U.S. Department of Labor

Infectious Diseases SER Background Document

OSHA

Section I. Introduction

OSHA may propose a new occupational safety and health rule on occupational exposure to infectious diseases that would cover exposures not already addressed by the Bloodborne Pathogens standard (29 CFR 1910.1030). In 2005, the American Federation of State, County & Municipal Employees (AFSCME) petitioned OSHA for a rule addressing pandemic influenza. And in 2009, AFSCME petitioned OSHA for a rule addressing occupational exposure to infectious diseases. In response to these requests, OSHA published a variety of guidance materials addressing pandemic influenza and is now considering the need for a standard addressing the broader issue of occupational exposure to infectious diseases. OSHA has developed a regulatory framework for an infectious diseases rule that demonstrates OSHA's current thinking on the elements that such a proposed rule would contain.

OSHA's regulatory framework would cover occupational exposure to contact, droplet and airborne transmissible infectious agents during the provision of direct patient care. The ID rule would also cover occupational exposure to contact, droplet and airborne transmissible infectious agents during the performance of other covered tasks when those tasks are performed in settings where direct patient care is provided or in the following three settings where contaminated materials are handled: (1) settings where the contaminated materials originate from settings where direct patient care is provided; (2) settings where employees are working with human remains; and (3) diagnostic, research, and production laboratory facilities. (Section V provides tables showing the affected industry sectors in detail.)

The regulatory framework would cover workplaces and tasks for which enhanced infection control measures (e.g., the Center for Disease Control and Prevention's (CDC's) standard and transmission based precautions) are recommended to protect workers. OSHA would not cover workers who have exposure to infectious diseases that can be adequately addressed by common public health measures (e.g., cough/sneeze etiquette and hand hygiene); this would include those who perform retail work and teachers and other non-medical school professionals. Any rule OSHA proposes would emphasize effective and consistent infection control practices with the goal of preventing transmission of infectious diseases to workers covered by the rule. OSHA believes that a rule as outlined in the regulatory framework would not only have the direct benefit of reducing occupational illness rates for covered workers, but also have the ancillary benefit of reducing illness rates for patients and other individuals, such as family members, who come into contact with covered workers.

It is widely recognized by experts in the field of occupational safety and health that a well-structured infection control program should include: (1) identification and isolation of infectious cases; (2) immunizations for vaccine-preventable diseases; (3) standard and transmission-based

precautions; (4) training; (5) personal protective equipment; (6) management of healthcare workers' risks of exposure to infected persons, including post-exposure prophylaxis; and (7) work restrictions for exposed or infected healthcare personnel (Siegel et al., 2007). The prevention strategies listed above are set forth in guidelines, such as those of the Healthcare Infection Control Practices Advisory Committee (HICPAC), a federal advisory committee that provides advice and guidance to the CDC and to the Secretary of the Department of Health and Human Services (HHS).

CDC/HICPAC's *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* (Siegel et al., 2007) (2007 CDC/HICPAC guidelines) were an update of the 1996 version of these guidelines (Garner et al., 1996). CDC updated the guidelines because of a number of developments in the healthcare industry. As stated in the executive summary of the 2007 CDC/HICPAC guidelines:

> The transition of healthcare delivery from primarily acute care hospitals to other healthcare settings (e.g., home care, ambulatory care, free-standing specialty care sites, long-term care) created a need for recommendations that can be applied in all healthcare settings using common principles of infection control practice, yet can be modified to reflect setting-specific needs. Accordingly, the revised guideline addresses the spectrum of healthcare delivery settings.

Further, as stated in the 2007 CDC/HICPAC guidelines, the objectives of these guidelines are to:

> 1) provide infection control recommendations for all components of the healthcare delivery system, including hospitals, long-term care facilities, ambulatory care, home care and hospice; 2) reaffirm Standard Precautions as the foundation for preventing transmission during patient care in all healthcare settings; 3) reaffirm the importance of implementing Transmission-Based Precautions . . .; and 4) provide epidemiologically sound and, whenever possible, evidence-based recommendations.

In the United States, the CDC is recognized by the healthcare industry as the source for information on current recommendations for infection control practices in all healthcare settings, and the 2007 CDC/HICPAC guidelines contain the core recommendations central to controlling the transmission of infectious diseases. These guidelines have been endorsed by professional associations such as the Association for Professionals in Infection Control and Epidemiology (APIC) (Smith et al., 2008), the Society for Healthcare Epidemiology of America (SHEA) (Smith et al., 2008), and the Association of Operative Registered Nurses (AORN) (Tarrac, 2008).

The field of infection control is evolving as more improved methods are developed to protect patients and workers from exposure to infectious agents, and as more is learned about the transmission of specific infectious diseases. CDC therefore publishes and updates infection control guidelines both for specific healthcare settings, such as outpatient settings (CDC, 2011e;

CDC, 2011f), and for specific diseases, such as noroviruses (CDC, 2011g), as necessary to address current concerns in infection control. However, CDC bases all of these guidelines on the 2007 CDC/HICPAC guidelines, which provide the core standard and transmission-based recommended precautions to protect patients and workers from exposure to infectious agents.

Some tasks defined as other covered tasks in the regulatory framework do not fall within the scope of CDC's infection control guidelines; these tasks are largely those conducted by workers in diagnostic, research, and production laboratory facilities and those conducted by workers involved in death care. The National Institutes of Health (NIH) independently, and in collaboration with CDC, provides recommendations for protecting workers in laboratory facilities from exposure to infectious agents (CDC/NIH, 2009, NIH, 2013). Individual states have infection control requirements that apply to death care workers (see, for example, Florida Department of State, 2000, 2004).

An ID rule would require covered employers to take these kinds of guidelines into consideration in developing and implementing their own infection control programs. However, a rule would not cover occupational exposure to bloodborne diseases, which is already covered by OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030). Also, while infectious diseases can be transmitted via contaminated food and water, or vectors such as rats and insects, these types of transmissions would not be covered by the rule, as OSHA does not believe that they constitute a significant route of occupational exposure for workers engaged in direct patient care and other covered tasks.

As an initial rulemaking step, and prior to the publication of a proposed rule, OSHA is convening a Small Business Advocacy Review Panel (SBAR Panel) in accordance with the Regulatory Flexibility Act, or RFA (Sections 601 through 612 of Title 5 of the United States Code). This Panel consists of members from OSHA, the Small Business Administration Office of Advocacy (SBA's Office of Advocacy, or Advocacy), and the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). The SBAR Panel identifies individuals representative of affected small entities, termed Small Entity Representatives (SERs). This process enables OSHA, with the assistance of Advocacy and OIRA, to obtain advice and recommendations from SERs about the potential impacts of a rule as outlined in the regulatory framework and about alternatives to the regulatory framework that may alleviate those impacts while meeting the objectives of the OSH Act.

The SBAR Panel has several purposes under the RFA, which establishes the requirements for a Panel. First the Panel provides an opportunity early in the rulemaking process for affected small employers and SBA's Office of Advocacy to provide comment to OSHA. Second, by reviewing the provisions of the regulatory framework, estimates of the potential impacts of a rule as outlined in the regulatory framework, and alternatives to the regulatory framework, SERs and the Panel can offer recommendations to OSHA on ways to tailor rules to make them more cost effective and less burdensome for affected small employers. Third, early comment permits

identification of different regulatory alternatives the Agency might consider. Finally, the Panel, in its SBAR Panel report, can provide specific recommendations for the Agency to consider on issues such as reporting requirements, timetables of compliance, "performance" rather than "design" (or specification) standards, and whether some groups, including small employers, would be exempt from all or part of the rule.

Following the SBAR Panel, OSHA's next step, if the rulemaking process is continued, would be to publish a proposed rule in the *Federal Register*. The Preamble to the proposed rule would include an Initial Regulatory Flexibility Analysis (IRFA) to accompany the proposal in order to focus attention on the potential impacts on small businesses. The IRFA would include a description of the Panel's recommendations and OSHA's responses to those recommendations. Sections 603(b) and (c) of the RFA set out the requirements for the IRFA:

> (b)(1) a description of the reasons why action by the Agency is being considered;
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> (b)(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
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> (b)(3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
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> (b)(4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;
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> (b)(5) an identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule; and
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> (c) a description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the proposed rule on small entities.

An alternative under Section 603(c) need not be unique to small entities. Rather, an alternative that meets OSHA's goals and reduces impacts for all affected entities can, and should, be considered as part of the Panel and regulatory flexibility analysis process.

OSHA is conducting this SBAR Panel early in the regulatory process in the interest of assuring that the Panel's report and recommendations can be fully considered in any subsequent rulemaking activities by the Agency. OSHA has not yet estimated the aggregate benefits and costs of a rule addressing occupational exposure to infectious diseases because the Agency is still conducting ongoing work that is necessary for such estimates. A contractor, hired by OSHA, has elicited the opinions of a group of infection control experts regarding current levels of compliance with recommended, non-mandatory infection control practices. Additionally, the contractor is developing a model to estimate the reduction in illnesses and fatalities potentially

attributable to a rule addressing occupational exposure to infectious diseases. OSHA and the contractor are also conducting additional research, including the gathering of additional data on the potential costs of such a rule and on the risk associated with exposure to infectious diseases. Thus, OSHA expects to expand its data sources, update its data, and conduct more extensive research on the costs, benefits, and impacts of such a rule from sources that are independent of the SBAR Panel process.

Under Section 609(b) of the RFA, the SBAR Panel must be provided any information that OSHA has available on issues related to paragraphs (3), (4), and (5) of Section 603(b), as well as Section 603(c), of the RFA. The SBAR Panel collects comments on these issues.

Consistent with these requirements, this document, the Small Entity Representative Background Document (the SER Background Document), provides such information to the individual SERs who have agreed to participate in this SBAR Review. The SER Background Document also satisfies the RFA's legal requirement that OSHA provide certain information to the Chief Counsel for Advocacy. OSHA has placed all references in this document in the public docket, OSHA-2010-0003, and will be happy to help SERs obtain any references they would like to see.[1]

The SER Background Document has been prepared to facilitate the SBAR Panel process. In addition to this introductory section, the SER Background Document contains the following sections:

- **Section II (pp. 7-8)** describes the legal requirements OSHA must meet if it engages in rulemaking;
- **Section III (pp. 9-26)** explains the reasons why action is being considered by OSHA;
- **Section IV (pp. 27-50)** summarizes and explains the important provisions of OSHA's regulatory framework;
- **Section V (pp. 51-58)** identifies the types of small entities that would likely be affected by a rule as outlined in the regulatory framework;
- **Section VI (pp. 59-112)** provides information on the potential impacts of a rule as outlined in the regulatory framework;
- **Section VII (pp. 113-118)** describes potentially duplicative or conflicting rules; and
- **Section VIII (pp. 119-134)** presents, for consideration by the SERs and the Panel, alternatives and/or options to the scope of, and provisions in, the regulatory framework.

Some of the most valuable contributions SERs make in the SBAR Panel process are their comments on the alternatives and/or options presented and their suggestions for other possible alternatives.

[1]All non-copyrighted references will be available online at regulations.gov in the docket for this potential rulemaking. Copyrighted materials are available for inspection through OSHA's docket office.

Appendix A contains the SBA definitions of small entities for all affected industries at the six-digit NAICS level. Appendix B contains a list of some of the relevant published infection control guidelines/regulations that are relevant to the regulatory framework.

Section II. Legal Basis for an OSHA Standard Addressing Occupational Exposure to Infectious Diseases

The Secretary of Labor promulgates and enforces occupational safety and health standards under authority granted by the Occupational Safety and Health Act of 1970 (the OSH Act).[2] OSHA must promulgate its standards by following specific procedures set forth in the OSH Act.[3]

Section 3(8) of the OSH Act defines an "occupational safety and health standard" as "a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment."[4] This definition has been interpreted to require the Agency to make a threshold showing of "significant risk" before it can promulgate a safety or health standard.[5] The Agency has discretion to "determine, in the first instance, what it considers to be a 'significant' risk," and in making this determination, the appropriate question is whether "a reasonable person might . . . consider the risk significant and take appropriate steps to decrease or eliminate it."[6] As such, the risk requirement is "not a mathematical straitjacket" and OSHA "has no duty to calculate the exact probability of harm."[7] Courts recognize that a determination of what constitutes significant risk will be "based largely on policy considerations."[8] The Agency "is not required to support its finding that a significant risk exists with anything approaching scientific certainty[,]" and "is free to use conservative assumptions" and "risk[] error on the side of overprotection rather than under protection."[9] It is sufficient for the Agency to make a general finding of significant risk; the Agency is not required to assess relative risk or disaggregate its significant risk analyses by hazard, workplace, or industry.[10]

OSHA standards must be both technologically and economically feasible.[11] The Supreme Court has defined feasibility as "capable of being done."[12] OSHA demonstrates that a standard is

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[2] 29 U.S.C. 651 *et seq*.
[3] 29 U.S.C. 655.
[4] 29 U.S.C. 652(8).
[5] *Indus. Union Dep't, AFL-CIO v Inst.* ("*Benzene*"), 448 U.S. 607 (1980) (plurality opinion).
[6] *Id*. at 655.
[7] *Id*.
[8] *Id.* at 655 n.62.
[9] *Id.* at 656; see also, for example, *Public Citizen Health Research Group v. Tyson* ("*Ethylene Oxide"*), 796 F.2d 1479, 1486 (D.C. Cir. 1986).
[10] See, for example, *UAW v. OSHA ("Lockout/Tagout II")*, 37 F.3d 665, 670 (D.C. Cir. 1994) (upholding OSHA's decision not to conduct individual significant risk analyses for various affected industries); *American Dental Ass'n v. Martin*, 984 F.2d 823, 827 (7th Cir. 1993) (OSHA is not required to evaluate risk "workplace by workplace"); *Associated Builders & Contractors, Inc. v. OSHA*, 862 F.2d 63, 68 (3d Cir. 1988) (noting that "the significant risk requirement must of necessity be satisfied by a general finding concerning all potentially covered industries"); *Ethylene Oxide*, 796 F.2d at 1502 n. 16 (rejecting the argument that the Secretary must find that each and every aspect of its standard eliminates a significant risk).
[11] *United Steelworkers v. Marshall* ("*Lead I*"), 647 F.2d 1189, 1264 (D.C. Cir. 1980).
[12] *Am. Textile Mfrs. Inst. v. Donovan* ("*Cotton Dust*"), 452 U.S. 490, 508-09 (1981).

technologically feasible "by pointing to technology that is either already in use or has been conceived and is reasonably capable of experimental refinement and distribution within the standard's deadlines."[13] In determining the economic feasibility of a standard, OSHA must consider the cost of compliance on an industry, rather than on individual employers. The "practical question" in an economic feasibility analysis "is whether the standard threatens the competitive stability of an industry . . . or whether any intra-industry or inter-industry discrimination in the standard might wreck such stability or lead to undue concentration."[14]

Section 6(b)(5) of the Act provides that, in promulgating a standard dealing with toxic materials or harmful physical agents, the Agency must "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity."[15] Thus, the OSH Act does not call for OSHA to use benefit-cost analysis as a basis for rulemaking.[16] Instead, OSHA must reduce significant risk to the extent technologically and economically feasible without regard to a balancing of costs and benefits.

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[13]*American Iron and Steel Inst. v. OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991) (*per curiam*) (internal citation omitted).
[14]*Lead I*, 647 F.2d at 1265.
[15]29 U.S.C. 655(b)(5).
[16]*Cotton Dust*, 452 U.S. at 509.

Section III. Reasons Why Action by the Agency is Being Considered

Infectious agents cause both healthcare-associated infections (HAIs) and occupationally-acquired infections in healthcare workers (HCWs). HAIs are recognized as a serious and costly problem in the U.S. healthcare system. According to the CDC, there are 1.7 million HAIs leading to approximately 99,000 patient deaths and $20 billion in additional healthcare costs in the U.S. system each year (CDC, 2013a). Preventing the spread of infectious diseases in healthcare and related settings benefits workers, as well as patients, given that there is a well-recognized link between patient safety and healthcare worker safety and that integration of patient and worker safety initiatives has been shown to improve both patient outcomes and worker protection (TJC, 2012).

OSHA does not have a standard that addresses occupational exposure to infectious agents transmitted by contact, droplet and airborne routes. OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) only covers infectious agents transmitted by the bloodborne route. Precautions used for bloodborne pathogens (termed universal precautions[17]) are not sufficient to protect people from infectious agents transmitted by the contact, droplet, and airborne routes. The Agency has been, and continues to be, concerned about occupational exposure to infectious diseases not addressed by the Agency's Bloodborne Pathogens standard. OSHA documented occupational exposure to, and infection with, *Mycobacterium tuberculosis* (TB) in its notice of proposed rulemaking entitled, "Occupational Exposure to Tuberculosis; Proposed Rule" (62 FR 54160, October 17, 1997). Though OSHA has not promulgated a final rule on TB, the Agency did issue a compliance directive addressing occupational exposure to TB. OSHA remains concerned about occupational exposure to TB, as well as numerous other infectious diseases, multidrug-resistant and totally drug-resistant infectious agents, and new and emerging infectious diseases (e.g., severe acute respiratory syndrome (SARS), 2009 H1N1 pandemic influenza, Middle East Respiratory Syndrome (MERS), and H7N9 avian influenza).

Infectious agents pose a unique hazard because, unlike chemical hazards: 1) Each infectious agent replicates within infected individuals; and 2) Infected individuals can transmit the agent to other individuals, who can then transmit it to additional people and so on, with exponential spread of the disease possible from expanding rounds of transmission. SARS, for example, spread from China to numerous other countries in a matter of months, ending with more than 8,000 infections and approximately 800 deaths (World Health Organization (WHO), 2004a).

On May 6, 2010, OSHA published a request for information (RFI) on infectious diseases in health care, laboratory, and other associated work settings, and in July 2011, the Agency held

[17]"Standard Precautions" is now the term generally used by the healthcare community and encompasses universal precautions with a few additional elements.

two stakeholder meetings to further discuss the issue.[18] Stakeholder comments in response to the RFI and a subsequent review of the literature (some of which is discussed in this section of the SER Background Document) indicate that workers providing direct patient care and performing other covered tasks (as those terms are defined in the regulatory framework) are at risk of harm from occupational exposure to infectious agents, and that implementing recognized and generally accepted good infection control practices reduces the risk of transmission of infectious agents to these workers.

OSHA does not have data on the exact number of occupationally-acquired infectious diseases in the United States and other developed countries because there are no centralized surveillance systems that specifically document all occupationally-acquired infectious diseases. This type of data also suffers from underreporting. For example, in the U.S., Singh (2011) and Sewell (1995) noted that underreporting of laboratory-associated infections is widely recognized and is in large part due to a lack of a systematic reporting system at the state, federal, or professional-society level that monitors these incidents. In another example, Harding & Byers (2006) state that "our ability to accurately quantify laboratory-associated infections (LAIs) is hampered by an indifference to and, frequently, an unwillingness to report these incidents". Despite this recognized underreporting, these authors determined from the literature on LAIs in a number of countries, that1,448 symptomatic LAIs, along with 36 deaths and 17 secondary infections had been documented over the 26-year period from 1979-2004. In an additional example from the Netherlands and the United Kingdom, Haagsma et al. (2012) state that "only a small number of work-related infectious diseases are reported to the designated registration systems." This is consistent with a review by Azaroff et al. (2002), where the authors state that documentation of the incidence of work-related injuries, illnesses, and fatalities in diverse workplaces is "fragmentary, unreliable, and inconsistent." The authors conclude that the actual incidence of work-related injuries, illnesses, and fatalities is underestimated by as much as several hundred percent. There are a number of reasons for underreporting, including: difficulty attributing illnesses to workplace contact; workers continuing to report to work despite being ill; workplace incentives to keep reported illness and injury numbers low; workers utilizing their private insurance for treatment over workers' compensation or employee health centers; and workers' fear of losing their jobs as a consequence of reporting exposures to their superiors.

Illness data reported by the Bureau of Labor Statistics (BLS) is likely subject to these under-reporting issues. For example, there were only 420 influenza cases, and only about 2,000 cases of workplace-related infectious and parasitic diseases, reported in the BLS Occupational Injuries and Illnesses and Fatal Injuries Profiles in 2012 (BLS, 2012).[19] Given the millions of cases of

[18]The public comments on the RFI and a summary of the stakeholder meetings can be accessed at www.regulations.gov (Docket# OSHA-2010-0003 is available at: http://www.regulations.gov/#!docketDetail;D=OSHA-2010-0003).

[19] In the BLS classification system, cases of influenza and cases of workplace-related infectious and parasitic diseases are grouped separately.

influenza that occur yearly in the U.S., it is very unlikely that only 420 cases would have been occupationally acquired in 2012. At the beginning of the 2009 H1N1 influenza pandemic, for example, CDC reported that 50 percent of the initial cases (13 of 26) identified in healthcare workers were deemed to have been acquired in a healthcare setting (CDC, 2009).

BLS recognizes that occupationally-acquired illnesses are underreported. According to BLS, the Statistics of Occupational Illnesses and Injuries (SOII) Survey measures the "number of new work-related illness cases that are recognized, diagnosed, and reported during the year" (BLS, 2007). However, "[i]n contrast [to] the overwhelming majority of the reported new illnesses," which are "easier to directly relate to workplace activity (for example, contact dermatitis or carpal tunnel syndrome)," there are "[s]ome conditions…[that] are difficult to relate to the workplace and are not adequately recognized and reported" (Id.).

As noted above, the United States does not have a surveillance system to document occupational exposure to infectious diseases. The limited surveillance information that is available on occupational exposure to infectious diseases among HCWs is mostly related to HCWs in hospitals. Some data exists from the National Surveillance System for Healthcare Workers (NaSH), which was a voluntary surveillance system developed by CDC to systematically collect information important to the prevention of occupational exposures and infections among HCWs. The NaSH consisted of data collection modules for monitoring and managing immunization and tuberculin skin-testing programs, and recording exposures to blood and body fluids, vaccine-preventable diseases, and tuberculosis. The only module that received even modest participation by hospitals was the module for recording exposures to blood and body fluids. Participation in this module grew from five hospitals in 1995 to 64 facilities in 2000, but decreased to 18 in 2007. The number of occupational exposures ranged from a low of 378 exposures in five hospitals in 1995 to a high of 4,334 occupational exposures in 64 hospitals in 2000. A tiny fraction of the total number of hospitals in the U.S. participated, and those that participated were mainly large, teaching hospitals in urban settings (CDC, 2011h).

Data on worker exposures and infections in non-hospital settings include surveys of employees, employers and/or public health agencies and information collected in outbreak investigations. For example, a survey of home healthcare providers found that 5.9 percent of workers had received treatment for lab-confirmed healthcare-associated bacterial infections (most commonly Methicillin-resistant *Staphylococcus aureus* (MRSA) or *Clostridium difficile*) and nearly 60 percent of the providers reported that their healthcare establishment did not have a written policy that covered infection control procedures recommended for dealing with antibiotic-resistant infections (Kenneley, 2012).

There are also numerous peer-reviewed journal articles that document occupationally-acquired illnesses and outbreaks in healthcare and related settings. Based on that evidence (discussed below), OSHA believes that the cases of occupationally-acquired illnesses reported in the SOII,

to OSHA, or through the workers' compensation system, seriously underestimate the true number of workplace-acquired illnesses resulting from contact with infectious agents.

OSHA is evaluating a large number of peer-reviewed journal articles relating to occupational exposure to infectious agents. The evidence thus far examined shows that there is a sustained prevalence of work-related infectious diseases in healthcare, laboratory, and associated work settings. These infectious diseases are caused by agents that are transmissible to humans by different routes, including the contact, droplet and airborne routes. A myriad of studies continues to document illnesses in HCWs resulting from occupational exposure to infectious agents. Some examples of the Agency's findings of peer-reviewed manuscripts on this topic are listed below.[20]

- Norovirus[21] – Primary transmission route is contact: In 2003, eighty-four workers in a long-term care facility contracted norovirus during an outbreak in Pennsylvania (Wu et al., 2005). More recently, a norovirus outbreak affected ninety patients and 265 HCWs in a hospital, with cases clustered in the coronary care and psychiatry units. Thirteen affected HCWs required emergency department visits or hospitalization (Johnston et al., 2007).
- Adenovirus infections[22] – Primary transmission route is droplet: In 2007, eight workers in an intensive care unit (ICU) in Texas were infected with adenovirus after caring for a patient suffering from the disease (Yun & Prakash, 2008). Similarly, from April through June 2007, fifteen health care trainees at one military hospital in Texas were hospitalized for pneumonia due to adenovirus that appeared to be occupationally-acquired (Lessa et al., 2009).
- Mumps[23] – Primary transmission route is droplet: In April through May 2006, seven workers at a tertiary care hospital contracted mumps during an outbreak in the facility. This outbreak led to fifty-nine employees missing a total of 282 work days (an average of 4.8 days per worker) due to having contracted mumps, being non-immune, or awaiting symptom evaluation or laboratory test results (Bonebrake et al., 2010).
- Pertussis[24] – Primary transmission route is droplet: A three-month pertussis outbreak in a community hospital in 1999 resulted in twelve of fifty-three HCWs in the surgical unit being infected with pertussis (Pascual et al., 2006). In 2003, ten HCWs at a Hematology-Oncology care unit in New Hampshire were infected with pertussis (Boulay et al., 2006) and eight workers at two different hospitals in Washington state contracted pertussis in 2004 (Baggett et al., 2007).

[20]Although many infectious agents can be transmitted via more than a single route, only the primary transmission route is listed.
[21]Gastroenteritis can be caused by norovirus.
[22]A number of diseases, including gastroenteritis, conjunctivitis, and pneumonia, can be caused by adenoviruses.
[23]Mumps is caused by a Rubulavirus.
[24]Pertussis (whooping cough) is caused by the bacterium *Bordetella pertussis*.

- Tuberculosis (TB) – Primary transmission route is airborne: A 2011 report on exposure to TB at a medical center in Arizona concluded that 18 employees had a newly positive TB skin test and one employee was diagnosed with active TB (de Perio & Niemeier, 2012). In a TB outbreak case in Nevada, a woman and her recently-delivered twins died from TB, and 61 people who had contact with the woman and/or her twins tested positive for TB infections (2 active, 59 latent). Of the active cases, 1 (50 percent) was a HCW. Of the latent cases, 21/59 (36 percent) were HCWs (Southern Nevada Health District, 2013). In a latent TB infection, the person is infected, but not symptomatic, and may or may not go on to have an active infection. If a person with latent TB infection gets appropriate treatment, however, it is much less likely the person will progress to an active TB infection. The high incidence of multi-drug resistant strains of TB amplifies the concern. A recent antibiotic resistance threat report by CDC classifies drug-resistant TB as a "serious" health threat in the United States (CDC, 2013b).

