company SEGs

There were also inconsistent entries for duplicate questions in the health assessment form relating to "at risk from dust exposure" criteria, e.g. dust exposure/CXR needed and working underground.

SEGs were defined recently by the DNRM as follows:[24] "SEGs are groups of workers who have the same general exposure to risk, for example:

- the similarity and frequency of the tasks they perform
- the materials and processes with which they work
- the similarity of the way they perform those tasks"

Table 2: Mines inspectorate SEG listing (from the DNRM information sheet)[6]

Underground Coal Mines SEGs	Task descriptions
Longwall production	Employees and contractors: • Operating shearer, maingate, chocks • Undertaking roof support, hanging/changing cables and hoses • Performing belt retraction, operating driftrunner and LHD
Development production	Employees and contractors: • Operating continuous miner, driftrunner, shuttle car, LHD, ram car • Undertaking roof and rib bolting • Hanging hoses, handling cables, hanging vent tubes, performing belt extensions, hanging brattice
Underground maintenance	Employees and contractors: • Performing mechanical maintenance services underground • Performing electrical maintenance underground • Undertaking mechanical repairs and vehicle servicing underground
Outbye supplies	Employees and contractors delivering supplies to underground locations on LHDs
Longwall moves	Employees and contractors operating dozers, LHDs, drift runners performing face retraction and installation. Any employees and contractors involved in the face retraction/ installation including fitters, electricians and mine technicians
Outbye construction/ infrastructure	Employees and contractors: • Operating grader, drift runner, LHD • Changing hoses, cables, tyres, lights and pipe work • Hanging hoses, pipes and cables • Undertaking roof and rib bolting, shovelling, secondary support, concreting underground
VCD installers	Employees and contractors spraying stoppings and using jackhammer
ERZ controllers	Employees and contractors performing inspections and statutory duties
Surface maintenance	Employees and contractors servicing/maintaining vehicles in surface workshop
Control room operator	Employees and contractors involved in control room operations
Belt splicers	Employees and contractors performing belt maintenance, splicing and commissioning
Boilermakers (surface)	Employees and contractors involved in steel fabricating, welding, oxy cutting, air gouging—surface workshop and CHPP workshop
Administration	Administration officers; stores; management
Resin Workers	Employees and contractors undertaking resin injection and void filling activities throughout the underground workings. This includes the use of polyurethane resins (PUR) and phenolic resins.
Stone Driveage	Employees and contractors involved in mining through stone, faults and intrusions. Generally this is for the purpose of mine expansion or drift construction. This does not include development or longwall workers who from time to time encounter small areas of faulted ground or stone banding.
Open-cut Coal Mines SEGs	**Task descriptions**

Pre-strip and overburden removal	Employees and contractors working in pre-strip areas of the mine and operating equipment (e.g. haul trucks, loaders, dozers, graders and excavators)
Coal removal	Employees and contractors involved in the removal of product coal (e.g. digger/shovel, dump trucks)
Open cut inspection services	Employees and contractors performing inspection and monitoring tasks in the mining and excavation areas (e.g. OCE and shift supervisors)
Road maintenance	Employees and contractors involved in road maintenance operations including grader and water truck
Boilermaker	Employees and contractors involved in steel fabricating, welding, oxy cutting, air gouging—surface workshop and CHPP workshop
Field Maintenance	Employees and contractors undertaking electrical and mechanical maintenance activities in the mining areas.
Blast crew	Employees and contractors undertaking blasting and shot firing duties
Tech services	Employees and contractors performing mine planning and design (includes surveyors, geotechnical engineers)
Exploration drillers	Employees and contractors undertaking exploration drilling operations
Blast hole drillers	Employees and contractors undertaking blast hole drilling operations
Belt splicers	Employers and contractors performing belt maintenance, splicing and commissioning
Warehousing	Employees and contractors undertaking warehousing activities including forklift operation
Administration	Administration officers; stores; management
Workshop	Employees and contractors undertaking electrical and mechanical maintenance and services in the workshop
Service crew	Employees and contractors supplying fuel, grease and oil to mobile plant throughout the mine.
Tyre fitters	Employees and contractors performing tyre handling, tyre fitting and tyre repair duties.
CHPP SEGs	**Task descriptions**
CHPP production	Employees and contractors involved in control room operations, hosing, clearing blockages, shovelling, bobcat ,general maintenance and train loading out
CHPP maintenance	Employees and contractors undertaking electrical and mechanical maintenance throughout the plant and in the workshop
CHPP laboratory	Employees and contractors taking samples and processing samples in CHPP laboratory
CHPP dozer	Employees and contractors operating CHPP stockpile dozer
Belt splicers	Employers and contractors performing belt maintenance, splicing and commissioning

The DNRM document lists generic SEGs in underground mines, open-cut mines and in CHPPs [24] (see Table 2). These SEG categories were devised by the Safety in Mines Testing and Research Station (SIMTARS), based on measurements of coal mine dust. A 2010 Queensland Government report contains the results of a survey, conducted on behalf of the DNRM, which revealed that only 39% of mines had implemented dust monitoring programs, characterised dust exposure and established SEGs.

The 2010 report also indicated that 11% of mines did not carry out monitoring, a further 26% monitored annually or less frequently, 31% only monitored on the day shift and only 25% adjusted the TWA for extended shifts.[6]

The Queensland Government dust self-assessment feedback report (2010)[6] stated that 76% of coal mines identified respirable silica as a hazardous dust at their site, and 29% identified that respirable coal dust might be a problem. Some company representatives reported that exposure monitoring for these dusts (performed outside respiratory protective equipment) are used to define SEGs.

SEGs are clearly useful to guide decisions about dust exposure monitoring and where dust control measures should be applied and to track exposure changes over time or when new processes or equipment are introduced. Therefore, conclusions about the use of SEGs for the purposes of deciding on requirement for CXR should not impact on the use of SEGs for these other important dust monitoring and control functions.

Limitations

The criteria to determine jobs "at risk from dust exposure" are not explicit in the regulations. The DNRM also do not specify which generic SEG categories fulfil these conditions. All underground workers (probably 13 of 15 underground SEGs) are likely to experience dust exposure, but some above-ground workers at underground sites, some open-cut miners and some workers at CHPPs may also be at risk.

It is unclear who decides which SEGs qualify as "at risk from dust exposure". This may depend on measured exposure data, but the companies varied in their approach. For example, several mine companies had a formal trigger, where recorded dust exposure exceeded the OEL or half the shift adjusted OEL (see Table 3).

Table 3: Company XXX corporate standard control categories (SIMTARS report)

Category	Personal exposure level	Control Zone
A	Exposure exceeds the OEL	**Intervention**
B	Exposure between 50% and 100% of the OEL	**Control**
C	Exposure between 10% and 50% of the OEL	**Supervisory**

In addition, dust generation at the mine may depend on the strata and whether the mine has been degassed. The use of a variety of dust control technologies also leads to situations where dust exposure for similar job categories may vary from mine to mine and between different coalfaces within a mine.

NMAs rely on the information completed by employers (including completion of the SEG information) in section 1 of the form to guide the decision about whether a coal miner requires a CXR, but there is generally no guidance for NMAs about the application or implication of SEGs. Several company health and safety representatives agreed that the decision about who required a CXRs and how frequently, should be the NMA's rather than the employer's decision. They also agreed that NMAs should be supported with training about SEGs and job categories with potential for high dust exposure.

Furthermore, workers' complete employment history, not just the job at the current health assessment, should also be taken into account when deciding about the CXR, because the likelihood of developing CMDLD is determined by cumulative exposure to dust over the whole working lifetime. This is particularly relevant to contractors (such as general labourers), who are more likely to have been employed in a range of jobs across various mines, and therefore deployed to different SEGs. In other words, the occupational history should identify the duties and tasks that have been performed.

The use of SEGs to categorise dust exposure has some merit, but is complex to operationalise. Even after taking into account workers' transition between different SEGs, SEGs themselves may change due to changes in dust levels when production or control measures change, and contractors would not necessarily have access to a company's dust monitoring data.

The SEGs should take into account silica as well as coal dust, as the exposure limit for silica is much lower than that for coal dust, so is more easily breached.

Lastly, if SEGs are used to define "at risk from dust exposure" they should be revisited and updated regularly if there are changes in the mine anticipated to change the dust exposure of jobs in the SEGs, e.g. strata, production methods or rates, and dust control measures.

9. Nominated Medical Advisers

We reviewed the list of NMA currently registered with the HSU. We examined their qualifications and their geographical coverage, and the information kit provided to newly-registered NMAs. We also had discussions with mine company health and safety and CFMEU representatives about their NMA appointment process, and how coal mine workers are referred to NMAs.

Current situation

Nominated Medical Advisers – Total number, clinic type and qualifications

In total, there are 237 NMAs registered to conduct the coal workers' health assessments. The NMAs practise in over 140 clinics and are based in five different States (see Appendix 5 for further details). Some NMAs practice in more than one clinic. The number of NMAs expanded during the mining boom (after 2005), but prior to this there were approximately 40 NMAs.

General Practitioners (GPs) accounted for 62% of NMAs, while specialist Occupational Physicians constituted the smallest proportion at 12%. Non-specialists or medical practitioners with general registration accounted for the remaining 26% of NMAs.

There were two main types of clinics in which the coal mine workers' health assessments were conducted, GP clinics and Occupational Health Service clinics. However, there were more than twice as many GP clinics as Occupational Health Service clinics (97 vs. 43).

The majority (about 90%) of NMAs and clinics are in Queensland. Although the coal workers' health assessments are undertaken in 28 different Queensland regions, these activities were concentrated in five main regions: Brisbane/Brisbane City, Mackay, Sunshine Coast, Rockhampton and the Gold Coast (Table 4 and Figure 3). The majority of these sites are a considerable distance from the mines and likely to cater for fly-in fly-out (FIFO) workers.

Table 4: Main locations of NMAs in Queensland, in 2015

Region	Occupational Physicians	General Practitioners
Mackay	2	28
Rockhampton	2	14
Sunshine Coast	0	14
Brisbane/Brisbane City	10	33
Gold Coast	1	8
Total	**15**	**97**

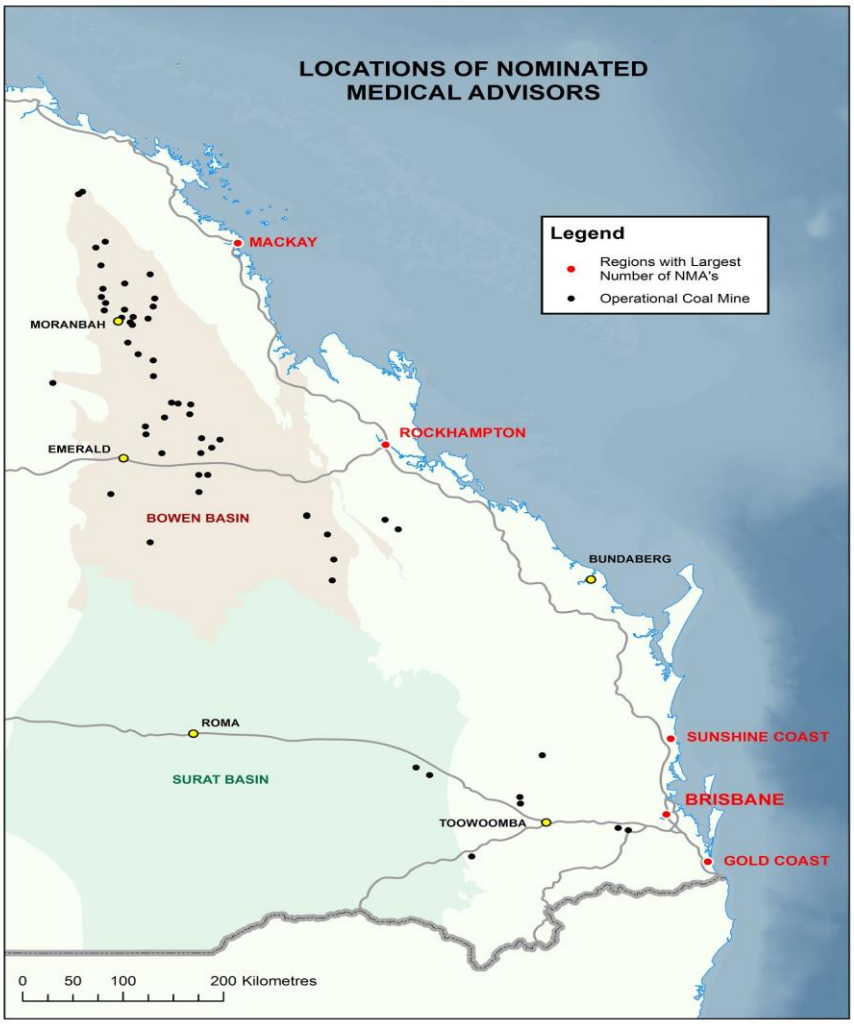


Figure 3: Underground mine and main locations of NMAs in Queensland (Figure courtesy of DNRM)

Nominated Medical Advisors - registration and training

There is no formal system for vetting the addition of NMAs to the list held by the DNRM, and selection of NMAs is at the discretion of the mine companies, contractors and labour hire firms. However, new doctors selected to become NMAs must be notified to the HSU.

The company and CFMEU representatives reported that though companies may have corporate medical advisors, NMAs are appointed by the specific mine sites, and in most cases are the local GPs. There may be up to two NMAs employed by companies per mine site, however labour-hire organisations tend to employ larger numbers of NMAs to cater for the geographical spread of their employees. For example, one company reported a pool of 20 to 30 medical advisers.

EMOs often perform the actual health assessments and complete section 3 of the form, but this is then forwarded to the company NMA to complete section 4. In this situation, the NMA has not collected the health information him/herself and so relies on the accuracy and quality of the information collected by the EMO or other health practitioners.

There is currently no formal training of NMAs prior to being registered to undertake coal mine workers' health assessments. However, regular meetings with NMAs were previously conducted by DNRM prior to the expansion of the number of NMAs during the mining boom. In addition, NMAs are not required to hold any specific qualifications apart from being a registered medical practitioner. Instead, the DNRM furnishes newly registered NMAs with an information kit. The current version (dated 24/2/15) is an 18-page document which outlines the process of the coal mine workers' health scheme, and an enclosed appendix illustrates examples of work restrictions relevant to nominated medical conditions, such as manual handling weight restrictions for musculoskeletal injury and diminished cardiovascular fitness. With respect to respiratory conditions, the information kit advises that individuals with chronic obstructive airways disease and pneumoconiosis are to avoid exposure to irritant airborne contaminants (including dusts) and should not work underground. However, there are no instructions or clinical standards to guide further evaluation and follow-up of abnormal clinical findings or newly diagnosed medical conditions, so the focus is mainly on fitness for work. NMAs are also advised not to disclose medical conditions on section 4.

Some companies reported a preference for NMAs with occupational medicine qualifications, but reiterated that local knowledge and mine proximity was important. In addition, most companies stated that they offered site visits for NMAs, particularly to their underground mines.

Limitations

There are currently too many NMAs on the HSU list who are eligible to perform health assessments under the current scheme. The inclusion of EMOs makes the pool of medical providers even larger. This situation has created challenges for the HSU in maintaining an accurate and up-to-date register of NMAs, especially as companies may not inform the DNRM of changes in appointments. Due to the large number of NMAs and the diverse geographical spread, it became more difficult to co-ordinate (previously held) NMA meetings and training and these are no longer held.

NMAs are advised to visit the mine sites for which they will be providing health assessment services under the scheme, but this is not mandated. Experienced medical providers working near the mines and/or those with specialist training in occupational medicine are likely to be familiar with hazards and risks specific to the coal mining industry. However, for many of the NMAs without a good knowledge of a coal mine worker's particular work environment, there are likely to be limitations in the conduct and quality of respiratory health assessments.

A large group of medical providers (NMAs and EMOs) with diverse qualifications and experience practising in a variety of clinic settings is likely to have further negative impact on quality assurance.

The lack of initial or ongoing training for NMAs is particularly concerning. There is currently no means of assessing NMAs' understanding of the content of the NMA information kit or its appropriate application, and no ongoing audit of NMAs' performance, apart from an administrative review at HSU. The main purpose of the information kit is to provide administrative procedures for conducting health assessments, rather than information about CMDLD or medical guidelines. There is no information in the kit about the primary purpose of the Coal Mine Workers' Health Scheme and no explicit instructions about the early signs of CMDLD, nor about procedures for clinical management/referral for suspected CMDLD cases.

Under the Regulations, the role and qualifications of the EMOs are undefined in the scheme, and EMOs are not required to be notified to the HSU. Given that more training and selection processes should be required for NMAs undertaking respiratory health assessments, allowing comparatively less trained EMOs to carry out the respiratory examination would continue to be a major weakness. Several companies highlighted the lack of quality control introduced by reliance on EMOs, especially where they are unfamiliar with mining work environments and the principles of health surveillance. However, they acknowledged that mine workers especially FIFO mine workers prefer to go to their local GPs, who may be an NMA or EMO, to conduct their health assessments.

10. Chest x-ray review

The purpose of this review was to identify deficiencies in the chest imaging component of the Coal Mine Workers' Health Scheme which may have contributed to the failure to identify early changes of CWP.

Sample size

The sample size of the number of coal miner CXRs required for the x-ray review was calculated[2] based on an estimated 3% prevalence of CWP (≥ 1/0 category by the ILO CXR classification system) among Queensland coal mine workers currently employed at a Queensland mine with more than 10 years of coal mine employment.

This estimate for prevalence is comparable to that reported by Blackley and colleagues [25] among underground coal miners in Kentucky, Virginia, and West Virginia, who participated in the USA Coal Workers' Health Surveillance Program between September 2005 and December 2012. A related study[26] found a 2.7% prevalence of at least ILO category 1 small opacities among coal workers who participated in the NIOSH surveillance program between 2000 and 2008. Based on these estimates, a sample size of 452 CXRs was determined to have enough power to detect a 3% prevalence of pneumoconiosis defined as ILO category 1/0 or greater.

The review team considered it important to include CXRs from as many mines as possible for this review. As some of the mines are small, the calculated number of CXRs needed was small and may not be representative. We therefore chose to request a minimum of 25 CXRs from each mine. The total requested was 478 CXRs. In addition, there are mine workers who are employed by contractors and work across different mines. We received 50 additional CXRs of miners for whom no mine was specified. It is likely that these CXRs were from miners who worked at a number of different mines. Ultimately, the total number of CXRs requested from DNRM was 528. The number of requested CXRs for coal miners from each mine is shown in Table 5.

[2] The formula used for this calculation is $\mathbf{n = (Z^2 \times P(1 - P))/e^2}$, where Z = value from standard normal distribution corresponding to desired CI (Z=1.96 for 95% CI), P is expected true proportion, and e is desired precision (half of the desired CI width).

Table 5: Number of CXRs by mine (numbers supplied by DNRM)

Mine	Number of mine workers[a]	Sample size	Number received	Number missing
Aquila – N/A	0	-	2	0
Broadmeadow	**683**	63	13	50
Carborough	314	27	14	13
Cook	362	32	25	7
Crinum – *closed*	223	25	13	12
Ensham	209	25	10	15
Grasstree	639	59	18	41
Grosvenor[b]	249	25	2	23
Kestrel	536	50	39	11
Moranbah North	649	59	15	44
Newlands	109	25	10	15
North Goonyella	275	27	6	21
Oaky No. 1	248	25	7	18
Oaky North	386	36	29	7
Mine Not Specified	N/A	50	50	0
Total	**4,887**	**528**	**253**	**277**

[a] Number of employees reported at the mine as of November, 2015.

[b] Mine with new development and therefore very few miners with 10 years of exposure.

Protocol for CXR review

1) ILO Classification

Small scars caused by the body's reaction to coal mine dust inhalation may manifest as small opacities seen on CXR. CXRs were classified according to the ILO Classification of Radiographs for Pneumoconiosis.[3] Briefly, this classification system is used to characterize opacities consistent with pneumoconiosis through the comparison of the chest radiograph of interest with standard radiographs issued by the ILO. Small opacities are described by their profusion (the number of opacities); affected zones of the lung; and their size and shape (rounded or irregular). Of these characteristics, the key item for the purpose of deciding whether pneumoconiosis is present is the profusion, which is rated on a 12-point scale. Digital radiographs from the worker are classified by comparison to the appropriate digital image from the ILO 2011D standards; analogue films are classified by comparison to the ILO 2000 analogue standards. A copy of the NIOSH reporting form can be found at: http://www.cdc.gov/niosh/topics/surveillance/ords/pdfs/CWHSP-ReadingForm-2.8.pdf.

2) Use of multiple certified B-readers

All images were classified by two NIOSH certified B-readers[3] in a protocol detailed below. An additional three B-readers were available for additional readings when the primary readers did not agree.

The following is a list of B-Readers who participated in this review.

1. Robert Cohen, MD, FCCP – Respiratory physician, B-Reader. NIOSH Project Officer, American College of Radiology Pneumoconiosis Task Force
2. Kathleen DePonte, MD – Radiologist, B-Reader. Member of NIOSH Coal Worker's Health Surveillance Panel, Member of American College of Radiology Pneumoconiosis Task Force
3. Edward Lee Petsonk, MD – Respiratory physician, B-Reader. Professor of Medicine, West Virginia University, Member of NIOSH Coal Worker's Health Surveillance Panel, NIOSH Project Officer for American College of Radiology Pneumoconiosis Task Force
4. David Lynch, MD – Radiologist, B-Reader. Professor of Radiology, National Jewish Health, University of Colorado School of Medicine, Denver Colorado. Member of NIOSH Coal Worker's Health Surveillance Panel, Member of American College of Radiology Pneumoconiosis Task Force
5. Jack Parker, MD – Respiratory physician, B-Reader. Chairman, Division of Pulmonary and Critical Care Medicine, West Virginia University. Member of NIOSH Coal Worker's Health Surveillance Panel

3) Classification of CXR quality

1. Good.
2. Acceptable, with no technical defect likely to impair classification of the radiograph for pneumoconiosis.
3. Acceptable, with some technical defect but still adequate for classification purposes.
4. Unacceptable for classification purposes.

