

# Infectious Diseases SBAR Panel Issues Document

## **Background**

The OSHA Bloodborne Pathogens (BBP) standard is very effective in protecting workers from exposure to some diseases; however, it only covers exposure to infectious diseases transmitted by the bloodborne route (e.g., HIV and hepatitis B and C). Therefore, OSHA is considering developing a new standard (i.e., rule) to protect workers from exposure to infectious diseases not already covered by the BBP standard. Unlike the BBP standard, which applies in any work setting where blood exposures may occur, the new standard would apply *only* in healthcare settings (e.g., hospitals, doctor's offices, long term care, school/factory nurse's stations) and a limited number of other settings (e.g., laboratories, facilities that handle medical waste, laundries). The new standard would not apply to workers who provide first aid only.

The new standard would require the use of standard and transmission-based precautions to protect workers that provide patient care. Standard precautions are the baseline infection control precautions that should be used in all healthcare settings all the time in order to prevent transmission of infectious diseases (e.g., medical gowns, gloves, goggles/face shields).

Transmission-based precautions are added as necessary (e.g., only when there is a known or suspected infection control risk to diseases transmitted by the contact, droplet and/or airborne routes); these precautions are tailored to the way the disease is transmitted and to the specific work settings and conditions in which they apply. Transmission-based precautions include:

- **Contact precautions** - Infection control practices designed to prevent or minimize transmission of *diseases transmitted through touching infected skin and/or contaminated materials/surfaces*. Major contact precautions include increased hand hygiene and glove use. Examples of contact-transmissible diseases: MRSA, norovirus infections, influenza.
- **Droplet precautions** - Infection control practices designed to prevent or minimize transmission of *diseases transmitted through large droplets that travel from the infected person over short distances* (e.g., through coughing). A major droplet precaution is the use of surgical masks. Examples of droplet-transmissible diseases: influenza, pertussis.
- **Airborne precautions** - Infection control measures designed to prevent or minimize transmission of *diseases transmitted through air over long distances*. Major airborne precautions include respiratory protection and greater use of isolation and containment procedures. Examples of airborne-transmissible diseases: TB, SARS, measles.

### **How Flexibility Is Built In To The New Standard**

Given that facilities that would be affected by the rule have different potential sources of infection, and that facilities vary in terms of their capacity to address potential sources of infection, OSHA's approach to the potential new standard is program-oriented (i.e., implementing a worker infection control plan) and largely performance-based. The OSHA regulatory framework does not reinvent the wheel, but instead is based on infection control regulations and guidelines that are already widely accepted (e.g. Centers for Disease Control and Prevention guidelines).

The basic elements of infection control practice are laid out in CDC and NIH guidance documents. Not surprisingly, the guidance documents recommend similar basic practices (e.g., hand hygiene, decontamination of materials and surfaces, hazard signage and labeling) for different settings. However, the implementation of these infection control practices in different settings and under different conditions will be affected by a number of factors including:

- Characteristics of patient populations vary by setting. For example, large city hospitals see different types of patients than rural hospitals or physicians' offices.
- Types of infectious agents and diseases commonly encountered vary by setting. For example, active TB is more often seen in some states than in other states and more often seen in hospitals than in physicians' offices.
- Sources of worker exposure to infectious agents (e.g., patients, corpses, contaminated wastes and equipment, cultures of viruses or bacteria, etc.) vary by setting and by the types of tasks performed by workers. For example, workers in research and production laboratories are exposed to infectious materials while workers in healthcare settings and clinical laboratories are exposed to both infectious patients and materials.
- Frequency and duration of worker exposure to infectious agents varies by setting and by tasks performed (e.g., workers in hospitals, nursing homes and laboratories are exposed to infectious patients and/or infectious materials on a daily basis while exposure would be less frequent in a physician's office).
- Characteristics (e.g., route of transmission) of the infectious agent(s) encountered will affect the nature and extent of worker exposures; the infectious agent(s) encountered vary by setting and by tasks performed.

This OSHA rule would not be "one size fits all," but instead would give covered employers considerable flexibility in tailoring their infection control plan to their specific settings and circumstances. The extent of exposure will vary, not just by the type of workplace, such as "hospitals" or "ambulatory care", but by the extent to which a given facility sees different types of patients, handles corpses, generates different kinds of waste, handles cultures in laboratories,

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does or does not decontaminate waste or contaminated equipment on site, etc. Affected facilities would implement protective measures based on the exact services they provide. Every facility makes choices that affect what risks their employees might be exposed to. Some examples of how employers would adapt their infection control plans to their specific circumstances include:

- Some employers would implement screening procedures to promptly identify patients with suspected airborne-transmissible diseases, and then refer those patients to other facilities rather than treat them onsite. Others would include precautions for onsite treatment of patients with suspected airborne-transmissible diseases in their infection control plans.
- Some employers (e.g., large hospitals) would perform onsite laboratory tests while others (e.g., small rural hospitals) may outsource laboratory testing.
- Some employers would limit worker exposure by designating specific staff to handle infectious patients who are in isolation. Others would train all relevant staff in isolation precautions and have a broader group of staff treat those patients.
- Employers of laboratory workers would offer vaccinations for the specific agent(s) used in that laboratory while employers in healthcare settings would offer the core vaccinations that CDC recommends as well as other vaccinations recommended for specific staff members by their healthcare providers.
- An exposure incident investigation in a research and production laboratory would generally involve tracking contaminated materials, while such an investigation in a healthcare setting would involve tracking infectious patients and contaminated materials. (Should a lab-acquired infection occur, however, lab workers would be tracked for infection).

Once employees are exposed to suspected or confirmed sources of infection, the standard would become more prescriptive as to what employers must do and what standard operating procedures (SOPs) come into effect. These include increased use of hand hygiene and gloves for contact-transmissible diseases; the use of surgical masks for droplet-transmissible diseases; and the use of respirators (and development of a respiratory protection program) for airborne-transmissible diseases.

### **What Employers Would Have To Do To Comply**

To comply with the OSHA standard, an employer would need to develop and implement a worker infection control plan (WICP) for its facility. Therefore, the first step in the rule would be to identify the potential sources of infection in the facility. The employer would then consider which employees are exposed to those sources of infection and develop precautions for those employees to follow to avoid infection. The WICP would have to designate a responsible

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administrator and be updated at least annually, and whenever necessary (e.g., new job procedures). Part of the plan would involve figuring out how contractors, vendors, and licensed independent medical practitioners who operate in the employer's facility can adhere to infection control practices that are consistent with the employer's plan.

The employer would develop, implement, and update written SOPs that are consistent with recognized and generally accepted good infection control practices (e.g., CDC guidelines) relevant to the employees during their job tasks.

All employers would develop SOPs for at least the following:

- Infectious agent hazard evaluations (to promptly identify suspected or confirmed sources of infectious agents) and communication of hazard evaluation results;
- Hand hygiene;
- Restricting food and cosmetics;
- Engineering, administrative and work practice controls, and personal protective equipment;
- Decontamination;
- Handling, containerization, transport, or disposal of contaminated materials;
- Occupational health services;
- Exposure incident investigations;
- Signage and labeling/color-coding
- Notification of occupational exposure during transfer, transport, shipping, or receipt of samples of infectious agents.

Employers who provide direct patient care would also develop SOPs for:

- Patient scheduling and intake/admittance;
- Standard, contact, droplet, and airborne precautions;
- Patient transport;
- Medical surge procedures.

Employers who perform other covered tasks (e.g., laundry services) would also develop SOPs for:

- Handling and intake of contaminated materials;
- Any other control measures necessary to prevent or minimize transmission of infectious agents;

In addition, laboratories would develop SOPs for implementing specific practices for handling infectious agents, including, as appropriate:

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- Engineering controls, such as biosafety cabinets, laboratory hoods, and other laboratory design and containment measures;
- Measures necessary to address uncontrolled releases of infectious agents;

Employers would need to provide medical services to employees who have occupational exposure. This would include medical screening, surveillance, and vaccinations, as well as post-exposure evaluations and follow-up for each employee who has had an exposure incident. When an employee is removed from his or her job or otherwise medically limited as a result of an exposure incident, the employer would be required to provide medical removal protection benefits (e.g., normal pay, offset by any workers' compensation pay).

