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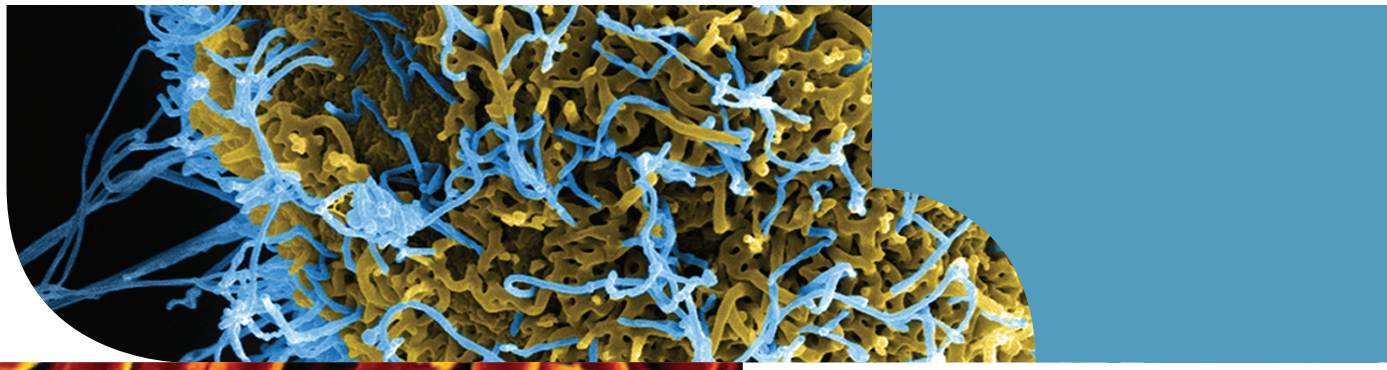
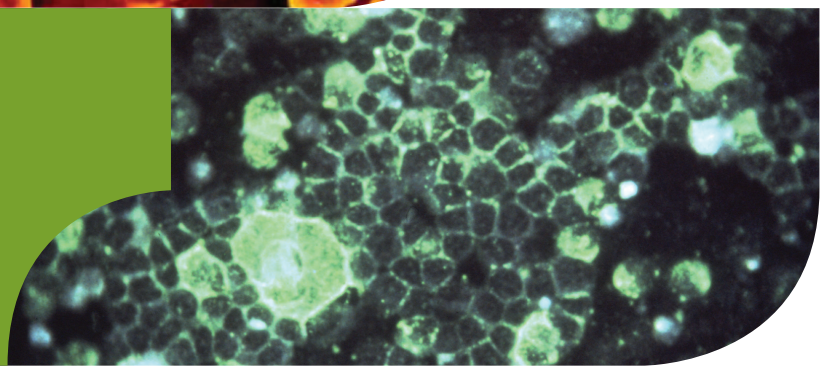


Pathogen Safety Data (PSD) Guide



OCTOBER 2016

This publication was made possible by contract number HHSN273201500075U from the National Institute of Environmental Health Sciences (NIEHS), NIH.
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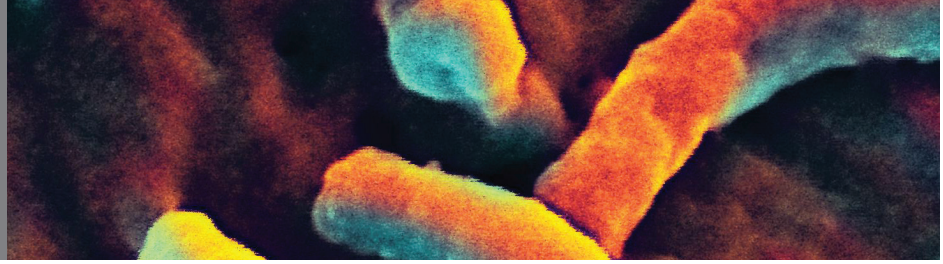

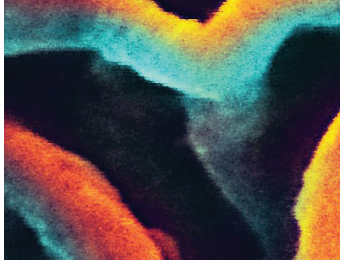

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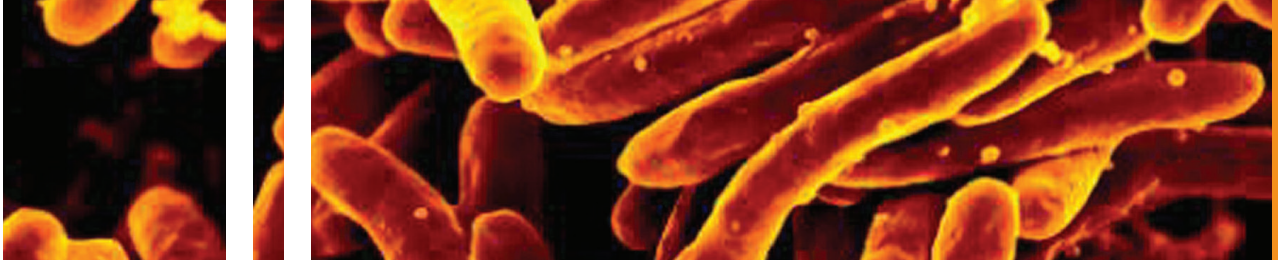
Cover photo (bottom) credit CDC/Dr. Craig Lyeria



SECTION I: INTRODUCTION AND BACKGROUND

Access to accurate and timely information about infectious pathogens is key to developing effective worker protection programs. The goal of this guide and its companion training module are to clarify the use of existing pathogen safety data (PSD) resources currently available for development of infectious disease occupational exposure control plans in a broad spectrum of industries.

The contents of the guide bridge existing infection prevention and control best practices, microbiological safety data from credible sources, and evidence-based all-hazard risk assessment models as an effort to promote biological safety outside of the laboratory setting.

Some of the major challenges in occupational risk assessment for infectious pathogens include absent or limited information on the following:

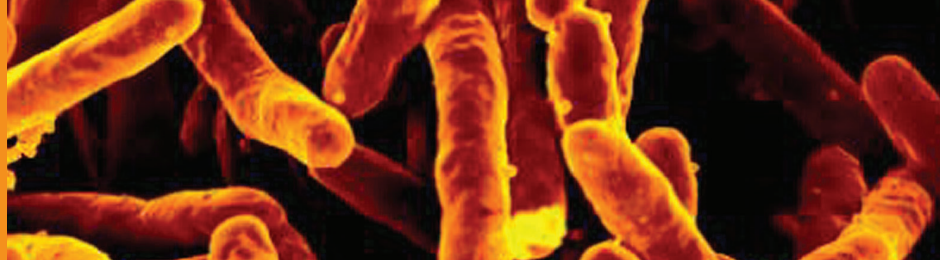
- Occupational exposure limits
- Toxicity
- Methods to measure airborne or surface concentrations
- Applicable information on infectious dose[1]
- Occupational exposure incident surveillance data[2]

These challenges increase the difficulty in applying existing pathogen safety data sources for occupational risk assessment and risk management decision making. The risk ranking approaches described in this guide provide a path forward.

Sections within this guidebook are intended to raise awareness of some key uses of pathogen safety data, including determining transmission routes, exposure controls, and workplace planning along with personal protection practices.

This National Institute of Environmental Health Sciences (NIEHS) Worker Training Program (WTP) PSD project is a collaboration with the Public Health Agency of Canada (PHAC), the National Institute of Occupational Safety and Health (NIOSH), and the U.S. National Library of Medicine (NLM).

1 The number of organisms required to infect a host.
2 There is no national database that collects reports about occupational exposure to infectious pathogens and any work related infections that result from them.



NIEHS WTP Ebola Response

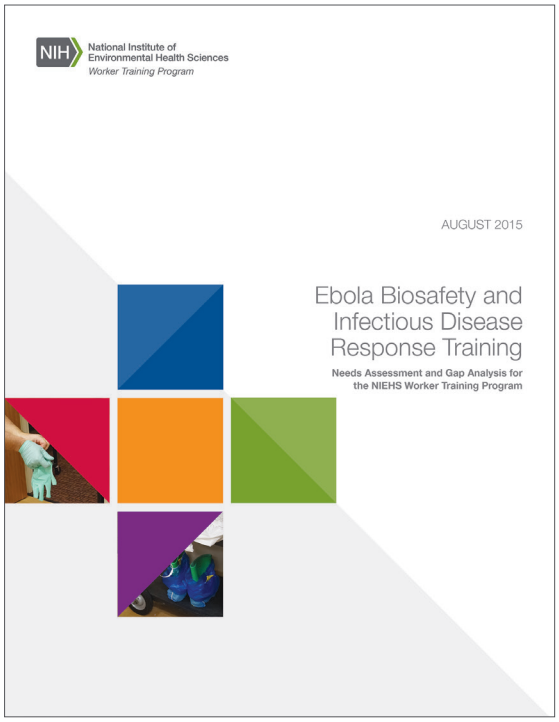
When the Ebola crisis hit the U.S. in 2014, the WTP went into action, tracking information and posting resources on Ebola virus disease (EVD). The goal was to provide critical safety and health information to protect high-risk populations potentially involved in emergency response and cleanup. In collaboration with federal partners NIEHS WTP is funding the Ebola Biosafety and Infectious Disease Response Training grant program.

Prior to funding awardees, NIEHS WTP conducted an Ebola Biosafety and Infectious Disease Response Training Needs Assessment and Gap Analysis, which consisted of a literature search, analysis of existing guidance, discussions with stakeholders, as well as focus groups in four cities: New York, Washington, Oakland, and Cincinnati. One of the major gaps identified was the difficulty in accessing pathogen safety data that is specific to the needs of worker safety and health. Many of the existing resources are focused on community health, traveler screening, patient care, and other functions. Upon researching the idea of developing a Pathogen Safety Data Sheet (PSDS) database, similar to the Safety Data Sheet (SDS) approach to chemical hazards, WTP determined that the resources necessary for such a project are not currently available. That led to the development of this Guide, a tool that can be used by employers and workers that is entirely focused on occupational exposure control for various infectious disease scenarios using existing resources.

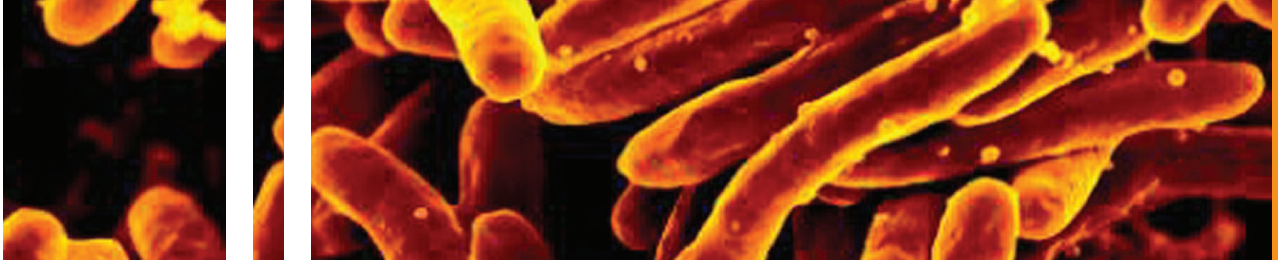
Results of the NIEHS Worker Training Program Ebola Needs Assessment. WTP learned about gaps in the availability of PSD for the purposes of occupational infection prevention and control activities through its work in responding to the 2014 Ebola crisis detailed below.

Gap 1C: Guidance issued by federal authorities was inconsistent and left out key items that adversely affected worker safety and health.

Gap 1 D: Resources on infectious diseases from trusted sources is sometimes conflicting or lacking in enough specificity to be immediately helpful.



For workers and trainers of workers potentially exposed to Ebola or infectious disease, The National Clearinghouse for Worker Safety and Health Training has produced an awareness and operations level PowerPoint (PPT) on Ebola that may be downloaded at:



https://tools.niehs.nih.gov/wetp/index.cfm?id=2542. This site also has links to Ebola infection control information from federal, state, academic, and labor sources.

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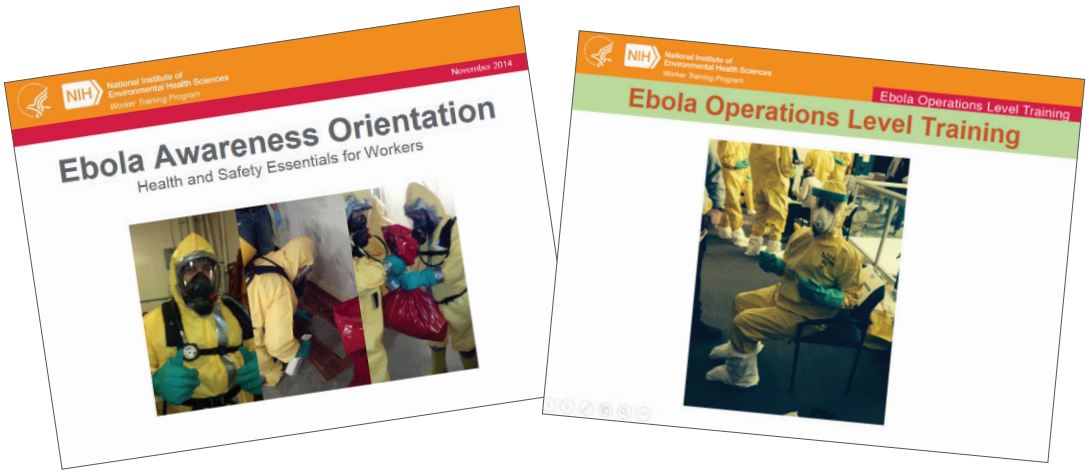


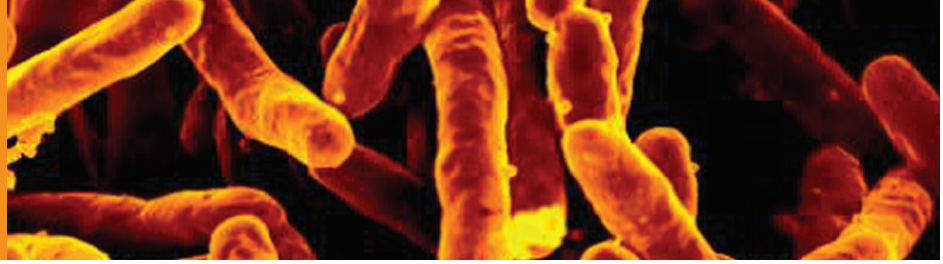
Intended Audience and Companion Training Module

The guidance in this booklet is primarily intended for workers and employers in industries with potential for occupational exposure to infectious pathogens. This Guide should be used as a reference for developing site specific infectious disease exposure control programs.

The companion training module may be integrated or adapted into existing training programs. It should not be used to replace a comprehensive pathogen specific training program and should be adapted to meet industry- and site-specific conditions by customizing it to targeted populations. A list of industries that may benefit from using this guide is in the table below.

Healthcare
Humanitarian aid
First responders and emergency personnel
Laboratory
Environmental services (clean-up and waste disposal)
Funeral and mortuary
Travel: airline, rail, ship
Border, customs, and quarantine workers

Industries and Occupations with potential exposure to infectious diseases

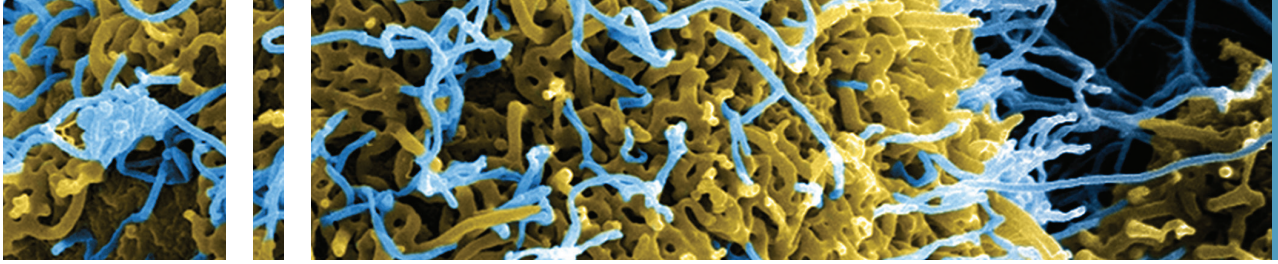


CAUTION

Laboratorians should refer to the CDC publication Biosafety in Microbiological and Biomedical Laboratories and the NIH guidelines, referenced on pages 23, 26 and 75. Hospitals and other healthcare facilities should refer to their specific state's public health laws and regulations as well as the OSHA standards detailed in this Guide.

Electronic Format and Glossary

This guide will also be available through the National Clearinghouse for Worker Safety and Health Training website in a PDF hyperlinked format. A companion glossary is in a separate document and defines terminology and acronyms that are commonly used in the sources of pathogen safety data.



SECTION II: PATHOGEN SAFETY DATA AND OCCUPATIONAL HAZARDS AND RISKS

Learning about the available pathogen safety resources and understanding their strengths and limitations helps to strengthen risk assessment and control efforts.