4) Classification of small and large opacity (presence and profusion) and reaching a final determination

1. Two classifications were considered to be in agreement if one of the following occurred:
    a. Both found one or more large opacities of 1 cm in size or greater consistent with complicated pneumoconiosis (category A, B, or C);
    b. Both found small opacities of less than 1 cm in size consistent with simple pneumoconiosis in the same major category (category 1, 2, or 3);
    c. Both classifications with finding of small opacities were within one minor category of each other, in this instance the higher minor category is selected (see ILO Classification 12-point scale, Table 6) except if there was a reading sequence of 0/1, 1/0, or 1/0, 0/1, which was not considered agreement; or,

[3] Note: B-readers are licensed medical practitioners who have been trained to classify images according to the ILO system and who have successfully passed an exam offered by the US NIOSH every 4 years.

d. Both classifications were negative (i.e., 0/-, 0/0, or 0/1) for opacities consistent with pneumoconiosis.

2. If there was agreement between the two classifications, as described above, the result was considered a final determination and reported.
3. When agreement was lacking, a third classification was obtained. If any two of the three classifications demonstrated agreement, the majority result was considered the final determination.
4. If agreement was lacking among the three classifications, independent classifications were obtained from two additional B-Readers and the final determination was the median category derived from the total of five classifications.

Table 6: ILO scale for classifying CXRs for pneumoconiosis

Opacity Size[a]	ILO Category	Classification of Pneumoconiosis
None	0/- 0/0 0/1	Negative
Small (<10 mm)	1/0 1/1 1/2 2/1 2/2 2/3 3/2 3/3 3/+	Simple
Large (≥10 mm)	A B C	Complicated

[a] As measured by the short-axis diameter.

5) Comparison of the final determination with the original reports on the x-rays to determine if there was a qualitative agreement

a. The original radiologist reports were reviewed by at least one qualified occupational pulmonologist. The vast majority of these reports did not use the ILO classification. For this reason, the reports were reviewed to determine if the radiologist recognized features consistent with pneumoconiosis and indicated this on the report.

b. The radiologist reports were categorised as:
(0) No report available
(1) Normal
(2) Abnormal with small opacities suggestive of simple pneumoconiosis
(3) Abnormal with large opacities suggestive of complicated pneumoconiosis
(4) Other abnormality reported, not suggestive of pneumoconiosis

c. The Coal Mine Workers' Health Scheme radiology report was considered to be in agreement with the final ILO reading by the CXR reviewers as follows:

(1) Normal – ILO categories 0/-, 0/0, or 0/1
(2) Suggestive of simple pneumoconiosis – ILO categories 1/0 through 3/+
(3) Suggestive of complicated pneumoconiosis – ILO category A, B, or C
(4) Other abnormality not suggestive of pneumoconiosis – ILO categories 0/-, 0/0, or 0/1

d. The NMA's final report was reviewed to determine if the NMA had reviewed the radiology report and made the appropriate recommendation with regard to fitness for work.

6) Report back to the DNRM

The DNRM are to receive the results, and have advised they will make arrangements to notify the relevant NMA, physician or individual, where there has been a finding through this review process.

Results

Originally, the DNRM provided 268 film prints of digital CXRs, which could not be used for the review because film prints of digital images are unreliable in the accurate assessment of the presence of pneumoconiotic opacities. The DNRM also provided 50 digital images in a time frame that was too late to be included for this report, but which will be evaluated later.

The results described here are of digital CXR images from 257 miners provided by the DNRM in time for this report. These images were selected for miners who met the eligibility criteria of 10 years of coal mining experience. CXRs received were taken between June 2009 and January 2016. Table 5 indicates the mines from which these CXRs were sourced. As shown in the table, while CXRs were sourced from every mine, several of these mines were represented by fewer than 10 CXRs (mainly the smaller mines). Also, less than 50% of requested CXRs from the following mines were able to be accessed by the time this report was issued: Broadmeadow, Ensham, Grasstree, Grosvenor, Moranbah North, Newlands, and Oaky Creek No. 1.

1) Quality Review

a. ILO Image Quality

Review of the ILO image quality scores showed that only 25% of CXRs were Quality 1, 55% were Quality 2, 19% were Quality 3, and 1% were Quality 4. The CXRs that were rated Quality 3 had technical defects that to some extent affected the ability to classify the images, although it was felt that classification was still possible. Images of Quality 3 should represent a much smaller proportion of CXR images in a surveillance program. Observed technical problems with the CXRs included images with poor positioning, (such as exclusion of portions of the lungs in the image or overlap of the lung fields by the shoulder blades), poor contrast, and excessive edge enhancement. These issues can make it difficult to accurately detect the small opacities of pneumoconiosis. Unfortunately, these technical problems cannot be resolved by manipulation of the digital images after image acquisition and processing has taken place.

b. Image Processing

Fifteen percent of the images that were reviewed had quality issues related to processing. Digital radiographic images undergo processing after acquisition. This "post processing" is performed at the radiographic unit in accordance with pre-programmed parameters set by the manufacturer, some of which are able to be modified by the user, according to user preferences. Typically, once these parameters are set at the radiographic unit for a specific type of examination, they are not changed on an individual patient basis. A digital receptor (which may be either a computerized radiography cassette or digital radiography detector) captures the image, and then the image is processed and sent to the Picture Archiving and Communication System (PACS) to be viewed and interpreted by the radiologist. While the radiologist can adjust some viewing settings, such as window and level (contrast and brightness) and magnification, he/she cannot undo or change the other elements of image processing at the PACS workstation.

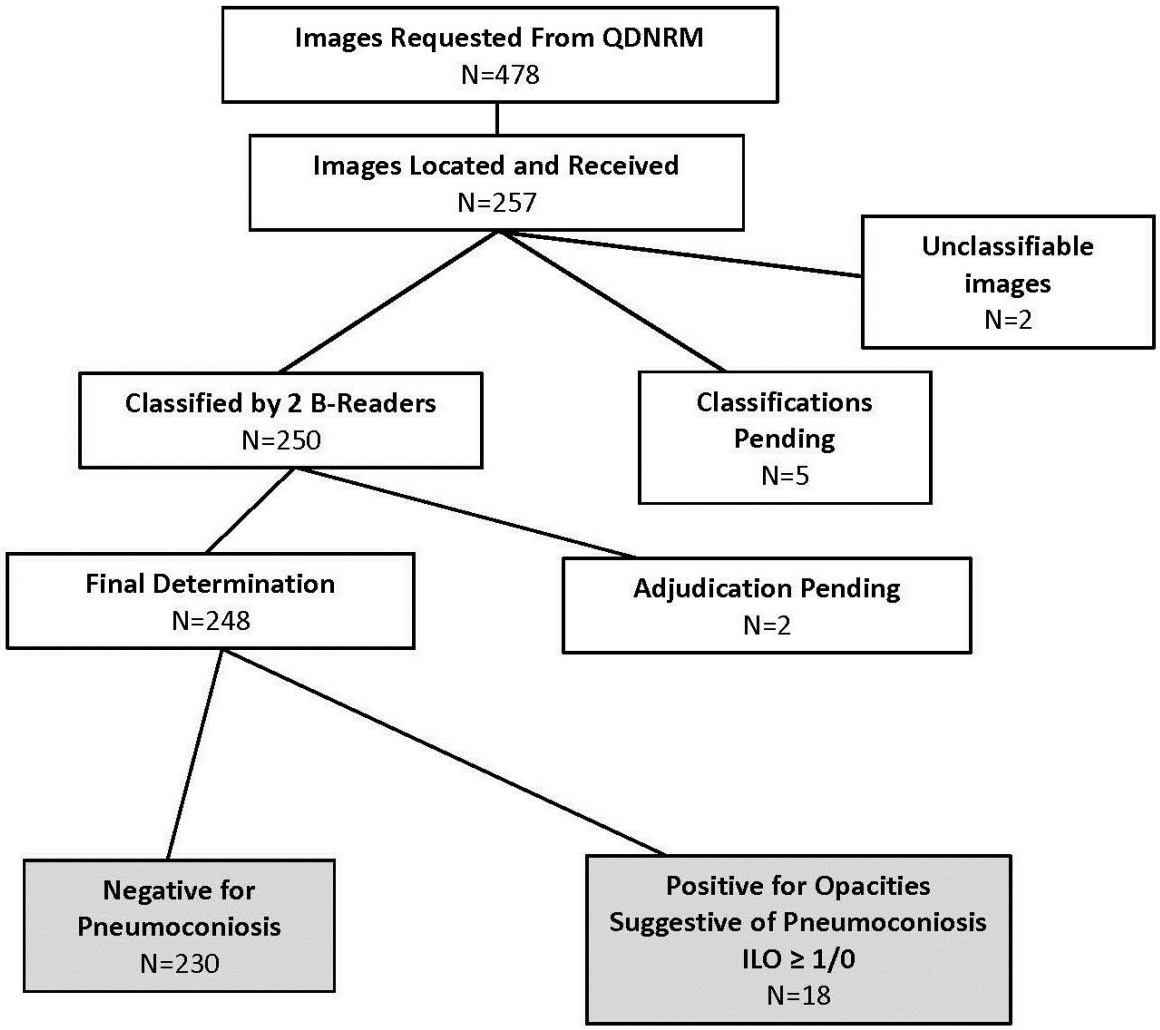
Post processing has evolved and improved over the years. The post processing modifications were developed with the primary purpose of improving the visibility of pathological changes. Initially these were primarily edge enhancement (unsharp masking) and noise reduction. More complex image-processing algorithms have been developed over the years to allow for optimal display of the wide dynamic range in radiographic images, particularly in chest films. Today's algorithms are more complex, but fundamentally have the same objective − to allow for better visualization of subtle pathology. While the image is enhanced to better display pathology, the same parameters also display normal structures more prominently and the reader must be able to recognize the subtle effects of image processing to separate anatomy from artefact. In the case of chest films, some image processing protocols will result in a "grainy" appearance to the lungs simulating certain types of small opacities. The radiologist who has set the image processing parameters to his/her preference and is used to this appearance as normal will recognize this appearance as normal. However, the same study, when sent to a different reader, may be interpreted as interstitial disease consistent with pneumoconiosis.

2) Presence or Absence of Pneumoconiosis

The CXRs were transmitted electronically to reviewers. All images were read according to the protocol described above. Given difficulties in receiving images in a timely fashion, only 250 images were classified by the time of this report (see Figure 4). Final determinations were obtained on 248 miners. Two CXRs were classified as unreadable (Quality 4).

Major Findings: No miner was found to have large opacities suggestive of complicated pneumoconiosis or progressive massive fibrosis. No miner was found to have small opacities consistent with of advanced or high-category (i.e., $\geq$ 2/1) simple pneumoconiosis. There were 18 miners, of the 248 (7.3%) with final determinations, whose CXRs were classified as having opacities at a profusion consistent with category 1 simple pneumoconiosis i.e. ILO classifications of 1/0, 1/1, or 1/2. Given the quality issues identified above and the possibility of emphysema resulting in irregular small opacities, it is recommended that these individuals undergo high resolution CT scanning prior to making a final diagnosis.

Figure 4: Flow chart of CXR review results



3) Comparison with Radiology Reports and NMA Reports

The radiology and NMA reports were analysed to determine whether or not the changes of pneumoconiosis were recognized and to determine if further action was taken. The results are shown in Table 7.

Three radiologist reports were not available for our review, leaving 15 reports. This comparison showed that only 2 out of these 15 (13%) CXRs identified by the reviewers as having features consistent with simple pneumoconiosis by chest radiograph were identified by the original radiologists as having interstitial abnormalities that could possibly be interpreted as evidence of pneumoconiosis. A number of these CXRs had irregular opacities. Irregular opacities have been well described in CWP,[27] although they may also occur with emphysema. The remainder (n=13) were classified as normal by the original radiologist. In neither case where possible pneumoconiosis was identified by the original radiologist did the NMA record a finding about possible CWP, nor was any recommendation made regarding fitness to work from a respiratory point of view.

Table 7: Comparison of findings of radiology reports and NMA assessment of the reports for those cases identified by the reviewers as having a final determination ≥ ILO category 1/0.

Case	Small Opacity Profusion	Radiologist Report	NMA Assessment of Report	NMA Action
1	1/0	Normal	Normal	Fit
2	1/0	Not available for review	None	Fit
3	1/0	Normal	Normal	Fit
4	1/0	Normal	Normal	Fit
5	1/0	Normal	Normal	Fit
6	1/0	Normal	Normal	Fit
7	1/0	Not available for review	None	Fit
8	1/0	Abnormal (Consistent with pneumoconiosis)	None	Fit
9	1/0	Normal	Normal	Not fit (right knee injury)
10	1/0	Normal	Normal	Fit
11	1/0	Not available for review	None	Fit
12	1/0	Normal	Normal	Fit
13	1/1	Abnormal (Consistent with pneumoconiosis)	None	Not fit (hearing, vision)
14	1/1	Normal	None	Fit
15	1/1	Normal	Normal	Fit
16	1/1	Normal	Normal	Fit
17	1/1	Normal	Normal	Fit
18	1/2	Normal	Normal	Fit

4) Findings from an additional Queensland radiology review

One coal mining company previously commissioned a review of all CXRs of its active miners, which was performed in 2015 and early 2016. Nearly 200 CXRs were reviewed using the same protocol we used in this study. Significant quality issues similar to those observed in the current review were identified. Although CT scans are generally **not** needed to make a radiographic diagnosis of pneumoconiosis, given the quality issues of those CXRs, miners with final determinations of simple pneumoconiosis were offered high-resolution CT (HRCT) scans to confirm the presence or absence of pneumoconiosis. While some of the CXRs had opacities that were verified by HRCT, the majority of these miners had negative HRCTs, so the quality issues of the CXRs led to over-reporting of simple pneumoconiosis. This is an important finding to assist in interpreting the findings in the current review.

11. Spirometry review

Spirometry is a standard investigative technique to assess lung function and is required for respiratory health assessments performed under the scheme. The aims of the review of spirometry procedures and testing were to:

1. Audit the spirometry equipment, quality control procedures and training and qualification of the spirometry technicians performing spirometry under the scheme.
2. Assess the quality of spirometry conducted as part of the current scheme for a sample of 258 coal mine workers.

The spirometry review therefore consisted of two components, which are discussed separately below.

11.1 Survey of spirometry equipment and training

We developed an online questionnaire to obtain information about spirometry testing, including the equipment used and their calibration procedures, and the qualifications and training of testers. A link to this online survey was distributed by the DNRM to all currently listed NMAs. The questionnaire is attached as Appendix 6 and participants' responses are summarised in Appendix 7.

Approximately one-third (74) of currently listed NMAs completed the online survey by the due date.

Results

Based on the responses, spirometry is mainly performed in GP (62%) or Occupational Medicine clinics (38%). Testing is primarily administered by registered nurses (77%) and medical practitioners (9%), but the qualifications of other staff performing spirometry include science graduate, GP and administration staff.

Forty percent of testers had over 10 years' experience in performing spirometry, however they conducted these tests infrequently. Only about a quarter performed more than 20 spirometry tests per month as part of the Coal Mine Workers' Health Scheme and more than 20 additional tests per week. Of the registered nurses performing spirometry, about a third had up to 5 years' experience, and approximately 20% performed 20 spirometry tests for the Coal Mine Workers' Health Scheme per month and more than 20 additional tests per week. In comparison, an accredited respiratory laboratory performs 15-20 spirometry tests per day (Professor Bruce Thompson, personal communication).

Spirometry training was limited. Approximately two-thirds of testers had attended a training course, but one-third were unable to specify the year this training was completed. Furthermore, 23% had completed their training more than three years ago. The National Asthma Council was the most frequently mentioned training course provider (35%), however just over one-fifth of responders could not nominate their training course organisation. Of the registered nurses

performing spirometry, only 42% had undertaken a spirometry training course and could recall the name of the course.

The limited training may contribute to the poor knowledge of the spirometry equipment, including quality control measures. One quarter of respondents did not know whether their spirometer had automated quality control, 10% were unsure how many manoeuvres were stored for each person tested and almost half did not know the reference values used by their equipment. On the other hand, every NMA reported their spirometers produced flow-volume graphical display and approximately 84% reported their spirometers stored 3 or more manoeuvres for each person tested.

Overall, the reported quality control and assurance of spirometry testing needs to be improved. For example, although 79% of spirometers were reported to have had a calibration check, most (66%) had not been calibrated in 2016. This is a significant inadequacy considering devices used in the study require daily calibration checks. Furthermore, only about one-third of spirometry sites participate in ongoing quality assurance programs.

Fourteen percent of sites do not have a post-bronchodilator spirometry routine, 10% did not use a weight measurement device and one respondent did not use a height measurement device during spirometry.

It is concerning that there were a number of other questions that high proportions of responders were unable to answer, for example, a third of respondents did not know the date of purchase of the spirometer. However, we were not certain that the survey was completed by the actual spirometry tester or technician; if more junior staff were involved, they may not know the answers to some of the more technical questions.

In summary, these data indicate that a majority of the spirometry performed under the scheme is likely to be of poor quality and more ongoing training and quality assurance is needed to reach accepted standards.

11.2 Spirometry quality and reading

The review team developed a protocol to examine the quality and accuracy of a sample of 260 spirograms performed under the current scheme. These were received from the DNRM and were for workers from a large number of mines. The protocol is included in Appendix 8**:** . Quality and accuracy of spirometry was assessed by two reviewers, Professor Bruce Thompson and Dr Ryan Hoy, who are both very experienced in interpreting lung function data according to the accepted standards of the ATS/ERS.

Results

In total, 256 spirometry results were evaluated, four others were illegible. Of the 256 spirograms, 102 were deemed to be of poor technical quality, i.e. the spirometry was poorly executed and did not allow meaningful interpretation. If these results are produced in an accredited respiratory laboratory they would be rejected and the tests, repeated.

154 spirometry results were included as they had sufficient demographic data for interpretation. In accordance with ATS/ERS standards, the lower limit of normal (LLN) was determined by the 5th percentile of a healthy, non-smoking population. The NHANES reference values were

used for the analysis. This most likely differed from NMAs' interpretation where pre-defined cut-off values are used to identify abnormality, such as $FEV_1/FVC < 0.70$ indicating airflow obstruction. FEV_1, forced expiratory volume in one second, is a measure of airflow limitation; FVC, forced vital capacity, is a measure of the total lung volume; and the ratio, FEV_1/FVC, is a measure of airway obstruction, i.e. where the airway is closed down and pushing air out of the lungs is impaired. Cut-off values are inaccurate and cause misclassification, specifically under-diagnosis of abnormalities in younger, taller individuals and over-diagnosis in those older or shorter.

Thirty spirometry results were assessed as abnormal, while the majority [n = 124 (81%)] were considered to be within normal limits by the reviewers.

Of the 30 spirograms with abnormalities, six showed mild obstructive disease patterns, and 24 showed "possible restriction" (21 with mild severity, and 3 with moderate severity). The NMA reports accurately identified only two of the abnormal spirometry results, the remaining 29 were reported as normal. These 29 abnormal results were from workers employed at a number of coal mines, however the largest proportion (10) were not registered with a particular mine.

Obstruction implies narrowing of the airways, and is usually the most common pattern identified with spirometry. Restriction implies reduction of lung capacity or volume, though this can only be confirmed with more specific and advanced lung function tests, including static (plethysmographic) lung volumes. Importantly, CMDLD includes both obstructive and restrictive respiratory diseases.

All 124 spirograms assessed as normal by the reviewers were also reported as normal by the NMAs. However, the actual data (FEV_1, FVC, and FEV_1/FVC) extracted from the spirogram by the reviewers and NMAs were consistent for 110 (89%) results. The main reason for lack of agreement was because the NMA did not select the most appropriate values, for example, the best results produced during the spirometry tests.

In summary, less than half of the spirometry results evaluated for this review had been accurately interpreted and reported by NMAs. The results of 130 are essentially unknown, though for different reasons: 4 were illegible photocopies; 102 were poor quality; and 24 showed "possible restriction". The review team recommends follow-up of these results, especially the three coal mine workers with moderate possible restrictive disease. In addition, although the six results that showed obstructive pattern were deemed mild, it is important that these individuals have had recent (and regular) spirometry, as obstructive respiratory disease can progress without appropriate treatment and management.

The DNRM have received the spirometry findings and have advised they will make arrangements to notify the relevant NMA, physician or individual, where there has been a finding through this review process.

Detailed measures to improve the quality of spirometry are provided in Appendix 9.

In addition, the Queensland Health Spirometry Guideline follows ATS requirements and is available at:

https://www.health.qld.gov.au/qhpolicy/docs/gdl/qh-gdl-386.pdf .

12. Health assessment form data handling and storage

We reviewed the system for data handling and storage used by DNRM, including accessibility by the NMAs of previous health assessments, through discussions with DNRM staff members. We also visited the data storage centre at Stafford to inspect and discuss the DNRM database and security arrangements.

Current situation

Data handling

The HSU receives full health assessments, including CXR reports and films from the NMAs by ordinary mail. The hard copy forms are initially checked by the data entry operators for completeness, for example to check that: individual health assessments consist of all seven pages; the worker's date of birth has been recorded consistently; spirometry results have been transcribed onto the appropriate section of the form; and the EMO examination date in section 3 corresponds with the EMO date in section 4. Incomplete and inaccurately completed health assessment forms are returned to the relevant NMAs for amendments. Although original CXR films (or CDs) and spirograms are supposed to be sent with their corresponding health assessments to the HSU, NMAs may not always comply with this requirement. In the case of spirometry printouts, there may be some uncertainty among NMAs about the requirement for these to be sent to DNRM.

Data storage

Prior to the mid-1990s all data from all health assessment forms were manually entered into a database. Since approximately the late 2000s, the forms have been scanned, and more recently only selected variables manually entered into the DNRM database at SIMTARS. The health assessments that are scanned are saved into the data entry operators' files on the SIMTARS hard drive, which is password protected. Individual health assessments files are renamed with the worker's surname and date of birth to aid search and retrieval upon request.