Employers would train workers before they start a job and at least annually thereafter. The initial training would be comprehensive, but the annual refresher training would be more limited. Additionally, there would be some limited recordkeeping requirements. Finally, the rule would require employers to comply with all provisions in the rule at no cost to employees.

The remainder of this document provides additional details about the contents of and provisions in the regulatory framework and raises questions that OSHA is interested in discussing with the SERs. This issues document should provide the SERs with enough information to understand OSHA's current thinking on the contents of an infectious diseases rule and allow the SERs to effectively participate in the panel process. OSHA encourages the SERs to review the regulatory framework outline and regulatory framework as well. Additional detail about the provisions of the regulatory framework, OSHA's preliminary estimates of unit costs, and additional discussion about the regulatory alternatives and options under consideration can be found in the full SER background document included in this package.

### **General Introductory Questions**

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In your experience, what components of an infection control plan are the most critical in protecting workers? Would a rule as outlined by the regulatory framework effectively and comprehensively protect workers from exposure to infectious diseases? Are there any infection control practices that OSHA has not included that you believe should be included in an infectious diseases rule? Are there any provisions that you believe are ineffective that OSHA has included but should not retain?

Do you find the performance-based approach outlined in the introduction and presented in full in the regulatory framework to be flexible?

How could OSHA structure a potential rule in order to provide additional flexibility?

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Do you feel confident that you could interpret the potential requirements included in the regulatory framework well enough to be in compliance with an infectious diseases rule?

Do you understand what needs to be done at your facility when a provision is not applicable to your setting?

What compliance assistance could OSHA provide if a rule as outlined in the regulatory framework were promulgated to best help small entities comply in the least burdensome manner?

Are the definitions clear and understandable? Are there any terms that OSHA has not defined that you feel should be defined?

### Scope Questions

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The regulatory framework would cover “occupational exposure of workers to contact, droplet, or airborne transmissible infectious agents during provision of direct patient care or performance of other covered tasks.” Direct patient care is defined in the regulatory framework, generally, as “[j]ob duties that involve the provision of healthcare services with hands-on or face-to-face contact with patients” where an employee is acting “under a license, certification, or registration to provide healthcare services within a legally permitted scope of practice,” or “under the supervision of a licensed/certified/registered employee.” This would include nurses, physicians, physical and occupational therapists, paramedics or emergency responders, and other healthcare employees who care for patients. This would not include employees who provide first aid only. Other covered tasks is defined in the regulatory framework as “[j]ob duties that do not involve direct patient care but still involve occupational exposure in settings where direct patient care is provided, or occupational exposure to contaminated materials originating from settings where direct patient care is provided or to human remains,” and “[j]ob duties that involve occupational exposure to contaminated materials in diagnostic, research or production facilities.” Examples of other covered tasks include: “providing patient support services (e.g., triage reception, housekeeping, food services, facility maintenance); handling, transporting, receiving or processing contaminated materials (e.g., laundering healthcare linens, transporting medical specimens, disposing of medical waste, reprocessing medical equipment); maintaining, servicing or repairing contaminated medical equipment; conducting autopsies (e.g., in medical examiners’ offices); performing mortuary services; manipulating and analyzing cultures, specimens, and human remains containing infectious agents in diagnostic, research and production facilities; and dispensing medications and/or medical supplies in settings where direct patient care is provided.”

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Are job duties covered under the definition of “direct patient care” clearly stated? Do you understand if your workplace is covered? If not, how can the definition be changed to make it clear whether your workplace is covered?

Are job duties and work settings covered under the definition of “other covered tasks” clearly stated? Do you understand if your workplace is covered? If not, how can the definition be changed to make it clear whether your workplace is covered?

The regulatory framework defines occupational exposure as “[e]xposure, which is or should be reasonably anticipated, to sources of infectious agents resulting from an employee’s execution of job duties that involve the provision of direct patient care or the performance of other covered tasks.”

Is the meaning of the term “occupational exposure” clearly defined? As the definition is written, do you understand how to determine whether there is occupational exposure in your workplace? If not, can you provide a more appropriate definition for your workplace?

OSHA has preliminarily determined that the following types of settings would be within the scope of a rule based on the regulatory framework:

- Offices of Physicians;
- Offices of Dentists;
- Other Patient Care, which includes ambulatory care facilities not otherwise listed;
- First Aid and Emergency Care, which includes ambulance services and first responders, as well as low-level immediate care at gatherings such as sporting events, conventions, or festivals;
- Hospitals;
- Long Term Care and Nursing Homes;
- Home Healthcare;
- Laboratories;
- Embedded Clinics in Schools, Correctional Facilities, and Industrial Facilities;
- Morgues, Mortuaries, and Other Death Care Services;
- Medical Equipment Activities; and
- Waste Collection and Handling and Commercial Laundries.

SERs who are interested can find a more detailed preliminary list of affected industries at the end of the SER background document, in Appendix A, SBA Definitions of Small Entities for all Affected Industries at the Six-Digit NAICS Level.

Based on your review of OSHA’s preliminary determination, are there any settings or tasks OSHA has not included that **should be** included? Are there settings or tasks that OSHA has included that **should not be** included?

## **Worker Infection Control Plan (WICP) Questions**

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A rule based on the regulatory framework would require “[e]ach employer having an employee(s) with occupational exposure during provision of direct patient care and/or performance of other covered tasks ... to develop and implement a written WICP designed to prevent or minimize the transmission of infectious agents to each employee.” OSHA anticipates that every covered employer would need to develop a WICP, and review and update its WICP at least annually, but preliminarily estimates that many employers – nearly all in some sectors, such as hospitals, laboratories, and nursing homes - already have infection control plans that would meet all or most of the requirements of a rule based on the regulatory framework.

Does your facility have a WICP? If your facility has a WICP, how long did it take you to develop it?

Does your facility have a WICP as a condition of participation in Medicare or Medicaid, per Centers for Medicare and Medicaid Services (CMS) regulations?

The WICP would be required to contain at least the following elements:

- The name and title of, and contact information for, the plan administrator responsible for WICP implementation and oversight;
- The name of the person(s) responsible for the daily management of the WICP;
- The required exposure determination; and
- The required standard operating procedures (SOPs).

If your facility has a WICP, does it have all of these elements? If not, which element(s) are missing? Are there reasons that these elements are not included in your WICP? What costs (e.g., hours of employee time, contracting resources) would you anticipate would be needed to add missing elements?

If your facility has a WICP, does the WICP cover contractors, vendors, or licensed independent practitioners with privileges? If your facility has a WICP, does your facility review and update its WICP regularly? If so, how frequently do updates occur? If your facility does not have a WICP, what obstacles, if any, do you foresee in developing and implementing a WICP?

How did you, or how would you, go about developing a WICP? On what source(s) (e.g., Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), professional organization(s), commercial source(s)) did you, or would you, rely in developing a WICP? Would you develop a comprehensive WICP independently or would you use or modify an

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existing WICP template? What costs (e.g., hours of employee time, purchase price of a commercial template) would you anticipate in developing and/or modifying such a template?

In your experience, what percentage of facilities such as yours develops a WICP?

Has your workplace made any sort of exposure determination of which types of workers may have occupational exposure to infectious agents? If so, what procedures did your facility use to make such a determination? Which workers (e.g., nurses, physicians, laundry workers, medical waste handlers, laboratory workers) do you believe have exposure to infectious agents in your workplace?

Table VI-1 of the SER Background Document (reproduced below) contains OSHA’s estimates of the average amount of employee time needed to create and update a WICP. Do the estimates for your type of facility seem reasonable? If not, please provide estimates that you believe are reasonable.