Current Pathogen Safety Data

A variety of data is generally available in pathogen safety data resources. There is no standard template shared by all agencies or organizations, and the information is updated at the organizations' discretion. This information often lacks details needed for understanding worker safety, is inconsistent or outdated, or is extremely technical, reducing workers ability to understand needed safety measures. The list at right outlines the possible types of Pathogen Safety Data available.

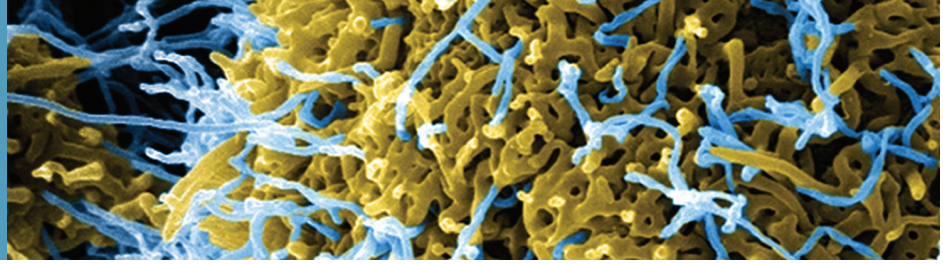
Common Problems with Pathogen Safety Data

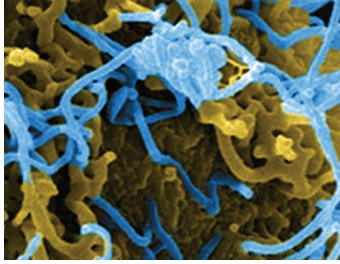
- Technical jargon
- Not specific to worker protection
- Inconsistent guidance
- Information on control measures lacks detail and specificity

Pathogen safety data may be used to develop industry and site specific infectious disease prevention and control plans. The complexity of these plans will depend on the type of work that is being done and whether or not the job tasks involve potential exposure to infectious agents.

EXAMPLES OF PATHOGEN SAFETY DATA

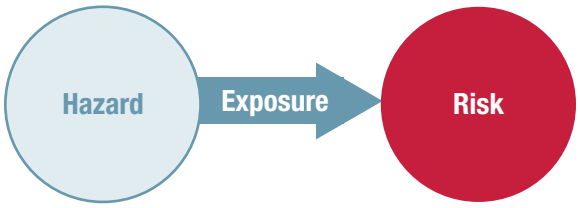
- Introduction
- Classification
  - Pathogen family/genus
  - Characterization
- Epidemiology
  - History of outbreaks
  - Incidence of disease
  - Prevalence of disease
- Pathogen Reservoirs
- Transmission route
- Pathogenesis
  - Clinical symptoms and signs
  - Stability and viability
- Diagnosis, Treatment, and Prevention
- Laboratory Hazards
- Exposure Controls
- Personal Protection
- Handling and Storage
- Regulatory and Other Information
- Date of Last Update
- Name and Institution of Preparer
- References





Introduction to Occupational Hazards and Risks

The main use of existing pathogen safety data is to identify and prevent occupational exposure to infectious disease hazards. Hazards may be defined as any source of potential damage or adverse health effects on a group of workers. Risks may be defined as the chance or probability that a person will be harmed or experience an adverse health effect if exposed to a hazard at work.



An Infectious Disease Occupational Exposure Control Plan

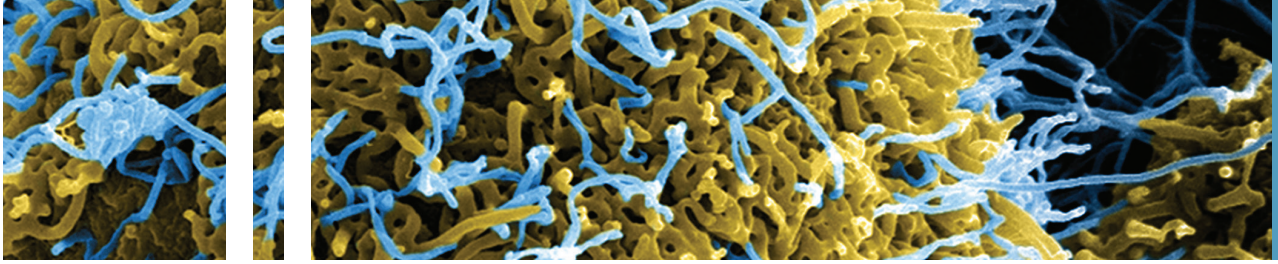
Prevention of occupational exposures to pathogens begins with employers to developing a written infectious disease occupational exposure control plan to assure procedures are in place to protect all employees who have potential contact with infectious agents.

Risk	Likelihood **x** Severity
Exposure	Contact with a chemical, physical, radiological, and/or biological agent
Assessment	A process of gathering, analyzing, and documenting; evaluation

The table on the next page outlines the key elements of an infectious disease occupational exposure control plan.[2,3]

The plan must be industry and site specific. Input from workers who perform the job tasks that generate potential exposure is essential. Additionally, a feedback loop should be designed into the plan to allow for continual process improvement. Other organizational stakeholders should include management decision makers, purchasing agents, operational managers, supervisors, human resources, and other functions that will play a role in implementing the plan. Pathogen safety data will be critical in many phases of plan development such as exposure determination, exposure control, decontamination, and post-exposure procedures. Consider sharing this guide and the related training module with members of the committee that are developing, implementing, and updating the plan. Once a process is established, the critical step is the risk assessment and selection of effective hazard controls. The OSHA bloodborne pathogens standard details requirements for worker protection from pathogens that are in blood, body fluids and other potentially infectious material (OPIM). Section III of this guide will cover more on the topic of risk assessment and includes a sample checklist for Risk Assessment.[4]

3 Cal/OSHA ATD Standard
4 Definition adapted from the Canadian Centre for Occupational Safety and Health



Key elements of an infectious disease exposure control plan

Management Commitment and Employee Involvement

- Designated plan administrator, accountability
- Committee process includes organizational stakeholders, workers, and union representatives
- Written exposure control plan

Risk Assessment

- Exposure determination
- Consideration of proximity to the contaminant source, virulence, pathogenicity, severity of potential health effects, environemental factors, effectiveness of controls, etc.

Hazard Control

- Hierarchy of controls: use engineering and admininstrative controls
- Selection of PPE and respirators
- Product selection committee includes end users
- Proper staffing and limit worker exposure to contaminated materials

Decontamination, Disinfection, and Sterilization

- Routine and targeted decontamination
- Handling, containerization, storage, transport, or disposal of contaminated materials
- Disinfection and sterilization of contaminated equipment and work areas.

Reporting & Recordkeeping

- Written procedures for reporting and recording exposures or cases
- Reporting to publc health authorities as per federal and state law

Training

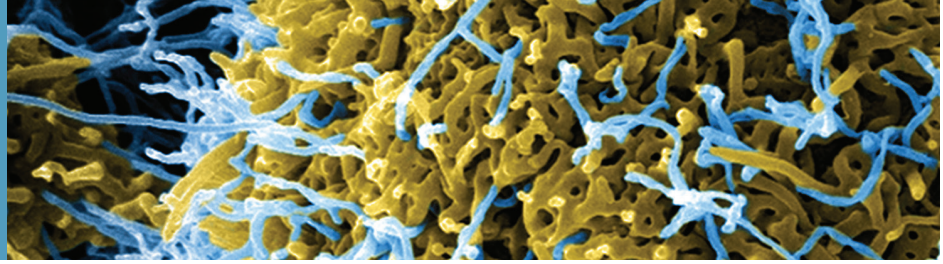
- Standard operating procedures in the written plan
- Donning and doffing PPE
- Frequency tied to demonstrated competency, at least annually
- Drills and refreshers

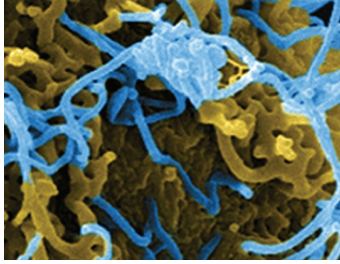
Post Exposure and Occupational Health Procedures

- Vaccinations, post exposure procedures, baseline medical testing, medical monitoring, medical removal protection (removal from exposure and protection of compensation)

Plan Updates/Evaluation

- At least annually
- New job tasks, new technology
- Exposures, emergining infections
- Record reviews, surveys, auditing, observations, equipment evaluations





Risk Assessment for Pathogens: Using Pathogen Safety Data

Occupational risk assessment is fundamental to establishing effective worker protection programs. A key element of an exposure control plan is a complete Risk Assessment for infectious hazards. This Risk Assessment can be identified as a process consisting of four components:

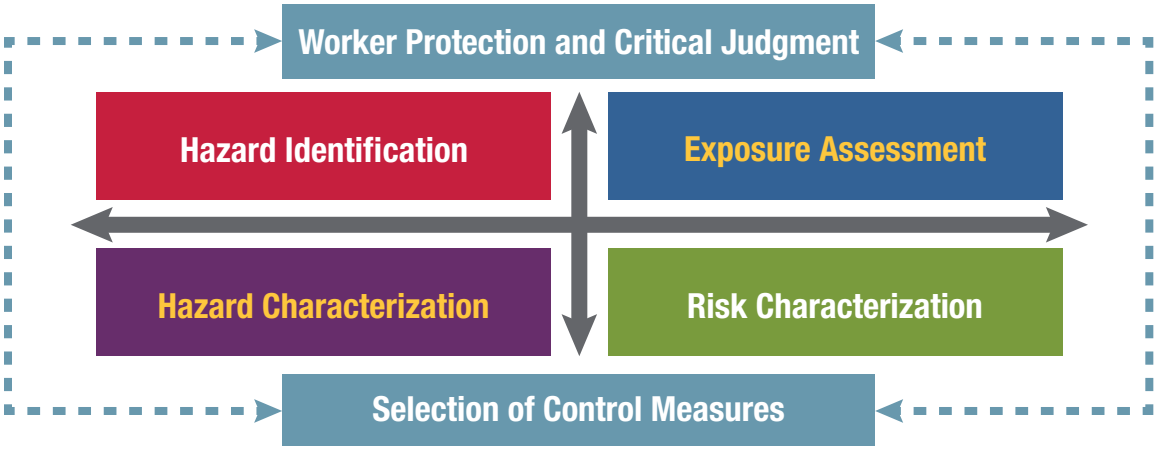
1) **Hazard identification:** *the process of identifying the pathogen*
2) **Hazard characterization:** *the process of understanding the threats posed by the pathogen*
3) **Exposure assessment:** *the process of understanding how a worker may be exposed*
4) **Risk characterization:** *the process of understanding the overall risk to a worker*

Hazard identification is the process of identifying the pathogens that are present in the workplace. Once the pathogen of concern is identified, pathogen safety data sheets may be used to help characterize the pathogens and in risk assessment and control.

Hazard characterization provides a description of the adverse effects of exposure, routes of transmission, time elapsed between exposure and onset of symptoms, ability to cause disease, survival in the environment, and the probability of adverse outcomes.

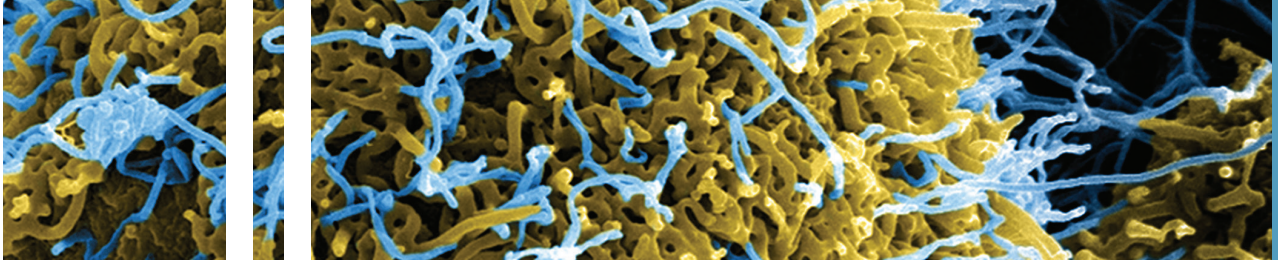
Exposure assessment evaluates the likelihood of exposure to the identified hazard. Occupational exposure refers to exposure to sources of infectious agents resulting from an employee's execution of job duties.[5] Risk characterization and assessment is essential to developing effective worker protection programs.

Risk Assessment can be "quantitative" and "qualitative". Quantitative methods involve measuring concentrations of actual hazards and comparing them to occupational exposure limits. Since this approach is not available for infectious pathogens, it is necessary to use qualitative methods that try to estimate exposure and risk.



Risk Assessment and Hazard Control Process

5 Adapted from OSHA's "Outline of Key Provisions in OSHA's Infectious Diseases Regulatory Framework

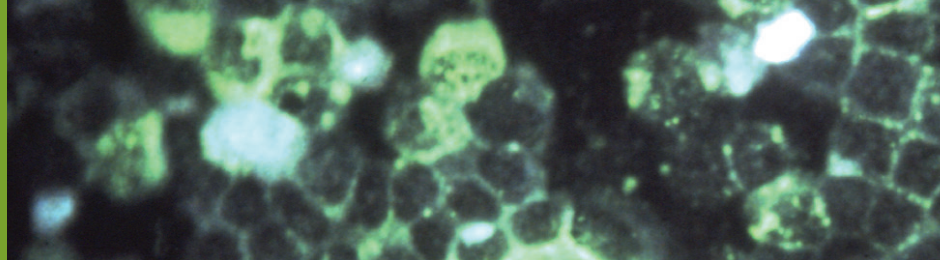


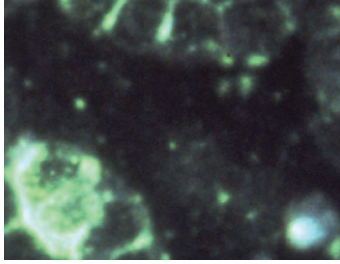
Means of Transmission

Learning how infectious diseases are transmitted is important for determining proper infection prevention and control measures and must be considered in Risk Assessment.

Microorganisms vary by size, the length of time that they can survive on surfaces or in the air and the way they are transmitted. There are four main routes of transmission listed below. Some pathogens have multiple routes of transmission, therefore it is also essential to determine if pathogens are transmitted person to person, from contaminated objects, or from animals and insects.

Contact	**Direct**	Direct physical contact between the source and the susceptible person, including exposure to skin and body secretions. Examples: Influenza virus; touching a wound; Infectious mononucleosis; chlamydia
	Indirect	Infectious agent deposited onto an object or surface (fomite) and survives long enough to transfer to another person who subsequently touches the object. These may include medical equipment, clothing, bedding or even drinking cups. Examples: Influenza; Norwalk, rhinovirus; gram-positive bacteria; gram-negative bacteria; atypical bacteria.
Droplet		Transmission expelled from respiratory secretions by coughing, sneezing or talking. Droplets are large particles that rapidly settle on surfaces or come in contact with the nose, mouth, or eyes. Examples: Meningococcus; Influenza; Respiratory syncytial virus (RSV)
Airborne		Transmission via aerosols (microscopic airborne particles) that stay suspended in the air. Can be spread via ventilation systems. Examples: Tuberculosis (TB); measles; chickenpox
Aerosol Transmissible		Infectious agents are suspended or present in particles or droplets and contact the eyes, nose, mouth or are inhaled. Examples: Ebola, Influenza, Mumps, Pertussis





SECTION III: EXISTING SOURCES OF PATHOGEN SAFETY DATA (PSD)

Readily available sources of PSD are listed below. For each of these resources this guide provides guidance on how to access them, their primary target audience, their use, strengths, and limitations. The end of this guide includes case studies where these resources can be applied.

- Public Health Agency of Canada
- U.S. Centers for Disease Control and Prevention
- National Institute of Allergy and Infectious Diseases
- The National Library of Medicine's WISER
- Occupational Safety and Health Administration
- The APHA's Control of Communicable Disease Manual
- World Health Organization

How to use Pathogen Safety Data

These sources of PSD provide information on specific infectious disease agents' characteristics such as pathogenicity, virulence, and means of transmission. This data can aid in conducting a workplace site specific risk assessment which is outlined in more detail in the Section III of this Guide. Some of these resources provide specific guidance on control measures, personal protective equipment (PPE), and respirators for healthcare and laboratory workers and may be used by inference for other industries with similar exposures. However, users should be cautious as these control recommendations may not apply to site specific conditions and often lack documentation detailing the basis for their selection. The use of any included references DOES NOT relieve employers from complying with applicable OSHA standards.