Hard copies of health assessments and CXR films are currently stored in boxes and shelves in storage facilities at three locations: Stafford, Geebung and Eagle Farm.

The storage facility at Stafford was acquired at the end of 2015. Health assessment files are segregated according to the first letter of surnames and each box is also given a numerical ID. The health assessment files are a mixture of records that have been entered but not scanned, those that are scanned but not entered and those that are entered and scanned. The warehouse is secured by a gate which requires a security code and a door which requires an access swipe card.

The storage facility at Geebung is based in a Government department in a privately-owned company, and has been in use from approximately 2011. All health assessment files at this facility have been scanned and entered into the DNRM database. The storage boxes have a barcode and an HSU registration number, and contain up to fifty files (a list of which is enclosed within the box). The health assessments can only be accessed by DNRM staff based at the facility.

The facility at Eagle Farm is used to store archived files, that is, health assessments that were completed between 1983 to the early 1990s. Most health assessments have been entered, but

no health assessments at this facility have been scanned. The files can only be accessed by Eagle Farm staff members. The DNRM database is only accessible by authorised HSU staff members.

CXR films are arranged alphabetically and some are stored separately from their corresponding health assessment files. X-ray wallets with unique registration numbers were previously used to store health assessment records for each worker, however this system ceased when scanning was introduced in the late 2000s. Therefore, the sequential health assessment records for a particular worker are often stored separately.

According to the 2015 Queensland Mines and Quarries annual report,[28] of 16,463 total health assessments received from NMAs in 2014/15 just under 3,000 assessments (<18%) had been entered into the database. A backlog of approximately 150,000 health assessments awaiting database entry had grown to almost 170,000 whilst this review was underway.

The DNRM has advised that steps are in place to clear this backlog, for example, by scanning and only entering key variables into the database. Furthermore, the health assessments for underground coal mine workers (which account for <10% of the 170,000) have been prioritised. As of 23 June 2016, 70,000 health assessments had been processed including 10,000 underground coal miners' assessments. The remaining assessments for underground workers are expected to be cleared by the end of 2016, and the backlog of the other health assessments by mid-2017.

Limitations

The process of sending and receiving health assessments by ordinary mail is not consistent with contemporary methods of transfer and receipt of medical records, which are predominantly electronic. NMAs are required to send the entire assessments but do not always submit CXR films or spirograms, so reliance on this means of communication is ineffective. Manual checking of documents for completeness and accuracy and manual database entry is slow, cumbersome and prone to quality issues as a result of human error. The DNRM review is purely administrative and involves no medical review or audit.

Scanning capability was introduced by the DNRM, in part to assist data storage, as well as searching and retrieval of files. However, with approximately 100,000 health assessments awaiting scanning, this process has not been maximally utilised. A mixture of scanned and/or entered health records is currently stored at three different locations and, although the files have been sorted alphabetically and numerically, access to records for a particular worker could be hampered by separate storage of the files. The sequential health assessments for individual workers have not been consistently linked and this contributes to inefficiencies of the data storage system and difficulties in accessing previous health assessment records.

Resources to enter data into the database did not increase when the number of health assessments increased during the mining boom, resulting in a large backlog of forms awaiting entry into the DNRM database. This further hampers access of previous records.

Electronic data entry by the NMA at the time of the health assessment would reduce workload for the HSU as scanning and manual entry would no longer be needed and facilitate completeness of data entry and medical review by HSU. Electronic data storage would also allow much easier access to previous health assessment forms by NMAs, though would have to comply with current privacy constraints. Importantly, it would facilitate collation and analysis of group surveillance data to assess trends in CMDLD.

13. Interstate and overseas health surveillance schemes for miners

We reviewed health surveillance systems for mine workers in Australia, and overseas including the USA (NIOSH), UK, South Africa and Japan. The purpose was to determine which components of these programs could be incorporated to improve the Queensland scheme. In Australia, only two other states have had a health assessment scheme for mine workers, and one of these, Western Australia (WA), has recently ceased its surveillance program.

New South Wales

This section is summarised from the NSW Coal Services (CS) website, and from discussions with Coal Services Health (CSH) representatives.

CS is a corporation owned equally by the NSW Mineral Council and the Trade Union (CFMEU) and was set up in 2002.[29] Among other functions, CS provide:

- occupational health and rehabilitation services for workers engaged in the coal industry, including providing preventative medical services, monitoring workers' health and investigating related health matters;
- collection, collation and dissemination of statistics relating to the health of workers engaged in the coal industry;
- promotion of the welfare of workers and former workers in the coal industry in the state;
- monitoring, promotion and specification of adequate training standards relating to health for workers engaged in the coal industry; and
- monitoring of dust levels in coal mines.

Business units within CS provide services to the coal industry. Health surveillance under Order 41[30] is provided by CSH, and dust exposure monitoring under Order 42[31] by Coal Mines Technical Services.

Services are provided by CS to CHPPs, underground and open-cut mines. Labour hire companies are included, so contractors must also have regular medicals. Any former coal miner, including retired mine workers within NSW can attend a CSH office for a medical assessment, and CXR, if clinically indicated. Retired miners are contacted through the relevant NSW Retired Miners Association and the mining union. Some retired miners choose to attend, while others may attend their own GP.

Pre-employment and periodic medicals (usually every 3 years) are carried out by CSH on workers at coal mines. CSH employs 8-9 doctors (usually occupational health specialists who are in training or who have completed their training) and other staff, e.g. nurses, at 5 clinics.

All periodic medicals are carried out by CSH, though some companies arrange their own pre-employment medicals they are required to send the data to CSH for quality checking and data entry.

Staff directly enter data from the medicals to an electronic system as it is collected. A miner's previous data, including the occupational history, is visible to medical staff who can examine previous symptomatology, spirometry, CXR etc. CSH thus have a complete occupational and health history of each coal miner in electronic form.

The respiratory component of the medical includes a symptom questionnaire (based on the standard British Medical Research Council questionnaire), spirometry and a CXR. Spirometry is carried out in-house by nurses trained by the Asthma Foundation, and who undergo regular in-house training and annual competency testing.

A CXR is normally recommended every 6 years for mine site workers. The decision about CXR frequency is made by the CSH doctor after examination of the whole work history and is based on knowledge of the 'at risk' jobs, rather than relying on SEGs which vary from site to site and over time. For some workers, depending on the history, symptoms and signs, a CXR may be recommended more frequently. For individuals not thought to be dust-exposed e.g. administrative staff, the CXR interval might be up to 12 years.

Most of the CXRs are taken at two CSH sites, but may also be taken at other facilities. A CXR is read by one of a small pool of CSH radiologists across the state. The radiologists are aware that the CXRs are from miners. They are familiar with the ILO classification but do not undergo any specific or extra training in respect of this classification. The radiologists report the films using the usual radiology form, rather than the ILO form.

Any adverse medical findings are discussed at weekly review meetings by medical staff and, where necessary, the worker and their GP are contacted. Respiratory specialists may then become involved and their findings would be fed back to the GP and to CSH. Where necessary, with the individual's permission, the findings are fed back to the company so that appropriate restrictions can be placed on work practices/exposures.

An information sheet on respiratory diseases related to coal dust exposure has been developed for workers.

Western Australia

Western Australia's MineHealth system ceased in January 2013 after the outcome of epidemiological studies of the surveillance system database showed that health assessments neither prevented nor detected ill-health at an early stage.

The requirements for undertaking health assessments are stipulated in *The Mines Safety and Inspection Regulations 1995*, and health surveillance for mining employees in WA was administered by the Department of Mines and Petroleum Resources Safety. Details of the surveillance scheme have been summarised from the publication 'Guide to health surveillance system for mining employees',[32] and thus was not specifically for coal mine workers.

Objectives of the scheme were clearly stated from the outset, which were to: assess health status on a regular basis; analyse collected data to detect adverse health effects at the earliest opportunity; and provide data for future epidemiological studies. As well as setting out the responsibility of employers, employees and responsible medical practitioner or approved persons, the guide also included detailed instructions about how to complete all components of the health assessment form.

The health surveillance scheme was applicable to all miners except those who fulfilled the exemption criteria, such as workers not exposed to significant levels of hazardous agents, and employees who work for a cumulative period of less than three months in a 12-month period. Employees were issued with a health surveillance card (with a unique number and expiration date) by the Department of Mines and Petroleum. Initial health assessments were to be completed within 3 months of commencing a job, and periodically at least every five years thereafter.

The approved medical assessment form was concise, included a formal respiratory questionnaire and had an entire page dedicated to spirometry which was to be conducted accorded to ATS standards. A doctor or "approved person" could undertake the assessments, however medical practitioners were required to complete a one-day approved persons course before performing lung function tests, and to attend refresher courses every 2 years unless exempted. Completed forms were submitted to the Mines Occupational Physician. Although there was no formal auditing of these forms, approvals to conduct the medicals were revoked if an "unacceptable" number of poor quality forms was submitted to Resources Safety.

CXRs were only required by employees who had worked in "designated work categories" in surface, underground and non-mining (such as tunnelling) environments for a specified duration, in WA or other states. A list of the "designated work categories" is provided in an appendix of the guide. CXRs were reviewed and reported by radiologists, but were no longer required to be reviewed by a CXR reader for coding purposes. Regulations required CXR reports to be recorded and, the employee notified of the results and given an explanation if follow-up was required. Medical practitioners were also required to specify remedial actions that were taken for abnormalities detected in other components of the health assessment.

All components of the health assessment, including the CXR film and radiology report, were forwarded to Resources Safety and transferred to the MINEHEALTH database.

NIOSH (USA)

The Respiratory Health Division of NIOSH, (within The Centers for Disease Control and Prevention) operates the Coal Workers' Health Surveillance Program (CWHSP) in the United States. The CWHSP was established by the Federal Coal Mine Health and Safety Act of 1969 and has been in continuous operation since 1970. The program is mandated by law, enforced by MSHA, part of the US Department of Labor and is administered by NIOSH. The CWHSP has operated four different programs since it began. These programs require that the operators participate by offering these services to all coal miners, however the miners are not obligated to participate. Participation rates have varied between 25% and 50% over the years.

1. Coal Workers' X-Ray Surveillance Program (CWXSP) 1970-2016

CWXSP operated from 1970 until February of 2016 when it was replaced by the newly legislated expanded program. This program collected demographic information and work histories in addition to performing CXR surveillance. Operators of underground coal mines were required to post a NIOSH-approved health examination plan providing health surveillance to their underground miners every five years. The operators chose the CXR facility and offered the miners the opportunity to go to those sites free of charge and obtain a CXR. The CXR was interpreted by on site physicians known as A-readers, and then sent to NIOSH for formal ILO classification by a panel of carefully selected B-readers for final determinations.

2. Miners Choice Program – 1999-2002

In addition to this program NIOSH and MSHA expanded participation to surface miners and also allowed miners to choose the site for their CXR rather than being required to go to the site selected by the coal operator. This program also consisted only of CXR screening and occupational histories.

3. Expanded Coal Workers' Health Surveillance Program (ECWHSP) – 2005 to present

The ECWHSP was developed in response to findings of increasing rates of pneumoconiosis and rapidly progressive pneumoconiosis detected by the CWXSP in certain areas of the country known as "hot spots". This program continues to this day. This program consists of a mobile

van operated by NIOSH, which travels throughout the country for several months of the year. The program offers CXRs which are transmitted directly to NIOSH for B-reader interpretation. The ECWHSP also collects information on respiratory symptoms, occupational histories, smoking status, blood pressure measurements, and spirometry testing.

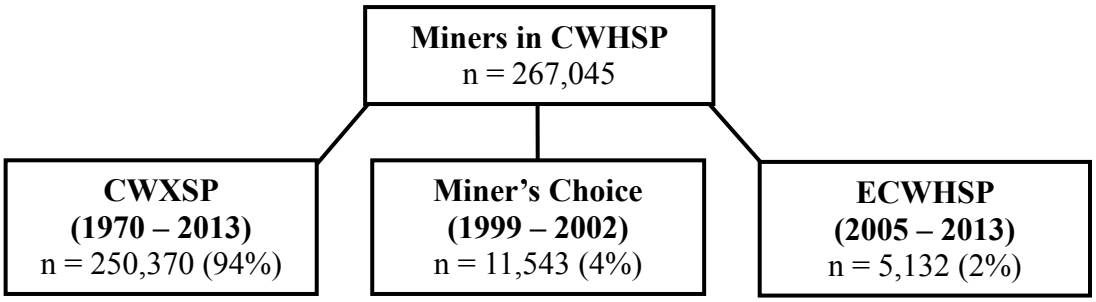


Figure 5: Distribution of coal miners in NIOSH's Coal Workers' Health Surveillance Program across different phases of the surveillance program, 1970 – 2013.

As noted in Figure 5, participation in the CWHSP is voluntary and as such, there is no set frequency of medical testing for participating miners, however operators have been required to offer testing every 5 years. Miners may appear in the program multiple times throughout their mining career, but participation is not required. It is not advised to receive more than one CXR within a 5 year time period, therefore while a miner may participate on a more frequent basis, they would be advised to undertake a CXR only once within a 5 year period. Miners are notified of their medical results after participation in the CWHSP. If evidence of disease or impairment is found, the miner in encouraged to follow up with their personal doctor. Employers are not notified of an employee's health status.

NIOSH reviews information on facilities which provide CXR screening and certifies those clinics before they may participate. NIOSH requires separate certification for x-ray and spirometry facilities which are based on the equipment used, the technician certifications, and a sample of CXRs or lung function tests for quality review by NIOSH experts. Facilities may be approved for x-rays only, spirometry only, or both see: http://www.cdc.gov/niosh/topics/surveillance /ords /pdfs/CWHSP-Facility-2.11.pdf.

Facilities that are NIOSH-approved for spirometry can provide the respiratory assessment as well as lung function test to the CWHSP. All persons administering spirometry exams must have successfully completed a NIOSH-approved Spirometry Training Course. This certification must be maintained through periodic refresher courses. Spirometry test results must be interpreted by physician or other health professional with appropriate state licenses for this service, in accordance with ATS guidelines for spirometry interpretation.

All CXRs taken as part of the CWHSP are read and interpreted by NIOSH-certified B-Readers. B-Readers are physicians who have demonstrated proficiency in interpreting and classifying CXRs specifically for pneumoconioses. B-Readers classify CXRs according to the ILO classification system see: (http://www.cdc.gov/niosh/topics/surveillance/ords/pdfs/CWHSP-ReadingForm-2.8.pdf). These physicians are tested every four years in order for their B-Reader certification to remain valid. The CWHSP data is collected, managed, and maintained by NIOSH staff. NIOSH uses

the CWHSP data to estimate disease prevalence and identify geographic areas of resurgent disease.

Detailed work histories for up to 13 previous mining positions are collected as part of the CWHSP. Work histories include the names of prior mines, which can be linked to geographic location, mine characteristics, and job titles. See: (http://www.cdc.gov/niosh/topics/surveillance /ords/pdfs/CWHSP-ReadingForm-2.8.pdf). The CWHSP also contains data on CXRs with a standardized ILO classification by independent NIOSH B-Readers. Spirometry with age, height, FEV_1, FVC, FEV_1/FVC ratio; smoking status (former/current/never); and data from respiratory symptom questionnaires are available starting in 2005. The CWHSP also contains demographic information such as sex and race/ethnicity, as well as the body weight of the participating miners.

NIOSH produces de-identified publicly available aggregate data sets from the CWHSP for research purposes in addition to the data sets maintained for internal research use.

United Kingdom

The last underground coal mine in the UK ceased operation in 2015, although many open cut coal mines remain in operation and silicosis remains an important occupational lung disease. The Health and Safety Executive has published guides for health surveillance for workers exposed to respirable crystalline silica (RCS), [33, 34] and these are summarised below. Although health monitoring is not mandatory, information contained in the publication will assist employers to comply with the *Control of Substances Hazardous to Health Regulations 2002* to control exposure and protect workers' health.

The guides begin by stating the purpose of health surveillance, and reiterate that it is never an alternative to proper exposure control. The categories of RCS-exposed workers for inclusion in surveillance are clearly outlined, and include individuals working in underground and open-cut environments in high-risk industries and occupational groups, as well as retirees. Health monitoring is also advised in situations where there have been previous work-related cases, where there is reliance on RPE as an exposure control measure; or where there is evidence of work-related ill-health in the industry.

Questionnaires and lung function tests are recommended at baseline, and annually thereafter, and sample proformas are enclosed in the guides. Posterior Anterior CXRs are advised at baseline (to enable comparisons with subsequent CXRs, after 15 years work history), and every three years thereafter unless advised otherwise by a health professional. The ILO classification is not explicitly recommended for CXR reading, though the grade of silicosis (if present) is to be recorded. Radiographs should be read by a suitably qualified radiologist. Spirometry is to be conducted and interpreted according to the ATS criteria, and both spirometry and CXRs should be assessed relative to previous results.

The results of the health surveillance should be explained to the workers by the health professionals, who could be a doctor or nurse, especially if silicosis is diagnosed. Although there are no prescribed clinical guidelines for management of abnormal findings, there are suggestions about what constitutes "abnormal" and the frequency of subsequent health assessments. For example, an abnormal lung function result includes an average drop in FEV_1 of 100mls per year, and spirometry should be repeated early if FEV_1 declines by 200mls or more. The Health and Safety Executive also recommend seeking the opinion of an appropriate occupational health professional for abnormal results, and to determine fitness for work and any action required to slow disease progression.

Health professionals are also required to collate, interpret and report the result trends across groups and individuals, in particular to identify the need for an employer to review and/or revise exposure risk assessments. Health results and records must be stored for 40 years.

Japan

Coal mine workers in Japan do not participate in a mandatory health surveillance scheme. However, it is one of six countries that participates in the Asian Intensive Reader of Pneumoconiosis project (AIR Pneumo). This is a non-government initiative to promote quality assurance of medical screening and surveillance for pneumoconioses. It was established in 2003 with an aim to upgrade skills of medical specialists in developing countries on the application of the ILO International Classification of Radiographs of Pneumoconioses, and to contribute to the implementation of the ILO/WHO Global Program for Elimination of Silicosis.

AIR Pneumo consists of three educational tools: attendance at an interactive 2.5 day-course, including a CXR view-box reading seminar and practice; provision of CXR teaching materials; and examination and certification of proficiency to read chest radiographs of pneumoconioses. The target audience includes chest physicians, radiologists, occupational physicians and GPs with an interest in occupational lung diseases [35]

South Africa

A number of minerals are mined and/or occur in South African mines, including gold, platinum and silica. Although mines are required by law to establish and maintain disease surveillance programs, there is no formal national or provincial health screening for mine workers in South Africa. [36] However, under the *Occupational Diseases in Mines and Works Act*, the pathology division of South Africa's National Institute of Occupational Health (NIOH) provides an autopsy service for deceased mine workers and former mine workers for the diagnosis of compensable disease, regardless of the clinical cause of death. The information is recorded in the Pathology Automation System database, and is currently the only source and resource for disease surveillance of occupational lung disease.

Mine medical officers, other doctors conducting medical examinations for former miners, and panel members who certify cases for compensation do not require specific qualifications to read CXRs. However, South Africa NIOH has recognised the utility of standardised reading and assessment of disease progression and will be presenting an ILO training program in November 2016. Importantly, the program will be tailored to local conditions, especially the high rates of pulmonary tuberculosis (David Rees, NIOH, personal communication).

14. Queensland medical capacity

We identified the specialist medical expertise and resources currently available in Queensland to contribute to the performance of high quality medical assessments for the early detection of CMDLD, including performance and interpretation of high quality CXR and spirometry. Based on the findings of aspects of this review outlined earlier in this report, specialist input will be needed for the following:

1. The development of clinical guidelines for NMAs to assist them in undertaking the respiratory health assessment, assessing coal dust exposure, identifying what signs/symptoms require follow up and further investigation, including specialist opinion when respiratory abnormalities are detected
2. High quality expertise in CMDLD among specialist respiratory physicians for referral and subsequent clinical management, including advice on reducing coal dust exposure of coal miners suspected of having CMDLD
3. A robust system for the reporting of CXRs by radiologists in line with the ILO classification, including relevant training and auditing
4. A robust system for the performance and reporting of spirometry to acceptable standards, including relevant training and auditing
5. Assistance in the development and delivery of training materials for NMAs and specialists involved in the health assessment scheme

Three relevant Australian specialist medical organisations are:

- The Royal Australian and New Zealand College of Radiologists (RANZCR)
- The Thoracic Society of Australia and New Zealand (TSANZ)
- The Australasian Faculty of occupational and Environmental Medicine (AFOEM) of the Royal Australasian College of Physicians (RACP)

These organisations have been contacted by the review team and all have indicated a strong willingness to assist in building improved capability in the health assessment scheme in Queensland in the areas indicated above. During the review, the RANZCR and TSANZ have each identified members in Queensland who are willing to provide relevant expertise to the scheme.

The Royal Australian College of General Practitioners is another Australian body relevant to building medical capacity within the scheme, as GPs are often the first point of contact for coal miners who develop respiratory symptoms. To start the process of increasing awareness among GPs, the review team has developed a CMDLD Fact Sheet for GPs, which was provided to the DNRM and distributed to Queensland GPs through Queensland Health (see Appendix 10).

Specific activities which would increase the quality and robustness of the respiratory component of the health assessment scheme for CMDLD in the future include:

- Introducing a training program for doctors, which they must successfully complete before being approved by the DNRM to perform respiratory health assessments for CMDLD.
- RANZCR, TSANZ and AFOEM will need to be involved in the design and running of this training program.
- Developing clinical guidelines to ensure consistency in identifying what respiratory abnormalities found at the health assessment require follow up and further

investigation, establishing consistent criteria in the diagnosis of CMDLD and appropriate management, including measures necessary to reduce or eliminate further coal dust exposure.