<b>Table VI-1</b>		
<b>Worker Infection Control Plan</b>		
<b>Estimated Compliance Burden per Establishment in Hours</b>		
<b>Setting</b>	<b>Initial Development</b>	<b>Annual review and update</b>
Offices of Physicians	24	6
Offices of Dentists	20	4
Other Patient Care	40	8
First Aid & Emergency Care	20	4
Hospitals	40	16
Long Term Care and Nursing Homes	40	8
Home Healthcare	40	8
Laboratories	40	8
Embedded Clinics in Schools	20	4
Embedded Clinics in Correctional Facilities	20	4
Morgue/Mortuaries	20	4
Embedded Clinics in Industry	20	4
Medical Equipment Activities	20	4
Waste Collection & Handling & Commercial Laundries	20	4

Source: Office of Regulatory Analysis, OSHA, based on ERG, 2013.

### Questions on Standard Operating Procedures (SOPs)

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Per the regulatory framework, OSHA’s approach would generally require that the employer develop, implement, and update written SOPs that are consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered by employees during their job tasks. In developing and updating SOPs, the employer would be required to consider applicable regulations (e.g., federal, state and local regulations) and current guidelines (e.g., those issued by the CDC and its Federal Advisory Committees, such as the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices, CDC/National Institutes of Health (NIH) Biosafety in Microbiological and Biomedical Laboratories guidance, and the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules). In the absence of such regulations and guidelines, the employer would be required to consider current guidance issued by professional organizations and accrediting bodies.

The regulatory framework would also require all affected work settings to develop and implement certain SOPs. In addition to the SOPs that would apply to all work settings, OSHA would require employers to develop and implement specific SOPs for work settings where direct patient care is provided and for work settings where other covered tasks are performed.

The following sections address the potential costs of, and any obstacles or difficulties that could be encountered when, implementing SOPs. OSHA included potential costs related to developing SOPs as part of the cost of developing a WICP (discussed previously in this document) and potential costs related to training workers to properly follow SOPs as part of the costs of training (discussed later in this document).

#### **SOPs for All Affected Work Settings**

##### **Infectious Agent Hazard Evaluation**

The regulatory framework would require affected employers to develop and implement “procedures to promptly identify suspected or confirmed sources of infectious agents that are present in the work setting by conducting timely infectious agent hazard evaluations.” OSHA does not expect, and would not require, that these evaluations be written documents; rather, OSHA anticipates that these procedures would be incorporated into routine activities. OSHA has preliminarily identified various ways that facilities can, and do, implement these procedures, including the following:

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- Establishments that see patients by appointment can incorporate questions on whether patients are experiencing symptoms of an infectious disease into an appointment reminder phone call or email;
- Establishments that see patients on a walk-in basis can have a list of questions about potential symptoms that can be asked as part of the patient check-in or initial triage;
- Establishments where patients are admitted (such as hospitals or nursing homes), can conduct evaluations as part of the normal observation and care of patients.

This list contains examples only; OSHA believes there would be many other ways for employers to comply.

How are suspected or confirmed sources of infectious agents (either sick patients, contaminated materials, or any other potential source) currently identified upon arrival at your facility? Does your facility conduct any sort of infectious agent hazard evaluation (e.g. during triage or patient scheduling)? How are these evaluations currently conducted?

OSHA has preliminarily concluded (pp. 65-66 of the SER Background Document) that conducting an infectious agent hazard evaluation would not result in additional costs (either additional time or materials to perform these activities). Do you agree with this conclusion? If not, what additional costs do you see being incurred to conduct these evaluations?

### **Hand Hygiene**

The regulatory framework includes a requirement for the development and implementation of “[p]rocedures to ensure that handwashing facilities are available and accessible, and for following recognized and generally accepted good infection control practices for hand hygiene.” At a minimum, hand hygiene should be performed before and after each patient encounter and, under some circumstances, at additional times during a patient encounter (for example, after contact with blood, body fluids, or contaminated surfaces (even if gloves are worn) or before invasive procedures). For workers who are handling hazardous or potentially hazardous materials, like medical waste or linens, hand hygiene should be performed at a minimum after gloves are removed and any time ungloved hands come into contact with known or suspected contaminated materials. OSHA believes that employers will be able to choose the most effective and most cost efficient means for their employees to perform hand hygiene (e.g., employers can provide alcohol-based hand sanitizers rather than installing additional sinks) so long as that method meets recognized and generally accepted good infection control practices.

Do you anticipate that a potential handwashing requirement based on the regulatory framework would require you to install additional handwashing facilities?

Do employees in your facility use hand sanitizers in lieu of soap and water washing and, if so, what type of hand sanitizer (e.g., alcohol-based, chlorhexidine, triclosan) is used? How often is a

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hand sanitizer used instead of hand washing and under what circumstances? How do you assure that workers are practicing appropriate hand hygiene?

Would your workplace have to modify your current hand hygiene procedures in order to comply with the potential requirements set out in the regulatory framework? If so, to what degree? What do you anticipate the costs of those changes to be? In your cost estimate, consider the programmatic or planning costs, costs related to providing hand hygiene facilities, and employee time needed to perform additional hand hygiene.

### **Engineering Controls**

Engineering controls involve making changes to the work environment to reduce, isolate, or remove the infectious agents' hazard from the workplace. Examples include airborne infection isolation rooms (AIIRs) in some hospitals, biosafety cabinets (BSCs), which are currently used in laboratories (both in hospitals and in separate laboratory facilities), and autopsy suites, which are currently used in morgues, mortuaries, and hospitals. The regulatory framework would require the development and implementation of procedures for the use of engineering controls in accordance with recognized and generally accepted good infection control practices, and would require that, where used, engineering controls be examined on a regular schedule, and maintained or replaced to ensure their effectiveness.

OSHA does not anticipate that a rule based on the regulatory framework would result in the installation of new or additional engineering controls, and OSHA expects that many of the affected sectors would not incur costs related to upgrading or improving engineering controls because many facilities do not have these types of controls and would not need them to comply with a rule as outlined in the regulatory framework. OSHA estimates that in some facilities where there are existing engineering controls, however, AIIRs, BSCs and autopsy suites would need to be appropriately upgraded and maintained.

Do you think OSHA should require the use of engineering controls even when recognized and generally accepted good infection control practices recommend the use of infection control measures other than engineering controls? If so, why? Moreover, what types of engineering controls are or should be used in your facility, and in what situations do those engineering controls need to be used?

Do you interpret the provision in the regulatory framework that states that facilities must develop and implement "procedures for the use of engineering, administrative and work practice controls in accordance with recognized and generally accepted good infection control practices" as potentially requiring facilities to install new engineering controls? For example, do you believe that in particular situations, and under recognized and generally accepted good infection control practices, employers would need to install engineering controls to comply with the regulatory framework?

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Does your workplace use AIIRs, BSCs, or autopsy suites to control the spread of infectious agents? If so, how often are they maintained (or certified)?

Are there any additional types of engineering controls (e.g., ventilation controls, ultraviolet (UV) environmental disinfection systems) that your facility uses to control the spread of infectious agents? If so, how often are they maintained (or certified)?

If your facility uses AIIRs, BSCs, autopsy suites, or other types of engineering controls to control the spread of infectious agents, do you anticipate that your facility would need to upgrade these engineering controls or change maintenance practices for engineering controls to meet the potential requirements in the regulatory framework? Please describe the reason for your answer and explain the upgrades that would be necessary.

Table VI-2 of the SER Background Document (reproduced below) contains costs for upgrading and maintaining AIIRs, autopsy suites, and BSCs. If you have experience with these controls, do you think these cost estimates are reasonable? If not, what are more appropriate cost estimates, given your experience?

Table VI-2						
Engineering Controls						
Setting	One-time Airborne Infection Isolation Room Upgrades	Annual Airborne Infection Isolation Room Maintenance	One-time Autopsy Suite Upgrades	Annual Autopsy Suite Maintenance	One-time Biological Safety Cabinet Upgrades	Annual Biological Safety Cabinet Maintenance
Hospitals	\$7,217	\$866	\$14,435	\$1,732	\$809	\$97
Laboratories	--	--	--	--	\$809	\$97
Morgue/Mortuaries	--	--	\$14,435	\$1,732	--	--

Source: Washington Consulting Group, 1994; OSHA, 1997; updated to 2012 dollars.

### Administrative and Work Practice Controls

Administrative controls are managerial measures that reduce occupational exposure by reducing the risk of transmission of, or infection by, infectious agents. For example, employers can implement policies that encourage or require ill employees to stay home, or for isolating patients with certain known or suspected infectious diseases (e.g., Influenza, TB).

