
Bio
safety
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LOCAL
PRACTICAL
SUSTAINABLE

Forward

The thoughts and concepts in this book are based upon many years of working in laboratories and training others to work safely. It is based upon the belief that everyone can be "a little safer tomorrow than they were yesterday." In all countries, at all resource levels, and in all settings, laboratory personnel can reduce the risk of working with microbiological agents. In my years of working around the world with a variety of people in a variety of facilities I have heard about many obstacles to improved biosafety; however, I firmly believe (and after reading this book, you will too) that actions can be taken to decrease your risk when working with pathogens. Even small, constant improvements, over time, will lead to long-lasting, significant and meaningful advances in biorisk management that can be accomplished in a local, practical, and sustainable manner.

Dedication and acknowledgement

I want to thank all the biosafety colleagues that I worked with over the years who helped shape the concepts presented in this book. Thank you to my editor, Hank Parker for a fabulous job of editing this book. Thank you to my son Erik for his ongoing encouragement to write this book and for providing the great cover art. A special thanks to my wife, Linda, for supporting me and the careful reading and critiquing of the book. I also want to acknowledge the help of all the students of biosafety that I have taught over the past year, who have helped create the need for this book, helped me better understand the wide range of situations where biosafety is needed and taught me so much.

Table of Contents

Introduction

There are many microbiological agents and biotoxins in the world (Figure 1), and many different professions that work with or have potential exposure to these potential hazards. The most common settings for microbial agents and biotoxins are hospitals, veterinary clinics, research laboratories, diagnostic laboratories, vaccine facilities and teaching laboratories. There are also many additional occupations, facilities, and environments where people and animals may become exposed to pathogens.

Figure 1

In typical biomedical facilities, such as a diagnostic or research laboratory, other non-biological threats to personnel include physical hazards (slips, trips and falls), chemical hazards, electrical hazards, fire hazards, radiation hazards, lazar hazards and other more specialized ones (e.g. nanoparticles, nanites). This book will only cover microbiological hazards; however, the concepts of controlling risks from microbiological hazards can also be applied to the other hazards. In fact, there is often a strong overlap between one hazard and another, meaning that controls may need to be applied to two or more hazards at once.

What is biosafety

Biosafety is defined by the World Health Organization as *" containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their accidental release."*[1] Safety with biological agents is not appreciably different from safety when working with other hazards, such as chemicals or radionucleotides. Decreases in risk can come from three broad areas: 1) practices and procedures, 2) safety equipment and 3) facility design. We will explore all of these in detail. When applying these principles, one must always keep in mind what is *practical* in the situation you find yourself in, what is *sustainable* with the resources you have and what *solutions* do you have *locally*. A common theme that will run throughout this book is the concept of practical, sustainable, and locally-based solutions. Working safely with pathogens has less to do with achieving a particular biosafety or containment level, than with managing risks with local resources that you can afford and sustain. You may also look to the international biorisk management CWA15793[2] as a guideline for structuring a biorisk management program at your location.

Figure 2

[1] Laboratory Biosafety Manual, 3rd Ed., World Health Organization, Geneva, 2004 https://www.who.int/csr/resources/publications/biosafety/en/Biosafety7.pdf

[2] Laboratory Biorisk Management Standard. CWA 15793:2011, https://absa.org/wp-content/uploads/2017/01/CWA15793_Feb2008.pdf

This book will cover generic ideas that everyone at every facility or situation can apply to improve biosafety and lower the risk or working with microbiological agents. If you interact with microbiological agents in your daily activities (work, play, hobbies, sports, etc.), you need to read this book. Depending upon the nature of that interaction and your location, some parts of this book may not directly apply to you, so feel free to skip around and focus on what you think is relevant and meaningful to your situation. There is something for everyone in this book and the book's principles and broad concepts will be helpful to all readers.

The book does not lay out rules and regulations, as these vary from country to country. Further, since there is no universal global standard for how to achieve biosafety, it is important to remember that the local situation must dictate the standard that is achieved with the resources available (remember the objective of "local, practical and sustainable" solutions). In any event, you should always follow all local and national regulations and abide by all international agreements and laws that your government ascribes to regarding the management of biological agents. In addition, excellent guidance and recommendations from the World Health Organization and other international bodies can also be used to supplement your local, practical, and sustainable practices.

Example: While doing a necropsy on a giraffe in Kenya (Figure 3) in the field where the animal dies, there is no biosafety standard that applies – you do the best you can with the basic principles of biosafety and the resources you have brought with you.

Figure 3

Example: When working with Tuberculosis in Canada there will be a number of laws, regulations, and standards (National and International) that must be followed describing the biosafety practices, equipment and facilities required.

Why biosafety

Why should you read this book and learn about biosafety? There are five overarching reasons: 1) to protect yourself from harmful microbiological agents; 2) to protect your friends, family, community members and animals from harmful microbiological agents; 3) to protect the environment from becoming contaminated by harmful microbiological agents; 4) to protect the integrity of your work (quality assurance); and 5) to be incompliance with all local, National and international regulations, treaties and conventions. We will cover each of these, in turn.

Your health

Let's start with you. Do you want to be in good health? I'm sure most people would say yes. The microbiological agents that you interact with can harm you. I'm sure this is not a surprise or news to you, but you probably don't think much about it during your day. The range of harm can be from subtle, slow and not immediately apparent, to rapidly deadly. Obviously, those agents that cause death get a great deal of attention and respect (for example Ebola) - but what about all those others that cause only mild symptoms of illness from which we recover? No matter what the symptoms are or how well you recover, you don't want to get unnecessarily exposed to any pathogenic microbiological agents.

Figure 4

No matter who you are, you are probably having daily interactions with microbiological agents. If you are preparing raw chicken in your kitchen for dinner, going on a plane or cruise ship, working in a hospital, or just doing yard work, you are having interactions with microbiological agents. They are everywhere and we interact with them daily! Again, you may not think about this, but it is true. Most of these interactions do not result in any significant disease or illness in us, but in some cases they do. Could that interaction have occurred with less exposure to the pathogen? If the answer is yes, then your biosafety practices could have been better.

Example: You go to an event with many people, many of whom are coughing and sneezing due to the common cold. You are at risk of becoming infected while interacting with these people and their microbes. What should you do to protect yourself? The principles in this book can be applied and will help.

Example: You work in a hospital as a nurse seeing patients all day. What should you do to better protect yourself from harmful biological agents? The principles in this book can be applied and will help.

Example: You work in a mortuary preparing the deceased, who have died from a variant of different causes, some of which may be infectious. What should you do to better protect yourself from harmful biological agents? The principles in this book can be applied and will help.

Example: You work in sanitation, either handling solid waste or have potential exposure to sewage. What should you do to better protect yourself from harmful biological agents? The principles in this book can be applied and will help.

Your community

You can play an important role in protecting your community from harmful disease. Your community is everyone else but you. It can be colleagues that you work with, your friends and family, and even your pets. If you become contaminated or infected with a microbiological agent you may transmit it to your community. Microbiological agents are always looking for a

new susceptible host in which to live and grow and there are many ways they can be transmitted from one host to another. This can be from person-to-person, person-to-animal, animal-to-person, animal-to-animal and even from the environment (surfaces, soil, water, air, food, etc.) to people and animals.

How you interact with the microbiological agent will have an impact upon how the agent is potentially transmitted to others.

Example: You work in a kitchen preparing food and you are cutting up raw meat with a knife. You then use that same knife to cut up raw vegetables which will be served uncooked. The risk of transmitting microbiological agents from the raw meat to the raw vegetables is high. Good biosafety practices would reduce this risk.

Example: You work in a veterinary clinic seeing patients all day. Ensuring that your equipment, hands, laboratory coat, and other items are not sources of microbiological transmission to other animals or people that enter the clinic is vital to preventing disease transmission.

Example: You work in a hospital as a nurse seeing patients all day. Ensuring that your clothing, watch, ring, phone, etc. (which you take home with you) are not contaminated is vital to protecting to family and anyone else you may contact on your way home. Good biosafety practices would reduce this risk.

Your environment

I'm sure, like most people, you care about your environment. This can be your local environment (like your workspace); the broader environment, like your community and its surroundings; even the world as a whole. Contamination of these environments with the microbiological agents you work with could occur if you are not careful of how they are handled.

Any place that handles microbiological agents also has to dispose of them. This may be a hospital where there are lots of organic materials (blood, feces, urine, sputum, etc.) that could be contaminated, or a diagnostic laboratory that is growing pure cultures of microbiological agents. If the pathogens are not completely destroyed before they are disposed of, other people or animals may get infected, and the environment (soil, air, water) may become contaminated. Therefore, correctly disposing of the agents you work with is vitally important. Think about how the pathogen might leave the facility where you work and consider the possibility that the organism is still alive. Ways the pathogen may leave the facility include: 1) through you, when you leave the facility carrying the agent in or on your body, 2) flushing the agent down the drain from the room in which you work, 3) carrying the agent out on a solid object (e.g. glassware, plasticware, paper, etc.) that is considered trash or garbage, 4) being released into the air, directly or indirectly from the room in which you work, 5) escaping with an infected animal that is accidentally released.

Example: You work in a diagnostic laboratory growing bacteria for antibiotic sensitivity testing. During this work, contamination of surfaces in your laboratory occurs. This leads to contamination of your mobile phone, which you then take home to your family.

Example: You work in a vaccine facility growing large amounts of a virus that causes disease in cattle, sheep and pigs. During your work, some infectious material flows down the drain to a power sewage system which then contaminates the land outside. Sheep grazing outside the facility become infected with the virus. Good biosafety practices would reduce this risk.

Example: You work in a diagnostic laboratory growing Mycobacterium tuberculosis for archiving. Contaminated plasticware is not properly sterilized before being discard and finds its way to the local open waste disposal site. Local garbage pickers become infected by handling the contaminated plasticware while scavenging for plastics. Good biosafety practices would reduce this risk.

Your work

The quality of your work is paramount to what you do. Your employer and your clients depend upon accurate results and high quality from your work. If cross contamination occurs or people start to lose confidence in the quality of your work, you may lose your job. Therefore, it is vital to make sure the microbiological agents stay where they are supposed to be. If the work product becomes contaminated, producing incorrect test results, people lose confidence in diagnostic facility and the accuracy of the results. In addition, your ability to work safely with pathogens nay come under question by supervisors and other authorities.

Your laws

In may countries there are laws and regulations governing all or part of what happens in a biomedical facility. As someone working in this area you MUST be in compliance with all local laws and regulations. There are also many standards or guidelines that apply to your profession that you should be following (e.g. Canadian Biosafety Standards and Guidelines – Figure 5; USA, Biosafety in Microbiological and Biomedical Laboratories – Figure 6). In addition, your country probably belongs to the United Nations, through which your country has agreed to abide by several international treaties and agreements. Some, like laws and regulations are mandatory, while others like standards, treaties, conventions and good practices are voluntary.

Figure 6

Figure 5

If you care about your health, the health of your family, the health of your environment and keeping your job – you will care about biosafety. By practicing good biosafety, you will decrease the chances of something bad happening to you, your community, your environment and your job.

Where to begin

Many people may be confused about biosafety from the start. People realize and agree that practicing good biosafety is important, but they don't know where to start. Rest assured, there is something for everyone to learn and do, but where you start depends a lot upon what job you have and how you interact with the microbiological agents. There is a lot to know, but not everyone needs to know everything about everything. Below is a small matrix showing areas of knowledge (competencies) and broad areas of occupation/function/role (what you do or what you are responsible for). If you think about the work you do (or role you play) in interacting with microbiological agents the matrix below may guide you as to areas that you might want to learn more about.

	Biosafety Officer	Laboratorian	Health care worker	Scientist	Animal Care Worker	Laboratory Manager	Veterinarian	Mortician	Sanitation Worker	Cleaning Staff
What is Biosafety	X	X	X	X	X	X	X	X	X	X
Risk Assessment	X			X	X	X	X	X	X	
Good microbiological practices	X			X		X	X			
Selection and use of PPE	X		X	X	X	X	X	X	X	X
Waste disposal	X		X	X	X	X	X	X	X	
Biosecurity	X			X	X	X				
Incident and Emergency Response	X	X	X	X	X	X	X	X	X	
Animal Biosafety	X				X		X			
Program management	X					X				

After looking at this matrix you may still feel overwhelmed. Not enough time to learn everything – what do I do? Start with what you think is the most important aspect and, based on your intuition determine what might be the area where you think the greatest harm could occur (to yourself, your community, or the environment). Start with what you think is the most interesting and most important. If you start with what is the most important and most interesting you are more likely to learn the most. Discuss with

your supervisor or biosafety officer (if you have one) about what you need to know. Be sure to share with others in your work place as you learn, because their health is your health and vice-versa!

The big picture

Before we jump into the competencies and things you might want to learn, let's begin with an overview of the big picture. Sometimes you have to see the whole forest before you start cutting down trees! Let's start with some broad concepts and ideas to set the scene for what you are about to learn. I'll put them in bullet form for now; later I'll bring you back to these concepts, in the context of what you have learned.

1) Biosafety is like any other safety (fire, life, chemical, radiation, etc.) in that it relies upon many layers/concepts of protection to function at its best. If one area of protection fails there will be another (based upon a different, but complementary concept) that will support it. The more layers you have, the better. This is not redundancy (where you have the multiple systems doing the same thing) but overlapping and complementary systems that support each other (see Fig 7).

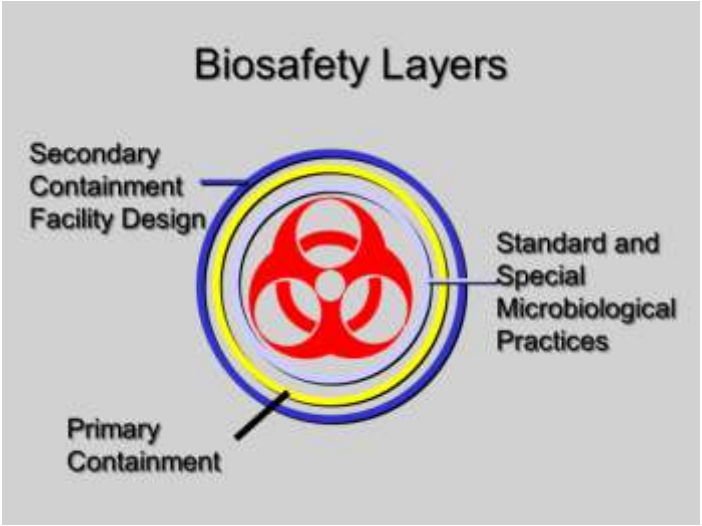


Figure 7

2) In biosafety, the three main layers/concepts of protection are: a) practices and procedures (what and how you do what you do); b) safety equipment (primary containment equipment you use and your personal protective equipment; and c) secondary containment, facility design (the building design and

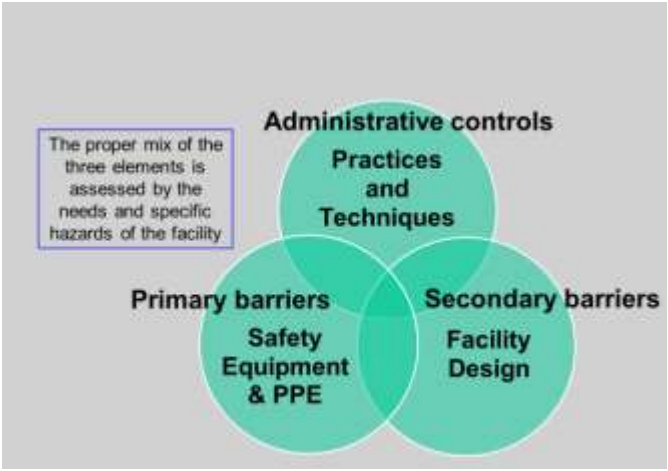
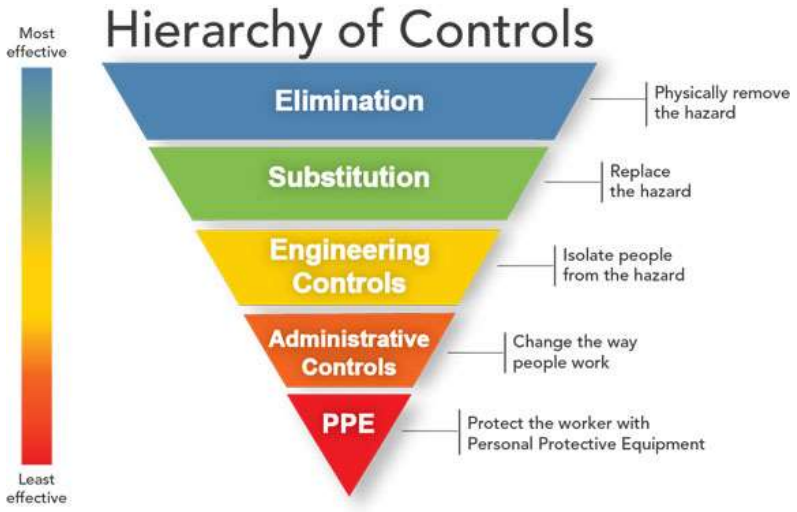


Figure 8

associated equipment) – see Figure 8. Each of these plays an important role in biosafety, but the degree of importance of each depends upon where you are working and the nature of the work. For example, if you are working in the field collecting water samples, maybe all you have and need are your practices and procedures and maybe a little PPE to keep you safe. However, if you are working in a high containment laboratory growing large amounts of Severe Acute Respiratory Syndrome (SARS) virus you need a good facility, excellent practices and procedures and certified safety equipment.

3) Biosafety, like other safety disciplines also uses a hierarchy of controls. These are: a) elimination (remove the hazard and risk); b) substitution/simplification (replace the hazard or reduce risk); c) engineering controls (use of equipment to reduce risk); d) administrative controls (use of training, signs, and documents to control risk); and e) personal protective equipment (using something on your body to protect you from the hazard). As shown in the picture below, these are listed in order from most effective (elimination) to least effective (PPE).



Infographic by NIOSH. Control methods at the top of graphic are potentially more effective and protective than those at the bottom. Following this hierarchy normally leads to the implementation of inherently safer systems, where the risk of illness or injury has been substantially reduced.

4) Everything you do in applying biosafety should be done based upon risk. This only makes sense—if there is no risk, there is no need to take precautions; if there is lots of risk, there's a need to take lots of precautions. The risk assessment should therefore tell you where to put your effort in the controls and ways in which you can lower the biorisk.

5) Safety is everyone's responsibility; everyone has a role to play. The safety of our neighbors, friends and colleagues depends upon us and your safety depends upon them. If you see something unsafe or you see someone doing something unsafe, say something. Your life may depend upon it!

6) Working together works. While everyone at your workplace may have a different role to play in safety, the strength comes when everyone works together. If one person doesn't follow the rules or doesn't want to do their part, it could jeopardize the entire team.
7) When at work or at play, microbiological agents can infect our bodies (or animals) via four main routes of entry: a) through breaks in the skin (cuts, abrasions, needle sticks, animal bites, etc.); b) through inhalation (breathing in air that contains the pathogen in quantities sufficient to start an infection); c) through ingestion via the mouth (eating, drinking, lipstick, smoking, etc.); and d) through the mucus membranes (areas where the skin turns inward into the body – the moist areas) of the eyes, nose, and mouth (usually through splashes or sprays but also through contact of the face with contaminated hands) – see Figure 9. If you think about blocking these routes of transmission, you can protect yourself (or animals) from getting infected.

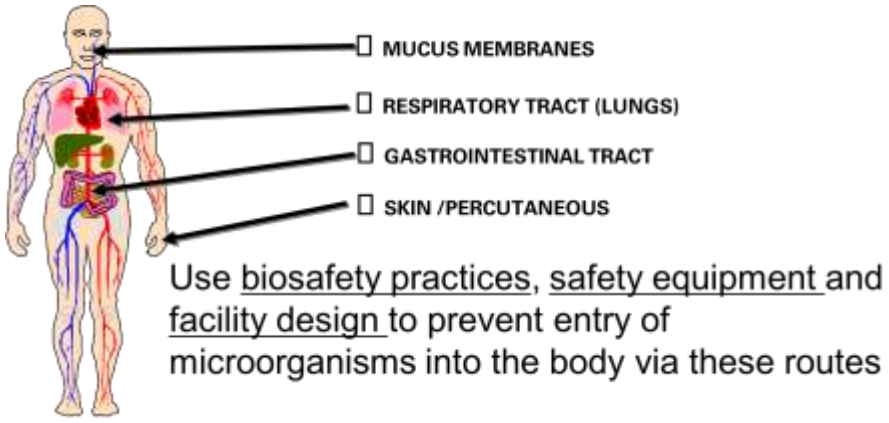


Figure 9

8) Infection occurs through a process whereby the pathogen leaves a reservoir and eventually results in noticeable disease. This is called the "chain of infection" and has multiple steps, as shown in Figure 10. Breaking this chain of infection with good biosafety is vital. At all parts of the chain, you have an opportunity to make a difference. Think about where the organism is (the reservoir) and try to keep it contained there unless you deliberately, and with appropriate procedures, remove it. Think about how the biological agent may move from (portals of exit), and be transmitted to (portals of entry) that reservoir to you, the community, or the environment. You can influence how that happens through good biosafety. Think about how susceptible you or your community members are to the biological agent.

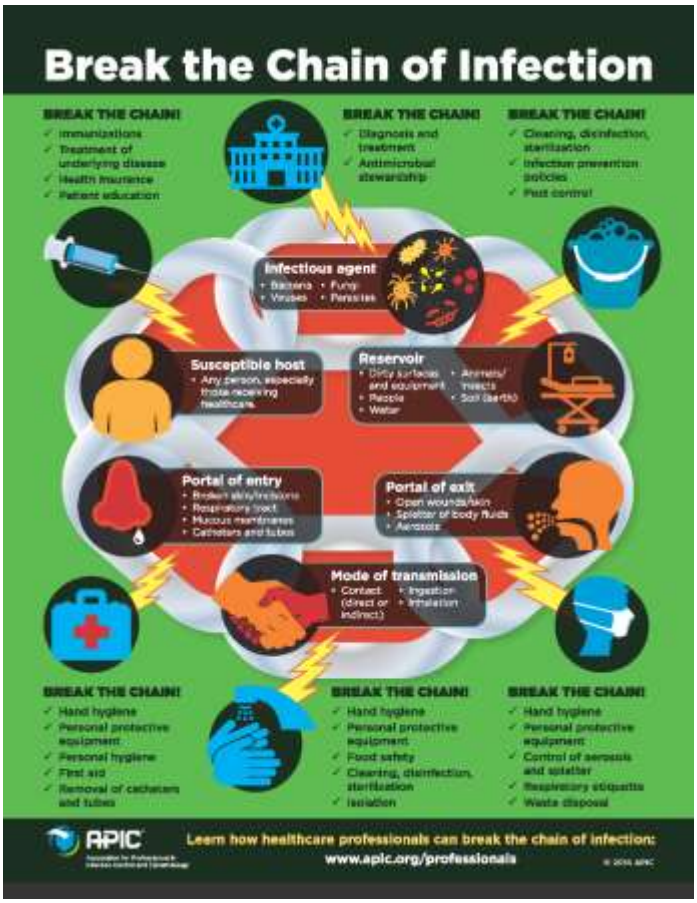


Figure 10

Infectious agent is the pathogen (germ) that causes diseases
Reservoir includes places in the environment where the pathogen lives (this includes people, animals and insects, medical equipment, and soil and water)
Portal of exit is the way the infectious agent leaves the reservoir (through open wounds, aerosols, and splatter of body fluids including coughing, sneezing, and saliva)
Mode of transmission is the way the infectious agent can be passed on (through direct or indirect contact, ingestion, or inhalation)
Portal of entry is the way the infectious agent can enter a new host (through broken skin, the respiratory tract, mucous membranes, and catheters and tubes)
Susceptible host can be *any* person (the most vulnerable of whom are receiving healthcare, are immunocompromised, or have invasive medical devices including lines, devices, and airways)

9) Work from "clean to dirty." Let me explain. We assume that when you come to work in the morning you are "clean" in that you are not contaminated or carrying any agents beyond your normal flora (natural microbiological agents that we all carry). So, begin you day with "clean activities" such as cell culture, making reagents, attending to uninfected animals, etc. End your day with the "dirtiest" activities such as handling contaminated waste, cleaning infected animals, or any procedure in which you think you might become contaminated. This procedure order will ensure that you do not tract pathogens back to non-contaminated areas or products. However, it also means that your will be doing the highest risk work at the end of the day and you may be the most contaminated just before going home.

10) Any time you impart energy to any product you are working with; you increase the chance that the product may move beyond where you want. Let me explain this as well. Imparting energy to a product is causing it to move or change. For example, when moving liquids via pressure (think about a syringe or pipette – Figure 11) there is risk that the liquid will spray out, if the containment fails (e.g., needle falls off). Centrifugation of samples is another common procedure that imparts energy to a product. If the containment breaks or leaks the product will spray (hopefully within the secondary containment). Liquids that drop on surfaces have energy and spray small droplets around the area (Figure 12)

Figure 11 Pipette spray

Figure 12 Liquid splash

These are just some general principles for you to think about. In this book, there will be a further explanation about most of these topics. If you have read nothing more than this, you are already better informed about biosafety than you were before. Think about what you apply from these concepts that is local, practical, and sustainable.

Risk assessment

You have probably heard this term used often in life. It is important, but do you know what it is and how you do a risk assessment? It can be very simple or very complex, but for our purposes I want to keep it simple and very practical. In fact (if you know it or not) you do risk assessment every day, all the time. We wouldn't have survived very long as a species if we didn't do risk assessments. In the simplest, form, risk assessment is simply determining if we are going to get hurt. For example, assessing your surroundings before crossing the road; smelling a food before you eat it, to determine if it is safe; deciding to go sky diving or not. Our brain does risk assessments all the time for us to help us in daily life to minimize bad things happening to us. When working with microbiological agents that can hurt us, it is a bit more difficult because the potential harm is not always obvious or immediate (unlike fire or physical damage). So, we have to be more thoughtful and think it out first (create a plan or standard operating procedure) and then follow the procedure to minimize the risk.

So, when working with microbiological agents what is the risk? There is the risk of: a) you getting exposed, contaminated or infected with the agent; b) a colleague or friend you work with getting exposed, contaminated or infected with the agent; c) the community (people or animals) getting exposed, contaminated or infected with the agent; d) the environment (air, water, land, etc.) getting contaminated with the agent; e) your work product becoming contaminated with the agent. All of these are undesirable events, so when we talk about risk it is usually something we want to avoid or minimize. So how do we do this?

Figure 13

First begin with recognizing that there is no risk if there is no hazard. What is a hazard? A hazard, simply put is something that can hurt you in some way. In this case, it is a microbiological agent that has the ability to damage you. If you eliminate the hazard, you eliminate the risk. Wow! Can it be as simple as that? Unfortunately, life is never that simple. We are surrounded by hazards in our life, but we often have control over which ones and how we deal with them.

Hazards come in many different forms. Some are easy to recognize (like fire), but others (like biological agents) are more difficult. Next time you are in your work environment think about what hazards (things that can hurt you) are in your work space. These include things like sharp objects (glass, knives, scissors, etc.), electricity, chemicals, physical objects that move (or could move); animals; soil; dust. You can see the list is long. We don't live in a sterile bubble, so there are hazards around us all the time.

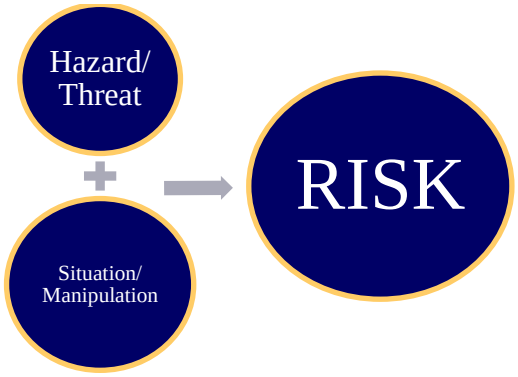
We cannot live life without being exposed to hazards, but we do not have to be hurt by them. Once you recognize the hazard, then you have to determine if that hazard will directly hurt you and how bad is it going to be. This is the process of risk assessment. Risk is a function of how

likely (probability) it is that the hazard will hurt you and how much damage will occur (consequences). Let's look at two extreme examples of this.

Example: If you have a strain of *Brucella abortus* (a very dangerous pathogen) in your freezer, but you never take it out, the probability of getting infected is very low, but the consequences (if you were infected) of getting very ill are bad.