- Establishing an accreditation system for spirometry to TSANZ standards, this will require input from TSANZ, especially respiratory scientists.
- Establishing a centralised system of independent dual reporting of digital CXRs performed for the scheme, involving a small group radiologists adequately trained in interpreting and reporting these films using the ILO classification and who are reporting on such films regularly enough to maintain skills. The dual reporting is important due to known high degree of variability among radiologists in detecting early opacities. Such a system would also involve ongoing clinical audit of a sample of CXRs and the radiologist reports to ensure that reporting standards among the radiologists are maintained. This model has been implemented successfully for mammographic screening.
- Conducting workshops at the annual conferences of the RANZCR, TSANZ and AFOEM, as is done in similar US medical bodies, to update involved members of these bodies in those aspects of CMDLD relevant to their specialty.
- Establishing a system of clinical grand round, which is a well-established medical system whereby relevant specialists meet to discuss cases requiring multidisciplinary expertise. For cases of CMDLD, such grand rounds would need to involve at least one radiologist, thoracic physician and occupational physician to fully assess workers found to have respiratory abnormalities suggestive of CMDLD at their respiratory health assessment.
- Establishing a system of health surveillance, involving the analysis and reporting of grouped results from the health assessment scheme to monitor trends across the industry and over time. This will require epidemiological input in the design of the surveillance system and analysis and reporting of the data. There are very few models for comprehensive surveillance of occupational disease in Australia, despite there being a strong need,[37] one being the Australian Mesothelioma Registry.[38] Such a surveillance system should include retired workers and those who have moved to another industry, given the long latency of the development of CMDLD after first exposure, which may only develop some years after ceasing work as a coal miner.
- One way that more accurate numbers and rates of CMDLD would be identified by the surveillance scheme would be to make CMDLD reportable diseases, as is the case with other diseases, such as cancer and communicable diseases. While cancer can usually be accurately diagnosed by pathology slides and communicable diseases can usually be accurately diagnosed by laboratory tests, the accurate diagnosis of respiratory diseases included in CMDLD do not rely on a single pathology or laboratory test, but require integrated consideration of the worker's cumulative exposure, respiratory symptomatology and physical signs, serial spirometry results, CXR findings and for specific conditions, other special investigations. Making all of the conditions included in CMDLD notifiable would require very specific diagnostic criteria to be set then consideration of establishing a medical panel to review possible cases, in line with the system used by the Dust Diseases Board in NSW or the Medical Panels in Victoria.

15. Other sources of data about the extent of CWP

As limited information was available to the review team about the extent of CWP among Queensland coal mine workers, we identified and examined routinely collected health data to help estimate the prevalence of CWP, from Queensland hospital records and workers' national and state-based compensation data. All of these data sources have their limitations, which are discussed below.

Queensland hospital data

To assist the review, Queensland Health undertook a preliminary search of its public hospital data to identify patients who had been hospitalised with CWP within the last five years.[39] The search was conducted using ICD-10 code J60: Coal Workers Pneumoconiosis. However, as this code includes CWP and other lung diseases associated with carbon exposure, a significant number of patients were identified who had not been Queensland coal miners, or coal miners at all. Relying solely on the J60 code for hospital inpatients overestimates the prevalence of CWP among Queensland mine workers as it includes:

- Non-miners with lung disease from exposure to carbon dust (the other major categories are anthracosis, and anthracosilicosis, but could have been coded using the silicosis code)
- The majority of the patients with a J60 code were found to have carbon pigment in lymph glands which were biopsied as part of a staging process for patients diagnosed with cancer
- Miners who worked overseas and/or interstate

To refine the search, the DNRM provided a list of over 100,000 people who had had a Queensland coal mine workers' medical since the inception of the scheme (in 1983), and this was cross-checked with Queensland public hospital records from the last 20 years. Twenty one individuals assigned a J60 code and who had been hospitalised between July 1995 and November 2015 were identified. The available hospital charts of these 21 individuals were reviewed by Queensland Health, and four were categorised as "probable" and seven as "possible" CWP cases.

De-identified data on ten of the possible and probable CWP cases were provided in the Queensland Health report.[39] (The other case details were not provided to avoid identification of the individual.) The mean age at hospitalisation for the ten cases was 69 years, though three individuals were under the age of 65. The majority were thus likely to have been retired at hospitalisation, but retired miners are not included in the current Coal Mine Workers' Health Scheme.

These findings could indicate that CWP is more prevalent among Queensland miners or former miners than otherwise known, and would be reinforced by the following factors:

- Queensland Health only has access to J60 codes and case history data from public hospitals, so cases only diagnosed or treated in private hospitals will not be identified and cannot be investigated.
- CWP may have been present in a miner or former miner, but may not have been diagnosed and therefore not coded. CWP with an ILO classification of 1/0 would be asymptomatic.

- Not all mine workers with CWP would have required hospitalisation.

However, as previously mentioned, a case being assigned a J60 code is not definitive identification of CWP, even after cross-referencing with the DNRM records and these cases would still need to be independently verified.

In summary, Queensland Health data indicate that more cases of CWP than those reported to DNRM have probably occurred in the past 20 years. However, limitations in the various data sources being compared make it difficult to reach firm conclusions on the incidence of CWP. It should also be noted that this review of cases by Queensland Health only looked at CWP and did not investigate other respiratory diseases among coal miners which are included in CMDLD.

Queensland compensation data

Q-COMP in Queensland is the authority responsible for the administration of WC claims. At the request of the review team, Q-COMP searched their claims database for compensation claims for CWP over the past 10 years. Because of the small numbers in each year, we have not provided yearly breakdowns, to preserve confidentiality. Instead we present summary findings. Over the past 10 years, there have been six accepted cases, with four being accepted in the 2015/16 year to date, while two were accepted in the late 2000s. There are also 6 pending cases, with five of these submitted in the current financial year, one rejected case and two withdrawn cases.

It should be noted that compensation claims have their limitations, especially for claims for disease as opposed to acute trauma, as the link between exposure and disease can easily be missed. Workers' compensation is only available for current workers, so retired workers are not eligible for wage replacement. Compensation payments usually require evidence of impairment or inability to work. However, the early stages of CWP are asymptomatic so a coal mine worker may not meet the requirements for compensation. Given the long latency of coal dust exposure until the onset of disease, compensation data are not an accurate indicator of the extent of CWP, nor other forms of CMDLD.

Safe Work Australia data

Safe Work Australia (SWA) collects national WC data. At the request of the review team, SWA extracted data for pneumoconiosis claims from 2000-01 to 2013-14. They found 236 accepted WC claims for respiratory diseases such as silicosis and pneumoconiosis (due to coal dust or other causes).

This included 162 WC claims for silicosis, 72 WC claims for pneumoconiosis (excluding asbestosis, CWP and silicosis), and 2 WC claims for CWP. Both of the CWP claims were from Victoria.[4] Of the total number of claims for all types of pneumoconiosis over this recent 13

[4]. In an earlier version of this report, this section contained some incorrectly information from SWA and read:
They found 237 accepted WC claims for respiratory diseases such as silicosis and pneumoconiosis (due to coal dust, asbestos, silica or other causes). (SWA website accessed 7/3/2016).
This included 162 WC claims for silicosis, 72 WC claims for pneumoconiosis (excluding asbestosis, CWP and silicosis), and 3 WC claims for CWP. Of the CWP claims, two were from NSW and the other was from WA. (See erratum at the beginning of this report for further details about these corrections.)

year period, 21 were from the mining sector, including 19 claims for silicosis and 2 claims for other respiratory diseases. (SWA data, personal communication)

It is important to note that SWA WC data, like the other data sources referred to above, also have several limitations. Notably, they do not capture all occurrences of disease as it only covers employees who are eligible for WC, and thus excludes self-employed and retired workers, as well as those who have been absent from work for less than five work days because of their condition.

There is some disparity between the SWA and Q-COMP WC data for CWP, which is mainly because SWA data lags state data collection, so it does not include recent cases. However, the two accepted WC claims for CWP in the late 2000s in the Q-COMP database were not identified in the SWA database. This highlights the limitations in any individual WC data source in identifying accurate data on disease prevalence or incidence.

16. Research framework to estimate CMDLD prevalence among coal miners

One part of the scope of the review was to outline a research framework to more accurately assess the prevalence of CMDLD among Queensland coal miners. This focus was thought important as little is known about the extent of CMDLD among Queensland coal miners and the other parts of the review were primarily aimed at assessing the quality and limitations of the scheme. In addition, the findings of previous chapter on other routine data sources cannot be relied upon to provide reliable estimates based on hospitalisations or WC claims. The CXR and spirometry review in this report examined CXRs from individuals who have worked for more than 10 years as a miner and accessible spirograms from DNRM. It is therefore not a random sample of miners and former miners and so it cannot be used to estimate the prevalence of CMDLD in Queensland.

As CMDLD can continue to develop after exposure has ceased, a survey to estimate the prevalence of CMDLD would need to include both current and former miners. Although the number of retired miners who participate is likely to be small, they are important as they are likely to have had the highest exposures. In addition, they may have left the industry due to development of respiratory problems, and a prevalence survey should capture this. The previous Rathus Abrahams CXR survey in 1984 included 7,784 employees, and though there were 123 retirees included, this was only a small proportion of retired miners.[15]

The proposed research framework is designed to estimate the current prevalence (number of existing cases) of CMDLD among Queensland coal mine workers, including those cases undetected by the current scheme.

Study design

The most appropriate research design to measure prevalence is a cross-sectional study, which involves measuring CMDLD in current and retired mine workers at one point in time. An advantage of this approach is that once participants are recruited they can be followed over time, longitudinally, to measure the incidence (new cases over time) of CMDLD. However, if a properly designed health surveillance program, based on the regular health assessments under a revised scheme was established, this could serve the same purpose as a longitudinal study.

Inclusion criteria

The most efficient approach would be to define the study group at risk of CMDLD with a minimum number of years of work in coal mines, such as 10 years. Setting this criterion will exclude those with minimal risk of having CMDLD at the time of the survey. This period is chosen as those with fewer years of exposure are at lower risk of developing disease and so would potentially dilute the recruitment efforts with no added benefit.

As referred to above, the study group should include current miners, retired miners andformer miners (i.e. those who are still working, but in jobs outside the coal mining industry) who meet the minimum work duration criterion. It is especially important to include retired and former miners, some of whom may have left the industry as a result of respiratory conditions and are likely to have had longer exposure to coal mine dust, be older, and consequently more likely to have developed CMDLD.

Ideally, miners should be recruited from all mining sectors, that is, underground and open-cut mines, and CHPPs. This will increase the study size and the statistical power of the study, and result in a greater ability to detect excess risks of CMDLD, even if the excess risk is low. If the study was small, then low risks may not be detected. Miners may have moved from one sector to another, an open cut miner may previously have worked underground and *vice versa*, so inclusion of the likely lower-exposed open-cut miners is important. In addition, the likely differences in extent of exposure between these sectors would be informative as analyses could be undertaken to assess risks of CMDLD at different levels of exposure.

Assembly of the study group

Current miners can be identified through companies, including contractors and labour-hire firms. Identifying retired and former miners is likely to be more difficult as their contact details might be unavailable, however the following records could be used:

- Company records
- Trade Union records
- Existing DNRM medical records

It will be important to develop a complete list of current, retired and former miners to approach to take part in the survey, as voluntary participation is very likely to introduce bias into the findings. Including a large number of volunteers may result in an over or an underestimation of those with CMDLD, and thus skew the actual disease prevalence found in the survey.

Contact and recruitment process

The record holders will need to provide access to contact details for participants in the survey. It will be important to establish the completeness of these records and to ensure that contact details for prospective participants are up to date. If up to date contact details are not available for former miners, then other sources of contact information, such as the electoral roll could be used.

Some organisations may be reluctant to provide this contact information because of data privacy concern. However, the Australian Privacy Principles do allow the disclosure of such information for medical research, especially if the research is deemed to be of high public interest, which would be the case with this survey.

The study would need approval from a properly constituted Human Research Ethics Committee (HREC). An HREC is usually interested in reviewing the study design, contact procedures (including the explanatory statement and consent forms), data collection and storage, means of feedback to participants and overall study governance. The HREC will also want reassurance that the researchers are acting independently of the companies, government and other stakeholders, and that confidentiality of the data will be preserved.

Eligible current miners and retired/former miners would be contacted by email, telephone or by post, and asked to participate in the study. They would be provided with a plain language explanatory statement about why the study is being carried out, the research team, what the study would entail and how they will be advised of their results. At enrolment into the study, participants must sign a consent form. The questionnaire part of the study survey could be designed to be completed online, by telephone or by mail.

There is a likelihood that some current miners or more probably former miners may not respond to the invitation. This may be because contact details were incorrect so the invitation was not

received, the individual is unwell or deceased, or because they are healthy and so are not interested. It would be important to know the number of eligible and invited workers so that the response rate can be calculated. Higher response rates provide more confidence in study findings, as it is less likely to be prone to participation bias and will also ensure that there is sufficient statistical power for the survey.

Follow up invitation reminders would be needed, with two reminders normally considered acceptable by the HREC.

Data to be collected

The first stage of data collection would be through a questionnaire. This would include:

- Respiratory symptom questionnaire (standard questionnaires are available)
- Relevant medical history, e.g. asthma, and a smoking history
- Full occupational history including duration of employment as a coal miner, types of mines and jobs held at each, and other relevant (non-mining) jobs

CXR and spirometry, and perhaps other respiratory tests would also need to be included. These would need to be performed at clinic(s) with sufficient quality control procedures. The respiratory health outcomes of interest (CMDLDs) would be defined (based on a mix of history, spirometry abnormalities and CXR abnormalities), prior to the start of the survey and the individuals fitting these defined criteria would be identified from the collected data.

Pilot study

The contact, recruitment and survey procedures would need to be piloted on a small sample of potential participants prior to the start of the main survey. The clinical investigations would also have to be piloted to ensure that they have adequate quality control and do not impose too great a travel burden on participants, some of whom may be elderly and possibly ill.

Study governance

The study should have a stakeholder Advisory Committee, including representatives from the DNRM, mine operators, the CFMEU, current employees, as well as other researcher(s) independent of the study team undertaking the survey. The members of the Committee would advise the research group about various aspects of the study, promote it to their members and facilitate dissemination of the findings.

A Scientific Advisory Group made up of three or four independent researchers can be a further way of ensuring the scientific integrity of the survey and its findings. The researchers' role would include reading the study protocol and suggesting means of strengthening its conduct, including data analyses. They can also provide an independent evaluation of the scientific merit of the study, as well as the quality and robustness of the findings and report.

17. An ideal Queensland coal mine workers' respiratory health assessment scheme

This section draws together the proposed modifications to the respiratory component of the scheme to address the identified limitations, as outlined in the previous sections of this report, and to outline the key aspects of a best practice scheme.

The purpose of the revised respiratory component of the scheme should be to:

- Identify reduced/impaired respiratory health indicative of CMDLD
- Provide appropriate referral for follow-up, diagnosis and management, including appropriate reductions in further exposure to dust, for coal mine workers with respiratory abnormalities
- Collect, analyse and report group surveillance data to monitor trends in CMDLD, and to inform Government, industry and trade unions reviews of dust exposure levels and occupational exposure limits for coal mines
- Provide feedback to mine companies where reduced/impaired respiratory health is likely to be due to coal mine dust exposure, so that exposure levels can be reviewed

The revised respiratory component of the scheme should include the following components:

- Current and former workers in underground and open-cut mines and CHPPs would be included
- All coal mine workers should be registered under the scheme on entry into the industry, and up-to-date contact details would be maintained
- A complete occupational history would be obtained from the worker on entry into the industry, and updated at subsequent health assessments
- Employers and workers would be informed about an upcoming periodic health assessment as part of the surveillance component of the scheme
- A limited pool of trained doctors would be approved by the DNRM after review of their qualifications and experience
- The training for these doctors should include the objectives and purpose of the scheme, CMDLD and associated diagnostic criteria and knowledge of the coal mining industry
- Doctors should be available in the main mining regions of Moranbah and Emerald, with additional offices sited in Mackay, Rockhampton and Brisbane for the convenience of drive-in-drive-out and fly-in-fly-out coal mine workers
- Respiratory health assessments would be completed at 3-5 year intervals and should include:
    - a comprehensive medical history, including smoking history
    - a standard respiratory symptom questionnaire
    - a focused respiratory physical examination
    - spirometry

  - a CXR (if assessed by the doctor as being indicated)

- CXRs would be dual read and reported according to the ILO classification by trained radiologists in a limited pool to ensure they read enough CXRs under the scheme to maintain skills
- The CXR interval should be determined by the doctor undertaking the health assessments and should take into account past and current exposure. More frequent assessments including CXR may be required for those workers with longer periods of higher dust exposure
- Spirometry would be conducted by a trained technician to TSANZ standards and interpreted by trained doctors
- There would be a process of clinical audit of the spirometry and CXR data
- Clinical guidelines including referral pathways for further investigations and specialist opinion are also established for workers with spirometry, CXR or other respiratory abnormalities, and these results are to be discussed with individual miners and their local doctor
- Cases of CMDLD identified under the scheme would be reported to DNRM after diagnosis
- Electronic data entry (with appropriate data security) is implemented so that current health assessments can be reviewed in the light of previous medical records
- DNRM oversees regular review of the respiratory health data to audit quality
- The collected respiratory health data are analysed at least annually as part of a health surveillance program to examine trends in CMDLD
- An implementation group which could include representatives of stakeholders and relevant medical bodies would be established to ensure that the new respiratory scheme is implemented and in a timely manner
- DNRM provides regular reports on the function and findings of the new scheme to the Coal Mining Safety and Health Advisory Committee[5] so that appropriate industry-wide action can be taken where indicated, for example review/revision of dust exposure levels.
- A review of the new scheme after its first 3 years of operation to confirm that it is meeting its objectives and regularly thereafter to ensure that it remains 'fit for purpose'.

[5]The Coal Mining Safety and Health Advisory Committee is a tripartite body set up by DNRM. Its mission statement includes the following: To represent and influence the industry to improve safety and health and to review and recommend improvements to safety and health in coal mines.

Glossary

ACGIH	American Conference of Governmental Industrial Hygienists
AFOEM	Australasian Faculty of Occupational and Environmental Medicine
AIHW	Australian Institute of health and Welfare
ATS	American Thoracic Society
CD	Compact Disc
CFMEU	Construction Forestry Mining and Energy Union
CHPP	Coal Handling and Preparation Plants
CMDLD	Coal Mine Dust Lung Disease
CMSHR	Coal Mining Safety and Health Regulation (2001)
COPD	Chronic Obstructive Pulmonary Disease
CS	Coal Services (NSW)
CSH	Coal Services Health (NSW)
CT	Computed Tomography
CWHSP	Coal Workers' Health Surveillance Program (US)
CWP	Coal Workers' Pneumoconiosis
CWXSP	Coal Workers' X-Ray Surveillance Program (US)
CXR	Chest X-ray
DICOM	Digital Imaging and Communications in Medicine
DNRM	Department of Natural Resources and Mines
ECWHSP	Enhanced Coal Workers Health Surveillance Program (US)
EMO	Examining Medical Officer
ERS	European Respiratory Society
FEV_1	Forced Expiratory Volume (in one second)
FVC	Forced Vital Capacity
GP	General Practitioners
HRCT	high-resolution CT
HREC	Human Research Ethics Committee
HSU	Health Surveillance Unit
IARC	International Agency for Research on Cancer
ICD	International Classification of Diseases
ILO	International Labour Organization
J60	ICD code for CWP which includes anthracosilicosis, anthracosis and coal worker lung
LLN	Lower Limit of Normal
MSHA	Mine Safety and Health Administration (US)
NIOH	South Africa's National Institute of Occupational Health
NIOSH	National Institute for Occupational Safety and Health (US)
NMA	Nominated Medical Adviser
NSW	New South Wales
OEL	Occupational Exposure Limits

PACS	Picture Archiving and Communication System
PMF	Progressive Massive Fibrosis
PPE	Personal Protective Equipment
Q-COMP	Queensland Compensation
RACP	Royal Australasian College of Physicians
RANZCR	Royal Australian and New Zealand College of Radiologists
RCS	Respirable Crystalline Silica
RPE	Respiratory Protective Equipment
SEG	Similar Exposure Group
SIMTARS	Safety in Mines Testing and Research Station
SMR	Standardized Mortality Ratio
STEL	Short Term Exposure Limit
SWA	Safe Work Australia
TLV	Threshold Limit Values
TSANZ	Thoracic Society of Australia and New Zealand
TWA	Time Weighted Average
U/G	Underground
WA	Western Australia
WC	Workers' Compensation
WHO	World Health Organisation

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Appendices

Appendix 1: Occupational exposure limits for coal dust and silica

There are two types of OEL, those such as the American Conference of Governmental Industrial Hygienists (ACGIH) which are health-based, and those that are regulatory or pragmatic limits (usually higher) which take into account the feasibility and cost-effectiveness of control (and sometimes measurement feasibility) in relation to the risks.

Coal Dust Exposure Limits

The ACGIH set Threshold Limit Values (TLVs) for coal dust in 1988, replacing the 2 mg/m^3 that had been proposed in 1971 with 0.4 mg/m^3 respirable fraction for anthracite and 0.9 mg/m^3 respirable fraction for bituminous coal.[41] The TLVs are set to prevent the development of COPD and PMF. The TLV documentation states that a small risk of the latter disease will remain at this TLV, and that exposure should be reduced to those lowest achievable and that silica exposure should also be controlled.[41]

Anthracite coal dust would appear to be more fibrogenic then bituminous coal dust and the ACGIH recommends lower exposure limits for dust from anthracite than from bituminous coal[41] based on risk modelling (see Table 8).