Work practice controls are measures that reduce the risk of transmission of, or infection by, infectious agents, by specifying the manner in which particular work tasks will be performed. For example, employers can implement policies that encourage or require the use of appropriate hand hygiene (hand soap or hand sanitizer, as appropriate).

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The regulatory framework would require the development and implementation of procedures for the use of administrative and work practice controls in accordance with recognized and generally accepted good infection control practices.

Are administrative controls to reduce occupational exposure used in your workplace and if so, which administrative controls are being used?

Are work practice controls to reduce occupational exposure being used in your workplace and, if so, which work practice controls are being used?

OSHA has preliminarily concluded (pp. 71-72 of the SER Background Document) that necessary administrative controls (other than promoting and providing vaccinations and enforcing the exclusion of ill employees from the workplace) and work practice controls (other than hand hygiene) could be implemented by modifying current practices and that compliance with the rule as outlined in the regulatory framework would not result in additional costs with respect to these administrative and work practice controls. Do you agree with this conclusion? Why?

Are there any administrative or work practice controls that OSHA has not addressed in its regulatory framework that would need to be implemented in order for your facility to comply with the potential requirements in the regulatory framework? Please describe.

### **Personal Protective Equipment (PPE)**

The regulatory framework would require the development and implementation of “procedures to provide, make readily accessible, and ensure that each employee uses PPE . . . in accordance with recognized and generally accepted good infection control practices” Examples of PPE include gloves, goggles, face shields, surgical masks, and respirators (e.g., N-95s).

What types of PPE are used in your facility to protect workers from exposure to infectious agents? How many of each type of PPE does your facility use on a daily, weekly, or monthly basis?

For each type of PPE that might be necessary in your facility, how many more of that type of PPE do you anticipate that your facility would have to purchase in order to comply with the potential requirements in the regulatory framework?

How do you ensure that workers at your facility are using PPE correctly?

Have you observed that the number of PPE items used by workers increases when they are dealing with known or suspected infectious agents?

The following discussion addresses the types of PPE that OSHA believes would be used by employers affected by a rule as outlined in the regulatory framework, and describes the Agency’s preliminary estimates of when such PPE would be used under a rule as outlined in the regulatory

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framework. This discussion covers gloves, facemasks (e.g., surgical masks), disposable gowns, disposable face shields, and N95 respirators.

Are there any other types of PPE you would expect to use under a rule as outlined in the regulatory framework? Are there additional situations, other than those listed below, where employees would need to wear PPE? What type of PPE would be needed in those situations? How often would employees be in such situations?

### ***Disposable Gloves***

OSHA preliminarily determined that a pair of disposable gloves would need to be donned by each worker prior to contact with each new patient and any time gloves become visibly soiled or before contact with potentially infectious materials. OSHA expects, based on these preliminary determinations, that most workers who have hands-on contact with patients will use at least one pair of gloves per patient encounter, and that workers who are handling infectious, or potentially infectious, waste or linens will use two to four pairs of disposable gloves per shift. OSHA also expects that laboratory workers will change gloves when gloves are contaminated, when glove integrity is compromised, when the worker takes breaks or switches tasks, or when otherwise necessary. OSHA preliminarily estimates that laboratory workers would use five to ten pairs of gloves in a workshift.

Are the preliminary estimates in the preceding paragraph consistent with your facility's use of disposable gloves? Are there additional times in your facility when disposable gloves are used to protect workers from exposure to infectious agents? During what types of activities are disposable gloves worn by employees in your facility?

How many pairs of disposable gloves does your facility use on a daily, weekly, or monthly basis? Do you anticipate your workers would have to use more disposable gloves under a rule as outlined in the regulatory framework? If so, how many additional pairs of gloves on a daily, weekly, or monthly basis?

### ***Facemasks (e.g., Surgical Masks)***

OSHA preliminarily determined that facemasks (e.g., surgical masks), which are needed for protection against suspected or confirmed cases of droplet transmissible diseases, can be worn by an employee until visibly soiled. OSHA believes, based on this preliminary determination, that workers providing direct patient care in settings where patients are being treated for suspected or confirmed droplet transmissible diseases (for example in some ambulatory care settings or in hospitals) will use one facemask (e.g., surgical mask) per shift, while workers in other settings will use facemasks or surgical masks less frequently. OSHA also anticipates that some facilities will use facemasks (e.g., surgical masks) on patients who have a suspected or confirmed case of a droplet transmissible disease and who can tolerate being masked.

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Are the preliminary estimates in the preceding paragraph consistent with your facility's use of facemasks (e.g., surgical masks)? Are there additional times in your facility when facemasks (e.g., surgical masks) are used to protect workers from exposure to infectious agents? During what types of activities are facemasks (e.g., surgical masks) worn by employees in your facility?

How many facemasks (e.g., surgical masks) does your facility use on a daily, weekly, or monthly basis? Do you anticipate that there would be additional situations in which your workers would need to use facemasks (e.g., surgical masks) under a rule as outlined in the regulatory framework? If so, how many additional facemasks (e.g., surgical masks) would be used on a daily, weekly, or monthly basis?

### ***Disposable Gowns***

OSHA preliminarily determined that disposable gowns need to be used when workers are working inside isolation rooms or when there is risk of the worker's skin or clothing becoming contaminated (e.g., during aerosol generating procedures, during some laboratory procedures, or while handling infectious waste or laundry). OSHA expects, based on these preliminary determinations, that one disposable gown will be used per worker for each interaction with a patient who is on isolation precautions or contact precautions. Workers handling infectious or potentially infectious waste or laundry, and laboratory workers, will use at least two disposable gowns per shift.

Are the preliminary estimates in the preceding paragraph consistent with your facility's use of disposable gowns? Are there additional times in your facility when disposable gowns are used to protect workers from exposure to infectious agents? During what types of activities are disposable gowns worn by employees in your facility?

How many disposable gowns does your facility use on a daily, weekly, or monthly basis? Do you anticipate that there would be additional situations in which your workers would need to use disposable gowns under a rule as outlined in the regulatory framework? If so, how many additional disposable gowns would be used on a daily, weekly, or monthly basis?

### ***Disposable Face Shields and Protective Eyewear***

OSHA preliminarily determined that disposable face shields are needed mainly when workers are potentially exposed to droplet spray and when workers are performing aerosol-generating activities in settings where direct patient care is provided and where other covered tasks (such as medical equipment reprocessing or in laboratories) are performed. Moreover, protective eyewear is used primarily when workers are potentially exposed to splashes or sprays and when performing aerosol-generating activities. OSHA expects, based on these preliminary determinations, that workers who are reprocessing medical equipment and workers who are performing autopsies will use at least two disposable face shields per shift, and that laboratory workers will use either one disposable face shield per shift or will be provided with one pair of

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reusable protective goggles. Some workers in dentists' offices will use one disposable face shield per patient and, additionally, a small percentage of workers in other ambulatory care facilities, hospitals, and long term care facilities will perform aerosol-generating activities in an average shift and will therefore need a disposable face shield while performing this work.

Are the preliminary estimates in the preceding paragraph consistent with your facility's use of disposable face shields and protective eyewear? Are there additional times in your facility when disposable face shields and protective eyewear are used to protect workers from exposure to infectious agents? During what types of activities are disposable face shields and protective eyewear worn by employees in your facility?

How many disposable face shields does your facility use, and how often is protective eyewear used, on a daily, weekly, or monthly basis? Do you anticipate that there would be additional situations in which your workers would need to use disposable face shields and protective eyewear under a rule as outlined in the regulatory framework? If so, how many additional disposable face shields would be used, and how often would protective eyewear be used, on a daily, weekly, or monthly basis?

### ***N95 Respirators***

OSHA believes, at this time, that facilities subject to a rule as outlined in the regulatory framework would use disposable N95 respirators only. OSHA preliminarily determined that N95 respirators, which are needed for protection against airborne transmissible diseases and during aerosol generating procedures and, like facemasks, can be worn until visibly soiled (one N95 respirator estimated to be used per work shift). OSHA expects, based on this preliminary determination, that healthcare workers that care for, and workers performing other covered tasks that bring them into contact with, patients who have confirmed or suspected airborne transmissible diseases (for example, housekeepers or food service workers who deliver food to rooms) would need one N95 respirator for each encounter with such patients. Some laboratory workers working in animal research facilities would also regularly use N95 respirators.