Example: If you have a strain of *E. coli* K12 (not pathogenic) and you use it on the open bench with no protection, the probability of getting infected is very high, but the consequences of getting sick is very low.

In life, we have thousands of different pathogens, varying widely in pathogenicity and being used in many different ways. The risk of getting infected or sick varies greatly. Risk assessment is important, but can be difficult to do. So, where do you start and how do you actually do a risk assessment?



What Risk?

Before doing a risk assessment you should be clear as to what risk you are trying to determine or quantify. Is the risk personally getting infected? Is the risk having the pathogen cross contaminate your work? Is the risk the pathogen escaping from the laboratory? Is the risk taking the pathogen home to your children? As you can see there are lots of different risks when working with pathogens. It is important to state up front what risk you are doing an assessment of. You may end up doing multiple assessments for different risks. To group the risks together or split them up in your assessment is up to you.

Example: You are working in an animal clinic with dog poop to determine if the animal has parasites. You realize there is risk of you getting infected from the poop (not only from the potential parasite eggs, but also from all the bacteria) and there is a potential for other animals in the clinic to get infected from the poop. You can do one risk assessment for both risks or separate them.

Sources of risk.

If we look a bit closer at the risk, we see that it basically comes from three areas: a) Pathogen, b) Procedure(s), c) Person. Think of this as the 3 Ps. Let's look at each of these a bit closer.

First, it is obvious that we need to have the hazard (the ***pathogen***) to create risk. However, consider what you know about this microbiological agent (Figure 14). Is it very harmful or not at all? Microbiological agents come in the full spectrum of virulence and pathogenicity. Therefore, understanding the agent or agents that you are working with is vitally important. Factors to consider about the agent are:

a. What is the infectious dose?
b. Does it infect humans?
c. Does it infect animals?
d. How can it be transmitted?
e. How stable is it in the environment?
f. How can it be destroyed?
g. Can an infection be treated?
h. Is there a preventative?
i. What is the incubation period?
j. What are the symptoms of infection in people?
k. others?

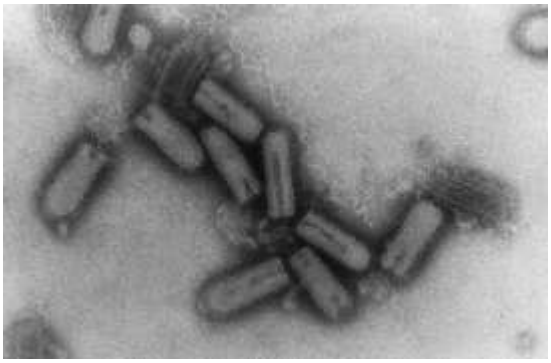


Figure 14

Some of these answers will be known and readily apparent; however, others will be more difficult to determine. To help with this process, a number of agencies around the world have attempted to categorize many of the common agents into classes (Risk Groups). All of these agencies have chosen four risk groups (1-4) based upon many of the factors listed above. Beware: Not all of these agencies use the same classification scheme of hierarchy (1-4). Some groups classify Risk Group 1 agents as the worst, while others classify those into Risk Group 4. While this is a good starting point to gather information about the inherent risk of the agent, please do not stop there. There are many deficiencies with this as the sole source to determine agent risk. For example, the agent may mutate (think influenza) and no longer be the pathogen described. It may have been genetically engineered or manipulated in the laboratory and no longer have the characteristics of the original. A similar agent may have a wide range of pathogenicity (e.g. Newcastle disease in chickens ranges from apathogenic to fatal). What if you work with samples known to have multiple agents? Or what if you work with samples in which it is unknown what agents they may or may not contain.

Second, the procedure or procedures you use to manipulate the agent or sample will have a large impact upon the risk of working with that agent (Figure 15). For example, not working with the agent at all would result in very little or low risk. However, directly inoculating or

Figure 15

consuming the agent would increase the risk dramatically. You should think about how the procedures create potential for the agent to enter you via the four classical portals of entry (percutaneous, respiratory, enteric, mucus membranes) if you are determining the risk of getting exposed or infected. If you do a risk assessment for the pathogen escaping from the facility you might want to evaluate the procedures that create release to the environment. For example: spills, splashes, agent disposal, animal use, aerosol creation, etcetera. As you can see, the procedure being used to manipulate the agent makes a large difference in increasing or lowering the inherent agent risk. When designing procedures, you should always consider:

a. creating more containment;
b. keeping the pathogen in containment longer;
c. minimizing the amount used;
d. not amplifying the agent any more than necessary;
e. incorporating engineering controls into the procedure;
f. incorporating strategically targeted personal protective equipment into the procedure;
g. ensuring terminal destruction of the agent at the end of the procedure as much as possible,

Figure 16

Third, who is working with the agent or sample can also have a large impact on risk (Figure 16). Obviously unskilled, untrained workers have a higher risk of making a mistake than highly skilled and trained operators. However, it is not always easy to determine who is highly skilled and trained because there is always a first time for everyone for every specific procedure, regardless of prior experience and training. So be extra careful when doing new procedures or hiring new workers. Try to put the best, most experienced workers on the most dangerous task and vice versa. Assess competency of workers as best as possible on a routine schedule. People change and skills wane due to various reasons (distraction, lack of sleep, age, drug use, etc.).

So, essentially, biorisk will be determined by "who does what procedure with what agent(s)." This is one of the main questions to ask when doing a risk assessment. You have to determine at what level of detail you want to ask this question. If you try to determine this for each person, for each procedure, for each agent, it could be a very long and tiring process. This may be the most exacting and provide the greatest detail, but may be unreasonable to accomplish. Therefore, most facilities usually conduct group assessments at the specific laboratory level, or agent level (for example, at the bacteriology laboratory or the tuberculosis laboratory) but it could be done at the facility level as well.

How to do a risk assessment

There is no one right way to do a risk assessment. There are many different models available to choose from varying from simple discussion to complex computer algorithms. A good example is one used by the Association of Public Health Laboratories in the USA.[3] Which one is right for your situation is entirely up to you to decide based upon your administration's requirements, complexity of the situation, resources available, and expertise. I will present here one model that is simple to do and semi-quantitative, based upon that recommended by WHO. It is very important to have a process in place that is approved by your administration and gives you the information you need (Figure 17). Having some numerical quantitation associated with the risk helps to rank the risk and therefore to help prioritize resources. The process is very generic and can be applied to virtually anything in your life that might cause risk. For example, if you wish to

Figure 17

apply this method to the chemicals in your work environment, it would also work very well.

The process described here is a 5-step method, that will result in a number from 1 to 25. The method asks you to first determine the risk without any controls so that you have a baseline from which you can determine how well your controls are working. The 5 steps are as follows: a) hazard identification; b) unmitigated risk determination; c) mitigated risk determination; d) determination of acceptable risk; and e) monitoring. I will explain each step in detail and provide some examples.

> **TIP** – Don't do this alone. Realize that you don't know everything and engage others to help you gather information and do the risk assessment. This can include anyone and everyone that has expertise in the area. People that might be included are the laboratory manager, the scientist, the technician, the animal care taker, the security staff, and others (e.g. cleaning staff). You may also include your local safety committee.

[3] Clinical Laboratory Preparedness and Response Guide. Association of Public Health Laboratories. American Society for Microbiology, 2016
https://www.aphl.org/aboutAPHL/publications/Documents/WORK_BlueBook.pdf

Step 1 – Hazard identification

Figure 18

Again, we start with the fact that you cannot have a risk without a hazard (see Figure 18). Therefore, step one is to identify the hazard(s). Think about where the work is being done and all the microbiological hazards that may be present there (either permanently or temporarily). In some situations that will be easy as there may only be one research scientist working with one agent in one laboratory. However, this is often not the case; real life is more complicated and it may not always be clear what hazards are present at any one time. If you come to the realization that you really don't know what hazards are in your work place, that should give you pause to reconsider your awareness and knowledge of potentially dangerous microbiological agents that may be present during a normal work day.

Step 2 – What is the unmitigated risk?

The next step is to sit with your team and ask yourself: What is the risk (please be sure to clearly define the risk) if no controls were used when doing the work? As discussed above, think about the three factors that influence the risk – pathogen, procedure(s) and person. Try to determine the probability of the risk occurring, and rank it on a scale of 1 to 5 (with 5 being the most likely). Then determine how bad that risk event will be (consequences) and again rank it on a scale of 1-5 (with 5 being the worst). When you multiple these numbers you will get a number ranging from 1 to 25. Remember this is with NO controls being applied – just like you were working on this pathogen at your kitchen table at home. We expect the numbers will be fairly high. If they aren't, that immediately tells you there is little risk and few, if any, precautions are needed. Multiplication of the likelihood and consequence numbers results in a risk matrix as shown. The numbers can then be put into classes or bands (based upon your discretion) into low (L) risk, moderate (M) risk or high (H) risk.

LIKELIHOOD	CONSEQUENCES				
	Insignificant (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
(5) Almost Certain	M	M	H	H	H
(4) Likely	M	M	M	H	H
(3) Possible	L	M	M	H	H
(2) Unlikely	L	L	M	M	H
(1) Rare	L	L	M	M	H

Example: You are culturing Brucella without any controls. Probability of getting infected with Brucella is high (5). Consequences of the infection are bad (4), but not catastrophic because we know we can treat a Brucella infection with antibiotics. If we multiple these we get 20. This immediately tells us that working with Brucella is high risk and appropriate controls need to be put into place or the chances of getting infected and very sick are high.

Step 3 – What is the mitigated risk?

If you've determined that there is a risk of something bad happening, you'll have to take precautionary action. This would include effective controls (from the hierarchy of controls) and risk mitigation. We will present and discuss control measure in some detail later in this book. For now, understand that your team needs to identify what controls are already in place and what additional controls must be added to reduce risks. Unless the work being done is new, it's likely that someone has already established and implemented some controls. However, your team needs to ask: a) are they the correct controls for the situation?; and b) are they working as expected? Often, we assume the controls in place are working, but, in reality, they may not be (e.g. wearing respiratory protection). Now that you know what controls are being applied to lower the risk, repeat the determination of probability and consequences for the same situation as you did in step 2. Hopefully you find the number you get now considerably reduced. If the number doesn't decrease much you either have the wrong controls or they aren't working.

Example: You are culturing Brucella now with controls. The probability of getting infected with Brucella when using controls is now low (2). Consequences of the infection are still bad (4). If we multiply these, we get 8. This tells us that controls have reduced the probability (chance) of getting infected, but not the consequences.

As you see in the example, the controls we apply in our work can affect the probability of the bad event occurring, but not always the consequences. We usually put our efforts and resources in preventing the bad event (lowering the probability) but focus less on fixing the problem (lowering consequences). If we do a good enough job in preventing the problem, then there should be no need to fix the problem. Still, we can sometimes influence consequences. For example, if you vaccinate a person against Rabies, they probably will not get Rabies if they become exposed and infected. We have altered the consequences of the infection from certain death to probable survival.

Step 4 – Determination of acceptable risk

Now that you have quantified the residual risk, you have to decide if this is acceptable. In reality you will never reduce risk to zero, so there will always be a number at the end of the process. Once your team has determined the residual risk, be sure to communicate this to senior management. Often senior management thinks all is well and nothing can go wrong – until it does. Then everyone starts asking questions. If you have clearly communicated to senior management that there is a chance (it may be small) that something can go wrong, they might not be so surprised when it does.

If, during your discussions with senior management, they are not happy with the remaining risk, then you need to determine what can be done to lower risk further. This usually requires more resources and money. Ask yourselves where improvements can be made in the mitigation of the risk through improvements or increases in controls. Example include more training, better personal protective equipment, better primary controls, and increased facility engineering controls. There are often many areas where improvements can be made; however, each costs time and money. Therefore, a strategic selection needs to be made to get the most reduction in risk with the least expenditure in resources. Easily said – but often difficult to do!

Figure 19

Finally, it is worth noting that what is acceptable risk in your situation (culture, country, location) may not be the same as what is acceptable to other people in other situations. Some countries and cultures are very risk adverse and will do practically anything to drive risk to a very low level. In other situations, a certain higher level of risk is tolerated and considered acceptable. Therefore, there is no one correct number to achieve or risk level to be obtained. It is very situational, and risk tolerance becomes very personal. Getting to the correct level of risk, involves a balance (Figure 19) between resources (money) and the amount of risk that can be tolerated.

How often to do a risk assessment? There is no one simple answer. The best answer is as often as possible. However, the practical and logical answer is: a) annually at a minimum; b) when something changes (pathogen, procedure, people); or c) when something goes wrong (accident investigation). Once you establish a process and a good team, it takes less time to do risk assessments. You may find that nothing has changed and that the initial assessment was correct at the time it was done and is still valid. This provides reassurance and the proof that you are doing all that you can (with the resources you have) to mitigate risk to an acceptable level.

So essentially everyone can do a risk assessment, because all you have to ask yourself is “who is doing what task and what hazard is involved?” Then you just need to think about what can happen, how likely is it that that thing can happen, and how bad will it be.

Example: Joy is mopping the laboratory floor. She is very tired because she couldn’t sleep very well last night. She is using a soapy type of cleaning agent that has been diluted in water. She is just wearing her regular clothes from home. What is the chance that she will slip on the floor during her work and if she falls, how bad could it be? Will she fall and hit her head and die or just slip and think nothing of it? How do you know what the probability is and what the outcome will be?

Risk mitigation

Let us now look at what we can do to manage the risk. You are probably already applying a lot of different risk controls in your normal work day, even though you may not think of them as risk controls. You probably inherited them when you started the job and were told "this is the way we do things here." For some, there was training on how to do things; others were given standard operating procedures; and still others just learned on the job by watching. Or there may have been a combination of approaches. You were told things like "be sure to close the door behind you," or "always wear your goggles when doing this," or "always do this task under the hood." Unless you are starting up a brand-new facility or procedure, there is usually already a set place, time and way of doing the job, which includes risk mitigation controls. Sometimes these are established by government regulations or community best practices, but sometimes they are just old habits started by someone long gone, that no longer make sense. Based upon what you know the risks are from your exercises above you should be able to apply risk mitigating controls in a local, practical, and sustainable manner.

As mentioned previously, risk controls can be loosely grouped into three baskets: a) Biosafety Practices and Procedures; b) Safety Equipment (primary barriers); and c) Facilities (secondary barriers). You can draw from each of these baskets to build the best combination of layered controls. Let's now look at each of those baskets.

Biosafety Practices and Procedures

First and foremost is you! What you do and how you do it, will make the biggest difference. No matter who you are or where you are working, having good practices and procedures is paramount. "Well-trained people can do good work in poor facilities with little equipment, but poorly-trained people may not do good work in excellent facilities with lots of equipment." How you do what you do is the most important thing in safety. Most accidents are caused by people, not by equipment or facility failures. Large noticeable events (accidents) are usually preceded by a series of small events (mistakes) which eventually add up. Training of personnel in their job functions is critical in reducing these mistakes so that large accidents do not occur.

Understanding the goal, principles, or desired outcome is the most important part. Once you know where you want to go, then you can determine (based upon resources at hand) how you are going to get there. Therefore, for each principle, I will provide options that will vary in efficacy and resources required. For each principle, always try to use the best practices possible which will allow you to achieve the best risk reduction. However, not every situation is ideal and the world isn't perfect, so do the best you can with what you have! Do what is local, practical, and sustainable.

The laboratory/procedure room/animal room

Let's start with the setting where you handle the pathogen or sample. While the room itself is not a "practice or procedure" workers need to understand that the practices and procedures will occur in this location. This is a special place; therefore, no one should be allowed to wander

into and out of this space. This should be a separate space where only microbiology work takes place. No one other than the approved staff should enter. Let's call it the containment zone. It is not an office; it is not a lunch room; it is not a hallway. The reasons are fairly simple and straightforward. There are potential spills that could occur; potential aerosols that may be created; and hazards (biological, chemical, electrical, etc.) that could arise. Therefore, some general, applicable principles are:

a. First, you have to define what this space is. Often it is one room or area, but it can also be multiple rooms or areas (a suite). Within this area, people can freely move around because they are not leaving the containment zone. Therefore, if you have multiple rooms people can walk from room to room (even through a hallway) and not have to do anything special (more about entry/exit procedures later).
b. Only authorized personnel enter this space. It is not open to the general public; it is not open to general staff in your organization; it is open to and used only by those staff that are trained and have a need to be there. Even other laboratorians that have general training and knowledge may be restricted from entering. The higher the potential risk, the more restrictive the access should be.
c. People entering this space must realize that they are entering a special place and should behave accordingly. Generally, this means wearing the appropriate clothing and acting in a professional manner. Depending upon the level of risk (back to risk assessment), you may enter with your street clothes (personal clothes from home), or you may have to change into other clothes that remain at the work place. Once in the room, you should put on some additional layers of clothing and other safety equipment, as determined by the risk assessment. These additional layers of clothing or safety equipment will remain in the room to either be cleaned and reused upon next entry, or disposed of. More on this later.
d. The room should be organized such that the highest risk work (work with the pathogen or sample) is done towards the back of the room (away from the entry door) and vice versa. This way entry/exit procedures are done in the part of the room with the least potential contamination.

<u>Option 1.</u> Ideally the room should be fully closed and have four walls, a ceiling, and a floor. This easily defines the space and allows restricted entry. There may be one main door for entry or several, depending upon the size of the room. The room should be dedicated to as few different functions as possible. For example, do not mix rooms used for housing animals with rooms functioning as laboratories. Ideally, the room should be purpose-built and used for a single pathogen or groups of pathogens. For example, rooms can be dedicated to bacteriology, virology, microscopy, mycology, parasitology, etcetera.

<u>Option 2.</u> If you cannot have dedicated rooms, then you may have to group the work based upon risk. For example, all high-risk work would be done in one very special room, while other

lower-risk routine work could be done in a larger, more generic spaces. You may have to have some small desks in this space where people can do limited amounts of paperwork.

Option 3. You only have a limited amount of space and must do all work in one room or outside. In this case, try to separate activities as much as possible within that space. For example, office work in one area, eating and drinking in another area and sample handling in another. Recognize the different spaces and do not cross contaminate. This is less than ideal and should be corrected as soon as possible.

How do I enter and exit this special place?

As stated above, the laboratory/animal room/procedure room (containment zone) is a special place. Therefore, the entry and exit procedures also need careful attention. Unlike entering your house, office, or car, entering/exiting the area where you work with pathogens needs to be done with care and attention.

Figure 20

First, be sure that you are authorized to enter. Don't just walk into a containment zone where you don't belong. You could be putting yourself at risk and breaking the rules. Second, read and obey the posted procedures for entering that containment zone. A sign should be on the door of the containment zone telling you what hazards you may encounter inside and what you should do to protect yourself (see Figure 20). The sign should contain the following minimum basic information:

1. The procedures for entering the zone (type of PPE required).
2. The supervisors name and contact information (should you have questions or need help).
3. The microbiological agents in use (hazard identification). If this is a security concern the information can be posted on the inside of the door.
4. Other hazards that might be in the zone e.g. electrical, noise, laser, toxins, etcetera.

For entry into the containment zone the most common procedures are:

a) Open the door, following established protocols (you may need access control tools, such as a key, card swipe, personal identification number or biometrics depending upon the level of security).
b) Securely close the door behind you and make sure no one enters with you (for security reasons).
c) Put on a protective garment that covers your body, especially the torso. This can be a standard front-closing laboratory coat; a rear-closing laboratory gown, or coveralls, depending upon what risks you might be encountering and how you might be exposed. This will help to prevent contamination of your street (personal) clothes. I will elaborate more on clothing selection later.

d) Put on a respirator (if needed). This is NOT a dust mask or surgical mask, but one that fits tight to your face and filters most all or most of the air entering your lungs. This will help protect your lungs from inhaling aerosols of pathogenic agents. It will NOT protect you from dangerous gases. I will discuss more about respiratory protection later.
e) Put on eye protection. There are many different styles and types. The selection should be based upon the risks encountered (back to risk assessment). This will help to protect your eyes from projectiles and splashes to the eyes, and will also stop you from touching your eyes. I will elaborate more on eye protection choices later.
f) Put on a pair of gloves. There are many different styles and types. The selection should be based upon the risks likely to be encountered (back to risk assessment). This will help protect your hands from contamination. I will provide more detail on hand protection choices later.
g) Put on dedicated shoes or shoe covers, if required. This is to ensure that any contamination that is on the floor and may get on your shoes, remains in the containment zone. I will discuss more about protective footwear later.

These are just generic steps – the <u>specific</u> details of how you enter your <u>specific</u> procedure room should be in your <u>specific</u> SOP

To *<u>exit</u>* from the containment zone the most common procedures are:

a) Turn off all equipment and secure all cultures.
b) Disinfect all surfaces.
c) Remove your contaminated gloves and place them in an appropriate container marked with the biohazard symbol for disposal later.
d) Remove your eye protection and wipe with an appropriate disinfectant for reuse.
e) Remove your respirator if you are wearing one. If disposable, place in the same container as your gloves. If reusable, wipe with an appropriate disinfectant for reuse.
f) Remove your shoe covers (if you are wearing them) and place in the same container as your gloves. Change shoes if you were wearing dedicated room shoes.
g) Remove your protective garment. If disposable, place in the same container as your gloves. If reusable and not soiled, hang up for reuse.
h) Wash your hands with soap and water for 30 seconds.
i) Open the door and make sure it is closed behind you before you leave the area.

These are just generic steps – the <u>specific</u> details of how you exit your <u>specific</u> procedure room should be in your <u>specific</u> SOP – do what is local, practical and sustainable.

How do I put on and take off my PPE?

The amount and type of PPE will be dictated by your risk assessment for the work being done. Some of it may be new and some may be reused. I will discuss each type of PPE and its appropriate use later. For now, let's just look at how to put on (donning) and take it off (doffing) the PPE that you are required to wear.

The order of donning PPE is primarily dictated by physical limitations. For example, it is difficult to put on a respirator once you are wearing eye protection. Therefore, depending upon what PPE is required there will be a specific sequence to donning. Make sure everything fits well (not too tight and not too loose) and is in good working order (e.g. ensure that the respirator isn't plugged and that the gloves don't have holes in them).

The order of doffing PPE can be very important. As a basic rule, take off the most contaminated item first and leave the least contaminated item for last (see poster, below). Try to be as careful as possible when taking items off, so as to not contaminate your clothing or your skin, as this defeats the purpose of wearing the PPE (to some degree). In general, the order of removal is gloves, then eye protection, then respirator, then foot protection, then body protection. However, the order can and will vary depending upon the type of work being done, the type of PPE being used, and risk assessment. Know the correct SOP and follow it. Gloves are most likely to be contaminated and should be removed carefully and slowly to avoid contaminating the environment or yourself. Figure 21 shows a brief description of a method that minimizes contamination during removal. However, do what is local, practical and sustainable.

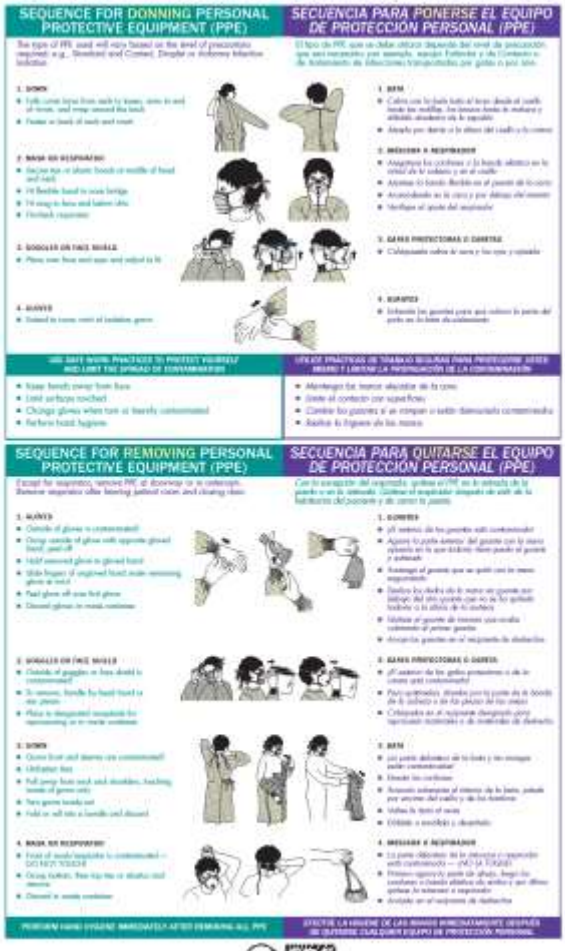


Figure 21

Always practice good microbiological techniques

As in any profession, there are good techniques that should be followed. They may not be rules or laws, but they are best practices and are usually learned in school when studying

microbiology. Many are common sense and help make the workplace safer, increase quality control, improve compliance with regulations, and make people feel like a team (if everyone does things the same way, people feel cohesive and support each other).

Some of these are:

Figure 22

a) Make sure the area you are working in has enough space and is not cluttered with other irrelevant objects (e.g. plants, papers, books, equipment, etc.). You need the correct amount of space to work – being cramped leads to bumps and spills. If a spill or splash occurs and the bench or floor is cluttered, then more items are potentially contaminated (e.g. a splash on your laboratory note book – how will you decontaminate that precious object?). Best not to keep irrelevant objects in your working space!
b) When doing any work with microbiological agents in any setting, work carefully, slowly, and deliberately. Pay attention to what you are doing and don't get distracted. Remember what you are working with could be dangerous or even fatal. If you feel distracted or fatigued, stop work! Take a rest, come back later and finish.
c) For quality assurance and quality control reasons, make sure to take careful notes of what you do. Write everything down and be sure to label clearly all materials and reagents.
d) Be sure to follow all Standard Operating Procedures (SOPs). They are there for a reason and will ensure that everyone does the work correctly and in the same way. If you follow all SOPs carefully, you will be safer and work will have greater consistency.
e) Minimize splashes, spills, aerosols, sprays, splatters, and creation of aerosols of the microbiological agent or the substance in which the agent may reside (e.g. water, soil, culture media, etc.). The more the agent gets spread around, the more likely it is to contaminate you, someone else, or the environment. Keep it contained! This is always rule number one of working with any hazard. Keep it contained to where you want it.
f) Any and all contaminated materials (solid or liquid) should immediately be placed in an appropriate container, labelled with the biosafety symbol, for immediate or delayed sterilization.
g) Always keep your workplace neat and tidy. This ensures that materials do not get spilled on, contaminated, or otherwise spoiled. It allows you to perform your task easily and with greater efficiency.
h) Minimize disruptions when doing your work (no chatting with friends, no listening to music, turn off your mobile devices). Distractions lead to mental lapses which could in turn lead to mistakes.

i) When working with any microbial pathogens (no matter what their risk group) always keep a liquid disinfectant on hand, which is either specific for the pathogen you are working with or broad spectrum.
j) Always apply the liquid disinfectant to decontaminate equipment, working surfaces, and containers before and after use.
k) When doing microbiology always be sure to use aseptic techniques to prevent contamination of other samples, yourself or the environment. Some aseptic techniques include:
    a. Begin your work day with doing tasks that do not involve pathogenic agents (clean work) followed by work with pathogens later in the day. This minimizes the potential for contamination of your work, reagents and negative controls.
    b. Avoid pouring media and reagents directly from bottles or flasks. This prevents drips and spills down the side of the vessel.
    c. Use sterile glass or disposable plastic pipettes and a pipettor to work with liquids, and use each pipette only once to avoid cross contamination. Do not unwrap sterile pipettes until they are to be used. Keep your pipettes at your work area.
    d. Always cap the bottles and flasks after use and seal multi-well plates with tape or place them in resealable bags to prevent microorganisms and airborne contaminants from gaining entry.
    e. Never uncover a sterile flask, bottle, petri dish, etcetera, until the instant you are ready to use it and never leave it open to the environment. Return the cover as soon as you are finished.
    f. If you remove a cap or cover, and have to put it down on the work surface, place the cap with opening facing down.
    g. Use only sterile glassware and other equipment.

There are no options here. There is no reason everyone cannot use good microbiological practices at all times under all circumstances. There is no need to compromise and not do your work to the highest level possible.

Always clean up any spills immediately

Let's face it – accidents can and will happen. Any time that primary containment of the pathogen is lost during your work, this could be considered a spill. If a pathogen escapes primary containment (spill or splash), it must be cleaned up immediately before it spreads further. The specifics of how the spill is cleaned up should be detailed in your incident/emergency response plan and you should have been trained on the technique. A detailed incident/emergency response plan will be presented later in this book.