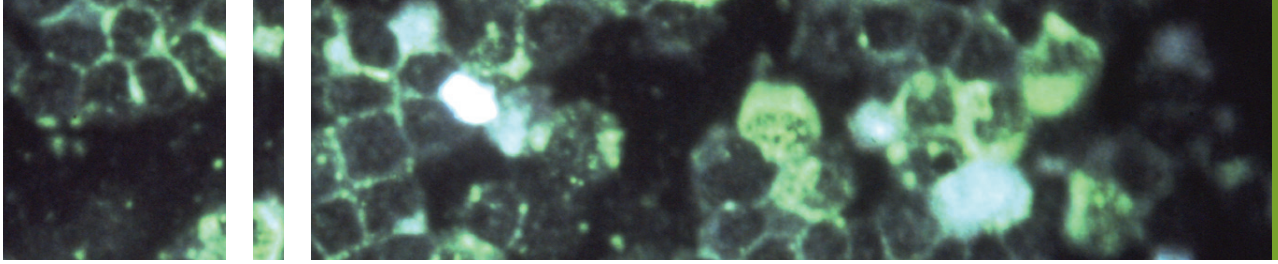
Pathogen Safety Data Resources

Public Health Agency of Canada | Agence de la santé publique du Canada

The **Public Health Agency of Canada** (PHAC) has established a database of some 200 pathogen safety data sheets that are available online and by smart phone app. The site describes the PSDSs as "…technical documents that describe the hazardous properties of a human pathogen and recommendations for work involving these agents in a laboratory setting."

PHAC developed its PSDs using a format similar to the safety data sheets required by OSHA for hazardous chemical under the hazard communication standard, 29 CFR 1910.1200. However, there are significant differences between SDS's and PSDs as outlined on the next page:

PHAC PSD website: *http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php*



Comparison of Elements in a Safety Data Sheet to a Pathogen Safety Data Sheet

Element (Examples)	SDS	PSDS
Hazard Identification	Chemical or Product	Infectious Agent
Composition	Name, components, CAS#, concentration	Name, Taxonomy
Hazard characterization	Toxicological information (e.g., LD50, carcinogenicity)	Pathogenicity, infectious dose, communicability, etc
Stability	Chemical stability, reactivity, incompatible materials	Drug susceptibility/resistance, survival outside the host
First aid	First aid measures	First aid measures, prophylaxis, immunization
Exposure controls	Exposure limits, protective equipment, engineering controls	Containment requirements (physical and operational controls), protective equipment
Handling and storage	Safe handling and storage, including incompatible chemicals	Spills, disposal, and storage
Physical and chemical properties	Odor, pH, flash point, etc.	N/A

Sections in a PHAC PSDS

Section I Infectious Agent: name, agent type (bacteria, virus, fungi, parasite, or prion), taxonomy (scientific classification), synonym or cross reference, and characteristics.

Section II Hazard Identification: pathogenicity, toxicity, pre-disposing factors, communicability, epidemiology, hosts, infectious dose, incubation period

Section III Dissemination: reservoir, zoonosis/ reverse zoonosis, vectors

Section IV: Stability and Viability: drug susceptibility, drug resistance, susceptibility to disinfectants, physical inactivation, survival outside host

Section V: First Aid/ Medical: surveillance (how can the pathogen be detected in an infected individual), symptoms, first aid/treatment, immunization, prophylaxis (pre and post exposure vaccinations or treatments)

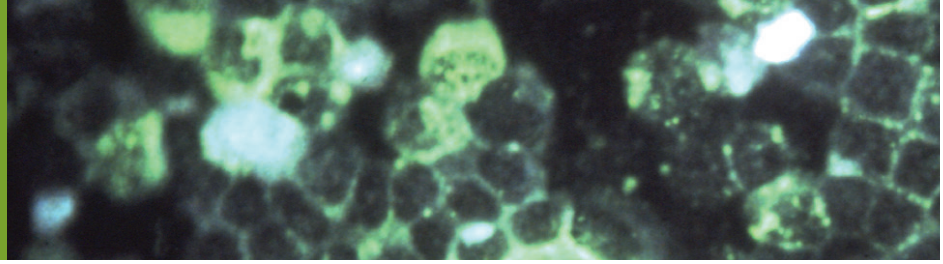
Section VI: Laboratory Hazards: laboratory -acquired infections, sources/ specimens, primary hazards (primary exposures), special hazards

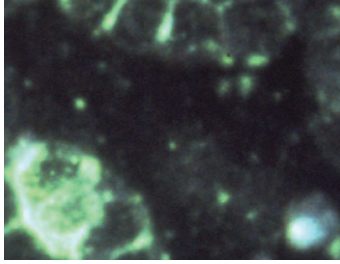
Section VII: Exposure Controls/ Personal Protection: Risk group classification, containment requirements, protective clothing, other precautions

Section VIII: Handling and Storage: spills, disposal, and storage

Section IX: Regulatory and Other Information: Canadian regulatory authorities

Date of Last Update, Name and Institution of Preparer, and References





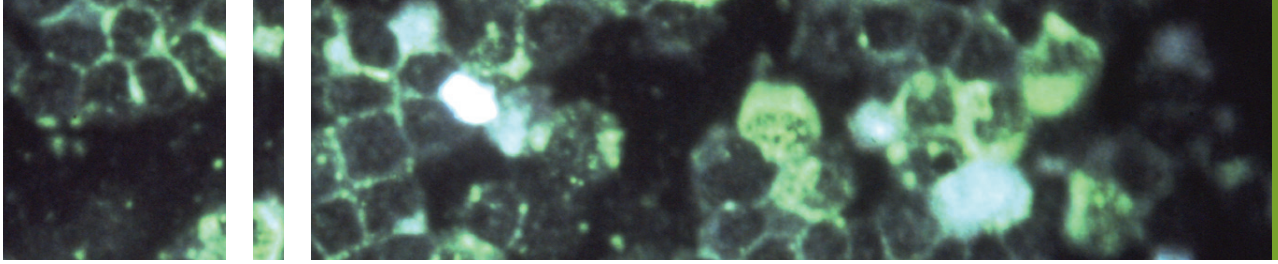
PHAC Sample PSDS's

Strengths: PSDSs are in a standard format, are peer reviewed for scientific accuracy, are comprehensive, and are recognized globally as a reliable source of information on infectious pathogens. Documents provide a very useful compilation of agent-specific information in a systematic template. SECTION VII - EXPOSURE CONTROLS / PERSONAL PROTECTION lists a "Risk Group Classification" and describe risk group levels for containment, referenced from the Canadian Law entitled the "Human pathogens and toxins act." These documents also use biosafety levels (BSL) to detail use of personal protective equipment and respirators. Biosafety levels 1 - 4 are used in the US, Canada, and Europe to describe precautions required to isolate dangerous biological agents in an enclosed laboratory facility. For some pathogens like Ebola, details on PPE and respirators for laboratory handling and transporting are in a separate linked document. The PSDS app (PSDS FTSS) is available to download in the Android, Amazon, Apple, and Window stores."

Limitations: Information is geared toward laboratories, is highly technical and contains information that is unrelated to worker protection. The database does not include PSDs on emerging infections such as MERS (Mid East Respiratory Syndrome) and Zika virus. The reason for this is that emerging infections typically feature a number of unknown characteristics. A limitation to the smartphone app includes the inability to search acronyms and requiring the knowledge of pathogen or disease names. There is a high usage of technical jargon. Readers should look up the terminology in the glossary to become familiar with the meaning of these terms.

The U.S. **Centers for Disease Control and Prevention** (CDC) describes itself as the nation's health protection agency. It has a broad public health mandate. Its organizational structure includes the Office of Infectious Diseases which has three centers: 1) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID); 2) National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP); and 3) National Center for Immunization and Respiratory

CDC
CENTERS FOR DISEASE™ CONTROL AND PREVENTION



Diseases (NCIRD). These centers work with state and local health departments, healthcare facilities, researchers, domestically and globally to prevent the spread of infectious diseases.

CDC's infectious disease pages contain dozens of links to detailed guidance documents on topics such as countries with confirmed cases, US case profile, people who may be at increased risk, frequently asked questions, information for healthcare professionals and laboratories, guidance for travel, and related materials.

The Healthcare Infection Control Practices Advisory Committee (HICPAC) is a federal advisory committee that provides advice to CDC and the Secretary of the Department of Health and Human Services (HHS) regarding the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections, antimicrobial resistance and related events in United States healthcare settings. HICPAC's *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* are a primary reference for infection prevention and control in healthcare facilities.

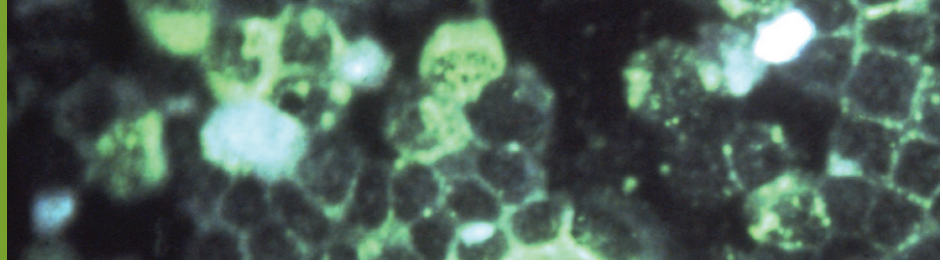
National Institute for Occupational Safety and Health (NIOSH) is part of the CDC. NIOSH was established under the Occupational Safety and Health Act of 1970 as the lead federal occupational safety and health research agency. NIOSH works closely with OSHA and conducts research, funds external researchers, develops guidelines, and provides education to safety and health professionals. NIOSH is legally responsible for certifying respiratory protective devices. NIOSH has made numerous recommendations about infectious disease hazards and controls over the years – separate from and in tandem with those of CDC.

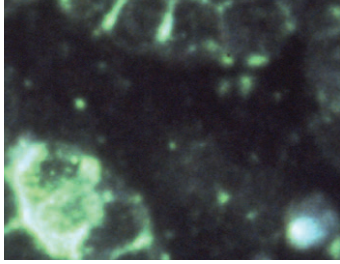
CDC Website: *http://www.cdc.gov/*

NIOSH Website: *http://www.cdc.gov/niosh/* The NIOSH A – Z index can be used to look up a specific pathogen.

Strengths: CDC's guidance is considered the authoritative source of information on infection control in the US and is a major contributor in controlling infectious disease worldwide. State and local health departments and healthcare facilities use CDC guidelines as a basis for developing infection control programs. Typically, CDC's website has information on transmission, risk of exposure, prevention, protection of healthcare and laboratory workers, diagnosis, outbreaks, and treatment.

Limitations: CDC guidance is primarily developed for the public and public health professionals, not occupational health. However, NIOSH guidance is specifically focused on worker protection. CDC web pages can be complex and it is difficult to find pathogen safety data available for occupational safety and health. Often relevant guidance is absent or merged into other guidelines for travelers, healthcare facilities, and protection of the public. For example,





in its Ebola guidelines, the CDC definition for Risk Categories (high, medium, low) is focused mainly on evaluating patients and travelers entering the country at certain airports or the potential for exposed people coming to an Emergency Room. This differs from the exposure assessment done for occupational health purposes where risk categories may be used to determine control measures, PPE, and respiratory protection.

The **National Institute of Allergy and Infectious Diseases** is part of the US National Institutes of Health. It is the lead federal agency that conducts and funds research to understand, treat, and prevent infectious, immunologic, and allergic diseases. NIAID's Health and Research Topics page includes links to more than 70 pathogens as well as information on related syndromes and disease classifications. There is also a link to emerging infectious diseases.

Website: *https://www.niaid.nih.gov/Pages/default.aspx*

Strengths: Reliable and easy to read information giving an overview of the pathogen, cause, transmission, symptoms and complications, diagnosis and treatment, vaccinations, and research.

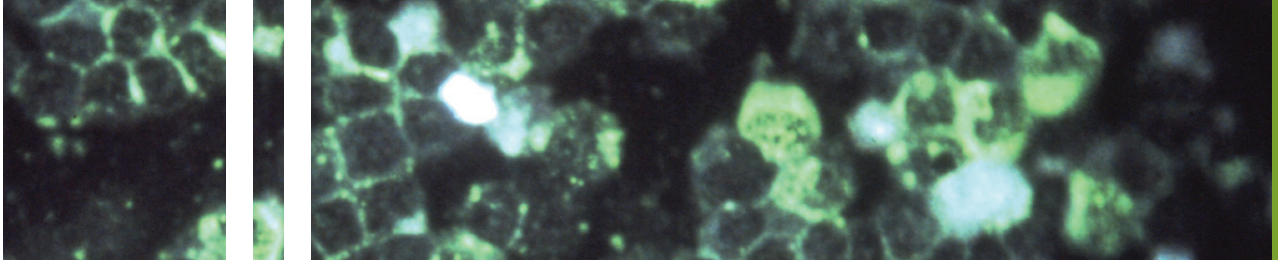
Limitations: The amount of information on the site varies depending on the pathogen. Some pathogens have no details. The information is not targeted for the purpose of occupational safety and health.

The **U.S. National Library of Medicine** (NLM) has established **WISER**, the Wireless Information System for Emergency Responders. WISER is designed to assist emergency responders in hazardous material incidents. This system provides a wide range of information on hazardous substances, including substance identification support, physical characteristics, human health information, and containment and suppression advice. It provides limited information on infectious diseases from USAMRIID's[6] Medical Management of Biological Causalities Handbook and the Weapons of Mass Destruction (WMD) Response Guidebook, as well as others. WISER is available on the web as well as an app for BlackBerry, iPhone, and Android devices.

Website: *https://wiser.nlm.nih.gov/*

Strengths: Users can search for pathogens/diseases using the "known substance list" under biologicals. The tool provides summary information in plain language in the following categories:

6 United States Army Medical Research Institute of Infectious Diseases



Signs and Symptoms, Diagnosis, Treatment, Prophylaxis, Isolation and Decontamination. Information and links to information on Emergency Response, WMD Response Guidelines, Protective Equipment and Clothing.

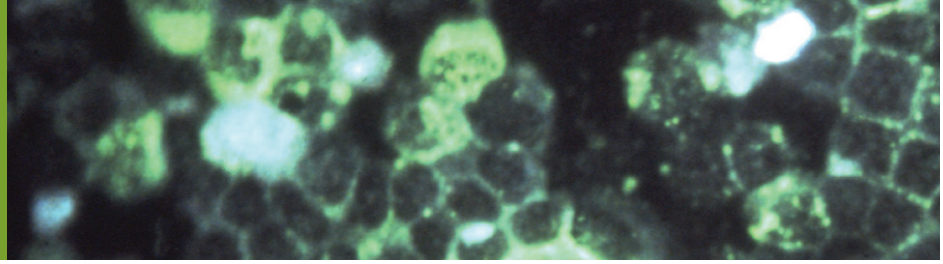
Limitations: WISER lists both diseases and pathogens. It includes the same descriptive statement for all viral hemorrhagic fevers, which constitute 20 of the 30 listings under biological hazards (often one or two named diseases per virus). It also includes two listings each (separate for disease/pathogen) for anthrax, smallpox, tularemia, botulism, and plague. Summary information has limited use for developing industry and site specific risk assessments. For example, the WMD Guidebook, under Personal Protection lists the same time, distance and shielding for following for all pathogens. This lack of specific information on specific diseases or pathogens may leave workers at risk.

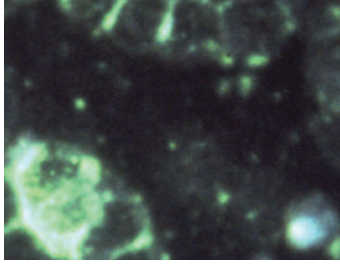
The **Occupational Safety and Health Administration** (OSHA) has the authority to enforce existing safety and health standards and promulgate new ones when there are significant hazards that are not addressed by existing standards. OSHA currently does NOT have an infectious disease standard or a database of PSDSs. OSHA relies on CDC as the source of pathogen safety data which it references in its Bloodborne Pathogens Standard, TB Guidelines, and elsewhere. OSHA has guidance on seasonal flu, pandemic flu, Methicillin-resistant Staphylococcus aureus (MRSA), Norovirus, Severe acute respiratory syndrome (SARS), Tuberculosis, and additional biological agents. The *additional agents* page includes biological toxins and infectious agents: Anthrax, Avian Flu, Bloodborne Pathogens and Needlestick Prevention, Botulism, Ebola, Foodborne Disease, Hantavirus, Legionnaire's Disease, Molds, Plague, Ricin, SARS, Smallpox, Tularemia, and Viral Hemorrhagic Fevers. OSHA has also developed a topic page on Ebola that includes background, hazard recognition, medical information, standards, control and prevention, and additional resources.

