Introduction to This Toolkit

This toolkit was developed to assist hospitals in developing and implementing effective respiratory protection programs, with an emphasis on preventing the transmission of aerosol transmissible diseases (ATDs) to healthcare personnel.

Healthcare personnel are paid and unpaid persons who provide patient care in a healthcare setting or support the delivery of healthcare by providing clerical, dietary, housekeeping, engineering, security, or maintenance services. Healthcare personnel may potentially be exposed to ATD pathogens. Aerosols are particles or droplets suspended in air. ATDs are diseases transmitted when infectious agents, which are suspended or present in particles or droplets, contact the mucous membranes or are inhaled.

Hospitals are unique work environments with challenging occupational health and safety issues. Some hospitals have health and safety personnel who are highly qualified to develop and implement appropriate policies and procedures to control workplace exposures. However, in many facilities with more limited resources, the role of the health and safety professional might be taken on as an added responsibility by someone in the nursing, employee health, or infection control department. This toolkit is written as a practical manual that can be used by anyone charged with setting up and maintaining a hospital respiratory protection program. A respirator is a device worn over the nose and mouth to protect the wearer from hazardous materials in the breathing zone.
In healthcare, the term respirator is also used to describe a mechanical ventilator that helps patients who are having difficulty breathing; this document does not address this type of medical equipment.

The body and appendices of the toolkit include links to references, educational resources, and electronic tools such as templates, sample forms, and educational materials. Some of the tools and resources were developed by the authors of this document, but we have also collected many more that were produced by other organizations and are available on the Internet.

This toolkit identifies existing public health guidance where available on the use of respiratory protection. Scientific evidence is continuously evolving, particularly with regard to disease transmission. Precautionary use of respiratory protection may be prudent where scientific uncertainty exists.
Why Hospitals Need a Respiratory Protection Program

Respiratory Hazards in the Healthcare Setting

The hospital environment contains hazards such as bacteria, viruses, and chemicals that may be inhaled by personnel and cause injury or illness. The approach for reducing exposure required by the Occupational Safety and Health Administration (OSHA) and accepted by health and safety professionals is to use a “hierarchy of controls.” This means we start with the most effective controls—the elimination of hazards or substitution of less hazardous processes, chemicals, or products. Next in the hierarchy are engineering controls, which involve isolating the hazard and/or using specialized ventilation (e.g., isolation rooms or laboratory hoods). Where these controls are not feasible or adequate, administrative controls (e.g., providing vaccinations or triaging chemical emergency patients) and work practices (e.g., following respiratory hygiene/cough etiquette strategies or keeping chemical containers capped) are used to reduce risk, most often by minimizing the extent or duration of the exposure, or reducing the number of employees exposed. Respirators and other personal protective equipment (PPE) are used as a last line of defense when exposures cannot be reduced to an acceptable level using these other methods. Each facility should develop policies and procedures which address the control methods used at their institution.

The hazards associated with ATDs (e.g., infectious patients with a transmissible disease or, in rare situations, environmental sources of anthrax or fungi) cannot be eliminated from or substituted out of the hospital setting. ATD pathogen exposures cannot routinely be measured in the air, and have no established occupational exposure limits. In addition, ATD pathogens vary in infectivity and severity of outcome. In order to protect employees from ATDs, healthcare facilities must implement comprehensive infection control plans utilizing a combination of engineering, administrative (including training and vaccination), and work practice controls, and provide for the use of respirators and other PPE.

Healthcare personnel who care for patients with ATDs must work in close proximity to the source of the hazard; even with controls in place, they are likely to have a higher risk of inhaling infectious aerosols (droplets and particles) than the general public. These personnel, and others with a higher risk of exposure related to the tasks they perform (e.g., lab or autopsy workers), must often be protected further through the proper use of PPE.
Respiratory Protection Reduces Inhalation of Aerosols

In order to understand how respirators can be used to protect healthcare personnel, it is important to understand what a respirator is and what it is not. One important distinction that must be made when discussing respirator use in healthcare settings is the difference between respirators and facemasks. Facemasks include surgical masks, which are fluid resistant, and procedure or isolation masks which are not fluid resistant. While some people may call both respirators and facemasks “masks,” this is incorrect as they are very different in their design, performance and purpose.

The purpose of a facemask, when worn by healthcare personnel, is twofold. As part of “Droplet Precautions” (explained in more detail later in this document), the surgical mask is worn to protect the wearer from large droplets or sprays of infectious body fluids from patients that otherwise could be directly transmitted to the mucous membranes in the wearer’s nose or mouth. In other instances, a facemask is worn by healthcare personnel to protect patients by reducing the amount of large droplets with infectious agents the wearer could introduce into the room by talking, sneezing, or coughing; this protection is especially important where sterile fields must be maintained, such as operating rooms.

The purpose of a facemask, when worn by a patient suspected or confirmed with an illness such as influenza or tuberculosis, is to reduce the amount of large infectious particles released as
the patient talks, sneezes, or coughs; this limits their concentration in the room air and reduces the infection risk to others who are present.

However, facemasks by design do not seal tightly to the wearer’s face. Therefore, they allow unfiltered air to easily flow around the sides of the facemask into the breathing zone and respiratory tract of the wearer. In addition, the materials used for facemasks are not regulated for their ability to filter particles and are known to vary greatly between models. This makes it possible for small particles to pass through or around the facemask and be inhaled by the wearer. **This is why they are not considered respiratory protection—facemasks do NOT provide the wearer with a reliable level of protection from inhaling smaller particles, including those emitted into the room air by a patient who is exhaling or coughing, or generated during certain medical procedures.**

The purpose of a respirator when worn by healthcare personnel, for example a N95 filtering facepiece respirator, is typically to protect the wearer by reducing the concentration of infectious particles in the air inhaled by the wearer. These particles may come from infectious patients who are exhaling, talking, sneezing, or coughing in the rooms in which healthcare personnel are working; from medical procedures performed on infectious patients (e.g., using bone saws or performing bronchoscopies); or from laboratory procedures (e.g., operating centrifuges, blenders, or aspiration equipment) that may aerosolize pathogens.

Respirators are designed and regulated to provide a known level of protection when used within the context of a comprehensive and effective respiratory protection program (see the “Types of Respiratory Protection” section on page 15). For example, filtering facepiece respirators are designed to seal tightly to the face when the proper model and size is selected for the individual by using a fit test procedure. The wearer can then be assured that inhaled air is forced through the filtering material, which allows contaminants to be captured and reduces exposure to both large droplets and small infectious particles.
Also available, and widely used in healthcare, is the surgical respirator—a filtering facepiece respirator with spray- or splash-resistant facemask material on the outside to protect the wearer from splashes (sometimes referred to as “surgical N95 respirators”). See Figure 2 below for further comparison of surgical masks, filtering facepiece respirators, and surgical respirators.

### FIGURE 2: SURGICAL MASKS, FILTERING FACEPIECE RESPIRATORS, AND SURGICAL RESPIRATORS

<table>
<thead>
<tr>
<th>Intended use when:</th>
<th>Surgical Masks</th>
<th>Filtering Facepiece Respirators</th>
<th>Surgical Respirators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worn by HCP¹</td>
<td>Do not protect against small airborne particles (aerosols) Protect the patient and sterile field by reducing the number of particles introduced into the room as HCP talk, sneeze, or cough Protect the wearer’s nose/mouth from splashes or sprays of large droplets of body fluids</td>
<td>Reduce HCP inhalation of both large droplets and small airborne particles (aerosols) Protect the patient by reducing the number of particles introduced into the room as HCP talk, sneeze, or cough</td>
<td>Reduce HCP inhalation of both large droplets and small airborne particles (aerosols) Protect the patient and sterile field by reducing the number of particles introduced into the room as HCP talk, sneeze, or cough Protect the wearer’s nose/mouth from splashes or sprays of large droplets of body fluids</td>
</tr>
<tr>
<td>Worn by patient</td>
<td>Protect HCP by reducing the number of particles introduced into the room as a patient talks, sneezes, or coughs</td>
<td>Not typically worn by patients</td>
<td>Not typically worn by patients</td>
</tr>
<tr>
<td>Fit testing required?</td>
<td>No, not designed to seal to the face</td>
<td>Yes, to ensure adequate seal to the face</td>
<td>Yes, to ensure adequate seal to the face</td>
</tr>
<tr>
<td>Government oversight</td>
<td>FDA² clears for marketing</td>
<td>NIOSH¹ provides certification</td>
<td>NIOSH provides certification and FDA clears for marketing</td>
</tr>
</tbody>
</table>

¹HCP = healthcare personnel
²FDA = United States Food and Drug Administration
³NIOSH = National Institute for Occupational Safety and Health
A two-page factsheet and a short video, in English and Spanish, on the differences between respirators and surgical masks are available from OSHA as training resources.