Depending upon where the spill is, how much was spilled and what was in the spilled material, this accident could range from a minor incident to a large emergency. Don't panic, but do respond appropriately. In almost all circumstances the spill will be very small and one that you can easily clean up yourself. The basic process is the same for most spills, which is: 1) cover the spill with absorbent material to stop it from spreading; 2) pour a liquid disinfectant, known to destroy the pathogens present, over the absorbent material (from the outside in to ensure the liquid flows inward); 3) allow a suitable contact time (5-30 minutes, depending upon the liquid disinfectant used and the pathogen); 4) remove the absorbent materials and repeat over a wider area (to ensure all small splashes and splatters are also removed). In any event, do what is local, practical, and sustainable.

> Option: If you can't clean up a spill immediately, call for someone else to help you or at least cover it with an absorbent material to stop it from spreading; then mark its location. As soon as possible, follow the above procedure to decontaminate the area.

Wash your hands

Since it is our hands that the most likely to encounter the pathogen or sample, they are most likely to become contaminated. Even if we are wearing gloves during the procedure our hands may still become contaminated. Therefore, it is very important to be able to wash your hands. It is especially important to wash your hands at the following times:

a. Before beginning work if you not wearing gloves or are concerned that you may be contaminating the work with the normal flora from your hands;
b. After removing your gloves between procedures or before exiting the procedure room;
c. Anytime that you think you have accidentally contaminated your hands during a procedure e.g., when a spill occurs, a glove breaks, you get a cut/needle stick;
d. At the end of the day before going home to ensure you are not bringing any pathogens home with you.

Figure 23

Wash your hands thoroughly for at least 20 seconds with soap and running water in a hand wash basin. The hand wash basin should NOT be the same as the laboratory sink, where you dispose of chemicals and wash glassware. This hand wash basin is dedicated to washing hands only. This way there is less potential for the sink and taps to become contaminated with other laboratory materials and reagents. Again, do what is local, practical, and sustainable.

> Option 1: If you do not have a dedicated hand wash basin you may use a laboratory sink. Ideally, this laboratory sink could be dedicated for hand washing only (if you have two or

more sinks in the laboratory). Alternatively, you may just have to use the one sink for all activities.

Option 2: If you do not have a sink or running water in the facility (or you are in the field) use a bucket or tub containing water and soap to wash your hands.

Option 3: If you do not have access to water you may have to use a hand sanitizer to temporarily disinfect your hands. As soon as you get to a location where there is running water, wash your hands with soap and water.

Dispose of contaminated materials immediately

Place all contaminated materials (e.g., cultures, blood, serum, pipettes, gloves, glassware) immediately into an appropriate container for daily or delayed decontamination. Think about the following guidelines when disposing of contaminated materials:

Follow waste segregation guidelines. We will discuss waste management more in a later section. What to do with the contaminated waste depends upon factors such as:

a. Is it solid or liquid?
b. Is it disposable or reusable?
c. Does it contain other, potentially harmful, substances, such as chemicals or radionucleotides?
d. Does it contain high, moderate or low risk pathogens?
e. Is it sharp, allowing it to puncture soft-walled containers?

Keep in mind the materials are still infectious and therefore, MUST be contained until such time that they can be decontaminated. Therefore, the materials must not spill, leak, fall, or poke out of the container. Higher risk biological materials should be decontaminated as soon as possible. Liquids can be put into hard-walled containers that preferably have a small opening and can be sealed (capped for transport and to minimize spills). Glass, strong plastics, or steel containers are good choices. Make sure the container is not over filled! Solids, such as beakers, plastic ware, pipettes, can also go into hard-walled containers similar to those used for liquids and may even be mixed with the liquids. Soft or small solids, such as pipette tips, gloves, paper masks, and disposable gowns may be placed in strong plastic bags. Sharp objects, such as needles, scalpel blades, capillary tubes, and broken glass MUST be placed in hard-walled, puncture resistant containers (glass, plastic or cardboard). We will look more at waste management later.

The exact details of what contaminated materials go into what type of container will depend a lot upon your local resources, conditions and regulations. Do what is local, practical, and sustainable.

Waste Management

This is a very important topic for a variety of different reasons. These include, but are not limited to:

a. Medical waste is often regulated in many countries. If not handled properly facilities can be fined or closed, due to regulatory infractions.
b. Medical waste can be infectious and therefore dangerous to the staff, the public and the environment. Therefore, careful waste management and validation of decontamination is important.
c. Resources can be wasted if the wrong waste is treated in the wrong way.
d. A lot of potentially contaminated waste is created, as facilities have moved toward single-use materials, creating a large burden on facilities.

Since this is such an important topic, let's begin with defining medical waste. A very general definition of medical waste is "A waste, or combination of wastes, which because of its quantity, concentration, or physical characteristics may either cause or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating illness, pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed."[4]

Medical waste is generated from all types of health care institutions, including hospitals, clinics, doctor's (including dental and veterinary) offices, and medical laboratories on a daily basis. Therefore, an infectious waste plan for your facility must exist and must be followed. The components of a comprehensive infectious waste management plan are:

1) Designation of infectious waste
2) Segregation of waste
3) Packaging
4) Storage
5) Treatment
6) Disposal
7) Contingency measures for emergency situations
8) Staff training

The steps may flow as shown below, beginning with the designation and generation of the waste, ending with the disposal or the treated waste. We will break each step down and take a closer look at the components and choices you have.

Designation and generation of waste

[4] Introduction to Hazardous Waste Identification (40 CFR Parts 261), United States Environmental Protection Agency, 2005

Step 1 - Designation and generation of infectious waste

The infectious waste plan for your facility should specify which wastes are to be managed as infectious wastes. This may also be clearly defined in your country's regulations. A responsible official or committee must be aware of what these are and should determine if any other miscellaneous wastes should be handled as an infectious waste. However, it is still the responsibility of the person generating the waste to ensure that all procedures are followed to ensure the safe and environmentally responsible disposal of the waste.

The types of waste that are generated from a biomedical facility are often complex and varied and may include: a) contaminated solids (e.g. pipets and plates); b) non-contaminated solids (e.g. paper, plastic wraps); c) equipment; d) liquids; e) air; f) chemicals; g) radiological; h) sharps; i) organic solids (e.g. animal carcasses, manure, feed, tissues, blood); j) personal protective equipment (e.g. gloves, gowns, respirators).

Part of responsible waste management is waste minimization (i.e., do not generate any more than you have to). This has to be a thoughtful process and one that is taken on by the entire staff in all areas. Some ideas include:

a) Substituting a non-hazardous material used in a process for a non-hazardous material.
b) Process changes (smaller scale, simpler procedure).
c) Neutralizing hazardous materials at the end of the process.
d) Recovering and reusing materials (e.g., use reusable cloth gowns versus disposable gowns).

While it is true that it is safer to use single-use materials (like plastic and paper) (because they can be directly disposed of once contaminated) this practice is wasteful and expensive. Try to use reusable, recyclable materials whenever appropriate, keeping in mind that this increases workload and may increase risk because of the extra handling required. Therefore, as a general guideline, use single-use materials for high-risk work and reusable materials for low-risk work (if possible). Think about what is local, practical, and sustainable in your situation.

Step 2 - Segregation of waste

As outlined above, an active biomedical facility generates a lot of waste that may be varied in type and nature. The waste generated must be segregated (i.e., sorted and separated) to ensure that the treatment it receives is correct for its nature/type and that resources are not wasted in treating something that does not need treatment. Only a segregation system can ensure that the waste will be treated according to the hazards of the waste; that the correct disposal routes are taken; and that the correct transportation equipment will be used. Without an effective segregation system, the complete waste stream must be considered as hazardous.

Proper segregation results in waste "streams" that then follow different paths. The most common waste streams that are generated by segregation in a biomedical facility are:

a. Biologically contaminated materials (medical waste – the waste we will focus most on in this section);
b. Non-biologically contaminated materials;
c. Chemical materials;
d. Radiological materials;
e. Pathological materials (organic solids);
f. Sharps (contaminated or non-contaminated);
g. Mixed waste (multiple hazards).

Figure 24

Since this book is about biosafety, the main focus here will be on waste streams that are contaminated with infectious microbiological agents. Treatment and handling of chemicals and radiological materials can be found in other books and on the internet. In order for proper segregation to work, here are some key points to keep in mind:

- ✓ Segregate the wastes at the point of origin based upon hazard.
- ✓ Use distinctive, clearly marked containers or plastic bags for the different types of wastes.
- ✓ Use of the universal biological hazard symbol on infectious waste containers as appropriate.
- ✓ Never mix any wastes that are already separate. This creates "mixed wastes" which are more difficult to deal with later.
- ✓ You can use color coding of waste streams to help with segregation (e.g. Figure 25)

COLOR CODE	TYPE OF CONTAINER	TYPE OF WASTE
Black	Trash Bin/Plastic bags	Non-infectious dry waste
Green	Trash Bin/plastic bag	Non-infectious wet waste(kitchen Dietary ,etc)
Yellow	Plastic bag(double bagging)	Infectious Pathologic waste
Red	Puncture proof container	sharps
Orange	containers	Radioactive waste

Figure 25

Some examples of segregation:

- ➢ A pure culture of Staphylococcus aureus ⟹ infectious waste stream

- Excess, unused 10% formalin ⟹ chemical waste stream
- A needle that was just used to draw blood from a patient ⟹ contaminated sharps waste stream
- An animal carcass ⟹ pathological waste stream (organic solid)
- Paper wrapper from a pipette ⟹ non-contaminated waste stream

Step 3 - Packaging

Once you have determined what waste stream that you will place your waste in, you must then select the correct type of package to put the material into. Select the type of packaging materials that are appropriate for the nature of waste. Factors to take into consideration should include: liquid or solid; infectious or non-infectious material; weight; sharp or non-sharp; reusable or disposable; and the type of treatment to be used. There are many different types of containers and packaging materials available depending upon your location and resource availability. Therefore, it is not possible to specify any specific type of packaging material. Some general guidelines are:

- ✓ Use packaging material that maintains its integrity during storage and transport (e.g. paper bags are usually not a good choice).
- ✓ Close the top of each container by closing, folding or tying as appropriate to ensure nothing falls out during transport or treatment.
- ✓ Place liquid wastes in capped/tightly stoppered bottles if possible and appropriate. If that is not possible, place in containers with lids to minimize splashes.
- ✓ Do not compact wastes before treatment. E.g. Don't push down on plastic bags to get more in or push more needles in a sharps container than it can hold.
- ✓ Ensure there is an appropriate label on the bag to indicate the type of hazard.
- ✓ Try to use color coded packaging as much as possible to indicate the type of waste or hazard within (e.g., red or yellow for infectious waste).

Examples of packaging:

- Strong red or yellow heat-resistant plastic bags pre-labelled with the biohazard symbol for many types of solid or semisolid infectious waste that are going to be autoclaved (e.g. Figure 26).

- Heat resistant bottles, flasks, pans or tanks for liquids that are going to be autoclaved (e.g. Figure 27). *Figure 26*

TIP - *Double packaging is always a good idea for better containment. If the plastic bags you have available are not thick enough, use two or three. Put a plastic bag inside a cardboard box or steel container for extra strength. Think about how you can creatively use two types of containers that you readily have on hand to ensure the pathogens are contained. Use what is local, practical, and sustainable in your situation.*

Figure 27

Packaging of sharps

Sharps are a special type of hazard and therefore need some special packaging. They may or may not be contaminated with other hazards, which must also be taken into consideration. Sharps are hazardous in themselves, because of their nature (they are sharp and may break your skin). Therefore, they must never be mixed in with other wastes and must always be identified as a sharp. Sharps come in many different shapes and sizes and their definition and packaging may be regulated in your location. The most common sharps found in biomedical facilities are needles, scalpels, scissors, knives, and broken glass. But there are many others that could also be treated as sharps. In general, anything that can puncture the skin should be considered a sharp and handled as such. For example, in some countries (or States) even small pipette tips can be considered a sharp, depending upon local regulations.

The most common sharps-related risks for spreading bloodborne pathogens occurs:

- Recapping needles;
- Failing to dispose of used needles properly in puncture-resistant sharps containers;
- Accidental breakage of the tubes used for collection of blood in a variety of health care settings.

Once an object has been classified as a sharp and you are going to dispose of it, separate it into reusable (e.g., knives and scissors) or disposable (e.g., needles and scalpels). Reusable sharps can be put into a container with water or a liquid disinfectant for later treatment and cleaning. For disposable sharps you can use a wide variety of containers, from commercially available (sharps boxes) to homemade (see Figure 28). Some guidelines for the container type and use are:

- Containers should be rigid puncture-resistant so that, when sealed, they are leak resistant and ideally cannot be reopened without great difficulty (people should NOT be able to access the used sharps again).
- Containers should have a small opening through which the sharp can enter, but that would prevent easy removal.

- Containers should be brightly colored (red or yellow), have a biohazard label, and have the word “sharps” written on them. *Figure 28*
- Containers should be accessible to employees, and be located as close as feasible to the immediate area where the sharps are used.
- Sharps containers must remain upright throughout use and be replaced routinely. They should not be overfilled (no more than ¾ full).
- Containers of contaminated sharps should be closed immediately after use.

There are many commercially available sharps containers for purchase. Since they are single-use there is an ongoing cost for their purchase.

Option: You can make your own providing they meet the requirements listed above. Use what is local, practical, and sustainable in your situation (e.g. Figure 29 showing use of an empty detergent bottle).

Figure 29

Step 4 - Storage

There are many times during the waste management process that wastes may need to be stored for shorter or longer times. When storing wastes make sure they are in an appropriate location (e.g. not in a hallway where the public may have access) and that they are appropriately labelled. If still infectious (i.e. before treatment) make sure no unauthorized people have access and the containers are not leaking or punctured. As a general guideline, the higher the risk of the pathogens contained in the waste, the sooner it should be treated. Therefore, only low-risk infectious materials should be stored for longer periods.

Step 5 – Treatment

As a general rule, all pathogens should be inactivated before leaving the biomedical facility. In other words, nothing should leave the facility that can still cause disease in humans or animals, or be a risk to the environment. Therefore, something must be done to the contaminated waste before the material leaves the facility. **The choice of what happens needs to be one that is carefully thought through, managed, and documented.**

There are several methods that have been successful in the treatment of infectious waste. Some of these treatments are:

a) Chemical
    a. Liquids (alcohols, aldehydes, phenolics, etc.)
    b. Alkaline Hydrolysis (digestion)
b) Thermal
    a. dry heat
    b. wet heat (steam autoclaving)

    c. boiling
    d. burning (incineration, plasma arc)
c) Gas/Vapor (formaldehyde, chlorine dioxide, ethylene oxide, hydrogen peroxide)
d) Irradiation (radiofrequency and microwave)

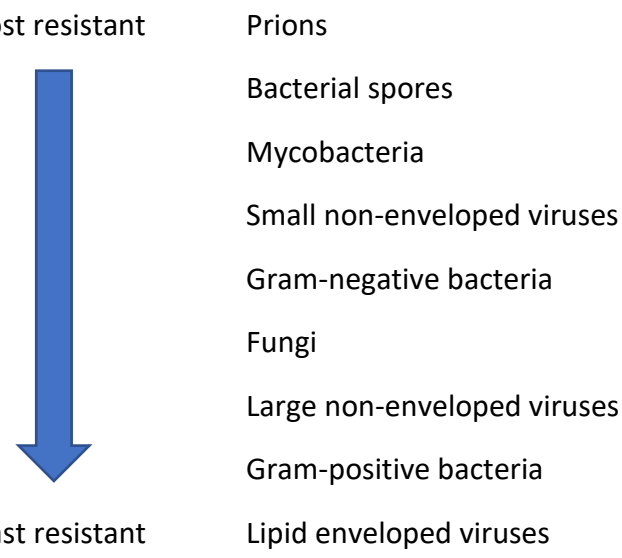
Which method to use depends on available resources, the materials being treated, and the type of pathogens involved. Entire books have been written on this subject area alone; therefore, only the main types of treatment used will be covered in this book. Factors that should be considered in the selection of an appropriate method include:

a. Degree of microbial killing required.
b. Type and number of organisms.
c. Amount of organic material present (is it clean?).
d. Are biofilms present?
e. Type & configuration of material to be treated.
f. Product factors (e.g. type, concentration, age, etc. of the product).
g. Duration and temperature of exposure.
h. pH, humidity.
i. Ease of use, safety, and cost.

The first step is to determine what level of destruction of the pathogen is desired or needed. By definition, there are different levels of destruction that can be achieved by different processes, as follows:

- ***Sterilization*** - Act or process, physical or chemical, that destroys or eliminates all forms of life, especially microorganisms. The definition is categorical and absolute: an item either is sterile or is not.
- ***Disinfection*** – A generally less lethal process than sterilization, it is the elimination of nearly all recognized pathogenic micro-organisms but not necessarily all microbial forms (e.g., bacterial spores).
- ***Decontamination*** – A process to remove contamination. Decontamination renders an area, device, item, or material safe to handle, that is, reasonably free from a risk of disease transmission.
- ***Antiseptic*** - A substance that prevents or arrests the growth or action of microbes, either by inhibiting their activity or by destroying them

The second step is to understand what microbiological agent or agents that you are trying to inactivate. Microorganisms have a broad range or resistance (or susceptibility) to being destroyed. In general, they can be ordered as shown below.



Chemical inactivation

In most cases chemical treatment will not result in sterilization, but rather disinfection/decontamination. Based upon their activity, the chemicals have been loosely categorized into three main levels of destructive ability:

Low level disinfection (e.g., hospital germicides used for housekeeping)

- Kills most vegetative bacteria and some fungi, but not *Mycobacterium*.
- Requires a minimum of 20 minutes of exposure.
- Examples include quaternary ammonium compounds.

Intermediate level disinfection (e.g., tuberculocides)

- Kills *Mycobacteria* and all vegetative bacteria, fungi, and most viruses.
- Requires a minimum of 20 minutes of Exposure.
- Examples include phenolics, iodophores, chlorine compounds, and alcohols.

High level disinfection (e.g., sporocides)

- Kills all microorganisms except high numbers of bacterial spores.
- Require 5-10 minutes of exposure.
- Examples: aldehydes, hydrogen peroxide, paracetic acid.

There is a very wide range of liquid disinfectants manufactured by many companies around the world. However, the most common ingredients found in most are:

- Alcohols (e.g., ethyl alcohol)
- Halogens (e.g., sodium and calcium hypochlorite)
- Quaternary Ammonium Compounds
- Phenolics
- Aldehydes (e.g. Formalin)
- Hydrogen peroxide

Most laboratories use one or more of the above chemicals for disinfection/decontamination. However, alcohol and sodium hypochlorite are still the two main chemical disinfectants used worldwide, because they are readily available and very inexpensive.

Alcohol A 70% (v/v) solution of alcohol (ethyl alcohol or isopropyl alcohol) can be rapidly effective in destroying a wide range of microorganisms in a variety of settings. However, once the alcohol concentration drops below 50% the ability to destroy microorganisms drops rapidly. Therefore, spraying 70% alcohol with a misting bottle is a poor idea. Better to use a squirt bottle to apply a liquid (not a mist). Due to the method by which alcohol works, it has a limited range of microorganisms that it can destroy. It does not destroy bacterial spores and hydrophilic viruses such as polio.[5]

Figure 30

Hypochlorite (bleach) This is a very good all-around disinfectant that works well in inactivating most microorganisms, under most circumstances. Large amounts of organic matter will degrade the ability of the hypochlorite to inactivate microorganisms. Therefore, surfaces should be as clean as possible before applying the liquid disinfectant. Be sure that there is at least 5 minutes contact time to allow the hypochlorite to work. Concentration is also important, therefore be sure to measure out the correct amount when diluting in water. Because household bleach contains 5.25%–6.15% sodium hypochlorite, or 52,500–61,500 ppm available chlorine, a 1:1,000 dilution provides about 53–62 ppm available chlorine, and a 1:10 dilution of household bleach provides about 5250–6150 ppm. Always read the label of the bleach that is being used and dilute to a use concentration that will give you approximately 5000 ppm or above if large

[5] Chemical Disinfectants, Guideline for Disinfection and Sterilization in Healthcare Facilities, USA Centers for Disease Control (2008). See https://www.cdc.gov/infectioncontrol/guidelines/disinfection/disinfection-methods/chemical.html

amounts of organic matter are present. The diluted solution will lose free available chlorine (the active radical) rapidly, therefore dilute no more than can be used in 3 days or less. Be careful when handling concentrated or diluted hypochlorite, as it is destructive on clothing, various materials (e.g. stainless steel) and of course living tissues (humans and animals). If you use it on stainless steel, be sure to wipe it off with water or another disinfectant that is less corrosive.[3]

There are many more chemical disinfectants available for use than just alcohol and bleach. The reader is referred to the many different books available on the internet on the various different products, their range of efficacy and use. Always refer to the manufacture's label for spectrum of microbial efficacy, dilution and cautions.

Validation It is difficult to validate the efficacy of chemical disinfection. Therefore, most people rely upon the manufacture to make the claim of what microbiological agents the particular chemical works against. This is why it is very important to follow the manufacturer's directions carefully and precisely, because that is how they validated the efficacy.

TIP *Many factors can alter the efficacy of a chemical disinfectant's ability to destroy microorganisms. Factors that affect chemical disinfection include:*

- *Age (keep as fresh as possible)*
- *Storage conditions (store at room temperature, away from strong light)*
- *Temperature at time of use (not too cold or too hot)*
- *Water hardness (hard water degrades performance)*
- *Amount of organic matter present (dirt will degrade performance)*
- *pH of final solution (neutral pH is best)*
- *Presence of other chemicals (chemicals can be destroyed by other chemicals)*

Consider these additional factors that may degrade the performance of your disinfectant and don't just assume it is killing the microorganisms that you are working with.

Thermal inactivation

Heat has been one of the oldest known means of destroying microorganisms, even before they were known to be a hazard. It is still one of the best, cheapest and most effective methods of destroying all pathogens. There are many different ways to generate heat that destroy microorganism, but here we will only cover the most common means in the laboratory. These are: a) boiling, b) wet heat (steam autoclaving), c) dry heat and d) burning (incineration).

Boiling This is still the simplest and most sustainable way of inactivating just about all microbial life. Any method of creating heat (electric, gas, propane, etcetera) in a water-containing, heat-resistant container (e.g., glass, metal, steel, plastic) will bring the water to 100C (e.g. Figure 31). Almost all solid items that are contaminated in the laboratory (e.g., plastics, metal, glass, needles, scissors, knives, cloth) can be immersed in boiling water in order to inactivate the contaminating pathogens. Be sure all closed vessels are partially opened to allow pressure to dissipate. Obviously, some things cannot be boiled because they will either melt or be destroyed (e.g., some soft plastics may dissolve, electronics will be destroyed, and some cloths may be destroyed). In addition, most liquids can also be heated this way to inactivate the pathogens. One should be careful to know what is in the liquid, as that chemical may be driven off with the heat and become a hazard unto itself.

Figure 31

Once the material is boiled for a sufficient amount of time (based upon the materials being treated, the pathogens being destroyed, and the medium) the liquid should be left to cool to room temperature and can then be poured down the drain. The solids can be disposed of as non-biomedical trash. Be careful if you are treating sharps (such as needles and scalpels) this way as they could still be sharp and potentially dangerous.

Autoclaving This is by far the most popular, most reliable and widely used method for heat inactivation of pathogens in a biomedical facility. Unlike with chemical treatment, autoclaves can achieve sterilization (complete destruction of all microbial life). Autoclaving is similar to boiling but, because it takes place in a closed container, the temperature can be increased to 121C or 132C under pressure (the two most common autoclave temperatures used). This allows for a shorter treatment time and potentially better efficacy of inactivation than boiling. Autoclaves come in a wide variety of sizes and styles. Some are manual, but many are automated with sophisticated monitoring.[6]

The very simplest autoclave is a pressure cooker—a closed container which can be heated to bring the liquid within to a temperature of 121C (e.g. Figure 32). These are typically small and manually operated, but will treat small loads of solids or liquids very effectively. This is a very simple,

Figure 32

[6] Steam Sterilization, Guideline for Disinfection and Sterilization in Healthcare Facilities, USA Centers for Disease Control (2008). See https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/steam.html

affordable and sustainable method of inactivating pathogens in a laboratory. The disadvantage is that they are manually operated and usually small.

Larger, automatically controlled autoclaves (e.g. Figure 33) can be purchased from a wide variety of manufacturers around the world. Some are floor models and top loading (e.g. Figure 34), while others are horizonal and side loading. There are two major types of larger automatic autoclaves: 1) gravity displacement, or 2) pre-vacuum. You must know what type of autoclave you have in order to know what run time is best for the various types of loads being treated. A gravity displacement autoclave allows steam into the autoclave, which will fill the autoclave chamber and push air out. If air is trapped in various spaces (especially in porous materials, inside bags or vessels) the steam will not penetrate well (or take longer) and therefore run times need to be increased. A pre-vacuum autoclave will draw a vacuum in the autoclave chamber before steam in allowed in, which removes much of the trapped air, therefore allowing the steam to penetrate better. Run times with pre-vacuum autoclaves can be significantly decreased and assurance of sterility of the entire load is increased. Therefore, porous materials (e.g. cloth, animal bedding, wood) are better treated in a pre-vacuum autoclave than a gravity displacement type.

Figure 33

Figure 34

There are many different types of autoclaves and many different loads that are treated; therefore, it is difficult to prescribe a specific treatment regime (time and temperature) that will work in all circumstances. It is important that each user validate sterilization for each autoclave and load type. For example, load types might consist of: a) 10 kg of linens; b) 2 – 5kg bags of solid plastic waste; c) 2 – 20L pails of liquids, etc. There are many different types of loads, each of which should be standardized as much as possible and treatment parameters validated. Once this is done, validation does not have to occur as often. Be sure to place a piece of autoclave tape (or similar indicator) on each load (see Figure 35). NOTE: Autoclave tape is <u>not</u> a means of validating efficacy; it simply differentiates heat-treated loads from untreated loads.

Figure 35

Example: If a common load type in your facility is plastic autoclave bags filled with solids (e.g. laboratory plastics, gloves, paper, disposable masks), you should establish a reasonable number of these bags that the autoclave (based upon its size) can accommodate. Validate the sterilization at 15 minutes. If sterilization is shown to fail, increase the run time until sterilization is achieved.

***TIP** – Do not overload any autoclave. Steam must penetrate and access all spaces within the load.*

***TIP** – With dry loads, such as laboratory plastics, place some water (e.g., 100 ml) within each bag to ensure steam in generated within the bag and the inner spaces of the plastics become moist. This will increase efficacy.*

Safety – Ensure that all containers are open (loosely capped) so that steam can readily enter and exit the containers in order to prevent a vessel from becoming pressurized and potentially exploding.

Safety – Do not autoclave known explosives, corrosives, or heat sensitive chemicals. They could explode or destroy your autoclave.

Validation This is an important part of proving that sterilization occurred. Many people assume that an autoclave always destroys all pathogens, but this may not be true. If you want to declare that you have destroyed all pathogens (including the hardiest) then you need to prove that sterilization occurred.

As part of validation you should have a log book for every autoclave, and record every autoclave run. The log book (e.g. Figure 36) should capture:

1) Date and time;
2) User;
3) Load type (e.g., cloth, solid waste, media, liquid)
4) Cycle type (liquid or vacuum)
5) Maximum time, pressure and temperature reached (see Figure 37);
6) Status of any validation indicator used.

Figure 36

Figure 37

Many modern autoclaves automatically generate and record much of this information. This facilitates data collection.

Validation indicators These are typically chemical or biological.

Chemical indicators (e.g. Figure 38) are less expensive than biological indicators and change color (or display other positive indication) after a certain time and temperature was reached. Chemical indicators are an excellent means of confirming that the autoclave did what you expected it to do. If you place the indicator deep into the middle of the load, you then know that any microorganism embedded that deeply actually reached a sufficiently high temperature for a long enough time. They do not confirm sterilization because this can only be done with biological indicators.

Figure 38

Biological indicators (e.g. Figure 39) usually consist of a carefully controlled amount of heat-resistant spores. By definition, a sterilization process must show a 6-log reduction in heat resistant spores. Therefore, biological indicators typically have 6 or even 7 logs of *Geobacillus stearothermophilus* spores suspended in a liquid media with a growth indicator. Several of these indicators are placed in and around the load. The run is then completed and the indicators are subsequently incubated for 24-72 hours. No color change indicates a successful autoclave run. A color change or change in turbidity is an indication that the spores are growing and the autoclave run did not produce sterilization. Indicators can be checked at 12, 24, 36, 48 and 72 hours. At the first sign of a change the test can be stopped. The autoclave run should be repeated with different parameters, or conditions. A common cause for failure to sterilize is lack of steam penetration.