Table 8: Predicated prevalence rates of CWP and PMF among US coal miners aged 58 following exposure 1 mg/m^3 respirable coal mine dust over a 40-year working life time (after ACGIH [41])

	% CWP Category 1 and greater	% CWP Category 2 and greater	% PMF
Anthracite	12.8	4.6	3.4
Bituminous	11.9	4.1	2.9

Table 9 lists the occupational exposure limits by country, mainly sourced from the German government website GESTIS in 2016.[42] The Australian and New Zealand limit of 3 mg/m^3 is the highest value listed for respirable dust. The UK Advisory Committee on Toxic Substances has expressed concern that the UK value of 2 mg/m^3 may not adequately protect health "because of doubts that the limit was not soundly-based". [42] The OEL of 2 mg/m^3 was included in the published UK 2002 list and its 2003 supplement, but was omitted from the published 2005 list.[42]

The ACGIH TLV for bituminous coal dust is less than a third of the current Australian exposure limit. Some of the OELs listed for the anthracite dust (0.4 mg/m$^{3)}$ are almost an order of magnitude lower than the Australian limit (Belgium, Ireland and Spain), but the GESTIS source[42] did not identify whether they applied as inhalable or respirable dust. Ontario uses the ACGIH TLVs values as respirable dust limits.

Table 9: Occupational exposure limits for coal mine dust [8, 21, 42-44]

Country	Coal Dust 8 Hour TWA mg/m^3			
	Anthracite	Bituminous	Inhalable fraction	Respirable fraction
Australia				**3**
NSW				**2.5**
ACGIH TLV	0.4 (1)	0.9 (1)		
Belgium	0.4	0.9		0.4
Canada - Ontario	0.4 (1)	0.9 (1)		
Denmark				2
Ireland	0.4	0.9		1.6
Latvia	4	4		
New Zealand				3 (3)
People's Republic of China			4 (2)	2.5 (2)
Singapore	2 (1)			
Spain	0.4	0.9		
South Korea				1
USA - OSHA PEL				2.4 (4)
USA - MSHA				1.5 (1)(4)
USA - NIOSH REL				1(1)
United Kingdom				2 (5)

(1) Respirable fraction or aerosol
(2) Free SiO2 < 10%
(3) 0.15 mg/m³ respirable quartz
(4) < 5% SiO_2 if >5% SiO_2, the standard is 10/% quartz
(5) No longer included in published lists

Silica Dust Exposure Limits

The international OELs for silica are listed in Table 10. The Australian workplace exposure limits for silica are similar to those of most countries, but higher than the TLV for respirable crystalline silica set by the ACGIH in 2006, and higher than the values set by many countries for cristobalite (the main form of crystalline silica). The ACGIH document states that the silica value was set to prevent lung cancer and the development of silicosis which had been identified in retirees.[45] Silica has been identified as a human carcinogen by the International Agency for Research on Cancer (IARC),[46] part of the World Health Organisation (WHO).

Table 10: 8 Hour TWA occupational exposure limits (OELs) and short-term exposure limits (STEL) listed for silica [42, 43, 47]

Country	Silica 8 Hour TWA mg/m^3				
	Quartz Cas 14808-60-7	Mineral Dust with Respirable Quartz	Respirable Crystalline Silica	Cristobalite, total Cas 14464-46-1	Tridymite Cas 15468-32-3
ACGIH			0.025	0.025	
Australia	0.1 (1)		0.1	0.1 (1)	0.1 (1)
Austria	0.15 (1)		0.15		0.15 (1)
Belgium	0.1		0.1	0.05	0.05
Canada - Ontario	0.1 (1)			0.05 (1)	
Canada - Québec	0.1		0.05		0.05
Denmark	0.3 (0.6 STEL)(2) 0.1 (0.2 STEL)(1)	0.5	0.05 (0.1 STEL)	0.15 (0.3 STEL)	0.15 (2)
Japan		E=3.0/(1.19 Q+1)(7)			0.05 (1)
Finland	0.05 (1)		0.05		0.05 (1)
France	0.1 (1)(3)			0.05 (1)(3)	0.05 (1)(3)
Hungary	0.15 (1)			0.15 (1)	0.15 (1)
Ireland	0.1 (1)		0.1	0.1 (1)	0.1 (1)
New Zealand	0.2 (1)			0.1 (1)	0.1 (1)
People's Republic of China	1 (1)(4) 0.7 (1)(5) 0.5 (1)(6)		0.7 (3) 0.3 (4) 0.2 (5)		
Singapore	0.1 (1)		(8)	0.05 (1)	0.05 (1)
South Korea	0.05			0.05 (1)	0.05
Spain	0.1 (1)			0.05 (1)	
Sweden	0.1 (1)			0.05 (1)	0.05 (1)
Switzerland	0.15 (1)		0.15	0.15 (1)	0.15 (1)
The Netherlands	0.075 (1)		0.0758	0.075 (1)	0.075 (1)
USA - NIOSH REL	0.05		0.05	0.05	0.05
USA - OSHA PEL				0.05 (1)	0.05 (1)
United Kingdom			0.1		

(1) Respirable dust, fraction or aerosol;
(2) Inhalable or total dust
(3) Restrictive statutory limit values
(4) 10% <= free SiO2 <= 50%
(5) 50% < free SiO2 <= 80%
(6) free SiO2 < 80%
(7) E = administrative control level; Q = content of free silica (percent) Dust of sand and stones, rocks, ores (minerals), metallic or carbon.
(8) See cristobalite, quartz, tridymite, tripoli

Appendix 2: Scope of the review of the respiratory component of the Coal Mine Workers' Health Scheme

A. The adequacy of the scope, processes, quality and reporting of the respiratory component of the existing medical assessment program, including information provided by the employer on risk of dust exposure, medical history, physical examination, chest radiography and spirometry, in detecting the early stages of coal mine dust lung disease.

B. The expertise and resources required, firstly to undertake high quality medical assessments (respiratory component) under the scheme, secondly to have effective referral pathways for suspected of a CMDLD, thirdly to use the gathered data to effectively implement a high quality medical surveillance program for the early detection of coal mine dust lung disease in Queensland coal miners and fourthly to make the information available to relevant stakeholders for necessary action.

C. The expertise and resources currently available in Queensland to perform medical assessments, perform and interpret high quality CXR and perform and interpret high quality spirometry. This will include a review of expertise and training of the current list of Nominated Medical Advisers, the use of EMOs and the specialist respiratory physicians available for referral and subsequent patient care.

D. Where deficiencies are found, make recommendations to improve the current program for the medical assessment of coal mine dust lung disease to achieve a state of the art program for the reliable detection of early disease.

E. Recommendations to build capacity in Queensland to ensure that a list is available of sufficient numbers of suitably qualified practitioners to be NMAs, respiratory physicians, trained personnel to carry out and interpret chest x-rays (CXR) and spirometry, where the current level of expertise and/or resources are found to be inadequate.

F. Depending upon findings from A, B and C, make recommendations for an interim strategy to handle undetected cases and ensure that the current cohort of mine workers is effectively screened for coal mine dust lung disease until longer term recommendations can be implemented.

G. Develop a methodology for the review of past x-rays and spirometry to estimate the extent of coal mine dust lung disease that may have been undetected by the medical assessment scheme.

H. Develop a research plan to measure the current prevalence of CMDLD in Queensland coal mine workers.

Appendix 3: Coal Mine Workers' Health Scheme - Health Assessment Form[6]

[6] The DNRM advised that NMAs have been issued with an amended form (dated 01/05/16) that includes additional instructions about: the category of coal mine workers who require a CXR; qualifications for individuals conducting spirometry and CXRs; and the standards for interpreting/reporting these tests, including the use of the ILO classification.

Coal Mine Workers' Health Scheme - Health Assessment Form

Section 46 Coal Mining Safety and Health Regulation 2001 **Form Number CMSHR 1**
(*Form approved by Chief Inspector under section 281 of the *Coal Mining Safety and Health Act 1999)

Name (Full Given Name(s) and Family Name)	**Date of Birth**

Privacy Obligations

Health surveillance information is collected by the Department of Employment, Economic Development and Innovation for the purpose of identifying medical conditions or impacts on health resulting from exposure to chemical and physical agents in the coal mining industry. It is collected under the authority of Part 6 – Division 2 of the *Coal Mining Safety and Health Regulation 2001*.

The Department will not disclose this information to any person except in accordance with the Regulation. The Regulation requires that the identity of a coal mine worker is protected when information is disclosed for research purposes.

Guidance Notes for completion of Health Assessment

Employer

- ❑ Must arrange for the Health Assessment of Coal Mine Worker.
- ❑ Must complete Section 1 on page 2 which includes informing the Examining Medical Officer or Nominated Medical Adviser if: a colour vision test is required; the worker is, or may be, exposed to dust (and therefore a chest x-ray is required); and the SEG (similar exposure group) of the worker.
- ❑ Must meet the cost of the Health Assessment.

Coal Mine Worker

- ❑ Must bring photo identification to have identity checked by the Examining Medical Officer.
- ❑ Must complete Section 2 on pages 2 to 3.
- ❑ In relation to Section 2 - Work History:
  - ***if the coal mine worker is commencing work*** – full work history must be provided; or
  - ***if the coal mine worker is already employed in the industry*** – only work history since last Health Assessment is required.
- ❑ Should request the Nominated Medical Adviser provide a copy of the Health Assessment Report and an explanation.

Examining Medical Officer/ Nominated Medical Adviser

- ❑ Must check photo identification provided by the Employee.
- ❑ Must review Section 1 and Section 2 (pages 2 to 3 with the coal mine worker and comment on any abnormality).
- ❑ Must complete Section 3 on pages 4 to 6
- ❑ Must attach a separate statement if space on Form is insufficient.
- ❑ Must take advice from the employer on the requirements for a colour vision test and/or chest x-ray.
- ❑ Must **not** complete the "Section 4 Health Assessment Report" if not a Nominated Medical Adviser.
- ❑ Must, where appropriate, forward the completed Health Assessment Form (intact) to Nominated Medical Adviser.

Nominated Medical Adviser

- ❑ Must review Sections 1, 2 and 3.
- ❑ Must assess whether the Health Assessment provides adequate information to make a report on the fitness for duty of the coal mine worker.
- ❑ If the coal mine worker has an abnormal colour vision and/or hearing result affecting fitness for duty, a practical test should be arranged.
- ❑ Must complete "Section 4 Health Assessment Report".
- ❑ Must provide an explanation of "Section 4 Health Assessment Report" to the Coal Mine Worker and, where practical, secure the signature of the Coal Mine Worker on the Health Assessment Report:
- ❑ Must provide a copy of "Section 4 Health Assessment Report" to:
  - the Coal Mine Worker at the address shown on page 2; and
  - the employer.
- ❑ Must forward a copy of the complete "Health Assessment Form" (all 7 pages) to the Health Surveillance Unit of the Department of Employment, Economic Development and Innovation.
- ❑ Must maintain secure records of the Health Assessment and associated documentation.

Approved by the Chief Inspector of Coal Mines under s281 of the Coal Mining Safety and Health Act (1999))

Section 1 – Employer to complete

Name of Nominated Medical Adviser

Employer

Coal Worker's Position

Description:

Generic SEG*: **Company SEG**:**

Mine (e.g. Southern Colliery)

SEGs are groups of workers with similar exposure
* Generic SEG is sourced from the list provided by Safety & Health ** Company SEG is the employer SEG

(a) Is the coal mine worker at risk from dust exposure (X-ray needed)?	❑ Yes	❑ No
(b) Will the coal mine worker be working underground?	❑ Yes	❑ No
(c) Does the coal mine worker require colour discrimination?	❑ Yes	❑ No
(d) Is the worker at risk from occupational noise?	❑ Yes	❑ No
(e) Is the worker at risk from hazardous chemicals? (comment)	❑ Yes	❑ No
(f) Are there hazardous duties requiring a specific fitness assessment? (comment)	❑ Yes	❑ No

Comment

Section 2 – Coal Mine Worker to complete

2.1 Coal Mine Worker

(a) Family Name

Given Name (s)

(b) Date of Birth

(d) ❑ Male ❑ Female

(e) Telephone:

(c) Address:

2.2 Work History (coal mine worker to refer to Guidance Notes on the coversheet)

Year		Job Title or Description	Employer
From	To		

2.3 Health-related History

		Yes	No
(a)	Have you previously had a medical examination under this scheme?	❑	❑
(b)	If Yes, when was the last examination?		
(c)	Have you been admitted to a hospital or undergone surgery or an operation?	❑	❑
(d)	Have you ever had an illness or operation that has prevented you from undertaking your normal duties for more than two weeks?	❑	❑
(e)	Have you ever had an injury that has prevented you from undertaking your normal duties for more than two weeks?	❑	❑
(f)	Are you taking any medication?	❑	❑
(g)	Do you use hearing protection whilst in noisy areas?	❑	❑
(h)	Do you currently smoke, or have you ever smoked?	❑	❑

(Supply details) START..... STOP ..... TYPE ... ... QUANTITY/ DAY .....

Examining Medical Officer's comments on Questions 2.1 to 2.3

Approved by the Chief Inspector of Coal Mines under s281 of the Coal Mining Safety and Health Act (1999))

2.4 Have you ever suffered from, or do you now suffer from, any of the following?

		Yes	No			Yes	No
(a)	Heart disease or heart surgery	❑	❑	(n)	Diabetes	❑	❑
(b)	Chest pain, angina or tightness in chest	❑	❑	(o)	Sciatica, lumbago, slipped disc	❑	❑
(c)	High blood pressure	❑	❑	(p)	Neck injury or whiplash	❑	❑
(d)	Asthma, bronchitis or other lung diseases	❑	❑	(q)	Back or neck pain which has prevented you from undertaking full duties	❑	❑
(e)	Abnormal shortness of breath or wheezing	❑	❑	(r)	Knee problems, cartilage injury	❑	❑
(f)	Deafness, loss of hearing or ear problems	❑	❑	(s)	Fractures or dislocations	❑	❑
(g)	Ringing noises in your ears	❑	❑	(t)	Shoulder, knee or any other joint injury	❑	❑
(h)	Other hearing difficulties	❑	❑	(u)	Hernia	❑	❑
(i)	Disease or disorder of the nervous system	❑	❑	(v)	Arthritis or rheumatism	❑	❑
(j)	Episodes of numbness or weakness	❑	❑	(w)	Dermatitis, eczema, or skin problems	❑	❑
(k)	Psychiatric illness	❑	❑	(x)	Allergies	❑	❑
(l)	Blackouts, fits or epilepsy	❑	❑	(y)	Allergic reaction or reaction to chemicals or dust	❑	❑
(m)	RSI, tenosynovitis, over-use syndrome or wrist strain	❑	❑				

2.5 Previous vaccinations and blood tests

(a) When were you last immunised against Tetanus? Year ☐

(b) When were you last immunised against Hepatitis A? Year ☐

(c) When were you last immunised against Hepatitis B? Year ☐

(d) When was your last cholesterol test? Year ☐

Examining Medical Officer's comments on Questions 2.4,and 2.5 .....

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Coal Mine Worker's Declaration (to be witnessed by Examining Medical Officer)

I certify to the best of my knowledge that the above information supplied by me is true and correct.
I understand that if any of the information given is knowingly false, my employment may be terminated.

Signature …… Date / /

Witness …….. Date / /

Section 3 – Clinical Findings – Examining Medical Officer to complete

3.0	**ID Check**	Type	
3.1	**Height**	cm	Comment
3.2	**Weight**	kg	

3.3 Vision — **Visual acuity**

		Uncorrected			Corrected	
		Right	Left		Right	Left
(a)-(b)	Distant	6/	6/	(e)-(f)	6/	6/
(c)-(d)	Near	N	N	(g)-(h)	N	N

3.4 Visual fields (by confrontation) — Abnormal ❑ Normal ❑

Colour Vision Test (if indicated by employer)
Ishihara (if abnormal, the NMA to arrange practical test) — Abnormal ❑ Normal ❑

3.5

3.6 Work-related colour vision practical test (if Ishihara test abnormal) — Unsatisfactory ❑ Satisfactory ❑

3.7 Hearing

Audiogram		500 Hz	1000 Hz	1500 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	8000 Hz
(a)-(h)	Left								
(i)-(p)	Right								

(q)	Time since last high noise exposure?	hours	
(r)	Audiogram result	Abnormal ❑	Normal ❑
(s)	Were hearing aids used	Yes ❑	No ❑
(t)	Auditory canals	Abnormal ❑	Normal ❑
(u)	Tympanic membranes	Abnormal ❑	Normal ❑

The result is normal if hearing threshold is 40dB or less in the better ear at 500, 1000, 1500 and 2000 Hz. If an abnormal result impacts on a coal mine worker's "fitness for duty", the NMA should consider a practical test.

Examining Medical Officer's comments on Questions 3.1 to 3.7 (Note any abnormality, including past noise exposure, workers' compensation claims and tinnitus)

3.8 Cardiovascular System

		Systolic	Diastolic		
(a)	Blood Pressure				
(b)	(Repeated if necessary				
(c)	Pulse rate	/min			
(d)	Peripheral pulses	Absent ❑		Present ❑	
(e)	Heart sounds	Abnormal ❑		Normal ❑	
(f)	Evidence of cardiac failure or oedema	Yes ❑		No ❑	
(g)	Varicose veins	Yes ❑		No ❑	
(h)	E.C.G. (if indicated by some abnormality)	Abnormal ❑		Normal ❑	

Examining Medical Officer's comments on Questions 3.8

Approved by the Chief Inspector of Coal Mines under s281 of the Coal Mining Safety and Health Act (1999))

3.9 Respiratory system

Litres	Observed		Predicted		Observed/Predicted %	
Forced exp. Vol. 1 sec- FEV_1	(b)		(e)		(h)	
Forced vital capacity - FVC	(c)		(f)		(i)	
FEV_1/FVC%	(d)		(g)			

3.10 Spirometry *(abnormal includes FEV_1/FVC<70%)* Abnormal ❑ Normal ❑

3.11 Auscultation of chest Abnormal ❑ Normal ❑

3.12 (a) Was chest x-ray undertaken (as advised by employer) Yes ❑ No ❑

(b) Date x-ray was taken / / ❑ ❑

(c) Quality of film? Unsatisfactory ❑ Satisfactory ❑

(d) What was the result? (Also attach x-ray film to this Report) Abnormal ❑ Normal ❑

3.13 Musculo-skeletal system

	Abnormal	Normal
(a) **Lower back**		
(i) Range of movement	❑	❑
(ii) Posture and gait	❑	❑
(iii) Straight leg raising	❑	❑
(b) **Neck** – range of movement	❑	❑
(c) **Joint movements**		
(i) Upper Limbs	❑	❑
(ii) Lower Limbs	❑	❑
(iii) Reflexes	❑	❑

3.14 Urinalysis and Blood Sugar

	Present	Absent
(a) Sugar	❑	❑
(b) Protein/albumin	❑	❑
(c) Blood	❑	❑
(d) Blood sugar analysis (optional)	❑	❑

3.15 Abdomen

(a) Abdominal scars	❑	❑
(b) Abdominal mass	❑	❑
(c) Hernia	❑	❑

3.16 Skin

(a) Eczema, dermatitis or allergy	❑	❑
(b) Skin cancer or other abnormality	❑	❑

Examining Medical Officer's comments on Questions 3.9 to 3.16

3.17 Is the coal mine worker's fitness for duty is likely to be affected by any of the following?

		Yes	No
(a)	Dietary Habits	❑	❑
(b)	Exercise routine	❑	❑
(c)	Stress Level	❑	❑
(d)	Alcohol Consumption	❑	❑
(e)	Drugs or medication not prescribed by a doctor	❑	❑

3.18 Is there any reason why the coal mine worker may be not fit for duty in relation to work:

		Yes	No
(a)	As an operator of (or working around) around heavy vehicles	❑	❑
(b)	Underground (including use of self-rescue breathing devices and escape)	❑	❑
(c)	Shift work	❑	❑
(d)	Performing heavy manual handling	❑	❑
(e)	In wet or muddy conditions	❑	❑
(f)	In dusty conditions	❑	❑
(g)	At height or on ladders	❑	❑
(h)	In confined spaces	❑	❑
(i)	While wearing safety footwear or other personal protective equipment such as ear plugs, glasses and respirators	❑	❑
(j)	Another capacity – define ……..	❑	❑

Examining Medical Officer's comments on Questions 3.17 and 3.18 .....

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Examining Medical Officer's name and address **Please print or stamp**	**Signature** **Date / /**

Approved by the Chief Inspector of Coal Mines under s281 of the Coal Mining Safety and Health Act (1999))

Approved Form - Section 4 – Health Assessment Report

Coal Mine Worker's Details

Family Name	Given Name(s)	Date of birth
		...../...../.....

Employer	Mine(s) (if applicable)

Examination Details

Date of Examination by EMO: ...../...../.....

Position (e.g. job title (generic)):

Is the assessment for underground work? Yes ❑ No ❑

As at the date of this examination, the coal mine worker:

❑ Is fit to undertake any position

❑ Is fit to undertake the proposed / current position

❑ Is suitable for and has no condition which precludes participation in mines rescue - See Mines Rescue Medical Guidelines
For Queensland Mines Rescue Service personnel / applicants only.

❑ Is fit to undertake the proposed / current position subject to the following restriction(s) (if necessary, outline a management program)

.....

.....

❑ Is not fit to undertake the proposed / current position because of the following restriction(s):

.....

.....

.....

.....

The duration of the restriction is: .....

Is a further review necessary? Yes ❑ Date / / No ❑

Specify full or type of review required: .....

Was a chest x-ray taken? Yes ❑ Date / / No ❑

As Nominated Medical Adviser I have explained the restriction / additional assessment to the worker Yes ❑ No ❑

As Nominated Medical Adviser I have provided a copy of Section 4 to the worker (refer Note a): Yes ❑

I have been advised of the outcome of this assessment. (Practical constraints prevent this from being a compulsory item)	**Coal Mine Worker's Signature**	**Date / /**
Nominated Medical Adviser's name and address: Practice stamp	**NMA's Signature:**	**Date / /**

Distribution:

(a) copy of Section 4 to coal mine worker at address shown on page 2; and

(b) copy of Section 4 to employer; or in the case of Mines Rescue membership a copy also to Queensland Mines Rescue Service, GPO Box 156, Dysart, Qld 4745; and

(c) copy of complete Health Assessment Form to Health Surveillance Unit, Simtars, Department of Natural Resources and Mines, PO Box 467, Goodna Qld 4300.

