

Your First Laboratory

Now What Do You Do?

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15 December 2015

Excitement and Fear

Brand new laboratory administrators—whether officer, enlisted, or civilian—generally succumb to the same sentiments: cheerful anticipation and a foreboding sense of anxiety. So many challenges and responsibilities remain ahead that it is easy to feel overwhelmed. A new lab administrator can tackle these responsibilities with a sense of empowerment that limits apprehension. Apart from the steady guidance of more experienced mentors, a new manager needs the right strategy to handle abundant challenges. This article summarizes basic, critical stages that every new lab leader should negotiate early to avoid problems and guarantee success.

The Quality Pulse

You are now a “laboratory administrator.” Most likely, you were a bench technologist before slipping off your lab coat and parking yourself behind a desk as the newest pencil-pushing denizen. Suddenly, concerns that were once the terrain of those “darn managers” are now yours; it is presently your turn to fret over quality assurance, meeting minutes, proficiency surveys, lab innovations, instrument validations, resources, personnel, budgets, and countless other things that fill the calendars of administrators. A comprehensive guide addressing laboratory management functions is impractical in a short piece. Rather, purpose is to provide a point of departure for taking those inaugural steps—the first few days or weeks—when assuming control of a new lab or lab section. One’s most important job as a lab administrator is being a quality assurance leader, and so one of your most important first endeavors will be measuring the “quality pulse” of the laboratory to determine its “health.” This telemetric overview will direct one towards the vital follow-on prescriptions and therapies that will require consideration in the months to come. The “quality pulse” is your journey’s first signpost, and includes the interconnected foci of *People, Procedures, Accreditation, Quality Control, and Resources*.

The purpose of this article is to provide new laboratory administrators with a template for success that is useful when assuming control of one’s first laboratory or laboratory section(s).

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SOCIETY SCOPE is published three times per year by the Society of Armed Forces Medical Laboratory Scientists (SAFMLS). Send SCOPE correspondence to scope@safmls.org. Address changes and annual dues (\$20) for SAFMLS membership can be paid via http://www.safmls.org/secretarys_page.html

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Editor's Page

Here ye Here ye! This is the call for submission of articles to the Society Scope! Capt Hase and I know that there are incredibly talented laboratorians in the military medical field and we want to hear from you. The Society Scope is a great way to show off the talent of you and your staff as well as raise important laboratory issues within our community. Your peers, consultants and your leaders all read the Scope...because they too are members of SAFMLS! SAFMLS is continuing to grow, especially now that we have partnered with CLMA, this provides a wider audience within the laboratory community. Publishing an article is an excellent way to stand apart from your peers and spotlight the accomplishments and leadership involvement in the laboratory.

The articles we seek do not have to be research in nature. If you look through our previous publications at www.safmls.org (Look for Society Scope on the left-hand of the www.safmls.org webpage), you will see we have articles about regulatory compliance, career corner, clinical applications and leadership development, for example. You can send us an overview of your experience from deployment or a spotlight of an event from your current hospital. We love those pictures!

There is no length format. If you have published your article in another publication, we can reprint as long as you request permission from the original publication. Don't forget that any article you submit for publication must be approved by your unit/base public affairs office. It is a fairly simple process with far reaching impact. Showcasing the hard work and accomplishments both at your home base and downrange is a great way to keep the SAFMLS organization growing and expanding.

So put those writing skills to test! We need to know what is taking place with you and at your unit.

Lt Col Paul Eden, USAF
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NEW DEADLINES for SAFMLS Society Scope:

Winter	Vol X Number 1	Deadline: 1 Jan
Summer	Vol X Number 2	Deadline: 1 May
Fall	Vol X Number 3	Deadline: 1 Sept

President's Message

COL Eva (Kris) Calero, US Army

It is so hard to believe that summer is coming to an end and the start of a new fiscal year is around the corner! I hope and trust everyone enjoyed these past months, and that hopefully you had some downtime to recharge, or start new activities with the added hours of light during this time of the year. With September looming, SAFMLS like other organizations is gearing up to a busy next two quarters culminating in our next annual meeting. The launch of this Scope edition will be followed by two more to close the calendar year. We need your articles! Our editors, Lt Col Eden and Capt Hase, USAF, are always on the lookout for articles. Remember SAFMLS is not exclusive of research articles, we can take articles about a project that improved your organization, deployment and career management tips. Also articles do not have to be original; if you have posted in another publication, we can reprint with permissions. Please reach out to them, and help us showcase the good work that everyone is doing out there to your peers and the other services and organizations that comprise SAFMLS members.

As well, as I am writing this, there are only days left before the call for posters for KnowledgeLab 2017 closes. While at this point we are veterans of two iterations, remember that CLMA's annual venue, KnowledgeLab, has an earlier schedule than SAFMLS had when it comes to submitting abstracts for workshops, short topics and posters. The call for speakers for workshops opens about a month after the conclusion of the annual venue. Also, while SAFMLS used to have the same deadline for short topics, workshops and posters, CLMA has a tiered approach. The call for posters is after the call for abstracts for workshops and short topics. A strong reminder that with our new partners, we compete for speaking slots with all CLMA members nationwide; therefore, once the deadlines close there is limited ability to squeeze in exceptions.

This year's KnowledgeLab (KnowledgeLab 2017 or KL17) will be in Nashville, TN, starting March 26th of 2017. Every service currently manages and provides guidance on the process to attend this venue (who and how to procure funds). SAFMLS will enhance this by putting out timely information on our website (www.safmfls.org), on the Scope and through the Consultants/ Specialty Leaders and Members at Large. One enhancement is that this year's venue has four times the amount of rooms at per diem rate than last year. Also remember we will like host service training sessions that Sunday. One reminder, registration is not open yet, and is tentatively scheduled for November-December of this year. In addition to the Scope publication, we will be sending a needs assessment survey to all of our SAFMLS members. We want to hear from you and how SAFMLS can better serve your professional needs. Lastly, we will be sending information about SAFMLS elections.

It will be a busy next two quarters; however I wanted to ensure to give you a high level overview of the months to come. Please stay tuned, be informed, be proactive, remain engaged and participate in these activities! SAFMLS is as strong as each of the input received from each of its members.



Consultant's Corner

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Specialty Leader to the Navy Surgeon General for Medical Technology
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I've met very few laboratory professionals that weren't very busy. I think that many in our field can be described as running around at 600 miles per hour with our hair on fire (smoldering, burnished, hair-free scalp in my case). We all know the lab is a demanding field, always ready to throw that next regulatory, staffing, or scope of practice change our way. There are times that I sit down Monday morning only to look up surprised to find that it has suddenly become Friday evening.