The peer-reviewed literature also suggests that HCWs are especially susceptible to exposures during the early stages of the emergence of novel infectious agents or novel strains of known infectious agents. Workers in laboratories that are tasked with the identification of the infectious agent causing the outbreak are similarly susceptible to exposures. In these cases, it is very likely that both the HCWs and laboratory workers that become infected with these novel agents have been occupationally-exposed rather than exposed in the community. Examples of such outbreaks are listed below.

- Severe Acute Respiratory Syndrome (SARS)[25] – Primary transmission route is droplet: Occupational exposure to SARS at a hospital in Toronto, Canada resulted in 42.5 percent of the HCWs who were exposed while performing their job duties becoming infected with the SARS virus (Ofner-Agostini et al., 2008). As of the end of 2003, the World Health Organization (WHO) reported that, of the 8,096 SARS cases reported worldwide, 21 percent occurred in HCWs (WHO, 2004a). Since the end of the SARS pandemic, the majority of reported SARS-CoV infections have occurred in laboratory workers, or individuals who had close contact with infected laboratory workers (WHO, 2003; WHO, 2004b; WHO, 2004c). At least thirteen individuals (six laboratory workers and seven individuals who had contact with those workers) contracted laboratory-associated SARS-CoV infections after WHO declared the end of the SARS pandemic (Liang et al., 2004).
- H1N1 pandemic influenza[26] – Primary transmission route is droplet: Near the beginning of the 2009 H1N1 pandemic, state health departments reported forty-eight cases of confirmed or probable cases of H1N1 infection in HCWs (CDC, 2009). Early in the

[25]Severe Acute Respiratory Syndrome is caused by the SARS coronavirus. As an emerging disease for which the transmission route(s) was unknown, airborne precautions were initially used to handle SARS.
[26]Influenza (flu) is caused by influenza A and B viruses. The 2009 strain of the influenza A H1N1 subtype caused the last influenza pandemic. Pandemic influenza refers to a worldwide epidemic caused by a new strain of influenza for which humans have little immunity and that, therefore, can spread quickly from human-to-human.

pandemic it was easier to identify the cases that were occupationally-related because there were not yet many cases in the community. Of the 26 cases where the source of infection could be identified, CDC determined that 13 (50 percent) of the cases were occupationally-acquired.

- Middle Eastern Respiratory Syndrome (MERS)[27] – Primary transmission route is not yet identified: WHO estimated that more than 25 percent (109/402) of individuals infected with MERS over a two-month period (April 11 – June 9, 2014) were HCWs (WHO, 2014a). Although MERS does not appear to be readily transmitted from person-to-person, many of the cases among both patients and HCWs have been acquired in healthcare settings (Zumla and Hui, 2014). The two MERS cases that have occurred in the United States as of May 2014 were HCWs who were infected in other countries and subsequently traveled into and around the United States while symptomatic. MERS testing done by Indiana and Florida Public Health Departments determined that 53 HCWs (Indiana) and 23 HCWs (Florida) who were exposed to the two infectious patients prior to implementation of isolation precautions were negative for MERS (CDC, 2014a; NBC, 2014a).
- Ebola – Primary transmission is through direct contact with a sick person's blood or body fluids or materials that have been contaminated with Ebola virus. WHO warns in an August 11, 2014 statement that "Ebola virus disease in West Africa continues to evolve in alarming ways, with no immediate end in sight," noting that 170 HCWs have been infected so far, with 80 of those HCWs dying (WHO, 2014b). Two HCWs from the U.S. who were infected in West Africa were transported back to the U.S. and were treated under high containment conditions and released (NBC, 2014b). Of high concern are people who do not know they are infected traveling into other countries via air travel. CDC has recently stated that it is possible that infectious diseases such as Ebola will spread to the U.S. due to the nature of global airline travel (Frieden, 2014) and outlines how U.S. hospitals should prepare for possible Ebola cases including the stringent precautions that should be used for suspected cases (Medscape.com, 2014).

While the patients who are the most ill with infectious diseases are most likely being treated in hospitals, there are several reasons why HCWs in ambulatory care settings are at particular risk of exposure to infectious diseases:

- Many patients with infectious diseases are treated in ambulatory care settings during the early stages of the disease while they are asymptomatic or have mild symptoms. Depending on the infectious agent's incubation period (i.e., the time between intitial infection and the first expression of symptoms) as well as the severity of the illness, people can be contagious for days, weeks or even longer without knowing that they have an infection that can be transmitted to others.

[27] MERS is caused by a coronavirus that is distinct from the coronavirus that caused the SARS outbreak.

- Primary care doctors and those in other ambulatory settings routinely see patients who may be colonized with infectious agents such as MRSA and Streptococcus. Although these colonized patients are not necessarily infected with the agent, the agent can be transmited to providers. The providers may then become colonized or infected.
- An increasing number of patients who are ill and symptomatic with an infectious disease are getting initial treatment at clinics that have urgent care or immediate care services, rather than being treated at hospital emergency rooms.
- Many patients with "childhood" illnesses such as measles, mumps and pertussis are being treated at clinics, not hospitals, unless they have severe cases. Currently, outbreaks of measles, mumps and pertussis are occurring in various countries, including the U.S.

While information on occupational exposures and infections in HCWs in ambulatory care settings is limited, data from outbreak investigations show that HCWs in these settings are exposed to infectious diseases. Examples of occupational exposure to infectious agents and HCW infections in ambulatory care settings include:

- Soft tissue and skin infections (SSTIs) – A study of skin infections treated in U.S. physicians' offices between 1993 and 2005 estimates that there were 6.3 million SSTIs, including those caused by MRSA, diagnosed annually during this time period (Pallin et al., 2014). Occupationally-acquired MRSA infections have been documented at ambulatory care settings including oncology, dental, and pediatric clinics, with a HCW fatality from MRSA at one pediatric clinic (Carpenter et al., 2008; Kassis et al., 2011; Roberts et al., 2011).
- Norovirus gastroenteritis – Based upon information obtained from insurance claim databases, a modeling study estimated that over an eight year period from 2001-2009, norovirus contributed to approximately 400,000 Emergency Department visits and 1.7 million office visits annually. This study concluded that norovirus is a substantial cause of gastroenteritis-related visits to ambulatory care facilities. (Gastanaduy, et al., 2013).
- Epidemic keratoconjunctivitis (EKV) – Outbreaks of highly contagious adenovirus eye infections in a neonatal intensive care unit (NICU) and twelve outpatient clinics in four states were reported to CDC during 2008-2010. Of the 212 cases that were associated with the outpatient clinics, 10 were HCWs. (CDC, 2013).
- TB – In a dental clinic in Washington state, a dental hygienist developed active TB and worked for several months while infectious, likely transmitting TB to a coworker and possibly also to several patients (Merte et al., 2014).
- Pertussis –A study of pediatric HCW exposure to and infection with pertussis showed that 1,193 confirmed HCW exposures were associated with 219 index cases[28], 7 of which were HCWs. The authors concluded that occupational exposures to pertussis occur frequently in pediatric healthcare settings (Kuncio et al., 2014).

[28] An index case is the first patient that indicates the existence of an outbreak.

Because HCWs are exposed to infectious diseases in a variety of settings, it is important for employers in all such settings to implement infection control practices. Good infection control practices are laid out in a number of non-mandatory guidelines (e.g., CDC/HICPAC guidelines) and are recognized and generally accepted by the industry. But evidence shows that many employers do not consistently adopt or rigorously enforce these guidelines, leaving both workers and patients at risk of contracting infectious diseases. When these practices are consistently and rigorously followed, they have proven effective at preventing the spread of infections. Some case examples are provided in Section C, below. Due to the lack of consistent and rigorous enforcement of current guidelines, certain workers are not adequately protected against the risk of occupational acquisition of infectious diseases, and OSHA believes that covering those workers under a rule as outlined in the regulatory framework would reduce their risk. The Agency believes that effective enforcement would result in more consistent and rigorous adherence to guidelines, and thus safer environments for both workers and patients.

As explained in Section II, Legal Basis for an OSHA Standard Addressing Occupational Exposure to Infectious Diseases, the Agency is required by statute to show that a rule is reasonably necessary and appropriate to provide a safe and healthful workplace. This has been interpreted to require OSHA to make a finding of significant risk before it promulgates a new standard. In evaluating significant risk, the Agency asks whether a reasonable person might regard the risk of harm to be significant and take steps to decrease or eliminate it. OSHA can find significant risk based on reasoning well-accepted by leading public health authorities and supported by the available scientific evidence showing that there is occupational exposure to broad categories of hazardous agents or work conditions that endanger workers in the absence of protections (e.g., Hazardous Chemicals in Laboratory Standard (55 Fed. Reg. 3300, 3302-06 (Jan. 31, 1990)), Hazard Communication Standard (59 Fed. Reg. 6126, 6131-32, 6136-40 (Feb. 9, 1994); 48 Fed. Reg. 53280, 53320-21 (Nov. 25, 1983)), Personal Protective Equipment Standard (59 Fed. Reg. 16334, 16335 (Apr. 6, 1994))). Below is a summary of the evidence showing that: (A) There is a well-recognized risk to workers associated with exposure to infectious agents during the provision of direct patient care and/or performance of other covered tasks; (B) Current infection control guidelines are non-mandatory, are not consistently and rigorously followed, and therefore are not sufficient to adequately reduce the risk of transmission of infectious agents to workers who provide direct patient care and/or perform other covered tasks; and (C) Following recognized and generally accepted good infection control practices considerably reduces the risk of transmission of infectious agents to workers providing direct patient care and/or performing other covered tasks.

OSHA plans to rely in part on study data documenting the occurrence of occupationally-acquired infectious disease among health care workers in work settings where the incidence of disease has been adequately investigated. The Agency is continuing to analyze the available information and

has not yet made any final determinations regarding risk; OSHA is interested in feedback from small entity representatives on the evidence presented below.

(A) There is a well-recognized risk to workers associated with exposure to infectious agents during the provision of direct patient care and/or performance of other covered tasks.

The risk associated with exposure to infectious agents during the provision of direct patient care and performance of other covered tasks has been known and documented for some time. Occupational risks are documented and discussed in guidelines of the CDC's HICPAC, a federal advisory committee that provides advice and guidance to the CDC on the practice of healthcare infection control in U.S. healthcare facilities. CDC/HICPAC's *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* (Siegel et al., 2007) and *Guideline for Infection Control in Health Care Personnel, 1998* (Bolyard et al., 1998) both highlight the risks to workers from exposure to infectious agents In its 1998 guidelines, the CDC/HICPAC wrote that its guidance for mitigating infectious disease risks applied to all workers in healthcare settings who have the "potential for exposure to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air," and that these workers:

> may include but are not limited to emergency medical service personnel, dental personnel, laboratory personnel, autopsy personnel, nurses, nursing assistants, physicians, technicians, therapists, pharmacists, students and trainees, contractual staff not employed by the health care facility, and persons not directly involved in patient care but potentially exposed to infectious agents (e.g., clerical, dietary, housekeeping, maintenance, and volunteer personnel).

The two CDC/HICPAC guidelines support the existence of risks associated with occupational exposure to infectious agents and infectious agent transmission from patient to worker, worker to patient, and worker to worker. The guidelines recommend appropriate precautions to prevent such exposure and transmissions and the resulting diseases. The Joint Commission (TJC), recognizing the link between patient safety and healthcare worker safety, recently issued a 171-page monograph entitled, *Improving Patient and Worker Safety: Opportunities for Synergy, Collaboration and Innovation* (TJC, 2012). TJC's monograph notes that HCWs experience some of the highest rates of nonfatal occupational illness and injury—exceeding even construction and manufacturing industries. The monograph outlines how integration of patient and worker safety initiatives results in both improved patient outcomes and worker protection.

OSHA believes that the 1998 and 2007 CDC/HICPAC guidelines, along with other authoritative guidance documents (e.g., CDC/NIH, 2009), and hundreds of peer-reviewed publications (some of which are cited in this document), demonstrate a well-recognized risk of occupational

exposure to infectious agents for workers providing direct patient care and/or performing other covered tasks.

These workers include physicians, nurses, emergency medical technicians, transport personnel, phlebotomists, and other patient-care staff that routinely have hands-on and face-to-face contact (i.e., direct patient care) with infected patients in facilities such as hospitals, urgent care clinics, physicians' offices (e.g., general practitioners/pediatricians), school infirmaries, and workplace occupational health clinics where sick or injured workers go for treatment (Siegel et al., 2007: section I.D). Healthcare workers are also at risk in less traditional healthcare settings where exposures to infectious agents are likely to occur (Siegel et al., 2007; section I.D.2). These settings include: home care settings where services are provided to patients often too ill to seek treatment outside of the home (Siegel et al., 2007; section I.D.2.c); nursing homes and other extended-care facilities where infections are common due to the long-term care of an elderly infirm population (Siegel et al., 2007; section I.D.2.a); and outpatient surgical, infusion treatment, and dialysis centers where the procedures employed pose increased opportunity for the spread of infectious agents (Siegel et al., 2007; section I.D.2.b). Healthcare workers in these ambulatory care and long-term care facilities are likely to be using invasive devices and equipment, such as catheters, vascular lines, and breathing and feeding tubes, that can facilitate the transmission of infectious disease.

As individuals harboring infectious agents may infect others while they are asymptomatic, the 2007 CDC/HICPAC guidelines express a concern about HCWs being exposed to infectious diseases even when they provide direct patient care to patients not known to be infectious (Siegel et al., 2007: section I.D). These occupational exposures can occur in professions that routinely engage in hands-on and face-to-face contact with patients, such as dentistry, ophthalmology/optometry, physical therapy, podiatry, and radiography. The risk to workers in settings that provide direct patient care may vary depending on frequency, duration and intensity of contact with the infected individuals. For example, a nurse that has frequent, intense contact with infected patients in a hospital or nursing home may be at relatively greater risk of contracting an infectious disease than a dental hygienist or optometrist who likely interacts with fewer infected patients.

In addition to concerns about the risk of occupational exposure to infectious diseases when workers provide direct patient care, the CDC and NIH recognize the risk of occupational exposure to infectious disease in biomedical and research laboratories that handle infectious agents (CDC/NIH, 2009). Likewise, laboratory and animal workers are at risk of occupational exposure to infectious agents in production laboratories that are engaged in the development and testing of vaccines against infectious agents and treatments for infectious diseases. Technicians that collect and process specimens contaminated with infectious agents in a clinical laboratory are also at risk of disease. Workers in death care settings (e.g., medical examiner's offices, morgues, and mortuaries) are routinely exposed to tissues and body parts that may be contaminated with infectious agents. In addition, workers that provide environmental services in

hospitals and long-term health care facilities, such as laundry, housekeeping, and waste handling (i.e. "other covered tasks" under the regulatory framework) may also come in contact with surfaces and other materials contaminated with infectious agents. Finally, workers involved in cleaning, repairing, and maintaining contaminated medical equipment are also at risk of occupational exposure to infectious agents.

The major goal of infection control is to prevent transmission of infectious diseases to patients and HCWs. This fundamental approach is set forth in the CDC/HICPAC guidelines (e.g., Bolyard et al., 1998; Siegel et al., 2007), which are comprehensive guidelines for infection prevention and control that are recognized both nationally and internationally. The guidelines address: the identification and isolation of infectious cases; immunizations for vaccine-preventable diseases; standard and transmission-based precautions; training; personal protective equipment (PPE); the management of HCWs' risk of exposure to infected persons, including post-exposure prophylaxis; and work restrictions for exposed or infected healthcare personnel.

The CDC/HICPAC guidelines for standard and transmission-based precautions are widely recognized by experts in the field of occupational safety and health, generally accepted, often cited as an efficient means to address infectious agent hazards, and directly applicable to the prevention of occupationally-acquired infections. In 2007, the CDC/HICPAC updated and modified its 1996 guidelines (Garner, 1996), in part, to accommodate changes in the healthcare industry, e.g., to specifically target the growing shift of healthcare delivery from primarily acute care hospitals to other diverse healthcare settings, including home care and ambulatory care settings, and to address the need for recommendations that could be applied to all healthcare settings (Siegel et al., 2007). Thus, OSHA has reason to believe that these guidelines are directly applicable, or readily adaptable, to the direct patient care and associated tasks that are addressed in the regulatory framework (also see prior discussion on the applicability of the CDC/HICPAC guidelines).

OSHA believes that the majority of employers that would be subject to a rule as outlined in the regulatory framework are familiar with, and have adopted at some level, infection control programs that are generally consistent with the CDC/HICPAC guidelines.[29] OSHA also finds that a large number of employers with workers performing other covered tasks, as that term is defined in the regulatory framework (for example, maintenance and housekeeping in healthcare settings), operate in facilities that have some level of infection control in order to meet professional association or other accreditation requirements. OSHA has compiled additional infection control guidelines and regulations, including guidelines that apply to settings, such as mortuaries and laboratories, in which only other covered tasks are performed. A list of the guidelines and regulations OSHA has compiled and analyzed is contained in Appendix B to this SER Background Document. OSHA would be interested in hearing from small entity

[29]The draft results of the Expert Panel elicitation verify that many employers have at least some elements of an infection control plan in place already. See Section VI: Description of Potential Impacts of a Rule as Outlined in the Regulatory framework for further discussion and the results of that Panel.

representatives regarding any additional guidelines or regulations they believe the Agency should consider.

(B) Current infection control guidelines are non-mandatory, are not consistently and rigorously followed, and therefore are not sufficient to adequately reduce the risk of transmission of infectious agents to workers who provide direct patient care and/or perform other covered tasks.

Some stakeholders asserted, in response to OSHA's RFI, that adequate worker protection is achieved through adherence to Centers for Medicare and Medicaid Services (CMS) regulations. CMS regulations condition a provider's participation in Medicare or Medicaid on the provider's implementation of an infection control program.[30] CMS regulations only cover providers that accept or collect payments from Medicare or Medicaid. CMS requires a certification, which involves an inspection covering infection control procedures as they affect patient safety for settings such as hospitals, nursing homes, home health agencies, hospices and some ambulatory care facilities such as rural health care clinics and ambulatory surgery centers. However, most physicians' offices and many kinds of clinics are not subject to CMS accreditation requirements. Additionally, healthcare providers need not, and some healthcare providers do not, accept Medicare and/or Medicaid. Furthermore, CMS regulations do not cover some workplaces, particularly workplaces where other covered tasks (but not direct patient care) are performed (e.g., medical equipment reprocessing facilities and research and production laboratory facilities).

In addition, OSHA has in place, enforcement mechanisms that CMS does not have and that would work in concert with CMS to achieve an even greater level of compliance. Compliance with the CMS regulations is generally validated through periodic accreditation surveys of facilities by CMS-approved accreditation organizations, including TJC, state survey agencies, and other accrediting organizations (e.g., Accreditation Association for Ambulatory Health Care (AAAHC)).

Evidence OSHA has examined thus far indicates that, notwithstanding the CMS regulations, many employers receiving Medicare and Medicaid funding are not fully conforming to nationally recognized infection control practices and guidelines. OSHA has, at its disposal, enforcement mechanisms that CMS does not have. For example, OSHA can respond to complaints, conduct random unannounced inspections, and conduct worksite inspections in response to complaints filed by workers. OSHA believes that the failure of employers to

[30]See, e.g., 42 CFR 482.42 (hospitals), 483.65 (long term care facilities), 483.470(l) (intermediate care facilities for individuals with intellectual disabilities), 485.62(b) (outpatient rehabilitation facilities). CMS interpretive guidelines say that to meet this condition, providers should ensure that their infection control programs conform to nationally-recognized infection control practices and guidelines, such as the CDC/HICPAC guidelines. See, e.g., CMS State Operations Manual App. A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, App. PP - Guidance to Surveyors for Long Term Care Facilities, App. J - Guidance to Surveyors: Intermediate Care Facilities for Persons With Mental Retardation (CMS, 2013a).

routinely and rigorously comply with recognized and generally accepted good infection control practices can be ameliorated through a joint effort between OSHA and CMS. CMS has been validating compliance through periodic accreditation surveys alongside OSHA's enforcement of its existing Bloodborne Pathogens standard for over twenty years. This has led to significant declines in bloodborne diseases among healthcare workers. OSHA believes that a similar joint effort with CMS focused on protecting workers from exposure to infectious agents transmitted by routes other than the bloodborne route would also be successful in improving infection control practices and providing additional protection to workers.

The lack of compliance with recommended infection control procedures has been recognized by the CDC, the Institute of Medicine (IOM), and the WHO, and has been documented in numerous peer-reviewed scientific publications. For example, when discussing HCW adherence to infection control guidelines in its 2007 guidance, CDC/HICPAC found (Siegel et al., 2007, pages 45-46):

> Adherence to recommended infection control practices decreases transmission of infectious agents in healthcare settings. However, several observational studies have shown limited adherence to recommended practices by healthcare personnel. Observed adherence to universal precautions ranged from 43% to 89%. However, the degree of adherence depended frequently on the practice that was assessed and, for glove use, the circumstance in which they were used. Appropriate glove use has ranged from a low of 15% to a high of 82%…Differences in observed adherence have been reported among occupational groups in the same healthcare facility and between experienced and non-experienced professionals. In surveys of health care personnel, self-reported adherence was generally higher than that reported in observational studies. Furthermore, where an observational component was included with a self-reported survey, self-perceived adherence was often greater than observed adherence. Among nurses and physicians, increasing years of experience is a negative predictor of adherence.

OSHA has found ample evidence of non-compliance with recommended guidelines in a number of areas including: hand hygiene, respiratory protective measures, hazard analyses, and appropriate laboratory infection control practices. The Agency details its findings below.

Hand Hygiene

Perhaps the most basic, and important, element of infection control is proper hand hygiene. Nonetheless, consistent and rigorous adherence to such a practice has been a challenge since Ignaz Semmelweis first identified its importance in 1847 (Semmelweis, 1861). There is ample guidance on the subject, most recently the 2009 WHO *Guidelines on Hand Hygiene in Health Care* (WHO, 2009). This guidance document provides HCWs, hospital administrators and

health authorities with a thorough review of evidence on hand hygiene in healthcare and specific recommendations to improve practices and reduce transmission of pathogenic microorganisms to patients and workers in healthcare settings. Chou et al. (2010) emphasized that despite the fact that hand hygiene is the best method of preventing transmission of infections in health care, compliance is usually suboptimal. Likewise, Allegranzi & Pittet (2009) published an extensive literature review that documents the widespread lack of compliance with proper hand hygiene procedures. In 2009, Turnberg et al. also published a study that surveyed nurses and doctors from five medical facilities, documenting the lack of compliance with both hand hygiene and respiratory protection guidelines. The study found that only 33 percent of 156 doctors, and only 43 percent of 266 nurses, reported practicing five recommended hand hygiene measures.

Respiratory Protective Measures

Turnberg et al. (2008) reported significant gaps in adherence to recommendations for the control of respiratory infections in a study that surveyed 630 workers (187 medical practitioners; 277 nurses and nurse aides; 82 allied professionals; and 84 administrative staff) at five medical centers in 2005. The study found shortcomings in overall personal and institutional use of CDC recommended practices, including the failure to comply with posted signs and with patient masking and separation, hand hygiene, and PPE practices. That study also identified deficiencies in staff training and written procedures. And in the same 2009 Turnberg et al. study referenced in the paragraph above, the authors found that only 8 percent of 177 doctors, and only 25 percent of 249 nurses, reported using recommended respiratory protection.

The IOM noted the lack of compliance with recommended infection control practices in its report on respiratory protective measures for HCWs exposed to pandemic influenza (IOM, 2009). The IOM concluded that:

> [A]lthough workers are aware of expert guidance and the risk they face, they often do not wear PPE when faced with conditions requiring its use. Such noncompliance is also seen in low rates of hand hygiene and use of gloves, respirators, and eye protection. To improve the compliance rates and thereby improve worker protection, a "culture of safety" for workers must be established in all healthcare organizations evidenced by senior leadership commitment.

Hazard Evaluations

Studies also indicate that many employers are not engaging in appropriate infectious agent hazard evaluations. Examples of occupationally-acquired infectious diseases resulting from inadequate infectious agent hazard evaluations include the following:

- Bacterial meningitis[31]: A report published in CDC's Morbidity and Mortality Weekly Report (MMWR) outlined the occupational transmission of *Neisseria meningitidis* to a police officer and a respiratory therapist in the course of their job duties (CDC, 2010a). The hospital emergency room personnel did not diagnose the patient with suspected meningococcal disease.
- Cowpox virus infection: The first known human case of laboratory-acquired cowpox virus infection recently occurred in the United States. Determination of the causative agent and the application of proper control and remediation measures were delayed because of an incomplete initial patient history that excluded the patient's occupation (McCollum et al., 2012).

These incidents are examples of many in the literature that underscore that HCWs must conduct a thorough infectious agent hazard evaluation. Infectious diseases are commonly not diagnosed definitively until after HCWs have been exposed. Performing thorough hazard evaluations improve the likelihood that the appropriate infection control procedures will be implemented for a particular infectious disease, even before the exact diagnosis has been made.

Laboratory-Acquired Infections (LAIs)

Lack of adherence to infection control measures is not limited to HCWs engaged in direct patient care (Harding and Byers, 2006). The failure to consistently use proper PPE, working with cultures outside of biological safety cabinets, and allowing unvaccinated workers to handle highly infectious materials have all led to illnesses among laboratory workers. Examples of LAIs include:

- Brucellosis[32]: In 2006, two laboratory workers in two separate laboratories became ill with brucellosis after working with specimens at their workplaces (CDC, 2008).
- MRSA infections: Two laboratory-acquired infections of MRSA were reported in laboratory workers in a European laboratory (Gosbell et al., 2003).

In some cases, the failure to follow infection control measures has even led to the deaths of laboratory workers. Examples of fatalities resulting from a lack of worker compliance with appropriate precautions include:

- Bacterial meningitis: CDC's MMWR reported a number of cases of transmission of *Neisseria meningitidis* to laboratory workers from patient samples, resulting in a fatality rate of 50 percent in the 16 cases cited (CDC, 2002a). After concluding its investigation into the death of a research laboratory worker from a meningitis infection, OSHA issued

[31]Meningitis can be caused by infection with viruses, bacteria, and other micro-organisms. Many species of bacteria, including *Neisseria meningitidis* can cause meningitis.
[32]Brucellosis or Undulant Fever is caused by various species of bacteria of the genus *Brucella*, including *B. abortus, B. canis, B. melitensis,* and *B. suis*. Brucellosis is the most commonly reported laboratory-acquired infection.

a notice of unsafe and unhealthful working conditions to the medical center that employed the laboratory worker (OSHA, 2013a).

- Plague[33]: Attenuated *Yersinia pestis* infected and killed a 60-year old laboratory worker who wasn't following proper infection control practices (CDC, 2011a).

(C) Following recognized and generally accepted good infection control practices considerably reduces the risk of transmission of infectious agents to workers providing direct patient care and/or performing other covered tasks.