**Multiple Approaches are Needed for Infection Prevention and Control**

Infection prevention and control measures are intended to reduce the spread of disease between patients, healthcare personnel, and visitors. Examples of infection control measures include employee vaccination; hand hygiene; and replacement or cleaning, disinfection, and sterilization of surgical instruments, patient-care devices, uniforms, and PPE. Multiple approaches are often required since many controls reduce hazards without eliminating them and many controls are subject to failure.

An effective infection prevention and control program must provide for early hazard identification (i.e., which patients have ATDs?), assessment (i.e., are the diseases high-risk or is there an increased likelihood of infection?), and control (i.e., which controls and PPE are necessary?).

A coordinated approach to implementing multiple preventive controls is provided by the Centers for Disease Control and Prevention (CDC) Healthcare Infection Control Practices Advisory Committee’s (HICPAC) *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*, which should be reviewed in its entirety by those responsible for infection control. The guideline describes Standard and Transmission-Based Precautions (discussed in more detail in the following section).

CDC and HICPAC state that transmission of an infectious disease requires three elements: a source of infectious agent, a susceptible host with a route of entry, and a mode of transmission. Standard Precautions are the foundation of infection control and represent the minimum infection prevention measures that apply to all patient care. They include practices such as hand hygiene, use of personal protective equipment (e.g., gloves, gowns, facemasks) depending on the anticipated exposure, cough etiquette, safe injection practices, and safe handling of potentially contaminated equipment or surfaces in the patient environment. Standard Precautions apply to all patients, clients, and staff, regardless of the presence of infectious agents, and are intended to reduce the risk of transmitting infections from known and unknown sources. When a patient is known or suspected to be infected and Standard Precautions are insufficient, CDC and HICPAC have prescribed one or more of three categories of Transmission-Based Precautions to eliminate or reduce the mode of transmission: Contact Precautions, Droplet Precautions, and Airborne Precautions.

Contact Precautions include the use of gloves and gowns to prevent the direct or indirect transmission of disease between patients and healthcare personnel. Droplet Precautions include the use of facemasks to prevent large droplets from travelling from the respiratory tract of a patient to the mucosal surfaces (i.e., nasal mucosa, conjunctivae, and, less frequently, the mouth) of the healthcare personnel and also include use of gloves, gowns, and eye protection if substantial spraying of body fluids is anticipated. Airborne Precautions reduce the risk of healthcare personnel inhaling small infectious airborne particles. Airborne Precautions require the use of respiratory protection.
Vaccination of healthcare personnel is another key component in preventing the transmission of diseases requiring Airborne and Droplet Precautions in hospitals. The CDC and some state and local health departments consider healthcare personnel to be at considerable risk for acquiring or transmitting ATDs including influenza, measles, mumps, rubella, pertussis, and varicella, and therefore recommend vaccination.

The 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

The 2007 CDC and HICPAC Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings applies to healthcare workplaces, including hospitals, long-term care facilities, ambulatory care, home care and hospice, which have the potential to expose employees to ATD pathogens. This guidance recommends that respiratory protection be used to protect certain workers performing specific tasks and that the use of respirators comply with the OSHA Respiratory Protection standard (29 CFR 1910.134; discussed in more detail on pages 13-14). The 2007 CDC and HICPAC Guideline serves as a primary resource supporting respirator use policies in healthcare, supplemented by newer guidance issued by CDC, OSHA, public health departments, as well as by relevant scientific literature.

CDC and HICPAC have categorized each ATD by its mode of transmission (droplet or airborne) and specified the applicable Transmission-Based Precautions for that agent (i.e., Droplet or Airborne Precautions); see Figure 3 and Figure 4 on pages 9 and 11 for complete listings.

In developing its guidance, CDC and HICPAC considered epidemiological studies of disease outbreaks, experimental studies, and information on aerosol behavior, and the Guideline reflects the professional opinion at that time. However, in most cases the relative contribution of each mode of transmission is not fully understood. CDC and HICPAC and other public health guidance should be regularly reviewed as the science develops so that the most up-to-date information is used to select respiratory protection.

CDC and HICPAC describe the distinction between droplet transmission and airborne transmission based on particle size and the distance and time over which the pathogens remain infectious. CDC and HICPAC indicate that droplets responsible for droplet transmission have traditionally been defined as being greater than 5 micrometers in diameter, while the particles or “droplet nuclei” responsible for airborne transmission are less than 5 micrometers in diameter and remain airborne and infectious long enough to travel substantial distances (e.g., through a ventilation system). Although a distance of 3 feet had historically been used to define the area of risk when working with
patients suspected or known to have diseases requiring Droplet Precautions, CDC and HICPAC report that infection has occurred at distances greater than 3 feet. Thus, CDC and HICPAC state that observing Droplet Precautions at a distance up to 6 or 10 feet or upon entry into the patient’s room may be prudent.

When Droplet Precautions are recommended, surgical masks function to reduce the transmission of large infectious droplets between the source (patient) and the mucosal surfaces of a susceptible host (healthcare personnel). When Airborne Precautions are recommended, respirators and other control measures, such as patient isolation in an airborne infection isolation room (AIIR) with specialized ventilation, are used to protect healthcare personnel from inhaling infectious particles that are of small diameter, likely to remain infectious over long time or distance, or both.

Airborne Transmission of Diseases: Factors that Affect Risk

Experimental studies as well as epidemiological evidence continue to inform our knowledge on how various diseases are transmitted. Aerosol studies show that infectious particles are released from a patient’s respiratory tract in a wide range of sizes, and the size of a droplet or particle quickly decreases as water evaporates from it. Particles up to 100 micrometers in diameter are known to be inhalable into the nose or mouth. Smaller particles stay airborne longer than larger particles, which increases exposure time and the distance the particles might travel. Particles of various sizes can remain suspended in air for hours, especially with high rates of air movement in the room. Small particles can travel on air currents and potentially be carried long distances from the source of generation.

The other factor affecting risk of infection is how long a specific pathogen can remain viable and infectious while suspended in air. We know that certain pathogens, such as *M. tuberculosis*, are able to remain infectious for a long time in the air. It is likely that this feature plays a critical role in determining if a pathogen is transmitted.

**FIGURE 3: CDC AND HICPAC—DISEASES/PATHOGENS REQUIRING AIRBORNE PRECAUTIONS**

- Aerosolizable spore-containing powders such as Anthrax/*Bacillus anthracis*
- Aspergillosis (if massive soft tissue infection with copious drainage and repeated irrigations required)
- Varicella (chickenpox) and herpes zoster (disseminated or in an immunocompromised host)/Varicella-zoster virus
- Measles (rubeola)/Measles virus
- Monkeypox/Monkeypox virus
- Severe acute respiratory syndrome (SARS)/SARS-associated coronavirus (SARS-CoV)
- Smallpox (variola)/Variola virus
- Tuberculosis (TB)/*Mycobacterium tuberculosis*
- Novel or emerging pathogens and any other disease for which public health guidelines recommend airborne infection isolation

1 Some of these diseases may require additional precautions such as contact precautions.

2 Hospitals need to look to CDC and public health authorities for the latest guidance. Respiratory protection may be advisable. For examples, see CDC’s latest guidance for novel influenza A viruses associated with severe disease and Middle East Respiratory Syndrome Coronavirus.
via the airborne route. However, for many other pathogens, there is less information available than for TB on how long they remain viable and infectious while airborne.

Healthcare personnel caring for patients who may be infected with a disease requiring Droplet Precautions may not just be at risk of exposure of their mucosa to sprays of large infectious droplets and possible subsequent disease—they may also be at risk of disease transmission from inhaling particles that are present in the room air and are infectious in the short-term and at closer distances. Disease transmission can only occur if the organism remains viable and infective while it is airborne and enough particles to represent an infectious dose (also not known for many organisms) are inhaled. The extent of this inhalation risk is not known for all diseases currently calling for Droplet Precautions. However, the use of respiratory protection in such instances as a precautionary measure could help to reduce the potential risk from inhalation exposure wherever small particle aerosol transmission may be possible. Nonetheless, in practice, most identified instances of infections transmitted by aerosols from patients to healthcare personnel occur due to lapses in administrative controls (e.g., failure to identify infected patients and implement appropriate precautions).