Figure 39

In reality, the autoclave mostly destroys all microorganisms quite effectively under most circumstances. Most organisms are quite heat labile; however, some forms of some organisms are more heat resistant (e.g. spores). So how much validation do you need to have? The answer depends upon what level of quality assurance you need to achieve and prove.

As mentioned above, once you have proved that a certain autoclave works with specified standardized load types you don't have to revalidate it as often (because you assume the parameters are similar from run to run). As a simple starting point, it is recommended to: a) put autoclave tape on all loads (this is not validation, but proof of treatment); b) use chemical indicators in loads once a week (to prove the autoclave is working as expected); and c) use biological indicators once a month to revalidate that sterility is being achieved. The final decision will have to be determined by your risk assessment and the management team.

Option: If you cannot validate your autoclave, just practice overkill. Treat materials longer (e.g. 2 times) than you think necessary. You can use run times of several hours to give you greater confidence that all the materials inside reached a high temperature for a sufficient time to destroy them. This is hard on your autoclave and is energy inefficient, but will give you some peace-of-mind.

Chemical disinfection of spaces (fumigation) - There are many times in a biomedical facility where heat or liquid disinfection of a space or piece of equipment is not feasible or is impractical. Several different chemicals can be aerosolized and put into a space to decontaminate all the surfaces they come in contact with. These chemical treatments include: a) vapor phase hydrogen peroxide (VHP); b) formaldehyde vapor; c) chlorine dioxide; and d) ethylene oxide. The oldest and most common is formaldehyde vapor. Formaldehyde is still widely used because it is very inexpensive and easy to use; however, it is a known carcinogen and is slowly being phased out due to its health risks. The other chemicals require fairly expensive machines to generate the aerosol and distribute them in the space.

Fumigation is commonly used in animal rooms after a liquid disinfectant is used in the following situations:(a) for entire rooms with all the equipment inside, after a major spill, or when the room needs to be thoroughly cleaned between studies; (b) on sensitive electronic equipment; or (c) on equipment with many small spaces and tubes, where only the air can reach.

In all cases, no matter what fumigant chemical is used, the space being fumigated must be sealed air-tight. If leakage of air from the space occurs the concentration of the chemical in the air falls quickly below active levels and decontamination may not occur. In addition, animals and people outside the space may be affected from leaked fumigant gas. Therefore, rooms or cabinets that are to be fumigated must be well constructed and tested for air leakage. Gas must be generated outside the space and pumped in, or the generator put into the room and the room sealed after exiting. As is done for autoclaving, efficacy of the fumigation process should be validated with biological indicators using spores impregnated into paper strips and placed into the fumigated space. Use several strips and put them in many different places with the equipment or space to be decontaminated to be sure the gas penetrated to all areas.

The reader is referred to the internet, manuals, or other books for the exact procedures to be used for each fumigation process. In addition, many companies sell fumigation equipment and offer training on how to conduct the process.

Step 6 - Disposal

Once your waste is decontaminated or sterilized what do you do with it? Based upon the segregation you initially started in step one, the waste may go to different locations.

Uncontaminated waste may go immediately to your normal household waste disposal system (e.g., city trash disposal).

Sterilized and decontaminated solid waste (e.g., autoclaved plastics) may also go directly to the normal household waste disposal system, since it is now safe to handle.

Sterilized and decontaminated liquids may be poured down the drain that goes to the municipal sewer system.

Sharps that have been decontaminated may be disposed of in the regular trash (if still contained or no longer sharp), or depending upon your local laws, may need to be shredded first to make them unusable and unrecognizable.

Pathological waste that has been sterilized may be buried or burned, depending upon your local resources and regulations.

These are just some general guidelines for waste disposal. **The exact requirements for waste disposal vary greatly around the world. Therefore, you MUST be sure to know and comply with your local waste disposal regulations.** Remember – your waste may be someone else's treasure (see Figure 40).

Figure 40

Contingency measures for emergency situations

What do you do when things go wrong and you can't follow your waste management plan? You should be prepared to have an alternate method of managing the various types of waste, in case your primary method fails. For example, if you only have one autoclave for all your sterilization needs, what will you do if it breaks down?

While there are too many different scenarios to be able to describe a specific alternative for all situations in all facilities in the world, there are some general concepts that should be applied. Options for waste management should include: a) storing the material longer (if possible) in a secure location for treatment later; b) using an alternative method of treatment for example chemical versus heat; c) packing the material very well and taking it off site to another treatment facility. If all else fails, boiling is always a good alternative for those items for which that is possible, as it destroys most microorganisms and is a low cost, readily available technology.

Alternative solutions may not have to be final. For example, if sterilization is required you may need to apply decontamination methods first and then store the material (as it is now safe but not sterile) until such time as sterilization becomes possible.

Staff training

A good waste management plan will only be as good as the training given to those that need to implement it. So please take the time and ensure that everyone is trained on all aspects of the plan. Even if you are not the laboratory manager or safety officer, you should make sure that everyone in the laboratory or animal room you are working in is trained so that everyone handles all waste correctly. Their mistakes may result in contamination of the laboratory and potential laboratory acquired infections.

Safety Equipment

As in any industry or occupation, safety equipment can be and should be used to protect people from the hazards of the working environment. In the biomedical facility, safety equipment can be categorized into two main sections. These are *personal protective equipment* (what one wears) and *primary containment devices* (often ventilated enclosures). In this section, we will explore each of these categories of safety equipment in detail and again provide a range of options you can chose from based upon your risk assessment and resources.

Personal protective equipment (PPE)

As the term states, personal protective equipment (PPE) is "personal" which means it is used by one person to protect only themselves. This type of safety equipment is usually considered a last resort for protection after the other methods of controlling the hazard have failed. It is the least powerful of the controls (as shown previously) and should not be relied upon alone to provide protection. PPE should always be used in conjunction with other controls to manage workplace biorisks.

Based on the risk assessment PPE should be used to block the various portals of entry pathogen(s) may use to enter the worker's body. As a reminder, the four primary ways by which a pathogen may enter the body are: a) inhalation; b) ingestion; c) mucous membranes of the face; or d) percutaneous (breaks in the skin). based upon your knowledge of Depending on how the pathogen is being used in the workplace and how it may infect the worker, various types of PPE can be used to block potential routes of exposure (e.g. Figure 41).

Figure 41

First and foremost, you should select PPE that will block the portal of entry of the pathogen based upon the type of exposure anticipated. For example, if your work may generate infectious aerosols, and the pathogen can enter the body via the respiratory route, then you must use a respirator. If you use knives or scalpels, you should use hand protection (e.g. cut resistant gloves) that protects from cuts. Other factors that must be considered when selecting PPE include:

a) Disposable (single use) or reusable materials. Using disposable PPE decreases the possibility of further exposure from contaminated PPE, but increases the cost of purchase and disposal. Reusable PPE may become contaminated and expose the next wearer, requires storage space, and requires that the equipment be cleaned; however, it is less expensive. Reusable PPE should have a specific and dedicated place near the exit of the facility for storage between uses. No personal belongings or clothing should be stored with this reusable PPE.
b) Fit. PPE must fit the wearer well (not too loose or too tight) to ensure maximum comfort and safety. For example, if gloves are too big, they will create a hazard in themselves and not protect the wearer.
c) Durability. PPE must not be so poorly made or thin that it does not work well or last long enough to protect the worker. You should consider shelf life and environmental stability. For example, if gloves are very thin and easily tear, they will need to be changed frequently, which is not cost effective.
d) Cost. Very affordable (cheap) PPE may not be very good and conversely very expensive PPE may not be affordable.

e) Comfort and wear ability. PPE must be comfortable enough that a user will not be reluctant to wear it during the time needed. For example, if the chosen PPE makes a user too hot, impedes their senses, is too heavy, or constrains their breathing, it will probably not be used correctly or for the necessary time period.
f) Regulations. In some countries, authorities may specify the type of PPE required for certain occupations. You should always be aware of the government regulations for your occupation, including required PPE.
g) Additional features. PPE manufactures may provide additional features for convenience or added safety. For example, a gown may have pockets or knit elastics cuffs.

This section will briefly look at several PPE options that you might select for work in the laboratory, animal house, or field.

Body protection. This PPE is often worn over other clothing to create a barrier between any potential biohazards and the worker's skin or clothing. Because it may become contaminated, it should always be left at the location where the biohazard contamination may have occurred, and should be changed or cleaned frequently. Examples follow.

a) Laboratory coat (Figure 42) - This garment is associated with the biomedical profession. It is typically white and front-buttoning, with pockets. While it symbolizes the profession. It is not very good PPE. It should only be used in very low-risk situations, and is not suitable for animal rooms or most laboratories. Because it is front-closing, with gaps and openings, it does not adequately protect the worker's front. Some styles wrap across the front of the body and close on the side; these are better and give more protection. Pockets are often misused (including to collect contaminated materials) and should not be present.

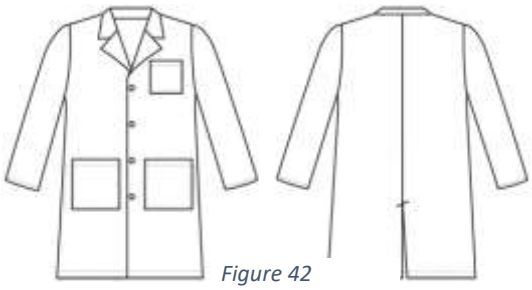


Figure 42

b) Gown (Figure 43) – this garment is better suited for use in most biomedical situations because it is rear-closing (protecting the worker's front completely), has no pockets and is usually long-sleeved with knit cuffs. If the gown is selected, the choices for further customization include: color, size, length, sleeve length, thickness of material, closure type.

Figure 43

c) Apron (Figure 44) – this garment is usually added on top of other body PPE to add an additional layer of protection to the front of the body. In the biomedical environment this is usually for additional splash protection from liquids, as the other body PPE is typically not water-resistant. Aprons usually drape around the neck and tie in the back. They can be made of a variety of different materials, lengths and styles. This is good for the necropsy areas.

Figure 44

d) Coveralls (Figure 45) – this garment covers the user from head to toe and is therefore suitable in environments where there is potential exposure of biohazards to the entire body (e.g. working with animals and field work). Typically, the wearer must sit down to don and doff this garment and therefore additional space and something to sit on must be provided. Additional selection choices include size, color, material type and thickness, closure type (zip, button or snap), attached boots, attached hood and sleeve length.

Figure 45

e) Nursing uniform or scrubs (Figure 46) – this type of PPE is usually two parts (bottoms and top) and is worn instead of the user's personal clothing. This is ideal for higher risk work where no personal clothing should be worn into the area where pathogens are being handled. This requires a place in the facility where the user can leave their personal clothing and change into this uniform. Typically, other body protection (described above) is worn on top of this uniform. Additional selection choices include size, color, material type and thickness, closure type (zip, button or snap for the bottoms) and sleeve length.

Figure 46

Option: If you don't have the ability to buy any of the above body protective PPE there is an alternative. You can just use normal clothing (e.g. pants, shirts, skirts, dresses, head covering) that covers as much of the body as possible. This clothing should be considered "dedicated" clothing for the laboratory and should be left in the biomedical facility where it is used. This clothing still forms a barrier between the worker and the biohazard and can be cleaned or disposed of and therefore, serves a valuable purpose. Any piece of plastic with a string can be used as an apron, if there is a splash hazard. Do what is local, practical and sustainable.

Hand protection – The worker's hands are the part of the body in closest contact with the biohazard, therefore proper selection and use of this PPE is very important. While there is a very wide range of glove types (e.g. Figure 47) available, only a few different types will be presented here. Some important factors to consider when selecting a glove type include resistance to penetration from chemicals and biologicals, abrasion resistance, length, thermal resistance and fit.

Figure 47

Please keep in mind that you do not have to use just one glove type at a time. Often it is desirable and useful to wear two pairs of gloves, because each provides a different type of protection from different hazards. For example, you may wear a pair of disposable nitrile gloves to protect from pathogens under a pair of cut/puncture resistant gloves to protect against percutaneous injury.

a) Disposable (single use) glove types include (not an exhaustive list)

    i) Latex—A natural rubber material that offers good resistance to many acids and bases when it is used in a reusable glove. Latex gloves offer very limited chemical resistance. Natural rubber offers reasonable abrasion resistance.
    ii) Nitrile—A synthetic rubber material that offers resistance to a variety of chemicals and good resistance to abrasion. It makes a good general-duty glove.
    iii) Butyl—A synthetic rubber material that offers the highest permeation resistance to gas and water vapors of all of the materials. This is especially suited for use with esters and ketones.
    iv) Neoprene—A synthetic rubber material that provides excellent tensile strength and heat resistance. Neoprene is well suited for many acids and caustics. It offers moderate abrasion resistance.
    v) Polyvinyl Chloride (PVC)—A synthetic thermoplastic polymer that provides excellent resistance to most acids and fats, and many hydrocarbons.
    vi) High density polyethylene (HDPE) - A synthetic thermoplastic polymer that provides economical protection from mild chemicals, oils, fats, punctures and abrasions.

b) Reusable

    i) Long rubber gloves – these would be suitable for washing glassware or handling chemicals (if appropriate for the chemical).
    ii) Thermal (hot/cold) resistant gloves – highly thermal resistant gloves are needed when handling very cold (-80C, liquid nitrogen) or very hot (autoclave) materials.
    iii) Leather gloves – these are often needed when handling animals that can bite or scratch.
    iv) Cut/puncture resistant gloves – when handling sharp objects that can puncture or cut the skin, workers should be wearing cut/puncture resistant gloves.

Option: If you do not have the resources to obtain any gloves, you should carefully consider the hazard. Chemicals can be very dangerous and should not be handled without some protective layer because many can penetrate intact skin. However, many biological agents do not penetrate intact skin and therefore work may continue if you are very careful not to break the skin. Your hands will become contaminated; therefore, you MUST wash your hands very thoroughly with soap and water after work. Obtain disposal gloves as soon as possible!

Eye protection

Wearing eye protection while working with potentially infectious pathogens is vital when there is a splash potential. The mucus membranes around the eye will readily absorb any pathogens and potentially create an infection in the worker. There are a variety of comfortable and affordable choices to protect your eyes and mucus membranes and therefore no reason not to wear eye protection. All the options are reusable and may potentially last a very long time, providing life-long protection.

a) Goggles (Figure 48) – goggles are tight-fitting to the face and therefore provide the best protection from any splashes coming from any direction. They can be worn over prescription eyeglasses and can be coated with anti-fog solution to prevent clouding from perspiration.

Figure 48

b) Safety glasses (Figure 49) – these glasses are typically used more to protect against flying objects from hitting the eye, but can be used in a biomedical facility, based upon a risk-assessment. Because they are not tight-fitting to the face, they may allow a splash to enter the eye from the side, but may be more comfortable to wear than goggles and they are less likely to fog.

Figure 49

c) Face shield (Figure 50) – a face shield is usually worn in addition to other eye protection options, but could be worn independently, based upon your risk assessment. A face shield easily fits on every head and will provide some impact and splash resistance. However, because it is open on the sides and bottom it may not be completely effective on its own. Some shields are UV resistant and therefore, also useful to protect the eyes from the UV hazards in the facility.

Figure 50

Options: If resources do not allow you to obtain any of the above eye protection options you need to consider other simple ways of putting a barrier between your eyes and the biohazard splash risk.

1) Any piece of transparent plastic will work. Please do not use glass, as this is introducing another hazard. A piece of plastic that can be supported on the bench as a shield between your eyes and the biohazard will work.

2) A face shield can easily be made out of light plastic material and attached to a headband of some type.

Mouth and nose protection

The mucus membranes of the mouth and nose can be readily contaminated in a biomedical facility from splashes, sprays or hand contact (face touching). Therefore, it is important to protect these mucus membranes of the nose and mouth with a barrier. In addition, these masks will also provide a barrier to contamination of the product with human saliva and commensal pathogens that may be accidentally released from the worker. The respirators, in addition to providing respiratory protection, also provide a barrier to incoming and outgoing pathogens and will be discussed below. Please make sure you are very clear that a surgical mask or dust mask will NOT stop aerosols from entering your respiratory tract. This includes infectious bioaerosols and vapors of harmful gases.

a) Surgical mask (Figure 51) - As the name implies, the surgical mask was invented to prevent surgeons from infecting their patients. It does prevent the user from expelling materials (e.g. contaminated saliva), but it also is the simplest and most affordable choice to protect the mucus membranes of the nose and mouth of the user from incoming contaminated materials. They come in a variety of styles, shapes and colors, but are essentially all the same. In its simplest forms, it consists of paper and plastic materials that are light and readily allow air to flow through, but block large particles from penetrating. Typically, masks have three layers: an inner white layer that absorbs moisture, a middle layer that filters the aerosolized particles, and an outer, colored layer that has some liquid resistance. They never fit tight to the face and therefore, air can and will flow around the side of the mask. Typically, they are single use and should be discarded after use, because they may become contaminated. However, they may be reused for a limited time if your risk assessment allows.

Figure 51

b) Dust mask (Figure 52) - Made of paper, it fits over your nose and mouth allowing air to flow through, but blocks large particles from entering through the material or directly contacting your mucus membranes.

Figure 52

Option: If resources do not allow you to obtain either of the above face mask protection options you can always source a locally produced mask made of cloth. With instructions, nearly anyone can cut and sew new or old fabric into an appropriate shape with ties at the top and bottom. Be sure the material isn't so thick that it is difficult to breath. A cloth mask will serve as a barrier to splashes to the face and will prevent the worker from contaminating the product. It is reusable by simple washing with soap and water. Do what is local, practical, and sustainable.

Respiratory protection

If, based upon you risk assessment, you believe there is a risk of inhaling infectious aerosols (e.g. Figure 53) then you need to wear a respiratory. Respirators, unlike the mask above, actually filter all the air that you breath because they fit tight to your face. Air filtering removes small particles from the air, but NOT gases. For a more in-depth discussion of respirators and how they work the reader is referred to the National Institute of Occupational Health and Safety (NIOSH).[7]

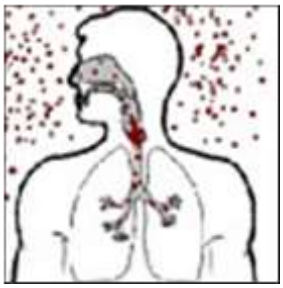


Figure 53

Respirator types include the following:

a) Filtering face mask - N95/FFP2/KN95 (Figure 54)

The simple filtering face mask is the most affordable choice of all the respirators. It can be used by most workers, but has limitations. Most important, it only works if it fits tight to the face of the user; therefore it MUST be fit-tested before use. If the wearer has facial hair or facial deformities the mask will not fit tight. For a full description of how to do a fit-test the reader is referred to the NIOSH website.[8] The mask must be carefully donned and doffed to ensure it is not deformed. Once in place the user should do a quick "seal-check" to ensure that the fit to the face is tight. The mask may be reused several times based upon your risk assessment.

Figure 54

[7] The National Institute for Occupational Safety and Health (NIOSH), USA Centers for Disease Control. See https://www.cdc.gov/niosh/index.htm.

[8] The National Institute for Occupational Safety and Health (NIOSH), USA Centers for Disease Control. See (https://www.cdc.gov/niosh/npptl/hospresptoolkit/fittesting.html).

b) Half-face respirator or painter's mask (Figure 55)

Figure 55

The half-face respirator, as the name implies, covers half the face of the user and is made of silicone rubber and elastic materials. This may provide an easier and better seal to the face than a paper mask. Filtering of air is provided by cartridges that attach to the side or front of the elastomeric mask. These filters can be changed regularly and even substituted with ones that remove gases, thereby making this respirator very versatile. Easily surface decontaminated, it can be reused. It also needs to be fit-tested to ensure that it is filtering all the air and potentially infectious aerosols.

c) Full-face respirator (Figure 56)

Figure 56

The full-face respirator, as the name implies, covers the entire face (eyes, nose and mouth) providing complete protection to the mucus membranes of the head and the respiratory track. This is an expensive option for respiratory protection and would be needed if the air contained gases that damaged the eyes. It is similar to the half-face respirator in that it is made of plastics and rubber, but a full-face respirator contains a glass window. It must also be fit-tested to ensure that it is filtering all the air and potentially infectious aerosols.

d) Powered Air Purifying Respirator (PAPR) (Figure 57)

Figure 57

The powered air purifying respirator, is similar to the full-face respirator; however, it has a motor that provides filtered air to the inside of the mask (hood) and the breathing zone of the user. There are different styles and types of PAPR, but, essentially, they are all the same in that they use filters to remove infectious aerosols. They then provide that filtered air to the user, creating a positive pressure of air inside the mask (hood) allowing the air to flow out. These respirators provide a very high degree of protection, but are very expensive. Similar to the full-face respirator, other cartridges can be used to filter out gases. Because there is positive pressure inside the mask they do not need to be fit-tested and therefore anybody can wear them.

Option: Since these are expensive to buy, you may be able to get someone locally to make something similar. All you need is a hood and some method of pushing HEPA-filtered air into the hood. Do what is local, practical and sustainable.

e) Self-contained breathing apparatus (SCBA) (Figure 58)
The SCBA is completely self-contained and can be used in areas where there is no or limited oxygen. It has its own supply of air and is mainly used for entering spaces that are life-threatening due to toxicity or lack of oxygen. These are often used by fire fighters. This apparatus is beyond the scope of this book and is rarely, if ever, needed in a biomedical facility.

Figure 58

Option: If resources do not allow you to obtain any of the above respirators, you will have to determine if the benefits of doing the work outweigh the risks. If you must proceed, you may be able to implement directional airflow to move infectious aerosols away from the breathing zone. Try to work upwind of the aerosol source if outside, set up a fan to blow air away from the worker, or use an extractor to pull air away. If you still do not feel safe, try and find another facility or laboratory that can do the work safely. Do what is local, practical, and sustainable.

Foot protection

a) Close-toed shoes
Ideally, workers should have dedicated laboratory shoes that are only worn in the biomedical facility. Any shoes that are worn in the laboratory should be closed-toed to ensure that skin and socks are covered and to provide protection of anything dropping on the toes.

b) Shoe covers (Figure 59)
If dedicated laboratory shoes cannot be used, it is possible to cover shoes with disposable plastic or cloth covers. A risk assessment must be done to determine if there is value in using these. They add to the cost of operation, are difficult to don and doff, and provide limited practical biosafety value.

Figure 59

c) Rubber boots
Rubber boots may be needed in wet environments, such as in an animal house or field work. These must be sized to the user and should be decontaminated as needed.

d) Steel-toed boots
If working with large animals that may step on the worker's toes, steel-toed boots are required to prevent physical injury.

Head protection

a) Disposable hair net (Figure 60)
A hair net is often used in the food industry to prevent contamination of the product. In the biomedical facility this may also be required. It prevents the hair or head from becoming contaminated if there is dust or materials in the air. Based upon your risk assessment a hair net may be appropriate PPE for example, when working with animals that are in open caging.

Figure 60

b) Helmet (Figure 61)
If working in an area where the head could be hit with falling objects or impact an overhead structure, a helmet may be appropriate. This is not usually needed in a biomedical facility, except maybe by the maintenance staff.

Figure 61

Hearing protection

Hearing protection may be needed in a biomedical facility when working around very loud equipment (e.g. sonicator) or when working with animals that make high decibel noises (e.g., pigs).

a. Ear plugs (Figure 62)
Ear plugs are the most cost-effective way of physically blocking noises. The best types are those used in the safety industry; these fit snuggly into the ear and block out most noise.

Figure 62

b. Ear muffs (Figure 63)
This hearing protection goes over the ear and can be used by multiple users, since it isn't personal. However, it should be surface cleaned between user. It provides good protection from loud noises, but is bulky.

Figure 63

Options: Do what is local, practical and sustainable. You can use almost any soft material put into the ear canal, which can be easily removed to dampen the sound level.

Primary containment (ventilated enclosures)

When working with any hazardous material (biological or chemical) in a biomedical facility, the first priority should always be to keep the hazard contained so that it cannot affect the worker, contaminate the environment. or impact the product. Therefore, as much as possible, the hazard should be contained within primary containment. One definition of primary containment is a device or container that is in direct contact with a hazardous material and is designed to limit the effects of harmful byproducts by reducing the risks of environmental and

human contamination. Since the container enclosing the hazard will need to be opened, the initial primary containment is lost. Therefore, addition primary containment in the form of a piece of safety equipment needs to be added, within which the container is opened. This safety equipment (e.g. biosafety cabinet) provides primary containment via a partial enclosure (walls) and directional airflow to a work surface to keep the aerosol hazards contained. While there are many primary containment devices, the following are most commonly found in a biomedical facility.

Note that each of these ventilated enclosures is different; each has a different purpose. The laboratory worker must be able to recognize the different types of cabinets and use the correct one for the purpose it was intended for. The cabinets can protect the worker, the product, or the environment, but not all of them can provide all of these protections. Therefore, it is important to recognize what protections each cabinet provides and to use it correctly. A fume hood only protects the worker; a clean bench only protects the product; a biosafety cabinet can protect the worker and environment (depending upon the type), as shown in the table below.

Many of these cabinets provide protection by passing air through high efficiency particulate air (HEPA) filters. These HEPA filters remove 0.3 microns particles with 99.97% efficiency. The filter is made of borosilicate fibers mounted on aluminum separators (Figure 64). Particles which are smaller or larger are removed with even greater efficiency. The filter works by three different mechanisms to trap particles (interception, impaction and diffusion – Figure 65) which allows it to trap particles of all sizes with equal to or greater than 99.97% efficiency. For the cabinet to provide protection, <u>all</u> the air moving through the cabinet <u>must</u> pass through the filter. Therefore, the filter must be sealed tight to the frame of the cabinet; the filter must not be blocked with dust; and the filter must not have holes. Regular BSC certification by a certified professional provides assurance that the HEPA filters are indeed filtering all the air properly. If greater filtering efficiency is desired

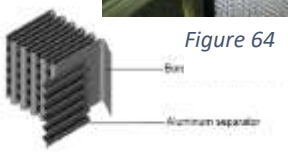


Figure 64

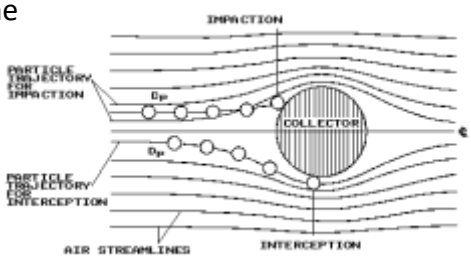


Figure 65

Primary Barrier	Personnel	Product	Environment
Fume Hood	x		
Clean Bench		x	
BSC Class I	x		x
BSC Class II	x	x	x
BSC Class III	x	x	x

or needed, Ultra-Low Particulate Air (ULPA) filters can be substituted for the HEPA filters, providing filtering efficiency of 99.999% at 0.3 micron. This is rarely or ever needed in a typical biomedical facility.

Chemical fume cabinet

This book pertains mainly to working with biological hazards, but chemicals are often used in the biomedical facility and are often mixed with biologicals. Therefore, chemical fume cabinets (Figure 66) will be briefly reviewed.

Figure 64

Two main types exist, ducted and recirculating (ductless). The principle is the same for both types, where air is drawn in from the front of the cabinet and either exhausted directly outside the building or filtered back to the room. Direct ducting to the outside is better, as there is no risk of chemicals, gases, or fumes being returned back to the workers in the facility. However, this requires physical ducts and an external exhaust fan.

The main function of a chemical fume hood (cabinet) is to keep all chemical aerosols and gases away from the worker (Figure 67). Therefore, this type of cabinet only protects the worker and not the product (because room air is drawn into the cabinet) or the environment (because there is no filtration of the exhaust air).

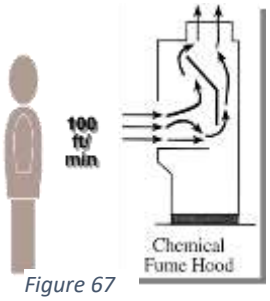


Figure 67

Having a fume hood in a biomedical facility is important if you are using chemicals; however, you must use it correctly and realize its limitations. The reader is referred to the internet for other resource information on fume cabinets as well as many excellent videos on their proper use.