This hectic schedule causes us each to develop means to cope with the constant stress of drinking from that fire hose. As a field with an abundance of introverts (I include myself in that category), many of us find ourselves becoming more insular and retreating to our safe spaces, where we can avoid interaction, do our paperwork, and occasionally catch up on our professional reading.

The end of a demanding week can make you want nothing more than to go home, put on those fuzzy slippers (mine are little bears) and catch up on the last season of the Walking Dead; but you'll be missing out on some incredibly rewarding experiences if you only do that. Our inclusion in a military service allows us the pride of being part of something larger than ourselves; being a SAFMLS/CLMA member allows us to do the same with our military and civilian laboratory peers.

For years SAFMLS presented an opportunity to meet my fellow lab officers that had been scattered to the four corners; catch up on their lives, learn how they had coped with some of the same hurdles I had, and receive mentoring to allow me to plot the next chapter of my life. Now, with the merger of the SAFMLS and CLMA communities, I have been able to take that fellowship to another level; adding in civilian peers, mentors, friends and co-conspirators in the practice of lab science. Twenty-five years ago, had anyone told me that I would eventually have mentors in six states, friends in another 10 states, and peers in over a dozen countries, I would have scoffed. I now look upon such circumstances as "normal" and am sorry for new acquaintances that don't have such a robust support network.

Opening up to these new experiences has allowed others to get to know me and judge my personal integrity and professionalism. That exposure has led to opportunities as a SAFMLS Board Member (member-at-large and now consultant/specialty leader), afforded chances to consult, chances to aid in the development of CLMA educational opportunities, serve on a board of certification, serve as a community college board member, and even teach. Each experience took an investment of my part, but the reward of being involved in the act of creating a better environment for laboratory science was motivating and re-energizing. The act of giving more of myself to the community also took something away from me - some of that stress. In its place, I found confidence and felt happy to be contributing.

Sure, we all work the bench at the beginning of our careers, but it's the path we blaze from there that defines us. I've had to learn to do a better job of imitating an extrovert and I can say with absolute certainty that you should too. Get off the bench and get involved. Give a presentation, present a poster, write a paper, and join our community in making the practice of lab science better. I guarantee that if you do, the chances are great that: our paths will cross, we'll get to know one another, that together - we'll make a positive contribution, and that our lives will be better for it. What have you got to lose? Meet me out there!



People

Some managerial authorities have clumsily bundled an organization's people with other assets, dubbing them "human resources." (Clinical Laboratory Management Association, 2000, p. 43) Oddly, that very designation imbues a taint of dehumanization. The organization's people are, in reality, a team, and the leader is, foremost, a team member. The secret to a lab's mission success begins and ends with the *team* of laboratorians performing the routine, everyday tasks that comprise the pre-analytical, analytical, and post-analytical aspects of quality diagnostic testing. Do you remember what it was like to be a "bench tech" or a "worker bee"? Remembering those experiences will serve any new lab administrator well. Never forget that the total lab team—not just its leadership—determines whether the lab effectively accomplishes its charge of providing fast, safe, accurate, and precise diagnostic data.

On your first day, schedule time to become acquainted with each person working in your lab or lab section. Meet first with any designated, subordinate leaders, such as the non-commissioned officer in-charge (NCOIC) or section supervisor; it is a good idea to conduct any formal, preliminary feedback required during these sessions. Then schedule time to meet with each lab professional on the team. Start a database or spreadsheet and record their names, nicknames, contact information, certifications, degrees, family members, birth dates, hobbies, additional duties, and so on. Insert a hyperlink within the database linking to the work schedule and other pertinent personnel rosters. Find out the concerns of each individual and take notes. Make certain that they understand your top concerns and that they also see you as a team member. What are your top priorities? Find out the organization's Mission, Vision, and Goals at all levels; lock the lab's top priorities to those primacies of the overarching organization. Keep track of these mission and vision statements, as they will be important when examining the lab's *procedures*—specifically the management plan. Finally, ask them what they expect from you and take heed—the organization's success begins and ends with these people!

Afterwards, once the laboratory is operating efficiently from an administrative outlook, schedule time to develop competency in a few laboratory sections. For example, being formally trained in specimen collection could help in instances of low manning or high volume scenarios. The people on your team are more likely to regard you as a team member—not just the boss—if you can accomplish simple, routine tasks occasionally when needed (e.g., receiving patients, logging specimens, performing phlebotomy, pouring off samples for referral, etc.). If you reach too far and aim to do too much on the bench then you risk having the team regard you as a burden rather than a blessing.

Finally, schedule a meeting with the medical director, usually—but not always—a pathologist or doctoral-level scientist. Depending on the circumstances, the director may work in the facility, but often works as a geographically separated consultant. The lab's accreditation certificates list the director's name; essentially, their name and professional reputation is at stake with each certified lab result, and it is your responsibility to inspire the director's confidence in the lab's ability to generate quality test results. To assist in focusing your energies, ascertain the medical director's current concerns—if any—with the laboratory. Lastly, reinforce that lab personnel must view you as the liaison to the medical director; the lab administrator partly exists to free the director from dealing with organizational minutiae. Ask the director to redirect any team member reporting mundane administrative issues back to you; those are your job and your medical director will appreciate the intervention.

The people on the team underpin all other facets of the laboratory that require an administrator's attention. One cannot completely understand the strengths and weaknesses of all personnel on the first day (e.g., the strongest laboratorian, the most knowledgeable in chemistry, the one with competency issues, the most skilled phlebotomist, etc.); those conclusions come with careful surveillance over time. However, one can commence fostering relationships on the first day to facilitate any needed alterations after a period of assessment. Understanding one's team is like sensing the first beat of a lab's quality pulse.

Procedures

Written procedures denote the next pulse of the lab's quality. Start with the administrative procedures—"Operating Instructions" (OIs) in Air Force parlance. Usually an "Administrative Binder" contains these OIs or

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procedures, and paraphrasing Lieutenant Colonel (retired) Dale Payne, “The administrative OIs are specifically the boss’s responsibility and domain.” Read the administrative procedures; compose notes for any potential changes; and then sign and date indicating your review in accordance with current document control policies. Start a laboratory procedure database, if one does not already exist; a simple spreadsheet is beneficial in documenting periodic procedure and document review and in signifying when the next assessment is due. The content and organization of an administrative procedure binder can vary depending on the laboratory’s mission and need, but generally, administrative procedures address the key areas listed in Table 1.