Respirator program administrators (RPAs) should keep current with the scientific literature about disease transmission and with changing public health recommendations. As an example, in 2010 the CDC issued new infection control guidance for seasonal influenza, a disease for which droplet precautions are recommended, stating that respiratory protection should be used when higher-risk, aerosol-generating procedures (discussed in more detail in the next section) are performed on a patient suspected or confirmed with influenza. In 2014, the CDC issued new guidance for Ebola virus disease recommending respirator use. Hospitals may always choose to adopt respiratory protection policies that are more protective than current public health guidance.

More Considerations About Respirator Use

Respiratory protection for ATDs must be selected based on the pathogen and the anticipated risk associated with specific job tasks to be performed by employees. For the protection of healthcare personnel performing patient care, both the likelihood that the patient may have an ATD and the nature of the procedure to be performed on the patient must be considered.

Identifying Patients with an ATD

In cases where a diagnosis has not yet been made, or the pathogen has not been identified and confirmed, the employer’s written respirator policies must provide healthcare personnel with clear direction on how to make decisions about the use of respiratory protection. A critical component of a respiratory protection

Photo: Haylard Health, Inc.

Worker wearing a filtering facepiece respirator.
program is training staff on the hospital’s policies regarding which situations should trigger respirator use. The training must be given to all caregivers and support staff, regardless of experience or skill set. Signage on patient rooms and notes in medical charts are additional ways in which respirator use policies and decisions are communicated between staff.

Personnel should be trained, consistent with facility respirator use policies, on how the patient’s signs and symptoms and clinical judgment about potential diagnoses relate to risk-based decisions on respirator use. For example, when a patient presents in the emergency room with a cough, fever, fatigue, night sweats, unexplained weight loss, and loss of appetite, healthcare personnel should suspect tuberculosis and appropriately isolate the patient and wear respiratory protection pending definitive diagnosis. Healthcare personnel should also consider the possible diseases and pathogens associated with the diagnostic tests that have been ordered for the patient and the diseases currently circulating in the population when making decisions about respiratory protection. See “Appendix A” on page 41 for a table of symptoms, potential pathogens, and recommended precautions based on Table 2 in CDC and HICPAC’s 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.
A prudent approach is to implement the use of respirators early on based on suspected diagnosis, for example in the emergency department, and discontinue it later if the patient is subsequently diagnosed with a disease that does not require respiratory protection. Other locations including operating rooms, intensive care units, and pulmonary units, may also require more frequent use of respirators and/or use of a higher level of respiratory protection due to the number of aerosol-generating procedures performed (discussed below).

**Performing Higher-Risk, Aerosol-Generating Procedures**

Aerosol-generating or cough-inducing procedures are procedures that can generate much higher concentrations of airborne particles and ATD pathogens as compared to coughing, sneezing, or speaking. The likelihood of exposure via contact with mucosal membranes and inhalation of aerosols is elevated when aerosol-generating procedures are performed and the airborne concentration of pathogens increases. See Figure 5 to the right for some examples of aerosol-generating procedures. Each hospital should review all procedures to determine which have a higher capacity for emitting infectious particles into the room air.

CDC and HICPAC recommend the use of respiratory protection when aerosol-generating procedures are performed on patients suspected or known to be infected with an illness or pathogen requiring Airborne Precautions. CDC also recommends respirators for aerosol-generating procedures on patients suspected or confirmed as having seasonal influenza, viral hemorrhagic fever, MERS-CoV, and novel influenza A viruses associated with severe disease. CDC and HICPAC consider *Neisseria meningitidis* a pathogen requiring Droplet Precautions, but acknowledge that aerosol-generating procedures have been associated with disease transmission. In the absence of definitive evidence, prudent practice suggests respirator use may be advisable when aerosol-generating procedures are performed on patients suspected or known to have diseases requiring Droplet Precautions.

**Novel or Other Pathogens Requiring Enhanced Protection**

As demonstrated by the emergence of SARS and avian influenza, there will be uncertainty around the routes of exposure with novel pathogens, as well as lack of immunity in the population and unknown severity of disease outcome. Public health authorities may recommend the use of respiratory protection by healthcare personnel and airborne infection isolation, at least until airborne transmission can

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**FIGURE 5: EXAMPLES OF AEROSOL-GENERATING PROCEDURES INCLUDE, BUT ARE NOT LIMITED TO:**

- Endotracheal intubation
- Open respiratory and airway suctioning
- Tracheostomy care
- Cardiopulmonary resuscitation
- Sputum induction
- Bronchoscopy
- Aerosolized administration of pentamidine or other medications
- Pulmonary function testing
- Autopsy, clinical, surgical, and laboratory procedures that may aerosolize pathogens, such as operating bone saws, centrifuges, blenders, and aspiration equipment.
be ruled out. **Federal OSHA** recommends that employers consider that the use of respiratory protection may be necessary when they are preparing for pandemic influenza. Specific recommendations about the need for Droplet or Airborne Precautions will be made at the time of an actual pandemic and based on such factors as transmissibility and severity of disease.

CDC and HICPAC recognize that certain infectious agents may be considered epidemiologically important and require enhanced protection, including the use of respiratory protection. Pathogens may be considered epidemiologically important if they have a propensity for transmission within healthcare facilities, are resistant to first-line therapies, or have high rates of morbidity and mortality. Pathogens may also be considered epidemiologically important if they are newly discovered, emerging, or re-emerging, and little or no information about their transmission, resistance, or disease rates is available. These pathogens may not be regularly encountered, but facilities and healthcare personnel must be prepared to consider and include these pathogens on differential diagnoses when appropriate, and implement infection control measures, including respiratory protection, when necessary.

**The OSHA Respiratory Protection Standard**

Hospitals and all other employers who require employees to use respiratory protection for control of exposures to airborne contaminants, including ATD pathogens, must comply with Federal OSHA’s Respiratory Protection standard, 29 CFR 1910.134, or the equivalent state standard. The OSHA Respiratory Protection standard establishes legally enforceable requirements about how respirators are to be used.

When respirator use is required, the Respiratory Protection standard requires that all employee use of respirators be done within the context of a comprehensive and effective respiratory protection program. The program must be in writing, have a designated respirator program administrator, and specify the employer’s policies and procedures for the use of respiratory protection in the facility. OSHA requires each respiratory protection program to include several specific elements, but leaves the specifics of the policies and procedures used to meet these requirements up to individual employers. See Figure 6 on page 14 for a summary of the key requirements of the standard (as it pertains to the use of air-purifying respirators) and the section of this document titled “Developing a Respiratory Protection Program” on page 19 for more information.

The Respiratory Protection standard does not specify the circumstances under which healthcare personnel must use respirators for protection against ATD pathogens. However, OSHA requires employers to evaluate the respiratory hazards in the workplace, and expects that hospitals develop their respiratory protection policies based on CDC/HICPAC and other public health guidance from CDC, state, and local health departments. In
the event of an OSHA compliance investigation, an employer’s failure to implement respirator use according to recognized and generally accepted good infection control practices and public health guidance could result in an OSHA citation.

The National Personal Protective Technology Laboratory (NPPTL) within the CDC’s National Institute for Occupational Safety and Health (NIOSH) tests respirators, reviews test data submitted by respirator manufacturers, and approves respiratory protection equipment when requested by respirator manufacturers. OSHA only permits use of NIOSH-approved respirators. NIOSH also conducts scientific research and develops guidance related to respiratory protection and other PPE. NIOSH research findings and recommendations may be considered by OSHA when setting or enforcing health and safety standards.

Twenty-seven states and territories operate Federal OSHA-approved State Occupational Safety and Health plans. State standards must be at least as effective as the corresponding Federal OSHA standards. California’s state OSHA program (Cal/OSHA) has promulgated the only specific, comprehensive aerosol transmissible diseases standard in the United States; any employer with workplaces in California must comply with these requirements which address respiratory protection and other areas of infection control.

The OSHA website provides a list of State Plans with links to their websites and additional information on each plan.