Option: If resources do not allow you to obtain a commercially built fume cabinet, you may be able to fabricate one locally using wood or metal. The principle is to have an enclosure with a small opening at the front, through which air flows inward. Basically, any enclosure with a fan drawing air into the cabinet and away from the worker will work. If you do not have electricity to power the fan you may attempt to use convection air flow. If the air in the exhaust tube is heated by the sun (or other heat source) it will rise, drawing air into the cabinet (a solar chimney – Figure 68). This will not be high volume or rate of air movement, but it will help to draw aerosols, gases, and fumes away from the worker.

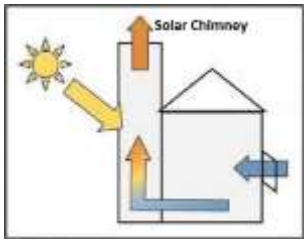


Figure 68

Clean bench (laminar flow cabinet)

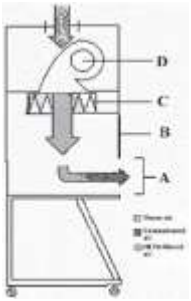


Figure 69

The clean bench (cabinet) or laminar flow cabinet is a bench for clean work with laminar (parallel lines) air flow. Two main types exist, vertical (Figure 69) or horizontal (Figure 70). Both are essentially the same, with air being drawn into the cabinet through a HEPA filter and then being pushed to the work surface either vertically (from the top down) or horizontally (back to front), with the air flowing out toward the worker (as shown).

This type of cabinet is designed to protect the product, but not the worker or the environment. Therefore, this cabinet should never be used when there are any hazards (chemical or biological) present in the product, as these hazards may be blown toward the worker and the room (as shown by the airflow in the diagrams). This cabinet should be used only for sterile microbiological work, such as pouring bacteriological media or handling sterile liquids (e.g. making PCR master mix, etc.). It should not be used for doing cell culture work, as cell cultures are living organisms which contain pathogens and may be cancerous cells. Readers are referred to the internet where they will find other resource information on clean benches and many excellent videos on proper use.

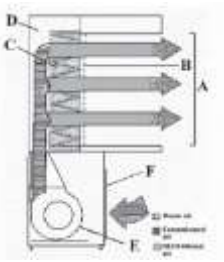


Figure 70

Biosafety cabinets

The biosafety cabinet (BSC) is by far the most important piece of safety equipment in a biomedical facility. Every laboratory should have at least one. There are three classes of BSC, I, II (five types), and III. It is important to know the differences between the classes and types of cabinets when making a risk-based decision regarding which cabinet to purchase. Users must be trained on how to use the cabinet correctly, and the cabinet should be certified for functionality on a risk-based time period.[9]

Class I This cabinet protects the worker and the environment, but not the product. It protects the worker by drawing air away from the user through a front opening and it protects the environment by HEPA filtering the exhaust air (Figure 71). It has a low intake air velocity or directional speed of 75 ft/minute into the cabinet through the sash opening. Class I cabinets are suitable for opening received samples, housing a centrifuge, changing animal cages, or doing necropsies--any work where the sterility or cleanliness of the product is not important.

Figure 71

[9] Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, USA Centers for Disease Control and the National Institutes of Health, 2009. See https://www.cdc.gov/labs/BMBL.html

Class II This cabinet protects the worker, the environment, and the product. It protects the worker by directing inflowing air away from the user, and it protects the environment and product by HEPA air filtration. There are five types: A1, A2, B1, B2, C. Type A cabinets can be free-standing in a room and do not require any services, other than electricity. Type B and C cabinets MUST be hard-ducted (directly connected to an exhaust duct with an additional fan). Therefore, these are harder to install, operate, and maintain Type A cabinets. Type B and C cabinets are selected and used when the work creates large aerosols of volatile organic vapors, small amounts of radionucleotides, or obnoxious vapors. Because they function similarly to a fume cabinet, they exhaust a lot of air from the facility, creating inward direction airflow, and removing conditioned (heated or cooled) air from the facility, which is a waste of energy.

Type A1 BSC. (Figure 72) Like the class I cabinet, the A1 cabinet also has a low intake velocity of 75 ft/minute. 70% of the air is recirculated back to the work surface through a HEPA filter and 30% is exhausted through a HEPA filter into the room. Due to the low intake velocity and that the plenum is under positive pressure, this is not a good choice for a BSC.

Figure 72

Type A2 BSC. (Figure 73) The A2 cabinet is probably the most popular of all the types of cabinets. It was originally called a B3 cabinet. It has an intake velocity of 100 ft/minute, which is higher than the Class I or Class II, type A1 cabinets. This provides better containment, as the air curtain is less likely to be disrupted. The plenums are under negative pressure because the fan motor is now at the top of the cabinet, as opposed to the bottom. Again, 70% of the air is returned back to the cabinet working surface and 30% of the air is exhausted through HEPA filters.

Figure 73

When exhausting a class II A2 BSC you have two choices. You can exhaust the HEPA filtered air back into the room or you can exhaust it through a canopy to the outside. There are advantages and disadvantages to both approaches. The simplest and easiest is to just put the cabinet in the room with the air being exhausted directly back into the room. The other option is to use a canopy connection in which the cabinet exhaust vent is directly under a thimble or canopy, which collects all the BSC exhaust air and pulls it out of the room (Figures 74 and 75). In addition to collecting all of the exhaust air from the BSC, this thimble exhaust also removes some of the room air as well. This of course requires a building duct and a strong external building exhaust fan. Although this option has the disadvantage of forcing the cabinet to remain in one place, it does give extra protection, because if the exhaust HEPA filter fails (allows infectious aerosols to escape)

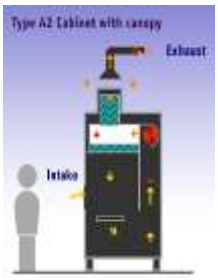


Figure 74

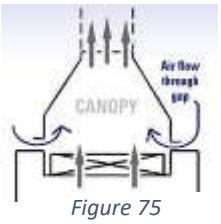


Figure 75

the infectious aerosols will be captured and drawn out of the room. Because the canopy captures all the BSC exhaust air and additional room air from the laboratory, it also creates some inward directional airflow into the laboratory.

Type B1 BSC. (Figure 76) The B1 cabinet has 30-40% recirculated air and 60-70% exhaust air, depending upon the manufacturer. The B1 cabinet also has a special feature, in that the air exhausted from the back of the cabinet is 100% exhausted. This allows the cabinet to be used for chemical or radionucleotides (similar to a fume hood) if you work in the back of the cabinet. This is helpful when working with volatile organic chemicals such are formalin for pathology so that all of those gases are drawn away. Therefore, these cabinets are a combination of a fume cabinet and a biosafety cabinet.

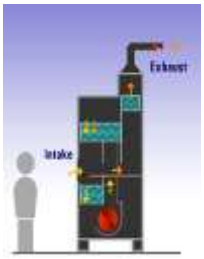


Figure 76

Type B2 BSC. (Figure 77) The B2 cabinet has a 100% air exhaust through HEPA filters to the outside. So, it is really like a fume cabinet, because it's taking all the air that it draws in and exhausts it to the outside. However, unlike a fume hood, the exhausted air and the air being returned to the work surface is HEPA filtered. This can be good if you're working with small amounts of radio nucleotides or volatile organic materials and infectious aerosols.

Figure 77

All class II B cabinets must be hard ducted to the outside. There has to be a physical hard connection between the building duct work and the biosafety cabinet. There's no canopy, there's no gap, and therefore no possibility for the air to go back into the room. This type of connection requires another exhaust fan in the building duct which pulls air from the BSC, in addition to the exhaust fan that's in the biosafety cabinet. The building exhaust fan (that's pulling air from the biosafety cabinet) must be working for the BSC to function correctly. Therefore, both the BSC fan and the building exhaust fan have to be interlocked. This way, if one breaks down, they both have to stop. Therefore, these cabinets are complex to install and operate, because they are now physically fixed and can only be in one place. They have to have dedicated duct work and an additional dedicated building exhaust fan, which are electrically interlocked. So, before you order and install a B cabinet you have to think very carefully about why you need this type of cabinet.

Type C BSC. (Figure 78) The class C biosafety cabinet is very much like a B1 cabinet, because it too has a variable amount of exhaust air. It has a 100 ft/minute inflow velocity with 50% of the air recirculated or exhausted through a HEPA filter. It has a special depression in the middle of the cabinet working surface, where 100% of the air is exhausted. Therefore, this cabinet, like the B1, can also be used for small amounts of chemicals or volatile organic vapors.


Figure 78

Class III (Figure 79) This cabinet protects the worker, the environment, and the product. It protects the worker by being completely closed and it protects the environment and product by HEPA air filtration. This is a completely enclosed gas-tight cabinet for which access to the product is through gloves built into the front, as shown. It has HEPA filtered air supply and double-HEPA filtered air exhaust. It has a 100 ft/minute inflow velocity, in case there is any leakage in the cabinet or there is a hole in the glove. There's no recirculation of air inside the cabinet. All the air that comes in, goes out. It provides complete containment, because the only way in or out for product is through a chemical dunk tank or through an autoclave that's connected on the side. This gives you a small, high containment space, for work with highly dangerous pathogens. It is expensive to buy, but it provides high containment for those times when you might have very high-risk work.

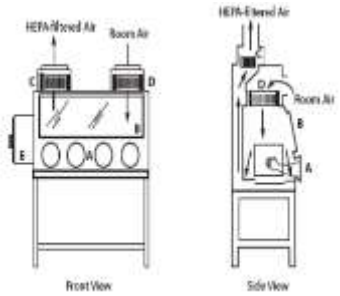


Figure 79

Biosafety cabinet selection and placement

What type of BSC you choose to buy and use depends a lot on the desired use. For most needs in a typical biomedical facility, a BSC Type II, A2 will suffice. Factors affecting your BSC purchase choice include: 1) What needs to be protected – the worker, the product, the environment?; 2) What types of work are being done in the cabinet?; 3) What types and quantities of chemical vapors will be generated by the work?; 4) If the cabinet requires a ducted ventilation system, is there an appropriate location for the cabinet and its ductwork? Further information on cabinet selection decisions can be found in the National Sanitation Foundation publication NSF49 Appendix E.[10]

Once a decision has been made regarding what type of cabinet to purchase, the user must also ensure the cabinet it located properly in the laboratory. As stated in NSF49 Appendix E[10], the cabinet should be located away from traffic patterns, doors, fans, ventilation registers, fume hoods, and any other air-handling device that could disrupt its airflow patterns. All windows in the room should be closed. The BSC should be located at the wall farthest from and facing the entry door. If this is not possible, the BSC should be located on the side wall perpendicular to the hinge side of the door. BSCs not connected to an exhaust system should have at least 12 inches (300 mm) clearance from the filter face and any overhead obstructions when the cabinet is in its final operating position, to allow for testing of the exhaust HEPA/ULPA filter.

All BSCs should be placed in a laboratory at a location that provides a minimum of:

— 6 inches (150 mm) from adjacent walls or columns.

— 6 inches (150 mm) between two BSCs.

[10] National Sanitation Foundation publication NSF49 Appendix E. https://www.nsf.org/newsroom_pdf/NSF_49-2016_Annex_E.pdf).

— 6 inches (150 mm) space between both sides of the cabinet and 6 inches (150 mm) behind the BSC to allow for service operations.

— 40 inches (1020 mm) of open space in front of the BSC.

— 60 inches (1520 mm) from opposing walls, bench tops and areas of occasional traffic.

— 20 inches (510 mm) between BSC and bench tops along a perpendicular wall.

— 100 inches (2540 mm) between two BSCs facing each other.

— 60 inches (1520 mm) from behind a doorway.

— 40 inches (1020 mm) from an adjacent doorway swing side.

— 6 inches (150 mm) from an adjacent doorway hinge side.

Further information on the different types of ventilated enclosures, situating them in the laboratory, and their certification can also be found in the United States guidance document, Biosafety in the Microbiological and Biomedical Laboratories.[11]

Options: If resources do not allow you to obtain a commercially built BSC you may be able to fabricate a cabinet locally using wood or metal (similar to the fume cabinet). The principle is to have an enclosure with a small opening at the front, though which air flows inward. Basically, any enclosure with a fan drawing air into the cabinet and away from the worker will work. If you do not have electricity to power the fan you may attempt to use convection air flow. If the air in the exhaust tube is heated by the sun (or other heat source) it will rise, drawing air into the cabinet. This will not be high volume or rate of air movement, but it will help to draw some infectious aerosols away from the worker. Unfortunately, it is difficult to fabricate HEPA filters locally, but you may be able to buy some. If you do not install HEPA filters on the exhaust, protection of the environment will not occur, but if it is exhausted away from susceptible species, dilution and sunlight will degrade the pathogen to the point of it no longer being infectious. If you do not install a supply HEPA filter, there will be no product protection. In this case, there is probably no need to supply air back to the work surface.

Certification of biosafety cabinets

Since biosafety cabinets are such an important piece of safety equipment, the user relies upon it to function correctly. This requires some specialized testing, by an approved testing individual, to certify that the cabinet is functioning as designed by the manufacturer.

Test equipment should be calibrated annually. The individual using the test equipment should have extensive training and be officially approved to certify the BSC. The field certifier may also

[11] Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, USA Centers for Disease Control and the National Institutes of Health, 2009. See https://www.cdc.gov/labs/BMBL.html

change the HEPA filters (if needed), repair the filters (if needed), and make adjustments to the BSC to correct deficiencies (if needed). Therefore, in most cases, a commercial company is paid to conduct the tests and certify the cabinet. Very large organizations with many BSC cabinets, may find it cost effective to have one of their own employees trained and to purchase their own test equipment, even though the equipment is expensive.

Field certification involves a series of tests to determine if the BSC is still operating according to the manufacturer's specifications. Two of the most common standards used for manufacturing BSCs are specifications from the National Sanitation Foundation (NSF 49) and the European Union (EN12469). In addition, several countries have their own national standards.

There are five primary certification tests for cabinets[8]. These are:

1) The down flow velocity test, which measures the velocity of air moving down into the cabinet from the supply filter.
2) The inflow velocity test which measures the velocity of air moving through the sash opening into the cabinet. That's the velocity of air that's protecting you because it's drawing air away from you.
3) The filter leak test which determines the integrity of the HEPA filters. Remember, in a class II cabinet there are two HEPA filters. One filter supplies air down to the work surface and the other protects the environment as the air is being exhausted from the cabinet.
4) The air flow smoke pattern test shows how the air is moving around the cabinet. Certifiers have to assess this to see if there are dead spots or leaks (indicated by smoke coming out of the cabinet).
5) The site installation integrity test to verify that the cabinet is in the right place, that all the alarms are working and that the cabinet is correctly connected to the building. For B type cabinets the certifier will check to see if the cabinet is hard ducted with an exhaust fan and that the fans are interlocked. If it is an A2 cabinet that has a canopy connection, the certifier will look for exhaust system performance alarms.

In addition, there are some extra secondary tests like UV intensity, sound, vibration, and grounding. If your cabinet fails any of those secondary tests, but passes the primary tests, it will still be certified, as the secondary tests are only optional and not required.

Field certification (or recertification) is required at the following times:

1) Before initial use. Even though it will be certified at the time of manufacture, the cabinet could be damaged in transit.,
2) After moving the biosafety cabinet. Moving could dislodge the filter from the frame.
3) Annually or on a regular basis, based upon your risk assessment. If the cabinet is not used often, you might extend the certification period to every two years. If it's used often and you want high assurance that the cabinet is working well, you may want to

recertify every six months. Your risk assessment should dictate your frequency of recertification.

4) After a filter replacement. This is usually done by certifiers when they test the cabinet. If your own staff replaces a filter, the BSC must be recertified.
5) After any internal cabinet repairs, such as a blower motor replacement.

The cabinet should be marked with the certification information somewhere on the outside of the cabinet. The certification sticker should indicate who did the work and when. The actual certification reports could be kept in the office with your logs. You need to keep a good record of each cabinet and when they were certified to prove that the cabinets are indeed working well. Keep in mind that the biosafety cabinet will protect you as well as you protect its functionality. Having it certified on a regular basis is a critical part of the overall process of keeping you, the environment, and your product safe.

Options: There aren't any good options to certifying the BSC because the apparatus is complex and requires the correct equipment. However, you can do some things to improve your confidence in the equipment's performance. You can hold tissue paper in front of the sash opening to confirm that air is indeed flowing inward (away from you). You can also generate some smoke outside and inside the BSC to observe the air patterns. Smoke can be produced with dry ice, commercial smoke guns. or even incense sticks.

Animal enclosures (individually ventilated cages)

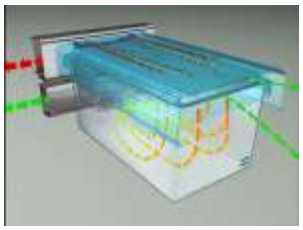


Figure 80

In addition to providing primary containment for samples being manipulated in the laboratory, primary containment can also be created for small animals that may be creating infectious bioaerosols. An individually ventilated cage (IVC) is a special type of animal enclosure incorporating HEPA filters for incoming and outgoing air. Figure 80, shows air going in on the bottom (green arrows) and potentially contaminated air being drawn out (red arrows). IVCs come in various versions and configurations, according to individual manufacturers; however, all designs provide complete containment of potential aerosols and allergens. The use of these cages will be discussed more in the animal biosafety section of this book.

Special enclosures

In addition, to situations requiring the above primary containment devices there are other circumstances when infectious aerosols, chemicals, gases or fumes need to be contained at the source, using other specialized equipment. For example, a fluorescent antibody cell sorter (FACS) machine creates a potentially infectious stream of particles, which should be contained. Special types of ventilated enclosures (cabinets) can be purchased in which the machine can be housed.

Some containment devices can be manufactured on site under unique or special circumstances. An enclosure made of flexible plastic can be fabricated to provide complete or partial containment of infectious aerosols. To create containment spaces of various sizes, it is not difficult to plastic bubbles with supply and exhaust fan moving air though HEPA filters.

Facilities

As discussed previously, the three main components to building a sound biorisk mitigation program include: 1) personnel practices and procedures (what you do); 2) safety equipment (including PPE); and 3) the facility itself (design and features). This section will cover some of the main features of basic biomedical facilities and then discuss various additional enhancements that can be added, based on assessed risks. Further information on facilities design from Canada[12], USA[13] and Australia[14] are also available on the internet as examples.

Some of these features create "secondary containment." Primary containment protects the worker; secondary containment enhances and overlaps primary containment by adding another layer of protection. Secondary containment is often thought of as protecting the environment because it keeps microbial pathogens inside the facility.

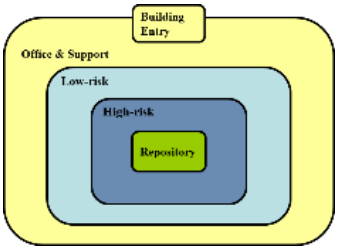


Figure 81

Facilities should always be designed or configured to ensure that no-risk (office space) or low-risk spaces are on the facility periphery and higher-risk spaces are on the inside (Figure 81). All spaces where there is no risk or low risk should be located together. Workflow should be organized and supported by the facility design, such that people move from non-contaminated areas (office, change rooms, dining area) to working areas (laboratories, animal rooms, etc.) in a linear fashion. The facility design should allow for two-way traffic into and out of spaces and support the use of PPE and other safety equipment as needed, when transitioning between spaces.

[12] Canadian Biosafety Guidelines, Containment Level 1: Physical Design and Operational Practice. 2017. https://www.canada.ca/content/dam/phac-aspc/documents/services/canadian-biosafety-standards-guidelines/guidance/containment-level-1-physical-design-operational-practices/pub-eng.pdf

[13] Design Requirements Manual, USA National Institutes of Health, 2020 https://www.orf.od.nih.gov/TechnicalResources/Documents/DRM/DRM1.503262020.pdf

[14] Safety in laboratories - Microbiological safety and containment. AS-NZS 2243-3. Ed 6, 2010 https://shop.standards.govt.nz/catalog/2243.3:2010(AS%7CNZS)/scope

Basic biomedical facility features

Figure 82

Any biomedical facility (e.g. laboratory, animal room, hospital room, diagnostic facility, necropsy room) is a specialized, dedicated space built to conduct a specialized activity (Figure 82). Therefore, it is not an office, or house or industrial space or any other space that was built for another purpose. Spaces specifically designated for work with microbial pathogens should have specific design features that support effective biorisk management. If certain facility features are absent or incorrect, this makes biorisk management more difficult. Therefore, it is essential that a facility handling microbial pathogens is designed or renovated to include essential features required to conduct the work safely. The main features are as follows:

1. The room (including walls, floors, ceiling, doors, and windows)
   A biomedical facility where pathogens are being handled needs to be a closed space. Working in an open environment (where there is no secondary containment) should be avoided, except in limited circumstances for field work (e.g., sample collection). At a minimum, a laboratory or animal house must have walls, floors, and ceilings to adequately enclose the space and define it as a special area where microbial pathogens can be handled.

   The main room can be further subdivided into smaller rooms for specialized functions (e.g. fluorescent microscopy, storage, etc.). Each of these rooms may be constructed of the same materials as the main facility or other materials depending upon the function.
   a. Floors and walls
      i. As much as possible these surfaces should be cleanable. This means that they should be made of materials or coated with a material that can be easily surface decontaminated with the typical liquid disinfectants used in the facility. There should be no cracks or crevices, paint should not be peeling, and all the surfaces should be readily accessible for surface decontamination.
      ii. Ideally, the floor and the wall should meet in such a way that there is no seam (space between the wall and floor) that could complicate cleaning. This seamless junction is often called a coved edge (Figure 83) and can be achieved in a number of different ways.

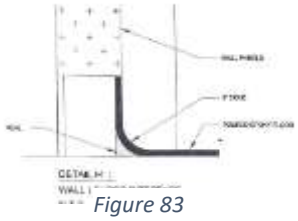


Figure 83

      iii. In laboratories, floor drains are not recommended because they may allow vermin and insects to enter the facility and pathogens to accidently escape into the sewer. In animal rooms, floor drains may be necessary to aid with washing the room thoroughly after use.
      iv. All penetrations through the wall or floor should be sealed to prevent vermin and insects from entering. Penetrations are any objects that interrupt the

uniform sealed surface, such as windows, doors, and utility entries (gas, water and electrical lines).

b. Ceilings
    i. Ideally these should also be cleanable, but in practice are often not made of the same materials as the walls and floors and are typically not surface decontaminated on a regular basis
    ii. There should be no access to the facility through the ceiling for biosecurity purposes.
    iii. All penetrations through the ceiling should be sealed to prevent vermin and insects from entering.

c. Doors
    i. Ideally every room should have at least two doors to allow escape in case one exit is blocked. Understandably, this is not always possible. Doors can be designed as "exit only" doors which do not have a handle on the outside. These only open from the inside via a handle or push bar and are used for emergency exit only.
    ii. The door should ideally have a vision panel (glass in the door) to allow observation into the laboratory before entering (for any hazards) and to allow people to see if the door is about to swing (for safety). (Figure 84)

Figure 84

    iii. Doors should ideally be equipped with automatic closers. these pull the door shut after it is opened (Figure 84).
    iv. All doors should have some means of locking for biosafety and biosecurity reasons. Interior doors that are used only by authorized staff during regular working hours may have a lock, though it may be rarely (if ever) used. Doors with card-swipe or key pad access are controlled via magnetic locks (show in Figure 84).

d. Windows
    i. Windows are desirable for the comfort of the worker, as they allow people to see out and natural light to enter (if on an outside wall).
    ii. Ideally widows should not be operable. However, this may not always be possible or desirable. If windows are opened there should be a process and method to ensure they are always shut and locked during off hours for biosecurity reasons. If they do open, they should, at a minimum, be fitted with tight fly screens in order to prevent vermin and insects from entering.

2. Casework (benches)

a. Benches should be made of materials and designed to safely support the weight of scientific equipment, such as incubators and centrifuges.
b. Ideally the benches should be easily movable to allow reconfiguration of the laboratory and to aid in cleaning. Benches on wheels will enable this.
c. Benches should be designed to allow easy cleaning underneath. Thus, if possible, benches should not sit directly on the floor, and should have open space underneath.
d. Bench surfaces must be easily cleanable and resistant to damage from liquid disinfectant solutions. This means they should be smooth, without any cracks, seams, ridges, or hollows, and be in good condition (no tears, blisters or holes).
e. Benches should have built-in storage for small laboratory consumables (e.g. gloves) and equipment. Ideally, these storage drawers should be reconfigurable to allow maximum flexibility for use. This allows for the cabinets under the benches to be easily moved around or removed (if necessary) to make room for equipment of further seating.
f. Lab benches should have spaces (e.g., knee holes) for comfortable seating. For proper ergonomics, workers should be able to position knees under the bench.

3. Utilities (water, power, gas, vacuum, drainage, ventilation)
    a. Power - There must be ample power to operate all laboratory equipment that may be used in the facility, as well as sufficient power outlets that can carry all anticipated power loads. Power outlets should be readily accessible and located in convenient places (such as on or under benches). Extension cords should not be used (or used on a very limited basis) as they can present fire hazards if overloaded.
    b. Sinks -
        i. Laboratory sink. One or more laboratory sinks should be provided in order to wash reusable glassware, decontaminate materials, dispose of liquids, and provide running water for diluting other materials. This sink should be different from the hand washing basin. It's usually a deeper sink made of special materials because of corrosive chemicals that may be used (Figure 85). It should be located at the end of the laboratory bench and be connected to the building via drain piping that is also resistant to the chemicals being used.

Figure 85

ii. Handwash basin. Handwashing is the most important hygienic principle people can adhere to, to prevent the transmission of communicable diseases. Therefore, a hand wash basin must be provided at the laboratory exit where PPE is removed; this will help ensure that people will wash their hands. The sink should be separate from the laboratory sink because the latter is used for disposing of chemicals and biologicals, and may be contaminated. A hand washing basin is specifically designed and dedicated for hand washing and should not be used for anything else. Ideally the taps should have hands-free operation to ensure they are not contaminated with dirty hands. Figure 86 shows a handwash basin that is foot operated.

Figure 86

Option: Even if you do not have a sink or running water, it is still very important to wash your hands after work is complete. Any basin of water with some soap can suffice. If you do not have access to water, use a hand sanitizer as a short-term substitute, but be sure to wash your hands with soap and water as soon as possible. Do what is local, practical, and sustainable.

c. Gas - The use of gas in a biomedical facility is discouraged because it presents an additional hazard; however, gas may be required to create a flame or heat for certain biomedical work. If gas is needed it should be limited to essential needs, and be limited in terms of amount and time used (to decrease the risk of fire or explosion). Therefore, piped gas services which run to all laboratories and are on all the time are highly discouraged. If gas is needed, it should be bottled and only brought into the facility in small amounts on an as needed basis.

d. Drains - Drains from biomedical facilities must be carefully and strategically used. Drains are an open penetration to the outside and, therefore, create biorisks, both from ingress of unwanted things and from egress of pathogens. There should be no more drains than the number that are essential to the operation of a facility. Unused drains should be capped and sealed. At a minimum, all sink drains should have a water trap (U or P trap) to create a barrier in the open drain. All drains must be made of material that is resistant to the corrosive effects of the chemicals that may be carried in them. Be sure to inspect drains frequently for leaks, and know where they drain to.

e. Ventilation - Any area where work is being done with microbial pathogens should have sufficient movement of air (fresh air in and old air out). At a minimum, there should be directional movement of clean fresh air coming in from the front of the facility (lowest risk) and flowing to the back of the facility, where it is removed.

Having a completely closed room which is cooled or heated, but where the air is recirculated is highly risky. Infectious aerosols, gases and smells will accumulate and create respiratory illnesses or diseases. How much air is moved through a facility, and how this is done, varies widely and depends on laboratory design and resources. Below are some options, ranging from the simplest and most sustainable to the most complex and expensive.

i. Convection devices. When warm air rises in a tube it will pull air into the bottom of the tube and create movement of air. This is also known as the chimney effect or solar tube in which air naturally flows up the chimney. Therefore, installing a chimney or tube at the back of a biomedical facility will immediately create some inward directional airflow into a room (Figure 87). The airflow will depend upon the height of the chimney, the size of the room, and the size (volume) of the chimney. If the air in the chimney is heated (for example by the sun) the air will rise faster and create more flow. This idea is totally sustainable, requires little to no maintenance, and no electricity. Unless the airflow is blocked, it should be fully reliable.