The CDC/HICPAC guidelines describe an approach to mitigating the risk from infectious agents through the use of a comprehensive infection control program employing standard and transmission-based precautions. CDC/HICPAC (Siegel et al., 2007) concluded that "adherence to recommended infection control practices decreases transmission of infectious agents in healthcare settings." OSHA believes that the guidelines provide both compelling and ample evidence to support the efficacy of such an approach.

The peer-reviewed literature is replete with studies of outbreaks of infectious diseases, often in hospitals or long term care facilities. In these studies, facilities that experienced an outbreak took corrective action by rigorously following recommended standard and transmission-based precautions. Once these precautions were implemented, studies showed that the risk and incidence of transmission was considerably lowered. Examples of successful reduction and/or elimination of infection risks by taking corrective actions include:

- *Clostridium difficile* infection[34]: Post-discharge and daily disinfection of inpatient rooms using bleach wipes was associated with a reduction in the incidence of hospital-acquired *Clostridium difficile* in patients on two hospital units (Orenstein et al., 2011).
- Norovirus: Poor cleaning techniques and delayed diagnoses of norovirus-infected patients resulted in increased transmission in a long-term care facility (Wu et al., 2005). Implementation of the following infection control practices eliminated the spread of norovirus within the facility: surveillance of patients; furloughing of infected workers; adherence of HCWs to contact precautions; proper use of PPE; hand hygiene; and extensive cleaning and decontamination.
- SARS: A SARS outbreak in one hospital in Hong Kong was stopped by implementing airborne and contact precautions, as well as programs for the early recognition, prompt isolation and appropriate treatment of infected individuals (Lee et al., 2003).

[33]Plague is caused by the bacterium *Yersenia pestis*. Attenuated strains are less virulent ones that are often handled with a lower level of safety precautions.
[34]Gastroenteritis can be caused by the bacterium *Clostridium difficile*. Epidemic strains of *Clostridium difficile* that are resistant to some antibiotics have resulted in an increasing number of healthcare-acquired and community-acquired infections.

- VRE[35]: Improved post-discharge and daily cleaning in a medical ICU reduced vancomycin-resistant *Enterococcus* (VRE) contamination of the environment and HCWs' hands, and reduced VRE cross-transmission (Hayden et al., 2006).

It should be noted that the literature often does not conclusively tie the origin of the outbreak in question to a facility's failure to routinely and rigorously follow recommended infection control practices. It is difficult to definitively prove causation in individual studies, which may have size or other limitations. Yet, there are many studies that conclude that outbreaks frequently arise in situations where some recommended infection control practice(s) are not being used, and demonstrate that the outbreaks end after more rigorous implementation of those missing practices. For this reason, OSHA believes that the evidence supports the position that many outbreaks can be prevented or minimized with correct infection control practices.

Reduced Risks to Patients Translates to Reduced Risks to HCWs

Several of the studies cited in this section found that following recommended infection control practices decreased risk to patients, without explicitly mentioning the decreased risk to HCWs. Recognized and generally accepted good infection control practices, such as administrative controls, work practice controls, engineering controls, and PPE, are, by their very nature, designed to decrease the risk of transmission of infectious diseases. It is a reasonable inference that study conclusions demonstrating risk reduction when recommended infection control practices are fully implemented apply equally to all individuals, whether they are patients, HCWs, or other workers that would be covered by a rule as outlined in the regulatory framework.

The Joint Commission published a monograph in 2012 entitled "Improving Patient and Worker Safety-Opportunities for Synergy, Collaboration and Innovation." The monograph was designed to "bridge safety-related concepts and topics that are often singled out within the specific disciplines of patient safety/quality improvement and occupational health and safety." By citing case studies that demonstrate hazards that affect patients, it emphasizes that these same hazards may also affect workers. It also states that "safety must include both patient and worker safety simultaneously, since staff working conditions are related to patient safety as well as occupational safety."

[35]Enteritis can be caused by various species of bacteria of the genus *Enterococcus*, including *E. faecalis* and *E. faecium*. Vancomycin-resistant Enterococci (VRE) are of special concern since vancomycin is considered an antibiotic of last resort.

OSHA's Bloodborne Pathogens Standard Reduces Risk to HCWs for Diseases Caused by Bloodborne Pathogens

Based in part on OSHA's experience with the Bloodborne Pathogens standard (29 CFR 1910.1030), OSHA believes that mandatory requirements and OSHA oversight will substantially reduce the risk of infectious diseases for affected workers. The Agency's past experience with human immunodeficiency virus (HIV) and hepatitis B virus (HBV) showed that, even though recommendations for control of these agents were previously in existence, promulgation of the Agency's Bloodborne Pathogens standard significantly improved worker safety and health. Surveillance data by Mahoney et al. (1997) documented a dramatic decline in the incidence of hepatitis B infections among HCWs, explaining that "[t]he decline in incidence of HBV infection since 1990 may be related to publication of the blood-borne pathogens standard by the Occupational Health and Safety Administration (sic) and the increase in vaccination coverage attributable to the Occupational Health and Safety Administration (sic)." Similarly, the CDC reported that, while there have been a total of 57 documented cases of occupational HIV transmission to HCWs in the United States, no confirmed cases have been reported since 1999 (CDC, 2011b). While this 12-year absence of confirmed occupational transmission cannot be completely attributed to promulgation of the Bloodborne Pathogens standard, the standard likely played a key role in preventing HIV infections in HCWs.

Recent analysis of the sharps safety provisions of the Bloodborne Pathogens standard (as mandated by the Needlestick Safety and Prevention Act (NSPA) - Pub. L. 106-430) by the International Healthcare Worker Safety Center at the University of Virginia found the provisions highly effective (Phillips et al., 2012). They found that there was a trend toward increasing rates of injuries before the legislation was enacted, which was followed by a drop of about 38 percent (95 percent confidence interval, 35 to 41 percent) in 2001, after the NSPA took effect. Subsequent injury rates, through 2005, remained well below pre-NSPA rates. Phillips et al. concluded that the revisions to the Bloodborne Pathogens standard contributed to the decline in percutaneous injuries among U.S. hospital workers, and support the concept that well-crafted standards supported by effective enforcement can result in a safer work environment and workforce.

Therefore, OSHA believes that the current non-mandatory approach to assuring appropriate implementation of infection control guidelines is not sufficient to adequately protect workers with occupational exposure to infectious diseases and that a rule as outlined in the regulatory framework is necessary to compel employers to follow recognized and generally accepted good infection control practices.

Section IV. Description of the Important Components in the Regulatory framework

Introduction

OSHA presents, in its regulatory framework, a potential programmatic approach to the protection of workers from occupational exposure to infectious diseases. The regulatory framework represents, in its entirety, OSHA's preferred alternative. The elements in the regulatory framework do not represent a list of provisions that OSHA may or may not include but instead represent all of the provisions the Agency believes, at this point, would constitute the best, most protective rule while providing the most flexibility and minimizing the burden on affected entities. While this framework represents OSHA's initial thinking, the Agency is still considering a number of alternatives and options (see Section VIII of this SER Background Document) and is open to considering additional alternatives or options that the SERs may present. OSHA welcomes feedback on all of the elements included in the regulatory framework.

The approach laid out in the regulatory framework would require employers to implement recognized and generally accepted good infection control practices such as those outlined in CDC infection control guidelines, CMS regulations, and CDC/National Institutes of Health (NIH) *Biosafety in Microbiological and Biomedical Laboratories* guidance. A typical OSHA program standard affords employers substantial flexibility in determining the best way to tailor protective measures to their workplaces, and, like most program standards, OSHA would require, among other things:

- an exposure determination;
- a written exposure control plan (referred to as a worker infection control plan (WICP) in the regulatory framework);
- methods of compliance (e.g., engineering,[36] administrative,[37] and work practice[38] controls, and PPE[39]);

[36]The regulatory framework defines engineering controls as measures that reduce, isolate, or remove the infectious agents' hazard from the workplace. Examples of engineering controls would include, but would not be limited to, airborne infection isolation rooms (AIIRs) and physical barriers, such as sneeze guards.

[37]The regulatory framework defines administrative controls as managerial measures that reduce the risk of transmission of, or infection by, infectious agents. Examples of administrative controls would include, but would not be limited to: promoting and providing vaccination; enforcing exclusion of ill employees from the workplace; setting up triage stations and separate areas for patients with suspected or confirmed infectious disease when they enter a healthcare facility; and assigning dedicated staff to minimize the number of employees exposed to those with a particular suspected or confirmed infectious disease.

[38]The regulatory framework defines work practice controls as measures designed to reduce the likelihood of transmission of infectious agents by specifying the manner of performing particular work tasks. Examples of work practice controls would include, but would not be limited to: performing tasks in a manner that minimizes generation of droplets or aerosols of infectious agents and practicing appropriate hand hygiene and respiratory hygiene/cough etiquette.

[39]The regulatory framework defines personal protective equipment (PPE) as specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard would not be considered PPE.

- medical screening, surveillance, and vaccinations;
- employee training; and
- recordkeeping.

Numerous studies (see Section III of this SER Background Document) find that fully implemented infection control plans are effective at reducing transmission of infectious agents and illnesses in both patients and workers. OSHA believes that many employers of workers with occupational exposure to infectious agents already have some (if not most) infection control plan elements in place and that the remainder usually have at least some familiarity with the elements introduced in the regulatory framework.

Moreover, responses to OSHA's RFI on infectious diseases (75 FR 24835, May 6, 2010)[40] and early site visits to healthcare facilities suggest that even very small employers can, and often do, implement infection control plan elements, and that small employers could successfully apply the programmatic elements in the regulatory framework. Thus, for many small employers, complying with a rule like the regulatory framework could simply involve:

- Evaluating their current written plan for completeness and adding missing elements;
- Identifying improvements needed in the implementation of their written plan and ensuring the elements of the plan are fully and rigorously followed;
- Verifying that employee health provisions, including vaccinations, are implemented and up-to-date; and
- Modifying their existing infection control training materials and using these modified materials to train employees in any areas where deficiencies in the existing program or in the implementation of the existing program have been identified.

There are at least two factors that could minimize the burden of compliance with a rule like the regulatory framework on some employers. First, all employers with employees who have occupational exposure to blood and other potentially infectious materials (as defined in the Bloodborne Pathogens (BBP) standard, 29 CFR 1910.1030) must already adhere to the BBP standard. These employers include most of the employers that would also be covered by a rule as outlined in the regulatory framework. Therefore, these employers should already be adhering to many of the types of practices that would be required by a rule as outlined in the regulatory framework to the extent these types of practices are already required by the BBP standard. For example, the BBP standard requires precautions such as hand hygiene, decontamination, exposure incident investigations, and hazard signage and labeling, which are also part of Standard Precautions. According to the regulatory framework, Standard Precautions are the "minimum infection control practices that apply to all direct patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is provided." In

[40]For example, see the following comments to the RFI, available under docket number OSHA-2010-0003 at Regulations.gov: OSHA-2010-0003-0021; OSHA-2010-0003-0022; OSHA-2010-0003-0064; OSHA-2010-0003-0173; and OSHA-2010-0003-0179.

addition to Standard Precautions, in some cases, transmission-based precautions would need to be implemented based on the hazard evaluation(s).

Second, OSHA wants to stress that each employer covered by the regulatory framework would only be tasked with developing and implementing a Worker Infection Control Plan (WICP) that is tailored to their specific work setting. The complexity of the WICP would largely be dictated by the size of the setting as well as the diversity and nature of job duties performed in that setting. For example, a larger setting such as a hospital would necessarily have a more complex WICP than a small setting such as a physician's or dentist's office.

For ambulatory care settings, the 2011 outpatient settings checklist (CDC, 2011f) demonstrates that most of the precautions that are recommended fall under Standard Precautions with transmission-based precautions implemented as needed. The next section explains why WICPs are not and cannot be "One Size Fits All".

Infection Control Plans (Including WICPs That Would be Required Under An OSHA Rule) Are Not and Cannot Be "One Size Fits All"

The basic elements of infection control practices for healthcare and related settings are laid out in the 2007 CDC/HICPAC guidance document and other guidance documents (e.g., BMBL and the NIH Guidelines for laboratories). Not surprisingly, the guidance documents recommend similar basic practices (e.g., hand hygiene, decontamination of infected materials and surfaces) for different settings. However, how these infection control practices are implemented in different settings and under different conditions will be affected by a number of factors.

- Sources and magnitude of worker exposure to infectious agents varies by setting.
  - In settings that provide direct patient care, appropriate precautions should be in place to protect workers from exposure to patients known or suspected to be infected or colonized with disease agents.
  - In all settings (including settings that provide direct patient care, morgues, laundries and laboratories), appropriate precautions should be in place to protect workers from exposure to infectious materials (e.g., contaminated materials and surfaces should be appropriately disinfected).
  - In hospitals, nursing homes and laboratories, there are longer exposures to infectious patients/contaminated materials.
  - In ambulatory care settings, worker exposures to infectious patients are frequently of shorter duration.
- Characteristics of patient populations vary by setting.
  - Immunocompromised patients, who are more susceptible to infectious diseases and are contagious for longer periods of time, are most likely to be seen in hospitals, nursing homes and specific types of ambulatory care settings (e.g., oncology clinics).
  - More severely ill infectious patients are treated in hospitals.

    - A greater number of infectious patients are seen in ambulatory care settings than in hospitals, though clinic patients frequently have mild or moderate symptoms.
- Characteristics of infectious agent(s), which affect level(s) of worker exposure, vary by setting.
    - The agent's route(s) of transmission will determine the types of precautions required (e.g., in settings that provide direct patient care, whether Standard Precautions are sufficient or transmission-based precautions (contact, droplet and/or airborne) will also need to be implemented).
- The severity of the disease due to the virulence of the infectious agent(s) is different for different agents. Individuals who have exposure to an infectious agent(s) that causes severe disease (e.g., active TB) are more likely to be treated in a hospital than in an ambulatory care setting.
- Types of infectious agents and diseases encountered vary by setting.
    - In hospitals and nursing homes, pneumonia, caused by a number of different infectious agents, is often seen.
    - In pediatric and family clinics, childhood infectious diseases such as mumps, measles, and pertussis are often seen.
    - In research laboratories, many different types of infectious agents capable of causing many different types of diseases are handled.

The 2007 CDC/HICPAC guidelines (which focus on settings that provide direct patient care) take all these various factors into consideration and recommend different ways to implement infection control practices that are appropriate for different types of settings. Examples of their recommendations (see pages 77-90 of the 2007 CDC/HICPAC guidelines) by setting, discussed below, include patient placement and patient transport using Standard Precautions versus transmission-based precautions.

Patient Placement - Standard Precautions

The potential for transmission of infectious agents should be considered when making patient-placement decisions. Place patients who pose a risk of transmission to others in a single-patient room, when available. Determine patient placement based on the following principles:

- Route(s) of transmission of the known or suspected infectious agent
- Risk factors for transmission from the infected patient
- Risk factors for adverse outcomes resulting from a healthcare-acquired infection(s) in other patients in the area or room being considered for patient-placement
- Availability of single-patient rooms
- Patient options for room-sharing (e.g., cohorting patients with the same infection)

Patient Placement - Contact Precautions

Acute care hospitals

Place patients in a single-patient room, when available. If single-patient rooms are in short supply, the following factors should be considered when making decisions on patient placement:

- Prioritize patients with conditions that may facilitate transmission (e.g., uncontained drainage, stool incontinence) for single-patient room placement.
- Place together in the same room (cohort) patients who are infected or colonized with the same infectious agent.
- Change protective attire and perform hand hygiene between contact with patients in the same room, regardless of whether one or both patients are on Contact Precautions.

Long-term care and other residential settings

Decisions regarding patient placement should be made on a case-by-case basis, balancing exposure to other patients in the room, the presence of factors that increase the likelihood of transmission, and the potential adverse psychological impact on the infected or colonized patient.

Ambulatory settings

Place patients in an examination room or cubicle as soon as possible.

Patient Placement - Droplet Precautions

Acute care hospitals

Place patients who require Droplet Precautions in a single-patient room when available. When single-patient rooms are in short supply, apply the following principles for making decisions on patient placement:

- Prioritize patients who have excessive cough and sputum production for single-patient room placement.
- Place together in the same room (cohort) patients who are infected with the same infectious agent and are suitable roommates.
- Change protective attire and perform hand hygiene between contact with patients in the same room, regardless of whether one patient or both patients are on Droplet Precautions.

Long-term care and other residential settings

Make decisions regarding patient placement on a case-by-case basis after considering exposure to other patients in the room and available alternatives.

Ambulatory settings

Place patients who require Droplet Precautions in an examination room or cubicle as soon as possible. Instruct patients to follow recommendations for Respiratory Hygiene/Cough Etiquette (which are available at www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm).

Patient Placement - Airborne Precautions

Acute care hospitals and long-term care settings

Place patients who require Airborne Precautions in an AIIR that has been constructed in accordance with current AIIR guidelines.

- When an AIIR is not available, transfer the patient to a facility that has an available AIIR.
- In the event of an outbreak or exposure involving large numbers of patients who require Airborne Precautions:
  - Consult infection control professionals before patient placement to determine the safety of alternative rooms that do not meet engineering requirements for an AIIR.
  - Place together (cohort) patients who are presumed to have the same infection (based on clinical presentation and diagnosis when known) in areas of the facility that are away from other patients, especially patients who are at increased risk for infection (e.g., immunocompromised patients).
  - Use temporary portable solutions (e.g., exhaust fan) to create a negative pressure environment in the converted area of the facility. Discharge air directly to the outside, away from people and air intakes, or direct all the air through HEPA filters before it is introduced to other air spaces.

Ambulatory settings

Develop systems (e.g., triage, signage) to identify patients with known or suspected infections that require Airborne Precautions upon entry into ambulatory settings.

- Place the patient in an AIIR as soon as possible.
- If an AIIR is not available, place a surgical mask on the patient and place him/her in an examination room. Once the patient leaves, the room should remain vacant for the appropriate time, generally one hour, to allow for a full exchange of air.
- Instruct patients with a known or suspected airborne infection to wear a surgical mask and observe Respiratory Hygiene/Cough Etiquette.
- Once in an AIIR, the mask may be removed; the mask should remain on if the patient is not in an AIIR.

Patient Transport – Standard Precautions

No special practices are recommended for transport of patients who are being handled under Standard Precautions.

Patient Transport - Contact Precautions

Acute care hospitals and long-term care and other residential settings

Limit transport and movement of patients outside of the room to medically-necessary purposes.

In any healthcare setting

When transport or movement is necessary,

- Ensure that infected or colonized areas of the patient's body are contained and covered.
- Remove and dispose of contaminated PPE and perform hand hygiene prior to transporting patients on Contact Precautions.
- Don clean PPE to handle the patient at the transport destination.

Patient Transport - Droplet Precautions

Acute care hospitals and long-term care and other residential settings

Limit transport and movement of patients outside of the room to medically-necessary purposes.

In any healthcare setting

When transport or movement is necessary, instruct patient to wear a surgical mask and follow Respiratory Hygiene/Cough Etiquette.

Patient Transport - Airborne Precautions

Acute care hospitals and long-term care and other residential settings

Limit transport and movement of patients outside of the room to medically-necessary purposes.

When transport or movement outside an AIIR is necessary:

- Instruct patients to wear a surgical mask, if possible, and observe Respiratory Hygiene/Cough Etiquette.
- For patients with skin lesions associated with varicella or smallpox or draining skin lesions caused by *M. tuberculosis*, cover the affected areas to prevent aerosolization or contact with the infectious agent in skin lesions.

Laboratories

Diagnostic laboratory facilities (e.g., clinical laboratories), research laboratory facilities, and production laboratory facilities are unique work environments that may pose special infectious disease risks to persons in or near them. Key documents that detail biological safety practices in laboratory facilities include: Biosafety in Microbiological and Biomedical Laboratories (CDC/NIH. 2009), NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH, 2013) and [CDC, 2012c]. The precautions in research and production laboratory facilities vary from those used in healthcare settings because laboratory workers are exposed to infectious materials rather than infectious patients. Workers in clinical laboratories can be exposed both to infectious materials and infectious patients. CDC/NIH recommends standard microbiological practices as well as practices for specific biosafety levels and disease agent-specific precautions (CDC/NIH. 2009),

One example of a difference between laboratory facilities and healthcare settings providing direct patient care is the type(s) of engineering controls used. Engineering controls recommended for laboratory facilities such as biosafety cabinets, laboratory hoods, and other laboratory design and containment measures are designed to protect the worker from exposure to infectious materials. In contrast, the types of engineering controls (e.g., AIIRs in hospitals) used in healthcare settings are designed to protect workers from exposure to infectious patients and contaminated materials.

The remainder of this section provides a broad overview of the regulatory framework and highlights some of its major elements.

Scope

Per the regulatory framework, OSHA would require that an infectious diseases rule apply to employers within federal OSHA's jurisdiction and include firms engaged in general industry sectors. If a rule is promulgated, states with OSHA-approved State Plans would be required to adopt an equivalent "at least as effective" standard covering both the private sector and state and local government workers, as applicable.[41]

Because infectious agents pose serious hazards to workers performing many types of tasks, per the regulatory framework, an infectious diseases rule would generally cover any worker with occupational exposure when that worker performs certain tasks described in the regulatory framework. An infectious diseases rule would not be limited to covering workers providing healthcare services only, or to covering specific workplaces or work settings only. An employer's workplace would fall within the scope of an infectious diseases rule if: (1) the employer's workers provide direct patient care (a term that is defined in the following paragraphs) or perform other covered tasks (a term that is also defined in detail in the following paragraphs); and (2) those workers have occupational exposure (i.e., exposure which is or should

[41]There are 27 States and territories with OSHA-approved plans, 5 of which are limited in coverage to public employees only.

be reasonably anticipated to sources of infectious agents resulting from a worker's execution of job duties that involve the provision of direct patient care or the performance of other covered tasks). OSHA notes that, under the regulatory framework, a worker would have "occupational exposure" even if that worker is subject only to the potential for being exposed to infectious agents during the performance of job duties that involve the provision of direct patient care or the performance of other covered tasks, so long as that potential is or should be reasonably anticipated.

Per the regulatory framework, OSHA would exclude occupational exposure as defined in OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030).

OSHA anticipates that employees working in settings to which the CDC/HICPAC guidelines apply (or to which guidelines for particular settings or medical specialties that are based upon the CDC/HICPAC guidelines apply), as well as employees working in other settings where there is occupational exposure, would fall within the scope of an infectious diseases rule. The employer would be required to determine whether its workers are covered during its development of a written infection control plan (discussed in further detail later in this section). Most small employers are used to working under guidelines and regulations that address infection control, such as those issued by CDC, NIH, CMS, and OSHA (e.g., the Bloodborne Pathogens standard). (See Appendix B of this document for a partial list of guidelines and regulations currently in place that address infection control in a variety of settings). As a result, the Agency does not believe that small employers would have difficulty determining whether their employees have occupational exposure during the provision of direct patient care or performance of other covered tasks.

The regulatory framework defines "direct patient care" as job duties that involve the provision of healthcare services with hands-on or face-to-face contact with patients, while acting under a license, certification, or registration to provide healthcare services within a legally permitted scope of practice, or while acting under the supervision of a licensed, certified, or registered employee. Nurses, physicians, physical and occupational therapists, paramedics, and emergency responders are examples of the types of workers who perform direct patient care. A pharmacist performing duties that involve hands-on contact with patients (e.g., administering vaccinations) is another example of a worker who performs direct patient care. However, a worker who provides first aid only would not be considered to provide direct patient care for the purposes of the regulatory framework. OSHA believes that general public health measures are adequate to protect workers who provide first aid only from the types of infectious agents covered by the regulatory framework, and that it would not be necessary to impose the burden of implementing and maintaining a comprehensive infection control plan for such workplace exposures.

Moreover, coming into hands-on or face-to-face contact with another individual would not necessarily constitute direct patient care. Personal trainers at gyms and cosmetologists may have hands-on or face-to-face contact with other individuals, but they are outside of the scope of the

regulatory framework, either because they are not licensed/certified/registered to provide healthcare services, or because they are not delivering healthcare services to patients. OSHA believes, at this stage, that exposures in these types of settings are more properly addressed by general public health measures.

"Other covered tasks" is defined in the regulatory framework as job 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. In addition, other covered tasks involve occupational exposure to contaminated materials in diagnostic, research or production facilities. Examples of other covered tasks would 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 that may contain infectious agents in diagnostic, research and production facilities; and dispensing medications and/or medical supplies in settings where direct patient care is provided.

While the scope of the regulatory framework is defined by the types of job tasks performed in a facility, and not by the industry classification(s) of the facility, OSHA has identified a number of industries where direct patient care and/or other covered tasks could be performed. OSHA has preliminarily estimated that direct patient care would be provided in, among other industries: hospitals; long-term care facilities and nursing homes; ambulatory care centers, including doctors' offices and dentists' offices; ambulatory surgical centers; medical clinics embedded in schools, correctional facilities, or industrial settings; home healthcare; and medical emergency delivery services (e.g., ambulances). Other covered tasks could be performed in all of the previously mentioned industries where direct patient care is provided, plus, among other industries: diagnostic, research, and production laboratory facilities; morgues and mortuaries; laundry facilities that handle linens from healthcare settings; medical waste collection and disposal facilities; medical equipment reprocessing facilities; and durable medical equipment supply companies that rent reusable equipment such as hospital beds and wheelchairs. Section V of this SER Background Document presents the industries that OSHA anticipates would likely be covered by an infectious diseases rule, and describes their characteristics, in more detail.

OSHA does not intend for the regulatory framework to cover veterinarians and veterinary technologists, technicians, or assistants, except when these workers perform duties defined as other covered tasks. For example, animal caregivers would be covered if they work in a research facility that handles infectious agents that can be transmitted to humans via contact, droplet or airborne route(s) or materials contaminated with such infectious agents.

Per the regulatory framework, an infectious diseases rule would not include in its scope certain job tasks, such as the tasks of prison guards and teachers, that are not other covered tasks. In addition, there are certain job classifications, for example flight attendants, that would not be covered because workers in those classifications generally do not provide direct patient care or perform other covered tasks. The tasks covered under the regulatory framework – unlike the typical duties of workers such as prison guards, teachers and flight attendants – would generally be subject to the standard and transmission-based precautions laid out in the CDC/HICPAC guidelines. Although many of the programmatic elements of the regulatory framework are already in place for the tasks covered under the regulatory framework, this is not generally the case for the tasks of prison guards, teachers and flight attendants. Note that under the regulatory framework, workers such as prison guards and teachers would be covered if they perform other covered tasks (e.g., a prison guard working in an embedded prison clinic).

OSHA is not suggesting that prison guards, teachers, and flight attendants not covered under the regulatory framework have no occupational exposure. Rather, it is the Agency's belief that such exposures are more appropriately addressed through general public health approaches and OSHA's Bloodborne Pathogens standard, rather than through the infection control measures envisaged in the regulatory framework. OSHA notes that it will continue to examine these job classifications carefully, and may explore ways to specifically address the infectious disease hazards associated with these job classifications in the future.