OSHA 1910.132 (D) HAZARD ASSESSMENT

- **Employers shall assess the workplace to determine PPE is necessary**
- **If hazards are present, the employer shall:**
  - **Select and have each affected employee use appropriate PPE for identified hazards**
  - **Communicate selection decisions**
  - **Select PPE that fits each employee**

The **OSHA Bloodborne Pathogens Standard** *29 CFR 1910.1030* requires an exposure determination that includes development of a list of job classifications and tasks that have reasonably anticipated exposure. The standard requires that all blood and body fluids and other potentially infectious material (OPIM) be treated as potentially infectious and that universal precautions are required to prevent contact of an employee's skin, eyes, mouth and mucous membranes with blood or OPIM. Where occupational exposure remains after the institution of engineering and work practice controls, the employer must provide PPE that prevents blood or OPIM from passing through to the employee's skin, eyes, mouth, mucous membranes or clothing. The standard requires at least an annual evaluation, selection, and implementation of



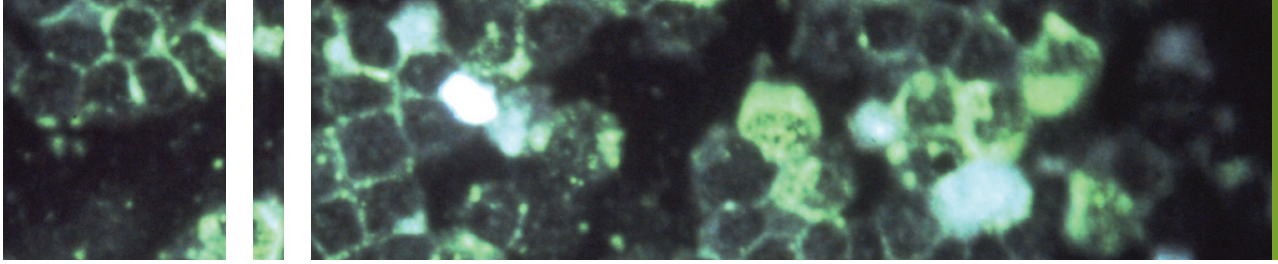


safety engineered sharps as they become available. OSHA requires that management solicit input from non-managerial employees. The standard also requires that employers provide appropriate PPE including gowns, aprons, body clothing, masks, eye protection, and face shields. The standard requires a comprehensive written Bloodborne Pathogens Exposure Control Plan (ECP) and annual worker training as well as on new or changing hazards.

The **Personal Protective Equipment Standard** *29 CFR 1910.132* requires employers to provide PPE for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers. Employers are also required to ensure PPE are used, and maintained in a sanitary and reliable condition. The employer is required to conduct an assessment to determine the need for PPE and to provide training, including how to properly don and doff.

The **Respiratory Protection Standard** *29 CFR 1910.134* requires employers to identify respiratory hazards and to use feasible engineering controls to reduce such hazards. When engineering controls are insufficient, employers must select respirators that are appropriate to the hazards that are present and develop a written respiratory protection program that details selection, types of respirators, fit testing, medical evaluations, maintenance and care, training/ retraining, and evaluation.

For the respiratory hazard of tuberculosis, OSHA updated its Compliance Directive, *CPL 02-02-078*, as of June 30, 2015. The title is **Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis**. This details requirements for worker protection from occupational exposure to TB enforced by OSHA compliance officers using the General Duty Clause and specific standards outlined above on PPE and respiratory protection. OSHA references the **CDC's Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005** *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=rr5417a1_e* which includes "Use of Risk Classification to Determine Need for TB Screening and Frequency of Screening Health Care Workers (HCW's)". The three risk categories are low risk, medium risk, and potential ongoing transmission. Similar risk categories are used for guidance on use of administrative, environmental, and respiratory protection controls needed. Refer to the CDC document for details.



The **Hazard Waste Operations and Emergency Response** (HAZWOPER) standard, *29 CFR 1910.120* applies to infectious materials. It describes health hazards from a hazardous substance could include infectious material associated with the work site or emergency site. The standard defines hazardous substance to include any biologic agent and other disease causing agent that may cause negative health effects. Spills of infectious material are also covered by the standard's requirements.

When OSHA doesn't have a specific standard it can conduct enforcement under its *General Duty Clause* of the OSH Act Section 5(a)(1) that states that employers have a general duty to provide work and a workplace free of recognized hazards t(hat are causing or likely to cause death or serious harm. OSHA has used the general duty clause to address MRSA, TB, and other infectious disease hazards.

Website: *www.osha.gov*

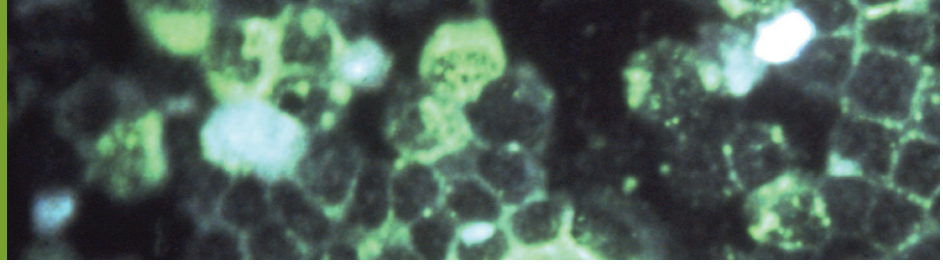
OSHA Infectious Diseases page: *https://www.osha.gov/SLTC/healthcarefacilities/infectious_diseases.html*

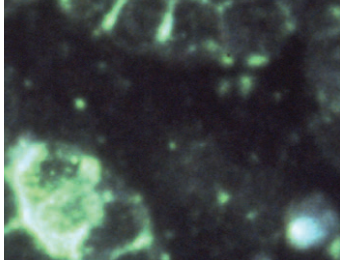
OSHA Tuberculosis page: *https://www.osha.gov/SLTC/tuberculosis/index.html*

Strengths: OSHA's Exposure Control Plan requirement in its Bloodborne Pathogens standard is an excellent model for how an exposure control plan should be developed for any infectious pathogen. Additionally, for infectious aerosols and airborne pathogens the requirements in the respiratory protection standard apply. Similarly, the PPE standard requires that all employers conduct risk assessments for PPE and provide it at no cost to employees who are required to use it.

Limitations: OSHA mainly relies on the CDC for pathogen safety data and establishment of risk categories to determine protection from infectious diseases. Additionally, OSHA does not currently have a generally applicable infectious disease standard that details steps employers must follow to protect workers.

Cal/OSHA, the OSHA state plan for California, established the first in the nation *Aerosol Transmissible Diseases* (ATD) standard in 2009. The standard requires covered employers to develop a comprehensive exposure control plan for ATDs. While not covering all infectious pathogens, this standard serves as a model for the nation. Compliance with the ATD standard is mandatory in California. However, users may benefit from reviewing its detailed requirements and approaches to hazard identification and control and related training materials on the Cal/OSHA website. A list of the pathogens covered by the Cal/OSHA ATD standard is in Appendix 2 of this document.





The **APHA Control of Communicable Disease Manual** (CCDM) is available in hardcopy, on the Web, and as an app. It contains 500 infectious agents. It is a 729-page book, a comprehensive resource that is available for purchase. There is no section dedicated to worker protection information. The APHA indicates that the resource "…promotes key concepts to control disease: proper nutrition; research; prevention and treatment; and sanitation." Each entry is arranged in an easy-to-consult format and divided into twelve sub-categories listed below.

CCDM categories include

- Clinical features
- Causative agent
- Diagnosis
- Occurrence
- Reservoir
- Incubation period
- Transmission
- Risk groups
- Prevention
- Management of patient
- Management of contacts and the immediate environment
- Special considerations

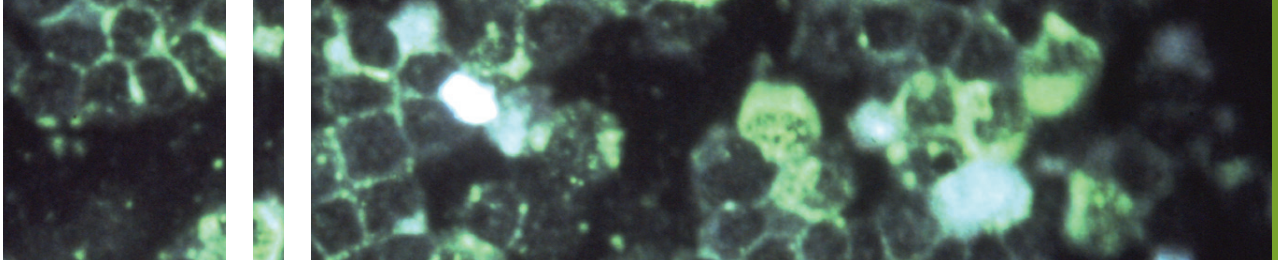
Website: *http://www.apha.org/ccdm*

Strengths: The information is easy to access, in a standard format, detailed and of high quality. CCDM contains information on emerging pathogens such as MERS and Zika. It includes a chapter on infection control, explanation of terms, abbreviations, and links to scientific journals,

Limitations: The summaries are not targeted for occupational risk assessment and control purposes.

The **World Health Organization** was established in 1948. WHO's primary role is to direct and coordinate international health within the United Nations' system. WHO is working with countries to increase and sustain access to prevention, treatment and care for HIV, tuberculosis, malaria and neglected tropical diseases and to reduce vaccine-preventable diseases. WHO's website has links to a number of pathogens that includes summaries on current and past outbreaks, technical information, publications, data and statistics, and WHO programs and projects.

Website: *http://www.who.int/en/*



Strengths: Information on a number of pathogens is presented and describes international activities to prevent and control outbreaks.
Limitations: The main focus of the infectious disease information on the WHO site is NOT for occupational safety and health purposes. WHO's primary role is to direct and coordinate international health within the United Nations' system.

Summary

There are several sources of pathogen safety data that may be used to facilitate development of occupational infection prevention and control programs. When selecting resources, it is important to be aware of their strengths and limitations. This PSD Guide and its companion training module should be used to strengthen collaborative efforts to protect workers from infectious disease hazards.

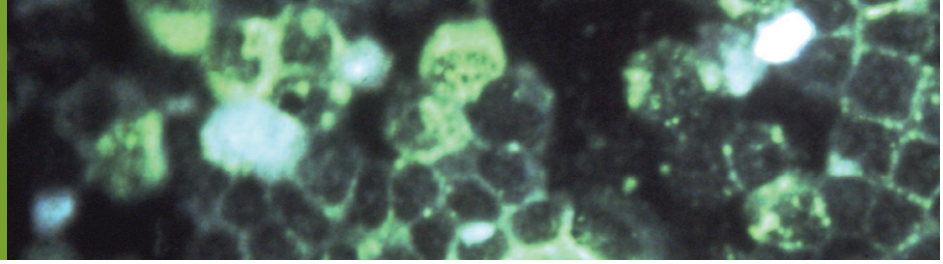
Rapid changes are occurring around infection control and biosafety training including new information on infectious pathogens, prevention technology, and treatment. Therefore, it is necessary to check frequently with the sources of information in this Guide. The NIEHS Worker Training Program encourages organizations to to embrace a creative multidisciplinary approach to accomplish the goals of personal protection, exposure control and an all-hazards model to biosafety in the workplace setting.

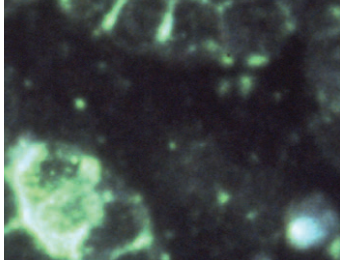
Additional Sources of Information

ASPR TRACIE is a website of the Assistant Secretary for Disaster Preparedness and Response (ASPR) stands for Technical Resources, Assistance Center, and Information Exchange. TRACIE was created to meet the information and technical assistance needs of regional ASPR staff, healthcare coalitions, healthcare entities, healthcare providers, emergency managers, public health practitioners, and others working in disaster medicine, healthcare system preparedness, and public health emergency preparedness. *https://asprtracie.hhs.gov/*

PUBMED is a search engine run by the National Library of Medicine. PubMed comprises more than 25 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to full-text content from PubMed Central and publisher websites. *http://www.ncbi.nlm.nih.gov/pubmed*

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition. Published by the CDC, this is a guidance document for safety and health in biomedical and clinical laboratories. Although specifically focused on laboratory settings, it contains rich information on risk assessment and clear methods of evaluating pathogens, work environments, and selection of appropriate control measures. Users should review the full BMBL guidelines if considering applying them to infection prevention and control activities. The basic principles of the BMBL are containment and risk assessment. "The fundamentals of containment include the microbiological practices, safety

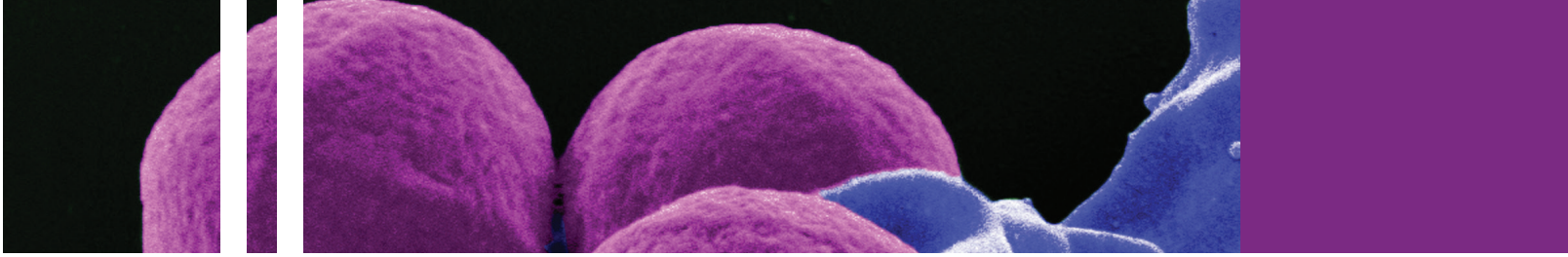




equipment, and facility safeguards that protect laboratory workers, the environment, and the public from exposure to infectious microorganisms that are handled and stored in the laboratory. Risk assessment is the process that enables the appropriate selection of microbiological practices, safety equipment, and facility safeguards that can prevent laboratory-associated infections (LAI)." A full text version is available on the CDC website: *http://www.cdc.gov/biosafety/publications/bmbl5/*

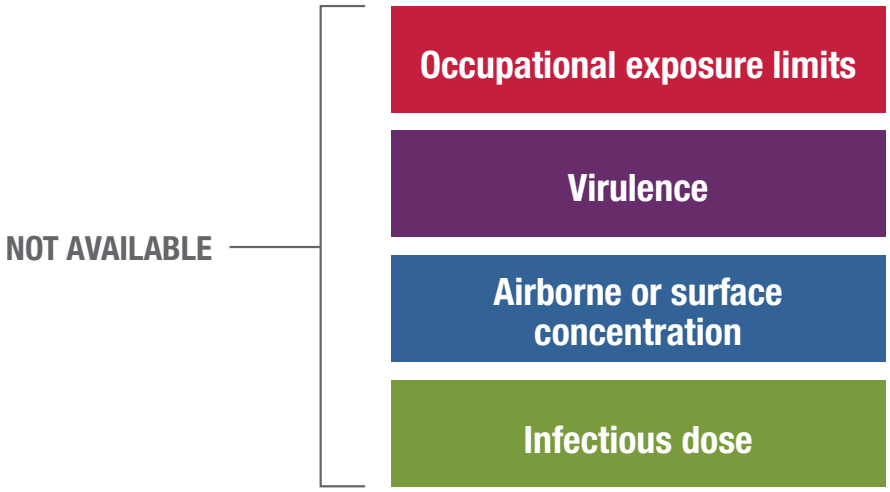
American Biological Safety Association was founded in 1984 to promote biosafety as a scientific discipline and serve the growing needs of biosafety professionals throughout the world. Its focus is on laboratory safety. Its goals are to provide a professional association that represents the interests and needs of practitioners of biological safety, and to provide a forum for the continued and timely exchange of biosafety information. *http://absa.org/ttGeneralBiosafety.html*

National Ebola Education and Training Center is comprised of faculty and staff from Emory University, the University of Nebraska Medical Center/Nebraska Medicine and the New York Health and Hospitals Corporation, Bellevue Hospital Center. All three of these healthcare institutions have safely and successfully treated patients with Ebola and have worked diligently over the past year to share their knowledge with other healthcare facilities and public health jurisdictions. The goal of the NETEC is to combine these resources into one comprehensive assessment, educational and training tool for healthcare systems throughout the United States. *http://netec.org/*

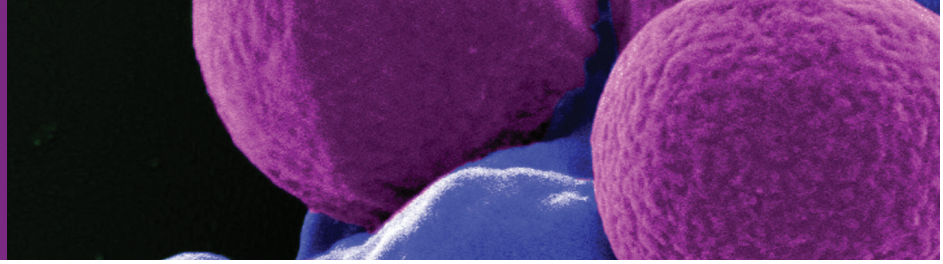


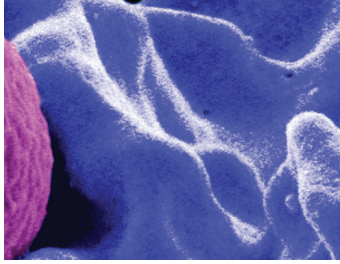
SECTION IV: OCCUPATIONAL EXPOSURE AND RISK ASSESSMENT FOR INFECTIOUS DISEASES

OSHA's standards on bloodborne pathogens, respiratory protection, and personal protective equipment all require employers to conduct an exposure assessment to protect workers from hazards. However an effective risk assessment for occupational exposure to an infectious agent should integrate these requirements into a site-specific exposure control plan. OSHA's bloodborne pathogens standard requirements are based on OSHA's determination that all bloodborne pathogens should be considered potentially infectious. As stated earlier, one of the biggest challenges in assessing occupational exposure to infectious pathogens is the absence or limited information that is traditionally used in exposure assessments listed below.