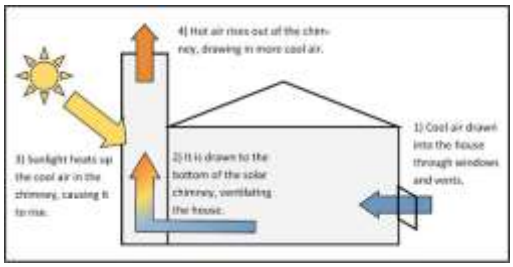


Figure 87

ii. Exhaust fans (Figure 88). These should be located at the back of the room. They require some electricity and maintenance, but will work very effectively at removing old air and allowing clean fresh air to flow in from the front. The amount of air movement will be dependent upon the number of fans, the size of the fans, and their speed. Be sure to exhaust the air up through the roof of the building (or through a wall to the outside where there are no susceptible people or animals).


Figure 88

iii. Operating fume cabinets. The operation of a fume cabinet or Class II, Type B cabinet (hard ducted) will create inward directional airflow into a room because these ventilated enclosures draw air out of the facility and exhaust them to the outside. Cabinets may be left on to achieve satisfactory air flow in a room.

iv. Thimble or canopy connections (Figure 89). These connections for a Type II, A cabinet will also draw some air out of the laboratory, creating inward directional airflow (see accompanying figure). They require an external exhaust fan which should be left on during working hours to draw air out of the laboratory.

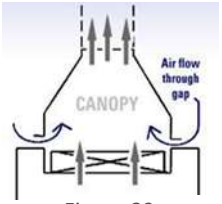


Figure 89

v. Ducted ventilation systems (Figure 90). These are the best way of moving air through a facility, but they are also the most expensive to build and maintain. This system uses ducts and fans to push fresh air into the room (supply air) and remove old air (exhaust air). The system also allows the user to condition (heat or cool) the air centrally, providing more uniform temperature and humidity control. Typically, these systems provide, single-pass air, in which none of the air is recirculated. Preconditioning air will add to the cost of running the facility.

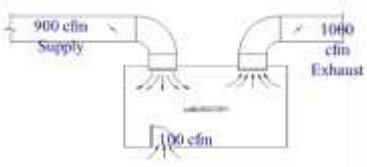


Figure 90

f. Lighting - For safety reasons it is very important to have sufficient light for workers, under all conditions and situations. Central lighting from the ceiling is often provided to illuminate the room; however, this may be inadequate for a task on the bench or in an animal room. Therefore, additional task lighting may be required. The amount of light available can easily be measured by simple light meters. In addition, consideration should be given to providing emergency egress lighting for times when power is interrupted. These units are wall mounted and battery operated, and provide enough light of sufficient duration to allow room occupants to close off their work and safely leave (Figure 91).


Figure 91

4. Safety equipment. This includes fire extinguishers, eyewash, chemical showers, and emergency kits:

a. Fire extinguishers - Most countries require fire extinguishers in laboratories. Ideally, these should be mounted on the wall (Figure 92), with proper signage. They should not simply sit on the floor because they may become inaccessible, lost, or knocked over. When designing a laboratory, consider the correct number and location for the fire extinguishers and allowing sufficient, accessible, and dedicated wall space for mounting. Fire extinguishers should be well-marked and at waist height.


Figure 92

b. Eyewash - Wherever biological materials or chemicals are used in a biomedical facility there should be a readily available eyewash station. These come in a variety of sizes and styles, but all function by providing running water to both eyes (Figure 93). The water should be clean, have a high flow rate, and be warm in order for a person to flush their eyes for 15 minutes. Most of these should be installed when the facility is built; however, it is possible to install them later. The eyewash station shown in Figure 94, can be installed on any laboratory sink, without disrupting the flow of water to the sink (a divertor valve directs water to the sink or the eye cups).

Figure 93

Figure 94

c. Chemical shower - A chemical shower (Figure 95) is a body shower that can wash off a large amount of spilled chemical. Though most biomedical facilities use only small amounts of chemicals, you may determine that you need a chemical shower, based upon your situation and risk assessment.

Figure 95

d. Emergency kits - As discussed in the emergency/incident response section, each biomedical facility should have the following three emergency kits readily available: 1) a chemical spill kit, 2) a biological spill kit, and 3) a first aid kit. Be sure to provide accessible space in the laboratory or facility to accommodate these kits.

5. Storage

All laboratories should be designed to ensure there's enough space for work and for storing the materials needed. Often laboratories are overcrowded and cluttered because of insufficient space, particularly for storage. Supplies not immediately needed should be securely stowed in dedicated storage space and away from work surfaces where interfere with work or become contaminated, complicating efforts to decontaminate a room after an accident or hazardous spill. Secure, dedicated storage spaces can be located under benches, in cupboards and drawers, and outside the laboratory. Be sure you provide for adequate storage of the following:

a. Chemicals - Chemicals require specific storage conditions. You should never store more chemicals in a working laboratory than is necessary but you should make room for small amounts of acids, volatile organics, dry powders, and other necessary chemical supplies. These should be placed in appropriate chemical storage cabinets (e.g. Figure 96), clearly labelled and locked (if necessary).

Figure 96

b. Biologicals - Biologicals may be stored in refrigerators at minus 20 degrees C, in freezers set to – minus 80 degrees C or in liquid nitrogen. Refrigerators

and freezers need dedicated space somewhere in the facility, in a location appropriate for the work. Sometimes a central repository (freezer farm) is the best way to handle the storage of pathogens for common use or for archival purposes.

c. Personal Protective Equipment - Space must be provided to enable staff to change from street clothes into laboratory clothes and don and doff PPE. Staff need to leave their street clothing on the outside of the laboratory, in a space separate from that used for storage of PPE. After working in the laboratory or animal room, workers should remove their PPE before they leave the laboratory. Therefore, a coat rack (Figure 97) and PPE storage area should be incorporated into the facility design. In addition to laboratory coats or gowns, PPE will include items like goggles, thermal resistant gloves, and respirators.

Figure 97

d. Waste - Facilities should include space for different types and sizes of waste containers (e.g. Figure 98), as all biomedical facilities must make provision for waste segregation, collection, and storage. All waste must be segregated at the point of generation and placed in the appropriate receptacle (e.g., plastic bags, solid boxes for sharps, pails or trays for liquids, or glass containers for chemicals). Waste receptacles need conveniently located spaces within your laboratory, ideally near where the biowaste is being generated. Sharps containers come in a variety of different sizes, all of which should be accommodated in the laboratory. Some have to be on the benches and some may be on the floors. Containers for large broken pieces of glass are usually large cardboard boxes; these need a large amount of space (Figure 99).

Figure 98

Figure 99

e. Plasticware and glassware - Biomedical facilities use a lot of plasticware and glassware. These unused materials should be stored in a dedicated location outside of the working laboratory before use. This dedicated space must be appropriately sized and designed to efficiently store the product.

Enhancements (risk-based additions to basic features)

Based upon a risk assessment, a variety of different enhancements to the basic laboratory design and features may be needed to lower biorisk. As additional enhancements can be costly for initial purchase, maintenance, and ongoing certification/calibration/validation, they should be added only if necessary. Typically, these enhancements are designed and built into the facility at the time of construction; however, it may be possible to add or modify an existing facility to include them later. A brief description of possible enhancements follows. If the reader is interested in learning more, they should consult a biosafety professional or an engineering firm with appropriate experience. Remember, these enhancements should be local, practical, and sustainable.

1) Room integrity

Laboratory rooms can be made more air-tight and leak-proof, enabling better control of airflow and fumigation. when necessary. This means that all penetrations and gaps, and cracks in the floors, walls, and ceilings should be sealed to prevent air from flowing in or out. This can be quite difficult and is best done at the time the facility is built.

Option: If this enhancement is needed after laboratory construction, it may be easiest to put another shell of durable material inside an existing room. Plastic panels can be added to existing walls or an entire new room can be built within an existing room. This may be a more feasible and cost-effective solution than altering the existing infrastructure.

2) Room security

The security of the room can be enhanced by installing more sophisticated locks, such as card readers, personal identification number keypads, or biometric readers. In addition, windows can be removed or made more resistant to breakage, and bars can be installed. Additional security measures include cameras, window break sensors, motion detectors, and alarms.

3) Ventilation

Air flow through the facility can be increased to provide more air changes per hour (optimally 6-10) with sustained inward directional airflow. This can only be achieved with a ducted ventilation system, where fans supply fresh air and remove old air. Fans should be sized to provide a large air exchange in the room. This will help to reduce potentially infectious aerosols in the room. The exhaust air can be HEPA filtered to ensure no infectious aerosols are released to the environment. To ensure a sustained inward airflow, more air is drawn out than is allowed to flow in; this creates a negative pressure in the room (Figure 100). Ventilation systems should be automated, to monitor and maintain negative pressure or airflow and control dampers and fan speeds. This is an essential hallmark of a high-containment facility.

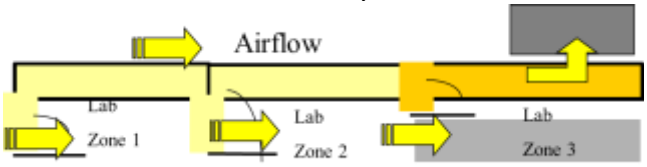


Figure 100

4) Shower-out

To ensure workers do not accidentally transport pathogens on their person when leaving the facility, a body shower upon exit is highly recommended. Before exiting a facility, personnel would remove all their clothing and take a body shower to ensure they are not harboring any pathogens. This requires a change room on the outside (clean side) of the shower where street clothing is left and a change room on the inside (laboratory side) of the shower where laboratory clothing and PPE is left before individuals enter the shower.

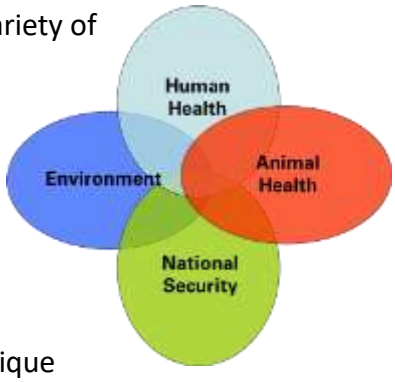
5) Room fumigation
   If necessary or desired, a room can be sterilized via fumigation if it is airtight and the fumigation process has been validated. A variety of fumigation gases or vapors that can be generated, either inside the room or outside, and then released into the room in high enough concentrations that biological indicators (spores) are killed in high enough numbers to prove that sterilization has occurred (see above chapter on validation of sterilization). In this case the spores are not in vials, but impregnated into paper strips. Fumigation requires a machine to generate the gas or vapor and an airtight room to ensure that the gas or vapor stays at a high enough concentration for long enough to kill the indicator spores.

6) Central effluent decontamination system
   If large amounts of contaminated liquids are produced, a central liquid effluent decontamination system may be required. This system will collect all the contaminated liquid and treat it to render it harmless or sterilized. Typically, these systems use contained piping to collect the effluent and then destroy the pathogens, through heat, chemicals, or a combination of heat and chemicals. These systems are commonly used to treat effluent from large animal holding facilities. Based on their risk assessment, some facilities choose to collect all liquid effluent from sinks, showers, toilets, floor drains, etc. and treat all this liquid in a central location.

7) Fumigation room
   Large pieces of equipment (e.g., biosafety cabinets) should be decontaminated before being removed for service or disposal. Facilities could add or designate a special room for fumigating large equipment before removal. Alternatively, the equipment can be fumigated within the laboratory itself.

In reality, you may have little control over your facilities. Your organization may not have the resources to maintain or improve them. However, a good facility will help manage biorisks, therefore always seek sufficient funding to maintain them and, whenever possible improve facilities. Even if your current facilities lack certain features, do the best that you can with what you have. For example, you may be able to implement procedural changes that can offset safety-related facility deficiencies. Do what is local, practical, and sustainable.

Animal biosafety



Laboratories throughout the world need to work with animals for a variety of reasons, including for the study of animal and zoonotic (and reverse zoonotic) diseases, and as models for human disease. Animals are not only important in terms of food security, but there are also many overlaps among animal health, human health, the environment, and national security. Consequently, animal biorisk management is an important concern in many laboratories. Major concepts are similar to those relating to the general management of laboratory biorisks, but animal biorisk management involves many unique aspects.

Even though many diseases are zoonotic, resulting in an overlap between public health and animal health, animal health is fundamentally different from public health. Public health is about protecting people, while animal health is about protecting animals, the food supply, pets (dogs and cats), and wild life from prevalent diseases. Therefore, animal biorisk assessment and management may be approached differently from public health biorisk assessment and biorisk management.

Working with animals introduces risks, not normally seen in the laboratory. There are unique risks to researchers/diagnosticians, to animal handlers, to research technicians, and to people in the community. There are also risks to other animals in the same animal house or animal room because animal diseases may be transmitted between species. In addition, there are risks to the environment, including the escape of an animal, or the release of contaminated materials or pathogens from animals or animal rooms to the surrounding environment, via aerosols or sewer systems. These unique risks must be assessed and managed in animal research facilities.

Animal biorisk assessment

Your approach to animal biorisk assessments should be similar to those of human health or laboratories. Always start by looking at risks posed by the agent, the procedure, the work environment, and the worker. These should all be considered to determine the risks to people working with animals; to the work product itself; to coworkers; to other animals in the facility or community (people and animals) outside of your work space; or to the external environment (including the air or water that surrounds the facility, wildlife and native plants). So, the risk assessment is the same process discussed before, including biosecurity. First, decide what risk you are evaluating. Then determine likelihood and consequences of this risk, in a matrix table. For example, the risk could be your potential exposure to a pathogen or a potential release to the environment or a potential infection of another animal within the room. Then determine the likelihood and consequences as low, medium or high using the same process as previously discussed in the risk assessment section (see previous section of risk assessment).

Risk classification factors can include things like:

1) Animal species. What are you working with? Chickens, cows, fish, monkeys, other?
2) What is the animal handling experience of the person that's manipulating this creature? It is very important to have people that understand the behavior of the species in question; behavior varies among species. Your animal handler should have species-specific experience.
3) The pathogenicity of the agent or agents that you're working with.
4) The route of transmission of infection.
5) The environmental stability of the agent. Because animals release so much urine and feces into their cage, environmental stability becomes an important factor.
6) The infectious dose to yourself or to other animals.
7) Data on mortality and pathogen shedding patterns. In many cases, the shedding patterns of the infected animals are unknown and may vary under stress. If an animal is stressed, will it shed more or less of this pathogen into the environment?
8) The quantity or concentration of the agent you are using.
9) Host range. Is the agent zoonotic? What animals can be infected?
10) What kind of experiment will you conduct with these animals? Is it short term (hours or days) or longer?
11) Will aerosols be generated? Will you use needles? Many factors in the experimental design could affect risk.
12) What type of animal housing will be employed? Open cage? Closed cage? Other?
13) Will you have an effective prophylaxis or treatment available for the pathogens being used? If you get infected or other animals get infected, what mitigating measures can you take?
14) Is the pathogen endemic or foreign to the region? This is an important issue. If the pathogen escapes from the laboratory could it cause a big problem for your region or nation? For example, foot and mouth disease (FMD) has eradicated from some countries. If FMD escapes from a research facility into an area free from the disease, it could be devastating to the country.
15) Is your government trying to eradicate a particular disease? If so, you may have to implement special precautions because of the consequences of a potential release to the environment.
16) Will a surveillance testing program be employed for the disease being studied? Avian influenza is a good example. In some countries, there's a lot of testing for avian influenza because they don't want influenza in the chicken population. When it occurs, it becomes a problem and needs to be eradicated.

As you see, there are many unique risk factors that should be considered when undertaking an animal biorisk assessment. The risk groups currently described by WHO aren’t fully applicable to animal pathogens and their unique risks, because they are focused primarily on human health and use human health risk concerns; however, in general, they can still be used. To

review the WHO risk groups: Risk Group 1: pathogens are unlikely to cause human or animal disease; Risk Group 2: pathogens would have moderate individual human risk and low animal community risk; Risk Group 3: pathogens would cause serious human or animal disease; Risk Group 4: pathogens would cause serious human or animal disease that cannot be treated. These risk groups classifications have an animal component, but they don't always take into consideration all of the other animal-specific risk factors that were previously mentioned. Therefore, you have to think beyond these risk groups for your work with animals and animal diseases. For a more in-depth discussion see the publication by Heckert and Kozlovac.[15]

Hierarchy of controls

The hierarchy of controls in animal biorisk management is similar to what we previously presented, related to humans, but this section focuses on animals and animal pathogens.

a. Elimination. If you don't have to use the animals or animal pathogens at all, then don't. It will make your work a lot safer.
b. Isolation and modification. Put the animal and animal pathogen within an enclosure so that it contains the pathogen and potential aerosols. This will substantially reduce risk. Consider using animal cells instead of the whole animal, if feasible. Similarly, if you can substitute a less virulent pathogen for the one in your study, do so.
c. Engineering controls. When possible, use biosafety cabinets or other ventilated enclosures (e.g. animal caging) that will contain and even remove infectious aerosols.
d. Administrative controls. Similar to the biosafety program for the laboratory, administrative controls are also an important part of animal biorisk management. An animal biorisk management program has to address the additional, animal-related potential risks and how they can be managed in the animal rooms. A specific animal biosafety manual should address those additional risks and describe how they are managed. This should be supported with specific SOPs for animal handling, potential accidents and injuries, and biosecurity. Staff selection is an important consideration. How will you recruit and hire trained staff with experience handling the animals that you're working with? What special practices and techniques will be advisable or necessary? These should be detailed in a manual. It is also very important to establish a medical surveillance program because of potential exposure to animal diseases and allergens. Only through a good medical surveillance program will you know if people are being exposed or infected.
e. Practices and procedures. Make sure all personnel who handle animals, collect samples, and conduct necropsies are well trained and know the practices and procedures required for the work and species involved.
f. Personal Protective Equipment. This is especially important here because of workers' proximity to animals and the substantial animal handling required.

[15] Heckert RA., Kozlovac JP. Biosafety levels for animal agriculture pathogens. Applied Biosafety 12:168-174, 2007.

Oversight and review

Many countries have a committee for oversight of animal health and welfare. This is sometimes called the Animal Care and Use Committee (IACUC). This committee serves as the advocate for animals and ensures that animals are used only when necessary; that the fewest possible number of animals is used; that animal living conditions are well maintained; and that animal pain or suffering is avoided and alleviated. A separate committee may look at safety issues encountered while using animals; this is often called the Institutional Biosafety Committee (IBC). This committee will review the pathogens being used in the animal research, and associated controls to ensure worker and animal safety. IBCs may look at registration and inventory control of both animals and pathogens. They may also manage signage and labeling for risk communication; at pathogen use and disposal; and, of course, careful and complete documentation.

Animal hazards and risks

I want to remind you again that, when you think about mitigating risk, you have to put together the proper mix of three elements: practices and techniques, safety equipment, and facility design. Use specific practices and techniques for handling animals, along with practices and techniques for handling the pathogens coming from those animals as well as anything that may be contaminated by pathogens (e.g., feces, urine, and samples). Safety equipment may include specialized kinds of animal enclosures and unique types of personal protective equipment for handling animals. Finally, the facility design for housing animals is specialized and unique in many ways. Remember that there's a lot of difference between an animal room and a laboratory. We will shortly discuss more about the three elements: practices and techniques, safety equipment, and facility design. The general concept is to layer the controls, one on top of another, because they are complementary and additive. No single control is perfect or complete in itself and, therefore, should not be relied upon solely for protection.

Similar to laboratory biosafety, controls representing each of the three elements need to be selected based upon the type and degree of risk. Some risks will be similar to those in a laboratory, and similar controls will mitigate those risks. However, there will be some new risks introduced by the use of animals; these require additional and unique controls.

Some additional hazards that you may see from working with animals include:

Physical risks of working with animals. Potential physical injuries from working with animals, particularly large animals, include being crushed, pinched, gored, bitten, or hit. Most animals are not tame and may become frightened. They may not intend to injure you, but in trying to escape capture, to avoid being touched, or in fear of being harmed they may thrash, jump, run, kick, bite, and butt.

Risk of pathogens being transmitted from animals to people (zoonosis) and vice versa.

Zoonoses are diseases of animals that may be secondarily transmitted to humans (Figure 101). They're often asymptomatic in the animal and you may not even know that the animal is infected. Reverse zoonosis, when pathogens move from people to animals, is called anthroponosis. An animal care taker, a technician, or a researcher can pass diseases to animals. Influenza is an example.

Figure 101

Percutaneous injury. Risk with sharps are greatly increased when working with animals. Animals have their own sharps for defense, including teeth, fangs, claws, beaks, spines, and shells. Research with animals may also involve sharp surgical instruments. Likewise, sharps are employed in animal necropsies. Animal surgery or necropsies may involve needles, scalpels, knives, and other surgical instruments. It is advisable to limit or eliminate the use of glass (e.g. Pasture pipettes, glass thermometers) in animal rooms; glass can easily break, especially in the presence of an agitated animal. If possible, substitute plastic for glass. If you must use glass, have available a broom and dust pan and a sharps container available to collect the broken glass. A spill kit may also be necessary. Also think about the sharps risk from cages or pens; these can have metal edges that could cut or pinch you.

Risk from aerosols and allergens. Animals generate substantial aerosols and potential allergens via dander, shed hair, dust, urine, feces, and animal bedding. Animal handlers, animal researchers, and the animals themselves may develop allergies of even respiratory diseases from breathing in these allergies. If you already have allergies to molds and dust, you may be especially susceptible to animal allergens.

Arthropod vectors. Unless the animals have been raised in a very clean or sterile environment, the animals will have their own resident flora, fauna, and microorganisms that could be transmitted to you or to other animals. These hitchhikers may include insects and parasites, especially if the animals are from the wild (e.g. Tick – Figure 102).

Figure 102

Release of the pathogens to the environment. Pathogens can affect people, other animals, and/or the environment (the environment in this case may be people or animals in the surrounding community). This could be a big issue if an animal pathogen is released into a region or country where the associated disease did not previously exist. Animal diseases being studied may be readily transmitted between animals and could cause an outbreak if released to the environment. In this context, I previously discussed foot and mouth disease (FMD). When pigs are infected with this virus, they generate a lot of infectious virus, in aerosol form. This could easily leave the facility and infect other animals outside.

Animal pathogens can be released from an animal room in a variety of ways:

i) Escape of the animal. As unlikely as that may sound, it happens. Animals, particularly small rodents, find their way out of cages for a variety of different reasons. Infected or uninfected, they present a risk.

ii) Escape of the pathogen. The pathogen could infect other animals within the facility or outside. Zoonotic diseases, such as brucella, may be transmitted to people within or outside the facility, if the associated pathogen escapes. The pathogen can escape via:

   (a) Water. A lot of water is used to wash down large animal rooms. If this water is not treated before release it could contaminate the environment.
   (b) Air. If not removed, infectious aerosols could be released through the ventilation system.
   (c) An infected animal carcass. How do you dispose of an animal carcass once you're finished with the work? If carcasses are not completely decontaminated or sterilized before they are placed in the outside environment. pathogens could be released.
   (d) Fecal material. This could be a vehicle for release of contained pathogens to the environment.
   (e) People. Persons working with animals could become contaminated and could accidentally carry out pathogens on their skin, hair, or nasal passages when they leave animal rooms.
   (f) Contaminated equipment. Equipment in or on animal rooms, cages, shovels, syringes, or anything in contact with animals. (fomites) could be become contaminated with pathogens and infectious fomites. If equipment is not properly disinfected the contamination could spread to another animal room, location, or susceptible host.

Animal BioRisk Mitigation

Physical Injury - To avoid injury you must control animals in your facility, so that they don't turn on you, inadvertently move, or bite. Each animal has its unique characteristics and movements; therefore, it is vital to enlist the help of someone who is very familiar with that species and knows how to capture and hold them safely. This can be done in a variety of ways:

(a) Physical restraint. You can use manual methods (with your hands, knees, elbows, and feet). It's helpful to have a second person, who is familiar with handling that animal species. to assist you.

(b) Caging and penning. A variety of cages or pen types (e.g., squeeze cages) can be employed to restrain animal movement. For large animals, penning and securing the animal's head is an option. There are even devices that can hold the animal and turn it over for you (mechanical tables that grab the animal and roll it over).

Figure 103

Figure 104

(c) Restraint assists. These are small pieces of equipment (e.g. Mouse restraint – Figure 103), used for small or large animals, that help to catch and contain the animal. They can calm the animal and present a certain part of the animal's body for you to work on. Common examples are rope, hobbles, crooks, neck pinchers, and bags.

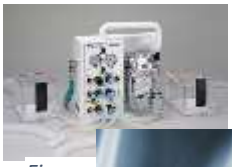


Figure .

(d) Chemical restraints (Figures 105 and 106). This requires the assistance of a veterinarian with access to a variety of chemicals to control the animal. These include gas anesthetics that can be released into the animal's environment or through a mask fitted to the animal's head to enable sedation or render it unconscious. You could also use injectable anesthetics. If catching and restraining the animal is too challenging, you can introduce an anesthetic or tranquilizer into the feed.

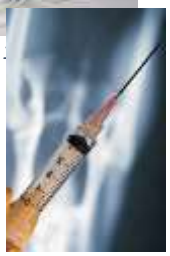
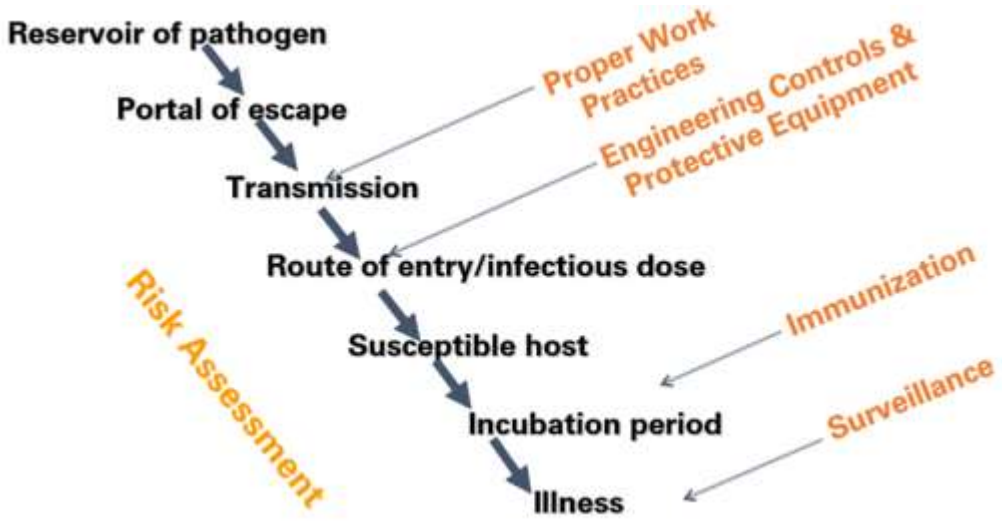


Figure 106

Disease Transmission. How do you stop the transmission of pathogens from animals to people and from people to animals? Your focus should be on breaking the chain of infection, as shown in the accompanying diagram. In this case the reservoir of the pathogen is the animal, the animal room, the animal waste, or the air in the room. You should consider the portal of escape and transmission routes of entry from this reservoir to other susceptible hosts (people or animals). Think about how the pathogen might be transmitted within the animal room, and the application of biorisk mitigation (proper work practices, engineering controls, protective equipment and facility design) to break the chain of infection. You may also use immunization to change host susceptibility (e.g., vaccination against rabies). Keep in mind the portals of entry of a pathogen into the body of a susceptible host (human or animal). These might include mucus membranes, the respiratory tract, the gastrointestinal tract, and wounds on the skin. Make a habit of applying effective biosafety practices, procedures, safety equipment, and facility design to break the chain of transmission by blocking potential routes of entry (see accompanying diagram). Further information for veterinarians or anyone working with animals can be found in the Compendium of Veterinary Standard Precautions for Zoonotic Disease Prevention in Veterinary Personnel.[16]

[16] Compendium of Veterinary Standard Precautions for Zoonotic Disease Prevention in Veterinary Personnel, National Association of State Public Health Veterinarians, Veterinary Infection Control Committee, 2015. http://www.nasphv.org/Documents/VeterinaryStandardPrecautions.pdf



Primary barriers

When working with animals, it is important to use primary barriers between the animal (representing the biohazard) and ourselves or other animals. Primary barrier options include engineering controls (e.g., animal enclosures), the biosafety cabinet, directional airflow, and PPE. The best primary barrier in an animal room is an enclosure or cage. The extent of animal cage containment would increase according to the risk. The biosafety cabinet can and should be used when you're manipulating small animals. You might also use facility design to create directional airflow, to move aerosols away from you or other animals. Finally, a variety of PPE can provide protection.