Approved by the Chief Inspector of Coal Mines under s281 of the Coal Mining Safety and Health Act (1999)

Appendix 4: Completion and quality assessment of a sample of 91 completed health assessment forms

	Section/Questions	Included in the DNRM dataset	If Y, degree of completeness	
Section 1	**Employer to complete**		Num.	Qual.
	Name of NMA	Yes	91/91	91/91
	Employer	Yes	82/91	79/82
	Coal workers' position - description	Yes	90/91	89/90
	Coal workers' position - generic SEG	Yes	4/91	-
	Coal workers' position – company SEG	Yes	0/91	0/0
	Mine	Yes	91/91	58/91
	(a) Dust exposure (X-ray needed?) - Y/N *(Duplicate Q – see section 3/3.12)*	Yes	60/91	56/91
	(b) Underground work - Y/N	Yes	66/91	66/66
Section 2	**Coal Mine Worker to complete**			
2.1	(a) Family Name, Given Names	N/A – De-identified data		
	(b) Date of Birth	Yes	91/91	91/91
	(c) Address	N/A – De-identified data		
	(d) Gender	Yes	91/91	91/91
	(e) Telephone	N/A – De-identified data		
2.2	**Work history**	No		
2.3	**Health-related history**			
	(a) Previous med./examination under scheme – Y/N	No		
	(b) If yes, date of last examination	No		
	(c) Current smoker, or ever smoked – Y/N Supply details – Start, Stop, Type, Quantity/day	Yes No	89/91	89/89
2.4	**Ever suffered from, or currently suffer from any of the following:**	No		
	(b) Chest pain, angina or tightness of chest – Y/N (?)	No		
	(d) Asthma, bronchitis or other lung diseases – Y/N	No		
	(e) Abnormal shortness of breath or wheezing – Y/N	No		
	(y) Allergic reaction or reaction to chemicals or dust – Y/N (?) – *irritant*	No		
	No detailed questions about respiratory symptoms			
Section 3	**Clinical Findings**			
3.1	Height	Yes	91/91	90/91
3.2	Weight	Yes	91/91	90/91
3.8	**Cardiovascular system**			
	(h) ECG - AbN/N (R-sided heart changes)	Yes	68	5/68
3.9	**Respiratory system**			
	(b) FEV_1 – observed	Yes	88/91	-

	Section/Questions	Included in the DNRM dataset	If Y, degree of completeness	
	(e) FEV_1 – predicted	Yes	88/91	-
	(h) FEV_1 – observed/predicted %	Yes	87/91	86/87
	(c) FVC – observed	Yes	88/91	-
	(f) FVC – predicted	Yes	88/91	-
	(i) FVC – observed/predicted %	Yes	87/91	84/87
	(d) FEV_1/FVC% - observed	Yes	88/91	85/88
	(g) FEV_1/FVC% - predicted	Yes	88/91	86/88
3.10	Spirometry – abnormal/normal	Yes	90/91	90/90
3.11	Auscultation of chest – abnormal/normal	Yes	90/91	90/90
3.12	CXR undertaken – Y/N	Yes	91/91	91/91
	Date CXR taken	Yes	85/91	83/85
	Quality of film – unsatisfactory/satisfactory	No		
	What was the result – AbN/N Attach film to report	Yes No	70/91	70/70
3.17	**Is coal mine worker's fitness for duty likely to be affected by any of the following**	No		
	No lifestyle question relating to respiratory system, e.g. smoking			
3.18	**Is there any reason why the coal mine worker may not be fit for duty in relation to work:**	No		
	(b) Underground (including use of self-rescue breathing devices & escape) – Y/N	No		
	(d) Performing heavy manual handling – Y/N	No		
	(f) In dusty conditions – Y/N	No		
	(h) In confined spaces – Y/N (?)			
	(i) While wearing safety footwear or other PPE such as ear plugs, glasses and respirators – Y/N	No		
Section 4	**Health Assessment Report**			
	Examination Details			
	Date of examination by EMO (Name of EMO – not on assessment form)	Yes Yes	91/91 59	0 2/59
	Is assessment for underground work – Y/N *(Duplicate Q – see Section 1)*	Yes	85	62/85
	Detail of restrictions	Yes		?4
	NMA explained restriction/additional assessment	No		
	1. Fit for duty – 5 options to select from with a tick 2. None of the options are specific for the respiratory system	Entered as "true" or "false"		
	NMA provided copy of Section 4 to worker - Y	No		
	Coal mine workers' signature/date	No		
	NMA's stamp & signature NMA date	Yes	91/91 91/91	91/91 91/91

Detailed explanation of the quality issues of completed health assessment forms

	Section/Questions	**No. of entries**	**Details**
Section 1	**Employer to complete**		
	Employer	3	"H", "Self", "Services"
	Coal workers' position - description	1	"U/G"
	Coal workers' position - generic SEG	-	
	Mine	33	12 "Unknown" BUT 11 with employer named; remainder no employer named 21 "Various mines" BUT 20 with employer named; remainder no employer named
	(a) Dust exposure (X-ray needed?) - Y/N (*Duplicate Q – see Section 3*)	35	4 "N", but CXR "Y" 31 blanks, but CXR "Y"
Section 3	**Clinical Findings**		
3.1	Height	1	"0" entered
3.2	Weight	1	"0" entered
3.8	**Cardiovascular system**		
	(h)ECG - AbN/N (R-sided heart changes)	63	"X" entered instead of "A" or "N"
3.9	**Respiratory system**		
3.9	FEV_1 – observed	-	
	FEV_1 – predicted	-	
	FEV_1 – observed/predicted %	1	FEV_1 observed & FEV_1 predicted but no %
	FVC – observed	-	
	FVC – predicted	-	
	FVC – observed/predicted %	3	FVC observed & FVC predicted but no % FVC observed > predicted but =100% FVC observed > predicted but <100%
	FEV_1/FVC% - observed	3	FEV_1 > FVC but <100%
	FEV_1/FVC% - predicted	2	FEV_1 > FVC but <100%
3.12	(b) Date CXR taken	2	Incomplete "11/10", "06/2001"

	Section/Questions	**No. of entries**	**Details**
Section 4	**Health Assessment Report** Examination Details		
	Date of examination by EMO (Name of EMO – not on assessment form, but in the DNRM database)	0 57	 55 with surnames only 2 with the names of the surgery
	59 medicals completed by an EMO (35 doctors in total, including 14 NMAs) 28 medicals completed by EMOs who are also NMAs		
	Is assessment for underground work – Y/N (*Duplicate question – see Section 1*)	23	Work U/G cf. U/G work Blank cf. "Y" (18) Blank cf. "N" (1) "N" cf. "Y" (3) "Y" cf. "N" (1)
	Detail of restrictions	4	Not clear from the details if these relate to a respiratory condition

Appendix 5: List of NMAs, by practice type and qualifications

In total, there were 237 Nominated Medical Advisers (NMAs) conducting the coal workers' health assessments, in over 140 surgeries and in five different States. The majority (146) of NMAs were General Practitioners who were mainly based in General Practice clinics, followed by Medical Practitioners (57) with General registration practising in both Occupational Health Service and General Practice clinics. There were only twenty-eight specialist Occupational Physicians participating in the coal workers' health scheme. The different surgeries included ninety-seven General Practice clinics and forty-three Occupational Health Service clinics.

Queensland

The majority (approximately 90%) of NMAs and surgeries where the coal workers' health assessments were conducted were in Queensland. The coal workers' health assessments were undertaken in twenty-eight Queensland regions and these activities were concentrated in six regions: Brisbane, Mackay, Sunshine Coast, Rockhampton, Gold Coast and Brisbane City.

In Brisbane there were forty-eight NMAs based in twenty-nine different surgeries, including nine Occupational Health Service clinics and sixteen General Practice clinics. Three specialist Occupational Physicians, three General Practitioners and seven non-specialists conducted the assessments in the Occupational Health Service clinics. There were an additional two specialist Occupational Physicians practising from private clinics. The General Practice clinics were comprised of twenty-six General Practitioners and five non-specialists.

In Mackay there were forty NMAs based in twenty different surgeries, including three Occupational Health Service clinics and seventeen General Practice clinics. Medical Practitioners in the Occupational Health Service clinics included one specialist Occupational Physician, five General Practitioners and one non-specialist. There were one specialist Occupational Physician, twenty-three General Practitioners and nine non-specialists in the General Practice clinics.

On the Sunshine Coast the coal workers' health assessments were conducted by nineteen NMAs, all of whom were based in General Practice clinics. The NMAs included fourteen General Practitioners, four non-specialists and no specialist Occupational Physicians.

In Rockhampton, the distribution of NMAs was similar to the Sunshine Coast, but there were two Occupational Health Service clinics.

On the Gold Coast there were 12 NMAs in eleven different surgeries, including two Occupational Health Service clinics and nine General Practices. Eight General Practitioners and two non-specialists were based in the General Practice clinics.

In Brisbane City there was a similar number of NMAs as the Gold Coast, but there were more Occupational Health Service clinics (5) than General Practice clinics (1). There were five Specialist Occupational Physicians, four General Practitioners and three non-specialists.

Other States

The coal workers' health assessment was conducted in four other States: New South Wales, Victoria, Western Australia and South Australia. There were twenty-seven NMAs, based in eleven different Occupational Health Centres and three General Practices. The Medical Practitioners included nine specialist Occupational Physicians, nine General Practitioners and nine non-specialists.

Appendix 6: Spirometry survey

Dear participants,

As part of our review of the operation of the Coal Mine Workers' Health Scheme, we are seeking further information about the conduct of spirometry during the health assessments.

This survey is being sent to all Medical Practitioners listed as Nominated Medical Advisers with the Queensland Department of Natural Resources and Mines.

The survey will take approximately 15 minutes to complete, however you may need the assistance of the technician, nurse or other individual(s) who actually perform the spirometry. It is important that you complete as many questions as possible before submitting the survey.

The data collected during this survey will be sent directly to Monash University for analysis. Only anonymised group data will be reported to the Queensland Department of Natural Resources and Mines.

Your assistance with our review is appreciated.

START OF SURVEY

1. Type of site where spirometry performed

☐ General Practice
☐ Occupational Health Clinic
☐ Hospital
☐ Other facility (please specify) _____

2. Manufacturer of spirometer

☐ Don't know
Please specify _____

3. Spirometer model

☐ Don't know
Please specify _____

4. Year spirometer acquired

☐ Don't know
Please specify year (XXXX) _____

5. Spirometer software version

☐ Don't know
Please specify _____

6. Does the spirometer have automated quality control?

☐ Yes
☐ No
☐ Don't know

7. Does the spirometer produce volume-time graphical displays?

☐ Yes
☐ No
☐ Don't know

8. Does the spirometer produce flow-volume graphical displays?

☐ Yes
☐ No
☐ Don't know

9. Does the spirometer store all manoeuvres performed for each individual tested?

☐ Yes
☐ No
☐ Don't know

10. How many manoeuvres does the spirometer store for each individual tested?

☐ 1
☐ 2
☐ 3
☐ More than 3
☐ Don't know

11. What is the electronic output format of the spirometer?

☐ 2005 American Thoracic Society/European Thoracic Society (ATS/ETS)
☐ Don't know
Other (please specify) _____

12. What software does the spirometer use for report generation?

☐ Don't know
Please specify _____

13. What reference values do the reports use? e.g. National Health and Nutrition Examination Survey (NHANES)

☐ Don't know
Please specify _____

14. How often is the spirometer calibrated?

☐ At least daily
☐ Weekly
☐ Monthly
☐ Less than monthly
☐ Don't know

15. Which year was it last calibrated?
Please specify year (XXXX) _____

16. Does the spirometer have a calibration check?

☐ Yes
☐ No
☐ Don't know

17. Do you take part in an on-going spirometry quality assurance program?

☐ Yes
☐ No
☐ Don't know

18. What year did you last participate in a quality assurance program (if applicable)?
Please specify year (XXXX) _____

19. Do you have a post-bronchodilator spirometry routine?

☐ Yes
☐ No
☐ Don't know

20. Is a spacer used to administer the bronchodilator?

☐ Yes
☐ No
☐ Don't know

21. Is a spirometry procedure manual available at the site where spirometry is performed?

☐ Yes
☐ No
☐ Don't know

22. Which year was the spirometry procedure manual last revised?
☐ Don't know
Please specify year (XXXX) _____

23. Is a height measurement device used during the spirometry?

☐ Yes
☐ No
☐ Don't know

24. Is a weight measurement device used during spirometry?
☐ Yes
☐ No
☐ Don't know

25. What are the qualifications of the person usually administering spirometry for the coal mine workers' health scheme?

☐ Medical practitioner
☐ Registered nurse
☐ Science graduate
☐ Don't know
Other (please specify) _____

26. How many spirometry tests, approximately, does he/she perform *per month* for the coal mine workers' health scheme?

☐ Fewer than 1 per month
☐ Between 1 and 5 per month
☐ Between 6 and 20 per month
☐ More than 20 per month

27. How many spirometry tests, approximately, does he/she perform *per week*, excluding tests performed for the coal mine workers' health scheme?

☐ Fewer than 1 per week
☐ Between 1 and 5 per week
☐ Between 6 and 20 per week
☐ More than 20 per week

28. How many years of experience at performing spirometry does he/she have?

☐ Fewer than 1 year
☐ Between 1 and 5 years
☐ Between 6 and 10 years
☐ More than 10 years

29. Has this person attended a spirometry training course?

☐ Yes
☐ No
☐ Don't know

30. If yes to question 29, which year did he/she attend the spirometry training course?

☐ Don't know
Please specify year (XXXX) _____

31. If yes to question 29, what was the name of the organisation that delivered the training?

☐ National Asthma Council
☐ Thoracic Society Australia and New Zealand (TSANZ)
☐ Don't know
Other (please specify) _____

Appendix 7: Summary of spirometry survey data

Question	Response	%	N	Total
1. Type of site where spirometry performed	General Practice	62.2	46	74
	Occupational Medicine Clinic	36.5	27	
	Hospital	0	0	
	Other (GP/Occ med clinic)	1.4	1	
2. Manufacturer of spirometer	MIR (variety)	21.1	15	71
	Vitalograph	19.7	14	
	QRS	9.9	7	
	Welch Allyn	7.0	5	
	Others (all fewer than 5 responses)	35.2	25	
	Don't know	7.0	5	
3. Spirometer model	MiniSpir	15.3	11	72
	Spiro	12.5	9	
	Alpha	8.3	6	
	Orbit	8.3	6	
	Other (all fewer than 5 responses)	43.1	31	
	Don't know	12.5	9	
4. Year spirometer acquired	Pre 2013	16.4	12	73
	2013	12.3	9	
	2014	9.6	7	
	2015	15.1	11	
	2016	12.3	9	
	Unclear	2.7	2	
	Don't know	31.5	23	
5. Spirometer software version	Winspiro	21.6	16	74
	Office medic	8.1	6	
	Other (all fewer than 5 responses)	50.0	37	
	Don't know	20.3	15	

Question	Response	%	N	Total
6. Does the spirometer have automated quality control?	Yes	63.8	44	69
	No	11.6	8	
	Don't know	24.6	17	
7. Does the spirometer produce volume-time graphical displays?	Yes	90.3	65	72
	No	4.2	3	
	Don't Know	5.6	4	
8. Does the spirometer produce flow-volume graphical displays?	Yes	100	74	74
	No	0	0	
	Don't Know	0	0	
9. Does the spirometer store all manoeuvres performed for each individual tested?	Yes	94.4	68	72
	No	1.4	1	
	Don't know	4.2	3	
10. How many manoeuvres does the spirometer store for each individual tested?	1	2.7	2	74
	2	4.1	3	
	3	33.8	25	
	More than 3	50.0	37	
	Don't know	9.5	7	
11. What is the electronic output format of the spirometer?	2005 American Thoracic Society/European Thoracic Society (ATS/ETS)	44.6	33	74
	Other (please specify) *European, CE or ERS (5) Other (3)*	10.8	8	
	Don't know	44.6	33	
12. What software does the spirometer use for report generation?	Winspiro	23.0	17	74
	Office medic	6.8	5	
	Medical director	6.8	5	
	Others (all fewer than 5 responses)	35.1	26	
	Don't know	28.4	21	
13. What reference values do the reports use? e.g. National Health and Nutrition Examination Survey (NHANES)	NHANES	21.9	16	73
	Knudsen	6.8	5	
	Other (all fewer than 5 responses)	24.7	18	
	Don't know	46.6	34	

Question	Response	%	N	Total
14. How often is the spirometer calibrated?	At least daily	19.4	14	72
	Weekly	5.6	4	
	Monthly	20.8	15	
	Less than monthly	41.7	30	
	Don't know	12.5	9	
15. Which year was it last calibrated?	Pre 2015	4.3	3	70
	2015	34.3	24	
	2016	50.0	35	
	Other e.g. unknown or self-calibrates	11.4	8	
16. Does the spirometer have a calibration check?	Yes	79.2	57	72
	No	6.9	5	
	Don't know	13.9	10	
17. Do you take part in an ongoing spirometry quality assurance program?	Yes	29.2	21	72
	No	59.7	43	
	Don't know	11.1	8	
18. What year did you last participate in a quality assurance program (if applicable)?	Pre 2015	16.2	6	38
	2015	29.7	11	
	2016	13.5	5	
	N/A	27.0	10	
	Other (all fewer than 5 responses)	13.5	6	
19. Do you have a post-bronchodilator spirometry routine?	Yes	79.7	59	74
	No	14.9	11	
	Don't know	5.4	4	
20. Is a spacer used to administer the bronchodilator?	Yes	78.1	57	73
	No	19.2	14	
	Don't know	2.7	2	
21. Is a spirometry procedure manual available at the site where spirometry is performed?	Yes	91.9	68	74
	No	6.8	5	
	Don't know	1.4	1	

Question	Response	%	N	Total
22. Which year was the spirometry procedure manual last revised?	Pre 2014	16.9	12	71
	2014	7.0	5	
	2015	19.7	14	
	2016	19.7	14	
	Other	4.2	3	
	Don't know	32.4	23	
23. Is a height measurement device used during the spirometry?	Yes	98.6	73	74
	No	1.4	1	
	Don't know	0	0	
24. Is a weight measurement device used during spirometry?	Yes	90.5	67	74
	No	9.5	7	
	Don't know	0	0	
25. What are the qualifications of the person usually administering spirometry for the coal mine workers' health scheme?	Medical practitioner	8.1	6	74
	Registered or enrolled nurse	81.1	60	
	Science graduate	1.4	1	
	Occ Med/Health screener	2.7	2	
	Clerical	2.7	2	
	Other	4.1	3	
	Don't know	0	0	
26. How many spirometry tests, approximately, does he/she perform per month for the coal mine workers' health scheme?	Fewer than 1 per month	4.1	3	74
	Between 1 and 5 per month	37.8	28	
	Between 6 and 20 per month	35.1	26	
	More than 20 per month	23.0	17	
27. How many spirometry tests, approximately, does he/she perform per week, excluding tests performed for the coal mine workers' health scheme?	Fewer than 1 per week	6.8	5	73
	Between 1 and 5 per week	37.0	27	
	Between 6 and 20 per week	30.1	22	
	More than 20 per week	26.0	19	

Question	Response	%	N	Total
28. How many years of experience at performing spirometry does he/she have?	Fewer than 1 year	0	0	74
	Between 1 and 5 years	33.8	25	
	Between 6 and 10 years	25.7	19	
	More than 10 years	40.5	30	
29. Has this person attended a spirometry training course?	Yes	62.2	46	74
	No	28.4	21	
	Don't know	9.5	7	
30. If yes to question 29, which year did he/she attend the spirometry training course?	Pre 2013	15.4	8	52
	2013	7.7	4	
	2014	11.5	6	
	2015	23.1	12	
	2016	3.8	2	
	Other	7.7	4	
	Don't know	30.8	16	
31. If yes to question 29, what was the name of the organisation that delivered the training?	National Asthma Council	35.4	17	48
	Thoracic Society Australia and New Zealand (TSANZ)	2.1	1	
	Don't know	22.9	11	
	Other (all fewer than 5 responses)	39.6	19	

Appendix 8: Spirometry review protocol

The quality and accuracy of a sample of approximately 300 spirograms and their corresponding Nominated Medical Adviser (NMA) reports were examined as part of the review. The sample of spirograms were selected to be representative of the various Queensland mines, and were restricted, where possible, to coal miners at a higher risk of developing changes in lung function, i.e. individuals with at least 10 years of underground work.

Dr Ryan Hoy and Professor Bruce Thompson are experienced in interpreting lung function data, and undertook the review.

The quality of spirometry was assessed according to the guidelines set out in the National Asthma Council handbook, *Spirometry – The measurement and interpretation of ventilatory function in clinical practice* and the 2005 American Thoracic Society/European Respiratory Society (ATS/ERS) Standardisation of Spirometry. In particular, there was specific evaluation of the presence of artefact (such as cough, leak and early termination), adequate start and satisfactory exhalation. Spirograms were deemed to be poor quality if one or more of the previously noted criteria are not acceptable. As well as the above criteria, the ATS/ERS Standards also requires three acceptable spirograms to be recorded and saved, and repeatability between tests to be present, that is, two largest values of forced vital capacity (FVC) must be within 0.150 L of each other and two largest values of forced expiratory volume in 1 second (FEV_1) must be within 0.150 L of each other. Spirograms were also evaluated for the presence of adequate documentation, repeatability of results and quality of spirometry.