Under the regulatory framework, direct patient care is defined, in part, as job duties involving hands-on or face-to-face contact with patients. An exception to this definition states that pharmacists who provide hands-on care (e.g., administer vaccinations) provide direct patient care, while those who perform duties that involve face-to-face contact only (e.g., dispense medications) do not provide direct patient care. Pharmacists who are dispensing medications and/or medical supplies in settings where direct patient care is provided, however, are performing other covered tasks and therefore fall under the scope of the regulatory framework if they have occupational exposure. OSHA believes, based on the evidence it has thus far analyzed, that general public health measures are adequate to protect pharmacists who neither provide direct patient care nor perform other covered tasks, as defined by the regulatory framework.

Per the regulatory framework, an infectious diseases rule would not apply to occupational exposures that are already covered by the Bloodborne Pathogens standard, 29 CFR 1910.1030. All other forms of occupational exposure to infectious agents that are transmissible to humans would be covered by an infectious diseases rule. The Agency expects that many employers would likely develop a unified infection control plan that addresses both occupational exposures to bloodborne hazards and to other sources of infectious agents.

OSHA notes that, unless otherwise stated in the regulatory framework, covered employers would also have to comply with other applicable provisions in Part 1910, such as the Respiratory

Protection standard (§1910.134), the Personal Protective Equipment standards (Subpart I); and the Specifications for Accident Prevention Signs and Tags standard (§1910.145).

Worker Infection Control Plan (WICP)

Per the regulatory framework, OSHA would require employers whose workers are within the scope of the regulatory framework to develop and implement a written worker infection control plan (WICP) designed to prevent or minimize the transmission of infectious agents to workers. The written WICP is the foundation of the regulatory framework. Because infection control must be practiced by everyone, it is imperative that workers are aware of and trained on the provisions in place in their workplaces. Having the WICP in written form is also essential to determine if the components of the plan have been implemented. OSHA believes that many employers of workers with occupational exposure have already developed WICPs for their workplaces and that these plans would fulfill most, if not all of, the requirements for a WICP, as specified under the regulatory framework. However, employers could choose to modify current elements or develop additional elements for their current infection control programs to help them better manage their programs, and to demonstrate that they are implementing and maintaining all elements of their programs.

According to the regulatory framework, OSHA would require that the WICP contain an exposure determination; identifying information regarding the plan administrator and the person(s) responsible for the daily management of the WICP; and the standard operating procedures (SOPs)[42] outlined in the regulatory framework (described in more detail in the discussion of Standard Operating Procedures Development and Implementation, below). With respect to the exposure determination, OSHA would require that the employer compile a list of all job categories in the workplace where all or some of the employees have occupational exposure during the provision of direct patient care and/or performance of other covered tasks. For example, in a hospital, an employer would include in its exposure determination job categories such as registered nurses, physicians, radiological technicians, and respiratory therapists, because some or all personnel in those categories have occupational exposure; a hospital probably would not include in its exposure determination job classifications such as accounting and HR, so long as no personnel in those categories have occupational exposure. OSHA would require that the exposure determination be made without regard to the use of PPE for the following reasons. 1) Sometimes exposures occur to people who are not directly working with the hazardous material and may not routinely use PPE. For these workers, part of the exposure determination process would involve assessing whether these workers should also use PPE and if so, what PPE would be appropriate; 2) In addition, several conditions must be met for PPE to effectively lessen exposures. The employee must be trained to use the PPE properly each time the task is performed, the PPE must fit properly and be appropriate for the task and finally the PPE must be

[42]The regulatory framework defines "standard operating procedure" as an organizational directive that establishes a standard course of action to accomplish a task or goal.

free of physical flaws that could compromise safety. If even one of these conditions is not fully met, protection cannot be assured. Therefore, all tasks that entail occupational exposure need to be included in the exposure determination, regardless of the PPE used, so that the workers who perform such tasks will be properly protected. OSHA does not anticipate that the preparation of the exposure determination would be burdensome for most employers.

Because of the continual emergence of new research and technology related to the prevention of occupational illness due to infectious agents, OSHA would require that employers (with input from non-managerial workers with occupational exposure) review and update their WICPs at least annually, and whenever necessary to reflect changes in occupational exposure, and that employers establish and maintain records of the reviews. These provisions would be similar to requirements in OSHA's Bloodborne Pathogens standard (§§1910.1030(c)(1)(iv), (c)(1)(v)).

Without such updates and reviews, there is a risk of the WICP becoming static and documented elements, such as SOPs, becoming out of date. In most settings where workers are exposed to infectious agents, changes in technology, new or emerging infectious agents, changes in job tasks, procedures, and job classifications, and other changes occur markedly over time. Each change in the work setting has the potential to create new occupational hazards that may need to be addressed and brought under control, or the potential to make one or more elements of the WICP outdated. OSHA's intent is that each establishment's WICP be structured so that it can evolve and change to meet new circumstances and needs. The Agency believes this would be assured by the WICP review process in the regulatory framework. Further, providing workers with opportunities to participate in the implementation and evaluation of the WICP is critical to ensuring that the plan is successful and effective. Involving workers allows employers to tap into the knowledge and insight that workers have about infectious agents, infection control practices, how work is conducted, and potential solutions to infection control issues.

Finally, per the regulatory framework, an infectious diseases rule would contain provisions that host employers (e.g., hospitals) would implement to protect their workers from infectious agent hazards. Under such a rule, OSHA would require that the host employer require that contractors, vendors, and licensed independent practitioners with privileges, at a minimum, adhere to infection control practices consistent with the host employer's WICP. OSHA would also generally require the host employer to ensure that its WICP is followed by each of its employees, even when instructions from a contractor, vendor or licensed independent practitioner with privileges are contrary to the host employer's WICP. Under such a rule, the host employer would allow its employees to follow contrary instructions from a contractor, vendor or licensed independent practitioner with privileges if the host employer could show that not following the contrary instructions would be a greater hazard to a patient(s) or an employee(s), or that following the contrary instructions is consistent with recognized and generally accepted good infection control practices. In concert with these provisions, OSHA would require that host employers ensure that a copy of the WICP is provided and accessible to workers, contractors, vendors, and licensed independent practitioners with privileges.

Standard Operating Procedures Development and Implementation

Per Section 4 of the regulatory framework, OSHA would generally require employers having a worker(s) covered by an infectious diseases rule to 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. To determine whether SOPs are consistent with such practices, OSHA would require that employers consider both applicable regulations, such as federal, state and local regulations, and current guidelines, such as those issued by the CDC, CDC/HICPAC, and NIH.[43] In the absence of such regulations and guidelines, OSHA would require that employers consider current guidance issued by professional organizations and accrediting bodies. Moreover, OSHA would require that employers develop, implement, and update written SOPs that are consistent with applicable requirements in Part 1910 (e.g., requirements contained in 29 CFR 1910.134, and 29 CFR 1910 Subpart I); and, if a recognized and generally accepted good infection control practice conflicts with an applicable requirement in Part 1910, employers would need to incorporate into its SOPs, and implement, the Part 1910 requirement.

SOPs for all employers: A rule based on the regulatory framework would require the SOPs for all employers in the scope of the regulatory framework to contain at least procedures for:

- Infectious agent hazard evaluations;
- Communication of hazard evaluation results;
- Hand hygiene;
- Food and cosmetics;
- Engineering, administrative, and work practice controls and PPE;
- Decontamination;
- Handling, containerization, transport, or disposal of contaminated materials;
- Occupational health services;
- Exposure incidents;
- Signage and labeling/color-coding; and
- Notification of occupational exposure during transfer, transport, shipping, or receipt of sources of infectious agents.

Below, OSHA highlights some of the SOPs for all affected work settings covered under the regulatory framework.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures for the conduct of timely infectious agent hazard evaluations to promptly identify

[43]The regulatory framework provides that, when conducting research on infection control practices, employers may consider research protocols that are not consistent with recognized and generally accepted good infection control practices, provided those protocols have been approved by an institutional review board and adequately address worker protection as a component of the overall protection of the human subjects.

suspected or confirmed sources of infectious agents that are present in the work setting. An effective hazard evaluation would anticipate a range of infectious agent hazards and appropriately link those hazards with standard and transmission-based precautions. In a healthcare setting, such an evaluation might include an assessment of a patient's infectious status based upon symptoms reported at scheduling and intake/admittance and/or a healthcare provider's index of suspicion based upon the provider's interactions with the patient. If the regulatory framework develops into a proposed rule, the Agency might include in that proposed rule a non-mandatory appendix that would explain how employers can conduct infectious agent hazard evaluations in different settings. OSHA would not require the hazard evaluations to be written documents, but would permit the hazard evaluations to be incorporated into routine activities, such as triage, scheduling, intake, or a preliminary assessment by a healthcare worker.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures to ensure that handwashing facilities are available and accessible, and for following recognized and generally accepted good infection control practices for hand hygiene.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures for the use of engineering, administrative, and work practice controls, and would require the employer to establish and implement procedures for the provision and use of PPE (e.g. gloves, gowns, laboratory coats, protective eyewear, face shields, facemasks, and respirators). OSHA would require that employers establish and implement SOPs in accordance with recognized and generally accepted good infection control practices, and thereby tailor their SOPs to their specific work settings and to the specific risks typically encountered in their workplaces. As such, OSHA notes in the regulatory framework that the Agency might permit adherence to the required hierarchy of controls, such as that required by 29 CFR 1910.134(a)(1), to be modified in accordance with recognized and generally accepted good infection control practices. Thus, for example, OSHA would permit an employer not to use certain engineering controls (e.g., airborne infection isolation rooms (AIIRs)) if it is consistent with recognized and generally accepted good infection control practices to use some combination of alternative engineering controls, administrative controls, work practice controls and PPE instead.

OSHA wrote the regulatory framework in this manner because OSHA recognizes that infection control practices normally rely upon a multi-layered and overlapping strategy of employing engineering, administrative, and work practice controls, as well as PPE. Moreover, the regulatory framework is consistent with OSHA's understanding that most workplaces outside of hospitals do not have AIIRs.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures for regular examination of existing engineering controls, and for maintaining or replacing existing engineering controls to ensure that engineering controls function properly and, thus, provide protection to workers as intended. OSHA would require the employer to establish

and implement procedures to prevent or minimize the generation of droplets or aerosols of infectious agents.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures for decontamination of contaminated materials (i.e., contaminated items and/or surfaces) and contaminated equipment. The Agency chose not to specify particular disinfectants or procedures for decontamination under the regulatory framework, as OSHA would require SOPs that are consistent with recognized and generally accepted good infection control practices relevant to their work setting. OSHA also believes that specifying particular disinfectants and procedures could have the effect of limiting the use of new products and of discouraging the development of new information relative to adequate decontamination.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures to provide occupational health services, including screening, surveillance, vaccinations and vaccination regimens (e.g., doses, intervals), post-exposure treatment and follow-up, and medical removal protection, that are consistent with recognized and generally accepted good infection control practices. Such potential requirements are discussed later in this section of this SER Background Document.

Per the regulatory framework, OSHA would require the employer to establish and implement procedures to investigate the circumstances surrounding each exposure incident, which is defined as a specific event in which a worker has been exposed to a suspected or confirmed source of an infectious agent(s), either without the benefit of the infection control practices that would be required by OSHA, or where the infection control practices that would be required by OSHA may not have adequately protected the worker from the exposure. These procedures would involve determining the cause of the incident, and whether existing policies, procedures, or training need to be revised to prevent future exposure incidents. For example, during an exposure incident investigation, a Physician or other Licensed Healthcare Professional (PLHCP) may conclude that a patient exposed a worker to a suspected or confirmed source of an infectious agent and that proper implementation of the employer's infection control practices may not have adequately protected the worker from the exposure. The exposure incident investigation will assist the employer in revising its SOPs to more fully protect workers and will help the employer identify which workers may need to receive occupational health services (which, again, are discussed below).

Additional SOPs for Direct Patient Care: Per the regulatory framework, OSHA would require employers whose workers provide direct patient care to develop, implement, and update, in addition to the SOPs for all affected work settings, SOPs that contain at least procedures for:

- Patient scheduling and intake/admittance;

- Standard Precautions;[44]
- Contact precautions;[45]
- Droplet precautions;[46]
- Airborne precautions;[47]
- Patient transport;
- Medical surge procedures; and
- Ensuring any other employee protection precautions necessary to address specific infectious diseases or circumstances.

Below, OSHA highlights some of the provisions in the regulatory framework addressing SOPs for employers whose workers provide direct patient care.

OSHA has concerns that workers exposed to airborne transmissible infectious diseases are not being adequately protected. Therefore, the regulatory framework includes provisions for the development, implementation, and update of SOPs associated with airborne precautions.

Per the regulatory framework, OSHA would require procedures for the temporary isolation and inter-facility transfer of an individual with a suspected or confirmed airborne-transmissible infectious disease if the employer's healthcare setting does not have an available AIIR. OSHA recognizes that there are certain situations where transfer may not be appropriate and notes that transfer would not be required if: a transfer would be medically detrimental to the individual's health; it is not medically necessary for the individual to remain in the healthcare facility (e.g., it is appropriate to send the individual home); or an AIIR becomes available at the facility.

Per the regulatory framework, OSHA would require procedures for ensuring proper AIIR operation if the employer's healthcare setting has an AIIR, including procedures for ensuring that each AIIR, associated ducting, and filtration are constructed, operated, and maintained so that they maintain negative pressure, achieve sufficient air changes per hour, properly exhaust contaminated air, and function to prevent or minimize transmission of infectious agents, and for ensuring that, when in use, each AIIR is monitored daily for maintenance of negative pressure.

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[44]The regulatory framework defines "Standard Precautions" as the minimum infection control practices that apply to all direct patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is provided.

[45]The regulatory framework defines "contact precautions" as infection control practices designed to prevent or minimize transmission of infectious agents spread by direct contact (i.e., infectious agent transmission from one infected individual to another individual without a contaminated intermediate item, surface, or individual) or indirect contact (i.e., infectious agent transmission through a contaminated intermediate item, surface, or individual) with an item, surface, or individual contaminated with, such an agent(s).

[46]The regulatory framework defines "droplet precautions" as infection control practices designed to prevent or minimize transmission of infectious agents spread through direct contact of droplets containing the infectious agent with an individual's respiratory or mucous membranes.

[47]The regulatory framework defines "airborne precautions" as infection control practices designed to prevent or minimize transmission of infectious agents that remain infectious over time and distance (e.g., between or across rooms; through ventilation systems) when suspended in the air.

OSHA believes that these procedures would ensure that AIIRs function properly when they are needed.

As stated, the Respiratory Protection standard (29 CFR 1910.134) would generally apply to the use of respirators by workers performing tasks covered by a rule as outlined in the regulatory framework. Per the regulatory framework, OSHA would require employers to establish and implement procedures for workers to use respiratory protection: when entering areas, rooms, or homes where individuals have been isolated; when transporting individuals with suspected or confirmed infectious disease in an enclosed vehicle; during aerosol-generating procedures; during maintenance of air systems or equipment reasonably likely to contain airborne-transmissible infectious agents; and whenever the infectious agent hazard evaluation indicates that respiratory protection is necessary for worker protection.[48] OSHA would also require employers to establish and implement procedures to ensure that facemasks are not used to provide respiratory protection when the use of respirators is required under 29 CFR 1910.134.

Per the regulatory framework, OSHA would require SOPs for any other worker protection precautions that are necessary to address specific infectious diseases or circumstances for direct patient care. As explained earlier, OSHA would generally require employers having a worker(s) covered by a rule as outlined in the regulatory framework to develop, implement, and update SOPs that are consistent with recognized and generally accepted good infection control practices relevant to their work setting. Such a rule would thus be performance-based. Nonetheless, OSHA chose to explicitly address some specific worker protection precautions in the regulatory framework because OSHA views these particular precautions as especially important for a good infection control program, and OSHA therefore wants to emphasize these precautions directly in the regulatory framework. However, OSHA would require employers to establish and implement SOPs not specifically addressed in the regulatory framework to ensure that their infection control programs are consistent with recognized and generally accepted good infection control practices relevant to their work settings. Employers would generally be able to determine whether their SOPs are consistent with such practices by considering both applicable regulations, such as federal, state and local regulations, and current guidelines, such as those issued by the CDC, CDC/HICPAC, and NIH, and, in the absence of such regulations and guidelines, guidance issued by professional organizations and accrediting bodies.

Additional SOPs for Other Covered Tasks: Per the regulatory framework, OSHA would require employers whose workers perform other covered tasks to develop, implement, and update SOPs, in addition to the SOPs for all affected work settings, that, at a minimum, contain procedures for:

- The handling and intake of contaminated materials;

[48]This list of procedures in the regulatory framework is non-exclusive (i.e., OSHA would require the employer to establish and implement procedures that would include, but would not be limited to, the procedures listed in the regulatory framework).

- The use of control measures necessary to prevent or minimize transmission of infectious agents;
- Implementing, in diagnostic, research, and production facilities, standard microbiological practices and any special practices for handling infectious agent(s) of a specific biosafety level, in addition to the other procedures outlined for other covered tasks; and
- Ensuring any other employee protection precautions necessary to address specific infectious diseases or circumstances.

Below, OSHA highlights some of the provisions in the regulatory framework addressing SOPs for employers whose workers perform other covered tasks.

Diagnostic laboratory facilities (e.g., clinical laboratories), research laboratory facilities, and production laboratory facilities are unique work environments that may pose special infectious disease risks to persons in or near them. In fact, CDC/NIH publishes guidelines specifically for biosafety in microbiological and biomedical laboratories (CDC/NIH, 2009). In addition, NIH's *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH, 2013) includes guidance on safe handling of recombinant and synthetic infectious agents. To ensure that workers in diagnostic, research, and production facilities are adequately protected, OSHA would require that employers of workers in these types of facilities include in their SOPs procedures for the implementation of standard microbiological practices and any special practices for handling infectious agent(s) of a specific biosafety level.

To this end, per the regulatory framework, OSHA would require the employer to establish and implement procedures to ensure the use of appropriate engineering controls (i.e. engineering controls that are necessary to ensure consistency with recognized and generally accepted good infection control practices). Appropriate engineering controls would include such controls as biosafety cabinets, laboratory hoods, and other laboratory design and containment measures. Per the regulatory framework, OSHA would also require the employer to establish and implement procedures to ensure that these engineering controls are appropriately constructed, operated, and maintained (e.g., proper air flow, exhaust air filtration, double access doors, special design requirements for Biosafety Level 3 and 4 facilities). Finally, OSHA would require the employer to establish and implement procedures necessary to address uncontrolled releases of infectious agents, including mitigation of such releases and prompt reporting of such incidents to appropriate authorities (e.g., federal, state, and local authorities).

Per the regulatory framework, OSHA would require SOPs for any other worker protection precautions that are necessary to address specific infectious diseases or circumstances for other covered tasks. OSHA discussed the rationale for this provision earlier in this section of the SER Background Document when discussing the analogous provision for SOPs related to direct patient care.

Medical Screening, Surveillance, and Vaccination

Early intervention, through testing, appropriate prophylaxis, and vaccination of occupationally exposed workers, can reduce the risk of infection among workers and patients. Moreover, since a single unprotected occupational exposure may result in an infection, post-exposure evaluation and follow-up after each exposure incident can mitigate the impact of the infection on the worker and can also help prevent additional infections of other workers and patients. Per the regulatory framework, OSHA would require employers to make medical screening, surveillance, and vaccinations available to each worker who falls within the scope of an infectious diseases rule, and to promptly provide a confidential post-exposure medical evaluation and appropriate follow-up to each worker who has had an exposure incident. In addition, OSHA would require the employer to make a confidential medical evaluation and appropriate follow-up available to each worker referred for such services following medical screening/surveillance. Similar requirements can be found in other OSHA standards, such as the Bloodborne Pathogens standard (§1910.1030), the Lead standard (§1910.1025), and the Chromium (VI) standard (§1910.1026).

Below, OSHA highlights some of the provisions in Section 5 of the regulatory framework.

Per the regulatory framework, OSHA would set forth specific requirements for vaccinations. Vaccination is generally considered an important component of an effective infection control program. The regulatory framework explains that an employer would be required to make available vaccinations and associated vaccination regimens (e.g., doses, intervals) that are consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered during the job tasks of the employee. The employer of a worker(s) in a research or production laboratory facility would be required to make available to that worker(s) any vaccinations specified in the employer's WICP, or determined by a PLHCP to be medically appropriate for a particular worker. For all other workers who fall under the scope of an infectious diseases rule, OSHA would require the employer, at a minimum, to make the following vaccinations available to each worker:

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

OSHA is interested in feedback from SERs on whether employees with occupational exposure at diagnostic laboratory facilities, like employees at research and production facilities, should be offered targeted vaccinations only, or whether they, like other employees that would be covered under a rule as outlined in the regulatory framework, should be offered the minimum set of

vaccinations listed above. OSHA believes that at least some employees in diagnostic laboratory facilities work with samples containing unidentified potentially infectious agents and, therefore, should be offered the minimum set (unlike workers in research and production laboratory settings, where the infectious agents to which workers have occupational exposure are known).

OSHA's aim in the regulatory framework is to promote and encourage worker cooperation in the vaccination program by ensuring that the employer offers appropriate vaccinations at no cost to employees and provides appropriate educational material on the benefits and risks of such vaccinations (the latter aim is described under Section 6, Training). Per the regulatory framework, OSHA would permit workers to decline required vaccinations, but, in such cases, the employer would be required to obtain and retain a signed declination statement and to make the vaccination available to any worker who decides to accept the vaccination after initially declining it. These provisions would encourage greater participation in the vaccination program by reiterating that a worker declining vaccination remains at a greater risk of acquiring infectious diseases than vaccinated workers, would benefit the employer by making it easier to determine vaccination status during the investigation of an exposure incident (e.g., because of the provision that would require signed declinations), and would allow resources to be directed toward improving the acceptance rate of the vaccination program.

Per the regulatory framework, OSHA would cover medical removal protection (MRP). The employer would be required to follow a PLHCP's recommendations concerning modifications or restrictions to a worker's job duties, or precautionary removal of a worker from the workplace (e.g., to protect patients or coworkers). When a worker has been removed from the job or is otherwise medically limited as a result of an exposure incident, the employer would be required to pay, to the worker, the worker's total normal earnings and to maintain the worker's seniority and all other worker rights and benefits, including the worker's job status. A rule that would require employers to provide MRP benefits would encourage employee participation in (and therefore increase the effectiveness of) the medical surveillance program that would be required by such a rule by ensuring that reporting symptoms or health conditions to the PLHCP would not result in loss of job or pay.

Per the regulatory framework, OSHA would permit several limitations on MRP benefits. Per the regulatory framework, OSHA would not require MRP benefits for those workers removed from their jobs or otherwise medically limited as a result of occupational exposure to the common cold or influenza, with one exception. In research and production laboratory facilities, if a worker is removed from the job or otherwise medically limited as a result of an exposure incident to any infectious agent with which the employee is working (including the common cold or influenza viruses), OSHA would require the employer to provide MRP benefits to the worker. Per the regulatory framework, OSHA would require the employer to provide medical removal benefits only until the worker is determined to be noninfectious or is otherwise able to return to normal duties, and, in any case, OSHA would limit the required provision of benefits to a period not exceeding 18 months. Any potential obligation to provide MRP benefits to a removed or

restricted worker would also be reduced to the extent that the worker 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 worker's removal. Finally, even if MRP benefits are not required in a particular case, under the regulatory framework, the employer would not be precluded from offering administrative or sick leave for medical removal of a worker.

Based on the regulatory framework, the employer would be required to ensure that employees' medical records are kept confidential and not disclosed or reported, without the employee's written consent, to any person within or outside the workplace, except as would be required by OSHA or as may be required by law. Regarding privacy issues under HIPAA regulations, OSHA's assessment is that as long as the information disclosed to employers by PLHCPs is limited to findings concerning a work-related illness or injury or workplace-related medical surveillance, and that the employee is given notice of such disclosure, that the regulatory framework's requirements for employers to receive, maintain, and possibly disclose employee health information are not in conflict with HIPAA.

Training

Section 6 of the regulatory framework covers worker training. Worker training is critical to the success of any infection control program. Unless workers have sufficient knowledge and understanding of the program, including how to recognize hazards and protect themselves, the intent and effectiveness of the program will be undermined. Per the regulatory framework, OSHA would require the employer to provide training as follows: initially, prior to the time of assignment to tasks where occupational exposure may take place; annually thereafter, not to exceed 12 months from the previous training; and supplemental training to address specific deficiencies. Both initial and periodic worker training are recognized as important components of an effective infection control program. Initial training provides information that workers need to protect themselves against occupational exposures to hazards, while periodic training refreshes worker knowledge, reinforces the importance of the infection control program, and provides a means of introducing new information and procedures (which is especially important in the infectious disease realm, given the likelihood of changes in technology, the possibility for the appearance of new or emerging infectious agents, and other changes that occur markedly over time).

To ensure that the employer's training program is adequate and meaningful, OSHA would require that the program: be overseen or conducted by a person knowledgeable in the program's subject matter as it relates to the workers' workplace; consist of material appropriate in content and vocabulary to the educational level, literacy, and language of workers; 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 provisions for worker training in the regulatory framework are performance-oriented, listing categories of information that would be provided to workers, including, among other elements: 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 practices (e.g., standard and transmission-based precautions) so that the worker can recognize tasks and other activities that may involve occupational exposure and take precautionary measures; information on vaccines that will be made available to the worker, 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 reasonable times and places at no cost to the worker; an explanation of the employer's WICP and the means by which the worker can obtain a copy of the plan; training on all of the SOPs developed as part of the WICP that are applicable to the worker'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 PPE.

OSHA believes that the approach taken in the regulatory framework would ensure that important information is communicated to workers that will enable workers to understand the hazards associated with infectious agents, while, at the same time, allowing employers the most flexible approach to providing training.

Recordkeeping

Like OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030), per the regulatory framework, OSHA would require a recordkeeping element in an infectious diseases rule. Per Section 7 of the regulatory framework, OSHA would require the employer to maintain medical records and exposure incident records for at least the duration of employment, plus 30 years. Maintenance of records for 30 years is currently a provision in the BBP standard. Like some of the diseases covered by the BBP standard (i.e., HIV and Hepatitis B), infectious diseases that would be covered under the ID rule may also have chronic, long-term effects such as cancer, negative reproductive consequences, and organ damage (e.g., lung damage from TB).

In addition, the employer would be required to retain records of WICP reviews for three years. The maintenance of WICP review records is important for employers to assure that they have addressed prior concerns as part of the continuous improvement process. The maintenance of exposure incident records would allow the employer to document elements such as the work setting and work task(s) being performed when the exposure incident(s) occurred, which would, in turn, allow the employer to focus efforts on decreasing or eliminating specific circumstances or routes of occupational exposures. The maintenance of medical records is essential to permit proper evaluation of the worker's immune status and proper healthcare management following an exposure incident. And the maintenance of all three types of records is important to allow

compliance with the potential obligation in the regulatory framework to make such records available to workers and OSHA upon request.