**FIGURE 6: SOME KEY REQUIREMENTS OF THE OSHA RESPIRATORY PROTECTION STANDARD**

- Written respiratory protection program with policies and procedures
- Designation of a program administrator
- Procedures for hazard evaluation and respirator selection
- Medical evaluation of respirator wearers
- Fit testing procedures for tight-fitting respirators (including filtering facepiece respirators)
- Procedures for proper use, storage, maintenance, repair, and disposal of respirators
- Training
- Program evaluation including consultation with employees
- Recordkeeping
Types of Respiratory Protection

Respirators are devices worn over the nose and mouth to protect the wearer from hazardous materials in the breathing zone.

Respirators are available in many types (described in detail below), models, and sizes from several manufacturers for a variety of applications. The most common types of respirators in healthcare are filtering facepiece respirators and powered air-purifying respirators (PAPRs). Different types of respirators are designed to provide different levels of protection and to protect against different hazards. Professional judgment along with the type of airborne contaminant, its concentration, its potential to cause a health effect in exposed personnel, and any applicable regulation dictate the type of respirator that must be worn. When information regarding the exposure is limited, the decision will rely more heavily on professional judgment and more protective respirators may be selected for use. Each facility’s written policies and training programs should specify whom to contact for questions or additional information.

OSHA has given each class of respirator an assigned protection factor (APF) to indicate the minimum level of protection that can be expected when the respirators are properly selected and used in a continuing, effective respiratory protection program. For higher-risk exposure situations (i.e., higher concentration of infectious particles), choosing a respirator with a higher APF provides a higher level of protection for the wearer. The APFs for different types of respirators are presented in Table 1 of the OSHA Respiratory Protection standard and in Appendix B of this document.

All respirators used in the workplace must be tested by the manufacturer and tested and certified by NIOSH. The two major types of respirators, air-purifying respirators and air-supplying respirators, are described below.

Air-Purifying Respirators

Air-purifying respirators (APRs) work by removing gases, vapors, aerosols (droplets and solid particles), or a combination of contaminants from the air through the use of filters, cartridges, or canisters. APRs with filters will remove particles and droplets (also called aerosols) from the inhaled air, while those with chemical cartridges or canisters are designed to remove gases and vapors. To help employers select the right protection for a specific contaminant, all filters, cartridges, and canisters must carry a label
approved by NIOSH. As a secondary means of identification, cartridges and canisters must also be color-coded as specified by NIOSH. Air-purifying respirators do not provide clean breathing air from a source independent of the work area; therefore, APRs cannot be worn in an oxygen-deficient atmosphere.

Filters come in various degrees of filtration efficiency (see Figure 7 on page 17 for more information on the NIOSH filter classes); however, leakage around the facepiece of a respirator plays a larger role than filter efficiency in determining the protection provided. When APRs are required to provide protection from ATD pathogens, they must be fitted with particulate filters at least as efficient as an N95 filter, not cartridges or canisters for gases and vapors.

Types of Air-Purifying Respirators

Non-powered, or negative-pressure, respirators have a tight-fitting facepiece, which can be either a half mask that covers the nose and mouth or a full facepiece that covers the nose, mouth, and eyes. They may be disposable (or “single-use,” meaning the filter is not replaceable and the respirator cannot be cleaned) filtering facepiece respirators where the entire facepiece is made of filtering material, or elastomeric respirators that have replaceable filters or cartridges.

“N95 respirator” is a term used in healthcare to refer to a half mask APR with a NIOSH-approved N95 particulate filter. An N95 respirator may be a filtering facepiece respirator or half mask elastomeric respirator; both have an APF of 10 and may be used in healthcare. These respirators are described as “negative-pressure” because the pressure inside the facepiece is negative during inhalation compared to the pressure outside the respirator. Filtering facepiece respirators are also available with other classes of filters and spray- or splash-resistant facemask material on the outside to protect the wearer from splashes (sometimes referred to as “surgical N95 respirators”).

Powered air-purifying respirators (PAPRs) may be used in healthcare when aerosol-generating procedures are performed, by hospital first receivers, or when the respirator user is not able to wear a tight-fitting respirator. PAPRs have a battery-powered blower that forces air in the room through filters (for particles) or cartridges (for gases or vapors) to clean it before delivering it to the breathing zone of the wearer. High-efficiency (HE) filters are the only
class of particulate filters available for powered air-purifying respirators. PAPRs are generally more protective than non-powered half mask respirators because the blower creates positive pressure inside the facepiece, reducing inward leakage of potentially contaminated air.

A PAPR may have a tight-fitting half or full facepiece or a loose-fitting facepiece, hood, or helmet. A PAPR has an OSHA APF of at least 25, compared to an APF of 10 for a filtering facepiece respirator or elastomeric half mask respirator; this means the PAPR reduces the aerosol concentration inhaled by the wearer to 1/25th of that in the room air, compared to a 1/10th reduction for half mask APRs. OSHA allows employers to use an APF of 1,000 for PAPRs with hoods when they have evidence from the manufacturer demonstrating performance at this level. OSHA does not require fit testing of loose-fitting PAPRs.

**Air-Supplying Respirators**

Air-supplying respirators (also known as atmosphere-supplying respirators) include supplied-air respirators and self-contained breathing apparatus (SCBAs). Air-supplying respirators work by providing clean breathing air from a source independent of the work area. Supplied-air respirators typically have higher APFs than APRs; the APF can be up to 1,000. These respirators obtain breathing air from a compressor or a large pressurized cylinder that is not carried by the user. SCBAs can have APFs of up to 10,000. They are usually equipped with a full facepiece and contain their own breathing air supply in a pressurized cylinder that is carried by the user.

### FIGURE 7: NIOSH FILTER CLASSES

<table>
<thead>
<tr>
<th>Filter Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N95</td>
<td>Filters at least 95% of airborne particles. Not resistant to oil.</td>
</tr>
<tr>
<td>N99</td>
<td>Filters at least 99% of airborne particles. Not resistant to oil.</td>
</tr>
<tr>
<td>N100</td>
<td>Filters at least 99.97% of airborne particles. Not resistant to oil.</td>
</tr>
<tr>
<td>R95</td>
<td>Filters at least 95% of airborne particles. Resistant to oil.</td>
</tr>
<tr>
<td>P95</td>
<td>Filters at least 95% of airborne particles. Oil proof (strongly resistant to oil).</td>
</tr>
<tr>
<td>P99</td>
<td>Filters at least 99% of airborne particles. Oil proof (strongly resistant to oil).</td>
</tr>
<tr>
<td>P100</td>
<td>Filters at least 99.97% of airborne particles. Oil proof (strongly resistant to oil).</td>
</tr>
<tr>
<td>HE (high-efficiency)</td>
<td>Filters at least 99.97% of airborne particles. For use on PAPRs only.</td>
</tr>
</tbody>
</table>
Air-supplying respirators may have a tight-fitting facepiece, which can be a half mask or a full facepiece, or a loose-fitting facepiece, hood, or helmet. They do not require filters or cartridges and will protect the wearer from all types of contaminants (particles, gases, and vapors) and, in certain cases, oxygen-deficient atmospheres. These respirators are less likely to be used in a hospital setting except, perhaps, by emergency responders or construction contractors.

See the “References, Resources, and Tools” section on page 36 for additional sources of information on respiratory protection.
Developing a Respiratory Protection Program

Assigning Responsibility

A key component of a successful respiratory protection program (RPP) is the assignment of responsibilities for the implementation and administration of the program. OSHA requires that “the program be administered by a suitably trained program administrator.” Although the respirator program administrator (RPA) does not have to be a health and safety professional, he or she must have knowledge of the principles of respiratory protection and the authority to implement the program. While the RPA must oversee the program, he or she can assign others to help manage and implement medical evaluations, training, fit testing, and other aspects of the program. See the “References, Resources, and Tools” section (pages 36-40) for training resources for RPAs.

Hospitals must decide how best to manage RPPs that cover personnel who must use respirators to reduce their exposure to specific chemicals only, ATD pathogens only, or both chemicals and ATD pathogens. These employee groups may work in very different departments with different supervisors and/or have different types of jobs. A single RPP with one program administrator is preferred to ensure consistency and accountability. However, if two separate RPPs and program administrators exist to cover respirator responsibilities for chemical versus infectious exposures, the employer must ensure that overall policies are coordinated, adequate technical expertise is available for each program, and that all aspects of both programs are effectively implemented.