The accuracy of spirometry results were interpreted in accordance with the 2005 ATS/ERS interpretive strategies. The lower limit of normal (LLN) is taken to be equal to the 5th percentile of a healthy, non-smoking population. Pattern and severity of abnormal results (or lung function impairment) were assessed according to the following ATS/ERS classification:

Obstruction

- FEV_1/VC < 5th percentile of predicted

Restriction

- Reduced VC does not prove a restrictive pulmonary defect, but may be suggestive of lung restriction when FEV_1/VC is normal or increased

Mixed defect

- FEV_1/VC and TLC < 5th percentile of predicted

Severity of Impairment

$FEV_1 \geq$ LLN (Normal)
70% reference $\leq FEV_1 <$ LLN (Mild)
60% reference $\leq FEV_1 <$ 70% reference (Moderate)
50% reference $\leq FEV_1 <$ 60% reference (Moderately Severe)
35% reference $\leq FEV_1 <$ 50% reference (Severe)
$FEV_1 <$ 35% reference (Very Severe)

Spirometry review procedure

1. The two reviewers independently examined the spirometry data according to the outlined criteria for acceptability and repeatability.
2. The following fields were extracted by a research assistant from the health assessment forms, and entered into an EXCEL spreadsheet (to facilitate data collation and analysis):
    - Study ID
    - Name of Mine
    - FEV_1 – observed, predicted, and observed/predicted %
    - FVC – observed, predicted, and observed/predicted %
    - FEV_1/FVC% – observed and predicted
    - Spirometry result – abnormal or normal
    - NMA/EMO comments
3. The following fields were assessed and extracted from the spirograms by the reviewers, where possible, and entered into an EXCEL spreadsheet:
    - Study ID
    - Reference values used
    - Data readable – Y/N (e.g. based on quality of photocopy)
    - ATS/ERS standards met – Y/N
    - Artefact free – Y/N
    - Good start – Y/N
    - Satisfactory exhalation – Y/N
    - 3 spirograms provided – Y/N
    - 2 largest FVC within 0.15l – Y/N
    - 2 largest FEV_1 within 0.15l – Y/N
    - Largest FVC, FVC % predicted
    - Largest FEV_1, FEV_1 % predicted
    - FEV_1/FVC, FEV_1/FVC % predicted
    - Interpretation – normal/abnormal
    - Obstructive – Y/N
    - Restrictive – Y/N
    - Severity
    - Other comments
4. The interpretation of the two reviewers was compared to determine whether there was agreement in evaluation of spirometry quality and the results.
    a) If there was agreement, the result was considered final and reported
    b) When agreement was lacking, reviewers met and discussed the results to reach agreement by consensus.
5. The final results were compared with the existing NMA reports (i.e. NMA/EMO results entered in Q3.9 and Q3.10 for agreement)
    a) Overall findings were reported, focusing on agreement between the existing reports and reviewers' interpretations.

   b) Where there was disagreement, any common features e.g. one particular mine will also be reported and/or investigated
6. Where a major discrepancy was found, the coal mine worker will be notified via DNRM and the appropriate medical practitioner(s) about results of the re-evaluation of their spirometry according to procedures within the Coal Mine Workers' Health Scheme.

Appendix 9: Detailed measures to improve quality of spirometry

1. Adoption of the 2013 American Thoracic Society (ATS) Technical Standards: Spirometry in the Occupational Setting, with development of consensus regarding each of the components (see ATS List below) specific to the task of underground coal mining in Queensland.
2. Spirometry must be performed at Thoracic Society of Australia and New Zealand (TSANZ) accredited respiratory laboratory. Currently, there are 10 TSANZ accredited respiratory laboratories in Queensland. A list of accredited laboratories and accreditation processes is available at:
   https://www.thoracic.org.au/respiratorylaboratoryaccreditation/australia
3. Spirometry testing facilities and staff require registration with the Coal Mine Health Surveillance Program. The testing facility and staff will be designated registration numbers, which need to be recorded on test results when performed and submitted to the Surveillance Program. Approval requires provision of documentation for review including:
   a. Documentation of current accreditation of the laboratory by TSANZ.
   b. Staff training certification: Each person administering spirometry must provide documentation of successful completion of an approved spirometry training program and refresher courses on a periodic basis as determined by TSANZ accreditation. The most recent TSANZ position paper regarding training courses recommends the duration of a spirometry training course is at least 10 hours, particularly if participants are spirometry naïve. A refresher course should be attended within the first 12 months of completion of the initial course, and thereafter every three years
4. Test performance and interpretation factors:
   a. Spirometry must be performed and recorded in accordance with current ATS/ERS Standardisation of Spirometry. Each session must have the goal of obtaining at least 3 acceptable spirograms with 2 repeatable forced expiratory manoeuvres.
   b. Spirometry tests should be interpreted by a physician or respiratory scientist with expertise in spirometry.
   c. Interpretation must follow the current ATS/ERS Interpretative strategies for lung function tests and use the fifth percentile lower limit of normal (LLN) to differentiate normality from abnormality, rather than a fixed value, such as 80% of predicted. In the workplace setting it has been noted that use of fixed values to detect abnormality will result in false negative results for younger workers and false-positive results in older workers.
   d. Data should be recorded and stored to allow interpretation of longitudinal changes to permit detection of greater than expected rate of decline.
   e. Detection of abnormal test results or greater than expected rates of decline must result in further evaluation of the worker. For example, if reduced a vital capacity is noted on spirometry the worker should be referred for more complex respiratory function tests including plethysmographic lung volumes and gas transfer.
5. Equipment factors:

   a. Spirometry system must be in a quality control program consistent with current ATS/ERS Standardisation of Spirometry and TSANZ accreditation manual.
   b. Use spirometers that can save and export all data and all flow–volume and volume–time curves and can display them on real-time graphical displays large enough for inspection of quality by scientists as tests are performed.
   c. Whenever possible, use the same type of spirometer for serial testing, and document the spirometer used.
   d. The spirometry software must automatically perform quality assurance checks on expiratory manoeuvers during the testing session.

6. Scientist/operator training:
   a. Provide scientists with initial training and periodic refresher courses by an approved spirometry training program, which should include hands-on practical experience.
   b. Use spirometers that can assess quality of tests and provide automated real-time feedback to technicians.
   c. Conduct ongoing review of the quality of spirometry tests that are performed and provide technicians timely, ongoing feedback about the quality of their tests and how to correct problems that are identified. This is also a requirement of TSANZ respiratory laboratory accreditation.
7. Spirometry results and other data to be specified must be submitted to the Coal Mine Health Surveillance Program with 14 days of completing the test. The Coal Mine Health Surveillance Program will undertake review of provided data by a respiratory physician for assessment of quality, validation of results and longitudinal change for individual workers. A database will be maintained of all spirometry results. Centralised review of all results will allow provision of recommendation for potential intervention for specific workers, testing sites and/or mine sites.

<u>Components of a workplace spirometry program from the 2013 Official American Thoracic Society (ATS) Technical Standards: Spirometry in the Occupational Setting</u>

1. Define purpose of the spirometry testing, such as:
   a. Medical surveillance (to detect effects of inhalational exposures/occupational lung diseases)
   b. Appropriate job placement (after hire, before job placement)
   c. Component of medical evaluation for respirator usage
   d. Component of an impairment or disability evaluation
2. Define parameters for the spirometry program, including:
   a. Inhalational exposures and lung diseases of concern
   b. Regulatory and workplace-mandated requirements
   c. Frequency of testing
   d. Workers to be tested (based on potential hazards or other concerns)
3. Clarify responsibility for evaluation of:
   a. The individual worker
   b. Aggregate analysis of the spirometry and other data collected on the group of workers
4. Clarify lines of communication of relevant information between the patient, employer, and medical provider.
5. Ensure that spirometers and technician training meet or exceed ATS recommendations.
6. Establish and maintain an effective quality assurance program.

7. Define appropriate spirometry reference values and interpretative strategies.
8. Establish triggers for further evaluation and initial action plan.

Standards incorporated in recommendations:

Pellegrino R, et al. ATS/ERS Task Force: Standardisation Of Lung Function Testing. Interpretative strategies for lung function tests. Eur Respir J 2005; 26: 948–968

Miller M.R, et al. ATS/ERS Task Force: Standardisation Of Lung Function Testing. Standardisation of spirometry. Eur Respir J 2005; 26: 319–338

Redlich C, et al. Official American Thoracic Society Technical Standards: Spirometry in the Occupational Setting. Am J Respir Crit Care Med 2014; 189 : 984–994

The National Institute for Occupational Safety and Health (NIOSH) Coal Mine Health Surveillance Program (CWHSP) Accessed 5/6/16.

http://www.cdc.gov/niosh/topics/surveillance/ords/coalminerhealth.html

Thoracic Society of Australia and New Zealand – Respiratory Function Laboratory Accreditation: Accessed 9/6/16

https://www.thoracic.org.au/respiratorylaboratoryaccreditation/respiratory-function-laboratory-accreditation

Appendix 10: Coal Miners Dust Lung Disease – Fact sheet for GPs

Coal Mine Dust Lung Disease – Fact sheet for GPs

Since May 2015, there have been six confirmed cases of coal workers' pneumoconiosis (CWP), one form of coal mine dust lung disease (CMDLD), reported among former and current Queensland coal mine workers, and the outcome of at least one suspected case is still pending. The Queensland Department of Natural Resources and Mines (DNRM) has commissioned an independent review of the respiratory component of the coal mine workers' health scheme, including an interim strategy to detect and manage further CMDLD cases. This fact sheet contains information for General Practitioners about CMDLD, to assist in the assessment and management of such cases. Due to the high media interest in this issue, many coal miners in Queensland are likely to be worried about their respiratory health and seek advice from their GP.

Summary

- Coal miners occupationally-exposed to respirable coal mine dust over several years are at risk of developing coal mine dust lung disease, which includes CWP, emphysema, chronic bronchitis, and lung function impairment.
- CMDLD should also be considered in former coal miners, such as retirees and ex-industry employees, who present with significant respiratory symptoms. These diseases develop gradually, usually after at least 10 years of exposure, however in sensitive miners or in cases of intense exposure symptoms may occur sooner.
- Typical symptoms of CMDLD include cough, sputum production, and shortness of breath, however individuals with early disease may be asymptomatic but may have detectable chest x-ray or spirometry findings.
- Early detection of CMDLD is based on chest imaging and lung function testing, usually with plain chest radiography and spirometry, along with careful evaluation of respiratory symptoms.
- Individuals who are or have been coal mine workers and are suspected of having CWP should be referred to a Respiratory and/or Occupational physician for further assessment. Links to lists of such physicians can be found at https://www.business.qld.gov.au/industry/mining/safety-health/mining-safety-health/medicals/coal-board-medical/pneumoconiosis-screening

About Coal Mine Dust Lung Disease

Coal mine dust lung disease is the broad term for diseases caused by coal mine dust exposure, and comprises a group of occupational lung diseases that result from the cumulative inhalation of respirable coal mine dust over several years. Coal miners are at risk of developing these diseases, which include pneumoconioses (coal workers' pneumoconiosis, silicosis, and mixed dust pneumoconiosis). Pneumoconiosis is a disease of the lung parenchyma caused by deposition of dust particles, and the reaction of lung tissue to the dust.

Emphysema, chronic bronchitis, lung function impairment, and diffuse dust-related fibrosis are other manifestations of the disease.

Coal workers' pneumoconiosis, the form of disease identified by chest imaging, can be further classified by severity: simple CWP which may be category 1, 2, or 3 reflecting increasing profusion of scars seen on chest imaging. The more severe stage of the disease known as complicated CWP or progressive massive fibrosis (PMF) is diagnosed when a scar is greater than one cm in diameter. The likelihood of CWP development is directly related to the intensity and duration of exposure to coal mine dust. The disease typically occurs after at least 10 years of exposure, and the risk of disease persists after exposure has ceased.

Under the current Queensland Coal Mine Workers' Health Scheme, all coal mine workers are required to undergo a medical assessment prior to the start of their employment at a coal mine, and then at least once every five years during their employment. Employees identified as at risk from dust exposure, in particular underground coal miners are also required to undertake chest x-rays as part of their health assessments. Given the long latency between exposure and disease occurrence, the population at risk extends to previous employees including retired coal miners and coal miners who have transferred to other industries. Coal workers' pneumoconiosis was thought to have been eradicated from Australia, with no new cases having been reported for many years. In light of the recent CWP cases increased vigilance is required among treating doctors, in particular GPs, to identify individuals with early stages of CWP.

Symptoms

Individuals with early-stage coal workers' pneumoconiosis are often asymptomatic, however typical symptoms of CWP (and other CMDLD) include cough, sputum production, wheezing, and shortness of breath. Progressive massive fibrosis is a debilitating and life-threatening condition, and individuals may present with more severe symptoms. Emphysema, chronic bronchitis and lung function impairment are well described adverse health outcomes of coal mine dust exposure and have the same presentation seen when caused by tobacco smoke exposure. The toxicity of tobacco smoke and coal mine dust are roughly equal in potency, and result in an additive effect.

Investigations

Detection of coal mine dust lung disease requires identification of relevant occupational exposure history and evaluation of respiratory symptoms, as well as chest imaging and lung function testing, which usually includes plain chest radiograph and spirometry. Chest imaging is interpreted using International Labour Office (ILO) criteria. Coal workers' pneumoconiosis is a more complex disease to diagnose, and suspected cases should be referred to specialist Respiratory or Occupational physicians for assessment and management. All confirmed cases of CWP should be reported to the Queensland Department of Natural Resources and Mines by treating specialists.

There is currently no effective treatment for coal workers' pneumoconiosis, and emphasis is therefore on early detection of asymptomatic or early-stage disease, and advice to avoid further exposure to coal mine dust and other respiratory hazards including smoking cessation.

Further information

The Queensland Department of Natural Resources and Mines has compiled a list of Respiratory physicians who can be contacted for further assessment of potential cases of CWP. A list of radiology clinics reporting chest x-rays to the ILO classification has also been compiled. These lists can be accessed on the Department's webpage, and will be regularly updated. See https://www.business.qld.gov.au/industry/mining/safety-health/mining-safety-health/medicals/coal-board-medical/pneumoconiosis-screening

Reference

Petsonk EL, Rose C, Cohen R. Coal Mine Dust Lung Disease – New Lessons from an Old Exposure. *Am J Respir Crit Care Med* 2013;187(11):1178-85.

Original research

Coal mine dust lung disease in miners killed in the Upper Big Branch disaster: a review of lung pathology and contemporary respirable dust levels in underground US coal mines

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ABSTRACT

Objectives In 2010, 29 coal miners died due to an explosion at the Upper Big Branch (UBB) mine in West Virginia, USA. Autopsy examinations of 24 individuals with evaluable lung tissue identified 17 considered to have coal workers' pneumoconiosis (CWP). The objectives of this study were to characterise histopathological findings of lung tissue from a sample of UBB fatalities and better understand the respirable dust concentrations experienced by these miners at UBB relative to other US coal mines.

Methods Occupational pulmonary pathologists evaluated lung tissue specimens from UBB fatalities for the presence of features of pneumoconiosis. Respirable dust and quartz samples submitted for regulatory compliance from all US underground coal mines prior to the disaster were analysed.

Results Families of seven UBB fatalities provided consent for the study. Histopathologic evidence of CWP was found in all seven cases. For the USA, central Appalachia and UBB, compliance dust samples showed the geometric mean for respirable dust was 0.468, 0.420 and 0.518 mg/m^3, respectively, and respirable quartz concentrations were 0.030, 0.038 and 0.061 mg/m^3. After adjusting for quartz concentrations, UBB exceeded the US permissible exposure limit (PEL) for respirable dust in 28% of samples.

Conclusions Although higher than average respirable dust and quartz levels were observed at UBB, over 200 US underground coal mines had higher dust concentrations than UBB and over 100 exceeded the PEL more frequently. Together with lung histopathological findings among UBB fatalities, these data suggest exposures leading to CWP in the USA are more prevalent than previously understood.

Key Messages

What is already known about this subject?

- The prevalence of radiographically identified coal workers' pneumoconiosis (CWP) has risen in the USA in the past two decades, despite enactment of limits on respirable coal mine dust exposure in 1969. Previous studies of lung tissue specimens among coal miners may have been subject to selection bias given that subjects had reason to access healthcare systems. In 2010, an explosion at the Upper Big Branch (UBB) underground coal mine in the USA killed 29 miners. Autopsy examination of 24 miners with evaluable lung tissue identified 17 considered to have CWP.

What are the new findings?

- In a rare look at the lung pathology of a random group of working miners with different tenures, histopathological examination of lung tissue from a sample of seven UBB victims by expert occupational pathologists demonstrated evidence of CWP in all specimens, including two miners with less than 5 years of coal mining tenure. Analysis of total respirable and quartz compliance dust samples at US underground coal mines showed many mines had higher dust concentrations and/or exceeded the permissible exposure limit (PEL) more frequently than UBB.

How might this impact on policy or clinical practice in the foreseeable future?

- Lung histopathological findings among UBB fatalities and analysis of dust samples suggest exposures leading to CWP in the USA are more prevalent than previously understood. Of note, mean dust levels were compliant under the existing PEL. This suggests that reduced exposure limits and strict enforcement of these levels by regulators are necessary.

INTRODUCTION

The prevalence of coal workers' pneumoconiosis (CWP), as identified on chest radiography, has risen among active US coal miners in the past two decades, despite a permissible exposure limit (PEL) of 2 mg/m^3 for respirable coal mine dust implemented in the USA in 1972.[1] Alarmingly, the prevalence of the most severe form of CWP, progressive massive fibrosis (PMF), has risen dramatically among long-tenured miners. The prevalence of PMF in central Appalachia—a region of the USA which includes Virginia, southern West Virginia and eastern Kentucky—is now approaching that was recorded before modern dust control regulations were in place.[2]

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On 5 April 2010, 29 coal miners were killed in an explosion in the Upper Big Branch (UBB) underground coal mine in Raleigh County, West Virginia, the worst mining disaster in the USA since 1970. Autopsy examinations of the victims performed by the medical examiners of the State of West Virginia revealed pathology consistent with CWP in 17 of the 24 cases with evaluable lung tissue.[3] We undertook the current study to further investigate and characterise the histopathologic findings of this group of active working coal miners, using a team of expert occupational pulmonary pathologists to evaluate lung tissue from seven UBB fatalities whose families provided consent for the study. We also obtained contemporary coal mine dust sampling data, submitted to document regulatory compliance, to ascertain whether respirable dust or quartz/silica levels were unusually elevated at UBB relative to underground coal mines in the central Appalachian region or the entire USA.

METHODS

Study population and procedures

After receiving approval from the Cook County Health and Hospital System's Institutional Review Board (protocol# 11-095), we obtained informed consent from the next of kin of victims of the UBB mine disaster. Next of kin of miners completed a questionnaire about demographic and occupational histories. Due to publicly known identities of the victims of the UBB mine explosion, potentially identifying data, such as age and duration of coal mining tenure, were not included in this manuscript.

Histologic definitions and pathologic scoring

Slides of formalin-fixed, paraffin-embedded lung tissue sections were obtained from the West Virginia Office of the Chief Medical Examiner, who had performed autopsy examinations of the study subjects. For each subject, between three and seven slides were made available for evaluation by study investigators. The slides were anonymised and evaluated by three expert occupational pulmonary pathologists (FHYG, JLA and AC). Study pathologists were aware that the subjects were UBB victims, but were otherwise blinded to the case histories. Lung tissue slides were graded for quality and for the presence of coal macules, coal nodules, silicosis, interstitial fibrosis, small airways disease, PMF, emphysema and smokers' macrophages using a standardised method. Lesions specific for CWP were classified according to published standards[4] as follows:

1. Coal dust macules were defined as a collection of coal mine dust-laden macrophages around a terminal respiratory bronchiole with mild reticulin fibrosis and minimal collagen. Macules were typically surrounded by centriacinar (focal) emphysema.
2. Coal dust nodules were defined as lesions larger and more fibrotic than macules, greater than 4 mm and less than 10 mm in size. Collagen fibres in coal dust nodules were haphazardly arranged.[4] Unlike coal dust macules, coal dust nodules could be found throughout the parenchyma.[4]
3. PMF was defined in this study as a coal mine dust-pigmented fibrotic lesion with irregular or whorled deposition of collagen fibres, with or without areas of necrosis, measuring 10 mm or more in longest axis. This size criterion is based on the definition in the US Federal Coal Mine Health and Safety Act of 1969.[5]

Other lesions, strongly associated with classic CWP and likely caused by exposure to coal mine dust, were defined as follows:

1. Silicotic nodules were defined by the presence of nodules with smooth borders and a central fibrotic area of laminated, whorled collagen.[6]
2. Interstitial fibrosis was defined as fibrosis of alveolar walls. For this study, the association between the fibrosis and coal mine dust deposition was required.
3. Mineral dust small airway disease was defined as fibrosis and narrowing of walls of membranous bronchioles with deposition of mineral dust particles.

Dust present in the specimens was evaluated by transmitted brightfield and polarised light microscopy (PLM). Strongly birefringent and elongated or platy particles were classified as silicates. Weakly birefringent particles were classified as silica.[7] After independent review and grading, the three pathologists met in a consensus conference to resolve differences in pathologic classification.

Coal mine dust analysis

To understand respirable dust and respirable quartz levels at UBB relative to other US underground coal mines, we analysed compliance coal mine dust samples. US coal mine operators collect respirable dust samples and submit them to the US Mine Safety and Health Administration (MSHA) for analysis, as required to demonstrate compliance with federal coal mine dust PELs. MSHA mine inspectors also collect respirable dust samples during periodic safety and health inspections. Until 2016, compliance sampling for coal mine dust was performed for at least 8 hours, regardless of the length of the worker's shift, and was permitted during shifts in which coal production was as low as 50% of average. Descriptors associated with collected samples include the date of sample collection; a mine identification number; sample cassette number; indication of collection of the sample by the coal mine operator versus a MSHA mine inspector; concentrations of respirable coal mine dust and, for a subset of samples, the percentage of respirable quartz dust by weight in the sample.

The measurements for mine dust samples collected at UBB during the period 1 January 2000 to 5 April 2010 were compared with similar results from other underground US coal mines, using the publicly available respirable coal mine dust and respirable quartz dust sampling data maintained by MSHA.[8] Respirable quartz concentrations were calculated based on the measured percentage of quartz in the sample and the respirable dust level from the same sample cassette.