Cost and Availability

Per the regulatory framework, OSHA would require that the implementation of all requirements be at no cost to the worker, that all time required by a worker to comply, including time for training, medical evaluations/procedures, and reasonable travel time (as appropriate), be considered compensable time, and that any required medical evaluations and procedures (including vaccinations and post-exposure evaluation and follow-up) and training be made available to the worker at reasonable times and places. OSHA believes that requiring employers to pay workers for the time associated with compliance with a rule as outlined in the regulatory framework, and giving workers reasonable opportunities to participate in medical evaluations and procedures and training, will help encourage worker participation in (and therefore increase the effectiveness of) a rule as outlined in the regulatory framework, and would help OSHA to ensure that employers are making good faith efforts to comply.

Section V. Description of the Entities, Establishments, and Employees Likely to be Affected by a Rule as Outlined in the Regulatory framework

Introduction

In this section of the SER Background Document, OSHA provides preliminary estimates of the number of affected entities, establishments, and employees for the industries that have settings that would be affected by a rule as outlined in the regulatory framework. The term "entity" describes a legal for-profit business, a non-profit organization, or a local governmental unit, whereas the term "establishment" describes a particular site of economic activity. Some entities own and operate more than one establishment.

As discussed in Section IV of this SER Background Document, OSHA would cover settings where direct patient care is provided and settings where other covered tasks are performed. The Agency has translated the settings where these tasks will be performed into the following four categories: (1) settings where direct patient care is provided; (2) settings where there are contaminated materials originating from settings where direct patient care is provided; (3) settings where there is exposure to human remains; and (4) diagnostic, research, and production laboratory facilities, where there is exposure to contaminated materials.

This analysis focused on worker tasks and the industries where those tasks that would expose workers to infectious agents would be performed.[49] This method accounts for the fact that an establishment may employ both workers who perform direct patient care and workers who perform other covered tasks (as those terms are used in the regulatory framework). For example, in hospital settings, doctors and nurses provide direct patient care, while custodial workers perform other covered tasks.

Finally, this analysis accounts only for entities that have employees. Entities that do not have employees (e.g., self-employed individuals) are not covered by OSHA.[50]

OSHA requests comments on the preliminary estimates in this section with respect to two issues. First, has OSHA stated clearly in the regulatory framework who would be covered by a rule as outlined in the regulatory framework, or would additional clarification of scope terms such as, "direct patient care", "other covered tasks", and "occupational exposure", be needed? Second, is the scope of worker tasks that would be covered appropriate? Should OSHA cover more types of worker tasks than are envisioned in the regulatory framework? Alternatively, should OSHA cover fewer worker tasks?

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[49] The setting "First Aid & Emergency Care" does not include settings where the only relevant task performed by employees is solely the provision of first aid by workers who are not medical caregivers. Pursuant to the regulatory framework, employees who are not medical personnel but who provide first aid only are not considered to provide direct patient care.

[50] This section of the SER Background Document lists OSHA's estimates, without describing in detail how OSHA derived those estimates. OSHA will provide SERs with a fuller description of its analysis upon request.

Criteria for Determining Whether For-Profit Businesses, Non-Profit Organizations, and Governmental Units are Small Entities

There are three types of small entities under the RFA: (1) small businesses; (2) small non-profit organizations; and (3) small governmental jurisdictions. The Small Business Administration (SBA) uses the North American Industry Classification System (NAICS) as a basis for determining whether businesses are small for given industries. SBA size criteria vary by industry, but are usually based on either number of employees or revenue.[51] A small non-profit organization is any not-for-profit enterprise that is independently owned and operated and not dominant in its field. Finally, a small governmental jurisdiction is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

Table V-1 displays size criteria, derived from SBA definitions, for for-profit entities that OSHA believes would be affected by a rule as outlined in the regulatory framework.

For the purposes of the analysis in Table V-1, OSHA grouped entities into aggregate categories made up of entities that are performing similar types of healthcare services or other covered tasks. These aggregated settings include entities from various NAICS industries. Since each six-digit NAICS industry has its own threshold for being considered a small entity by SBA, the SBA size criteria often appear as ranges in Table V-1. The SBA criteria and corresponding OSHA-estimated employee size thresholds by six-digit NAICS industry are presented in Appendix A at the end of this document. (OSHA converted the SBA revenue criteria for for-profit entities to an equivalent employee size threshold, as shown in Table V-1.)[52]

The SBA criteria and corresponding OSHA-derived employee size thresholds are more fully documented in Appendix A at the end of this document.

[51] *See* 13 CFR § 121.201. These other measures are sometimes product output measures.

[52] For those industries with a revenue criterion, OSHA calculated the average revenue for each employment size class in the Census data and identified the largest size class where average revenue is less than the SBA definition. Only one SBA criterion listed in Appendix A is based on neither revenue nor number of employees. That SBA criterion is based on megawatt hours, and is associated with the Electric Power Generation, Transmission, and Distribution Industry only.

Table V-1. SBA Size Definitions for For-Profit Entities by Setting				
Setting	**SBA size criteria based on revenue (range, if applicable) ($millions)**	**SBA size criteria based on other criteria**	**SBA size criteria based on number of employees (range, if applicable)**	**SBA Criteria converted to employees (range, if applicable)**
Offices of Physicians	$10			100
Offices of Dentists	$7			100
Other Patient Care	$2 - 35.5			10 - 500
First Aid & Emergency Care	$7 - 30			100 - 500
Hospitals	$7 - 34.5			100 - 500
Nursing Homes	$7 - 13.5			500
Home Healthcare	$7 - 13.5			100 - 500
Laboratories	$12 - 13.5		500	100 - 500
Embedded Clinics in Schools	$7			100 - 500
Embedded Clinics in Correctional Facilities	$35.5			500
Morgue/Mortuaries	$7			100
Embedded Clinics in Industry	$7 - 25.5	4 million megawatt hours	100 - 1,500	100 - 1,500
Medical Equipment Activities	$7			20 - 100
Waste Collection & Handling & Commercial Laundries	$12.5 - 35.5			100 - 500

Note: There are some ranges in the SBA criteria above because some settings contain multiple NAICS industries with non-identical size or revenue thresholds.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on SBA, 2010 and Census Bureau, 2007.

Affected Entities and Establishments

Table V-2 presents OSHA's preliminary estimate of the number of affected entities, establishments, small entities, and very small entities (i.e., entities with fewer than 20 employees) for each type of setting presented above. This preliminary estimate shows that, out of an estimated 637,000 entities that would be affected by a rule as outlined in the regulatory framework, approximately 625,000 are SBA-defined small entities and approximately 555,000 are very small entities. Moreover, approximately 217,000 of the affected SBA-defined small entities are non-profit.

Table V-2. Total Affected Entities and Establishments by Size and Setting				
Setting	All Entities	All Establishments	SBA Defined Small Entities	Entities With Fewer Than 20 Employees
Offices of Physicians				
Private For-Profit and Government-Owned	182,128	209,792	179,417	164,521
Non-Profit	8,954	10,314	8,954	8,088
Offices of Dentists				
Private For-Profit and Government-Owned	119,758	127,530	119,570	116,053
Non-Profit	426	454	426	413
Other Patient Care				
Private For-Profit and Government-Owned	45,656	54,067	44,183	40,487
Non-Profit	7,090	10,187	7,090	6,288
First Aid & Emergency Care				
Private For-Profit and Government-Owned	2,653	3,579	2,375	1,736
Non-Profit	1,016	1,474	1,016	665
Hospitals				
Private For-Profit and Government-Owned	2,240	3,919	338	276
Non-Profit	1,773	2,992	1,773	218
Long Term Care and Nursing Homes				
Private For-Profit and Government-Owned	22,010	41,410	20,026	11,012
Non-Profit	12,368	31,771	12,368	6,188
Home Healthcare				
Private For-Profit and Government-Owned	16,155	24,000	14,062	14,175
Non-Profit	179,486	181,214	179,486	157,491
Laboratories				
Private For-Profit and Government-Owned	4,351	6,421	4,020	3,396
Non-Profit	288	398	288	225
Embedded Clinics in Schools				
Private For-Profit and Government-Owned	3,014	10,200	2,217	1,420
Non-Profit	4,574	5,229	4,574	2,155
Embedded Clinics in Correctional Facilities				
Private For-Profit and Government-Owned	599	962	386	223
Non-Profit	0	0	0	0
Morgue/Mortuaries				
Private For-Profit and Government-Owned	9,628	12,420	9,416	8,934
Non-Profit	1,338	1,744	1,338	1,241
Embedded Clinics in Industry				
Private For-Profit and Government-Owned	2,320	2,960	2,198	1,845
Non-Profit	3	5	3	3
Medical Equipment Activities				
Private For-Profit and Government-Owned	3,459	7,635	3,311	3,041
Non-Profit	5	11	5	4
Waste Collection & Handling & Commercial Laundries				
Private For-Profit and Government-Owned	6,140	7,736	5,918	5,163
Non-Profit	33	40	33	28
Total				
Private For-Profit and Government-Owned	**420,111**	**512,631**	**407,439**	**372,280**
Non-Profit	**217,354**	**245,833**	**217,354**	**183,006**
Total - All	**637,465**	**758,464**	**624,793**	**555,286**

Note: OSHA assumes that all non-profits are small entities by SBA criteria.
Totals may not equal the sum of the components due to rounding

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on Census Bureau, 2007, Census Bureau, 2009, and BLS, 2010.

Affected Employees

Tables V-3a, V-3b, and V-3c present, by size and setting, OSHA's preliminary estimates of the number of employees that would be affected by a rule as outlined in the regulatory framework, including employees that provide direct patient care and employees that perform other covered tasks, and the total number of employees in both groups (i.e., the total number of employees that would be affected by a rule as outlined in the regulatory framework). As shown in Table V-3c, OSHA preliminarily estimates that approximately 9 million employees would be affected by a rule as outlined in the regulatory framework, and that of these, about 5.8 million are employed by SBA-defined small entities. These preliminary estimates show that approximately 2.2 million workers in SBA-defined for-profit small entities and small government entities provide direct patient care, while an additional 203,000 workers in those entities are engaged in other covered tasks (as those terms are used in the regulatory framework). The Agency preliminarily estimates that approximately 3 million workers provide direct patient care, and 300,000 workers perform other covered tasks, at SBA-defined small, non-profit entities. OSHA preliminarily estimates that 1.5 million workers are employed by entities with fewer than 20 employees, where approximately 1.3 million workers provide direct patient care, while about 140,000 perform other covered tasks.

Table V-3a. Number of Affected Employees Providing Direct Patient Care by Size Classification and			
	Number of Employees at:		
Setting	All Entities	SBA Defined Small Entities	Entities with Fewer than 20 Employees
Offices of Physicians			
Private For-Profit and Government-Owned	1,049,598	655,817	460,179
Non-Profit	175,473	175,473	76,933
Offices of Dentists			
Private For-Profit and Government-Owned	543,261	506,956	476,988
Non-Profit	3,401	3,401	2,986
Other Patient Care			
Private For-Profit and Government-Owned	393,261	167,746	71,485
Non-Profit	133,689	133,689	24,301
First Aid & Emergency Care			
Private For-Profit and Government-Owned	88,881	34,338	14,740
Non-Profit	29,317	29,317	4,862
Hospitals			
Private For-Profit and Government-Owned	1,135,344	60,518	266
Non-Profit	1,995,594	1,995,594	468
Long Term Care and Nursing Homes			
Private For-Profit and Government-Owned	1,112,497	543,940	92,543
Non-Profit	594,079	594,079	49,419
Home Healthcare			
Private For-Profit and Government-Owned	504,525	233,617	37,976
Non-Profit	130,573	130,573	9,828
Embedded Clinics in Schools			
Private For-Profit and Government-Owned	39,908	4,245	3,367
Non-Profit	13,000	13,000	1,097
Embedded Clinics in Correctional Facilities			
Private For-Profit and Government-Owned	10,440	282	85
Non-Profit	0	0	0
Embedded Clinics in Industry			
Private For-Profit and Government-Owned	4,101	2,007	453
Non-Profit	25	25	3
Medical Equipment Activities			
Private For-Profit and Government-Owned	3,890	1,425	2,937
Non-Profit	0	0	0
Waste Collection & Handling & Commercial Laundries			
Private For-Profit and Government-Owned	1,135	487	348
Non-Profit	7	7	2
Total Direct Patient Care			
Private For-Profit and Government-Owned	**4,886,841**	**2,211,378**	**1,161,368**
Non-Profit	**3,075,159**	**3,075,159**	**169,900**
Total Direct Patient Care - All	**7,962,000**	**5,286,537**	**1,331,268**

Note: Totals may not equal the sum of the components due to rounding.
Source: see Table V-3c.

Table V-3b. Number of Affected Employees Performing Other Covered Tasks by Size and Setting			
	Number of Employees at:		
Setting	All Entities	SBA Defined Small Entities	Entities with Fewer than 20 Employees
Offices of Physicians			
Private For-Profit and Government-Owned	11,312	6,358	4,959
Non-Profit	1,891	1,891	829
Offices of Dentists			
Private For-Profit and Government-Owned	5,147	4,800	4,519
Non-Profit	32	32	28
Other Patient Care			
Private For-Profit and Government-Owned	59,862	19,756	3,247
Non-Profit	698	698	38
First Aid & Emergency Care			
Private For-Profit and Government-Owned	233	38	38
Non-Profit	80	80	13
Hospitals			
Private For-Profit and Government-Owned	151,699	18,341	36
Non-Profit	208,618	208,618	49
Long Term Care and Nursing Homes			
Private For-Profit and Government-Owned	128,767	33,314	6,396
Non-Profit	56,804	56,804	2,822
Home Healthcare			
Private For-Profit and Government-Owned	1,910	528	263
Non-Profit	974	974	134
Laboratories			
Private For-Profit and Government-Owned	196,383	43,253	36,668
Non-Profit	25,270	25,270	4,718
Embedded Clinics in Schools			
Private For-Profit and Government-Owned	48	204	4
Non-Profit	352	352	32
Embedded Clinics in Correctional Facilities			
Private For-Profit and Government-Owned	4,368	800	264
Non-Profit	0	0	0
Morgue/Mortuaries			
Private For-Profit and Government-Owned	63,319	47,468	46,387
Non-Profit	6,987	6,987	5,119
Embedded Clinics in Industry			
Private For-Profit and Government-Owned	7,556	2,314	1,511
Non-Profit	4	4	1
Medical Equipment Activities			
Private For-Profit and Government-Owned	21,298	7,682	15,126
Non-Profit	2	2	1
Waste Collection & Handling & Commercial Laundries			
Private For-Profit and Government-Owned	48,439	18,466	11,738
Non-Profit	168	168	41
Total Other Covered Tasks			
Private For-Profit and Government-Owned	**700,340**	**203,323**	**131,156**
Non-Profit	**301,880**	**301,880**	**13,825**
Total Other Covered Tasks - All	**1,002,220**	**505,203**	**144,981**

Note: Totals may not equal the sum of the components due to rounding.
Source: see Table V-3c.

Table V-3c. Total Affected Employees by Size and Setting			
	Number of Employees at:		
Setting	All Entities	SBA Defined Small Entities	Entities with Fewer than 20 Employees
Total Affected Employees			
Private For-Profit and Government-Owned	**5,587,181**	**2,414,701**	**1,292,524**
Non-Profit	**3,377,040**	**3,377,040**	**183,725**
Total Affected Employees - All	**8,964,221**	**5,791,741**	**1,476,249**

Note: Totals may not equal the sum of the components due to rounding.

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on Census Bureau, 2007, Census Bureau, 2009, and BLS, 2010.

Section VI. Description of Potential Impacts of a Rule as Outlined in the Regulatory framework

A. Introduction

In this section, OSHA presents preliminary estimates of potential impacts on employers who would be required to come into compliance with the provisions of a rule as outlined in the regulatory framework. Here and throughout this SBAR Panel process, the Agency will not be presenting aggregate costs but, instead, will be focusing on potential impacts presented in their simplest and most natural units of measure—sometimes as dollars and sometimes as time requirements. The potential impacts of concern here are those of a single item or action, such as a worker receiving a vaccination. In this example, there would be two relevant impacts: (1) the cost of a single dose of the vaccine, reported in dollars; and (2) the time necessary for a nurse to provide, and the worker to receive, the vaccine, reported in minutes or hours. Such impacts help generalize the discussion because many unit costs do not vary by setting or establishment size.

While the unit costs may be the same for various types and sizes of settings, the total costs will be highly dependent on the type of facility and on the number and types of infectious agents a given facility would typically encounter. Some of the costs would be incurred one time, up front for all facilities (e.g., developing a WICP or written respiratory protection program if the facility currently does not have one), but many of the costs (e.g., hand hygiene or PPE use) are based on the number of interactions workers have with infectious patients or materials. In addition, the flexibility inherent in a program standard allows employers whose facilities generally do not treat infectious patients to take simple steps to deal with such patients. For example, a small podiatrist's or dentist's office could simply require patients presenting with flu-like symptoms or symptoms of a respiratory illness to reschedule their appointments, rather than implement full droplet and/or airborne precautions for their workers. (The offices would, however, still be required to institute Standard Precautions for their workers). Some of these various compliance methods were addressed in Section IV of this document, and, throughout this section, OSHA will discuss how the total costs of a provision might vary based on the type or size of a facility.

For the purposes of the SBREFA process and panel, OSHA developed preliminary estimates of unit costs for almost all items in the regulatory framework that would result in costs to employers if those items were included in a rule. As mentioned above, these unit costs account for the cost or time for a single item to be purchased or for a single action to be taken. In developing these estimates, OSHA based unit costs on those actions and costs the Agency preliminarily determined an employer would need to undertake or bear to comply with the regulatory framework. OSHA assigned costs in either dollars, for items that would need to be purchased, or in time, where an action would need to be taken. OSHA preliminarily concludes that some provisions of the regulatory framework would not have associated costs because, for example,

the Agency believes that a provision is already standard practice or that complying with a provision would require only a modification of current practices without requiring additional time or resources. OSHA presents a summary table, Table VI-9, that shows all estimated unit costs at the end of this section.

In addition to preliminary estimates of unit costs, OSHA developed preliminary estimates of levels of current compliance with many of the provisions of a rule as outlined in the regulatory framework. These estimates are discussed in more detail throughout this section of the SER Background Document.

1. Preliminary Estimates of Unit Costs

An employer's total costs will depend on: the number of employees the employer has that would be affected under the scope of a rule as outlined in the regulatory framework; the number of times certain procedures would need to be completed or the number of nondurable items (such as gloves, soap, or vaccines) employees would need to use to comply with a rule as outlined in the regulatory framework; the hours that would be needed to ensure that contractors, vendors, and licensed independent practitioners with privileges, at a minimum, adhere to infection control practices consistent with the employer's WICP (assuming the employer is a host employer); and the extent to which the employer is already in compliance with provisions in the regulatory framework. OSHA is still in the process of developing estimates for these elements. Most importantly, the Agency has not yet made a preliminary determination as to the number of workers who would be subject to the requirements of any given potential provisions (i.e. how many workers will need to be vaccinated or how many workers will receive respirator fit-testing). Because the work to develop key estimates is still in progress, OSHA will not be presenting total costs as a part of this SER Background Document.

2. Preliminary Estimates of Current Compliance

The preliminary analysis in this section of the SER Background Document summarizes preliminary evidence of current baseline compliance in settings that would be subject to a rule as outlined in the regulatory framework. The source of this data is a Draft Report on the Expert Elicitation on Infectious Disease Control in Healthcare and Other Settings (hereafter "Draft Report on Current Compliance" or "Draft Report"), conducted by OSHA's contractor, Eastern Research Group, Inc. ("ERG"), in 2013. As with other non-copyrighted references in this SER Background Document, the Draft Report is available online under docket number OSHA-2010-0003.[53]

[53] The categorization of settings used in the Draft Report differs slightly from that presented in Section V, Description of the Entities, Establishments, and Employees Likely to be Affected by a Rule as Outlined in the regulatory framework, in this SER Background Document. Please see Table VI-10 at the end of this section of the SER Background Document for the categorization used in the Draft Report on Current Compliance. For more information, please see the full Draft Report.

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 throughout this section of the SER Background Document. If OSHA engages in rulemaking, it will take any such feedback into consideration in preparing a preliminary estimate of baseline compliance and total costs to industry.

OSHA's preliminary estimates of current levels of compliance, presented in this section of the SER Background Document, are the average of the experts' responses, which were weighted based on the experts' self-reported confidence levels. The experts were asked to judge their levels of confidence in their answers to both the overall questions and the occupational settings at issue in the questions, and those levels of confidence were used to give proportionally more weight to answers given by more confident respondents (see Section 2.2.6 of the Draft Report). While the range of answers varied widely on many questions and for many settings (see Appendix A to the Draft Report), the weighted average and the median were relatively close. As stated above, OSHA has made no final determination on current levels of compliance and seeks additional feedback from the SERs on the preliminary estimates of levels of compliance presented in this section of the SER Background Document.

OSHA discusses specific estimates of baseline compliance in relevant parts of this section of the SER Background Document. See Table VI-10, at the end of this section of the SER Background Document, for more details regarding OSHA's preliminary estimates of compliance. And as stated earlier, ERG's full Draft Report is available in the docket.

3. Request for Feedback

OSHA encourages the SERs to comment on all elements of this preliminary cost analysis, including the preliminary estimates presented here and any estimates not presented because the Agency is still in the process of developing them. OSHA solicits comments about the following issues:

- Are the unit costs that are presented in this 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 the understanding of the SERs?

- Are the Agency's preliminary estimates of current compliance consistent with what the SER's have observed in their own industries?

- Are the Agency's preliminary determinations with respect to the provisions of the regulatory framework for which most employers would not incur additional costs, over and above current practice, consistent with the understanding of the SERs? If not, what additional costs, over and above current practice, would employers need to bear to comply with the relevant provisions of a rule as outlined in the regulatory framework?

- 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?

OSHA will solicit further comment on specific cost issues throughout this section of the SER Background Document, but also welcomes comments on issues not specifically addressed. OSHA considers the feedback and information provided by the SERs to be a very important part of the development of the preliminary economic analysis and the initial regulatory flexibility analysis and welcomes all comments.

B. Potential Impacts of Provisions in the Regulatory framework

1. Worker Infection Control Plan (WICP)

Per the regulatory framework, OSHA would require employers to develop written WICPs designed to prevent or minimize the transmission of infectious agents to each worker. The WICP could be part of a larger plan, such as one addressing patient safety or bloodborne pathogens, but, in such cases, the WICP would need to be a cohesive document, in and of itself, or there would need to be a guiding document that identifies the elements of the larger plan that comprise the WICP.

OSHA would require that the WICP include a write-up of 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;
- An exposure determination; and
- The SOPs for the employer's work setting(s).

OSHA would require employers to review and update the WICP at least annually, and to share the WICP with contractors, vendors, licensed, independent practitioners with privileges, and the employer's workers.

As shown in Table VI-1, below, OSHA preliminarily estimates that the time required initially to complete a written WICP ranges from 20 hours for lower risk work settings to 40 hours for higher risk work settings. Lower risk work settings are work settings, such as embedded clinics in schools and industry and medical equipment handling and reprocessing facilities, that have fewer types of healthcare workers and where workers either have fewer encounters with potentially infectious patients or are potentially exposed to fewer types of infectious agents. Higher risk work settings are work settings, such as hospitals and other patient care settings, that have the most types of healthcare workers and where workers have more encounters with potentially infectious patients and are potentially exposed to the widest range of possible infectious agents.

The estimates presented here and below in Table VI-1 with respect to initial development of the WICP are based on the median estimates of the time necessary to prepare a WICP, as estimated by the expert panel on current compliance. These time estimates assume that employers would be formulating a WICP from start to finish and do not take into account the fact that some employers currently have WICPs that would be either partially or fully in compliance with a rule as outlined in the regulatory framework. One participant in the panel initially suggested that it would take a hospital 2,880 hours to develop a WICP, but reduced this response to 480 hours in a second round of questioning (see Section 4.1 of the Draft Report). The remaining experts reported that facilities could augment or tweak available templates to fit their particular settings (*Id.*). Given the availability of infection control plans for purchase, OSHA believes the preliminary estimates in Table VI-1 are reasonable, but the Agency is still developing the estimates and would be interested in feedback from the SERs on the issue.

As shown in Table VI-1, OSHA preliminarily estimates that the time necessary to review and update a WICP annually, and to share the WICP with all affected parties, would range from four hours for lower risk work settings to sixteen hours for the highest risk industry—hospitals. As with the preliminary estimates of WICP development time, these estimates are based on the responses of the expert panel.

Table VI-1		
Worker Infection Control Plan		
Estimated Compliance Burden per Establishment in Hours		
Setting	Initial Development	Annual review and update
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.

Costs related to developing and updating a WICP would be incurred by all facilities not currently in compliance with this potential provision. As shown in Table VI-1, different types of settings would have different costs, a variability that is based on the number of patients, the volume of infectious materials handled, and the number of types of infectious diseases that might be encountered, in different types of settings. Some facilities may have even lower costs to develop their plans than the costs shown in Table VI-1 if their workers do not have reasonably anticipated exposure to certain types of infectious diseases. For example, an employer would only incur costs to develop a plan related to contact-transmissible diseases if the employer reasonably anticipates that workers would be exposed to contact-transmissible diseases.

Based on the estimates of the experts questioned by OSHA's contractor, the Agency preliminarily estimates that about 94 percent of hospitals, 90 percent of long term care facilities and nursing homes, and 90 percent of laboratories have a written WICP (see Table VI-10 and Draft Report). On the other hand, just 39 percent of establishments in "other occupational settings," which includes morgues and mortuaries, waste collection and handling services, and laundry services, are preliminarily estimated to have a written WICP (*Id.*). Finally, between about 40 and 60 percent of establishments in the other settings examined are preliminarily estimated to have a written WICP (*Id.*).

Also, based on the estimates of the experts questioned by OSHA's contractor, the Agency preliminarily estimates that most hospitals (77 percent) and laboratories (70 percent), as well as a majority of nursing home and long-term care facilities (63 percent), review their WICPs on an annual basis (*Id.*). A smaller percentage of physicians' offices (16 percent), dentists' offices (18 percent), and "other occupational settings" (12 percent) are preliminarily estimated to review their WICPs annually. OSHA welcomes feedback from the SERs on these preliminary estimates of current levels of compliance (*Id.*).