Performing a Hazard Evaluation

The purpose of the hazard evaluation is to identify and evaluate potential exposures in the workplace that might require the use of respiratory protection. Once identified, these exposures must be assessed to determine how often they are expected to occur and the level of exposure, so that they can be controlled to the extent feasible and, if required, appropriate respiratory protection can be selected.

A hazard evaluation must be completed for all respiratory hazards, including chemical exposures and exposure to infectious agents. In the case of infectious agents, it is not generally feasible to quantify the level of exposure, nor is it known what level of exposure will cause infection in a specific individual. Therefore, respirators for infectious agents must be selected according to anticipated exposure by task and according to recognized and generally accepted good infection control practices and public health guidance such as that provided by CDC’s HICPAC, Federal and state OSHA, and state health departments. These organizations should be consulted for guidance in assessing the hazards associated with novel or emerging infectious diseases.
When conducting a hazard evaluation in the patient care setting, it is useful to systematically consider all of the activities in your units.

First, think about who will be in contact with patients who may have ATDs, such as tuberculosis or influenza. ATDs are divided by CDC’s HICPAC into two categories: (1) diseases requiring Airborne Precautions; and (2) diseases requiring Droplet Precautions. See Figure 3 and Figure 4 on pages 9 and 11 for complete lists of these diseases. You should also review local, state, and federal public health guidance to identify whether there are any additional diseases that should be considered (e.g., a novel pathogen currently circulating in the community).

The following questions should help to guide your thinking about who in your facility may be reasonably anticipated to be exposed to patients or other sources of ATD pathogens.

- Who is exposed to suspected or confirmed cases of ATDs?
- Who will greet and triage patients?
- Who will provide care for ATD patients?
- Who will be performing aerosol-generating procedures on patients with ATDs, on cadavers, or in laboratories? See Figure 5 on page 12 for examples of aerosol-generating procedures.
- Who will be cleaning the ATD patient rooms?
- Do you have contractors (e.g., those who service ventilation systems), or temporary workers in your facility who are reasonably anticipated to be exposed to patients or equipment that may be a source of ATD pathogens?
- Who will be designated as a first receiver of victims exposed to unknown radiological, biological, or chemical agents?
- Do you have physicians, students, volunteers, or others who are not hospital employees and are reasonably anticipated to be exposed to ATD pathogens? See Figure 8 on page 21.

Based on an assessment of the potential exposure hazards, you will then make a determination regarding the minimum level of respiratory protection required for these exposures. Consider the PPE (including type of respirator) and other controls that you will require for each combination of task (aerosol-generating procedures, direct patient care, providing services in patient rooms, etc.) and disease or hazard. This topic will be discussed further in the section on “Respirator Selection.”

Finally, think about other hospital employees who may have exposure to respiratory hazards other than ATD pathogens that cannot be feasibly reduced by engineering, administrative, or work practice controls. For chemical exposures, airborne concentrations should be measured in order to determine the level of respiratory protection that will be needed to reduce the exposure to acceptable levels.

- Are there housekeeping or maintenance personnel who are exposed to chemicals used in cleaning, repairs, or facility maintenance?
- Is anyone in central supply exposed to hazardous chemicals used in disinfection or sterilization?
- Are there research or clinical laboratories with staff who will need respiratory protection?
- Is anyone exposed to anesthetic waste gases or hazardous drugs?

If you do not have the expertise in-house to complete a hazard assessment, an industrial hygienist can be consulted. The American
Industrial Hygiene Association (AIHA) provides a list of consultants. You may also ask for help from your workers’ compensation insurance carrier or, if your business is small or medium-sized, from the OSHA On-site Consultation Program.

Developing Policies and Procedures

Once you have determined who will administer the program and which employees will be included, you are ready to develop the policies and procedures that will make up your written RPP. The RPP must have a section that addresses each of the elements described below. A template for a written RPP appears in Appendix D of this document. It was specifically designed for hospitals, and you may find that customizing it is the easiest way to develop your written program. If you choose to do this, it is best to use this toolkit and the template together. The following sections go through the process of developing each of the required elements of your written program.

Respirator Selection

In this section of your written RPP, you should document the results of your hazard evaluation and determine which types of respirators will be used by specific staff or job titles, and for specific tasks or procedures. You may want to put all of this information into a table or spreadsheet either in the body of your written program, or as an appendix. The guidelines from CDC/HICPAC and other public health guidance include recommendations for minimum respiratory protection for certain tasks and infectious agents. However, employers are always responsible for assessing the respiratory hazards, controlling identified hazards, and providing a workplace free from hazards likely to cause serious harm. The employer can always choose to select a higher level of respiratory protection than the minimum required.

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**FIGURE 8: ESTABLISH POLICIES REGARDING NON-EMPLOYEES**

You must consider what your respirator policy will be regarding non-employees. Although they may not be employed by the hospital, your facility shares some responsibility for ensuring the protection of physicians with privileges to practice in the facility, students, contractors, and volunteers. All people working and volunteering in the hospital should be required to follow your policies on respirator use for protection from infectious agents as well as chemicals such as asbestos, formaldehyde, and ethylene oxide. A clear statement indicating who is responsible for implementing all elements of the respirator program for these people should be part of your written policy. In many cases, including non-employee doctors, contractors, and volunteers in the hospital’s respiratory protection program will be the best way to ensure consistent and effective protection.

See the following web sites for OSHA policies and procedures for multi-employer worksites.

- OSHA’s Multi-Employer Citation Policy (CPL2-0.124)
- Interpretation of the Bloodborne Pathogens standard at a multi-employer worksite
Based on current recognized and generally accepted infection control practices, employees who perform any of the following activities that involve a patient suspected or confirmed with a disease requiring Airborne Precautions should wear respiratory protection at least as protective as an N95 respirator when:

- Entering an airborne infection isolation (AII) room or area in use for AII;
- Present during the performance of procedures or services;
- Repairing, replacing, or maintaining air systems or equipment that might contain or generate aerosolized pathogens;
- The patient has left the area and the room air has not yet been adequately ventilated to clear contaminants;
- Performing decontamination procedures;
- Working in a residence where the patient is located;
- Transporting the patient within the facility when the patient is not masked; or
- Transporting the patient in an enclosed vehicle (e.g., van, car, ambulance, or helicopter).

Properly fitted filtering facepiece respirators (or equivalent) are expected to reduce exposures to one-tenth of the concentration that is in the air, based on OSHA’s APF of 10.

Any employee performing an aerosol-generating procedure on a patient suspected or confirmed with a disease requiring Airborne Precautions, or who is in the area where the procedure is being performed, can be exposed to much higher levels of infectious aerosols. These employees should wear a respirator with an APF of 10 and should consider wearing a respirator with a higher APF, such as a PAPR with a HEPA filter, unless the procedure is performed with the patient in a ventilated enclosure. A PAPR with a loose-fitting facepiece and a HEPA filter is expected to reduce exposure to airborne contaminants to 1/25th of the concentration in the room.

The CDC recommends that personnel performing an aerosol-generating procedure on a patient suspected or confirmed with seasonal influenza wear at least an N95 respirator, even though influenza has previously been considered a disease requiring only Droplet Precautions (ordinarily calling for a surgical mask). The latest guidance from CDC recommends the use of respirators for all patient-care activities on patients who may be infected with a novel influenza A virus associated with severe disease.

In the case of an influenza pandemic, OSHA (as well as CDC and other public health agencies) will make specific recommendations on a case-by-case basis after considering information available at that time. OSHA recommends that employers be prepared to use a NIOSH-approved N95 respirator for routine care. In some instances a more protective respirator may be necessary.

The Respiratory Protection Selection Guide for Aerosol Transmissible Diseases included as Figure 9 on page 24 will be useful in making appropriate respirator selections for specific diseases and tasks, and for training your staff on respirator use. The selection guide is based on recommendations from the 2007 CDC/HICPAC Guidelines, CDC, and OSHA.

**Selecting Respiratory Protection in the Laboratory or Autopsy Setting**

Assessment of exposure risk and selection of respirators and other control measures for hospital laboratory and autopsy workers exposed to ATD pathogens must be based on consideration of different factors than those for
workers providing patient care. In the lab, the primary factors include the pathogen that is likely to be present in the material being handled (which may be unknown), and whether the procedures to be performed by the employee are likely to generate aerosols.