We determined the proportion of samples for each underground coal mine that exceeded the PEL for respirable coal mine dust. During the study period, the PEL for respirable coal mine dust in samples with 5% quartz or less was 2 mg/m^3. The PEL for samples with greater than 5% quartz is determined by the following formula:

$$\text{PEL} = \frac{10\,\frac{\text{mg}}{\text{m3}}}{\%\text{Quartz}}.$$

Samples from underground coal mines designated by MSHA as valid and collected during a work shift of at least 8 hours were included for analysis. Intake air samples were excluded. Also excluded were samples taken from 'Part 90' coal miners, who had been designated to perform work in areas with lower average dust concentrations due to a finding of pneumoconiosis. Concentrations for respirable dust and quartz were imputed if their original value was less than the minimum quantifiable concentration (MQC) based on the distribution of quantifiable samples MQC/√2.[9]

Table 1 Summary of lung pathologic classification of miners from Upper Big Branch coal mine

Case	Coal mining tenure (years)	Number of slides	Coal macules	Coal nodules	Silicotic nodules	Interstitial fibrosis	Small airways disease	PMF	Emphysema	Smokers' macrophages
1	25.1–30	7	+	–	–	–	–	–	–	–
2	≤5	4	+	–	–	–	–	–	–	–
3	>30	3	+	+	+	+	–	+*	+	–
4	5.1–10	4	+	+	–	+	+	–	–	+
5	10.1–15	7	+	–	–	–	+	–	–	–
6	20.1–25	3	+	–	–	+	–	–	–	–
7	≤5	6	+	–	–	–	–	–	–	–

*Lesion consistent with PMF, but truncated during sample processing.
PMF, progressive massive fibrosis.

Respirable dust and quartz data from UBB were compared with national data for underground coal mines. Additionally, UBB data were compared with corresponding data for underground coal mines in central Appalachia, here defined as mines in southern West Virginia, eastern Kentucky and the entire state of Virginia, which, until a recent administrative change, corresponded to MSHA districts 4, 5 and 12.

Statistical analysis

All statistical analyses were performed using SAS V.9.4 (SAS Institute). Data for total respirable dust and quartz levels were best represented by a lognormal function and summarised by geometric means. The significance of differences in means was determined using t-tests. A p value less than 0.05 was considered significant.

RESULTS

Study population

We attempted to obtain informed consent from the next of kin of the 24 miner fatalities at UBB who had potentially evaluable lung tissue at autopsy. The next of kin of seven miners provided informed consent for the study. All subjects were male, whose mean age was 43 years (SD 10 years). Mean coal mining employment experience was 15.4 years (SD 12.2 years), with mean tenure at the UBB coal mine of 8.9 years (SD 7.3 years) and other coal mine employment 6.5 years (SD 8 years). Two of the seven miners had less than 5 years of total coal mining experience. All seven subjects were among the 17 miners previously found to have pathology consistent with CWP on autopsy examination by medical examiners of the State of West Virginia.

Examination of lung tissue specimens

Histological examination of autopsy slides found features of simple CWP in all seven subjects (100%) (table 1 and figures 1 and 2), including both subjects with less than 5 years of mining. One subject, who had over 25 years of coal mining experience, was found to have coal macules, coal nodules and silicotic nodules. Additionally, this subject had a lesion consistent with PMF (figure 3A–C) and extensive interstitial fibrosis (figure 3D).

Examination of tissue using PLM revealed extensive deposition of strongly and weakly birefringent particles, consistent with silicate and silica particles, respectively (figures 1B,2B and 3C), in all miners. Bituminous coal dust particles were observed, recognised by their characteristic shape and colour (figure 2A) and weak red birefringence in polarised light (figure 2B).

Respirable dust and quartz dust

Coal mine dust exposures experienced by miners at UBB were compared with that experienced by all US coal miners through an analysis of dust samples collected for regulatory compliance purposes. Records of 454 894 respirable coal mine dust samples from 1363 US underground coal mines from the period 1 January 2000 to 5 April 2010, the date of the UBB mine explosion (table 2), were analysed. Of these, 9316 (2.1%) were less than the MQC and the respirable dust concentrations were

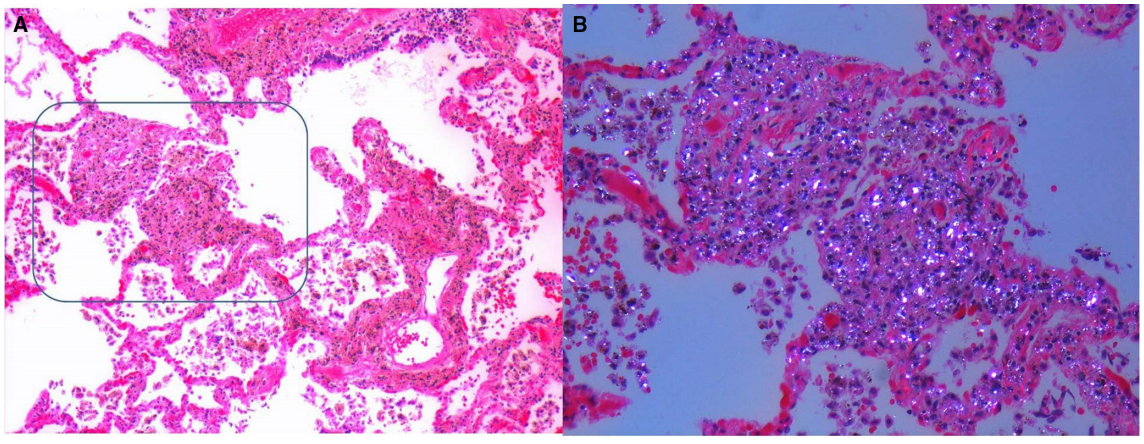

Figure 1 Case 4 from table 1. Upper Big Branch coal miner with 5.1–10 years of underground mining. (A) H&E-stained section of lung parenchyma showing a coal macule at right and two small micronodules (box) with mild interstitial fibrosis (original magnification ×200). (B) Polarised light microscopy of area outlined in box showing large quantities of strongly and weakly birefringent particles within the micronodules consistent with silicates and silica, respectively (original magnification ×400).

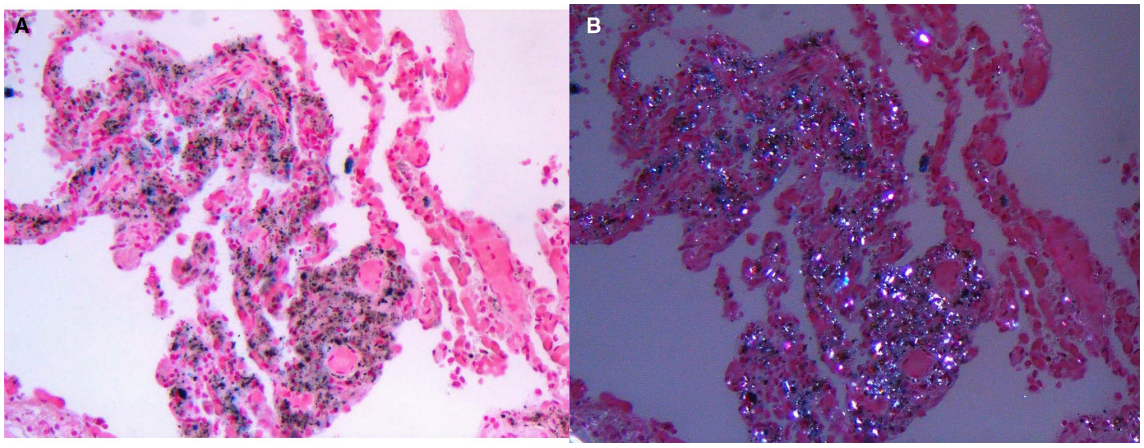

Figure 2 Case 5 from table 1. Coal miner with 10.1–15 years of underground mining. (A) Iron-stained section of lung parenchyma showing small coal dust macule. The black particles show the classic features of bituminous coal mine dust without evidence of combustion products. (B) Polarised light microscopy image of same region showing large numbers of birefringent particles consistent with silica and silicates (original magnification ×400). In addition, some of the bituminous particles show characteristic red birefringence.

imputed. Coal mine operators obtained 55.6% of the samples, while the remaining 44.4% were collected by MSHA mine inspectors. Similarly, 56.3% and 55.6% of dust samples were obtained by coal mine operators in central Appalachia (MSHA districts 4, 5 and 12) and UBB, respectively.

During this period, the geometric mean of respirable dust compliance sampling for all US coal mines was 0.468 mg/m^3. For the 800 underground coal mines located in central Appalachia, the geometric mean of respirable dust compliance samples was 0.420 mg/m^3. At UBB, the geometric mean for respirable

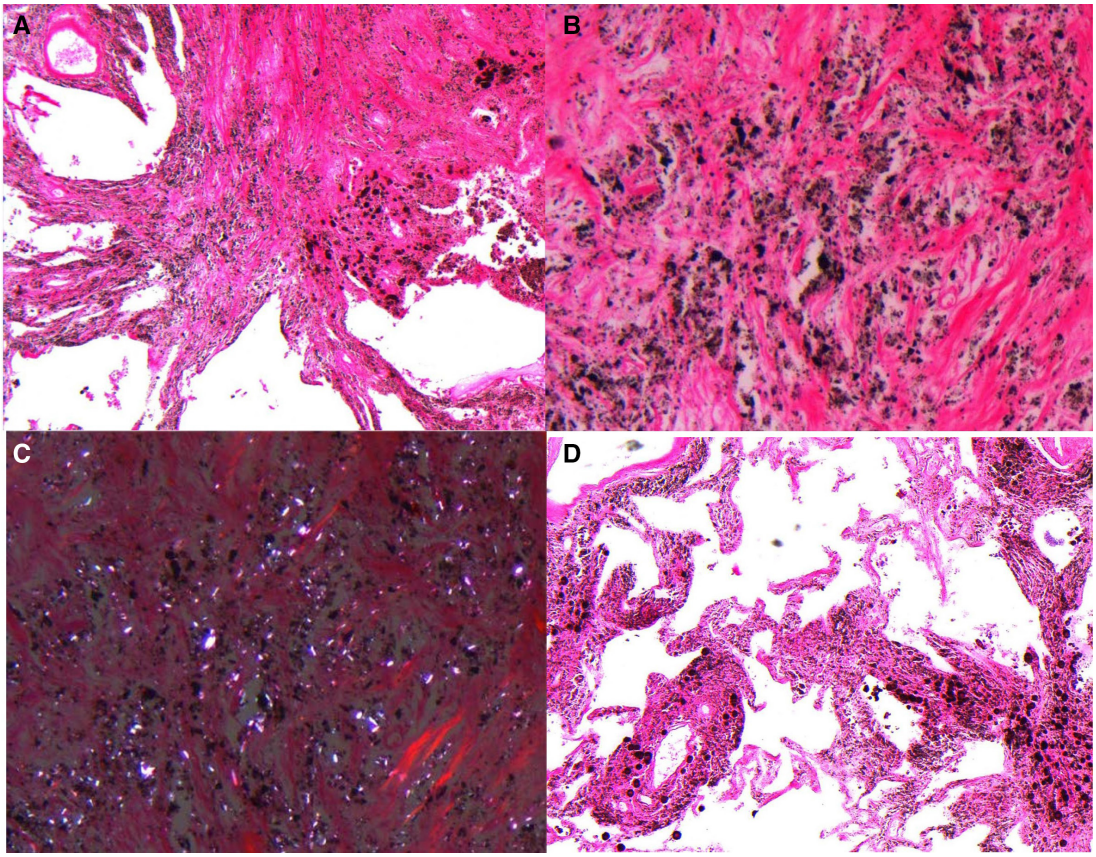

Figure 3 Case 3 from table 1. A coal miner with over 30 years of underground mining. (A) H&E-stained section of lung parenchyma showing large nodular lesion of coal workers' pneumoconiosis consistent with truncated progressive massive fibrosis (original magnification ×50). (B) Higher magnification of dust in the lesion showing black carbonaceous dust particles in a matrix of pink scar (collagen) tissue (original magnification ×400). (C) Same region as (B), photographed under polarised light, showing large numbers of birefringent mineral dust particles. Note the birefringent properties of the collagen fibres (bottom right) used as an internal control. (D) Separate area from same case showing emphysema and extensive bridging interstitial fibrosis connecting coal dust nodules (original magnification ×50).

Table 2 Samples of respirable coal mine dust and respirable quartz, 2000–2010

	Total mines sampled (total respirable dust)	No. of samples	Total respirable dust, GM (mg/m^3) (95% CI)	Total mines sampled (quartz)	No. of samples	Per cent quartz, GM (mg/m^3) (95% CI)	Total quartz, GM (mg/m^3) (95% CI)
Upper Big Branch mine	1	2349	0.518 (0.497 to 0.540)	1	377	7.74 (7.26 to 8.25)	0.061 (0.056 to 0.067)
Central Appalachia	800	241 322	0.420 (0.418 to 0.422)	766	39 510	5.17 (5.13 to 5.22)	0.038 (0.038 to 0.038)
USA	1363	454 894	0.468 (0.467 to 0.469)	1307	78 983	4.06 (4.03 to 4.08)	0.030 (0.030 to 0.031)

GM, geometric mean.

dust compliance samples was 0.518 mg/m^3, 11% higher than for all US coal mines and 23% higher than for central Appalachia ($p<0.0001$ for both comparisons). The geometric mean of UBB respirable dust compliance samples was at the 73rd percentile nationally (IQR 0.312–0.527 mg/m^3; 95th percentile 0.786 mg/m^3) and at the 78th percentile for central Appalachia (IQR 0.315–0.498 mg/m^3; 95th percentile 0.712 mg/m^3).

Of the respirable coal mine dust samples during the study period, 78 983 (17%) were analysed for quartz; 2429 (3.1%) were less than the MQC and were imputed. Coal mine operators obtained 4.3% of the samples analysed for quartz, while the remaining 95.7% were collected by MSHA mine inspectors. Operator-obtained samples comprised 5.7% and 10.3% of samples analysed for quartz in central Appalachia and at UBB, respectively. Among the 377 respirable dust samples from UBB analysed for quartz, the geometric mean of per cent quartz was 7.74%, significantly higher than the corresponding values for the USA and central Appalachia (table 2; $p<0.0001$ for both comparisons). The geometric mean concentration of respirable quartz for these UBB samples was 102% higher than the US geometric mean and 61% higher than the geometric mean for central Appalachia ($p<0.0001$ for both comparisons). UBB was in the 87th percentile nationally for respirable quartz concentration (IQR 0.025–0.050 mg/m^3; 95th percentile 0.077 mg/m^3) and 85th percentile in central Appalachia (IQR 0.030–0.053 mg/m^3; 95th percentile 0.077 mg/m^3).

Respirable dust levels at UBB exceeded 2.0 mg/m^3 on 8.1% of compliance dust samples overall. This exceedance rate was in the 81st percentile nationally (IQR 1.8%–7.0%; 95th percentile 14%) and the 81st percentile in central Appalachia (IQR 1.7%–7.0%; 95th percentile 14%). After adjusting the PEL based on quartz content, respirable dust levels at UBB exceeded the applicable PEL on 28% of samples in which quartz concentrations were also measured. This exceedance rate was in the 89th percentile nationally (IQR 6%–20%; 95th percentile 36%) and 85th percentile in central Appalachia (IQR 5%–23%; 95th percentile 43%).

DISCUSSION

This study examined lung tissue from autopsied coal workers killed by a coal mine explosion in 2010. Systematic expert histopathological evaluation confirmed the presence of pneumoconiosis among all seven study subjects, who were relatively young US miners (mean age 43 years). Although the study sample was small, it corroborates the local medical examiner's report of the larger group of UBB victims: Of the 17 UBB victims with CWP described in the report, 5 were reported to have had less than 10 years of experience as coal miners, while 9 were reported to have over 30 years.[3] All but one of the 17 victims with CWP started working after the implementation of a federal PEL of 2.0 mg/m^3 in 1972.[3] Although our finding of features of CWP in two miners with less than 5 years of coal mine employment initially seemed surprising, it is biologically plausible and consistent with other reports. Coal miners with as little as 7.5 years of coal mine tenure were found to have radiographically diagnosed PMF among a series of 138 West Virginia coal miners.[10] Harris *et al* recently reported the development of histopathologically confirmed PMF in an individual with an 8-year history of coal mine employment.[11] These reports demonstrate that a decades-long history of exposure to coal mine dust is not necessary to develop significant CWP when the exposure is excessive.

The US Coal Mine Health and Safety Act of 1969 led to the establishment of the PEL for respirable coal mine dust in the USA and was intended to prevent the development of advanced CWP. Previously published analysis of respirable coal mine dust levels in US coal mines detailed a long-term decline in the proportion of dust samples exceeding the 2.0 mg/m^3 dust limit from 1982 to 2017.[12] Despite these limits, after an initial 89% decline in the prevalence of CWP, disease prevalence among active coal miners in the USA has increased since the late 1990s, particularly in the central Appalachian region.[1] The increased prevalence of CWP has been attributed in part to increased respirable crystalline silica exposure among miners,[13] as well as work in smaller mines and the mining of thinner seams of coal.[14]

The rise in prevalence of CWP identified on plain chest radiography done for medical surveillance likely underestimates the true prevalence of CWP due to the relative insensitivity of this imaging modality. Vallyathan *et al* examined the correlation of chest radiologic findings with examination of autopsy lung tissue in a cohort of 430 deceased central Appalachian coal miners.[15] Although 97% of subjects were found to have histopathologic evidence of CWP, only 67% of subjects in the cohort had radiographic opacities of profusion of at least 1/0 before death. We were unable to obtain chest radiographs to determine whether the subjects of our study had radiologic findings of CWP. However, it is notable that the radiographic prevalence of CWP among long-tenured central Appalachian coal miners in 2010 was less than 15%.[1]

In the decade prior to the mine explosion, compliance dust samples submitted from UBB showed significantly higher means for respirable dust, respirable quartz and per cent quartz, compared with the corresponding means for the entire USA and the central Appalachian region. It is notable, however, that during this period, 27% of US underground coal mines had higher mean respirable dust concentrations and 13% had higher mean respirable quartz concentrations than UBB. UBB did not have the highest dust levels even when compared with its neighbours in central Appalachia, the epicentre of resurgent CWP in the USA.[16] Overall, 22% and 15% of underground coal mines in central Appalachia had higher mean respirable dust and quartz concentrations, respectively, than UBB. Another important measure of dust control is the number of samples at a mine that exceed the PEL for respirable dust. More than 10% of underground coal mines in the USA and central Appalachia had higher exceedance rates than UBB. Given these data, it is likely that UBB was not the worst dust control offender in the USA. Many

other mines had dust levels likely conferring increased risk of coal mine dust lung disease. Histopathologic analysis of lung tissue is more sensitive than plain chest radiography for CWP. The findings of this study, a rare look at the lung pathology of a random group of working miners with different tenures, lend credence to the concern that the burden of coal mine dust lung disease among active coal miners is likely higher than currently understood.

Although reports suggest a long-term decline in respirable dust levels in US coal mines, it has been observed that these measurements may not be a representative of the dust levels experienced by US coal miners during typical working conditions.[10 17 18] Miners have reported that proper ventilation practices were not consistently adhered to and that ventilation plans were more closely followed when MSHA inspectors were present.[19] Further, miners have also reported improper dust sampling processes to ensure compliance with the PEL, including covering the samplers to reduce dust collection[20] or placing them in areas of the mine known to have lower dust levels.[19 21] During the period of interest in our study, compliance sampling for coal mine dust was allowed during shifts in which production was as low as 50% of average. Sample pumps could legally be stopped after 8 hours, regardless of the actual length of the miner's work shift.[22] These loopholes in US coal mine dust sampling regulations may explain, in part, the discordance between declining compliance dust levels and increasingly higher rates of CWP. Compliance sampling may have lawfully documented exposures below the applicable PEL while, during unmonitored production, miners could have been exposed to more respirable dust. However, these loopholes alone cannot explain why disease levels markedly declined after the implementation of regulations in 1973 and then surged in the 1990s without any change in coal mine dust regulations. Of note, many loopholes in the regulations were addressed in a 2014 revision of the coal mine dust regulations.[22]

The clinical significance of the histopathologic evidence of CWP among study subjects is not clear as there were no pulmonary function studies or other evaluations available for review. It is possible that the victims had no significant respiratory impairment at the time of their deaths. However, given that radiographic CWP and physiologic decline may develop or worsen even after exposure has ceased[23–27] and that disease incidence and severity increase with cumulative coal mine dust exposure,[28 29] we believe our findings in these victims are clinically important.

Another limitation of the study was the difficulty in apportioning the specific contribution of exposures at UBB versus other mining jobs. The families of the deceased miners attempted to give accurate occupational and exposure histories, but often were unable to provide important details such as job tenure, specific tasks, dust suppression techniques and use of personal protective equipment. It is likely that exposures at multiple coal mines contributed to our subjects' histopathological findings. However, we note that while sampling at UBB showed elevations in respirable and quartz dust levels compared with national and regional levels, many other coal mines submitted samples with similar or higher levels of respirable dust and quartz during the same period.

CONCLUSION

Histopathological evidence of CWP was present in all seven fatalities of the UBB coal mine explosion whose lung tissues were available for this study. It not only revealed classic lesions of CWP but, importantly, also revealed extensive deposition of birefringent particles consistent with silica and silicates in the miners' lungs. We also found that compliance dust samples from UBB showed significantly higher respirable dust and quartz levels than the corresponding mean levels for the USA and central Appalachia from 2000 to 2010. Disturbingly, more than one quarter of underground US coal mines had higher mean respirable dust concentrations than UBB and 13% had higher respirable quartz concentrations. This implies that disease burden of CWP among active underground coal miners in the USA may be higher than currently recognised. The high rate of CWP features observed in this sample of miners, whose exposures occurred almost entirely after the enactment of modern respirable dust limits in the USA, strongly supports the need for additional interventions to prevent CWP and reduce the burden of disabling coal mine dust lung disease.

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