Additionally, all potential routes of occupational transmission also may not be known. To overcome this absence of information a number of experts have recommended the use of banding using risk groups. This is explained more fully in Appendix 1. A Sample Checklist for Risk Assessment is on page 40–42. Feel free to modify the checklist to meet industry and site specific needs.





Getting Started

The first step is to establish a process for conducting the risk assessment and developing a written exposure control plan. This process may vary by industry, but the key component is to establish a committee, sub-committee, or task force that has the necessary resources and authority to complete an effective and timely risk assessment and facilitates employee involvement. Engaging front line workers is key to developing, implementing, and evaluating interventions to improve infection prevention and control.[7] Organizations may use their own safety and health experts to help guide this critical work or bring in outside expertise from government, academia, labor, or the private sector. The process should include key stakeholders such as management decision makers, operations, purchasing, maintenance, supervision, human resources, and especially workers who will have direct experience with the tasks and operations that present a potential for exposure to infectious pathogens. Where there is a collective bargaining agreement, labor union representatives should be included.

Caution: The brief overview of risk assessment techniques in this Guide are not necessarily applicable to all industries and settings. Specifically, laboratories should follow the Biosafety in Microbiological and Biomedical Laboratories and the NIH guidelines and Hospitals and Healthcare Facilities must comply with their State's Public Health Laws and Regulations.

Key Considerations in the Risk Assessment

Consider the sources and pathways in which workers may be exposed to any potential infectious pathogens. The assessment should document risk factors for all job classifications and tasks that have potential for routine or episodic exposure to the pathogen that is being evaluated. This will make it easier to place employees into similar exposure risk groups where workers are performing similar tasks with similar exposures to infectious agents. Some of the key considerations are listed below:

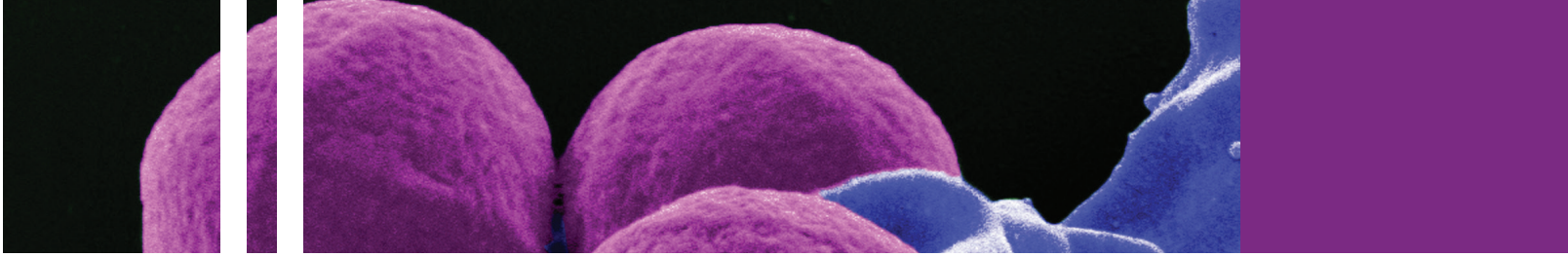
Will job tasks include potential exposure to infectious materials?

What is the proximity of workers to the contagious individual, contaminated waste, surfaces/equipment, or animals?

Will workers be at risk for exposure through contact, splash, inhalation, ingestion, or injection?

Will job tasks, work environment, fatigue, and related factors increase risk of exposure or illness?

7 Frontline Hospital Workers and the Worker Safety/Patient Safety Nexus, Jt Comm J Qual Patient Saf. 2013 Apr; 39(4): 185–192., R. Sokas, et al



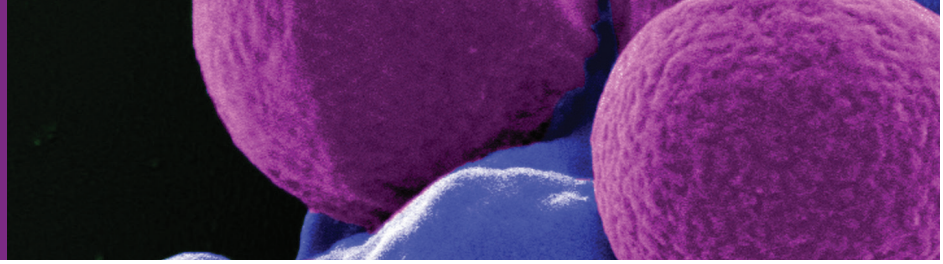
After a list of job classifications and tasks is developed that have potential for exposure, key characteristics of the pathogen, potential exposure pathways, and effectiveness of exiting controls should be documented:

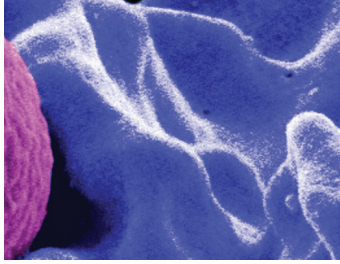
- **Pathogenicity, virulence, and infectious dose**
- **Severity of potential health effects**
- **Environmental survivability and transmission**
- **Potential for sprays, splashes, and aerosols generated during work-related procedures**
- **Effectiveness of existing controls**

Some of the methods used to evaluate infectious disease hazards use the sources or actions listed below. Be aware that there is a recognized problem with underreporting[8] of work related infectious disease exposures and illnesses that reduce the value of looking back at injury and illness records:

- **Worksite inspections, checklists**
- **Injury and illness records**
- **Job descriptions**
- **Worker surveys, focus groups**
- **Industry publications**

8 Economic Burden of Occupational Injury and Illness in the United States, Milbank Q. 2011 Dec; 89(4): 728–772, J Paul Leigh





Completing the Risk Assessment

The methods displayed in this Guide are a few basic approaches that organizations may use for risk assessment. The key is to tailor the risk assessment process to the specific needs and resources of each organization and to involve front line workers in all facets of these activities. A completed risk assessment will include documentation of the following five steps:

Step 1: Identify hazards

- Employers have a duty to assess the health and safety risks faced by their *workers*.

Step 2: Decide who may be harmed, and how.

- Identify who is at risk including full- and *part-time employees* as well as agency and *contract* staff, visitors, clients, and members of the public on the premises.
- Employers must review work routines in all the different locations and situations where their staff are employed.
- Employers should recognize the additional vulnerability for health and safety of young workers, disabled employees, shift workers, and pregnant or breastfeeding women.

Step 3: Assess the risks and take action.

- This means employers must consider how likely it is that each hazard could cause harm. Even after all precautions have been taken, some risk usually remains. Employers must decide for each remaining hazard whether the risk remains high, medium or low.

Step 4: Make a record of the findings.

- Employers should record in writing the main findings of the risk assessment. This record should include details of any hazards noted in the risk assessment, and action taken to reduce or eliminate risk.
- This record provides proof that the assessment was carried out, and is used as the basis for a later review of work practices. The risk assessment is a working document that should be available to all employees.

Step 5: Review the risk assessment.

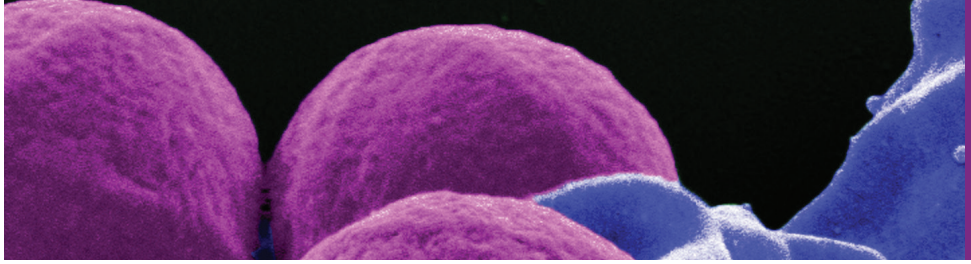
- A risk assessment should be kept under review in order to ensure that safe practices are being followed; and
- To take into account any new conditions, equipment, technology, or hazards that may present themselves.

Records

Keeping records of risk assessments and control measures is very important. OSHA required assessments may include keeping records for a specific number of years. A best practice is to record date of origin and updates on the written documents.

Records should show that each employer:

- Conducted an effect hazard assessment.
- Determined the risks of those hazards.



- Implemented control measures suitable for the risk.
- Reviewed and monitored all hazards in the workplace.

The tables on the next two pages provide a more visual summary of the risk assessment process and exposure risk classification.

Pathogen Safety Data: What-Where-When-How Risk Assessment Flow Chart

ESTABLISH a stakeholder process.
SELECT Pathogen Safety and Risk Assessment data source: PHAC, CDC, NIOSH, etc.
REVIEW Last Updated Date of source.

↓

RESEARCH information.
WHAT: Is the pathogen bacterial, virus, fungi, parasite or prion?

↓

WHERE: Reservoir or geographic location for pathogen?
WHEN: Incubation period and; HOW infection is disseminated, transmitted, or acquired?

↓

HOW: How are workers at risk?
IDENTIFY at-risk objects, equipment, tasks, environments in your workplace and ascertain **HOW** often risk occurs?

↓

CLASSIFY RISK Likelihood x Severity—Low, Intermediate, or High-Risk?
ASSESS level of contact with hazardous material during work?

↓

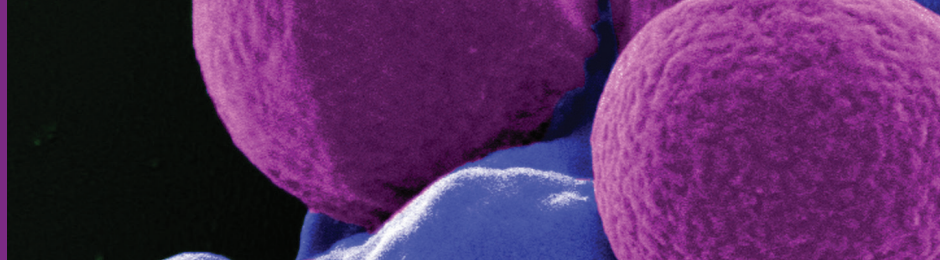
WHAT: Select exposure control measures that will provide required protections.
USE hierarchy of controls.

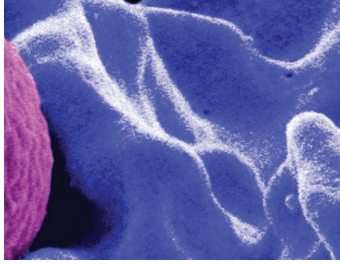
↓

WHAT: Site specific exposure control plan
WHEN: Implementation plan
HOW: Hazard communication and post-exposure procedures.

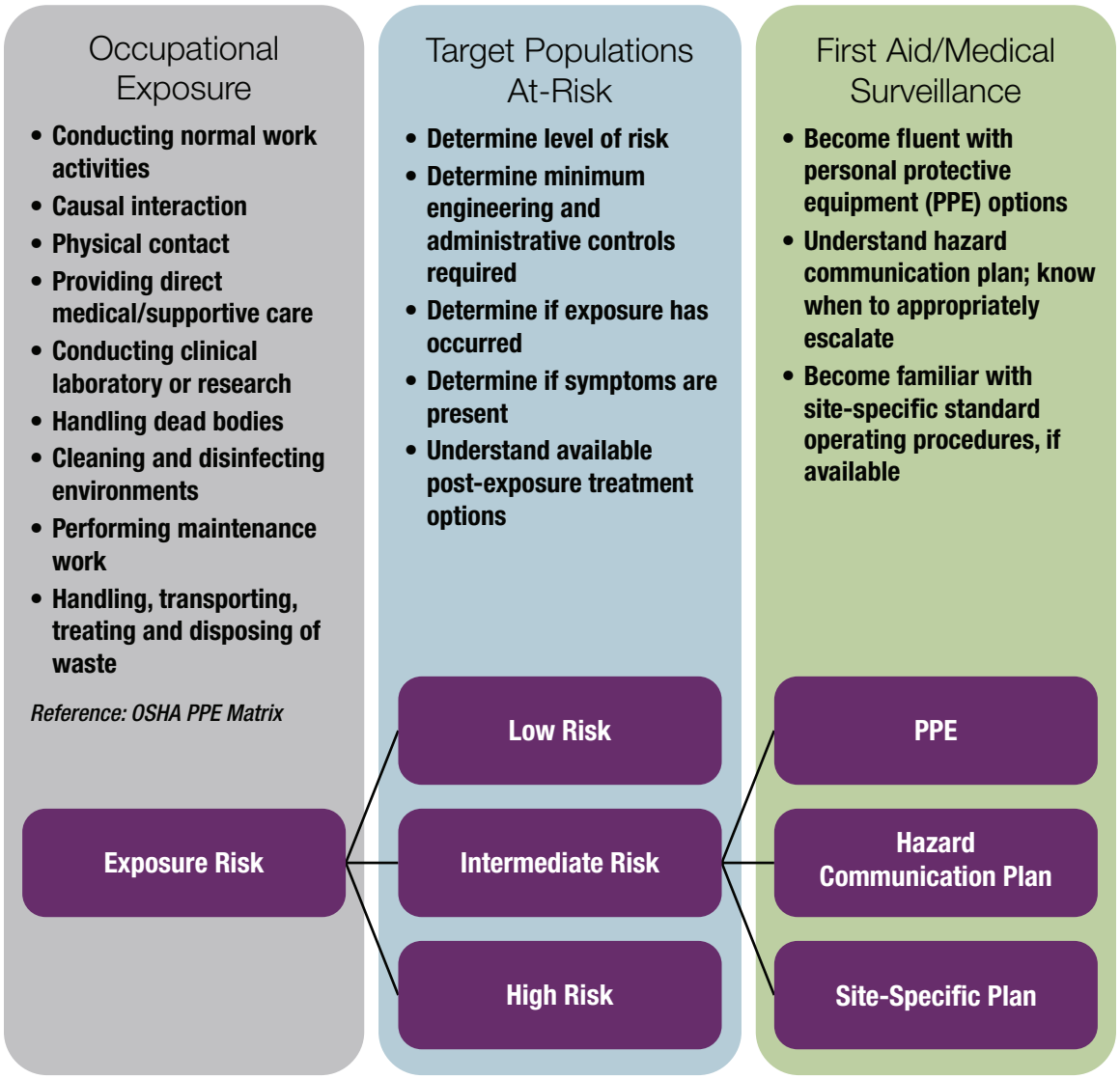
↓

CONTINUED TRAINING: Awareness, operations, and/or hands-on training.

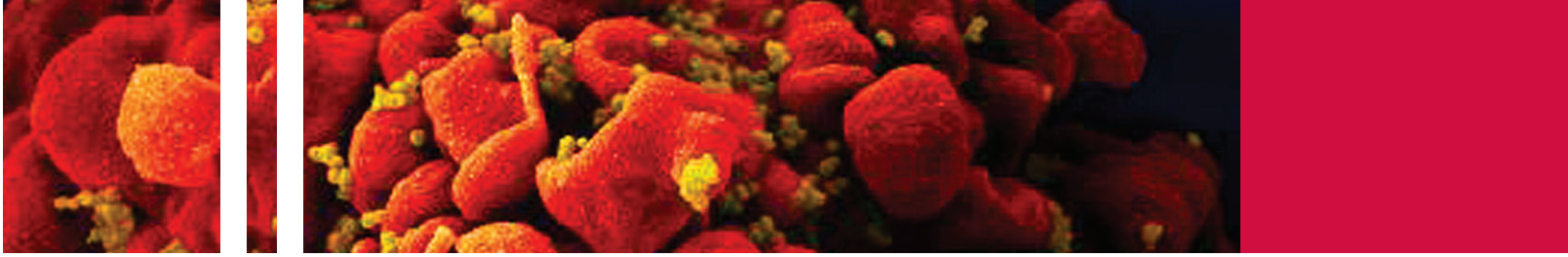




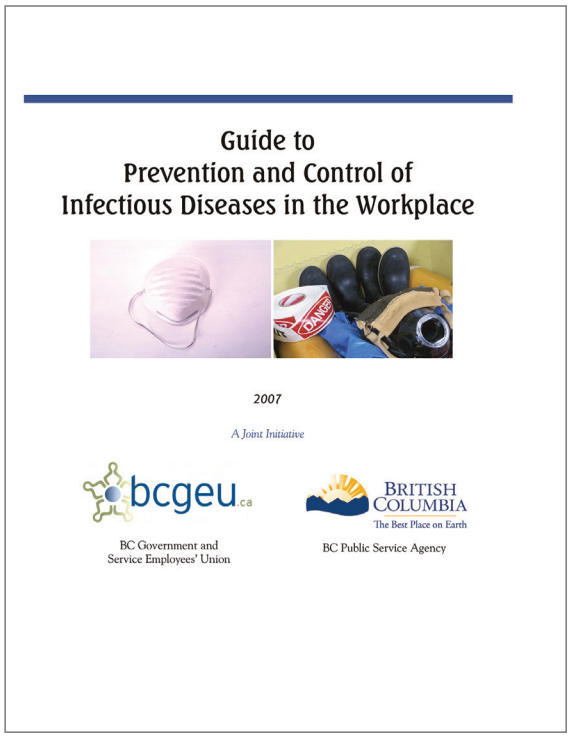
Pathogen Safety Data: Understanding Exposure Risk Classification



This is a summary of the steps to developing an effective infectious disease occupational exposure control plan. The process emphasizes the ability to gather available data on known pathogens; understand where and how workers in specific classifications or job settings are affected based on job description, level of contact; classify level of risk exposure; understand and practice prevention, protection, evaluation, communication and post-exposure protocols. This approach is most applicable in settings where the pathogen is known. When the pathogen is unknown, the highest level of protection should be used.