2. Implementation of Standard Operating Procedures ("SOPs")

OSHA is presenting the potential impacts for implementation of the elements of the SOPs laid out in the regulatory framework. Under a rule as outlined in the regulatory framework, individual employers would not incur costs associated with all of these elements since the SOPs each employer develops would be dependent on the types of risk seen in that employer's work setting(s). For example, a dentist's office would not incur costs to maintain an airborne infection isolation room (AIIR) since this type of establishment would not have one. Where OSHA has estimated that only certain settings are affected by a given provision in the regulatory framework, the unit costs are presented for those settings only. In addition, OSHA has preliminarily found that the implementation of some of these procedures will involve changes in work practices without additional time or equipment costs, other than those costs associated with incorporating these new work practices into a WICP, which is addressed above, and training on these new work practices, which is addressed below.

a. SOPs For All Affected Work Settings

Per the regulatory framework, all employers would be required to develop and implement certain SOPs, including SOPs on:

Infectious Agent Hazard Evaluations and Communication of Hazard Evaluation Results

Per the regulatory framework, OSHA would require employers to implement SOPs for the conduct of infectious agent hazard evaluations to identify suspected or confirmed sources of infectious agents. Based on OSHA's current thinking, the hazard evaluation would not need to be a written document and could be incorporated into routine activities, such as triage and patient scheduling. OSHA would require the employer to communicate the results of the hazard evaluation and the status of any suspected or confirmed sources of infectious agents to the person(s) responsible for implementing appropriate worker protection precautions.

OSHA preliminarily concludes that performing an infectious agent hazard evaluation, and communicating the results of that evaluation, as those potential provisions are laid out in the regulatory framework, would not take additional time over existing practice, and could be accomplished by modifying current job duties. Additional training (discussed later in this section of the SER Background Document) would provide workers with the background

knowledge and procedures necessary to perform evaluations and communicate results in the course of their normal job duties.

Moreover, per the Draft Report of Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that 81 percent of hospitals, and 79 percent of long-term care facilities and nursing homes, already conduct infectious agent hazard evaluations. OSHA also preliminarily estimates that only 20 percent of establishments in "other occupational settings," which includes morgues and mortuaries and waste handling and laundry services, only 28 percent of dentists' offices and between about 40 and 60 percent of establishments in the remaining settings already conduct these activities. As mentioned previously, OSHA considers these estimates to be preliminary and is interested in incorporating feedback from the SERs on current levels of compliance in preparing final estimates for the preliminary economic analysis.

OSHA is interested in any information the SERs have on this issue. OSHA also asks the following:

- How are hazard evaluations currently performed and how are those results communicated to the relevant parties?
- Would conducting a hazard evaluation, as described both above and in Section IV of this document, require additional time above that preliminarily estimated by OSHA?
- To what extent are facilities currently complying with this potential requirement?

Hand Hygiene

Per the regulatory framework, OSHA would require employers to have SOPs to ensure that handwashing facilities are available and accessible, and that recognized and generally accepted good infection control practices for hand hygiene are followed. CDC recommendations on hand hygiene vary depending on the specific circumstances. In general, CDC recommends handwashing with soap and water, or if handwashing facilities are not available, using alcohol-based hand sanitizers containing at least 60 percent alcohol (CDC, 2013c). In situations where healthcare workers (HCWs) are routinely providing care to numerous patients, CDC recommends, in the absence of visible soiling of hands, using approved alcohol-based hand sanitizers rather than soap and water (CDC, 2002a). Using such hand sanitizers improves hand hygiene compliance due to their convenience and lower levels of associated dermatitis. In laboratories, however, CDC/NIH recommends handwashing with soap and water (CDC/NIH, 2009).

OSHA preliminarily estimates, based on WHO recommendations (WHO 2011a, WHO 2011b), that proper hand hygiene using soap and water washing takes 50 seconds of a worker's time, and that hand hygiene using an alcohol-based hand sanitizer in an effective manner takes 25 seconds of a worker's time. These times are estimated to be consistent across all settings within the scope of the regulatory framework.

While the time necessary to perform hand hygiene is consistent across facilities, the total costs of implementing SOPs for hand hygiene would vary based on the number of employees, the number of patients with which those employees interact on a daily basis (or, for workers handling infectious materials, the number of times gloves are removed during a work shift), and the type of hand hygiene (soap and water or alcohol-based) employed. Hand hygiene should be performed at a minimum 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) or, 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 anytime ungloved hands come into contact with known or suspected contaminated materials. Second, since alcohol-based hand rubs take less time for employees to use and the dispensers can be easily mounted in most settings, employers may, in certain situations, be able to achieve compliance with this potential provision in a less costly manner.

In small facilities that have only a few employees who interact directly with patients, the number of times hand hygiene is performed, and therefore the cost of implementing SOPs for hand hygiene, would be considerably lower than the corresponding numbers for large providers with many employees and patients. Likewise, in settings where other covered tasks are performed, like laundry facilities, waste handling facilities, or laboratories, the costs for hand hygiene would depend on the number of employees. As a result, a smaller facility would have lower total costs. The cost to individual facilities will also depend on the extent to which workers are currently performing hand hygiene. If the workers in a given facility are always, or almost always, performing appropriate hand hygiene, the additional costs to comply with a rule based on OSHA's regulatory framework would be low compared to the higher costs in a comparably-sized facility where workers do not currently perform appropriate hand hygiene.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that workers in laboratories have the highest baseline compliance rate (practicing proper hand hygiene 80 percent of the time), that workers in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, have the lowest baseline compliance rate (practicing proper hand hygiene 34 percent of the time), and that workers in the remaining settings practice proper hand hygiene about 50 to 60 percent of the time. The Agency welcomes feedback from the SERs on these preliminary estimates of current compliance.

Food and Cosmetics

Per the regulatory framework, OSHA would require implementation of procedures for restricting, to areas where there is no occupational exposure during provision of direct patient care and/or performance of other covered tasks, activities such as eating, drinking, smoking, applying cosmetics or lip balm, handling contact lenses, and storing food and drink.

OSHA preliminarily concludes that such restrictions are standard practice in all healthcare facilities and in facilities that handle potentially contaminated waste and, therefore, that employers would not incur costs to comply with this provision in a rule as outlined in the regulatory framework.

The Agency is interested in any feedback on this issue the SERs may have to offer. Do the SERs agree with OSHA's determination that there are no costs associated with this potential provision? What additional actions, if any, would employers need to take, or what costs might they incur, to comply with this potential provision?

Engineering Controls

Per the regulatory framework, OSHA would require employers to implement procedures to examine existing engineering controls on a regular schedule and to ensure that those controls are maintained or replaced to ensure their effectiveness and thereby provide their intended protections. OSHA would also require that employers that have healthcare settings with airborne infection isolation rooms (AIIRs) implement procedures for ensuring proper AIIR operation. These would include procedures for ensuring that each AIIR, associated ducting, and filtration are constructed, operated, and maintained so that they maintain negative pressure, achieve sufficient air changes per hour, properly exhaust contaminated air, and function to prevent or minimize transmission of infectious agents, and for ensuring that, when in use, each AIIR is monitored daily for maintenance of negative pressure. Finally, in diagnostic, research, and production laboratory facilities, OSHA would require procedures to ensure the appropriate construction, operation, and maintenance (e.g., proper air flow, exhaust air filtration, double access doors, special design requirements for Biosafety Level 3 and 4 facilities) of engineering controls (such as biosafety cabinets (BSCs), laboratory hoods, and other laboratory design and containment measures).

OSHA has preliminarily estimated that certain types of engineering controls currently used to control the spread of infectious agents (e.g., AIIRs, autopsy suites, and BSCs) may need to be upgraded or improved by some establishments to comply with a rule as outlined in the regulatory framework. The Agency does not anticipate that such a rule would result in the installation of new or additional engineering controls. And OSHA expects that many of the sectors affected by a rule as outlined in the regulatory framework 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.

For the purposes of this preliminary analysis, OSHA is estimating the cost of upgrading and maintaining AIIRs, autopsy suites, and BSCs. These estimates include one-time costs to upgrade

or perform major maintenance in order to bring existing AIIRs, autopsy suites, and BSCs into compliance with accepted engineering or other recognized and accepted standards and yearly costs thereafter for facilities to continue to maintain those controls in working order. Under a rule as outlined in the regulatory framework, these potential upgrading and maintenance costs would only be incurred by facilities that (1) have these types of engineering controls and (2) are not currently maintaining those controls to the proper standards.

Based on analyses performed in conjunction with OSHA's proposed rule addressing occupational exposure to tuberculosis (TB), 64 FR 54160 (Oct. 17, 1997), the Agency preliminarily estimates that, for those facilities that would need to do so, there would be a one-time cost of $7,217 to upgrade an AIIR so that it functions properly (e.g., maintains negative air pressure relative to the surrounding areas, completes the recommended number of hourly air exchanges). This is based on an estimated cost of approximately $48 per square foot to purchase and install material, including ducting, fans, and HEPA filters, in an average isolation room measuring 150 square feet (WCG, 1994, updated to 2012 dollars). OSHA also preliminarily estimates that it will cost $866 annually for facilities that are not properly maintaining their existing AIIRs to do so (an estimated 12 percent of the cost of upgrading an AIIR). This maintenance cost would be incurred annually and represents the cost to facilities to properly maintain their AIIRs during a given year. The provisions of a rule as outlined in the regulatory framework would not require facilities that do not have AIIRs to install them, and OSHA expects that costs associated with upgrading and maintaining AIIRs would only apply to hospitals, and that some percentage of facilities would not incur costs relating to upgrading or maintaining AIIRs because they either do not have AIIRs or are already properly maintaining them.

OSHA also preliminarily concludes that some funeral homes, morgues and mortuaries, and hospitals would need to upgrade their autopsy suites to comply with a rule based on the regulatory framework. The Agency preliminarily estimates that these upgrades will cost $14,435 per facility, which includes the installation of HEPA filtration, if necessary, and upgrading ventilation systems to achieve adequate negative pressure (WCG, 1994, updated to 2012 dollars) and represents a one-time cost for facilities that would need to bring their existing autopsy suites into compliance with existing engineering standards or other applicable guidelines or specifications. In addition to those upgrades, OSHA estimates that facilities not currently maintaining their autopsy suites would incur annual maintenance costs of $1,732 annually (estimated at 12 percent of the cost of upgrading an autopsy suite). OSHA preliminarily concludes that only hospitals, morgues, and mortuaries have autopsy suites and some of these establishments would incur such costs. The remaining establishments are preliminarily believed to be maintaining their autopsy suites to industry standards.

Finally, OSHA preliminarily concludes that some diagnostic, research, and production laboratory facilities – including clinical laboratories which can be located within a hospital – would need to

upgrade and properly maintain their existing BSCs. The Agency preliminarily estimates that it would cost $809 initially for a BSC to be upgraded properly and $97 for a BSC to be maintained properly (OSHA, 1997, updated to 2012 dollars). The initial cost represents a one-time cost for facilities that would need to upgrade or perform major maintenance on their existing equipment in order to bring it into compliance with existing applicable guidelines or standards. The annual cost would be incurred each year by facilities in order to continue to properly maintain their upgraded equipment. Establishments whose BSCs are currently being maintained properly would not incur any additional maintenance costs associated with a rule as outlined in the regulatory framework. OSHA preliminarily concludes that only hospitals and diagnostic, research, and production laboratory facilities will have BSCs.

OSHA summarizes the unit costs associated with engineering controls in Table VI-2, below.

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.

Because of the flexibility of the regulatory framework, a facility with an AIIR that does not want to upgrade and maintain that room would not need to do so as long as the facility does not use the room for isolation purposes. (However, per the regulatory framework, this facility would need to develop SOPs for the temporary isolation and inter-facility transfer of individuals with suspected or confirmed airborne infectious diseases to facilities with functional AIIRs.) Likewise, a laboratory that does not wish to upgrade and maintain its BSCs would not need to do so as long as the facility does not use the BSC for infectious agent containment purposes. Instead, the facility could use the certified BSCs at a different laboratory for certain steps in a procedure they are performing, use alternative containment (such as a fume hood) where appropriate, or redesign experiments to use materials and/or procedures that do not call for containment in a BSC.

Based on the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that most hospitals (83 percent) that have AIIRs properly maintain them. OSHA also preliminarily estimates that 91 percent of hospitals and 94 percent of laboratory facilities that have BSCs properly maintain them. Finally, OSHA preliminarily estimates that 83

percent of hospitals and 58 percent of morgues and mortuaries that have autopsy suites properly maintain them. OSHA considers these estimates to be preliminary and welcomes any feedback the SERs can offer on current compliance. This feedback would assist OSHA in developing estimates for the proposed rule, if OSHA engages rulemaking.

OSHA also asks the following:

Are facilities or sectors currently using any types of engineering controls that have not been discussed in this section of the SER Background Document to control the spread of infectious agents?

- Do SERs interpret the provisions as outlined in the regulatory framework as potentially requiring facilities to install new, rather than to upgrade and maintain existing, engineering controls? For example, do SERs believe that there are instances where a facility's WICP, when written to the specifications in the regulatory framework, would result in those facilities needing to install engineering controls (either those listed above or those not identified by OSHA) to comply with a rule as outlined in the regulatory framework?

Administrative and Work Practice Controls

Per the regulatory framework, OSHA would require that employers implement procedures for the use of administrative and work practice controls to minimize transmission of, and infection by, infectious agents. As discussed below, OSHA has preliminarily concluded that some administrative controls and most work practice controls necessary to minimize transmission of, and infection by, infectious agents can be achieved through modification of current practices and that compliance with a rule as outlined in the regulatory framework would result in no additional costs to employers. As always, the Agency welcomes feedback from the SERs on this determination. Are there controls – either administrative or work practice - that OSHA has not considered that would need to be implemented to comply with a rule based on the regulatory framework? If so, would these controls result in additional time or materials costs to the affected facilities?

Per the regulatory framework, administrative controls would include, but are not limited to: promoting and providing vaccinations; enforcing the exclusion of ill employees from the workplace; setting up triage stations and separate areas for patients with suspected or confirmed infectious diseases when they enter the facility; and assigning dedicated staff to patients with suspected or confirmed infectious diseases to minimize the number of employees exposed. While OSHA preliminarily concludes that, under a rule as outlined in the regulatory framework, there would be costs associated with promoting and providing vaccinations and enforcing the exclusion of ill employees from the workplace, OSHA discusses these costs later in this section of the SER Background Document. The Agency preliminarily concludes that setting up triage

stations and separate areas for patients with suspected or confirmed infectious diseases when they enter a healthcare facility, and implementing administrative controls related to staffing, may require modifications in the way tasks are performed, but should not take additional time or resources.

Per the regulatory framework, work practice controls would include, but are not limited to, performing tasks in a manner that minimizes generation of droplets or aerosols of infectious agents and practicing appropriate hand hygiene and respiratory hygiene/cough etiquette. See the discussion, earlier in this section of the SER Background Document, regarding OSHA's preliminarily estimates of the costs associated with hand hygiene. OSHA preliminarily concludes that other work practice controls can be implemented through modifications in current practices and that these modifications would not require additional time or materials over current practices.

Personal Protective Equipment

Per the regulatory framework, OSHA would require that employers implement procedures to provide, make readily accessible, and ensure that each employee uses appropriate PPE (such as, but not limited to, gloves, gowns, laboratory coats, face shields, facemasks, and respirators). Compliance with the PPE provisions described in the regulatory framework would involve the selection of the correct type of PPE for each specific type of situation, the implementation of procedures for the correct donning and removal of PPE, the provision of designated containers for disposable PPE or reusable PPE, and the implementation of procedures for the laundering of PPE (e.g., lab coats, scrubs). The potential costs for a provision on developing (as opposed to implementing) PPE guidelines (with the exception of developing and establishing a respiratory protection program) are covered by the earlier discussion of the costs associated with developing a WICP, and any training related to the proper selection or use of PPE is addressed as part of the training discussion later in this section of the SER Background Document. The potential costs associated with respiratory protection programs are addressed below, under the heading "Respiratory Protection."

The total cost to establishments to provide PPE would vary based on the type of infectious agents that may be encountered in the workplace, and the number of encounters workers will have with sources of infectious agents during a given period. In settings where employees do not routinely see patients with infectious diseases, facilities could have extremely low costs for this potential provision. Such employers could reduce costs even more by further reducing employee exposure. For instance, if dentists' offices or ophthalmologists' offices require that patients displaying flu-like symptoms or symptoms of a respiratory illness reschedule their appointments, the offices would not need to provide PPE as droplet and/or airborne precautions for their workers (although they would still need to provide PPE to institute the Standard Precautions that

would be required under a rule as outlined in the regulatory framework and to comply with OSHA's Bloodborne Pathogens standard (to the extent that standard is applicable)).

The cost of implementing SOPs for PPE provision and use will also vary by the size of a facility and by the number of patients that the facility sees. A small practice with few employees and low patient volume may have very low costs for PPE while a large hospital with hundreds of workers and patients on any given day may have much higher costs for PPE. Standard Precautions should be used in all healthcare settings. In ambulatory care settings, many patients who are more severely ill with symptoms for which transmission-based precautions are appropriate are routinely transferred to hospitals or other similar settings. The additional gloves required for transmission-based precautions, therefore, would not be needed as often in ambulatory care settings; as a result, the overall cost of gloves would be lower in these facilities.

While the per-facility cost of implementing the SOPs for employer's providing PPE and the use of PPE will vary by facility type and size, the per-unit cost of PPE should be comparable across establishments and work settings. OSHA preliminarily estimates that a pair of disposable gloves costs $0.16 (Staples.com, 2013) and 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. Facemasks (e.g., surgical masks), which are needed for protection against suspected or confirmed cases of droplet transmissible diseases, cost $0.13 per piece (GlobalCareMarket.com, 2013), and can be worn by an employee until visibly soiled (one surgical mask estimated to be used per work shift). N95 respirators, which are needed for protection against airborne transmissible diseases and during aerosol generating procedures, can be purchased for $0.33 each (Amazon.com, 2013), and, like facemasks, can be worn until visibly soiled, (one N95 respirator estimated to be used per work shift). Disposable gowns cost $2.42 each (Grainger, 2013a) and 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). Disposable face shields can be purchased for $4.55 (Grainger, 2013b) and 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. Finally, protective eyewear can be purchased for $2.05 per pair (Uline.com, 2013) and is used primarily when workers are potentially exposed to splashes or sprays and when performing aerosol-generating activities. Table VI-3 below details the estimated per-unit costs of PPE.

Table VI-3		
Personal Protective Equipment		
Estimated Per Unit Cost		
Item	Cost	
Gloves (pair)	$0.16	[1]
Facemasks (e.g., surgical mask)	$0.13	[2]
N95 respirators	$0.33	[3]
Gowns	$2.42	[4]
Face Shield	$4.55	[5]
Protective eyewear (e.g., safety glasses, safety goggles)	$2.05	[6]

Source: [1] Staples.com, 2013; [2] GlobalcareMarket.com, 2013;
[3] Amazon.com, 2013; [4] Grainger, 2013a;
[5] Grainger, 2013b; [6] Uline.com, 2013.

Employers will only need to provide PPE appropriate to their facility. If a facility does not perform aerosol generating procedures or have patients in isolation rooms, that facility would not need to provide PPE needed for those circumstances.

According to the Draft Report on Current Compliance, and as shown in Table VI-10, employees in laboratories are estimated to be using PPE, where appropriate, 86 percent of the time, with employees in hospitals and dentists' offices also estimated to have a relatively high level of compliance at 76 percent each. Employees in "other occupational settings," including morgues and mortuaries and waste handling, and laundry services, are estimated to be using PPE, when appropriate, just 35 percent of the time, and workers in the remaining settings are estimated to be using appropriate PPE between 40 and 60 percent of the time.

In addition to welcoming feedback on both unit costs and current levels of compliance, OSHA is interested in the number of encounters a worker would have in a given time period that would require the use of PPE, the number of items of PPE used in a given time period (for example, how many pairs of gloves would a worker need during a work shift), and the number of ***additional*** encounters that would require the use of PPE under a rule based on the regulatory framework (for example, how many additional times would a worker need to use gloves, above and beyond what is currently used, as a result of a rule based on the regulatory framework). The Agency welcomes any information that would assist in estimating the additional PPE needs that would result from the promulgation of a rule as outlined in the regulatory framework that would be above the preliminary compliance rates shown above.

Respiratory Protection

This section presents potential costs for establishing a respiratory protection program (other than costs for providing respirators, which have been described above). Under a rule based on the regulatory framework, employers would generally have to develop, establish, and implement procedures that are consistent with OSHA's Respiratory Protection standard (29 CFR 1910.134). At present, OSHA has not made any determination about the extent to which compliant respiratory protection programs are currently in place at establishments potentially affected by a rule based on the regulatory framework, but the Agency presents its preliminary estimates, based on the Draft Report on Current Compliance, at the end of the present discussion on respirators.

According to OSHA's Respiratory Protection standard, employers whose workers are required to wear respirators during the course of their job duties must establish a written respiratory protection program (OSHA, 1998). A respiratory protection program must contain the following elements:

- Procedures for selecting respirators;
- Medical evaluations of employees required to use respirators;
- Fit testing procedures;
- Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;
- Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators;
- Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators;
- Training of employees in the respiratory hazards and proper use of respirators; and
- Procedures for regularly evaluating the effectiveness of the program.

In this section, OSHA is evaluating the potential costs for program establishment and implementation, medical evaluation, fit testing, and training. OSHA believes, at this time, that facilities subject to a rule as outlined in the regulatory framework would use disposable N95 respirators only, and therefore would not need to clean or disinfect their respirators, nor would they need to ensure adequate air quality, quantity and flow of breathing air, since they would not be using atmosphere-supplying respirators. Potential recordkeeping costs are addressed, separately, in the discussion of potential recordkeeping costs.

Based on OSHA's Respiratory Protection information collection request (ICR), OSHA estimates that an infection control professional at a high risk establishment would take eight hours to develop a written respiratory protection program initially, and four hours annually to maintain the program (OSHA, 2011). And the Agency estimates that an infection control professional at a low risk establishment would take four hours to develop a written program initially, and two

hours to maintain the program annually (OSHA, 2011). As stated below, OSHA expects that the per-facility cost to develop and implement a respiratory protection program will vary by setting and facility size. While OSHA has not currently made any determination as to which settings and facilities potentially affected by a rule based on the regulatory framework would be high risk and which would be low risk, the Agency welcomes any feedback the SERs may have on the issue.

The Respiratory Protection standard requires employers to provide a medical evaluation to determine the employee's ability to use a respirator before the employee is fit tested or required to use the respirator in the workplace (OSHA, 1998). The medical evaluation may be done in the form of a medical questionnaire that is included in an appendix to the Respiratory Protection standard. The questionnaire is completed by the employee and reviewed by a PLHCP for certain answers that would indicate that the employee needs to be further evaluated by a medical professional. Although some workers who undergo the medical evaluation would require a follow-up medical examination that must include any medical tests, consultations, or diagnostic procedures that a PLHCP deems necessary, most initial medical evaluations do not require a follow-up medical examination. Moreover, employers must provide additional medical re-evaluations to workers under specific conditions, such as where: a symptom is displayed by the employee; there is a change in workplace conditions that may result in a substantial increase in the physiological burden on the employee; the respiratory protection program administrator or a manager or a PLHCP notices a need for reevaluation; or fit testing reveals an issue (OSHA, 1998). If a worker must travel to a doctor’s office or hospital to receive a medical evaluation or re-evaluation, or a follow-up medical examination, OSHA preliminarily estimates that the employer would incur costs equal to 30 minutes of travel time, plus $5.00 in travel costs, for that worker. The total unit cost of this travel time in dollars would depend on the wage of the affected worker.

For this analysis, OSHA is preliminarily estimating two different types of unit costs associated with the medical re-evaluation requirement of the Respirator Protection standard. OSHA preliminarily believes that an employer would accrue the first type of unit cost when there is a change in work conditions, such as the introduction of a new hazard or a new process, or a switch to a different type of respirator. In this case, a medical re-evaluation will consist of the worker repeating the initial medical evaluation (i.e. filling out a questionnaire) and potentially undergoing the same type of medical examination as a worker who is newly required to wear a respirator. OSHA also preliminarily believes that an employer would accrue the second type of cost when a worker has been given an initial medical evaluation (and a possible follow-up medical examination), but a new or worsening health condition requires that worker to receive an additional follow-up medical examination with a PLHCP, and to potentially undergo additional tests or diagnostic procedures.

Based on the Respiratory Protection ICR, OSHA preliminarily estimates that: the questionnaire associated with the initial medical evaluation (or with the re-evaluation necessitated by a change in work conditions) requires 15 minutes of the worker's time to complete and five minutes for a PLHCP to review; and any follow-up medical examination associated with the initial medical evaluation (or with the re-evaluation necessitated by a change in work conditions) requires one hour of the worker's time, and costs, on average, $294.75 per worker, which includes the cost of any required tests, consultations, or diagnostic procedures, as well as the cost of the examination (OSHA, 2011).

The Agency also preliminarily estimates that a medical re-evaluation required by a new or worsening health condition will take 30 minutes of a worker's time, and that any associated follow-up medical examination that involves a visit with a PLHCP will cost $138 (FAIR Health, 2013; AMA, 2008; AHRQ, 2011a). OSHA preliminarily estimates that the follow-up medical examination associated with this type of re-evaluation is less burdensome than the initial follow-up medical examination (and less burdensome than the re-evaluation necessitated by a change in work conditions) because the medical examination is an evaluation of an already identified issue or (in the case of a potential issue not identified during the initial evaluation) a less serious issue that does not need extensive testing.

The Respiratory Protection standard requires that, before a worker is required to use a respirator with a negative or positive pressure tight-fitting facepiece, the employee must be fit tested with the same make, model, style, and size of respirator that will be used (OSHA, 1998). OSHA estimates, based on the Respiratory Protection ICR, that fit testing performed by an employer takes 30 minutes of the worker's time and 30 minutes of the fit tester's time, and that the process uses $1.15 worth of materials (OSHA, 2011). Some percentage of workplaces may be able to obtain fit testing services at no cost from the respirator manufacturer, and, in such cases, each worker would take 30 minutes to complete a fit test. Furthermore, some workplaces may opt to have fit testing performed by an outside contractor, and in such cases, OSHA estimates the fit testing would take 30 minutes of the worker's time and would cost $76.68 per worker who is fit tested (OSHA, 2011).

Table VI-4 below summarizes the potential costs, discussed above, that are associated with respiratory protection, including the estimated costs of the written respiratory protection plan, the medical evaluation and examination, and fit testing.

Table VI-4 Respiratory Protection			
Written Respiratory Protection Plan			
Facility Type	**Initial development**	**Annual review and update**	
High risk	8 hours	4 hours	
Low risk	4 hours	2 hours	
Medical Evaluation and Examination			
Activity	**Employee Time, in Hours**	**PLCHP Time, in Hours**	**Costs of Medical Exam**
Initial Medical Evaluation or Re-evaluation[1]	0.25	0.08	--
Follow-up Medical Exams if necessary [2]	1	--	$294.75
Additional Medical Re-evaluation[3]	0.5	--	$138
Fit Testing			
Provider	**Employee Time, in Hours**	**Fit Tester Time, in Hours**	**Additional Costs, per Employee**
Manufacturer	0.5	--	--
In-house	0.5	0.5	$1.15[4]
Contractor	0.5	--	$76.68[5]

[1] Cost for re-evaluation for changes in work conditions only.