Procedure Number	Title	Content
44-1-01	Management Plan	Mission, Vision, Goals, etc.
44-1-02	General Policies	Accreditations, Duty Hours, Leave, Lab Guide, etc.
44-1-03	Quality Assurance Program	Overarching QA/QC guidelines
44-1-04	Preventive Maintenance	Maintenance policies (i.e., frequency, pipettes, etc.)
44-1-05	Performance Improvement (PI)	PI and Risk Management policies/activities
44-1-06	Proficiency Testing	Description of PT policies/activities
44-1-07	Result Review	Daily result review actions
44-1-08	Fraud, Waste, Abuse (FWA)	Prevention of FWA
44-1-09	Document Control	How procedures/forms are written/tracked
44-1-10	Notification Values	Actions taken for critical/abnormal results
44-1-11	Method Verification	Procedures for bringing on new tests
44-1-12	Reference Policies	Tests that the lab refers and to which lab
44-1-13	Personnel Policies	Job descriptions/responsibilities/
44-1-14	Consumables	How to inventory/rotate/order/organize supplies
44-1-15	Water Quality	Applicable if making reagent grade water
44-1-16	Security/Privacy	HIPAA, Privacy Act, and other related requirements
44-1-17	Workload	Activities used to measure/track workload/budgets
44-1-18	Competency/Training	Education, training, and competency policies
44-1-19	Recognition	Internal award program

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After reading through the administrative procedures, review the laboratory safety program (e.g., occupational health, ergonomics, fire safety, etc.); the chemical hygiene plan, chemical inventory, and chemical safety data sheets (SDS, formerly MSDS or material safety data sheets); and hazardous communications binder. These may be located in one binder or separate binders, but they are essential and closely related to the lab's administrative procedures. Draft notes for any updates or changes required.

Next, review the Laboratory Guide (LG), which is a publication made available to the facility's medical staff that describes general laboratory information (hours of operation, contact information, etc.); the test menu (i.e., the tests your lab performs); and specimen requirements. Policies addressing specimen collection, specimen rejection, patient recall, and release of results fit nicely in the LG, which functions as the formal interface between the lab and professional staff, communicating policies and requirements mandating their awareness. Always develop or edit the LG in close coordination with the facility's Chief of Medical Staff.

Only after reviewing the aforementioned procedures should one begin reviewing individual test procedures in each lab section. Start with specimen collections (i.e., more generalized) and work towards testing areas such as microbiology (i.e., more focused). Look for inconsistencies or conflicts with the overall administrative policies and procedures already reviewed and make notes on which require modification.

The Clinical Laboratory Standards Institute (CLSI) provides administrators great starting points for authoring laboratory procedures. The CLSI standard GP2-A describes in detail how to draft, publish, and control documents within the laboratory. (Clinical Laboratory Standards Institute, 2006) Your lab should have a library of these standards. If it does not, contact the Center for Laboratory Medicine Services (CLMS) to inquire about receiving access to them (<https://info.health.mil/hco/clinicsup/hsd/hs/cclm/SitePages/Home.aspx>).

Procedures describe what the team does—what it can and cannot do—in achieving the mission and goals of the laboratory. Subsequent to people, procedures are the next most important beat of the lab's quality pulse. Reviewing procedures thoroughly elucidates for the new administrator what should occur on a daily basis to maintain quality

Accreditation

The third crest of the quality is the laboratory's accreditation—external validation of the lab's excellence. One or more professional organizations accredit most clinical laboratories, and an accrediting agency, like the College of American Pathologists (CAP) or The Joint Commission, inspects a laboratory and issues an accreditation certificate, provided the laboratory meets stringent standards. Additionally, a military lab must have one or more *current* Clinical Laboratory Improvement Program (CLIP) certificates issued by the Defense Health Agency (DHA) that denote the complexity of testing the laboratory can perform (e.g., waived testing, moderate complexity, etc.). The CLIP is the military equivalent of the Clinical Laboratory Improvement Amendment program managed by the Centers for Medicare and Medicaid Services (CMS). If the lab's CLIP certificates are not current or close to expiring, contact the CLMS at the DHA immediately (<https://info.health.mil/hco/clinicsup/hsd/hs/cclm/SitePages/Home.aspx>)!

A major stipulation of most accrediting agencies is that the accredited lab uses a valid form of proficiency testing (PT)—consisting of recurrent unknown specimens that the laboratory receives and processes throughout the year for each test the lab performs. Often an accrediting agency markets and sells its own PT programs (e.g., CAP Surveys). After meeting the lab team, dissecting procedures, and reviewing all accreditation certificates, access and review the laboratory's PT records. Find out whether the laboratory has failed any surveys, and if so, what was done to identify and correct any problems. Beyond misses and failures, examine the records closely for statistical trends. Ensure the laboratory has a robust PT tracking database that logs pertinent information (e.g., PT titles, due dates, performing technicians, results received, trends, etc.). Create an electronic reminder to check this PT database twice frequent and regularly to meet all suspenses and flag problem areas.

During the second week of your new management gig, review the most recent accreditation inspection findings. Download the most recent standards (i.e., "checklists") from the lab's accrediting agency and perform a self-inspection. It makes sense to perform this inspection in parallel with the laboratory procedure review described earlier, as procedures often directly refer to specific standards and vice versa. Once this initial inspection is complete, a new lab manager probably has a good idea which areas will require attention to maintain the lab's accreditation.

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Achieving and maintaining accreditation without significant issues is another signifier of lab health. Well-maintained accreditation is the third pulsation of quality that one can directly observe.

Quality Control (QC)

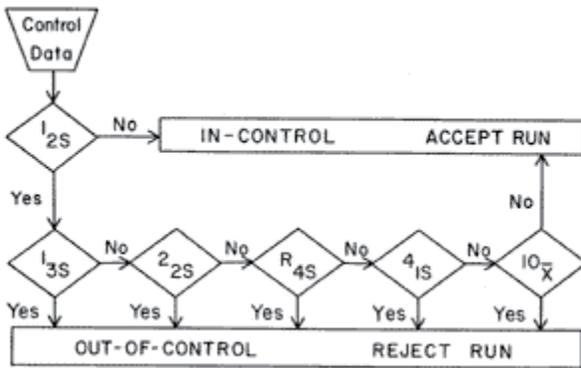


Figure 1 - Westgard Rules

Without a good QC program, a laboratory's quality pulse flat-lines. Properly performed QC provides the laboratory day-to-day confidence in its testing accuracy and precision. An entire administrative procedure should be devoted to broadly describing your lab's general QC requirements, while section or test-specific QC requirements can be written into their respective procedures. As previously discussed, the best way to review a QC program is to compare the laboratory's QC procedure against the accrediting agency's QC standards. A general QC program should address *qualitative* and *quantitative* QC requirements (i.e., levels performed, frequency, and acceptability criteria); it should address how to identify and investigate QC problems

and how to correct issues. For example, including "Westgard Rules" (Figure 1) for quantitative QC monitoring in the general QC procedure is a good idea. (Westgard, 2015) Most importantly, a QC procedure must always state that *results cannot be released* if QC is beyond acceptable limits.