Are the preliminary estimates in the preceding paragraph consistent with your facility's use of N95 respirators? Are there additional times in your facility when N95 respirators are used to protect workers from exposure to infectious agents? During what types of activities are N95 respirators worn by employees in your facility?

How many N95 respirators does your facility use on a daily, weekly, or monthly basis? Do you anticipate that there would be additional situations in which your workers would need to use N95 respirators under a rule as outlined in the regulatory framework? If so, how many additional N95 respirators would be used on a daily, weekly, or monthly basis?

If your facility has employees who wear respirators, do you have a written respiratory protection program? Do you provide initial medical evaluations to employees who wear respirators during

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the performance of their job duties? Under what circumstances do you re-evaluate workers who wear respirators, and how frequently does that re-evaluation happen?

Does your facility currently provide fit testing for respiratory protective equipment prior to use by employees? How frequently is fit testing done? At your facility, do you provide fit testing in-house or is it provided by an outside contractor or by a respirator manufacturer? If your facility does not provide fit testing for employees who wear or may need to wear respirators, what is the reasoning behind that decision?

Table VI-4 of the SER Background Document (reproduced below) contains estimates of the time and costs associated with fit testing and most other applicable parts of a respirator program. Do these estimates seem reasonable? If not, please provide your own estimates and indicate why you do not think OSHA's estimates are appropriate.

<b>Table VI-4 Respiratory Protection</b>			
<b>Written Respiratory Protection Plan</b>			
<b>Facility Type</b>	<b>Initial development</b>	<b>Annual review and update</b>	
High risk	8 hours	4 hours	
Low risk	4 hours	2 hours	
<b>Medical Evaluation and Examination</b>			
<b>Activity</b>	<b>Employee Time, in Hours</b>	<b>PLCHP Time, in Hours</b>	<b>Costs of Medical Exam</b>
Initial Medical Evaluation or Re-evaluation <sup>1</sup>	0.25	0.08	--
Follow-up Medical Exams if necessary <sup>2</sup>	1	--	\$294.75
Additional Medical Re-evaluation <sup>3</sup>	0.5	--	\$138
<b>Fit Testing</b>			
<b>Provider</b>	<b>Employee Time, in Hours</b>	<b>Fit Tester Time, in Hours</b>	<b>Additional Costs, per Employee</b>
Manufacturer	0.5	--	--
In-house	0.5	0.5	\$1.15 <sup>4</sup>
Contractor	0.5	--	\$76.68 <sup>5</sup>
<sup>1</sup> Cost for re-evaluation for changes in work conditions only.			
<sup>2</sup> Cost of follow-up exams is for both follow-up exams necessary as a result of initial evaluations and re-evaluations due to changes in work conditions.			
<sup>3</sup> Cost for medical re-evaluation resulting from new or worsening health conditions.			
<sup>4</sup> Additional costs represent materials used for fit testing.			
<sup>5</sup> Additional costs represent the estimated per-employee charge for an outside contractor to provide fit testing.			
Source: OSHA, 2011, FAIR Health, 2013; AMA, 2008; AHRQ, 2011a.			

As stated, OSHA believes, at this time, that facilities subject to a rule as outlined in the regulatory framework would use disposable N95 respirators only. Does your facility use

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disposable respirators only, or does your facility use reusable respirators? What type(s) of respirators are used in your facility to protect workers from exposure to infectious agents?

### **Decontamination and Handling, Containerization, Transport, or Disposal of Contaminated Materials**

Decontamination is the use of various means (physical, radiological, and/or chemical) to remove, inactivate, or destroy infectious agents. A rule based on the regulatory framework would require development and implementation of procedures for “routine and targeted decontamination of all contaminated materials (i.e., contaminated items and/or surfaces) in the work setting that could be a source of occupational exposure.” Decontamination can encompass cleaning, disinfection, and sterilization. The regulatory framework does not prescribe any particular cleaning, disinfection, or sterilization methods, nor does OSHA intend to require employers to use specific cleaning products or follow specific cleaning schedules. Decontamination procedures must be consistent with recognized and generally accepted good infection control practices, however. OSHA expects, for example, that, in some settings where direct patient care is provided, patient rooms would need to be decontaminated between patients.

A rule based on the regulatory framework would also require development and implementation of procedures to ensure that contaminated materials that could be a source of occupational exposure to infectious agents are properly containerized and labeled in order to prevent leaks and minimize worker contact with infectious materials during collection, handling, processing, storage, transport, shipping, or disposal.

OSHA has preliminarily concluded that that the regulatory framework’s potential decontamination requirement can be accomplished in the same amount of time affected employers are currently devoting to decontamination practices.

Do you agree with OSHA’s conclusion that employers can comply with the regulatory framework’s potential decontamination requirement in the same amount of time currently being devoted to decontamination practices?

If you do not agree with this conclusion, how much additional time (e.g., hours) and expense annually (over current decontamination practices) would your facility need to spend performing decontamination in order to meet this potential requirement? If possible, please provide the basis for your estimate (e.g. specify the additional minutes needed per decontamination event multiplied by the estimated events occurring annually).

Similarly, OSHA has concluded that facilities affected by this potential rulemaking are already subject to requirements related to handling, containerization, transport, or disposal of contaminated materials due to existing OSHA, Department of Transportation (DOT), or other applicable state-level requirements. Due to these existing requirements, OSHA has preliminarily

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concluded that affected facilities would incur no additional costs for this potential requirement. Do you agree with this conclusion?

If you do not agree with this conclusion, what additional measures would your facility need to undertake in order to meet the potential requirements presented in the regulatory framework?

### **Exposure Incidents**

The regulatory framework defines an exposure incident as a “specific event in which an employee has been exposed to a suspected or confirmed source of an infectious agent(s), either without the benefit” of required infection control practices, or where these “infection control practices may not have adequately protected the employee from the exposure.” The regulatory framework would require affected facilities to develop and implement “[p]rocedures to investigate the circumstances surrounding each exposure incident, including determination of the cause of the incident, and whether existing policies, procedures, or training need to be revised to prevent future exposure incidents.”

How does your facility currently deal with incidents where workers are exposed to suspected or confirmed infectious patients or materials?

Does your facility perform any type of investigation of these types of exposure incidents? How is a typical investigation conducted, and how long does such an investigation take? How are the results documented? How frequently do such investigations take place, and do you anticipate that this provision would require you to conduct additional exposure incident investigations?

OSHA preliminary estimated that the investigation of an exposure incident would take thirty minutes, on average, which takes into account both very simple investigations, which may take far less than 30 minutes (because, for example, the exposure incident involves an easily identified cause and existing policies, procedures, and training are readily determined to be adequate), and more complex investigations, which may take more than 30 minutes to complete. Do you agree with this estimation? If not, what do you believe is a more reasonable estimate? Please provide your alternative estimate as both an average and as a range. Also, please indicate your anticipated ratio of simple investigations to complex investigations.

Do you anticipate that your workplace would need to modify current procedures to investigate exposure incidents to comply with a rule as outlined in the regulatory framework? What do you anticipate you would need to do differently? What do you estimate the cost (including development and implementation) of such changes would be?

Do you have a procedure in place to notify CDC and/or your state or local public health department about reportable infectious diseases? Is this required by your state or local public health department?

### Additional SOPs for Work Settings Where Direct Patient Care is Provided

In addition to the SOPs that would be required for all affected work settings, employers whose employees provide direct patient care would be required to develop and implement additional SOPs. Examples of such SOPs include procedures for patient scheduling and intake/admittance, standard and transmission-based precautions (e.g., contact, droplet, and airborne precautions), and patient transport, as well as procedures for the implementation of temporary control measures for medical surge conditions.

Do you anticipate that your facility will need to modify its SOPs, or the implementation of those SOPs related to the use of standard and transmission-based precautions, in order to comply with potential requirements of the regulatory framework? What do you anticipate you would need to do differently?