SECTION V: INFECTION PREVENTION AND CONTROL: BEST PRACTICE EXAMPLE AND ADDITIONAL RESOURCES



Guide to
Prevention and Control of
Infectious Diseases in the Workplace

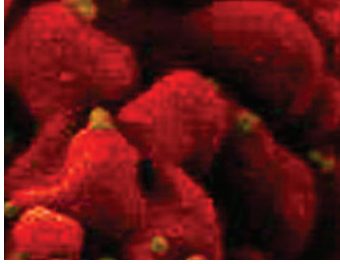
2007

A Joint Initiative

bcgeu.ca
BC Government and Service Employees' Union

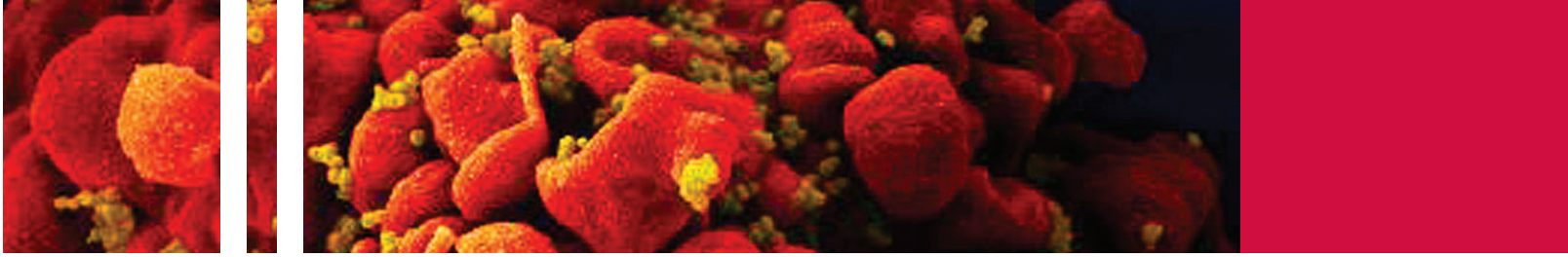
British Columbia
The Best Place on Earth
BC Public Service Agency

The tables on the next pages are an example of a best practice approach to risk assessment and do no cover all occupations and industries that have potential exposure to infectious pathogens. The tables were modified from the *"Guide to Prevention and Control of Infectious Diseases in the Workplace,"* **a joint project of the British Columbia Government and Service Employees' Union and the British Columbia Public Service Agency. Consider adapting this approach to risk assessment. With this method, occupational groups are aligned with potential exposures by the source and type of infectious disease, matched to the hazard group. NOTE that some of the infectious diseases are in more than one hazard category. Ebola is an example that is both a blood, body fluids and respiratory hazard.**



Sample Infectious Disease Hazard Groups

Hazards	Infectious Agents/Diseases	Transmission Source
Blood and body fluid (OPIM)	Hep B, C, D HIV Ebola Lassa Fever	human blood, body fluids, OPIM, fomites human blood, body fluids, OPIM, fomites human blood, body fluids, OPIM human blood, body fluids, OPIM
Respiratory droplets, aerosols	Tuberculosis Measles Ebola MERS SARS	Droplets, coughing, sneezing coughing, sneezing Infectious aerosols, fomites
Animal vector (animal carrier required by the pathogen)	Hantavirus Rabies Lyme Disease Cryptosporidiosis Giardiasis Zika Ebola MERS SARS	Deer mouse feces; rodent urine and feces Bat saliva Tick bites Animal /human feces, contaminated water Animal feces, contaminated water *a. Aedes* or *A. albopictus* mosquitos Fruit bat or primate (suspected) Bats and camels (suspected) Exotic animals: Himalayan palm civets and raccoon dogs

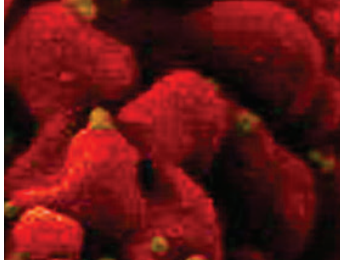


The table below matches job classifications with job tasks and hazard groups.

Job Classifications	Job Tasks	Hazard Groups
First Responders	Provide immediate care to ill and injured patients	Blood and Body Fluid Respiratory
Security, Police, Corrections Officers, etc.	Restraining Arresting Searching Transporting	Blood and Body Fluid Respiratory Animal (dog bites)
Environmental Services	Cleaning blood and body fluids and contaminated facilities, equipment, and materials	Blood and Body Fluid Respiratory
Funeral and Mortuary Services	Exposure to blood and body fluids and contaminated equipment and materials while transporting and handling corpses.	Blood and Body Fluid Respiratory

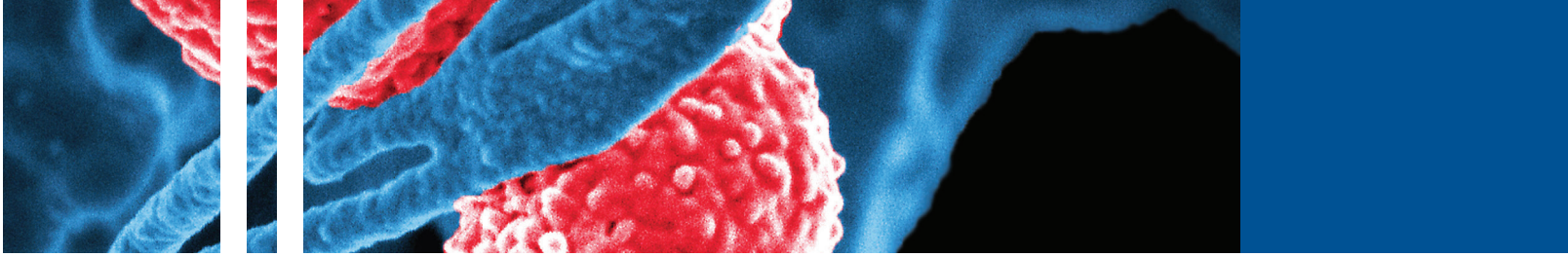
This table provides a more specific list of definitions of routes of exposure.

Route of Exposure	Explanations for Risk Identification
Needlestick or sharp	Puncture or cutting of the skin by object
Non-intact skin	Open cut, sore or rash contact with blood or body fluid
Human bite	Human bite to skin
Mucous membrane	Blood or body fluid contacting eyes, nose or mouth
Feces	Hepatitis A or other pathogens from food handlers with contaminated hands
Air	Inhalation of aerosols or airborne pathogens generated from coughing, vomiting, etc.
Urine, saliva, feces	Contact by skin, ingestion or inhalation of animal or human sources
Contaminated water	Ingesting water contaminated by animal feces
Bite/Scratch	Contact with animal biting or scratching skin



Classification of Infectious Microorganisms by Risk Group

Risk Group Classification	NIH Guidelines for Research involving Recombinant DNA Molecules 20022	World Health Organization Laboratory Biosafety Manual 3rd Edition 20041
Risk Group 1	Agents not associated with disease in healthy adult humans.	(No or low individual and community risk) A microorganism unlikely to cause human or animal disease.
Risk Group 2	Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are often available.	(Moderate individual risk; low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
Risk Group 3	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).	(High individual risk; low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
Risk Group 4	Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).	(High individual and community risk) A pathogen that usually causes serious human or animal disease and can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available
Risk groups from NIH and WHO are similar to those used by the BMBL.		



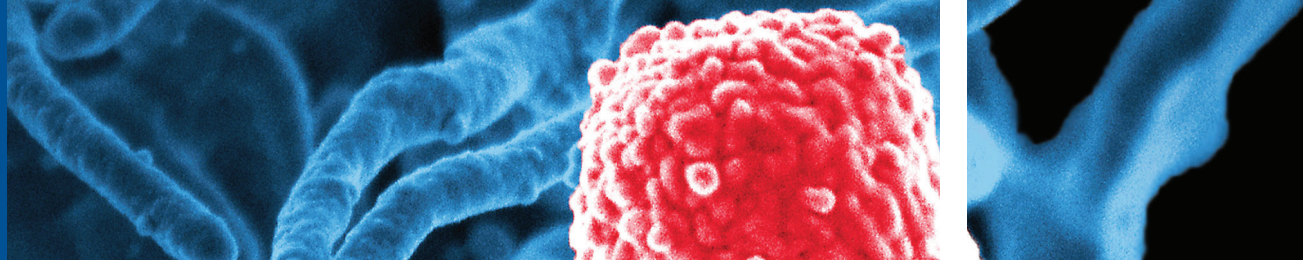
SECTION VI: SELECTION OF CONTROL MEASURES

Once the risk assessment is completed, the next step is to select appropriate control measures to prevent exposure to infectious pathogens. The graphic below lists some of the main considerations that will be evaluated during the risk assessment to help guide selection of controls.

- What is the likelihood of exposure?
- What are the consequences?
- Have exposures occurred?
- Does exposure result from specific job duties?
- Hierarchy of controls?

A basic principle in occupational health is to use the hierarchy of control measures in the selection process. The graphic shows the hierarchy of controls listed in decreasing order of preference. Modification, containment and ventilation are considered engineering controls. Use of isolation rooms with negative air pressure are an example of an engineering control for infectious aerosols or airborne diseases like tuberculosis. Why is PPE the least desirable control? It does nothing to eliminate or reduce the hazard. If it fails, workers are exposed. It is uncomfortable and can contribute to fatigue, overheating, and stress. It is easily contaminated during the removal process and then poses a risk to affected workers.

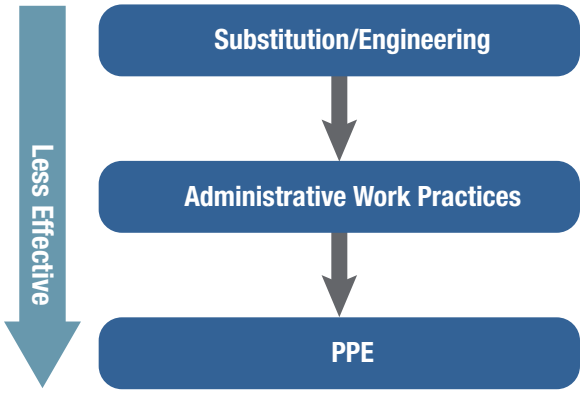
Typically, a combination of control measures is necessary for worker protection from infectious diseases. For example, in a negative pressure isolation room (engineering control) housing a contagious or suspect TB patient, workers will also wear respiratory protection and PPE.



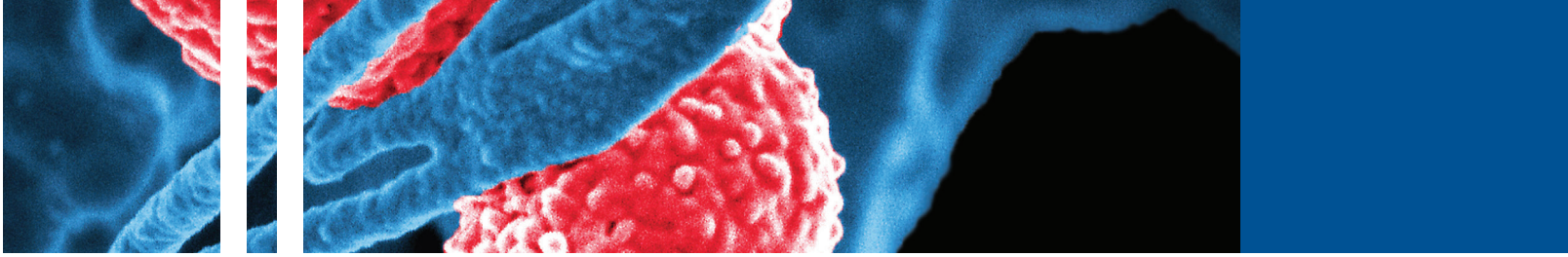
Applying a safety factor

It is not unusual to find a lack of information on risk factors for infectious diseases. This is especially the case with new and emerging pathogens. When there is scientific uncertainty it is important to build in a "safety factor", sometimes called the "precautionary principle".[9] Practically, this means selecting a higher level of protection until the risk factors are more clearly characterized. For example, the University of Nebraska Biocontainment Unit conducted a detailed risk assessment for over 25 different clinical laboratory tests to determine safe laboratory procedures and locations for each of them. Some of the main determinations were the need to ban the use of open tubes outside of BSL-3 biosafety cabinets, centrifuging using safety cups or sealed rotors to prevent microdroplet generation, and use of enhanced PPE and respiratory protection. With Ebola and other highly pathogenic and contagious organisms, there is no room for error.

The Hierarchy of Control Measures



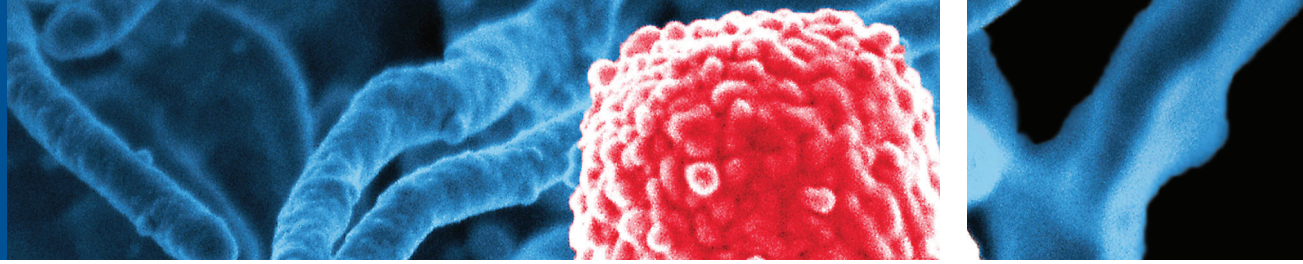
9 The precautionary principle, proposed as a new guideline in environmental decision making, has four central components: taking preventive action in the face of uncertainty; shifting the burden of proof to the proponents of an activity; exploring a wide range of alternatives to possibly harmful actions; and increasing public participation in decision making. Reference: Environ Health Perspect. 2001 Sep; 109(9): 871–876, D Kriebel, et al



Hierarchy of Controls	Examples of controls
Elimination or substitution	Not applicable to infectious disease hazards
Engineering	Tongs or other tools Safer Medical Devices Sharps containers Ventilation Leak/puncture proof container Closed systems HEPA Filtration Ultraviolet Lights Disinfector, Sterilizer, Autoclave
Administrative (work practice controls)	Policies and procedures Buddy system Redesign of work process, flow Avoid areas where hazards are present Training and education Hand washing Job task rotation Adequate staffing Hazard communication, labeling, signage Hire experts to control/clean up biohazards
PPE	Gloves Face shields Goggles Respirators Hoods Protective gowns Other protective suits or shields

Pictured at right is an example of an engineering control: use of plastic to contain contamination in an ambulance used to transport an Ebola patient to the Nebraska Biocontainment Unit. This barrier also makes it easier for emergency personnel to clean, decontaminate, and disinfect the ambulance.

Using 6 mil plastic liner inside ambulance. Photo courtesy of Pre-Hospital Emergency Care Journal, December 2014



OSHA/EPA Protection Levels

Appendix B of the OSHA HAZWOPER standard defines the OSHA/EPA Protection Levels A, B, C, and D. Some industries may be required to or voluntarily choose to use the HAZWOPER approach to selecting PPE and respirators when engineering and administrative controls aren't sufficient to protect workers. For example, environmental service workers who are involved in dealing with spills, clean-up, and shipping of hazardous biological materials must be be trained and protected as required by the OSHA HAZWOPER standard. The protection levels are described as:

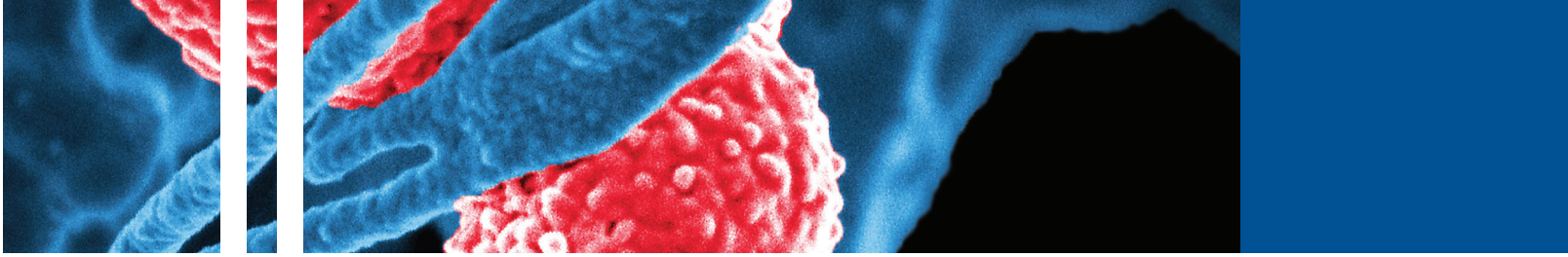
Level A: To be selected where the hazards are unknown or unquantifiable or when the greatest level of skin, respiratory and eye protection is required.