In the past, laboratories were able to perform QC on certain tests less often than daily (i.e., QC each new lot or shipment), provided they met minimum manufacturer guidelines. CMS has mandated new risk mitigation requirements effective 1 January 2016 for laboratories wishing to continue this practice. Some accrediting agencies further refined these new requirements. Under CAP, laboratories must have Individualized Quality Control Plans (IQCPs) in-place for non-waived complexity tests where at least two levels of external QC are performed less often than once per-day of patient testing, while still meeting minimum manufacturer QC requirements. Test systems other than microbiological systems (i.e., bacteriological media, identification testing, and antimicrobial susceptibility testing) must also have an internal control for IQCP eligibility under CAP. QC performed in accordance with an IQCP (for non-microbiological QC) must be performed at least every thirty-one days and for new lots/shipments of reagent (e.g., certain serum hCG kits). An IQCP for qualifying test systems must be approved initially and reviewed annually by the Medical Director. IQCP is a fairly complex subject to describe thoroughly in a short paper, but it should address pre-analytic, analytic, and post-analytic sources of error and have three components: A *Risk Assessment* (i.e., identifying where risks are *unacceptable* and how those will be mitigated); a *Quality Control Plan* (i.e., QCP - processes used to monitor quality across all potential sources of error); and a *Quality Assessment* (i.e., processes used to monitor and refine QCP effectiveness). (College of American Pathologists, 2015)

Another important facet of a lab's QC program is peer appraisal. For quantitative testing (e.g., chemistry, hematology, etc.), ensure that the lab is enrolled in a peer comparison program that studies the lab's monthly and cumulative lab QC results and statistically compares them to other labs with the same instrument and reagents. This is an additional, important step in a lab's QC program that is especially helpful when troubleshooting QC, calibration, or PT issues.

There is no way around having a robust, healthy QC program if the laboratory expects to maintain accreditation and continue releasing reliable results. Reviewing your lab's QC program is essential to initially assessing the overall quality of your new lab or lab section.

Resources

The last beat of the waveform to examine when measuring quality is, perhaps, not very exciting to discuss, but it is the most interconnected of the various nodes and critical to the operation of the laboratory. Your laboratory does nothing without *resources*. In the author's opinion, *resources* refer to materials or service-related assets (and the funds needed to buy them) used in the operation of the laboratory, such as supplies, utilities, capital

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equipment, reagents, etc. There is room for a dispassionate view of so-called *human resources*, but it is the author's opinion that it should be limited to an examination of workload volume to support attaining the correct manning levels for the laboratory.

Resources always equate to dollars and cost accounting. There are direct costs (reagents, controls, consumables, workload, etc.); indirect costs (wasted reagents, clerical supplies, repairs, maintenance, etc.); and overhead costs (office salaries, safety, quality assurance, specimen collection, etc.). Capital expenses are those related to large equipment acquisitions, such as automated analyzers. (Clinical Laboratory Management Association, 2000) Civilian lab administrators must deal with these concepts somewhat differently than military lab administrators. Civilian labs are often more concerned with a true *cost-per-reportable* with respect to reimbursement, return on investment, and potential profit, whereas military labs do not directly control many of the variables that would enable the lab to become a true profit center. Tests performed in a civilian laboratory must make sense from a financial standpoint; the cost to perform a test must equal reimbursement for the test, at a minimum. Reimbursement and traditional cost accounting are not often as complex an undertaking from a military lab's perspective, as such labs are not driven towards profit and often are not required to calculate detailed costs versus budget; the point is to be aware of the lab's local costs and control them.

During your first weeks, look at the lab's resources from an overarching viewpoint. Ask to see the Clinical Laboratory Management Indicator (CLMI) reports from the past year. The Laboratory NCOIC prepares these documents each month and forwards them to DHA/CLMS, which uses the reports to determine the allotted staffing for each laboratory; think of DHA partially as the "human resources office" for AF military labs. The CLMI report contains raw data that provides a valuable snapshot of the lab's resource utilization. First, the report shows the lab's monthly test volume and supply expenditures. The report lists the number of *full time equivalents* (FTEs, i.e., people) assigned currently, the productivity per person, and the monthly expenditures. Use this information to graph your lab's monthly resource utilization to track when spikes or troughs occur. (Figure 2) These data

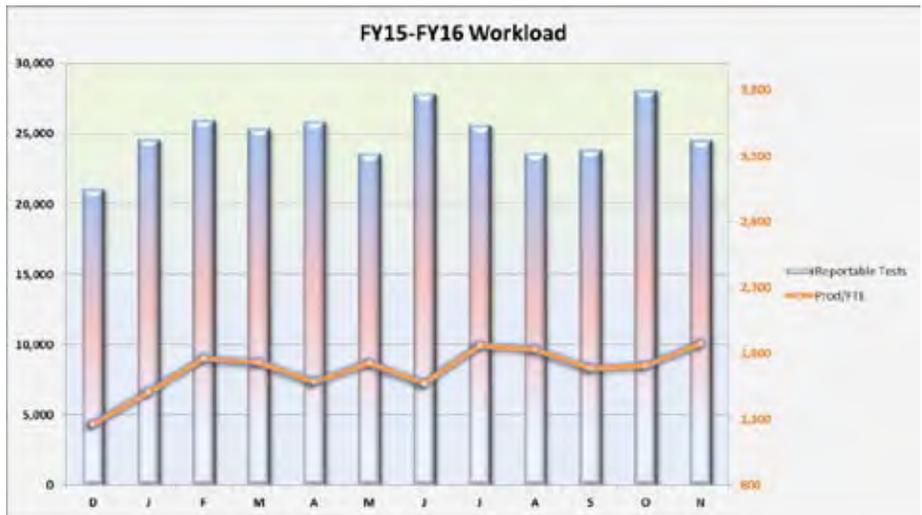


Figure 1 - Westgard Rules

will enable a lab manager to better advocate for new equipment or additional people when upward trends occur; a good lab administrator always knows their current cost of doing business and the return on investment.