Laboratory worker protection policies should be described in a written biosafety plan, developed by the lab biological safety officer and other personnel with knowledge of laboratory procedures as well as worker protection expertise. The primary resource for lab biosafety, including risk assessment, recommended practices, selection of controls, and containment levels, is the CDC's *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*.

Your written RPP should cover laboratory workers and specify the level of respiratory protection required for different pathogens or job tasks, in accord with the biosafety plan and other written lab operating procedures.

Stay Informed as Public Health Guidance is Updated

Keep in mind that respiratory protection requirements to protect against infectious diseases are based on guidance or requirements from OSHA, CDC/NIOSH, and state or other public health agencies. It is important to stay informed about any changes in public health guidance and regulations as new pathogens emerge or relevant new scientific information becomes available. You will then need to consider how your facility's policies and practices may need to change to conform to new regulations and guidance.

The CDC now recommends the use of respiratory protection with at least an APF of 10, such as a filtering facepiece respirator, in addition to airborne infection isolation where feasible, when aerosol-generating procedures are performed on patients with suspected or confirmed influenza. This recommendation raises the issue of whether respirator use during aerosol-generating procedures should also be considered for other infectious diseases (e.g., pertussis, meningococcal disease) that currently call for Droplet Precautions. For example, at least one study has demonstrated airborne transmission of pertussis. An even more protective approach would be to require respiratory protection for all procedures performed on patients with diseases requiring Droplet Precautions, because spontaneous coughs and sneezes can also generate infectious aerosols.

Existing guidance may continue to change with advances in infectious disease research, in the design of respiratory protection to address concerns about issues such as comfort and ease of communication, and/or as hospitals gain more experience with their respirator programs.
### FIGURE 9: RESPIRATORY PROTECTION SELECTION GUIDE FOR AEROSOL TRANSMISSIBLE DISEASES

The employer is responsible for selecting PPE, including but not limited to respiratory protection, appropriate for the hazard and the environment. The employer can always choose to select a higher level of respiratory protection than the minimum required.

<table>
<thead>
<tr>
<th>Disease (suspected or confirmed)</th>
<th>Job Task</th>
<th>Respiratory Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diseases requiring Airborne Precautions¹</td>
<td>Routine patient care and support operations</td>
<td>At least an N95 respirator</td>
</tr>
<tr>
<td></td>
<td>Aerosol-generating procedures²</td>
<td>At least an N95 respirator³</td>
</tr>
<tr>
<td>Seasonal influenza and viral hemorrhagic fever (VHF)</td>
<td>Routine patient care and support operations</td>
<td>At a minimum use a surgical mask⁴,⁵ An N95 respirator may reduce aerosol exposure</td>
</tr>
<tr>
<td></td>
<td>Aerosol-generating procedures⁶</td>
<td>At least an N95 respirator⁶,⁷</td>
</tr>
<tr>
<td>Other diseases requiring Droplet Precautions⁸</td>
<td>Routine patient care and support operations, including aerosol-generating procedures⁹</td>
<td>At a minimum use a surgical mask⁴ An N95 respirator may reduce aerosol exposure</td>
</tr>
<tr>
<td>Novel pathogens/pandemic influenza</td>
<td></td>
<td>Follow current public health guidance</td>
</tr>
</tbody>
</table>

¹See list on page 9.
²See definition on page 12.
³Cal/OSHA requires at least a PAPR.
⁴A surgical mask is not a respirator but can be effective in blocking large particles.
⁵October 2014 CDC guidance for Ebola virus disease recommends at least an N95 respirator.
⁶CDC’s Prevention Strategies for Seasonal Influenza in Healthcare Settings.
⁷See page 119 of CDC and HICPAC’s 2007 Guideline for Isolation Precautions for precautions for VHF.
⁸See list on page 11.
PAPRs Used by First Receivers
You may also have employees who have been designated first receivers for emergency response purposes. These employees are expected to decontaminate or provide initial care for victims of a biological or chemical emergency. When their exposures may be to unknown substances, hospital first receivers are required to have special training and use the most protective type of PAPR approved by NIOSH for chemical, biological, radiological, and nuclear (CBRN) exposures. These PAPRs have a full facepiece, or a hood or helmet, and a combination HE filter and chemical cartridge. They must be a type that has an APF of 1,000, meaning that it will reduce the exposure of the wearer to 1/1000th of the airborne contaminant concentration. Refer to OSHA Best Practices for Hospital-Based First Receivers of Victims from Mass Casualty Incidents Involving the Release of Hazardous Substances for more information on PPE for first receivers.

Use of Respirators and Maintaining a Sterile Field
Yet another consideration is which respirators to use for aerosol-generating or other procedures conducted in operating rooms or other settings that involve maintaining a “sterile field” free of microorganisms. There is some concern that exhaled air from wearers of PAPRs or APRs with exhalation valves can flow into and potentially contaminate the sterile field.

Local exhaust ventilation and adequate dilution ventilation should be used where possible at the source of aerosol generation to reduce the need for respiratory protection. Surgical respirators (without exhalation valves) should be selected for use in environments where a sterile field must be maintained. Currently, there is insufficient evidence to support the safe use of PAPRs in these environments.

Respirators for Chemical Gas or Vapor Hazards
In a hospital setting, respiratory hazards may include gases and vapors. These contaminants may come from procedures using hazardous drugs (including some cancer chemotherapy drugs, antiviral drugs, hormones, and bioengineered drugs) and chemicals (e.g., anesthetic waste gases or equipment sterilization) or cleaning and maintenance activities. It is important to note that N95 filtering facepiece respirators, PAPRs, or other types of APRs, when used with only particulate or HE filters, will not protect the wearer from gas or vapor exposures. Filters are designed to remove particles from the air, but will not remove gases or vapors (e.g., glutaraldehyde, formaldehyde, or ethylene oxide) from the air.

If you need help selecting respirators for exposures to hazards other than infectious agents, the following resources will be helpful in making
your selection. The NIOSH Respirator Trusted-Source Information Page provides information on the selection and use of respirators, and both the NIOSH Respirator Selection Logic and Federal OSHA Respirator e-Tool (which contains OSHA’s updated APFs) aid in the selection of respirators and the development of a change schedule for cartridges. See Figure 10 to the right for a summary of respirator selection considerations for ATD pathogens.

**Respirator Use**

In this section of your written RPP, describe your facility’s policies regarding the use of respirators. Include detailed procedures for the routine use of respirators. For example, describe proper procedures for inspecting and putting on (donning) the respirators used at the hospital, and train users to always perform a user seal check whenever they put on a tight-fitting respirator. Describe and demonstrate proper respirator-specific procedures for taking the respirator off (doffing) and explain the importance of the sequence of removal of the respirator with other PPE so as to avoid self-contamination (see the CDC slide show and the figures on pages 134-135 of CDC and HICPAC’s 2007 Guideline for Isolation Precautions). Employees should also be trained to recognize when the respirator is not working correctly (e.g., if employee is experiencing symptoms from exposure to chemicals, or having difficulty breathing).

In order to clearly state your policies for respirator use, it might be helpful to answer the following question. What will your policy be for employees with facial hair or other conditions that prevent a good seal to the face? Employees who use tight-fitting respirators are not permitted to have facial hair that interferes with the facepiece seal or valve function. Hospitals may provide loose-fitting PAPRs to employees who have facial hair,

**FIGURE 10: SUMMARY OF RESPIRATOR SELECTION CONSIDERATIONS FOR AEROSOL TRANSMISSIBLE DISEASE PATHOGENS**

- Determine who has potential occupational exposure to ATD pathogens, the level of exposure they are likely to encounter, and how frequently they may be exposed for each task they perform. Be sure to consider the hierarchy of controls before resorting to the use of respiratory protection.

- Use federal, state, and local public health and occupational health and safety guidelines and regulations for choosing the appropriate level of protection for each task that results in exposures that cannot be prevented through other types of controls (e.g., engineering controls such as ventilation).

- Make sure the respirators you have selected are NIOSH-approved and provide the appropriate level of protection from all types of contaminants (particles and gases or vapors) as needed. Consult an industrial hygienist if you have questions about the level of protection provided. For example, make sure the PAPRs used by first receivers have an assigned protection factor of 1,000. Consult your supplier if you have questions about the level of protection provided.