OSHA has preliminarily concluded that, at facilities that provide direct patient care, there would be no additional costs to develop and implement SOPs for the following procedures because these procedures are standard practice, the costs of developing and implementing these procedures are accounted for under the costs associated with the development and implementation of general SOPs for all affected work settings, or these procedures could be implemented through modification of current practices:

- Procedures for patient scheduling and intake/admittance (p. 83 of the SER Background Document);
- Standard, contact, droplet, and airborne precautions (other than costs associated with PPE (including respiratory protection), hand hygiene, the maintenance of existing engineering controls, and work practice controls to minimize the generation of aerosols during certain procedures) (p. 83 of the SER Background Document); and
- Procedures for patient transport (p. 83 of the SER Background Document).

Do you agree with OSHA's preliminary finding that there would be no additional costs to develop and implement the above SOPs? If not, what actions would your facility need to perform, or what items would your facility need to purchase, in order to comply with these potential requirements? What would be the additional cost involved, both for developing and for implementing the additional SOPs and changes in operation?

#### **Medical Surge Procedures**

This potential requirement in the regulatory framework would only apply to employers that provide services under medical surge conditions (e.g., employers, such as hospitals, clinics with urgent care services, and emergency responders/ambulances, that handle emergency/urgent care situations), and would require those facilities to develop and implement procedures for temporary control measures to be taken during such conditions.

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OSHA has not yet examined the costs of implementing medical surge procedures (see p. 83 of the SER Background Document). If the potential requirement for developing and implementing SOPs for medical surge procedures applies to your workplace, what SOPs do you currently have in place to address medical surges? Do you anticipate your facility would need to modify any SOPs to comply with this potential requirement of the regulatory framework? If so, what costs (e.g., hours of employee time) would you anticipate in developing and implementing such an SOP, including engineering controls (e.g. for temporary AIIAs) and stockpiling PPE? What costs do you estimate for changes in worker activities to comply with these SOPs in cases where they must be implemented?

### **Additional SOPs for Work Settings Where Other Covered Tasks are Performed**

Employers whose employees perform other covered tasks would be required to develop and implement SOPs in addition to the SOPs that would be required for all affected work settings.

As discussed above, other covered tasks include job duties that do not involve direct patient care, but still involve occupational exposure in settings where direct patient care is provided (e.g., triage reception, housekeeping, food services, facilities maintenance), and job duties that involve occupational exposure to contaminated materials originating from settings where direct patient care is provided or to human remains (e.g., laundering healthcare linens, transporting medical specimens).

OSHA has preliminarily concluded that, at facilities that perform other covered tasks, there would be no additional costs to develop and implement SOPs for the following procedures because these procedures are standard practice, the costs of developing and implementing these procedures are accounted for under the costs associated with the development and implementation of general SOPs for all affected work settings, or these procedures could be implemented through modification of current practices:

- Procedures for handling and intake of contaminated materials; and
- Procedures for the use of control measures necessary to prevent or minimize transmission of infectious agents.

For your facility, do you anticipate that you would incur additional costs under a rule as outlined in the regulatory framework to develop and implement these SOPs?

Other covered tasks also includes job duties that involve occupational exposure to contaminated materials in diagnostic, research, or production laboratory facilities. Per the regulatory

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framework, OSHA would require diagnostic, research and production laboratory facilities to develop and implement SOPs for the following activities:

- Procedures for standard microbiological practices and any special practices for handling infectious agent(s) of a specific biosafety level, including, as appropriate;
  - Engineering controls, such as biosafety cabinets, laboratory hoods, and other laboratory design and containment measures, which must be appropriately constructed, operated, and maintained; and
  - Measures necessary to address uncontrolled releases of infectious agents, including mitigation of such releases and prompt reporting of such incidents to appropriate authorities.

OSHA discussed the potential costs associated with upgrading and maintaining engineering controls in its discussion of potential costs for general SOPs, above. The Agency did not identify any additional potential costs associated with implementing measures to address uncontrolled releases of infectious agents, but welcomes any additional information the SERs can provide on the issue. In OSHA's preliminary estimation, these measures would rarely need to be implemented, but would involve (1) planning for such circumstances, which, the Agency preliminarily believes, affected firms are already doing, and (2) training workers on these measures (which OSHA costs separately).

Do you agree with OSHA's preliminary finding about the costs of this potential requirement? If not, what actions would your facility need to perform, or what items would your facility need to purchase, to comply with this potential requirement? What would the items or actions cost?

## **Questions on Medical Screening, Surveillance, and Vaccination**

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### **Vaccinations**

The regulatory framework would require that vaccinations, and associated vaccination regimens (e.g., doses, intervals), be made available consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered during the job tasks of the employee. For workers in research and production laboratories, this would mean that the employer would need to make available any vaccination(s) specified in the employer's WICP, or determined by a physician or other licensed healthcare provider (PLHCP) to be medically appropriate for a particular employee. For other settings this would mean that the employer would, at a minimum, need to make the follow vaccinations available:

- Influenza (Seasonal and Pandemic);
- Measles, Mumps and Rubella (MMR);

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- Tetanus, Diphtheria, and Pertussis (Tdap);
- Varicella; and
- Any other vaccination(s) that is specified in the employer's WICP, or determined by a PLHCP to be medically appropriate for a particular employee (e.g., the meningococcal vaccine).

Vaccinations would not need to be made available to an employee with occupational exposure if the employer has documented that the employee's vaccination is up-to-date, antibody testing has revealed that the employee is immune, or a vaccine(s) is contraindicated for medical reasons.

In addition, employers would need to provide training on vaccinations prior to an employee's initial job placement, and offer required vaccinations after the training has been provided. A worker could decline a vaccination(s) but the employer would need to ensure that the worker completes a vaccine declination form (a sample of which is included with the regulatory framework), and if that worker decided at a later date to accept the vaccine(s), the employer would need to make the vaccine(s) available at that time.

Follow-up testing (e.g., antibody titer) would need to be provided according to generally recognized and accepted good infection control practices.

OSHA preliminarily expects that all employers of workers in facilities where direct patient care is provided would need to make an annual flu shot available to their workers annually. However, OSHA also preliminarily expects that many workers would already be protected from many other diseases for which vaccines would need to be made available: many of these workers will likely already be protected because they either received the vaccines during childhood (which is routine), or previously contracted the disease (and thus became immune).

Does your facility offer workers the full complement of CDC/ACIP recommended vaccines (listed above), or, as appropriate, the full complement of CDC/NIH BMBL recommended vaccines? Does your facility offer vaccines in accord with state-level vaccine requirements that are less extensive (as opposed to the more extensive ACIP/CDC or CDC/NIH BMBL recommendations) Does your facility offer vaccines in addition to those recommended by ACIP/CDC or CDC/NIH BMBL that are required by a state or local public health department? If so, which additional vaccine(s) are offered? Please explain any additional reasons (e.g. cost, risk consideration, vaccine availability, etc.) as to why you offer fewer, or more, vaccines than is recommended by CDC/ACIP or CDC/NIH.

In your estimation, what percentage of workers in your facility currently need to be vaccinated prior to job placement (either because they have not been vaccinated previously, or cannot prove their immunity to the infectious disease[s] for which your facility requires vaccinations)? What percentage of your workers have declined vaccine(s) and what are the reasons they have provided for doing so (e.g. religious beliefs, side effects, etc.)?

### Medical Screening and Surveillance, and Medical Evaluation and Follow-up

#### *Medical Screening and Surveillance*

The regulatory framework would require employers with employees who have occupational exposure during the provision of direct patient care and/or the performance of other covered tasks to make available to those employees medical screening and surveillance, as deemed appropriate by a PLHCP. In its preliminary cost estimates, OSHA assumed that medical screening would take the form of a pre-placement questionnaire that determines immunization status and obtains the employee's medical history as it pertains to any conditions that might predispose him or her to acquiring or transmitting infectious diseases. OSHA recognizes, however, that some facilities may opt for a more extensive full physical.