Laboratorians (people) use *resources*, quality control, and procedures and in an accredited laboratory to produce quality diagnostic information. Resource utilization may not seem important but it is the final, crosscutting peak observed in assessing the lab's quality waveform.

Conclusion

Taking a basic quality pulse immediately after assuming control of a laboratory or lab section greatly enhances a new lab administrator's likelihood of success. That pulse always begins with *people* and progresses to the *procedures* those people use every day. Subsequent considerations include scrutinizing the building blocks of achieving and maintaining *accreditation* and the laboratory's *quality control* rubric. Finally, the new administrator must examine the lab's *resources* to create a resource utilization dashboard to maintain informed awareness. Taking account of these basic peaks and valleys will help establish a quality rhythm for the laboratory.

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Biosafety and Biosecurity Culture Matters

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"The single overarching finding of this [AMERITHRAX] investigation is that a determined adversary cannot be prevented from obtaining very dangerous biological materials intended for nefarious purposes, if not from DoD laboratories, then from other sources". Recommendations include making "changes to monitoring activities to improve effectiveness without introducing overly intrusive measures. Hold periodic meetings with laboratory personnel to reinforce values, moral obligations, and observations that should be reported"—Report of the Defense Science Board Task Force on Department of Defense Biological Safety and Security Program, May 2009

The United States Government conducts and funds biomedical and life sciences research which is crucial to the long term health security and wellness of the public, animals, plants, the environment, and our economy. Federal departments and agencies are committed to fostering progress in these areas to include responsible research involving biological agents and toxins, conducted in a safe and secure manner. Basic and applied life science research are instrumental in developing national capabilities to mitigate the risks of infectious diseases and environmental risks, whether naturally occurring, deliberate, or accidental.

Reinforcing norms of safe and responsible conduct is one of the objectives of the National Strategy for Countering Biological Threats which highlights actions that should be taken to reinforce a culture of responsibility, awareness, and vigilance among all who utilize and benefit from the life sciences. Reinforcing these norms is critical to counteracting diversion of the life sciences for harmful purposes.

The Federal Experts Security Advisory Panel (FESAP) was established by Executive Order 13546 on July 2, 2010 to provide recommendations regarding the security of biological select agents and toxins (BSAT) to the Secretaries of Health and Human Services and Agriculture, and the Attorney General. Prompted by a string of laboratory incidents, the White House National Security Council staff tasked the FESAP, in September 2014, to undertake a comprehensive review and identify specific recommendations to strengthen the Government's biosafety and biosecurity practices and oversight of federally-funded activities involving (but not limited to) BSAT, consistent with the need to realize such activities' public health and security benefits.

The FESAP recommended several actions to strengthen and sustain the culture of biosafety, biosecurity, and the responsible conduct of science at the federal level such as promoting bioethics training that addresses the fundamental safety and security responsibilities expected of all life scientists; development and incorporation of bioethics modules into laboratory biosafety and laboratory biosecurity training and/or research design; and the development of semi-quantitative methods to evaluate the efficacy of training, education, codes of conduct, and similar interventions to reduce risk and improve safety in domestic research laboratories housing infectious agents and toxins. The FESAP also emphasized that training should include discussions of ethical and legal considerations, as well as the social relevance of life science research, and the range of dual-use conundrums and

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dilemmas that may arise. The FESAP's recommended discussions would emphasize the impact of science and technology on society, health, and national security, and highlight efforts that should be undertaken to encourage institutional leadership to support and implement bioethics components within their institution's training programs. In order to achieve these goals, the FESAP generated several interagency working groups to address these recommendations.

In order to advance the implementation of FESAP's recommendation on the culture of biosafety, biosecurity, and responsible conduct of life sciences, the United States Government established an interagency working group with representation from 15 offices and organizations across five federal departments and agencies, including Department of Defense (DoD). This interagency working group is co-chaired by the US Department of Health and Human Services / Office of the Assistant Secretary for Preparedness and Response and the US Department of Agriculture / Animal and Plant Health Inspection Service. This working group defined culture (as it relates to biorisk management) as "an assembly of beliefs, attitudes, and patterns of behavior of individuals and organizations that can support, complement or enhance operating procedures, rules, and practices as well as professional standards and ethics designed to prevent the loss, theft, misuse, and diversion of biological agents, related materials, technology or equipment, and the unintentional or intentional exposure to (or release of) biological agents".

Strengthening and sustaining an organizational culture emphasizing biosafety, biosecurity, and responsible conduct, is an ongoing process based on the following elements:

- * Management systems which prioritize biosafety, biosecurity, and responsible conduct (i.e. processes, procedures and programs in the organization which prioritize biorisk management and have an important impact on the biosafety/biosecurity functions);
- * Behavior of leadership and personnel to foster more effective biosafety and biosecurity systems. Leadership behavior should emphasize inter alia expectations, decision making, management/ supervisory oversight, effective communication, and motivation;
- * Principles for guiding decisions and behavior include motivation, leadership, commitment and responsibility, professionalism and competence, learning and improvement, maintaining public trust;
- * Beliefs and attitudes on biosafety and biosecurity should be assessed periodically and reinforced through training and education aiming to: raise awareness on the risks associated with working in a laboratory with biological materials (e.g., accidental exposure, infection or release; intentional theft and/or misuse; others such as radiological/chemical/physical safety), the potential ramifications if such risk events were to occur and risk mitigation strategies; raise awareness and increase understanding of the ethical, legal, and societal issues and consequences concerning biomedical/life sciences research, development, and associated technologies; raise awareness and place emphasis on the importance of quality systems and practices in laboratory biosafety and biosecurity training and research design; review codes of ethics and social responsibility guidelines in biomedical/life sciences research; and review biosafety, biosecurity, and dual use research of concern (DURC) regulations, guidelines, policies and procedures, and any other specified training requirements.

Albert Einstein reportedly had a sign in his office that stated: "Not everything that counts can be counted, and not everything that can be counted counts". Here is some food for thought for the members of the Society of American Federal Medical Laboratory Scientists (SAFMLS): what are the specific metrics and measures for evaluating the baseline and progress in strengthening and sustaining an organizational culture? What indicators shall we use for a systematic/periodic assessment to understand the efficiency/effectiveness of an organization's biorisk management framework, causality of system breakdowns or analysis of incidents, sources of human error or breaches of biosafety/biosecurity, or the efficiency/effectiveness of training?