When working with animals, primary barriers and PPE are most important. Manufacturers offer animal caging systems that are significant improvements over those available in the past. Previously, most animal cages were open-topped, allowing pathogens and other materials inside the cage to be released into the room. The room would then become contaminated, necessitating that room occupants wear extensive, uncomfortable PPE. Now manufacturers provide caging systems that allow for partial or full containment of the animal and infectious aerosols and allergens that the animal may be producing. The barrier is now at the primary containment animal caging level that contains infectious materials at the source and reduces the need for extensive PPE.

Figure 107

Figure 108

Depictions of various different animal caging systems are shown in Figures 107-109. Figure 107 shows a traditional open-caging system. To contain large materials and droplets, filter-top caging systems were introduced (Figure 108). These are not HEPA filters, so infectious aerosols and allergens could still be released. However, this was an advancement in primary containment animal caging. Today, full containment caging systems are available. These are called individually- ventilated (IVC) cages; air is HEPA-filtered in and out. Figure 109

shows air going in on the bottom (green arrows) and potentially contaminated air being drawn out (red arrows) of the full containment IVC.

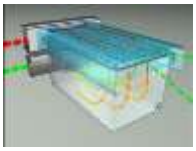


Figure 109

Figure 110 shows what the animal caging system looks like in practice. The cages are put onto racks that you can roll into a room. You can take one cage off without disturbing the other cages because each one has its own separate ventilation equipment system. In the rack designs there is a box on the side where the fans that move air through the individual cages are located. These systems are expensive to purchase, but, if you need complete containment of the animals and the infectious aerosols and allergens that they may produce, IVCs are a good solution.

Figure 110

Another engineering control for protecting animal care workers engaged in changing cages is a machine that creates a down draft of air from the top down through the bottom. Figure 111 shows how the air moves from the top, after it is cleaned, down to the work surface, and then out through the bottom. This creates a curtain of air between the worker and potential contaminants in the cages. This is called a cage change station. It is very useful in removing infectious aerosols, allergens, and other materials and keeping these contaminants away from the breathing zone of personnel working with small animals.

Figure 111

When you work with small animals, a biosafety cabinet can be an effective primary barrier between you and the infectious aerosols and allergens that the animals may carry. The accompanying photo shows a researcher working with an animal in a biosafety cabinet. Biosafety cabinets can be a particularly good choice for examining or conducting necropsies on small animals that may release infectious aerosols. Note that the individual depicted is also wearing a powered air purifying respirator, thus providing two levels of protection for additional safety.

A Class II, A2 biosafety cabinet, as used in a laboratory, would be a good choice; air is recirculated back into the animal room. An even better choice would be a Class II, A2 biosafety cabinet that is thimble- or canopy-connected, as discussed previously. This system captures all exhaust air from the cabinet, and some room air, and removes it from the animal room through a ducted ventilation system. This effectively removes all potential allergens and unpleasant smells that could leak through the HEPA filter. If you are working with volatile organic chemicals, or formaldehyde (as during necropsy), you may need a Class II, B2 biosafety cabinet. You may recall from the previous section that this type of cabinet needs to be hard ducted to the building exhaust. All biosafety cabinets have to be recertified on a regular basis, ideally annually. Figure 112 shows someone doing a necropsy on an animal in a biosafety cabinet.

Figure 112

Personal Protective Equipment

When animals are not contained, close proximity to animals raises additional risks. Therefore, workers must take additional precautions, including specialized PPE. Care should be taken to select the right kind of PPE, based upon the animal species and the specific hazards that might be present. This, in turn, should be based on your risk assessment. Since animal rooms present more potential for contamination of workers than in laboratories, it's a good idea to have single-use disposable PPE, including. gloves, gowns, shoe covers, and hair covers. After use, both reusable and disposable PPE should be removed and properly contained in the animal room or ante-room. Because the PPE is potentially contaminated, it needs to be carefully handled before it's sent to the laundry or disposed of.

Body protection: People working in animal rooms should wear appropriate body covering. Nursing uniforms or scrubs can serve as inner layers (Figure 113). In addition, at a minimum, everyone should wear wrap-around, solid rear-closing gowns or coveralls; these are worn over the scrubs. Front-buttoning laboratory coats are not suitable because they have too many openings and there's too much potential for contamination of your street clothing. You may also consider disposable PPE that is worn over your scrubs.

Figure 113

Arm protection: Figure 113 depicts a sleeve guard. A specialized piece of PPE that protects against bites (monkeys may be especially likely to bite on the forearm). It extends from the elbow to the wrist.

Figure 114

Hand protection: In most cases, you'll be handling the animals with your hands, so your glove selection is of paramount importance. You may decide to double-glove, with latex or nitrile gloves (typically used in the laboratory) serving as the first barrier of protection, and a second, outer pair of thicker gloves, made out of leather or another material that protects against cuts, scratches, bites, and accidental inoculations "Finger armor" may also be useful. This is shown in green in Figure 115. It represents a reinforced part of the gloves that provides additional resistance to punctures and cuts in in thumbs and forefingers—the parts of the hand most susceptible to needle sticks. For necropsies or other work involving scalpels or knives, another option is cut resistant gloves. These are made out of various different materials including metal and Kevlar. A chain mail glove is often used by those working in butcher shops or abattoirs (Figure 116).

Figure 115

Figure 116

Respiratory protection: Based upon your risk assessment respiratory protection may be needed. All of the options used in the laboratory can also be used in the animal room. Keep in mind the extra breathing difficulty respirators cause and the fact that they can be easily dislodged when working with large animals. The accompanying picture shows a person wearing

a powered air purifying respirator. This equipment offers good respiratory protection, and also protects the mouth, nose, and eyes from any splashes. This is also a good option when working with animals that are not in containment caging.

Option: If, for financial or other reasons, you choose not to use disposable PPE, you can manufacture your own reusable PPE from materials that can be decontaminated. Most clothing can be autoclaved or soaked in bleach and then washed before reuse. Eye protection, respirators and gloves may also be decontaminated with a suitable liquid disinfectant and reused.

Room decontamination

It is important to routinely decontaminate animal rooms. Make sure that the disinfectant used is effective for all pathogens that may be present in that environment. You'll need a broad-spectrum disinfectant because animals continually excrete a lot of "normal pathogens," including in confined animal rooms. A broad-spectrum disinfectant should be applied to all surfaces, including walls, counter tops, floors, and the animal cages. Disinfecting should be done immediately after\ a spill of any blood or biohazardous material, and routinely upon the completion of work activities. Make sure that the chemical disinfectant is not harmful to the animals, as animals will be exposed to the chemicals. You may be wearing PPE but the animals are not!

Percutaneous Injury

Since working with animals may involve use of sharps, let's consider how we might lower the risk of a sharps injury in an animal room or necropsy area. First, review the use of sharps to make sure you minimize their usage. Think about which ones you need and which ones you may not need. Consider changing protocols to minimize sharps usage around animals and to remove as many sharps as possible from animal spaces. If you can use a dull instrument instead of a sharp one, do so. Make sure the animals are restrained; When they move or squirm around, that increases the potential for accidental inoculation or cuts. Don't try to recap, bend, or shear used needles or remove from disposable syringes; these practices could result in accidental sticks. Used sharps should go directly into a sharps container immediately after use. Make sure that sharps containers are appropriate for the work that you're doing, that they're the correct size, that they're sufficiently numerous, and that they're placed close to where the animal caretaker or worker is using the sharp. No one should walk around with a sharp.

Animal necropsies can be dangerous procedures. A necropsy requires taking the animal apart with sharp instruments, for examination collection of samples. It's imperative that the process be done safely to workers from potential aerosols, splashes, and cuts. Necropsies produce a lot of contaminated sharps, such as needles, scalpel blades, scissors, and bones that may be fragmented or broken. An animal's sharp teeth a risk for cuts and resultant contamination. At the end of the necropsy, all contaminated sharps must be cleaned and decontaminated, or disposed of. If possible, try and substitute "safe sharps" for regular sharps. These specially engineered types of sharps that make them safer (Figure 117) and the International Sharps Injury Prevention Society (http://isips.org) for more information. In summary, necropsies present a high-risk percutaneous injuries and special precautions are required.

Figure 117

Arthropod and Insect Vectors

Figure 118

It's important to recognize and identify potentially harmful arthropods, including insects, and to exclude or eliminate these from animal spaces. Arthropods may be potential vectors of pathogens on animals, particularly if you're working with feral animals. Trapped animals brought into animal rooms may harbor biting insects such as fleas, lice, mosquitoes (Figure 118) and ticks; these insects may carry disease. If you can't remove them from the animal, you may wish to eliminate these animals from the study and your animal house. In addition, animals may carry internal parasites that you may not be aware of or that could be difficult to eliminate. Internal parasites can also be vectors of diseases that could be transmitted to you or to other animals in the room. In a more open environment, such as a barn, this could be especially problematic.

Remember that animal feces, food, and water attract insects, such as flies. In an open environment this is most likely. Animals also attract mosquitoes that can harbor diseases that could be transmitted to you, as well. IACUC and IBC committees can review your research plan and make recommendations for controlling risks from arthropods in general and insects in particular.

Pathogen Release

To prevent the release of pathogens into the environment, primary containment systems may not be feasible for some animals, particularly large animals. Therefore, secondary containment—the facility design itself—becomes more important. The following sections present a variety of animal facility design concepts.

Facilities

There are a number of unique features of rooms in which animals are kept that need to be addressed during design or renovation. Needless to say, animal rooms have substantially different requirements than offices, laboratories, or storage spaces. Animal rooms must support specialized functions and require special construction materials and maintenance. These functions and requirements should be addressed during design or renovation of research facilities.

Basic animal facility design

Animal facilities must be separated from the main traffic areas, so people don't accidentally stray into them. They should have restricted access, using keys, cards, or other entry devices. Doors should be self-closing and self-locking; they should be kept closed and should always open inward. A hand wash sink should be positioned at the door exit (Figure 119). Rooms should not have air recirculation: All air drawn into animal rooms should be exhausted, because of the smells that animals produce. It is recommended that the room be under negative pressure. If more air is pulled out of the room than is allowed to go in, the room will have negative pressure with inward directional air flow. Ideally, there should be an autoclave nearby, to allow ready decontamination of animal bedding and waste.

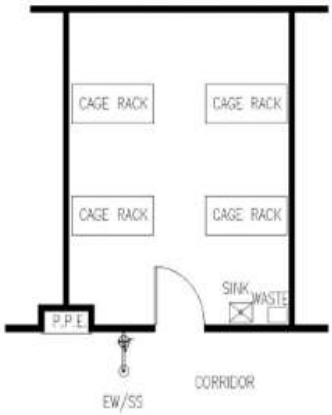


Figure 119

Animal room enhancements

Depending on your risk assessment, additional facility enhancements can further increase protections. These include greater control of ventilation systems to eliminate any potential for release of infectious aerosols from animal rooms. You might incorporate HEPA filtration on the exhaust, with interlocked supply and exhaust fans, so the room will not become pressurized. Personal exit showers will enable full-body decontamination of persons exiting the room. Vent stacks, sewer lines, and other piping systems could be contained. An effluent decontamination system will treat wastes that are washed down floor drains before their release to the environment. Additional PPE may be required, especially if animals are not fully contained or restrained—often the case for large animals. This will necessitate change rooms inside and outside of containment.

Figure 120 shows a simplistic design of a small animal holding room. You see the entrance at the bottom of the room, with an ante-room, sink, and shower; the animal room itself is in the middle. At the back of the room, you can see a pass-through autoclave for all wastes; these are immediately sterilized and passed out of the facility. A biosafety cabinet is located within the animal room; primary containment of animals is accomplished in individually ventilated cages on racks. These are just some of the enhancements that may be required, based on your risk assessment.

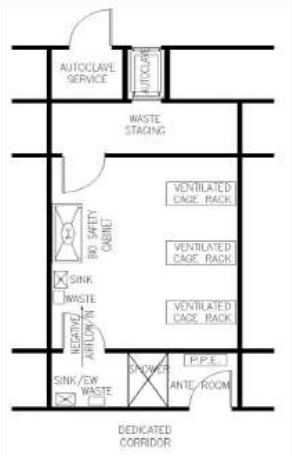


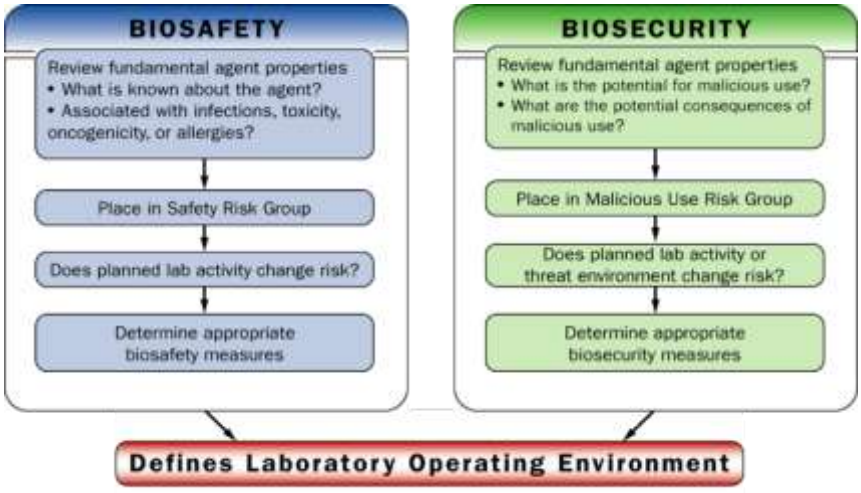
Figure 120

To the extent possible, animals should be secured within primary containment, but this is not always possible, especially for large animals. For situations where animals have highly communicable infectious diseases, but primary containment is not feasible, the United States Department of Agriculture (USDA) has defined a special level of containment, called biosafety level 3Ag (or ABSL3-Ag for agriculture). This is a special building design that incorporates many of the animal biosafety level 4 features in it. These features include personal change rooms with showers; personnel and equipment airlocks; double door autoclaves; single pass directional pressure; gradient air systems with air filtration on the supply and exhaust; and electrical interlocks to prevent positive pressurization of the spaces. In addition, there must be a central effluent liquid decontamination system, sealed interior surfaces, (this ensures that the room is completely airtight, so that there is no potential leakage of anything from the room), and rigorous certification and validation of the room and the systems that support it. These environmental controls are very expensive and are difficult to build and maintain, but they ensure that the animal is secure within its own primary containment zone—the room itself is the primary containment area. However, entry and exit will be challenging for personnel who have to work with these infected animals. If you need such a system, details of their design and construction can be found in the US BMBL and the USDA Agriculture Research Service facilities and design standards, 242.1 (this describes the construction standards for ABSL3-Ag from a very detailed engineering point of use.[17]

[17] ARS Facilities and design standards, 242.1 United States Department of Agriculture, Agriculture Research Service. See https://osp.od.nih.gov/wp-content/uploads/2013/06/USDA%20BSL-3(Ag).pdf).

Biosecurity

Biosafety and biosecurity are inseparable. Together they define the laboratory operating environment. Biosafety is all about understanding pathogens in a laboratory environment, putting them into risk groups, doing risk assessments, determining what kind of controls you need, putting those controls into practice, and then making sure they're working. In the accompanying figure, the chart on the left, in blue, addresses biosafety considerations. Biosecurity, depicted in green on the chart on the right, starts with assessing the agent properties, then doing a security risk assessment by considering what threats there might be and vulnerabilities arising from somebody misusing those pathogens, putting appropriate controls into place, and monitoring them for effectiveness. Although the processes for biosafety and biosecurity are similar, the two have different goals: biosafety is about keeping the pathogens safe while biosecurity addresses keeping the pathogens secure. They both work hand in hand to define the laboratory operating environment.



The following sections will cover biosecurity in more detail. Biosecurity is defined as "preventing the loss, theft or misuse of microorganisms, biological materials and research related information" (USA BMBL). In essence this involves protecting pathogens from dangerous people. Further information can be found from the World Health Organization.[18]

Why would you need a biosecurity program? There are several reasons:

1) To deter criminals, activists, and bioterrorists from acquiring materials to potentially do harm to humans or to agricultural assets (animals and plants), or to inflict economic damage. It stands to reason that some of the pathogens in your workplace may have the potential to be dangerous. They may cause highly communicable diseases, resulting in mortality and morbidity in animals and people. They must be kept secure from malevolent actors.

[18] Laboratory biosecurity guidance, World Health Organization, 2006.
https://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

2) A biosecurity program can also protect the employees and coworkers by improving the security of laboratory assets. Effective biosecurity will deter theft, including of our personal property and computers.
3) A biosecurity program will enhance emergency preparedness, by improving protections during incidents and accidents.
4) Biosecurity will also protect products and reduce business liability. Business liability is a particular concern in private industry, including in the pharmaceutical industry, because of the risk of theft of proprietary information.

Biosecurity risk assessment

As for biosafety, the first step in managing your biosecurity program is to do a risk assessment. This is similar to a biosafety risk assessment, but there are important differences. The biosecurity risk assessment is an analysis of the probability and consequences resulting from the potential loss theft or misuse of the pathogens and toxins. It determines which assets (if any) require protective measures. As with biosafety, you will determine which pathogens are more important than others from a security perspective. This will help management identify effective protective measures whose costs are proportional to the risks. We want to invest in protecting assets that are most sensitive to misuse.

To establish a biosecurity program, you should first identify and prioritize the biological agents and toxins in your facility. This requires a thorough inventory. Next, you should rank and prioritize inventoried agents and toxins based on their threat potential. They can be categorized by risk groups. This is similar to what is done for biosafety; however, for biosecurity, agents and toxins should be categorized into malicious use risk groups (see below). Based on specific security scenarios, you will determine the likelihood of losing an agent or pathogen, or that it would be diverted or stolen. Then you will design and develop a risk management program incorporating needed controls. Finally, you should regularly evaluate the institution's risk posture, protection objectives and effectiveness of the current biosecurity measures.

Malicious use risk groups

Malicious use risk groups are similar to biosafety risk groups, but must consider the potential harm that could arise from loss or misuse of the pathogen. Based on potential consequences of loss or misuse of agents or toxins, malicious use risk groups could be categorized as follows:

1) *No malicious use*: Insignificant or no consequences.
2) *Low malicious risk group:* Agent or toxin would be difficult to disseminate or use; limited consequences.
3) *Moderate malicious risk group*: Organisms would be relatively difficult to disseminate; localized consequences with low to moderate casualties.

4) *High malicious risk group*: Agents or toxins would not be particularly difficult to disseminate; national and international consequences with moderate to high casualties and economic damage.
5) *Extreme malicious risk group*: Though not found in nature, because they have been eradicated, they could represent genetically engineered pathogens or substances that would be easy to disseminate and that would cause tremendous economic damage (high morbidity and mortality). They might also comprise an agent that has been eradicated but for which samples still remain in secure storage. A good example is smallpox; if ever released, it would cause tremendous human costs and economic disaster.

Biosecurity Risk Mitigation

Now that you understand a little bit about risk assessment relating to biosecurity concerns, let's now turn our attention to mitigation. What kind of security components could be implemented in the risk mitigation process? Typically, there are five main components:

1) Physical security.
2) Personnel security.
3) Material handling and control measures.
4) Transport security.
5) Information security.

These all operate under the larger umbrella of program management and practices. Each component should be implemented in a graded fashion, based on the risk assessment. So, depending on the degree of biosecurity risk for your pathogens and toxins, you would apply appropriate biosecurity from the applicable security group category (Figure 121). Let's look at each of these.

Figure 121

Physical Security

This is often what people focus on when they think about security, because it's an obvious concern. It involves access control and monitoring. Sometimes physical security is referred to as the "gates, guards and guns," because they're such visible components of measures n to keep people out of secure spaces and to prevent unauthorized removal of assets. In designing an effective physical security program, you should first assess existing physical security measures for buildings, labs, surrounding premises, and biological material storage area(s). In conducting these assessments, you might first tour your facilities to determine what kind of physical security measures are already in place, and any gaps or shortfalls. Is access limited to authorized employees, based on the need to enter particularly sensitive areas? What areas do visitors have access to, and are escorts required, and for what areas (including animal areas)? In developing a physical security program, bear in mind that measures should be implemented in a graded fashion. Not everything needs to be protected to the same degree. Based on your risk

assessment, you may find that some areas need a lot more protection than others. This could include intrusion detection, to alert staff in the event of unauthorized access. Another question to consider: Do you need a guard force to respond to a potential intrusion, and what resultant actions would they undertake?

Figure 122 shows a graded or layered security system. The outer ring indicates perimeter security, which could be a fence or a wall surrounding the laboratory compound. This would be the first barrier for visitors, unwelcome or otherwise. The building that you work in should have some sort of access control system (Figure 123), allowing only authorized people to enter offices and support areas (shown in yellow). Then there should be further restriction and access control for entrants to low-risk laboratory areas (shown in light blue). If you have a high-risk area (shown in dark blue), there should be further restrictions. Finally, the middle area (in dark yellow) may serve as the repository of valuable pathogens and high-risk pathogens. Very few people should have access to this area. This is the concept of graded security from a physical access point of view.

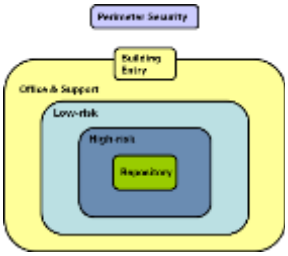


Figure 122

Figure 123

Personnel security

According to the American Biological Safety Association biosecurity task force, “it's vital that individuals, working with or have access to pathogens, are responsible, reliable, well trained and trustworthy.” This is important, since people who work with pathogens generally have the greatest knowledge about and access to them. Therefore, a personal reliability program is essential. How do you know people are trustworthy? That's what the personal reliability program is all about. The program is designed to ensure that only trustworthy individuals have access to valuable high-risk pathogens and associated assets (Figure 124). A personal reliability program is often developed with the human resources department because the latter has the tools and knowledge to effectively screen people and ensure that the right people are working with your pathogens. The components of the program could include assessments of educational level and training to provide confidence in the competence of people assigned to work with pathogens. The training could include demonstrations of laboratory proficiency. People with access to valuable pathogens may also be subject to background checks, where they are asked to reveal certain parts of their history. This helps to assure that they are reliable and trustworthy.

Figure 124

A security badge (Figure 125) is an important component of a personal reliability program. Everyone working in your organization should have a badge that's been issued to them by the organization, to show that they’re an authorized person. There may be different badges for different areas, perhaps in different colors for different sections.

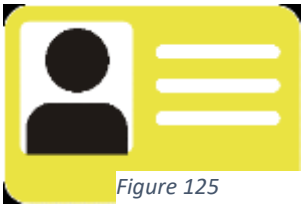


Figure 125

Ideally the badge should include a personal photo to facilitate identification. You might consider requiring that badges are turned in at the end of the work day. This helps to ensure that badges are not forgotten, lost, or stolen. If a badge is lost or stolen, that should be reported right away to your security team. Badges should be returned if a person is terminated or permanently leaves the work place. If you have temporary employees or visiting scientists, they should be issued temporary badges that they must return their badges at the end of their limited terms.

Material Control and Accountability

This involves inventorying of and accountability for all valuable biological materials (VBM) in your facility. First, you should determine what those valuable biological materials are. Then you must establish a material control and accountability system. Inventorying allows you to know the exact amount of, description of, storage locations of, and identity of personnel with access to all VBM on your premises, as well as to track the movement of any VBM as it is transferred to its final destination. Accountability involves knowing who is responsible for VBM at all times, and to ensure that the inventory is accurately maintained. All inventory and accountability procedures must be fully documented and supported with good standard operating procedures. This will ensure that people handling these biological materials are doing it correctly. You have to know exactly what agents exist in your facility at any given time, their locations, who is currently responsible for them. This must include a rigorous, tightly controlled check-in, check-out procedure. Among the challenges for VBM inventory and control is that biological materials replicate themselves; this makes it very difficult to know the exact quantity of the working stocks (those used on a daily basis) of organisms, at any point in time. But inventorying and tracking of repository stocks (those archived for long-term storage and reference) can and should be done. Remember that all pathogens should have an associated responsible person. Somebody needs to be responsible for maintaining the inventory and to be accountable for any discrepancies.

Transport Security

What happens when the pathogen leaves your laboratory and is being moved to another place? Transport policies have to include accountability measures for the movement of the materials either within an institution or if you're moving it from one facility or institute to another, or between countries. Transport policies require appropriate documentation, material accountability, and control procedures for pathogens in transit. This includes a chain of custody to monitor, at all times, who possesses the pathogen and its location During the shipping phase, the transport phase, and the receiving phase. Chain of custody information would include, but is not necessarily limited to, names and addresses of the senders and receivers, dates and times of shipping, and quantities removed or destroyed during work with the VBM. Records must also show when the work was done, where it was done, and by whom.

Information Security

This involves policies for handling sensitive biosecurity information, for example a facility's security plans would likely indicate locations of all doors cameras, and power lines. This can be considered as sensitive security information that somebody could misuse. Similarly, information on access control codes or lock codes could be misused by the wrong persons, so must be secured. Consider also your biological agent inventories and storage locations. This information is sensitive. Computers routinely store information that may be sensitive. At a minimum, you must have password access to all computers and control equipment, servers, and software where data is stored. Your most sensitive computer and servers should be disconnected from the internet, so that unauthorized individuals cannot access your information. Information security also requires protecting information that is too sensitive for, public distribution. To limit its distribution, such information should be labelled as restricted; very few people should ever see this information. Give this some serious thought, knowing that you may be harboring a lot of security-related sensitive information that others may seek. Your risk assessment process will help you determine what information should be safeguarded. Not everybody thinks about information security when considering biosecurity, but it is important to do so. After all, knowledge is power.

Program management

Program management is an important part of both safety and security. It's an overarching component that includes both programs and often bridges the two. Program management will guide and oversees both security and safety. It will define program objectives and ensure that the program has proper resources. Both finances and staffing address the sustainability of the program, by making sure that there are enough resources for risk mitigation. Program management should include regular training, which should be spelled out in a written plan or manual. This manual can be a standalone document or incorporated in safety and security manuals with comprehensive guidance plans. A responsible person should implement and oversee the plan.

The biosecurity program management plan should outline the roles and responsibilities of each involved individual, including the laboratory manager, principal investigators, technicians, and security staff. It should outline all security measures being used, along with related policies and procedures. It should describe an incident response plan covering what to do if you find materials are lost or stolen, or if there's an intruder. The manuals have to be specific for each organization. While biosecurity manuals may have a lot of commonalities from one facility to another, each facility is sufficiently different to warrant its own specific provisions, based on laboratory-specific risk assessments. These risk assessments must include risks related to high risk, valuable biological materials that require application of security-specific components. All the standard operating procedures need to be written to support the manuals describing exactly how people handle all those five security parts.

Security updates and reevaluations are very important. Whenever you install new doors, hire new employees, or obtain new pathogens, you should reevaluate your biosecurity plan. Risk assessments and programs have to be reviewed and updated regularly (perhaps annually) or following any security or biosecurity-related incident. If you experience a security-related incident, you should determine how it happened and what you need to do to prevent a recurrence. Remember that change is a constant. New things happen all the time, so you must review your biosecurity plan and reevaluate as needed.

A good tool to help you evaluate your biosecurity posture is available at https://www.bureaubiosecurity.nl/en/toolkit.

Incident/Emergency response plans

Life happens. As you know, things can and do go wrong during a normal work day. Something abnormal occurs and things change. This chapter will cover some of the basics of preparing for and responding to common incidents and emergencies in a biomedical facility. Since you work in a facility where potentially dangerous pathogens are handled, responses to incidents and emergencies will be different incidents and emergencies occurring in an office. You will still be responsible for handling pathogens safely and securely, even during an unexpected event. So, preparing, planning, training, and practicing for these events is crucial.