What type of medical screening does your facility provide to newly hired employees? Do employees complete a medical history questionnaire only, or do you provide a more extensive initial medical screening? Do you anticipate that your facility's medical screenings would need to change to comply with the potential requirements in the regulatory framework?

What type of on-going medical surveillance does your facility currently conduct? OSHA preliminarily identified on-going TB testing as the only medical surveillance that is currently conducted on a routine basis. What types of medical surveillance, other than TB testing, do you believe your facility would need to conduct to comply with the potential requirements in the regulatory framework?

#### *Medical Evaluation and Follow-up*

The regulatory framework would require employers to make available confidential medical evaluations and appropriate follow-ups to employees who are referred from medical screening or surveillance programs, or as a result of an exposure incident (see the discussion of "Exposure Incidents," above, for the regulatory framework's definition of "exposure incident"). The medical evaluation and follow-up as a result of an exposure incident would need to include at least the following elements:

- Documentation of the route(s) of exposure and the circumstances under which the exposure incident occurred;
- Identification and documentation of the source, unless the employer could establish that identification is not feasible or is prohibited by federal, state or local law;
- Appropriate baseline testing of the exposed employee(s), after consent is obtained, for use in determining future seroconversion or infection;
- Post-exposure prophylaxis and treatment appropriate to the infectious agent(s) of concern;
- Counseling, as necessary;
- Evaluation of reported illnesses that could be attributable to the exposure; and

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- Recommendations, if any, for modifications or restrictions to the employee's job duties or for precautionary removal of the employee from the workplace.

What procedures do you have for employees to report suspected cases of occupationally acquired infectious diseases?

OSHA would evaluate, in the preliminary economic analysis for a proposed rule, the full costs of diagnosing, providing post-exposure prophylaxis for, and treating, workplace acquired infectious diseases. The SER background document demonstrates how such an analysis might be completed for three sample diseases: influenza, TB, and MRSA. OSHA determined the treatment regimens for those diseases based on information from CDC or from medical practitioners. The analysis accounts for any necessary vaccinations, tests or diagnostics, drug therapies, and hospitalizations. These preliminary estimates for treatment regimens are contained in Tables VI-7 and VI-8 in the SER background document (pp. 98-100).

For the preliminary economic analysis, OSHA is planning to derive the cost of diagnostic and other testing from Current Procedural Terminology (CPT) codes, the cost of medication from the VA's *Drug Pharmaceutical Prices - Federal Supply Schedule*, and the cost of hospitalization from the International Statistical Classification of Diseases and Related Health Problems (ICD-9) codes. OSHA intends to combine the costs of these elements to arrive at a per-case cost to treat a worker with a given disease.

Do you agree with this methodology? What recommendations do you have for OSHA, either on source data or on methodology, that would help the Agency arrive at the best estimates of the cost for diagnosing, providing post-exposure prophylaxis for, and treating, workplace acquired infectious diseases?

The estimates in the SER background document do not take into account health insurance or workers' compensation coverage, both of which may reduce the actual burden to the employer of treating a case of an occupationally acquired infectious disease. OSHA has addressed this issue in past rulemakings (in the ergonomics rulemaking, for example) by discounting the cost to employers to account for insurance or workers' compensation; thus, the Agency is aware of the issue but is still in the process of determining how to apply such a discount in this instance and what the appropriate discount would be for the purposes of a rule based on the regulatory framework.

Does your facility provide medical treatment for workers who become ill with an infectious disease? Do you distinguish illness that results from an exposure in the workplace from illness that results from an exposure that occurs outside of the workplace? If treatment is provided, how is it provided (e.g., in-house, by the worker's personal doctor, through a doctor selected by the employer), and how is it paid for?

How frequently do you see cases of workers becoming ill as a result of workplace exposures in your facility? Have you ever had a worker become severely ill due to an exposure to infectious agents in the workplace?

### **Medical Removal Protection (MRP)**

The regulatory framework would require employers to follow the PLHCP's recommendations concerning modifications or restrictions to an employee's job duties or precautionary removal of an employee from the workplace (for example, in order to protect patients and co-workers). Except for most cases of occupational exposure to the common cold or influenza, OSHA would also require the employer to provide an employee removed from the job, or otherwise medically limited as a result of an exposure incident, with medical removal protection benefits (*i.e.*, an employer would be required to pay the employee's total normal earnings and maintain the employee's seniority and all other employee rights, and benefits).

OSHA intends to estimate the full costs of medical removal protection and associated benefits in the preliminary economic analysis for a proposed rule. In the SER background document, OSHA analyzed this burden in the context of estimating the costs for diagnosing, providing post-exposure prophylaxis for, and treating the three sample diseases discussed above (influenza, TB, and MRSA). However, OSHA has thus far only estimated the per-case time period for which employers would be required to provide medical removal protection.

As implied above, one issue OSHA intends to address in estimating the full cost of medical removal protection and associated benefits is the effect of workers' compensation coverage associated with medical removal. To this end, the regulatory framework would reduce the employer's obligation to provide medical removal protection benefits to the extent that the employee receives compensation for earnings lost during the period of removal, either from a publicly- or employer-funded compensation program, or from employment with another employer made possible by virtue of the employee's removal.

Per the regulatory framework, employers would only be required to provide medical removal protection for as long as an employee is infectious, not to exceed a period of 18 months. In most cases of occupationally-acquired infections, the worker is treated as an outpatient; the duration of medical removal protection would vary depending on the disease (see, for example, discussion of influenza, in the SER background document).

Does your facility restrict a worker's duties or require that a worker not report to work if he or she is ill, or potentially ill, with an infectious disease? If so, how does your facility determine the period of time for which the worker's duties will be restricted or the worker cannot report to work? If workers are restricted from reporting to work, are those workers paid at their normal rate during the time they cannot work? What considerations would/do you make for providing

pay and benefits to workers restricted from their normal work duties as a result of an exposure incident? Please describe any problems with doing so.

One regulatory option specified in Section VIII of the SER Background Document (Option 7, p. 133) is a requirement for all employers to provide medical removal and protection benefits for the common cold and influenza. What is your opinion of this option?

### Training Questions

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The regulatory framework would require the training of affected workers initially (prior to placement), annually, and as needed to address specific deficiencies. The training program would need to be overseen or conducted by a person knowledgeable in the program's subject matter, consist of material appropriate to educational level, literacy, and language of employees, and provide an opportunity for interactive questions and answers with a person knowledgeable in the program's subject matter as it relates to the workplace.

The initial training program would need to contain, at a minimum, the following elements:

- An accessible copy of the OSHA standard and an explanation of its contents;
- A general explanation of the epidemiology and symptoms of common infectious diseases, including the signs and symptoms of infectious diseases that require further medical evaluation;
- An explanation of the modes of transmission of infectious agents and applicable infection control procedures (e.g., standard and transmission-based precautions) so that the employee can recognize tasks and other activities that may involve occupational exposure and take precautionary measures;
- Information on vaccine(s) that would be required to be made available to the employee, including their efficacy, contraindications, likelihood and severity of possible adverse health effects, method of administration, the benefits of being vaccinated, and that the vaccines and vaccinations will be offered at no cost to the employee and at reasonable times and places;
- An explanation of the employer's WICP and the means by which the employee can obtain a copy of the written plan;
- Training on all of the SOPs developed as part of the WICP that are applicable to the employee's duties;
- An explanation of the use and limitations of engineering, work practice, and administrative controls; and
- Information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of personal protective equipment.

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The annual training program would need to contain, at a minimum, the following elements:

- Information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of personal protective equipment;
- All of the SOPs developed as part of the WICP that are applicable to the employee's duties; and
- Information on vaccine(s) that would be required to be made available to the employee in the year of the training, including their efficacy, contraindications, likelihood and severity of possible adverse health effects, method of administration, the benefits of being vaccinated, and that the vaccines and vaccinations would be required to be offered at no cost and at reasonable times and places.

Does your facility provide training for employees on infection control practices and procedures? If so, is the training provided upon hire, on a recurring basis, or both? What is the frequency of recurring training? How many hours do typical pre-placement training sessions last? How many hours do typical refresher training sessions last?