[2] 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.

[3] Cost for medical re-evaluation resulting from new or worsening health conditions.

[4] Additional costs represent materials used for fit testing.

[5] 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.

Like other elements of a rule based on the regulatory framework, OSHA expects that the per-facility cost to develop and implement a respiratory protection program will vary greatly by setting and facility size. For example, a rule as outlined in the regulatory framework would add no respirator-related costs for establishments that do not normally see patients who are seeking treatment for the type of infectious diseases that would require respiratory protection (such as the majority of physical therapist or podiatrist offices).

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that workers in laboratories have the highest estimated baseline use of respirators where airborne infection is possible, about 85 percent of the time, and workers in hospitals are estimated to be using respirators appropriately 64 percent of the time. Four settings have estimated compliance rates for respirator use below 40 percent. These include other "occupational settings," including morgues and mortuaries and waste handling and laundry services (26 percent), physicians' offices (29 percent), other ambulatory care settings (33 percent), and dentists' offices (38 percent).

Also, per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that 86 percent of laboratories are providing initial fit testing and 57 percent are providing annual fit testing. Similarly, 84 percent of hospitals are estimated to be providing initial fit testing and 61 percent are estimated to be providing annual fit testing. Physicians' offices and establishments in "other occupational settings" are estimated to be the least compliant with these provisions of the Respiratory Protection standard, with baseline compliance rates for initial fit testing of 23 and 17 percent, respectively, and for annual fit testing of 14 and 15 percent, respectively. Establishments in the remaining settings are estimated to have baseline compliance rates of about 40 percent for initial fit testing, and between 15 and 30 percent for annual fit testing.

Finally, per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates the levels of current compliance with the Respiratory Protection standard's requirement to provide medical evaluations to employees prior to fit-testing. According to these estimates, 84 percent of hospitals, 71 percent of laboratories, and only 15 percent of establishments in "other occupational settings," are providing medical clearance to respirator-wearing employees. No other setting is estimated to have a baseline compliance rate of more than 38 percent (long term care and nursing homes), with most estimated to have a baseline compliance rate of between 20 and 27 percent.

OSHA welcomes any feedback the SERs may have on these preliminary estimates of current compliance.

Decontamination

Per the regulatory framework, OSHA would require implementation of procedures for routine and targeted decontamination of contaminated materials (i.e., contaminated items and/or surfaces) in the work setting that could be a source of occupational exposure. Decontamination encompasses cleaning, disinfection, and sterilization.

The regulatory framework does not prescribe any particular cleaning, disinfection, or sterilization methods that employers would be required to use, nor does OSHA intend to specify cleaning products or cleaning schedules. OSHA would require that employers generally be required to develop and implement decontamination procedures that are consistent with recognized and generally accepted good infection control practices. Employers would also need to follow EPA hazardous waste regulations (which are discussed in this SER Background Document in Section VII, "Description of Any Duplicative, Overlapping, or Conflicting Rules").

OSHA preliminarily concludes that appropriate decontamination procedures could be implemented through modifications in current practices and these modifications would not require additional time or materials over current practices. Studies have found no correlation

between the amount of time spent cleaning a room and the thoroughness of the cleaning (Rupp, 2013; Carling, 2008). This suggests that training workers to correctly disinfect rooms and equipment is an effective way to improve the thoroughness of decontamination procedures without devoting extra time to decontamination. Additional training (discussed later in this section of the SER Background Document) would provide workers with the background knowledge and procedures necessary for them to appropriately decontaminate contaminated items and surfaces.

OSHA believes that the flexibility of the approach presented in the regulatory framework would be key to keeping costs of complying with this provision at a minimum (or, as the Agency preliminarily estimates, no greater than current costs of cleaning and decontamination). Indeed, the flexibility of the regulatory framework would permit employers to reduce current costs, as less expensive decontamination products or methods are developed. Since the regulatory framework does not dictate what cleaning products must be used or how cleaning must be done, facilities could choose less costly disinfection products or methods so long as those products or methods are consistent with recognized and generally accepted good infection control practices.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that 71 percent of hospitals and 71 percent of laboratories properly clean and disinfect surfaces, giving these settings the highest baseline compliance rates for this provision of the regulatory framework. Only an estimated 25 percent of facilities in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, properly clean and disinfect surfaces, giving these settings the lowest baseline compliance rates. Facilities in other ambulatory care settings and physicians' offices have estimated baseline compliance rates of 34 and 35 percent, respectively, and facilities in the remaining settings have estimated baseline compliance rates of between about 40 and 50 percent.

OSHA welcomes any feedback on these estimates. Do you agree with OSHA's preliminary finding that, with adequate training, facilities not currently cleaning and disinfecting surfaces properly could do so in the same amount of time and with the same materials they are currently using? And do you agree with OSHA's preliminary estimates of baseline compliance?

Handling, containerization, transport, or disposal of contaminated materials

Per the regulatory framework, OSHA would require employers to implement 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's Bloodborne Pathogens standard (29 CFR 1910.1030) also contains requirements related to the safe handling, processing, storage, transport, shipping and disposal of contaminated materials. The Agency does not expect that most employers would incur additional costs related to handling, processing, storage, transport, shipping or disposal of contaminated materials above the costs attributed to the Bloodborne Pathogens standard. In addition, a number of establishments are already following the Department of Transportation's (DOT's) Hazardous Materials Regulations that involve requirements for the storage, transport and shipping of infectious or potentially infectious agents (these requirements are discussed in this SER Background Document in Section VII, "Description of Any Duplicative, Overlapping, or Conflicting Rules"), as well as applicable state-level requirements on transporting hazardous materials.

The Agency is interested in whether, in the opinion of the SERs, firms would incur additional costs in complying with this provision of the regulatory framework. Do the SERs agree with the Agency's preliminary determination that by following current rules, an employer would be in compliance with this provision? Are there additional potential costs that OSHA has failed to take into consideration?

Exposure incidents

Per the regulatory framework, OSHA would require establishments to investigate the circumstances surrounding each exposure incident, including a determination of the cause of the incident and whether existing policies, procedures, or training need to be revised to prevent future exposure incidents. OSHA preliminarily estimates that an exposure incident investigation would take, on average, 30 minutes. This average is meant to take 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 that require more than 30 minutes to fully investigate. OSHA has not made any determination as to the number of exposure incidents that facilities may need to investigate in a given year, but the Agency welcomes feedback from the SERs on the question.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that hospitals are currently investigating exposure incidents 82 percent of the time, while laboratories are estimated to be doing so 85 percent of the time. Dentists' offices, physicians' offices, and employers in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, are estimated to be currently investigating exposure incidents about 30 percent of the time. OSHA welcomes any feedback the SERs may have to offer on these estimates of current levels of compliance.

Signage and Labeling/Color-coding

Per the regulatory framework, OSHA would require employers to implement procedures for the use of signage and labeling/color-coding to convey an appropriate hazard warning to workers throughout the employer's work settings. In addition, under the regulatory framework, OSHA would require employers to implement procedures for the use of signage and labeling/color-coding to convey an appropriate hazard warning to workers outside the employer's work settings in cases where the workers could come in contact with contaminated materials that originated in the employer's workplace (e.g., dirty linens) during collection, handling, processing, storage, transport, shipping, and disposal activities.

OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) also contains requirements related to signage and labeling/color-coding. The Agency does not expect that most employers would incur additional costs related to signage and labeling/color-coding above the costs attributed to the Bloodborne Pathogens standard. OSHA therefore preliminarily concludes that where employers comply with the Bloodborne Pathogens standard, the costs of this potential provision will be negligible. In addition, a number of establishments are already following signage and labeling procedures in accordance with DOT's hazardous materials requirements (these requirements are discussed in this SER Background Document in Section VII, "Description of Any Duplicative, Overlapping, or Conflicting Rules").

OSHA welcomes feedback from the SERs on the determination that compliance with this potential provision will not result in additional costs to employers. Do the SERs agree with this determination, or do the SERs feel that OSHA has failed to consider costs associated with this potential provision? If the SERs feel that the Agency is incorrect in this determination, how would current practices need to change for a firm to comply with this potential provision?

b. Implementation of Standard Operating Procedures for Direct Patient Care

In addition to the general SOPs discussed above, per the regulatory framework, OSHA would require the development and implementation of SOPs that are specific to direct patient care. This section discusses potential provisions that are specific to direct patient care. As always, OSHA welcomes any feedback the SERs have on the preliminary determinations presented in this section. Do you agree with OSHA's preliminary conclusions? Are there any procedures that OSHA has not considered that would need to be implemented as a result of the provisions in the regulatory framework that would result in costs – either time or materials?

Patient scheduling and intake/admittance

For employers that conduct patient scheduling and intake/admittance, OSHA would require implementation of SOPs to promptly identify individuals with suspected or confirmed infectious

diseases in order to initiate appropriate infection control practices. OSHA preliminarily concludes that these procedures could be achieved by modification of current work practices and therefore would not require any additional time for affected establishments to comply.

Procedures for implementing SOPs for standard, contact, droplet, and airborne precautions

OSHA would require implementation of SOPs for standard, contact, droplet, and airborne precautions. OSHA analyzed the major elements of these forms of precautions under the general SOP implementation discussed above. For example, the previous section details OSHA's estimated potential costs for the use of PPE (including respirators), hand hygiene, the maintenance of existing engineering controls, and work practice controls to minimize the generation of aerosols during certain procedures. The Agency has not identified any additional activities that potentially affected establishments would need to undertake to comply with these provisions of the regulatory framework, but OSHA welcomes any feedback from the SERs on this issue.

Procedures for patient transport

OSHA has preliminarily concluded that affected establishments would not incur costs associated with implementing SOPs for patient transport, which OSHA would require, per the regulatory framework. The Agency believes that facilities that would need to transfer patients under this potential requirement (mainly hospitals, nursing homes or long term care facilities, and embedded clinics in prisons) are already meeting this potential requirement. Any other facility where direct patient care is provided would not be caring for patients who would need this type of transport. As always, OSHA welcomes feedback on this preliminary determination. Do the SERs believe that this potential provision would require patient transport above what is currently standard practice?

Medical surge procedures

OSHA has not yet examined the costs of implementing medical surge procedures. For those employers who are not yet implementing adequate procedures, there would certainly be planning costs, as well as costs for the implementation of procedures for surge conditions that will depend on the nature of the surge situation. OSHA welcomes SER input on the costs associated with these activities.

c. Implementation of Standard Operating Procedures for Other Covered Tasks

In addition to the general SOPs discussed above, per the regulatory framework, OSHA would require SOPs that are specific to other covered tasks. This section discusses potential provisions

that are specific to other covered tasks. As always, OSHA welcomes any feedback the SERs have on the preliminary determinations presented in this section. Do you agree with OSHA's preliminary conclusions? Are there any procedures that OSHA has not considered that would need to be implemented as a result of these potential provisions that would result in costs – either time or materials?

Procedures for handling and intake of contaminated materials and procedures for the use of necessary control measures

Similar to the discussion in the section on general SOPs about handling contaminated materials, OSHA does not expect that most employers would incur additional costs in conjunction with this provision of the regulatory framework. OSHA anticipates that any establishments in the scope of a rule based on the regulatory framework would currently be familiar with, and have procedures for, handling and intake of contaminated materials, and for using necessary control measures.

Engineering controls

OSHA discussed the potential costs associated with upgrading and maintaining engineering controls in its discussion of potential costs for general SOPs, above.

Measures necessary to address uncontrolled releases of infectious agents, including mitigation of such releases and prompt reporting of such incidents to appropriate authorities

Per the regulatory framework, this provision would be specific to diagnostic, research, and production laboratory facilities. 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. OSHA addresses any training costs associated with this potential requirement later in this section of the SER Background Document.

Do the SERs agree with OSHA's preliminary determination? Would the implementation of this draft provision of the regulatory framework result in additional costs that the Agency has not considered?

3. Medical screening, surveillance, and vaccination

The following sections address the implementation of occupational health services that could be required by OSHA, per the regulatory framework. These services could include vaccinations, medical screening and surveillance, medical evaluation and follow-up, maintenance of exposure incident records, and medical removal protection.

Vaccination

Per the regulatory framework, OSHA would require employers to make available to their employees vaccinations that are consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered during the job tasks of the employee. With the exception of employees in research and production laboratory facilities, employers could be required to make available to their employees, at a minimum, the following vaccinations:

- Influenza (Seasonal and Pandemic);
- Measles, Mumps and Rubella (MMR);
- Tetanus, Diphtheria, and Pertussis (Tdap);
- Varicella; and
- Any other vaccination(s) that is required by the employer's WICP, or determined by a PLHCP to be medically appropriate for a particular worker (e.g., the meningococcal vaccine.)

OSHA believes that making the specified vaccinations available would generally protect affected workers from the infectious agents to which they have occupational exposure. However, employers of employees in research and production laboratory facilities may be required to make available to those employees only those vaccinations that the employer determines are relevant to their work settings. For example, workers in a research laboratory handling one infectious agent only (e.g., *Neisseria meningitidis* bacteria) would be offered one vaccination only (in the example, the meningococcal vaccine) because they are not working with other infectious agents.

As outlined in the regulatory framework, OSHA could exempt an employer from offering a vaccination to a worker where the employer has documented that the worker has already received the vaccination, antibody testing reveals immunity, or the vaccine is contraindicated for medical reasons. OSHA preliminarily estimates the cost per vaccine as shown in Table VI-5 below.

Table VI-5		
Vaccinations		
Cost per Vaccine		
Influenza	$13.13	[1]
MMR	$54.07	[1]
Varicella	$181.10	[1]
Tdap	$39.31	[1]
Meningococcal	$111.83	[1]
Typhoid	$24.87	[2]
Inactivated Polio	$23.18	[3]

Source: [1] CDC, 2013d; CDC, 2012a. [2] VA, 2013; CDC, 2012a. [3] VA, 2013; CDC, 2011c.

In addition to the cost of the vaccine, OSHA preliminarily estimates that it would take 5 minutes of a worker's time to receive a vaccine on-site, plus 5 minutes of a PLHCP's time to administer each vaccine. Most workers potentially affected by a rule based on the regulatory framework would be able to receive a vaccine at their worksite, but if a worker must travel off-site to receive a vaccine, OSHA preliminarily estimates that it would take 30 minutes of his or her time plus $5.00 in travel costs.

Like many other elements of a rule based on the regulatory framework, the per-facility cost to make vaccinations available would vary based on the size and type of facility. OSHA delineated specific vaccines in the regulatory framework (influenza, MMR, Varicella, and Tdap) because OSHA preliminarily believes that employers in most settings would need to make these vaccines – and only these vaccines – available to the majority of their employees.

Per the regulatory framework, an employer would be required to ensure that an employee fill out a vaccine declination form when that employee declines a vaccination. The Agency preliminarily estimates that it would take two minutes of a worker's time to decline a vaccine and five minutes of an administrative assistant's time to process and file such a form.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that 85 percent of hospitals currently offer their workers the full complement of CDC/ACIP recommended vaccines and 72 percent of laboratories offer their workers the full complement of CDC/NIH BMBL recommended vaccines. About 30 percent of establishments in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, dentists' offices, and physicians' offices, and about 40 percent of establishments in the remaining settings, currently offer their workers the full complement of recommended vaccines.

Also per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that, for most settings except hospitals, a higher percentage of establishments make vaccines available in accord with state-level vaccine requirements that are less extensive (as opposed to the more extensive ACIP/CDC or CDC/NIH BMBL recommendations). OSHA preliminarily estimates that about 50 percent of physicians' offices and dentists' offices (the low end of baseline compliance), and about 60 to 80 percent of establishments in the remaining settings, offer workers vaccines in accord with state-level vaccine requirements.

OSHA welcomes feedback from the SERs on these preliminary estimates of current compliance.

Medical Screening and Surveillance

Per the regulatory framework, OSHA would require employers to provide medical screening and surveillance to their employees who have occupational exposure during the provision of direct patient care or the performance of other covered tasks. The costs of medical screening and surveillance for each establishment, like many other provisions in the regulatory framework, would depend largely on the size of the establishment. A small provider with few employees and low turnover would incur minimal costs, while a large provider with hundreds of employees and high turnover would incur higher total costs, to comply with this provision.

Furthermore, the flexibility inherent in the regulatory framework would allow each employer to comply with the provision in a manner appropriate for their individual facility. As such, employers could choose a less costly method of medical screening and surveillance so long as the chosen method is effective.

For example, medical screening could take the form of a pre-placement "health inventory" that determines immunization status and obtains histories of any conditions that might predispose personnel to acquiring or transmitting infectious diseases. Medical surveillance could also encompass initial and yearly TB testing. OSHA addresses the potential costs associated with employees who have a positive result on a TB screening test in the following section on medical follow-up and medical removal protection.

OSHA preliminarily estimates that medical screening that includes a questionnaire filled out by new employees would take 10 minutes of time to complete. And the Agency estimates that reviewing and verifying the information in the questionnaire with a PLHCP would take an additional 15 minutes of the employee's time plus 15 minutes of a PLHCP's time. Workers who need to travel to an off-site location to complete their medical screening would incur an estimated additional 30 minutes of travel time plus $5.00 in travel costs. The total unit cost of this screening in dollars would depend on the wage of the affected worker.

Under a rule as outlined in the regulatory framework, an employer whose WICP requires that it perform a TB test on its workers may choose to obtain a basic medical history and administer a

TB test at the same time. OSHA preliminarily estimates costs for these procedures based on the payment to a medical provider for conducting medical screening and performing testing services, as well as employee time needed to undergo these procedures (including employee time associated with having a test read by a PLHCP, if applicable). Based on analyses conducted in conjunction with OSHA's proposed rule addressing occupational exposure to TB, OSHA preliminarily estimates that the medical screening portion of these procedures would cost $27, and, factoring in this $27 cost, that performance of medical screening and administration of a TB test at the same time would: (1) require 1 hour of the employee's time and cost $70, if the employee is administered a single step TB test; or (2) require 1.5 hours of an employee's time and cost $113, if the employee is administered a two-step TB test; or (3) require 30 minutes of an employee's time and cost $326, if the employee is given an IGRA (Interferon Gamma Release Assay) test (OSHA, 1997, updated to 2012 dollars, FAIR Health, 2013). OSHA preliminarily estimates that an IGRA costs $298.94 versus $43 for a single step skin test and $86 for a two-step skin test – but some employers may opt for the IGRA due to convenience because the IGRA can be administered in one visit (FAIR Health, 2013). Workers who need to travel to an off-site location to complete their medical screening plus TB test would incur an estimated additional 30 minutes of travel time plus $5.00 in travel costs.

OSHA also preliminarily estimates costs associated with an employee undergoing a TB test alone (without medical screening at the same time). As above, OSHA preliminarily estimates costs for a TB test alone based on the payment to a medical provider for performing testing services, as well as employee time needed to undergo the test (including employee time associated with having the test read by a PLHCP, if applicable). OSHA preliminarily estimates that administration of a TB test alone would: (1) require 1 hour of the employee's time and cost $43, if the employee is administered a single step TB test; or (2) require 1.5 hours of an employee's time and cost $86, if the employee is administered a two-step TB test; or (3) require 30 minutes of an employee's time, and cost $298.94, if the employee is given an IGRA (FAIR Health, 2013). Workers who need to travel to an off-site location to complete their TB test would incur an estimated additional 30 minutes of travel time plus $5.00 in travel costs.

Although full-pre-placement physical examinations would not be required by a rule as outlined in the regulatory framework, OSHA preliminarily estimates that establishments who choose to provide full pre-placement physical examinations to their employees would incur costs equivalent to one hour of the employee's time plus an additional $175, representing payment to a medical provider for testing services (OSHA, 1997, updated to 2012 dollars). Workers who need to travel to an off-site location to complete their physical would incur an estimated additional 30 minutes of travel time plus $5.00 in travel costs.

OSHA summarizes the potential costs associated with the potential requirements for medical screening and surveillance in Table VI-6 below. All potential costs associated with recordkeeping are addressed in the recordkeeping discussion later in this section of the SER Background Document.

Table VI-6			
Medical Screening and Surveillance Estimated Compliance Burden per Employee			
Type of Screening/Surveillance	Employee Time, in Hours	PHLCP Time, in Hours	Additional Costs[1]
Health Inventory only	0.42	0.25	--
Health Inventory plus TB test			
Single Step Test	1		$70
Two Step Test	1.5		$113
IGRA	0.5		$326
TB Test only			
Single Step Test	1		$43
Two Step Test	1.5		$86
IGRA	0.5		$299
Full Physical	1		$175

[1]Additional costs represent payments to medical providers for testing or exam services.

Source: OSHA, 1997; FAIR Health, 2013.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that hospitals currently provide pre-placement screenings (either in the form of a health inventory questionnaire or a full physical exam) to 70 percent of workers, and diagnostic testing to 90 percent of workers receiving such screenings. Three settings (long term care and nursing homes, home healthcare agencies, and laboratories) are preliminarily estimated to provide pre-placement medical screenings to roughly 50 percent of workers. Laboratories are estimated to provide diagnostic testing to 71 percent of the workers being screened. And OSHA estimates that long term care facilities and nursing homes and home healthcare agencies provide diagnostic testing to about 45 percent of screened workers. OSHA preliminarily estimates that in the remaining settings employers provide pre-placement medical screenings to between 10 percent and 19 percent of workers, with diagnostic testing provided to between 17 percent and 41 percent of workers receiving screens. OSHA welcomes any feedback or additional information the SERs may have on these preliminary estimates of current compliance.

Medical Evaluation, Follow-up, and Medical Removal Protection

Per the regulatory framework, OSHA would require that the employer make available to a worker a confidential medical evaluation and appropriate follow-up, either after a referral from a medical screening or surveillance program (provided a PLHCP has determined that the medical evaluation and appropriate follow-up is necessitated by a workplace exposure, as opposed to a non-workplace exposure), or after a report of an exposure incident. OSHA would also require that a confidential medical evaluation and appropriate follow-up after an exposure incident include the following elements: the route(s) and circumstances of the exposure; documentation of the source of the exposure (unless the employer can establish that identification is not feasible or prohibited by law); baseline testing; post-exposure prophylaxis and treatment; appropriate counseling; evaluation of reported illnesses that may be attributable to exposure; and, as necessary, recommendations for job modifications or restrictions or for precautionary removal of the employee from the workplace. Finally, except for most cases of occupational exposure to the common cold or influenza, OSHA would require medical removal protection benefits, *i.e.*, that, an employer pay the total normal earnings and maintain the seniority, rights, and benefits of an employee removed from the job or otherwise medically limited as a result of an exposure incident.

For the purposes of this SER Background Document, OSHA preliminarily estimates the full unit costs of diagnosing and treating a select few workplace acquired infectious diseases, as well as the medical restriction times associated with the infectious diseases. This means that OSHA will be discussing the potential costs of any relevant drug therapies, recommended post-exposure vaccines, any doctor's visits or testing necessary to diagnose a suspected infectious disease, any treatments for the disease, and any recommended days of medical restriction.

Employers would only be required to provide medical removal protection for as long as an employee is infectious. In most cases of occupationally-acquired infections, the worker is treated as an outpatient, and, the duration of medical removal protection would generally vary, depending on the disease (see, for example, discussion of influenza, below). In cases where a worker is hospitalized as a result of a workplace-acquired MRSA infection, OSHA has preliminarily estimated that once that worker is released from the hospital, he or she is usually no longer infectious and therefore no longer subject to medical removal protection. Because of this assumption, days of hospitalization for MRSA (where relevant) are assumed to be equal to days of work restriction subject to medical removal protection coverage. Cases of TB will require that medical removal protection be provided for three to four weeks in addition to any time the worker would be hospitalized.

This section will not be deriving a single estimate for the cost of post-exposure prophylactic treatment or a total estimated cost for treating a given case of an infectious disease. It also does not estimate how many cases may be expected in a given year, or how many workers may

potentially need post exposure prophylaxis or medical evaluation, follow-up or medical removal protection.

The total, per-establishment costs of these potential provisions are largely dependent on the number of employees an establishment has and on the number and type of infectious diseases to which employees in that establishment have occupational exposure. Similar to many OSHA standards, it would not be uncommon for some facilities to have years in which no workers become ill as a result of a workplace exposure. Some facilities are unlikely to ever see a patient with many of the diseases that would be covered under a rule as specified in the regulatory framework (e.g., it would be unlikely that podiatrists and optometrists would see patients with active TB or an infection with *Clostridium difficile*). Finally, many infectious diseases are relatively uncommon in the United States, and only a handful of facilities would even see one case in a given year.

The estimates presented below also 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 ergonomic 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. OSHA welcomes any feedback the SERs may have on how the costs of treating occupationally acquired infectious diseases are currently being borne and how that might change as a result of a rule based on the regulatory framework.

While the Agency usually uses a generalized estimate for medical removal protection, after examining the range of the most common infectious diseases and the infectious diseases specifically addressed by public health officials, OSHA has determined that the range of treatment requirements and medical removal recommendations are too varied for a generalized estimate to be reasonable. For this SER Background Document, OSHA will be examining the potential costs for medical evaluation, follow-up, post exposure prophylaxis and medical removal protection for three diseases: influenza, tuberculosis, and MRSA. The Agency believes that these diseases are representative of the types of infectious diseases that will be included in a full analysis. They were chosen to show how OSHA would undertake this analysis for what OSHA preliminarily considers a low-cost but common disease (influenza), a high-cost but low incidence disease (tuberculosis), and a disease with multiple possible manifestations from relatively low cost to very high cost (MRSA). If the Agency proceeds with proposing a rule based on the regulatory framework, OSHA anticipates expanding this analysis to account for potential costs related to medical evaluation, follow-up, post exposure prophylaxis and medical removal protection for additional diseases, including measles, mumps, rubella, pertussis, varicella, meningococcal disease, typhoid, SARS, norovirus, VRE, adenovirus, and Group A Streptococcus (GAS). These agents – those being evaluated for this SER Background Document

and those that would be evaluated for a proposal – are diseases covered by the CDC's guidelines for post-exposure treatment for healthcare workers (CDC, 2011d), plus those that the Agency has preliminarily concluded represent the most common infectious agents to which workers within the potential scope of a rule based on the regulatory framework are exposed. It is currently OSHA's intent to cover post-exposure treatment and medical removal for most occupationally acquired infectious diseases amongst the covered worker population. For the three diseases OSHA looked at for this SER Background Document, the treatment, treatment costs, and days of medical restriction for exposed workers – both those with a suspected case of the disease and those with a confirmed case of the disease – are presented below in Tables VI-7 and VI-8.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily concludes that hospitals and laboratories are already highly compliant with a potential requirement to provide post exposure prophylactic treatments, as recommended by the CDC/HICPAC guidelines. OSHA estimates that hospitals provide post exposure prophylactic treatment 91 percent of the time, while laboratories provide post exposure prophylactic treatment 86 percent of the time. Three settings are estimated to be providing post exposure prophylactic treatment more than 60 percent of the time: other ambulatory care settings (62 percent), home healthcare agencies (66 percent), and nursing homes and long-term care facilities (68 percent). Employers in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, are estimated to provide post exposure prophylactic treatment just 32 percent of the time.