Not all incidents are emergencies. Your response during an unexpected event can make a big difference in helping to correct the situation or possibly making it worse. It is important to know the differences between incidents and emergencies and how to handle each. This is not always easy, so we propose the following categories and responses to help you:

> *Minor incident. -This type of incident is small and can be dealt with locally in a small amount of time. No major response is required and no alerts are required; however, the safety officer or laboratory manager should be informed and a written incident report may be advisable. Examples include minor cuts, brief power outages, and transient alarms on biosafety cabinets or animal isolators.*
>
> *Major incident. This is a significant incident that doesn't rise to the level of an emergency. Personnel should stop work, secure their cultures or animals, and await further instruction. In case the work stoppage may be prolonged, personnel should prepare accordingly. Examples include sustained power failures, minor fires that are quickly put out, and predicted impending weather problems.*
>
> *Minor emergency. A minor emergency would require an immediate response involving all personnel in the laboratory or animal room. Personnel should stop all work, secure their cultures or animals (if possible), move to a safe location, and await further instructions. Evacuation may be required and personnel should be prepared to do so, in a rapid and orderly fashion. Examples include major biological or chemical spills in the laboratory or animal room, minor earthquakes, and fire that are being controlled.*
>
> *Major emergency. This connotes a serious situation that requires the immediate evacuation of all personnel from the laboratory or animal room. In a major emergency, biocontainment protocols may be suspended; the focus is on preserving the life of personnel. Workers should immediately stop all work, alert others, and walk quickly to the nearest exit while removing PPE and dropping it. Personnel should then immediately exit the facility and go to the designated assembly point if safe to do so. Examples include major explosions in the facility, severe earthquakes, releases of toxic gas, and armed aggression.*

The exact response to each of the above categories depends on your local situation and the level of containment that you are working in. Therefore, it is important to have a plan prepared in advance for the most likely incidents and emergencies; less likely situations should be handled based on their general category. Determining the most likely events should be based on a risk assessment, the probability of their occurrence, and the expected magnitude or severity of the outcome. You could use a scale of 1-3 to rank each event on its probability and magnitude, as follows:

Probability (likelihood of occurrence)

1 = low or minimal

2 = medium or moderate

3 = high or substantial

Magnitude (potential harm to health or environment)

1 = minimal harm

2 = moderate harm

3 = substantial harm

Some of the most common events that occur in a biomedical facility are: a) loss of containment (spills, splashes, leaks); b) medical issues (cuts, fainting, heart attack); c) fire (usually small and contained); d) explosion (usually small and contained); and e) loss of power. This is not a complete list and there can be many others.

Once you have identified your top 10 (or more) most likely and most serious incidents/emergencies you should then put together a response plan. As you can see in the graphic below, this starts with planning and preparation. For the planning and preparation phase you should assemble a team of people who are knowledgeable about the type of incidents or emergencies and have a vested interest in seeing them handled correctly. The team should think about the how to best handle each identified incident/emergency and should then write a standard operating procedure (SOP). The SOP should at a minimum clearly state the nature of the event, the alert designation, how the event is assessed, who responds, and how the event is addressed A drill is useful to test the SOP and train the staff. The drill would present a hypothetical incident or emergency, include an alert, require an assessment of the situation, and involve mobilization of people or resources. Results of the drill will provide feedback to the team to enable further modification of the SOP and future training sessions.

Here are some common incidents and emergencies that might occur in your facility, and some recommended preparation and responses.

Spills

Spill response and clean-up (outside biosafety cabinet) on the floor

Have a complete biological spill kit ready to go before you start the clean-up (see description below). Initiate cleanup as soon as possible. Spill kit should be readily accessible and somewhere near the exit door or just outside.

Biological spill kit (Figure 126)

Figure 126

- Disposable gowns (waterproof that close in the back)
- Gloves (double if necessary)
- Disposable shoe covers
- N-95 respirator
- Eye goggles or full-face shield that fits over N-95 respirator
- Effective disinfectant agent (e.g. 10% bleach, made fresh)
- Absorbent paper towels; may also include diking material or spill pillows for large spills
- Small disposable broom with dustpan, and tongs or forceps for sharps
- Biohazard waste bags
- Sharps container
- A waterproof copy of the SOP that includes spill response and cleanup procedures
- Caution tape to close off the area (if necessary) or door sign

a) If infectious aerosols were NOT created (judgment determination)

- **DO NOT PANIC**

- Alert people in the immediate area of the spill
- If body contamination has occurred, follow the procedures outlined below for personal contamination
- Retrieve the biological spill kit
- Starting at the edges and working toward the center of the spill, cover the spill with paper towels or other absorbent material
- Carefully pour disinfectant over the absorbent material and spill, starting around the edges and working toward the center. Saturate the area with the disinfectant
- Allow sufficient contact time for the disinfectant to inactivate all material in the spill: for non-viscous spills, 15-20 minutes; for viscous spills, 30 minutes
- Use tongs/forceps to pick up sharp objects (broken glass, etcetera) that may punture gloves
- Wipe up spill with paper towels, working from edge to center
- Clean the spill area with fresh paper towels soaked in disinfectant. Wipe down all reachable cabinet surfaces with disinfectant
- Place disposable contaminated materials into red biohazard bags and autoclave them before discarding as regulated medical waste
- Place contaminated reusable items in biohazard bags or heat resistant pans or containers with lids before autoclaving and further clean-up
- Remove protective clothing used during clean-up and place in biohazard bag for autoclaving
- Inform the laboratory supervisor/principal investigator/BSO about the spill and successful clean-up as soon as possible

b) If infectious aerosols were created (judgment determination) and the room will be evacuated

- **DO NOT PANIC**
- Alert people in the immediate area of spill, hold your breath, and quickly evacuate the room or area
- Close the area, post a "DO NOT ENTER" sign or use caution tape, and allow agents to settle (~30 minutes)
- Identify any agent's specific issues (e.g. strain involved, infectious dose)
- Assess the degree of contamination and formulate a plan for the action required
- Assemble a spill response and cleanup team
- Before re-entering the room to proceed with clean-up, don gowns, gloves, shoe covers, a full covered face shield, and a N-95 mask, if applicable (PPE from spill kit)
- Starting at the edges and working toward the center of the spill, cover the spill with paper towels or other absorbent material
- Carefully pour disinfectant over the absorbent material and spill, starting around the edges and working toward the center. Saturate the area with the disinfectant
- Allow sufficient contact time for the disinfectant to inactivate all material in the spill: for non-viscous spills, 15-20 minutes; for viscous spills, 30 minutes
- Use tongs/forceps to pick up sharp objects (including broken glass) that may puncture gloves

- Use paper towels to wipe up spill, working from the edges to the center
- Discard absorbent materials in biohazard waste bags as you clean-up the spill
- Clean the spill area with fresh paper towels soaked in disinfectant. Thoroughly wet the spill area and allow to disinfect for approximately 15-20 minutes
- Discard cleanup materials in biohazard bags, along with any contaminated PPE
- Close and secure bags, then place bags in second biohazard bags. Secure outer bags and disinfect by autoclaving (steam sterilization)

Spill response and clean-up procedures inside biosafety cabinet

- Starting at the edges and working toward the center of the spill, cover the spill with paper towels or other absorbent material
- Carefully pour disinfectant over the absorbent material and spill, starting around the edges and working toward the center. Saturate the area with the disinfectant
- Allow sufficient contact time for the disinfectant to inactivate all material in the spill: for non-viscous spills, 15-20 minutes; for viscous spills, 30 minutes
- Wipe up spill with paper towels, working from edge to center
- Clean the spill area with fresh paper towels soaked in disinfectant. Wipe down all reachable cabinet surfaces with disinfectant
- If cabinet has a catch basin, flood the basin with disinfectant (if large amounts of contaminated liquid have entered the catch basin)
- Place disposable contaminated materials into red biohazard bags and autoclave before discarding
- Place contaminated reusable items in biohazard bags or heat-resistant pans or containers with lids before autoclaving and further clean-up
- Expose non-autoclavable materials to disinfectant, 20 minutes contact time, before removing them from the BSC
- The cabinet should be run for 15 minutes after clean-up before resuming work or turning off the cabinet
- Inform all users of the BSC as well as the laboratory supervisor/principal investigator about the spill and successful clean-up as soon as possible
- Record the incident

Injuries/Illnesses/Emergency Medical Events

Physical Injuries (e.g. fall, slip, trip)

- Assess the extent of injury
- Call for help if needed (laboratory colleague, security, emergency services, etc., depending on the degree of injury)
- Stabilize the person and determine if they can return to work or not
- If the individual is unable to continue work, help remove all PPE (without doing further harm) and assist with evacuation to a place where they can be met by emergency services

- If badly injured, the person should be left in place, and made comfortable until emergency services can safely remove them
- If working in a high containment facility emergency services may not be allowed in, therefore the injured person may need to be moved to the door or airlock where they will be met by emergency services

Illness (e.g. abdominal pain, shortness of breath, dizziness)

- If an individual is experiencing these problems, help the person to a seated position where they will not fall
- Determine the degree of seriousness of their problem and call for help if needed (laboratory colleague, security, emergency services, etc.)
- Ask someone else to secure their work
- Help them remove their PPE (if necessary). Depending on their condition, assist them to return home or to obtain medical assistance, including at a hospital

Unconsciousness (if you find a person on the floor unconscious)

Assess the scene first – DO NOT RUSH TO THEIR AID – there may be additional dangers to you (toxic gas, electrical hazard, etc.)

- If deemed safe, assess the person quickly
- Try to wake them and call to them
- Check for breathing
- Check for a pulse
- Conduct first aid (if trained to do so) and call for help
- Ensure that their airway is open (head tilt)
- Listen and look for breathing after a head tilt
- Determine if they have blood circulation by pressing on their finger nail or finger and looking for capillary refill (blanching and recolonization of the area)

Continue above until breathing, pulse and capillary refill return to normal. Have emergency services transport them to a hospital as soon as possible.

Percutaneous injury (e.g. needle stick injury, cut, animal bite, scratch)

- In the event of a needle stick or other sharps injury, remove glove(s) on the victim's exposed hand and the outer glove on the unexposed hand and vigorously wash the affected area with soap and water for 15 minutes. Apply first aid as required.
- Seek medical attention and report the injury to the biosafety officer (if you have one) and facility manager.

Personnel Contamination

Mucus membrane exposure of the face (e.g. splash or spray to the eyes, nose or mouth)

- Due to the PPE required during entry procedures, it is not anticipated that hazardous materials will come in contact with employees' eyes. If eye contact does occur with a biological or chemical, however, promptly **flush the eyes for at least 15 minutes** using the nearest laboratory eye wash station. After flushing, seek medical attention as needed and complete an incident report form. The MSDS for the chemical shall be consulted to assist in determining other appropriate first aid measures.
- In the event that infectious material has been inhaled via a respirator or isolator breach, avoid further inhalation and remove victim from the hazard. Summon help, tell your co-workers about the incident and potential danger, then remove victim from the facility. Seek medical attention and report the injury to the BSO and facility manager.

Biological spill on the skin.

Due to the PPE required during entry procedures, it is not anticipated that hazardous materials will come in contact with the skin. However, if skin contact does occur:

- Immediately flush the area with flowing water, depending on the nature of the spill. For some chemicals flushing with water is not advisable (e.g. phenol). If it's a biological agent or toxin, use flowing water for fifteen minutes to dilute and flush away.
- If the spill affects a hand, remove any jewelry (rings or watch) and thoroughly wash the entire hand(s) with warm water.
- If it was a chemical spill and there's no visible burn, wash with soap and water (if appropriate for the chemical; see above).
- Check the chemical material safety data sheets or other information for removal procedures and any possible delayed effects from the chemical.
- Seek medical attention. Be sure to take along the Material Safety Data Sheet for the chemical involved.

Spill of a chemical on clothing.

- Don't waste time wiping away the chemical or trying to neutralize it. Immediately remove any contaminated clothing and go to the safety shower.
- Call for someone to help you to the shower.
- Use the safety shower if it is large spill. The idea is to use a large amount of water to dilute the chemical along with removal any contaminated clothing, shoes, and jewelry.
- Time is critical to prevent any serious skin burns or absorption of the chemical into the body.
- If the chemical is corrosive, don't be modest; remove clothing as quickly as possible, because you want to limit the amount of time that the chemical is in contact with the body.

- Have someone get a gown to wrap yourself in and seek medical attention immediately

Spill of a biological agent or toxin on clothing.

- Depending upon how large the spill is you may wish to call for help.
- Remove any contaminated PPE and see if the material has seeped through to the next layer of clothing.
- Remove outer layer of clothing, and the next layer if the material has leaked through.
- If the biological material has seeped through to the skin, treat the contaminated skin with flowing water, as described above.
- Decontaminate the contaminated clothing with a liquid disinfectant or autoclave. This is why street clothing or home clothing should not be worn in the laboratory.

Power loss

Brief

- In the event of a power outage, stop work and wait to determine the length of the outage.
- Cover your work and close all vessels while waiting, as the airflow in the room or BSC will slow or stop.
- If the power returns, wait for a few minutes for the working environment (airflow, lighting, etc.) to return to normal and then continue work

Extended

- If the power does not come on after a considerable time, close all open vessels and prepare to stop work, as per normal procedures.
- If lights are lost, find an alternative light source.
- Avoid opening refrigerators and freezers any longer than necessary.
- Exit the facility as per normal procedures, using additional light sources as necessary.

Program review and performance assessment – Audits, inspection and certifications

Finally, we get to one of the most important parts of biorisk management: the performance component. This involves the process of determining if established biorisk mitigation procedures are working. In this section we will look at why you should conduct audits and inspections, and continuously question your biorisk management program. How can you be confident that that your facility is as safe as possible and that it will remain that way?

Biosafety and biosecurity procedures are more important than ever before. We've seen a tremendous amount of interest from different governments at local, national, and international levels, asking questions about the way biomedical facilities are operated. All facilities, old and new, are under increased scrutiny. Can you be sure that you are ready to operate a new or existing research or diagnostic facility in a safe and secure manner, with well-trained people who are doing the right things? Can you effectively manage your daily risks? Are your safety and security concerns being addressed by the biorisk management programs in place? Audit and inspection program will definitely help you determine how well you are achieving your biorisk management goals.

Never assume that things are working the way you planned, or as you think they should. Always be prepared to take a hard look and ask a lot of questions; collect all relevant data; and try to determine what is working and what is not. This will allow you to identify possible failures before they become accidents and to avoid the blame game that could ensue after an unexpected incident, when the vulnerability was right there in front of you at the time, waiting to be discovered. It is always better to know about a potential problem in advance, rather than to be surprised. Don't just wait for something bad to happen. An effective review process also allows you to apply the W5 approach—who, what, where, why, and when—after an incident occurs. The bottom line: Conduct audits and inspections on a regular basis, gather and re4cord all relevant information, take corrective measures as appropriate, and stay informed.

Let’s spend a little time on terminology. With regard to performance assessments, a lot of different terms get thrown around and these are often misused. These include the words “inspection,” “audit,” “accreditation,” “certification,” “evaluation,” and “compliance.” These words are not interchangeable; you must be careful about their use to ensure clarity. Let’s discuss each of these terms.

Inspection

An inspection is a snapshot of the physical conditions observed at the site, at a particular point in time. It's a useful tool for identifying non-compliance with established safety procedures. There are a number of reasons for conducting an inspection:

1) It's a time-honored part of any safety program, a long-standing practice in all safety industries. If you don't look, you can't find a potential safety problem.
2) An inspection may be warranted after an incident or accident. If something goes wrong you should find out why.
3) Inspection and audit records can be reviewed by regulators seeking confirmation that the institution is investing time and effort to maintain safety systems. Inspections will allow you to correct deficiencies on an ongoing basis, and to demonstrate completeness of your records for review by inspectors.
4) Other cognizant organizations and agencies may review your records or schedule their own audits and inspections.
5) Inspections will help you confirm that that you meet national or international biosafety standards (see above).
6) Finally, you need to be compliant with other national regulations and rules, not directly pertaining to biosafety. Examples are waste regulations and employment laws. Inspections will help you ensure that you are in compliance.

Audit

An audit is not the same as an inspection. An audit is a comprehensive evaluation of the entire biorisk management program. It reviews arrangements currently in place to ensure the effective operation of a biosafety program. This is a much bigger and more involved process than an inspection. inspections are limited in time, may not identify underlining issues, and are usually carried out using checklists. Inspections may not present an accurate indication of what's really going on. In addition, they are usually qualitative and not necessarily scored. Audits, on the other hand, are very comprehensive. They may take an extended length of time (possibly days) and will identify underlying root causes for observed deficiencies. Audits are usually carried out using an audit protocol, and they're able to drill down until all the issues are identified. They can present an accurate picture of what's going on, and they often employ a quantitative scoring system. To summarize: Inspections are done quickly and provide a snapshot in time, while audits provide a comprehensive assessment of a facility’s biosafety procedures and practices.

Accreditation

Accreditation is another term commonly used in discussions about certifications, audits, and inspections. In this context, accreditation is confirmation that an entity has established, documented, implemented and maintained a risk management system that oversees the operation of the laboratory and that applicable, designed maintenance and operational

regulations, guidelines and standards have been met. An accrediting organization has to be credible and knowledgeable. It must have the correct expertise and experience to evaluate your facility and determine if you are adhering to the applicable design, maintenance, and operation regulations. A number of organizations fulfill these criteria. In the United States, the American Biological Safety Association will come to your facility and provide accreditation at biosafety levels 2 or 3.

Certification

Certification is often confused with accreditation, but there are important differences between the two. In this context, certification involves documented testing to a standard issued by the certifying body. National or international organizations issue the standards, and the testing is usually performed by a third party with certifying authority. A good example is biosafety cabinet certification, conducted third party's personnel who have been vetted by a reference organization through some system of documented training and successful testing. Biosafety cabinet certifiers are use calibrated equipment and conduct certifications according to established standards.

Compliance

Compliance is another term commonly associated with inspections. In this context, compliance means that an interested individual states that an entity is adhering to prescribed standards. This is not necessarily based on independent third-party observation, approval, or documentation. Anyone can prescribe standards—parties involved, an associated industry group, or a recognized certification organization. Thus, the meaning of "compliance" is fairly loose. It simply indicates that an organization is adhering to someone's (presumably someone knowledgeable) prescribed standards. So, be careful when using the term "compliance" since it doesn't have the same authority or approval that certification or accreditation has.

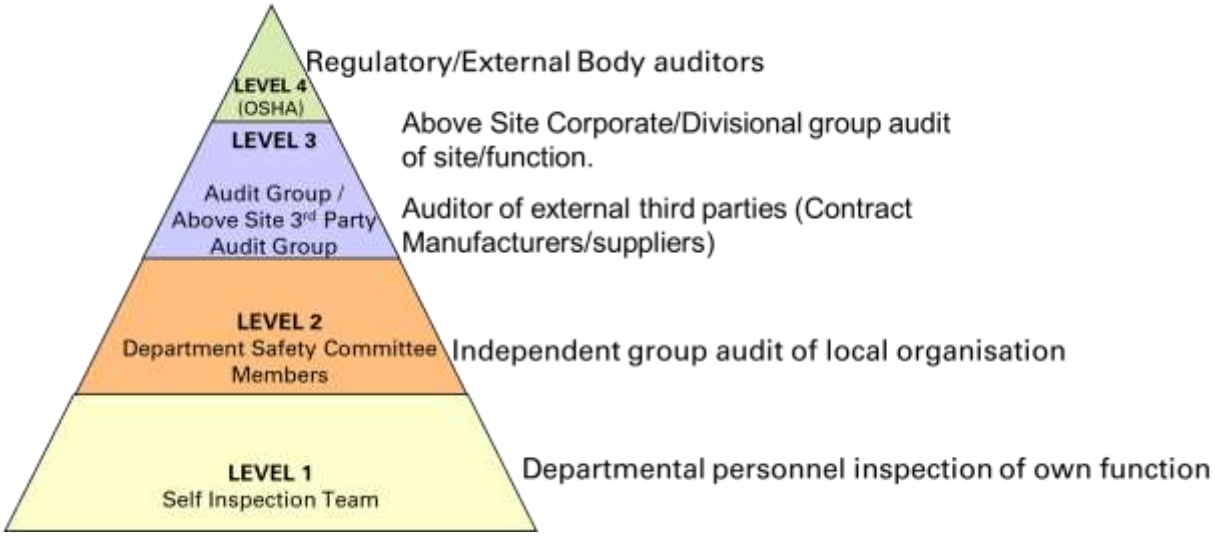
Goals of an inspection or auditing program

Why *inspect*? The goal of a biosafety inspection is to improve performance, compliance, and practices in a biomedical facility. It can help an organization meet local, national, and international requirements and expectations. It will also provide added value to an organizations' s environmental health and safety management system. The goal is to make a facility more biosafe in the future than it has been in the past. The intent of an inspection program is not to find fault or punish somebody for doing something wrong, or to check boxes, but to improve overall safety.

Why *audit*? The primary goal is to promote compliance with organization standards and government dictates. Second, an audit will also ensure the uniform application of an organization's standards. That's particularly important in a large organization with multiple locations. Third, an audit helps an organization in the implementation of management systems. This especially pertinent to a biorisk management program. Fourth, an audit can uncover the root cause of problems or deficiencies, and lead to appropriate corrective actions.

In summary, a continuous cycle of audits and inspections will improve overall management performance.

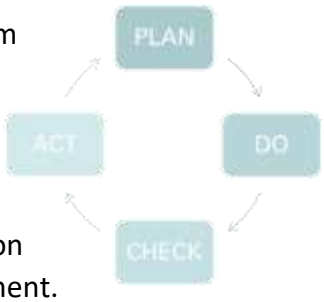
There are several tiers of inspections and audits, as shown in the accompanying pyramid diagram. From base to peak, inspections and audits grow more detailed and complex. The lowest tier constitutes self-inspection. This can be accomplished by any facility employee, even on a daily basis, as the employees looks for safety deficiencies. In the next tier, a departmental inspection team investigates individual laboratories to determine compliance with prescribed biorisk management procedures. This team could be a departmental safety committee, an independent group, or representatives from a local organization who have been invited to look at your facility. The next tier would be a third-party, external auditor from the corporate, divisional, or ministry level (if you're working in a government). These audits are more serious, open, and binding. The highest tier represents an inspection from an official government body, such as the Occupational Health and Safety Administration (OSHA) in the United States. The inspection or audit will focus on regulatory compliance. Non-compliance at this level leads to fines or work stoppage.



Planning an inspection or audit

An audit or inspection program should be based on the plan-do-check-act cycle, common in many different industries and activities. Planning is the first step. This involves developing your checklist or your audit protocol. Think about how to do this and then implement your plan. Next, arrange for the specific entity that will conduct the audit or inspection. Then communicate the plan to the people that will be inspected or audited. If your inspectors or auditors are from within your organization, they should first be trained. Next, conduct the audit or inspection. On completion, compile the data, analyze it, and compare it with other years or other facilities. Pay particular attention to the degree of compliance with prescribed protocols. Finally, you should act to address identified deficiencies. This will require effective

communications with those who will make the needed corrections. A corrective action plan will help to validate and verify that deficiencies have indeed been corrected. Of course, plans should be adjusted as necessary or advisable. In summary, the plan-do-check-act cycle is a circle that will feed into your next planning cycle.



Be careful that you don't create a laboratory assessment or inspection system that only generates documents, rather than results. Simply filling out an inspection checklist will not change anything. If you find a deficiency, you must address it. Records of inspection may document that inspections and audits were done by the right people using the right tools, but, unless you actually act on the results, nothing will change. Remember, the inspection or audit process is not to find fault, but to identify areas that need improvement.

When you build your assessment tool, you should specify the issue or item being assessed. Will you be addressing a regulatory requirement or best practices guidance? Where did your checklist items derive from? It's always good to be able to refer back to some standard, regulation, or published guidance, so that doesn't come across as simply your opinion. The inspection or audit team leader must decide in advance what inspection checklist will be used, and what standards guidelines will be addressed. The assessment tool can be based on generic safety check lists; laboratory-specific items can be added, as needed, based on the hazards and the risks specific to the facility or laboratory. Thus, there may be different checklists for the bacteriology lab, virology laboratory, the necropsy spaces, and other areas, based on their individual hazards and risks. Available resources and time may also affect your decisions about the depth and duration of the inspection or audit,

There are many different ways to do inspections and audits. The trend is to go paperless and move toward electronic methods. Electronic technology allows use of hand-held devices such as personal digital assistants, tablets, and smart phones. Required software should be preloaded on device before taking them into inspected area(s). Smart devices make it easy to take pictures or record audio, enabling a more efficient and accurate record of the inspection or audit, and facilitates moving information onto spreadsheets or databases. GPS location coordinates can be used to record, date, time, and location of the event. Electronic information can be easily shared with government agencies or other entities interested in what laboratories are doing and their compliance with prescribed standards.

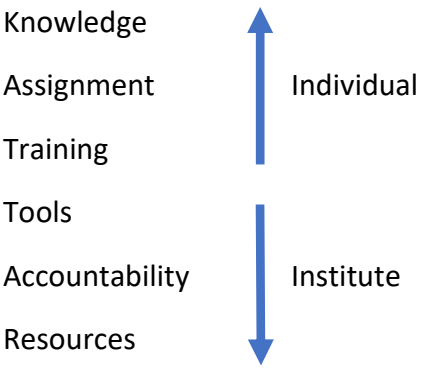
Corrective action plan

Once deficiencies are found, a, specific corrective action plan must be established; it is not enough to simply say: We have a problem, so we'll fix it. First, the laboratory must identify the responsible party for correcting a particular issue. Depending on the issue, different individuals may have different assignments for remedying deficiencies. Second, there should be an implementation schedule with an indication of when each deficiency will be corrected. This

schedule should show a start date, specific milestones along the way and a completion date. You should ensure that identified deficiencies are clear, to prevent confusion about the actual problem(s) and necessary corrective actions. The identified completion date should be a hard stop date, meaning that the identified deficiency must be corrected by a specific time. Any delay must have a strong justification, and all cognizant parties should be informed. Finally, closure documentation is essential. You should ensure that all responsible persons sign off on the completed report, confirming that identified deficiencies were corrected to the satisfaction of the inspection team.

Root cause analysis

You may hear the term “root cause analysis.” This refers to determining what the fundamental cause or basis of an identified problem. It can be a single or multifactorial cause. Causes can be related to insufficient knowledge, misunderstood or disregarded assignments, insufficient training, a deficiency of resources or tools, a failure to specify accountability, or a combination of these (see accompanying diagram).



As the diagram indicates, problems traced back to lack of knowledge, assignments, and training usually reside with the individual carrying out the task. Problems related to a lack of tools, accountability, and resources typically lie more with the institution that's responsible for providing these. Therefore, when you identify the root cause of a problem or deficiency, you may also home in on the party (parties) responsible for responding to and fixing the problem. Is it an individual or the institution? For example, if you find needles found in the regular waste containers, is this an institutional problem (poor training and enforcement or lack of sharps containers) or an individual problem (carelessness or negligence)? It may be some of both—and the issues/problems themselves may have multifactorial causes.

Documentation

Don't forget about documentation. Everything that you're doing, including inspection and audit reports, should be clearly and thoroughly recorded. Document, document, document! There is

a saying that, if it isn't documented, it wasn't done. If you don't have a paper or electronic trail you can't confirm the correction of a deficiency, or even that it existed. Again, use technology to help you document. In addition, an electronic system can remind you to do certain activities on a regular basis. Today, all information can be stored in the cloud, so that is not lost.

What are you inspecting or auditing?

Finally, I want you to think about what are you inspecting or auditing. There must be some documented standard, guideline, best practices, or regulation with which you seek compliance. For example, are you in compliance with waste management regulations in your country? Are you following established international health guidelines? Are you adhering to local requirements for managing personnel safety? Your goal is to be in compliance with local, national, and international guidelines, standards, and regulations. Note that international health guidelines apply to all countries, but are not strictly regulatory. All cognizant personnel should be aware of the specific standards for which they're accountable. Inspectors and auditors should ensure that the institute is aware of the standard, guideline, regulation, or best practice that will be applied for the assessment.

Final thoughts

As I have tried to demonstrate throughout this book, there is no one comprehensive or perfect answer to how to conduct or implement biosafety. The answer is very much dependent upon the situation, the problems encountered, and resources available to manage the problems. Risk/biorisk perceptions vary greatly across the world. Therefore, the best approach is to first identify the specific hazards and the risks that arise from those hazards. This can be done by first conducting a preliminary inspection or audit. Then, through discussions with the workers and leadership, you can begin to devise ways to eliminate or mitigate the hazards and lower the risks, by strengthening biorisk management. Applying the principles discussed throughout this book and understanding that there are many available options, should give you confidence that you can establish a biosafe facility, even with limited resources. Remember this motto:

Do something today to make yourself safer tomorrow

Thank you for reading this book. Be Safe – Be Biosafe!