OSHA preliminarily estimated that initial training that would be required under a rule as outlined in the regulatory framework would take two or three hours (depending on the type of facility and job tasks of the worker), that it would take a total of 30 hours to initially develop training materials, and that refresher training that would be required under a rule as outlined in the regulatory framework would also take two or three hours (again, depending on the type of facility and job tasks of the worker) (see p. 101 of the SER Background Document). Do you believe these are adequate amounts of time for the training development, initial training, and refresher training potentially required by the regulatory framework?

### **Questions on Duplicative, Overlapping, and Conflicting Rules**

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OSHA has examined a number of existing Federal rules and has not identified any that would conflict with the potential requirements presented in the regulatory framework (see Section VII of the SER Background Document, pp. 113-118). Do you see any conflict between what OSHA may require and what other Federal rules require? OSHA also concludes that there would be minimal duplication or overlap between other Federal rules, and a rule as outlined in the regulatory framework. Do you agree that there is minimal duplication or overlap? If your facility participates in Medicare or Medicaid, how does the OSHA framework compare to the infection control plans developed for those programs?

### Questions on Regulatory Alternatives and Options

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Section VIII of the SER Background Document (pp. 119-134) identifies ten alternatives, under the Regulatory Flexibility Act, that would minimize the significant economic impact on small entities, and also identifies eight regulatory options that OSHA is also considering. The regulatory alternatives are as follows:

- Alternative 1 would develop an infectious diseases rule that is specification-oriented rather than performance-oriented.
- Alternative 2 would rely on enforcement under the General Duty Clause.
- Alternative 3 would exempt very small entities (those with fewer than 20 workers) from all requirements of an infectious diseases rule.
- Alternative 4 would apply an infectious diseases rule to workers providing direct patient care, but not to workers performing other covered tasks.
- Alternative 5 would exempt very small employers (those with fewer than 20 workers) from written documentation requirements.
- Alternative 6 would exclude from an infectious diseases rule any requirement that employers that have workers that provide direct patient care include contact precautions in their SOPs.
- Alternative 7 would exclude from an infectious diseases rule any requirement that employers make vaccinations available.
- Alternative 8 would exclude from an infectious diseases rule any requirement that employers provide medical removal protection benefits.
- Alternative 9 would only include initial training and training-as-needed in an infectious diseases rule.
- Alternative 10 would add additional time for small employers to phase-in compliance with an infectious diseases rule.

The regulatory options under consideration are as follows:

- Option 1 would include in the scope of an infectious diseases rule workers who perform first aid only.
- Option 2 would define other covered tasks to include a greater range of tasks (e.g., tasks done by teachers and prison guards) and to cover tasks performed by flight attendants while on airplanes.
- Option 3 would define direct patient care to include all tasks performed by pharmacists that involve face-to-face contact.
- Option 4 would add increased specificity to the exposure determination that would be required.
- Option 5 would require written documentation for infectious agent hazard evaluations.

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- Option 6 would require hospitals to follow the hierarchy of controls as required in OSHA’s Respiratory Protection Standard (29 CFR 1910.134(a)(1)), and to have in their workplaces an appropriate number of airborne infection isolation rooms (AIIRs).
- Option 7 would require all employers to provide medical removal protection benefits for common cold and influenza.
- Option 8 would require employers whose workplace settings have workers that provide direct patient care to develop and display signage in patient rooms encouraging patients to request that workers use proper hand hygiene before any direct patient care is provided.

OSHA would appreciate all comments on any of these alternatives and options, and any other alternative(s) or options you would like to suggest. This could include alternatives or options about changes in scope for specific potential requirements, or all potential requirements, and also the alternative of no new regulation at all.

Are there any elements of the regulatory framework that you believe would not be effective or useful in your work setting and thus represent potential requirements that OSHA should not adopt? Which elements and why?

### **Estimates of Current Compliance**

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The following table presents OSHA’s preliminary estimates of current compliance with selected provisions of the regulatory framework. These estimates represent OSHA’s initial estimate of the percent of affected establishments that are currently complying with the listed provisions. In this table, “other occupational settings” includes morgues, mortuaries and death care services, waste collection and handling, and laundry. The estimates in this table are derived from a Draft Report on the Expert Elicitation on Infectious Disease Control in Healthcare and Other Settings (hereafter “Draft Report”), conducted by OSHA’s contractor, Eastern Research Group, Inc. (ERG), in 2013.

ERG prepared the Draft Report by eliciting opinions from a panel of experts on infection control about the levels of current compliance with many of the provisions outlined in the regulatory framework. While the Draft Report has assisted OSHA in establishing preliminary estimates of current compliance, the Agency is still reviewing these estimates and is interested in any feedback the SERs may have on the levels of current compliance presented here.

More information on these estimates is available in the Section VI of the SER background document, Description of Potential Impacts of a Rule as Outlined in the Regulatory Framework,

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and a more extensive table (Table VI-10) can be found at the end of that section (pp. 110-112). The full Draft Report is available online under docket number OSHA-2010-0003.

<b>Preliminary Estimates of Current Compliance with Selected Provisions of the Regulatory Framework on Infectious Diseases</b>								
Regulatory Framework Provision	Physicians'		Dentists'		Other		Other	
	Hospitals	Offices	Offices	Ambulatory	Long Term	Home	Laboratories	Occupational
				Care Settings	Care &	Healthcare		Settings
					Nursing Homes	Agencies		
Written infection control plan (WICP)	94%	42%	54%	49%	90%	62%	90%	39%
Annual WICP review	77%	16%	18%	34%	63%	49%	70%	12%
Infectious agent hazard evaluation	81%	51%	28%	56%	79%	43%	62%	20%
Hand hygiene	58%	51%	66%	57%	56%	63%	80%	34%
Engineering controls - AIIR maintained	83%	--	--	--	--	--	--	--
Engineering controls - BSCs certified at least annually	91%	--	--	--	--	--	94%	--
Engineering controls - Autopsy suites maintained	83%	--	--	--	--	--	--	58%
Personal protective equipment	76%	46%	76%	54%	56%	58%	86%	35%
Respirators	64%	29%	38%	33%	51%	57%	85%	26%
Decontamination	71%	35%	51%	34%	47%	44%	71%	25%
Exposure incidents	82%	34%	30%	47%	64%	49%	85%	29%
Vaccinations	85%	33%	30%	37%	42%	42%	72%	29%
Medical screening (physical and/or questionnaire)	70%	19%	13%	16%	51%	46%	47%	10%
Post-exposure prophylaxis (PEP)	91%	48%	44%	62%	68%	66%	86%	32%
Post-exposure testing	88%	44%	45%	58%	68%	64%	86%	34%
Restrict worker's normal duties and/or assign alternative job duties when required	77%	44%	45%	49%	60%	46%	66%	23%
Direct the worker not to come to work when required	59%	29%	35%	30%	48%	50%	49%	27%
Initial training	84%	25%	33%	41%	72%	68%	87%	23%
Annual refresher training	75%	18%	16%	24%	54%	50%	79%	14%

Source: ERG, 2013.

Are the Agency's preliminary estimates of current compliance consistent with what you have observed in your own industry? Please elaborate as specifically as possible.

### Additional Questions

What additional actions, if any, do you believe your facility would need to undertake to comply with the potential requirements in the regulatory framework?

Are you aware of an increase or decrease in the prevalence of antibiotic resistant organisms (AROs) in your workplace? If there has been an increase, has your facility modified its infection control measures in any way and, if so, what measures were taken? Which measures reduced the prevalence of AROs? If there has been a decrease in the prevalence of AROs, what did your facility do?

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Are there any specific provisions that you believe are unclear that OSHA should clarify or eliminate?

Are there areas where greater specification would be useful (i.e., for certain types of facilities or for certain provisions)?

Are the unit costs that are discussed in this issues document or in the cost section of the SER Background Document reasonable?

Are there types of costs, actions, or items that the Agency is either over- or under-estimating, or that the Agency has failed to consider at all?

Are the Agency's preliminary estimates of the actions that an employer would be required to undertake to comply with individual provisions in the regulatory framework consistent with your understanding?

Are there any potential provisions for which OSHA has presented cost estimates that the SERs believe would not require employers to undertake additional actions or incur additional costs, over and above current practice?