SAFMLS members should promote within their organizations and DoD at large, a culture of responsibility, scientific excellence, and effective biorisk management. Such a culture is a critical enabler of advancing science and maintaining public trust in the biomedical/life sciences research enterprise.

Disclaimer. The views expressed in this presentation are those of the author and may not necessarily reflect the official policy or position of the Uniformed Services University of the Health Sciences, Department of Defense, or the U.S. Government.

Note. In her civilian capacity, MAJ Perkins co-chairs the interagency working group tasked with implementation of FESAP recommendation on strengthening the culture of biosafety, biosecurity, and responsible conduct. This article contains key outreach messages developed by this group which have been shared broadly with federal departments and agencies and non-governmental (professional organizations and academia stakeholders) to be further customized as needed and used in their own outreach, training and educational activities. For more information on FESAP and US Government's policies on biorisk management, see: <http://www.phe.gov> or contact the author at dana.perkins@usuhs.edu.

Diagnostic Services Available Within the DOD

United States Army Medical Command (MEDCOM) supports testing at several locations within the Department of Defense (DOD).

These College of American Pathologists (CAP) accredited laboratories are available to provide quality testing to any DOD Medical Treatment Facility (MTF) at minimal cost to the MTF.

The Scope will feature one or two of these laboratories in the next several editions.

If you are one such laboratory please contact MAJ Yvonne Beale, Yvonne.M.Beale.mil@mail.mil to be included in future editions of the SCOPE.

If there are laboratory tests that you currently send to a commercial laboratory at cost please review the list of services currently available to you in this column and consider the cost savings of sending the test to one of our facilities.

If you have a test that is currently sent out that you would like to see the DOD bring in house let us know and we will work towards identifying a laboratory that would be able to bring this test in house.

There are three CAP accredited laboratories on Walter Reed Army Institute of Research(WRAIR)campus, the HIV Diagnostics and Reference Laboratory (HDRL), the Leishmania Laboratory (LDL) and the Multidrug Resistant organism Repository and Surveillance network (MRSN).

Test menu for each site:

HIV Diagnostic and Reference Laboratory

Serology

HIV Combo Ag/AB

HIV-1 Western Blot (WB) Supplemental

HIV 1/2 Multispot Rapid Test

Molecular

HIV-1 Viral Load (COBAS AmpliPrep/ COBAS TaqMan

HCV Viral Load (COBAS AmpliPrep/ COBAS TaqMan

HIV-1 RNA Qualitative Assay (APTIMA)

HCV RNA Qualitative Assay (APTIMA)

HIV-1 Resistance Genotype

HIV-1 Phenotype (sent out to Monogram Biosciences)

HIV-1 Trofile (sent out to Monogram Biosciences)

HIV-1 DNA PCR, HIV-2 DNA PCR-2

POC

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Julian M. Stewart, CPT, MS

Laboratory Manager

HIV Diagnostic and Reference Laboratory(HDRL)

301 319-3173(phone/voice mail)

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TEST	SPECIMEN	COMMENTS
		Factor II (Prothrombin), 20210G → A. <i>INDICATION:</i> thrombophilia, recurrent SAB or fetal demise.
FRAGILE X SYNDROME Including: Fragile X PCR Fragile X Southern	3 - 5 ml Whole Blood (EDTA) Cultured Amniocytes	Includes initial PCR test and reflex Southern, if indicated. <i>INDICATION:</i> mental retardation, diagnosis confirmation, prenatal diagnosis, maternal carrier status with suggestive family history. *Prenatal testing of amniocytes requires a sample of mother's blood for maternal cell contamination studies.
FRIEDREICH ATAXIA Including: FA PCR FA Southern	3 - 5 ml Whole Blood (EDTA)	Includes initial PCR test and reflex Southern, if indicated. <i>INDICATION:</i> suspected clinical diagnosis, presymptomatic diagnosis with known familial mutation. <i>CONTRAINDICATION:</i> presymptomatic diagnosis (minors).
HEREDITARY HEMOCHROMATOSIS	3 - 5 ml Whole Blood (EDTA)	Testing for the C282Y and H63D mutations. Testing is not available for minors <18 years of age. <i>INDICATION:</i> suspected or confirmed clinical diagnosis. NOTE: Presymptomatic and carrier testing is not recommended due to very low penetrance and no clinical utility. <i>CONTRAINDICATION:</i> prenatal diagnosis, minors.
HUNTINGTON DISEASE Including: HD PCR	3 - 5 ml Whole Blood (EDTA)	Includes initial PCR test and reflex Southern, if indicated. Testing for symptomatic individuals. Presymptomatic testing of family members requires additional paperwork. Call for details.

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TEST	SPECIMEN	COMMENTS
HD Southern		<p><i>INDICATION:</i> diagnosis confirmation, suspected clinical diagnosis, prenatal diagnosis, presymptomatic diagnosis with known familial mutation.</p> <p><i>CONTRAININDICATION:</i> refusal to follow testing protocol for pre-symptomatic diagnosis, pre-symptomatic diagnosis in minors</p>
METHYLENETETRA-HYDROFOLATE REDUCTASE (MTHFR)	3 - 5 ml Whole Blood (EDTA)	<p>Testing for 677 C>T polymorphism.</p> <p>NOTE: Current recommendations from professional organizations are that this test not be performed. Recent research has indicated limited or absent clinical utility.</p>
MYOTONIC DYSTROPHY	3 - 5 ml Whole Blood (EDTA)	Includes initial PCR test and reflex Southern, if indicated.
Including:	Cultured Amniocytes	Suspected diagnosis. Prenatal testing available.
MYO PCR		*Prenatal testing also requires a sample of mother's blood for maternal cell contamination studies.
MYO Southern		
PRADER- WILLI/ ANGELMAN SYNDROME (PWS/AS)	3 - 5 ml Whole Blood (EDTA)	Methylation-sensitive PCR.
	Cultured Amniocytes	<p><i>INDICATION:</i> neonatal hypotonia, diagnosis confirmation, prenatal diagnosis.</p> <p>*Prenatal testing of amniocytes also requires a sample of mother's blood for maternal cell contamination studies.</p>
Includes:		
PWS/AS DNA Deletion Testing		
PWS/AS Methylation		
PWS/AS Probe cyto		
PWS/AS UPD		
PROTHROMBIN MUTATION	3 - 5 ml Whole Blood (EDTA)	Testing for 20210 G>A polymorphism.
Includes:		Always performed as a panel with Factor V Leiden .
Factor II		