Level B: The highest level of respiratory protection is necessary but a lesser level of skin protection is needed.

Level C: The concentration(s) and type(s) of airborne substances is known and the criteria for using air-purifying respirators are met.

Level D: Normal work clothes and minimal protection where no known contaminant is present.

NYC Environmental Contractors and Mason Tenders' Training Center. Photo by Jonathan Rosen, Courtesy of Mason Tender's, LIUNA



Selection of Respiratory Protection

In some instances, health agencies such as CDC, NIOSH, and OSHA have recommended use of specific respirators for protection from infectious agents that are an inhalation hazard. For example, CDC's guidelines for PPE for protection of healthcare workers involved in evaluating and treating Ebola patients call for the use of a fit tested N95 or a Powered Air Purifying Respirator (PAPR), together with an ensemble of fluid resistant PPE. During the H1N1 pandemic, a tight fitting, fit tested, N95 was also recommended to protect healthcare workers treating infected patients. Although these recommendations are critical during emergencies, organizations should have the capacity to conduct their own evaluations.

The lack of occupational exposure limits and methods for measuring the concentration of infectious particles in air has led a number of experts to recommend a control banding approach to respiratory protection, described on the next page.

Sector: Healthcare or Other

Risk Group: 1 to 4 (low to high)

5 Control Levels/ Ventilation

Generation Rate 1 to 5 (Very high to None)

Surgical masks are not respirators. Surgical masks are not designed to protect workers from inhalation of infectious particles. They are designed to provide protection from droplets, but do not provide a tight seal around the mask or effectively filter out particles. For more information, visit the NIOSH website: *http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3healthcare.html#d*

Resource: OSHA, CDC, NIOSH "Hospital Respiratory Protection Program Toolkit, *http://www.irsst.qc.ca/bioaerosol/accueil.aspx?l=en*

Resources for Respirator Program Administrators, May, 2015: *http://www.cdc.gov/niosh/docs/2015-117/pdfs/2015-117.pdf*

irsst Institut de recherche Robert-Sauvé en santé et en sécurité du travail

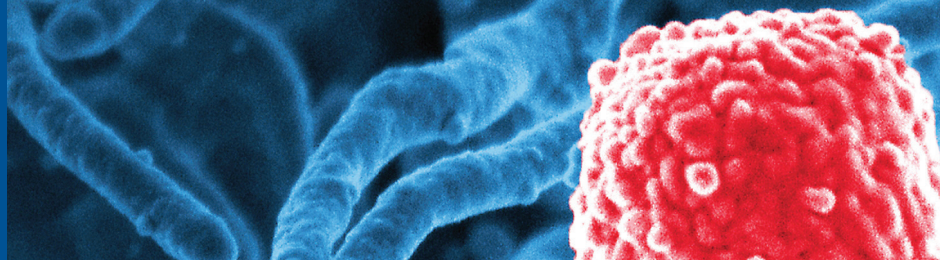
A SUPPORT TOOL FOR CHOOSING RESPIRATORY PROTECTION AGAINST BIOAEROSOLS

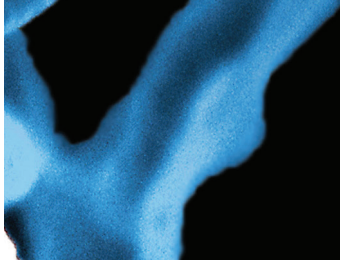
IRRST ONLINE TOOL

The Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST) created an online tool to help with selection of appropriate, effective respiratory protection against infectious and non-infectious bioaerosols found in the workplace, which can be a complex task because of the lack of bioaerosol exposure standards.

The tool is designed for stakeholders in industrial hygiene and occupational health and safety and health professionals and physicians in a variety of sectors, including: Healthcare, Agriculture, Industry, Municipalities, Businesses, and Others.

It employs a six-step approach that uses control banding, based on the hazard associated with bioaerosols and the exposure level of workers. The site includes several examples drawn from case studies to illustrate the approach. The six steps are listed in the chart on the left. Results can be downloaded in PDF format. Keep in mind that many countries have different assigned protection factors (APFs).





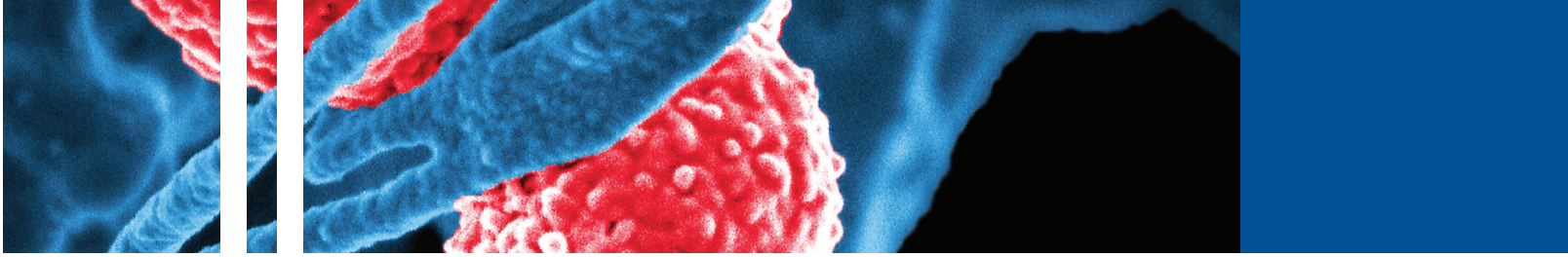
Control Banding

Control banding started in the pharmaceutical industry for controlling exposures to drugs and similar materials that do not have exposure limits and are not easy to measure in the air. It has been applied to chemical hazards and for respiratory protection for infectious aerosols. NIOSH describes Control banding (CB) as "a technique used to guide the assessment and management of workplace risks. It is a generic technique that determines a control measure (for example dilution ventilation, engineering controls, containment, etc.) based on a range or "band" of hazards (such as skin/eye irritant, very toxic, carcinogenic, etc) and exposures (small, medium, large exposure). It is an approach that is based on two pillars; the fact that there are a limited number of control approaches, and that many problems have been met and solved before. CB uses the solutions that experts have developed previously to control occupational chemical exposures, and applying them to other tasks with similar exposure situations. It is an approach that focuses resources on exposure controls and describes how strictly a risk needs to be managed."

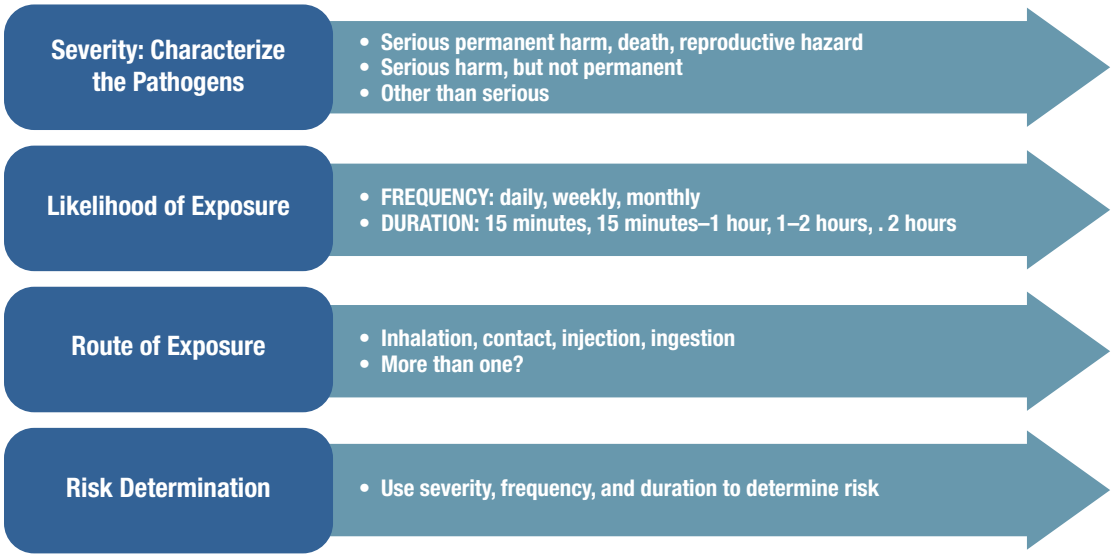
Key Determinants in Qualitative Risk Assessment Used in Control Banding are Severity, Likelihood, and Risk. For each of these determinations a scale is used such as high risk, medium risk, and low risk or a numerical approach would use risk categories 1, 2, and 3. Teams doing risk assessment should be conservative in the face of uncertainty and err on the side of protection. An example of risk categories is in OSHA's TB Compliance Directive where reference is made to the CDC TB Guidelines recommendation that covered employers conduct an initial and ongoing risk assessment using the CDC risk categories. The OSHA document defines them as follows:

> *"The classification of* **low risk** *should apply to settings in which workers are not expected to encounter persons with TB or clinical specimens that might contain M. tuberculosis. The classification of* **medium risk** *should apply to settings in which workers will or will possibly be exposed to persons with TB disease or to clinical specimens that might contain* M. tuberculosis. *The "***potential ongoing transmission***" classification should apply temporarily to any setting where there is evidence suggestive of person-to-person (e.g., patient-to-patient, patient-to-worker, worker-to-patient, or worker-to-worker) transmission of M. tuberculosis during the preceding year. See 2005 CDC Guidelines, p. 10."*

These categories are used to assess the type of control measures that are implemented as well as the frequency of skin testing and other program elements.



The definitions for the key determinants in a control banding approach to risk assessment are in the graphic below:



Assigned Protection Factors

Respirators provide different levels of protection based on their design. OSHA designates Assigned Protection Factors (APF). The APF indicates the reduction in exposure that a properly fitted and donned respirator will reduce the level of contamination inside the respirator compared to the contaminated environment. A properly fitted N95 is capable of a 10 times reduction.

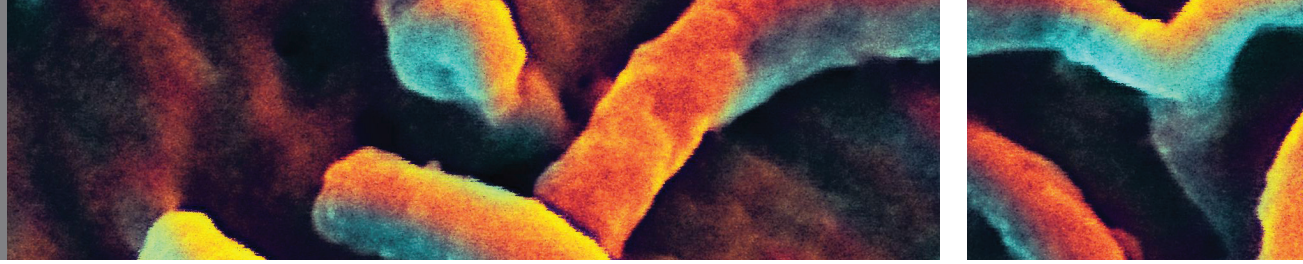
Next Steps

Please share these materials with other individuals concerned with developing effective infectious disease occupational exposure control programs. This PSD Guide should help clarify the content of existing PSD resources as organizations develop their own exposure control plans. Keep in mind the importance of tailoring programs to the specific conditions and needs of each industry and workplace.

Feel free to reach out for assistance to the agencies and organizations that provide the pathogen safety data that we have highlighted in this guide. Remember that national and state regulations and guidelines are continuously updated as new information becomes available. Therefore, it is advised to visit websites frequently to look for updated and new information.

The information contained in this Guide and the related training module are in the public domain. It is free to use and adapt when developing:

1) Training for organizational leaders and other personnel involved in infectious disease prevention and control activities.
2) Drills where quick access to pathogen safety data is key to emergency response.
3) Routine evaluation of the exposure control plan.



APPENDIX 1: SAMPLE RISK ASSESSMENT WORKSHEET

Date:

Name(s):

Location (organization and department or unit):

Address:

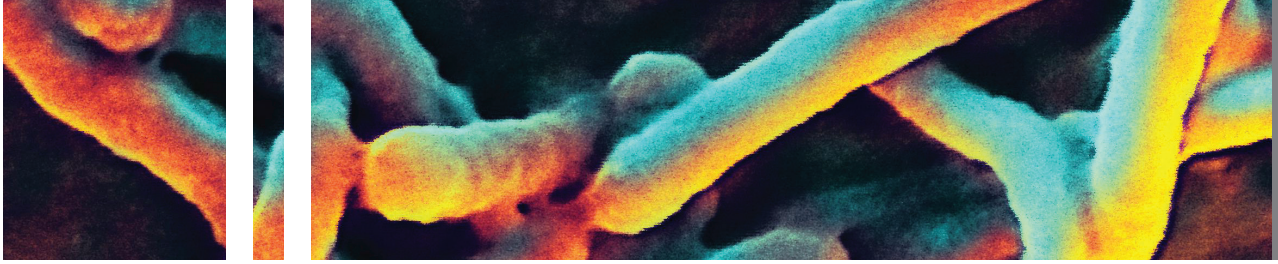
Instructions: Generally, it is most effective when a team works together to conduct the assessment. Complete the worksheet by listing responses, answers to the questions, and listing action steps, and dates and people responsible for completion.

Pathogen Data

Pathogen Safety Data Source:	
Agent identification and type:	
Means of transmission:	
Virulence and toxicity:	
Geographic considerations:	
Incubation period:	

Management Commitment and Worker Involvement

Does a committee of representatives meet regularly to plan and oversee the Pathogen Exposure Control Program?	
Are appropriate stakeholders on the committee from management and labor?	
Has the facility appointed a qualified person to administer the program?	
Is there a written exposure control plan, updated at least annually?	
Does the committee and front line workers participate in selecting safety equipment, writing policies, and worker training?	



Occupational Job Risk Analysis

Does the written exposure control plan identify:

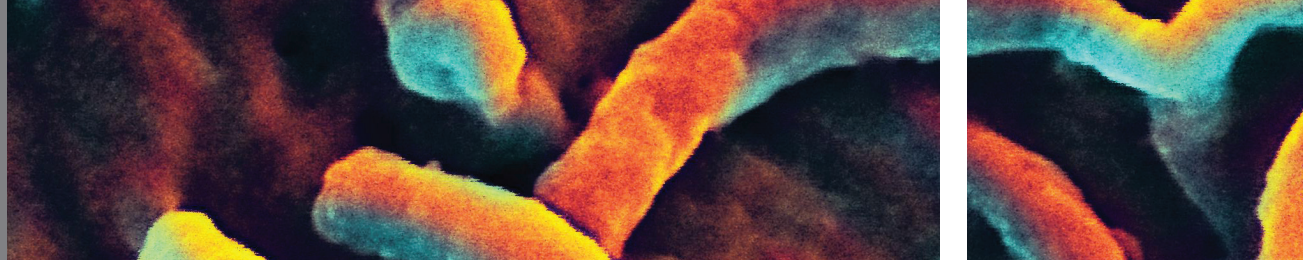
Job classifications/departments with potential exposure?	
Objects or equipment with potential exposure risk?	
Tasks, equipment, and scenarios with potential exposure?	
Frequency of exposure?	

Contact Level and Risk Classification

Conducting normal work activities	
Casual interaction	
Physical contact	
Providing direct medical or supportive care	
Conducting clinical laboratory work	
Conducting scientific research	
Handling dead bodies	
Cleaning and disinfecting environments	
Performing maintenance work	
Handling, transporting, treating and disposing of waste	
Other (describe):	
Self-perceived likelihood of exposure	Low Intermediate High

Hazard Controls

Review/ selection of engineering controls	
Review/ selection of administrative controls	
Review/selection of PPE	
Review /selection for respiratory protection (if needed)	



Exposure Assessment

Has exposure occurred?	
Were workers protected?	
Have public health authorities been notified and consulted?	
Are symptoms present?	
Have incidents been investigated?	
Have corrective actions been implemented?	