- Stay aware of the potential for counterfeit respirators, particularly during pandemic outbreaks. Refer to NIOSH’s Trusted Source Page and the OSHA/NIOSH video on counterfeit respirators for more information.

- Make sure that the chosen respirator is not putting the patient at risk and that use is consistent with other infection prevention policies.

- Stay aware of changes in respirator selection guidance.
or for whom other respirators available at the facility do not provide an acceptable fit. This is acceptable as long as employees consistently use the loose-fitting PAPR when required, have been trained in its use, and the PAPR provides adequate protection for the specific hazard (i.e., is equipped with the correct type of filter or cartridge).

List the reasons for which an employee might leave a contaminated area to adjust or replace his or her respirator. These should include problems with the use of the respirator such as difficulty breathing, loss of face seal, gross contamination or saturation of the filter material, etc. This list should include a policy that wearers of respirators with chemical cartridges must leave the contaminated area to replace the cartridges or respirator when they detect breakthrough of the contaminant or because the usable service life has been reached, as indicated in the change-out schedule provided by the program administrator.

**Storage, Maintenance, Repair, and Disposal**

This section should include, for each type of respirator, detailed and specific procedures for storage, maintenance, repair, and disposal. These procedures should include a description of where respirators are stored in each unit or department, how they should be stored between uses by a respirator user (if allowed), how they will be maintained and who is responsible for maintenance, and who is responsible for ensuring an adequate supply.

Most hospitals keep carts of N95 filtering facepiece respirators in each unit or outside the isolation rooms, while PAPRs are often kept in central supply and are ordered when needed for aerosol-generating procedures. Some hospitals have decided that since most aerosol-generating procedures will be done by the respiratory therapy department, the PAPRs will be stored there. Some hospitals issue PAPR hoods to individuals who are responsible for maintaining them, while central supply or materials management is responsible for decontaminating PAPR motors and blower units and charging batteries. Whatever you decide works best for your facility should be described here.

Filtering facepiece respirators are designed to be worn by one individual (i.e., not shared) and disposed of after use. Users should discard respirators when they become unsuitable for further use due to excessive breathing resistance (e.g., particulates clogging the filter), unacceptable contamination/soiling, or physical damage. Filtering facepiece respirators should be removed with minimal handling and disposed of properly. Hand hygiene should always be performed after removing a respirator.

From the standpoint of the wearer’s protection, filtering facepiece respirators may be taken off and put on again as long as they are not damaged or soiled, or contaminated inside the facepiece. However, a respirator used in the care of an infectious patient should be considered
potentially contaminated with infectious material on the outside and a source of contact transmission for healthcare personnel or patients. Therefore, the risk of contaminating the inside of the respirator through improper handling and the risk of infecting the patient must be weighed when making decisions about redonning filtering facepiece respirators. Tuberculosis is not transmitted via contact and, therefore, reuse by the same wearer is acceptable as long as the filtering facepiece respirator is not damaged or soiled.

Describe your facility’s policies regarding use and disposal of filtering facepiece respirators in the written RPP, including policies, procedures, and training to reduce the potential for contact transmission. If different policies on reuse may be implemented in the event of a respirator shortage, the RPP should address those policies (or be updated to document changes in policies).

You should also describe procedures to follow when users discover problems with respirators.

- To whom do they report the problem?
- Who does the repairs?
- Who decides when to discard a reusable respirator and replace it rather than trying to repair it?
- What are the procedures for disposal of used or damaged filtering facepiece respirators?

NIOSH has issued guidance on extended use and limited reuse of N95 filtering facepiece respirators in healthcare settings.

Medical Evaluations

The OSHA Respiratory Protection standard (29 CFR 1910.134) requires that employees be medically evaluated and cleared for respirator use prior to wearing a respirator or being fit tested. The use of some types of respirators can cause an increased resistance to breathing or a build-up of carbon dioxide inside the facepiece. This can lead to medical complications in some individuals for whom it may not be safe to wear a respirator. It may also be unsafe for someone with moderate to severe claustrophobia to wear a respirator. Medical evaluations must be provided by the employer during work time and at no cost to the employee.
the expected physical work effort, additional protective clothing and equipment to be worn, and temperature and humidity extremes that may be encountered. This information is critical to the healthcare professional’s determination regarding the employee’s ability to use a respirator.

Part A of Appendix C of the OSHA Respiratory Protection standard is a questionnaire that solicits information that must be reviewed by a physician or other licensed healthcare professional either in questionnaire format, or in person during a visit to the PLHCP. The PLHCP may be a hospital employee, but must not be the employee’s supervisor. If the hospital does not have internal occupational health services, the PLHCP may be a contracted provider. The best outside sources for such evaluations are occupational medicine providers or clinics (see organizations listed in the “References, Resources, and Tools” section of this document starting at page 36). These clinics provide medical clearance for respirator use and may also provide fit testing services.

Make sure that you are clear about where the questionnaires will be sent for evaluation, and describe these procedures in your written RPP. The completed questionnaires are considered personal health information, so there must be a procedure by which they are confidentially provided to the PLHCP. Completed questionnaires must be maintained as confidential medical records and may not be accessible to the employee’s supervisor (see “Recordkeeping” on page 33).

Based on the answers to the questionnaire, as well as on a physical exam or any other tests the PLHCP deems necessary, the PLHCP must make a determination as to whether the individual can safely wear the respirator. Information that is useful for the medical evaluation of respirator users is provided in ANSI/AIHA Z88.6-2006, a voluntary consensus standard. (See “American National Standards Institute (ANSI)” on page 38.) The PLHCP must inform the employer (RPA or supervisor) in writing whether the individual is cleared for respirator use, cleared with certain conditions or restrictions (e.g., only for PAPR use, only for limited duration, etc.), or not cleared for respirator use, whether there is a need for a follow-up medical evaluation, or if the individual requires periodic medical reevaluation. The details of any medical evaluation, including specific medical diagnoses or test results, should not be shared with the employer or supervisor.

Your program should include a clear policy as to what will be done if someone is not cleared for respirator use. Employees who are not cleared
cannot be exposed to situations in which a respirator is necessary to protect them. If the PLHCP determines that a person designated to use a non-powered air-purifying respirator cannot do so without added health risks, the employer must provide a PAPR (assuming the PLHCP determines that the person can use one and the RPA determines that it will provide adequate protection).

**Fit Testing**

Fit testing is one of the most important parts of the respirator program because it is the only recognized tool to assess the fit of a specific respirator model and size to the face of the user. OSHA requires employers to make available a sufficient number of models and sizes of respirators so that employees can be provided with a respirator that is comfortable and fits well. Employees are only allowed to use the make, model, style, and size of respirator or respirators for which they have been successfully fitted.

Fit testing is required for all users of respirators with tight-fitting facepieces, including filtering facepiece respirators. The fit test ensures that, when donned properly, the selected brand and size of respirator fits adequately to protect the wearer from excessive inward leakage of contaminant through the face seal. The fit test must be repeated annually and whenever the employee reports—or the employer, PLHCP, supervisor, or program administrator makes visual observations of—any changes in the employee’s physical condition, such as weight gain or loss, facial scarring, or dental changes, that could alter fit of the facepiece.

Describe your procedures for coordinating fit testing for your staff, as well as the specific, detailed fit testing protocol that will be used.

The OSHA Respiratory Protection standard Appendix A has specific protocols which must be followed exactly in fit testing employees for respirators, and it is acceptable to copy and paste one or more of these into your RPP. First, there are general requirements that pertain to selecting an appropriately sized respirator, some basic training on donning the respirator and performing a user seal check, and descriptions of the specific exercises that are to be performed.
during the fit test to verify an adequate seal during several routine work activities. Second, there are detailed protocols for four different qualitative (i.e., wearer indicates fit based on detection of a chemical) fit tests and three quantitative (i.e., provides a numerical test result) fit tests from which you may choose.

**Qualitative Tests:** There are four qualitative fit test protocols specified in the Respiratory Protection standard. Either the saccharin or Bitrex® fit test protocol may be used for fit testing APRs, including filtering facepiece respirators, for particulate exposure. The APF for qualitative fit tests is limited to 10, even for respirators with a full facepiece. In these tests, the user is exposed to a saccharin (sweet-tasting) or Bitrex® (bitter-tasting) aerosol. It is up to the respirator user to let the tester know if he or she tastes the test aerosol at any time. Because these tests rely on the user’s subjective detection of leakage when challenged with a test agent, the protocols require pre-screening to determine each user’s ability to detect the specific test agent.