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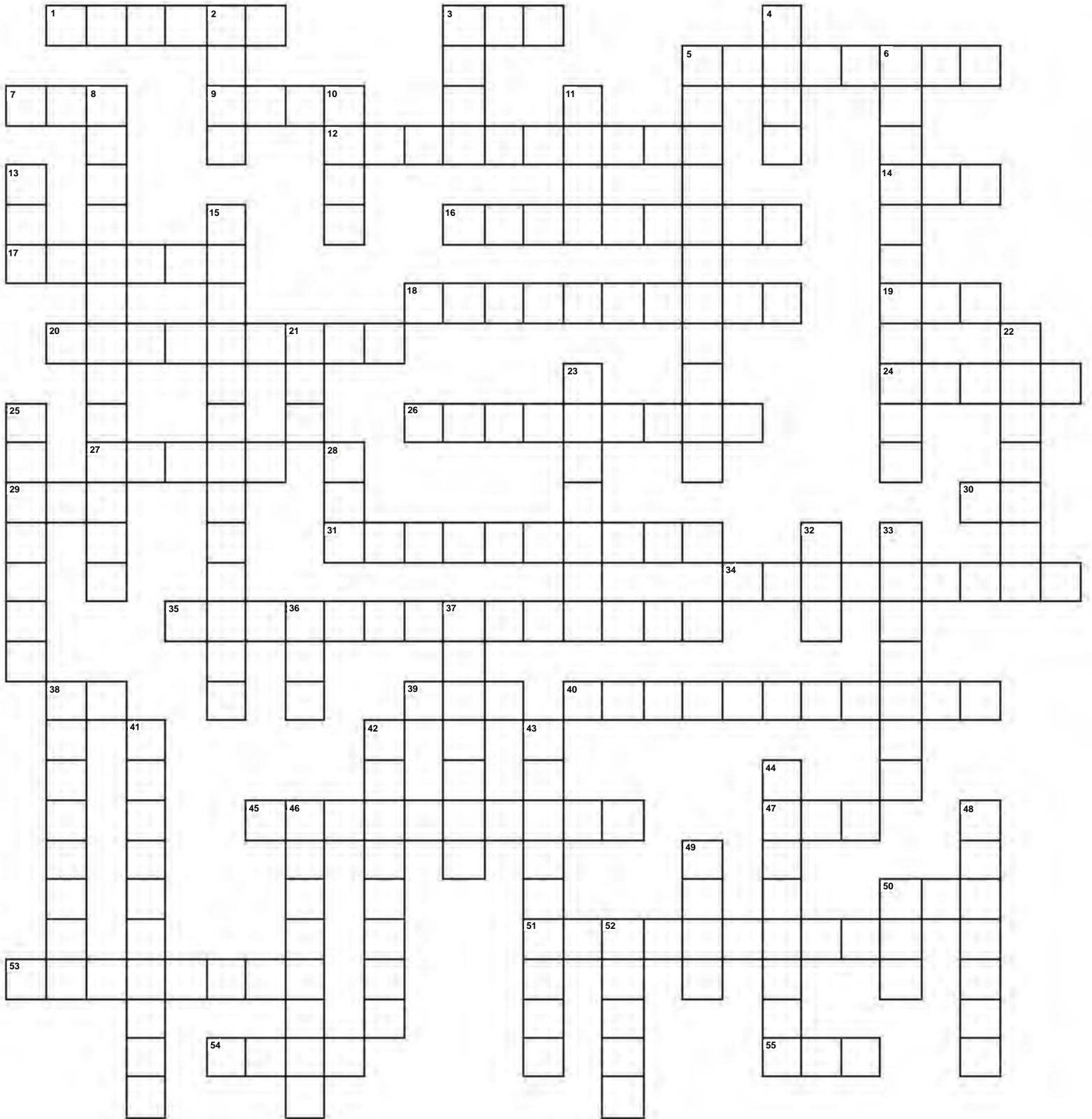
TEST	SPECIMEN	COMMENTS
RETT SYNDROME	3 - 5 ml Whole Blood (EDTA)	<p>Sequencing of all coding exons of the MECP2 gene, plus MLPA for large deletions and duplications.</p> <p>Accepted from Pediatric Neurology, Genetics, or Developmental Pediatrics only.</p>
Single Site Mutation Testing (any gene)	3 - 5 ml Whole Blood (EDTA)	<p>This is for testing of known familial mutations (in any gene). A copy of a laboratory report showing the known familial mutations is required.</p> <p>This must be coordinated with the laboratory prior to ordering. Please contact the laboratory if interested in having testing done for a specific known mutation.</p> <p>2Sanger sequencing is utilized for this assay. Since these assays are always custom-designed for the specific patient, turnaround time will vary.</p>
SPINAL MUSCULAR ATROPHY TYPE 1 (WERDNIG-HOFFMAN)	<p>3 - 5 ml Whole Blood (EDTA)</p> <p>Cultured Amniocytes</p>	<p><i>INDICATION:</i> suspected clinical diagnosis, prenatal diagnosis with known familial deletions, carrier screening.</p> <p>*Prenatal testing of amniocytes requires a sample of mother's blood for maternal cell contamination studies.</p>
SPINOCEREBELLAR ATAXIA PANEL (SCA1, SCA2, SCA3, [MACHADO-JOSEPH DISEASE], SCA6, & SCA7)	3 - 5 ml Whole Blood (EDTA)	<p>PCR-based testing for CAG expansions in five (5) genes, Southern not included. Presymptomatic testing of family members requires additional paperwork. Call for details.</p> <p><i>INDICATION:</i> suspected clinical diagnosis, presymptomatic diagnosis with known familial mutation.</p> <p><i>CONTRAINDICATION:</i> pre-symptomatic diagnosis in minors.</p>

POC:

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CROSSWORD PUZZLE

Culture of Biosafety, Biosecurity, and Responsible Conduct



ACROSS

- 1 A principle, plan, or course of action that the Executive branch of the Federal Government can establish it through the use of both regulations and guidance documents
- 3 Biosafety cabinet
- 5 Systematic investigation aimed at the discovery or interpretation of facts, revisions of accepted theories or laws in the light of new facts, or practical application of new or revised theories or laws, including the processes of experimentation, development, testing, and evaluation
- 7 Security Risk Assessment
- 9 Recombinant DNA
- 12 Such agents include any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious disease capable of causing death, disease or other biological malfunction in a human, an animal, a plant, or another living organism deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment
- 14 Presidential Policy Directive
- 16 "biological" and "hazard" combined
- 17 Public Health Emergency Medical Countermeasures Enterprise
- 18 A rule based on a statute
- 19 Select agent regulations
- 20 The ethics of medical and biological research
- 24 A type of research that is meant to increase our scientific knowledge base with regard to certain phenomena or behavior
- 26 The application of combinations of laboratory practice and procedures, laboratory facilities, safety equipment, and appropriate occupational health programs when working with potentially infectious microorganisms and other biohazards
- 27 The toxic material or document of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism or any poisonous isomer or biological product or derivative of such a substance
- 29 An infection resulting from exposure to an infectious agent in a laboratory
- 30 Responsible Official
- 31 When applied to risk, it is a process used to identify the hazardous characteristics of a known infectious agent or potentially infectious agent or material, the activities that can result in exposure to such an agent, the likelihood that such exposure will cause a laboratory-acquired infection (LAI) and the probable consequences of such an infection
- 34 The Biosafety Review...or an agent of individuals afflicted with a facility whose functions typically extend beyond those of the "institutional biosafety committee" (IBC) as described in the NIH Guidelines
- 35 For all high and maximum containment facilities, it refers to the physical containment barriers in a facility such as contained

- dressing and shower rooms, sealed service penetrations, specialized doors, entry and exit avenues to prevent cross-contamination, specialized air handling systems and containment control, personal protective equipment, biosafety cabinets, etc.
- 38 The individual designated by a research entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of the project or program
- 39 Specialized clothing or equipment worn by an employee for protection against a hazard
- 40 The protection of hazardous biological agents, including toxins, from loss, theft, diversion, or intentional misuse
- 45 The effective...of disks posed by working with hazardous biological agents in laboratories; it includes a range of practices and procedures to ensure the biosecurity, biosafety, and biocontainment of high-consequence pathogens
- 47 A body of rules of conduct of binding legal force and effect, for instance the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- 50 Biosafety level
- 51 Likely to spread infection
- 53 A laboratory event that may include exposure of staff or the public to an infectious, potentially infectious, or zoonotic agent; environmental release of a biological hazard; escape of infected animals or vectors; spill of a biohazard outside of a primary containment device; loss or theft of biohazardous agents and other loss of containment; or equipment failure in conjunction with a biohazard (e.g., centrifuge accident) that may lead to a release of a hazardous agent within the laboratory environment or outside the laboratory environment
- 54 National Plant Diagnostic Network
- 55 Laboratory Response Network

DOWN

- 2 Chemical, biological, radiological, and nuclear
- 3 Biosafety in Microbiological and Biomedical Laboratories
- 4 Biological Select Agents and Toxins
- 5 An assurance that individuals with access to dangerous pathogens are trustworthy, reliable, and physically and mentally competent
- 6 This type of conduct in research is simply good citizenship applied to professional life
- 8 An objective assessment of an institution's biosafety/ biocontainment or biorisk management program by an independent body
- 10 Designations of laboratories for work with biohazards used in a vivarium that include zoonotic or human pathogens
- 11 When referring to contaminant is BSL-3
- 13 Select Agents Program
- 15 Validating the expertise and credentials of an individual or an engineering control and in some cases a laboratory facility
- 21 Institutional Biosafety Committee
- 22 A microscopic organism such as a bacterium, fungus, protozoan, or virus
- 23 When referring to contaminant is BSL-4
- 25 An assumed truth which is part of the organizational culture (plural)
- 28 Deoxyribonucleic acid

- 32 Subject Matter Expert
- 33 The combination of the probability of the occurrence of harm and th severity of that harm where the source of harm is a biological agent or toxin (adapted from ISO/IEC Guide 51:1999)
- 36 Code of Federal Regulations
- 37 ...biosafety and biocontainment research- Research designed to generate science-based practices and procedures, engineering controls, personal protective equipment, and risk-assessment methodologies necessary to optimize the safety of research facilities; and to keep safety equipment, practices, and procedures up to date
- 38 A microorganism (including bacteria, viruses, rickettsia, parasites, fungi) or other agent, such as proteinaceous infectious particle (prion) that can cause disease in humans, animals, or plants
- 41 Standards or principles written by an organization to assist in the effectiveness of an operation, or to recommend a course of action
- 42 The action of teaching someone a particular skill or type of behavior
- 43 The process of a multi-tiered, often overlapping system, from principal investigators at individual laboratories to agencies of the Federal Government-seeking to ensure the safety of biological laboratories and their activities through compliance with existing laws, regulations, policies, standards, and guidelines on biosafety and biocontamination
- 44 A type of laboratory where diagnostic or other screening procedures are performed on blood or other potentially infectious materials
- 46 A manner of thinking, feeling, or behaving that reflects a state of mind or disposition and is fundamental to the culture of biosafety, biosecurity, and responsible conduct
- 48 An assembly of beliefs, attitudes, and patterns of behavior of individuals and organizations that can support, complement or enhance operating procedures, rules and practices as well as professional standards and ethics designed to prevent the loss, theft, misuse, diversion, of biological agents, related materials, technology or equipment, and the unintentional or intentional exposure to (or release of) biological agents
- 49 National Registry of Certified Microbiologists
- 50 Biosafety officer or biological safety officer
- 52 Federal Experts Security Advisory Panel



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ANSWERS TO Culture of Biosafety, Biosecurity, and Responsible Conduct Puzzle

POLICY										BSC				RESEARCH														
SRAC			RDNA				M			RESEARCH																		
SC			N				B			H			E				A			E								
S			S				G			I				P			P											
A			C				L			BIOHAZARD																		
PHEMCE										REGULATION										ON								
D			R				B			I				M														
BIOETHICS										L										SAR								
T			I				B			M				I			M											
B			A				F			C				BIOSAFETY														
E			T				O			X			I				Y			E								
L			A				I			C			N				I			R								
I			O				A			ASSESSMENT										S								
E			N				T			U			C				O			M								
F			S				BIOCONTAINMENT										E			O								
S			O				N			R			P				BIOSECURITY											
P			I				G			T			L				O			S								
A			T				H			I			V				C			K								
H			O				D			MANAGEMENT										L			A					
G			E				L			T			I				N			B			S					
E			L				I			N			I				S			I				N				
INCIDENT										N			G			I				N			F			E		
N			E				U			G			H				E			M				C				
S			N				P			D				N			T			A				P				
S			E				N			P				D			N			L				R				
S			E				N			P				D			N			L				R				
S			E				N			P				D			N			L				R				

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