Post exposure procedures and medical surveillance

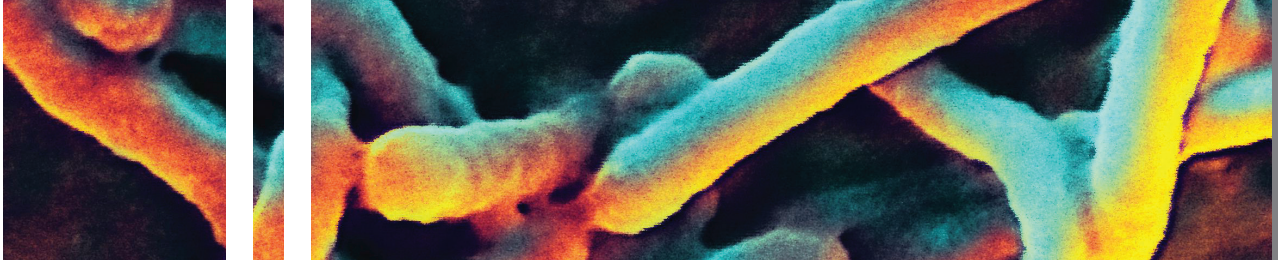
Are agent specific post exposure procedures in place?	
Are systems in place to monitor workers' health who work in areas with exposure to pathogens?	
Are systems in place for medical removal and medical removal benefits?	

Hazard Communication and Training

Agent specific directions and signage and operating procedures are in place?	
Rapid communication systems are in place to address hazards?	
Annual training is provided that covers the key elements of the pathogen exposure control plan and reviews site specific risks and control measures?	
Training is provided by qualified personnel?	
Participants have an opportunity to ask questions?	
Participants are afforded time to practice donning and doffing, and decontamination of PPE and respirators.	
Systems are in place to assess competency in using safety equipment?	

Reporting and Recordkeeping

Written procedures are in place and implemented for reporting risks and exposures?	
Follow-up includes incident investigation and implementation of corrective measures?	
Injury and Illness records are maintained as required by OSHA?	



APPENDIX 2: CAL/OSHA ATD LIST OF AEROSOL TRANSMISSIBLE DISEASES/PATHOGENS

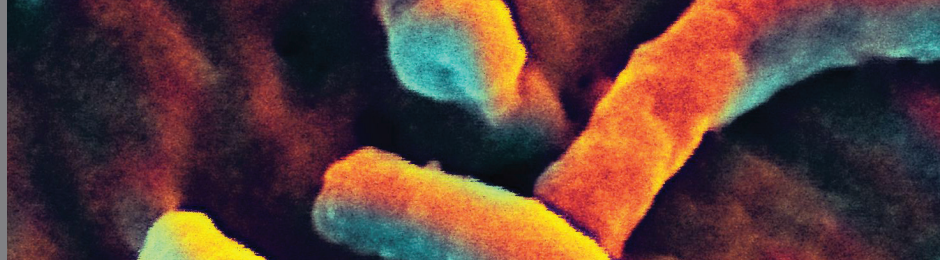
This list is available as part of Appendix A of the CALOSH ATD standard

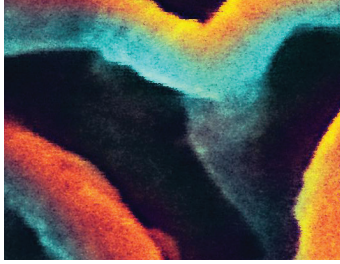
Appendix A – Aerosol Transmissible Diseases/Pathogens (Mandatory)

This appendix contains a list of diseases and pathogens which are to be considered aerosol transmissible pathogens or diseases for the purpose of Section 5199. Employers are required to provide the protections required by Section 5199 according to whether the disease or pathogen requires airborne infection isolation or droplet precautions as indicated by the two lists below and on the next page.

Diseases/Pathogens Requiring Airborne Infection Isolation

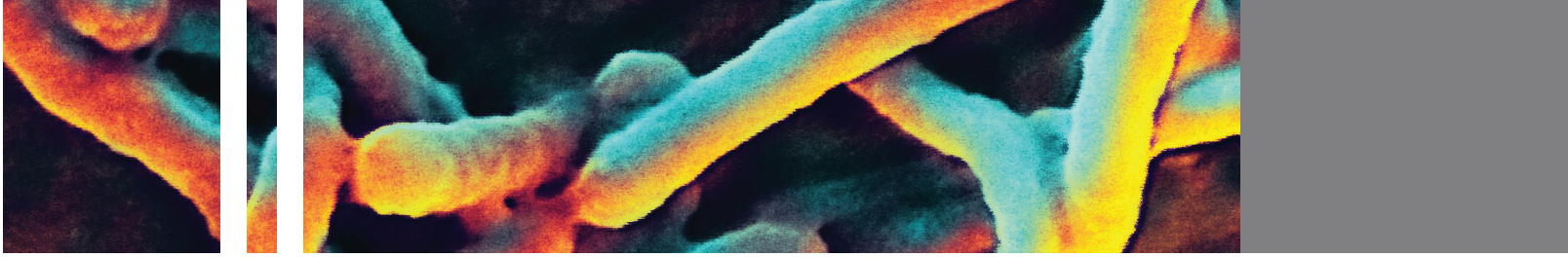
- Aerosolizable spore-containing powder or other substance that is capable of causing serious human disease,e.g. Anthrax/*Bacillus anthracis*
- Avian influenza/Avian influenza A viruses (strains capable of causing serious disease in humans)
- Varicella disease (chickenpox, shingles)/Varicella zoster and Herpes zoster viruses, disseminated disease in any patient. Localized disease in immunocompromised patient until disseminated infection ruled out
- Measles (rubeola)/Measles virus
- Monkeypox/Monkeypox virus
- Novel or unknown pathogens
- Severe acute respiratory syndrome (SARS)
- Smallpox (variola)/Varioloa virus
- Tuberculosis (TB)/*Mycobacterium tuberculosis*—Extrapulmonary, draining lesion; Pulmonary or laryngeal disease, confirmed; Pulmonary or laryngeal disease, suspected
- Any other disease for which public health guidelines recommend airborne infection isolation





Diseases/Pathogens Requiring Droplet Precautions

- Diphtheria pharyngeal
- Epiglottitis, due to *Haemophilus influenzae* type b
- Haemophilus influenzae Serotype b (Hib) disease/*Haemophilus influenzae* serotype b—Infants and children
- Influenza, human (typical seasonal variations)/influenza viruses
- Meningitis
  - *Haemophilus influenzae*, type b known or suspected
  - *Neisseria meningitidis* (meningococcal) known or suspected
- Meningococcal disease sepsis, pneumonia (see also meningitis)
- Mumps (infectious parotitis)/Mumps virus
- Mycoplasmal pneumonia
- Parvovirus B19 infection (erythema infectiosum)
- Pertussis (whooping cough)
- Pharyngitis in infants and young children/Adenovirus, Orthomyxoviridae, Epstein-Barr virus, Herpes simplex virus,
- Pneumonia
  - Adenovirus
  - Haemophilus influenzae Serotype b, infants and children
  - Meningococcal
  - *Mycoplasma, primary atypical*
  - *Streptococcus Group A*
- Pneumonic plague/*Yersinia pestis*
- Rubella virus infection (German measles)/Rubella virus
- Severe acute respiratory syndrome (SARS)
- Streptococcal disease (group A streptococcus)
  - Skin, wound or burn, Major
  - Pharyngitis in infants and young children
  - Pneumonia
  - Scarlet fever in infants and young children
  - Serious invasive disease
- Viral hemorrhagic fevers due to Lassa, Ebola, Marburg, Crimean-Congo fever viruses (airborne infection isolation and respirator use may be required for aerosol-generating procedures)
- Any other disease for which public health guidelines recommend droplet precautions



APPENDIX 3: RESOURCES AND REFERENCES

Government Guidance and Standards

- *Cal/OSHA Interim Guidance on Ebola Virus in Inpatient Hospital Settings*
  Cal/OSHA, November 2014
- *OSHA Directives CPL 2-0.158 - Inspection Procedures for the Respiratory Protection Standard*
  DOL/OSHA, June 26, 2014
- *California Occupational Safety and Health Standard: Aerosol Transmissible Diseases*
  Cal/OSHA, July 2009
- *Aerosol Transmissible Disease Prevention Program (model program)*
  Shasta County- California, November 2012
- *Biosafety in Microbiological and Biomedical Laboratories BMBL 5th Edition Chapter II*
  HHS, December 2009

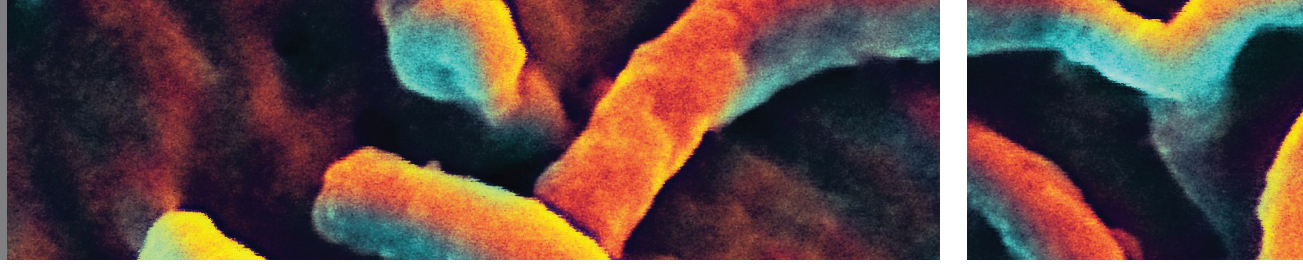
Risk Assessment Guidance

- *Guide to Prevention and Control of Infectious Diseases in the Workplace*
  British Columbia Canada Government and Service Employees' Union and BC Public Service Agency, 2007
- *Guide to Infection Prevention in Emergency Medical Services*
  Association for Professionals in Infection Control and Epidemiology, Inc. (APIC), January 2013

Respiratory Protection Guidance

Workplace Health and Safety Programs

- *Respiratory Protection Program Evaluation Checklist and Instructions for Use*
  California Department of Public Health, Occupational Health Branch, August 2015
- *Respirator Selection Guide for Aerosol Transmissible Diseases*
  California Department of Public Health, Occupational Health Branch, August 2015
- *Implementing Respiratory Protection Programs in Hospitals:* A guide for respirator program administrators
  California Department of Public Health, Occupational Health Branch, August 2015
- *Implementing Hospital Respiratory Protection Programs:* Strategies from the Field
  The Joint Commission, May 2015



- *Hospital Respiratory Protection Program Toolkit:* Resources for Respirator Program Administrators
  CDC/NIOSH, May 2015
- *How to Properly Put on and Take off a Disposable Respirator*
  CDC/NIOSH, February 2010 (Also in Spanish)
- *Respiratory Infection Control:* Respirators Versus Surgical Masks
  OSHA, May 2009

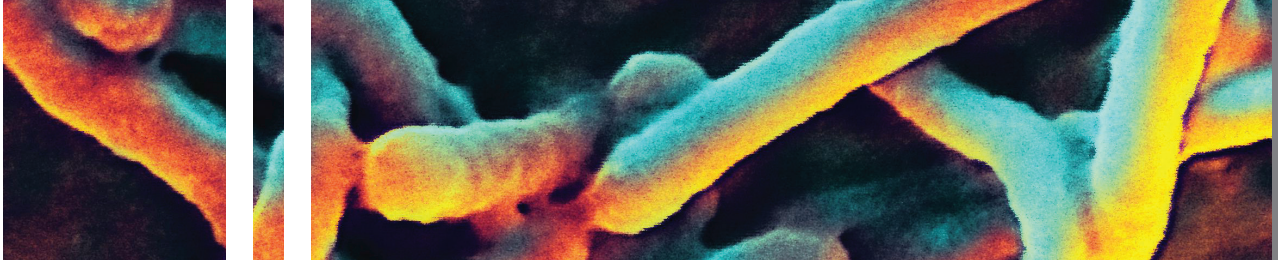
Peer Reviewed Publications

Workplace Health and Safety Programs

- *Using the Pillars of Infection Prevention to Build an Effective Program for Reducing the Transmission of Emerging and Reemerging Infections*
  Current Environmental Health Reports, September 2015
- *Protecting the Frontline: Designing an Infection Prevention Platform for Preventing Emerging Respiratory Viral Illnesses in Healthcare Personnel*
  Infection Control and Hospital Epidemiology, March 2015

Respirator Selection and Effectiveness

- *The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary* Institute of Medicine, 2015
- *Development of a Control Banding Method for Selecting Respiratory Protection Against Bioaerosols*
  The Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST), December 2013
- *Do Respirators Protect Health-Care Workers From Airborne Infectious Diseases?*
  Respiratory Care, December 2008
- *Capture of 0.1-µm aerosol particles containing viable H1N1 influenza virus by N95 filtering*
- *facepiece respirators*
  Journal of Occupational and Environmental Hygiene, January 2016
- *Hospital respiratory protection practices in 6 U.S. states: A public health evaluation study*
  American Journal of Infection Control, January 2015
- *NIOSH Health and Safety Practices Survey of Healthcare Workers: Training and Awareness of Employer Safety Procedures*
  American Journal of Industrial Medicine, June 2014
- *The Use of Respirators to Reduce Inhalation of Airborne Biological Agents*
  Journal of Occupational and Environmental Hygiene, May 2013
- *B95: A new respirator for health care personnel*
  American Journal of Infection Control, December 2013



- *Fit Testing Respirators for Public Health Medical Emergencies*
  Journal of Occupational and Environmental Hygiene, September 2010
- *A Schlieren Optical Study of the Human Cough with and Without Wearing Masks for Aerosol Infection Control*
  Journal of the Royal Society- Interface, October 2009
- *Comparison of Performance of Three Different Types of Respiratory Protection Devices*
  Journal of Occupational and Environmental Hygiene, September 2006
- *Health Care Workers and Respiratory Protection: Is the User Seal Check a Surrogate for Respirator Fit-Testing?*
  Journal of Occupational and Environmental Hygiene, April 2011

Aerosols

- *Distribution of Airborne Influenza Virus and Respiratory Syncytial Virus in an Urgent Care Medical Clinic*
  Clinical Infectious Diseases, October 2009
- *COMMENTARY: Ebola virus transmission via contact and aerosol—a new paradigm*
  University of Minnesota CIDRPA, November 2014
- *Issues Affecting Respirator Selection for Workers Exposed to Infectious Aerosols:* Emphasis on Healthcare Settings
  Applied Biosafety, January 2004
- *Selecting Respirators for Control of Worker Exposure to Infectious Aerosols*
  Infection Control and Hospital Epidemiology, February 1999

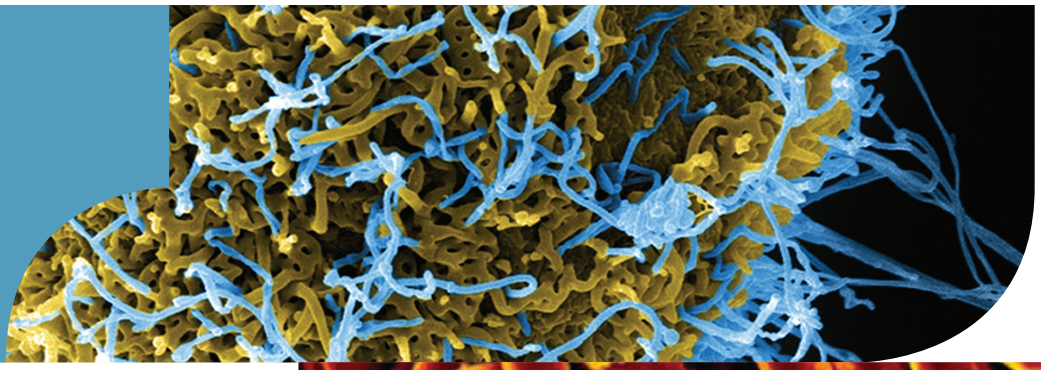
Reports and other Reference Materials

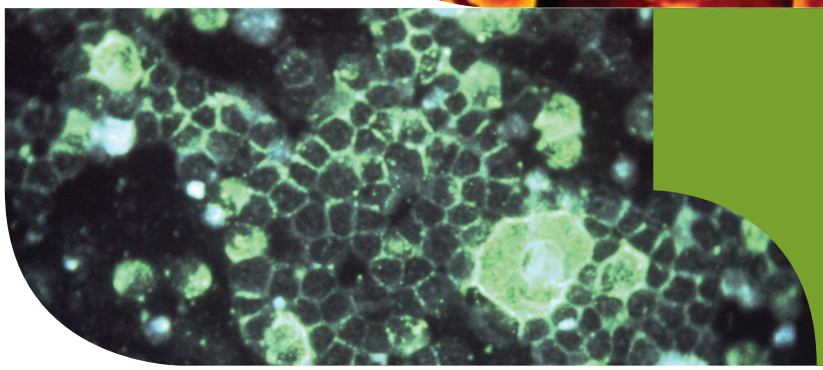
PPE Selection and Risk Assessment

- *Contamination of Health Care Personnel During Removal of Personal Protective Equipment*
  JAMA, October 2015
- *Development of a Methodology to Detect Viable Airborne Virus Using Personal Aerosol Samplers*
  EPA and NIOSH, December 2010
- *The SOBANE Risk Management Strategy and the Déparis Method for the Participatory Screening of Risks*
  International Archives of Occupational and Environmental Health, June 2004

Other Articles

- *Preparedness through Daily Practice: The Myths of Respiratory Protection in Healthcare*
  CDC/NIOSH, March 2016
- *Mechanisms of Pathogenesis, Infective Dose and Virulence in Human Parasites*
  PLoS Pathogens, February 2012





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