**Quantitative Tests:** There are three approved quantitative fit tests and all require an investment in relatively expensive equipment. The most common quantitative protocol used in hospitals is the ambient aerosol condensation nuclei counter (CNC) test. With the correct equipment, this test protocol can be used for all types of respirators and provides an automated calculation of the effectiveness of fit (fit factor) by consecutively measuring and comparing the concentration of airborne particles inside and outside the facepiece.

It is critical that the person conducting the fit testing follows one of the protocols written in the Respiratory Protection standard. Most hospitals do qualitative fit testing using either the saccharin or Bitrex® protocol. There are some, however, who do quantitative fit testing.

It is the program administrator’s responsibility to ensure that the person conducting the fit tests is competent. There is no licensing or certification required for someone to do fit testing; anyone can do it as long as they understand how to

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**FIGURE 11: SUMMARY OF FIT TEST REQUIREMENTS**

- All employees required to wear tight-fitting respirators must be fit tested after receiving medical clearance, prior to respirator use, and annually thereafter.
- An OSHA-accepted fit test protocol must be followed exactly as it is written in the standard. This may be a qualitative test using Bitrex® or saccharin, or a quantitative test using a condensation nuclei counter or another appropriate instrument.
- Fit testing must be performed by an individual knowledgeable in respiratory protection, and qualified to follow the protocol and train the employee to properly put on and take off the respirator.
- Records of fit tests must be kept on file until the next annual test is performed, and you must make sure that employees use only the respirator model and size for which they have passed a fit test.
- There is no fit test requirement for PAPRs with loose-fitting facepieces, hoods, or helmets. A PAPR with a tight-fitting facepiece requires fit testing (with the blower off).
follow the protocol and are skilled at training people on how to put on and take off a respirator and perform a user seal check. In some hospitals, the employee health department or an occupational health clinic is responsible for both medical evaluations and fit testing, and they can be done in one visit. In other hospitals, the infection preventionist is responsible for fit testing the healthcare personnel with filtering facepiece respirators. Still others train each of the unit managers to fit test their own staff so that one person is not charged with fit testing hundreds of employees. Some hospitals do all of their fit testing and training in one month. Others spread it out so that each employee is tested on or before the anniversary date of his or her previous fit test. You should decide which approaches work best for you and your facility.

Employees can only wear the respirator model and size for which they have successfully passed a fit test. Employers should implement a mechanism to ensure that employees know the manufacturer, model, and size of respirator they can wear. Some hospitals issue wallet-sized cards containing this information, while others place stickers on the back of employee badges.

Fit testing is critical to ensure the safety of the employees relying on their respirators for the expected degree of protection. If hospital personnel do not have the time or skills to conduct fit testing, there are consultants who provide fit testing services. In addition to these consultants, some of the respirator manufacturers will provide train-the-trainer services so you can have multiple in-house staff with these skills. There are also some workers’ compensation insurance companies that provide similar assistance to their customers.

A summary of fit test requirements appears in Figure 11 on page 31.

Training

Employee training is a critical component of an effective RPP. It requires significant time and resources and must be conducted prior to respirator use, at least annually thereafter, and whenever necessary due to changes in the workplace or identified inadequacies in the employee’s knowledge. The annual fit test provides an opportunity for hands-on learning and serves to reinforce some of the topics covered in training. Some hospitals include respirator training as part of a skills day for their healthcare professionals and require them to pass a competency test.

This section of your written program must include both the mechanism for getting everyone trained in a way that they can understand and a description of the curriculum, including all of the topics that are required by the standard to be covered. These are:

- Why the respirator is necessary (including when it must be worn);
- Why proper fit, usage, and maintenance is crucial to its effectiveness;
- What the limitations and capabilities of the respirator are;
- Hands-on demonstration of how to inspect, put on, remove, use, and check the seal of the respirator;
- What the procedures are for storage and maintenance;
- How to recognize medical signs or symptoms that limit or prevent the safe, effective use of respirators;
- The general requirements of the OSHA Respiratory Protection standard;
- How to identify and react to respirator malfunctions; and
- How to use the respirator in emergencies (e.g., chemical release) if appropriate.
There are a number of educational tools (including slide presentations, posters, and flyers) listed in the “References, Resources, and Tools” section at the end of this document. You may use these materials during your annual training and as needed year-round to make sure that employees are up-to-date on their knowledge of respiratory protection and its proper use. However, you must ensure that respirator users are fully trained on the specific risks, programs, and procedures at your hospital; can correctly put on and take off their respirators; and can recognize when their respirator needs to be repaired or replaced.

**Recordkeeping**

The respirator standard requires that several types of records be maintained. The written RPP must be maintained in a location that is accessible to all program participants, and it must be made available to OSHA on request. We recommend documenting the changes that are made to the RPP along with any evaluation checklists that are completed during program evaluation (see next section). The current program, however, can be kept online for access by participants.

You must also keep a record of the employee medical evaluations. The questionnaires and any notes from physical exams are medically confidential, so these are often maintained by the PLHCP who does the medical clearance evaluations. They must be maintained for 30 years after termination of employment. The medical clearance letters that are provided by the PLHCP should be kept on file by the RPA as evidence that the employee has been cleared. It makes sense to keep these with the fit test records.

Fit test records must be kept on file until a new fit test is completed, so there should always be a record for each tight-fitting respirator user indicating that he or she has passed a fit test within the last 12 months.

The Respiratory Protection standard requires that the following information be kept in the fit test record:

- Name or employee ID;
- Type of fit test performed;
- Specific make, model, style, and size of respirator tested;
- Date of test; and
- Pass/fail result from qualitative test or printout from quantitative test.

Links to a sample fit test record form and a fit test verification card are provided as resources. Software to track RPP participants and provide reminders of requirement (e.g., medical clearance, fit testing, and training) due dates can be developed in-house or purchased.

**Program Evaluation**

Regular program evaluation is required by the standard and it is critical to successful implementation. There should be a section in your written program that describes how you will evaluate the implementation and effectiveness of your program. The standard does not require this to be done at specific intervals (i.e., annually). It requires that the workplace be evaluated as necessary to ensure that the provisions of the written program are being implemented effectively. It also requires that the employer regularly consult employees to assess their views on the effectiveness of the program.
This means that the RPA, or whoever has been designated to evaluate the program, should observe respirators being put on and taken off, availability, storage, maintenance, and other practices in all units where respirators are commonly used. The systems in place to manage respirator use should be evaluated to ensure that they support the behaviors you expect to observe among employees. If someone is not using a respirator when he or she is supposed to, consider all the possibilities why this may be happening. Some hospitals use a labor-management health and safety committee to tap into the knowledge and experience of employees and obtain feedback and suggestions for improvements, while others survey or interview respirator users.

Any deficiencies in the implementation of policies and procedures that are discovered as a result of the evaluation must be corrected in a timely manner. In some cases, this might mean revising the written program to conform to actual practices as long as the procedures being followed comply with the standard. In other cases, it might mean retraining personnel on some aspect of the program, or assigning a loose-fitting PAPR to someone who had been using a filtering facepiece respirator, but has since grown a beard.

An evaluation checklist, with instructions on how to use it, is provided in Appendix C of this document. It will make the process of evaluation a bit easier as well as more standardized and comprehensive. You are not required to use a checklist, but it is one way to make sure that you do the evaluations and track any improvements you make.
Summary

Healthcare personnel are at increased risk for exposure to ATD pathogens and, when other controls have been considered and implemented as appropriate, may be required to use respiratory protection.

In order for respirators to provide effective protection they must be properly selected, used, and maintained as part of a written program, which describes how employers will provide employees adequate medical evaluations, training, and fit testing. The program must be evaluated regularly through observation and obtaining input from all respirator users and persons involved in implementing the program. Public health guidance and regulations must be regularly reviewed for changes and utilized to identify tasks and pathogens requiring the use of respiratory protection.
“This course was developed from the public domain documents: Hospital Respiratory Protection Program Toolkit: Resources for Respirator Program Administrators (2015), Occupational Safety & Health Administration (OSHA Publication Number 3767-05 2015)”