OSHA also preliminarily concludes that hospitals and laboratories are already highly compliant with a potential requirement to provide post exposure testing for workers exposed to suspected or confirmed sources of infectious diseases. OSHA estimates that employers in those settings provide such testing 88 and 86 percent of the time, respectively. Employers in other ambulatory care settings, home healthcare agencies, and nursing homes and long-term care facilities provide such post exposure testing an estimated 55 to 70 percent of the time, while employers in "other occupational settings" provide such post exposure testing just an estimated 34 percent of the time.

OSHA also preliminarily estimates baseline compliance rates with respect to: (1) the percentage of the time that employers restrict workers' normal duties and/or assign them alternative job duties when they have a known or suspected infectious disease; (2) the percentage of employers that direct workers not to come to work when they have a known or suspected infectious disease; and (3) the percentage of the time that employers provide normal pay and benefits during periods in which workers with a known or suspected infectious disease are directed not to come to work. OSHA preliminarily estimates that 77 percent of the time, hospitals already restrict or alter workers' duties when they have a known or suspected infectious disease, and that 59 percent of hospitals direct those workers not to come to work. With respect to long term care and nursing home facilities and laboratories, OSHA estimates that 60 and 66 percent of the time,

respectively, employers in those settings restrict the duties of workers who have a known or suspected infectious disease and that, for each of those settings, just under 50 percent of employers direct affected workers not to come to work. The Agency estimates that between 40 and 50 percent of the time, physicians' offices, dentists' offices and employers in other ambulatory care settings restrict the duties of affected workers, and that about 30 to 35 percent of employers in those settings direct affected workers not to come to work. Employers in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, have the lowest estimated baseline compliance rates. Employers in those settings are estimated to restrict the duties of affected workers 23 percent of the time. And an estimated 27 percent of employers in those settings direct affected workers to not report to work.

While the percentage of employers estimated to be currently directing workers with a suspected or confirmed infectious disease to not report to work is relatively low for most settings (between 25 and 50 percent of employers in all settings except hospitals (59 percent)), the percentage of the time that employers are estimated to provide pay in the event workers are told not to report to work is relatively high. In all settings except two (home healthcare (45 percent) and "other occupational settings" (41 percent)), OSHA estimates that employers pay affected workers at least 60 percent of the time, with hospitals estimated to be providing pay most frequently (84 percent of the time). OSHA is interested in any feedback or additional information that the SERs could supply on these preliminary estimates of the levels of current compliance with these draft provisions.

The remainder of the discussion on medical evaluation, follow-up, and medical removal protection outlines the potential costs of post exposure prophylaxis, related testing and treatment, and the estimated number of days a worker would need to be excluded from the workplace based on current guidelines and the potential requirements of a rule as outlined in the regulatory framework. This information is also contained in Tables VI-7 and VI-8, at the end of the discussion.

Influenza

OSHA assumes, based on recommendations from the CDC (CDC, 2011d), that, as part of exposure incident-related post-exposure prophylaxis, a worker exposed to influenza should be offered a vaccine – estimated to cost $13.13 - if they have not already received the vaccine (CDC, 2013d). The same CDC source recommends that an exposed worker needs the following post-exposure prophylactic treatment: either Oseltamivir 75 mg once a day for 10 days, or Zanamivir 10 mg (inhalation) once a day for 10 days.[54] CDC guidance states that widespread or routine use of antiviral medications for chemoprophylaxis is not recommended but instead suggests close monitoring of exposed individuals with early initiation of antiviral treatment

[54] More recent CDC guidance advises a 7-day course of either drug, but OSHA has used the earlier recommendation of a 10-day course of treatment for costing purposes in this SER Background Document. OSHA will reexamine this preliminary decision if it decides to engage in rulemaking.

(CDC, 2011d). OSHA has not made any determination as to the percentage of workers exposed to influenza who may be offered post-exposure prophylactic treatment, but the Agency preliminarily calculates, based on the average of the total cost for Oseltamivir and Zanamivir, that the average post-exposure preventative chemoprophylaxis for influenza is $69.03 per exposed, vaccinated worker (including the average cost of medication only) and $82.16 per exposed, unvaccinated worker (including both the cost of vaccination and the average cost of medication) (VA, 2013; PDR, 2013).

If a worker becomes ill with a case of influenza, CDC recommends the following treatment: either Oseltamivir twice a day for 5 days; or Zanamivir twice a day for 5 days. OSHA preliminarily estimates that treatment would cost, on average, $69.03, based on the average of the total cost for Oseltamivir and Zanamivir. In addition, some workers may be given a rapid influenza diagnostic test, which OSHA estimates will cost $105. OSHA has made no determination about the number of workers with influenza who may receive diagnostic testing, but welcomes comments from the SERs on this issue. In sum, OSHA estimates a treatment cost of $69.03 per worker who is offered antiviral medication only, and $174.03 per worker who is offered both diagnostic testing and antiviral medication (CDC, 2011d; VA, 2013; PDR, 2013; AHRQ, 2011a). And OSHA estimates that any employer whose workers would need to travel to an off-site location to receive tests would incur costs equal to 30 minutes of the worker's time for the time spent in transit plus $5.00 in travel costs.

With respect to influenza, a rule based on the regulatory framework would require medical removal protection benefits for one type of worker only: a research or production laboratory worker removed from the job or otherwise medically limited as a result of an occupational exposure incident to an infectious agent (influenza) with which he or she is working. It is easier to identify that influenza has been occupationally acquired in laboratories where specific infectious agents are being handled on a daily basis, than it is in other settings. Current guidelines recommend that a worker with an active case of influenza be excluded from work until at least 24 hours after they no longer have a fever (without the use of fever-reducing medicines such as acetaminophen). Further, workers in certain settings may be temporarily reassigned or excluded from work for 7 days from symptom onset or until the resolution of all non-cough symptoms, whichever is longer (CDC, 2011d, CDC, 2013e).

Tuberculosis

OSHA addresses the potential costs of routine screening for TB in the previous section on medical screening and surveillance. A worker with a positive TB skin test or IGRA may be referred to a PLHCP for a chest x-ray and a determination regarding whether the worker has latent or active TB. OSHA preliminarily estimates that a chest x-ray will cost $44 and take approximately thirty minutes of worker time for the x-ray plus an additional thirty minutes to review the results with a PLHCP. The exam is estimated to cost $138 (FAIR Health, 2013; AMA, 2008). If a worker must travel to a doctor's office or hospital to receive a chest x-ray,

OSHA preliminarily estimates that the employer would incur costs equal to 30 minutes of travel time for that worker plus $5.00 in travel costs.

Cases of latent TB are treated with a six-to-nine month course of isoniazid, either daily or two times a week. OSHA preliminarily estimates that isoniazid costs $0.05 per dose, resulting in a cost of $2.70 for 52 doses (a six month, twice a week course of treatment), $9.36 for 180 doses (a six month, daily dose course of treatment), $3.95 for 76 doses (a nine month, twice a week course of treatment), and $14.04 for 270 doses (a nine month daily course of treatment). Cases of latent TB can also be treated with a four-month course of rifampin once a day, which, OSHA preliminarily estimates, costs $1.82 per dose, or $218.82 for 120 doses (CDC, 2013f, VA, 2013). OSHA has not, at this time, made any determination as to the percentage of workers treated for latent TB who are treated with rifampin versus isoniazid, but the Agency welcomes comments from the SERs on the issue.

In addition to medication, workers treated for latent TB need to be seen by a doctor monthly to be administered a liver injury test. OSHA preliminarily estimates that each office visit costs $138 and each hepatic function panel costs $46.12, for a total cost for doctor's visits and liver tests of $1,104.72 for a six month course of treatment, or $1,657.08 for a nine month course of treatment (AHRQ, 2011a).

OSHA preliminarily estimates that workers suspected of having an active case of TB, but who are eventually diagnosed with something other than TB, require a stay in a hospital isolation room for an average of 4 days. The total cost of this hospitalization, and any related tests and treatments, is preliminarily estimated to be $12,578 (AHRQ, 2011a). A worker who is confirmed to have an active case of TB will require, on average, an 8.3 day stay in a hospital isolation room, and the total cost of this hospitalization, and any related tests and treatments, is preliminarily estimated to be $42,327 (AHRQ, 2011a).

Treatment for an active case of TB would depend on the extent of disease and microbial antibiotic sensitivity, but it usually involves 6-9 months of a four drug regimen. The initial treatment phase from the CDC recommended treatment is eight weeks of daily doses (56 doses total) of four different medications: isoniazid, rifampin, ethambutol, and pyrazinamide, followed by 18 weeks of daily doses (126 doses) of isoniazid and rifampin, or 18 weeks of twice weekly doses (36 doses) of isoniazid and rifampin. OSHA preliminarily estimates that isoniazid costs $0.05 per dose, rifampin costs $1.82 per dose, ethambutol costs $1.77 per dose, and pyrazinamide costs $1.29 per dose. This results in a total cost for the initial phase of treatment of $276.29. For the daily dose option, the continuation phase of treatment is preliminarily estimated to cost $236.10. For the twice-weekly dose option, the continuation phase of treatment is preliminarily estimated to cost $67.46 (CDC, 2013g, OSHA, 1997, VA, 2013). In addition to treatment, a worker with an active case of TB that a PLHCP has determined was workplace acquired would need to be excluded from the workplace for three to four weeks (CDC, 2012b).

MRSA

Presently, no prophylactic treatment is recommended after an exposure to an active MRSA infection. An active MRSA infection may result in a skin or soft tissue infection, which can be treated with topical antibiotic ointments, or may result in a skin abscess, which must be incised and drained and requires clinic or emergency department visits. Some skin infections become severe and will need oral antibiotics (Liu et al. 2011).

OSHA preliminarily estimates that an average active case of a MRSA-related skin or soft tissue infection will be diagnosed with a wound culture screening only, which is preliminarily estimated to cost $48.88. If that culture is positive for MRSA, the worker will likely receive a second wound culture screening, this time with a colony count estimation (preliminarily estimated to cost an additional $32.01), and if that second culture is positive, the worker will likely receive a third wound culture screening, this time with molecular typing, either by nucleic acid probe (preliminarily estimated to cost an additional $100.80), or by pulsed-field gel electrophoresis (preliminarily estimated to cost an additional $46.20) (FAIR Health, 2013). Any employer whose workers would need to travel to an off-site location to receive these diagnostic tests would incur costs equal to 30 minutes of that worker's time for the time spent in transit plus $5.00 in travel costs. OSHA has not yet made a determination as to how many workers displaying a skin or soft tissue infection would be offered each type of diagnostic test and believes that some workers would be offered treatment without undergoing some or all of the testing described above. OSHA welcomes feedback from the SERs on this issue.

OSHA preliminarily estimates that, for less serious cases, which do not require hospitalization, some workers positively diagnosed with MRSA-related skin and soft tissue infection may, depending on the location of the infection and the worker's job duties, require one week of medical restriction and treatment with a course of a topical antibiotic (Liu et al. 2011). The topical treatment is preliminarily estimated to cost $0.94 per dose, and necessitate 10 doses, for a total cost of $9.43 (VA, 2013; PDR, 2013; Liu et al., 2011). In some cases, a worker with a MRSA-related skin or soft tissue infection will receive a course of oral antibiotics, either Bactrim or Clindamycin, in addition to topical treatment. OSHA preliminarily estimates that a course of Bactrim costs $33.60 (28 doses at $1.20 per dose) and a course of Clindamycin costs $47.04 (42 doses at $1.12 per dose) (PDR, 2013; VA, 2013) If the infection results in an abscess, OSHA preliminarily concludes that the worker will need the abscess incised and drained. This procedure can be done in a doctor's office or in an emergency department. The abscess will either be drained through needle aspiration or through manual aspiration. OSHA preliminarily estimates that the procedure costs between $329 and $650, depending on how complicated the procedure is (AHRQ, 2011a). OSHA also preliminarily estimates that the procedure takes between 60 and 90 minutes of an employee's time, plus an additional 30 minutes and $5.00 in travel costs if the worker needs to travel to an off-site location.

In rare cases, MRSA may cause serious infections, such as complicated soft tissue infections, endocarditis, pneumonia, meningitis and bone (osteomyelitis) or joint infections. These infections may require hospitalization, which may include surgical intervention, intensive medical therapy, and extended recovery time.

At this time, OSHA has not made any determination as to how many workplace-acquired MRSA infections there are in a given year, or any determination as to the percentage of those infections that are of the very serious type that are expensive to treat and require hospitalization. The Agency welcomes any information the SERs can provide on the issue.

OSHA has, however, made preliminary estimates of the time and costs associated with hospitalizations for serious MRSA infections and various complications that can result from serious MRSA infections. OSHA preliminarily estimates: (1) that a serious MRSA-related skin and soft tissue infection requiring hospitalization results in nine days in the hospital, and costs $64,447; (2) that MRSA-related pneumonia requires eight days in the hospital, and costs $45,212; (3) that, depending on the location of the infection, MRSA-related osteomyelitis requires between five and eight days (average of just over six) in the hospital and costs between $25,262 and $53,791 (average of $39,067); (4) that MRSA-related endocarditis requires nine days in the hospital, and costs $62,051; and (5) that MRSA-related meningitis requires eight days in the hospital, and costs $50,258 (AHRQ, 2011a; CMS, 2013b).

A worker with a MRSA skin or soft tissue infection may require medical restriction, depending on the extent of the infection and the worker's job duties. The Agency preliminarily concludes that workers will be non-infectious upon release from the hospital and would no longer be entitled to medical removal protection benefits under a rule as outlined in the regulatory framework.

Table VI-7

Post-Exposure Prophylaxis and Medical Follow-up by Worker Characteristic and Infectious Agent

Preventative Treatment or Treatment of Non-Active Cases Only

Disease	Worker Type	Diagnostic Testing and Treatment, type	Diagnostic Testing and Treatment Cost		Vaccine Recommended Post-exposure		Vaccine Cost per dose		Doses		Vaccine Cost		Medication Recommended		Medication cost per dose		Recommended Doses		Medication Total Cost
Influenza	Unvaccinated				Yes	[1]	$13.13	[3]	1	[4]	$13.13	[3][4	Oseltamivir	[1]	$8.05	[3]	10	[1][4]	$80.53
													Zanamivir	[1]	$5.75	[3]	10	[1][4]	$57.52
	Vaccinated				No	[1]							Oseltamivir	[1]	$8.05	[3]	10	[1][4]	$80.53
													Zanamivir	[1]	$5.75	[3]	10	[1][4]	$57.52
Tuberculosis	Workers with	Chest x-ray	$44	[5]	No	[6]	N/A		N/A		N/A		Isoniazide	[2]	$0.05	[3]	52[1]	[2]	$2.70
	Latent TB	Initial appointment with PLHCP	$138	[5]													180[2]	[2]	$9.36
		Appointment with PLHCP, monthly for 6 or 9 months	$828 or $1,242	[5]													76[3]	[2]	$3.95
		Liver Injury Test, monthly for 6 or 9 months	$276.72 or $415.08	[5]													270[4]	[2]	$14.04
													Rifampin	[2]	$1.82	[3]	120[5]	[2]	$218.62

1 - number of doses reflects a six month (26 week), twice weekly dose course of treatment
2 - number of doses reflects a six month, daily dose course of treatment assuming a thirty day month
3 - number of doses reflects a nine month (38 week), twice weekly dose course of treatment
4 - number of doses reflects a nine month, daily dose course of treatment assuming a thirty day month
5 - number of doses reflects a four month, daily dose course of treatment assuming a thirty day month

Note: Totals may not sum due to rounding.

Sources:	
[1]	CDC, 2011d
[2]	CDC, 2013e
[3]	VA, 2013
[4]	PDR, 2013
[5]	FAIR Health, 2013
[6]	Bolyard et al., 1998

Table VI-8

Treatment by Infectious Agent

Active Case Treatment

Disease	Worker Type	Diagnostic Testing, type	Diagnostic Testing and Treatment cost		Medication Recommended		Medication cost per dose		Recommended Doses		Medication Total Cost	Days of Hospitalization		Cost of Hospitlization	
Influenza	All workers	Rapid Influenza Diagnostic Test	$105	[2]	Oseltamivir (Tamiflu)	[1]	$8.05	[7]	10	[1][6]	$80.53				
					Zanamivir (Relenza)	[1]	$5.75	[7]	10	[1][6]	$57.52				
Tuberculosis	Workers with Active TB				Isoniazid (initial)	[3]	$0.05	[7]	56	[3]	$2.91	4 days[1]	[4] [5]	$12,578	[4] [5]
					Rifampin (initial)	[3]	$1.82	[7]	56	[3]	$102.02				
					Ethambutol (initial)	[3]	$1.77	[7]	56	[3]	$99.12				
					Pyrazinamide (initial)	[3]	$1.29	[7]	56	[3]	$72.24	8.3 days[2]	[4] [5]	$42,327	[4] [5]
					Total Cost (initial)						$276.29				
					Isoniazid + Rifampin (daily continuation)	[3]	$1.87	[7]	126	[3]	$236.10				
					Isoniazid + Rifampin (semiweekly continuation)	[3]	$1.87	[7]	36	[3]	$67.46				
MRSA	Workers with skin and soft tissue infection	Wound Culture Screening	$48.88	[2]	Topical antibiotic	[9]	$0.94	[7]	10	[6]	$9.43	9 days	[4] [5]	$64,447	[4] [5]
		Wound Culture Screening with Colony Estimation	$32.01	[2]	Bactrim	[10]	$1.20	[7]	28	[6]	$33.60				
		Wound Culture Typing - nucleic acid probe	$100.80	[2]	Clindamycin	[9]	$1.12	[7]	42	[6]	$47.04				
		Wound Culture Typing - pulse gel field	$46.20	[2]											
		Abscess draining[3]	$329 - $650	[2] [8]											
	Workers with MRSA related pneumonia											8 days	[4] [5]	$45,212	[4] [5]
	Workers with MRSA related osteomyelitis											6-8 days[4]	[4] [5]	$25,262 - $53,791	[4] [5]
	Workers with MRSA related endocarditis											9 days	[4] [5]	$62,051	[4] [5]
	Workers with MRSA related meningitis											8 days	[4] [5]	$50,258	[4] [5]

1 - Represents hospitalization for a worker who is suspected of having active TB but who is ultimately found to not have TB.
2 - Represents hospitalization for a worker who is confirmed to have an active case of TB.
3 - Cost of the procedure is estimated to vary based on complexity.
4 - Time and cost of hospitalization are estimated to vary based on where the osteomyelitis manifests.

Note: Totals may not equal the sum of the components due to rounding.

Sources:	
[1]	CDC, 2011d
[2]	FAIR Health, 2013
[3]	CDC, 2013g
[4]	AHRQ, 2011a
[5]	CMS, 2013b
[6]	PDR, 2013
[7]	VA, 2013
[8]	AHRQ, 2011b
[9]	Patel et al., 2013
[10]	Malebranche, 2005

4. Training

Per the regulatory framework, OSHA would require that employers institute a training program and ensure each worker who has occupational exposure during provision of direct patient care and/or performance of other covered tasks participates in the program. OSHA would also require that training be provided initially, prior to the time of assignment to tasks where occupational exposure may take place, and that the initial training contain, at a minimum:

- An accessible copy of a rule as outlined in the regulatory framework 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;
- Information on vaccine(s) that will be made available to the worker;
- An explanation of the employer's WICP and the means by which the worker 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 worker's duties;
- An explanation of the use and limitations of engineering, administrative and work practice controls; and
- Information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of PPE.

The annual refresher training program, as presented in the regulatory framework, would be required to address at least the following elements:

- Information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of PPE.
- All of the SOPs developed as part of the WICP that are applicable to the worker's duties, and;

- Information on vaccination(s) that will be made available to the worker in the year of training.

OSHA preliminarily estimates that it would take a total of 30 hours for the individual who would be training exposed workers to develop training materials. The initial training is preliminarily estimated to take either two or three hours, depending on the job tasks of the workers, and the annual refresher training is also preliminarily estimated to take two or three hours, again depending on the job tasks of the workers.

Per the Draft Report on Current Compliance, and as shown in Table VI-10, OSHA preliminarily estimates that laboratories provide 86 percent of workers with appropriate training and that hospitals provide 84 percent of workers with appropriate training. Moreover, laboratories provide an estimated 79 percent of workers with annual refresher training, and hospitals provide an estimated 75 percent of workers with annual refresher training. Home healthcare and long term care and nursing homes also are estimated to have relatively high levels of compliance with training requirements. Home healthcare agencies provide an estimated 68 percent of workers with appropriate training, and long term care and nursing home establishments provide an estimated 72 percent of workers with appropriate training. Further, home healthcare agencies provide an estimated 50 percent of workers with annual refresher training, and long term care and nursing home establishments provide an estimated 54 percent of workers with annual refresher training. Employers in "other occupational settings," including morgues and mortuaries and waste handling and laundry services, provide only an estimated 23 percent of workers with appropriate training, and physicians' offices provide only an estimated 25 percent of workers with appropriate training; baseline compliance rates for annual refresher training are estimated to be only 14 percent and 18 percent in those settings, respectively. OSHA welcomes any feedback the SERs may have to offer on these preliminary estimates of current compliance.

5. Recordkeeping

Per the regulatory framework, OSHA would require employers to maintain the following records: medical records generated in conjunction with medical screening and surveillance (including evaluations, examinations, testing, follow-up, and vaccinations); exposure incident records; and WICP review records. In addition, OSHA's Respiratory Protection Standard (29 CFR 1910.134), discussed earlier in this section of the SER Background document, requires the employer to maintain records regarding medical evaluations, fit testing, and the respiratory protection program (29 CFR 1910.134(m). OSHA anticipates that a final rule as outlined in the regulatory framework would have costs associated with all of these recordkeeping provisions.

OSHA preliminarily concludes that there would be no additional costs associated with a provision of the regulatory framework that would require maintenance of WICP review records. The costs associated with reviewing and updating the WICP were addressed previously in this section of the SER Background Document. Likewise, the Agency preliminarily estimates that

there would not be any additional recordkeeping costs associated with a respiratory protection program, above the cost of the time to develop the program, which costs OSHA also addressed previously in this section of the SER Background Document.

OSHA preliminarily estimates that it would take 25 minutes to create and file records for each medical screening performed in conjunction with the medical screening and surveillance provisions of the regulatory framework. This estimate is based on estimates of 10 minutes to create a file for each new employee, as estimated in OSHA's 2010 ICR for bloodborne pathogens (OSHA, 2010), and 15 minutes for recordkeeping associated with initial medical screenings, as estimated in OSHA's PEA for the Proposed Rule on Silica (OSHA, 2013a). In addition, based on the 2011 ICR for OSHA's Respiratory Protection standard, the Agency preliminarily estimates that any medical evaluation, done for the purposes of evaluating a worker's ability to use a respirator, or as a result of a worker having a medical evaluation per the regulatory framework, would generate a medical record, which would take five minutes for a record-keeper to maintain (OSHA, 2011). For vaccinations, the time requirement is estimated to be 15 minutes per employee for a record-keeper to create and file a vaccination record (OSHA, 1991), or five minutes for the record-keeper to create and file a signed declination form. OSHA also preliminarily estimates that an additional five minutes per year, per employee will be necessary to update vaccination records in settings where workers would be required to get annual vaccines, such as the flu vaccine. For respirator fit-testing, the Respiratory Protection ICR suggests a recordkeeping unit cost of five minutes annually per fit test (OSHA, 2011).

OSHA preliminarily estimates that employers would spend 15 minutes generating and filing exposure incident records in accordance with a rule as outlined in the regulatory framework. The Agency estimated costs related to the investigation of exposure incidents earlier in this section of the SER Background Document, and estimates that the information potentially required in the exposure incident records would be collected during those investigations. The additional 15 minutes accounted for here is the time OSHA estimates it would take for an employer to transfer the information to a formal record and to file that record. OSHA notes that, per the regulatory framework, OSHA would require that each exposure incident record include a description of any post-exposure evaluations and follow-ups that were performed, the results of those evaluations, and the dates on which they occurred. As noted above, OSHA preliminarily estimates that it would take a record-keeper five minutes to maintain records related to medical evaluations, and any post-exposure evaluations and follow-ups that result from an exposure incident and that take place after the exposure incident record is initially generated will, likewise, take an additional five minutes to document (over the 15 minutes that OSHA preliminarily estimates would be needed to generate and file the exposure incident record).

OSHA requests comments on the time required to create, file, and maintain records that would be required under a rule as outlined in the regulatory framework.

C. Summary of Preliminary Estimates of Unit Costs

Table VI-9, below, presents all of OSHA's preliminary estimates of the potential unit costs of compliance that would be associated with provisions of a rule as outlined in regulatory framework for infectious diseases. OSHA discussed how these unit costs were derived throughout this section of the SER Background Document. To the extent SERs seek clarification about the entries in Table VI-9, they should refer to this discussion.

Table VI-9 Unit Cost Summary Table

Cost Category	Cost	Frequency	Comments/Assumptions
Worker Infection Control Plan			
Developing Plan	20-40 hours	One Time	Time varies depending on complexity of setting
Annual Update of Plan	4-16 hours	Annually	Time varies depending on complexity of setting
Standard Operating Procedures			
Hazard Evaluation	No extra cost	Per patient	Can be achieved with adjustments to current practice (cost of training is below)
Hand Hygiene (soap and water)	50 seconds	See Comments and Assumptions column	Before/after patient contact, also for certain other activities (contact with contaminated surfaces,inserting catheter, etc.)
Hand Hygiene (alcohol hand-rub)	25 seconds	See Comments and Assumptions column	Before/after patient contact, also for certain other activities (contact with contaminated surfaces, inserting catheter, etc.)
Restricted areas for employee eating and related activities	No extra cost	One time	Estimated to already be in place
Setting up triage stations/Separate areas for suspected/confirmed cases	No extra cost	One time	Can be achieved with adjustments to current practice
Decontamination of materials/surfaces	No extra cost	As established by employer's SOPs	Can be achieved with adjustments to current practice (cost of training is below)
Handling, containerization, transport, or disposal of contaminated materials	No extra cost	Per Event	Can be achieved with adjustments to current practice (Often already covered by Bloodborne Pathogens Standard)
Exposure Incident Investigation	30 minutes	Per incident	
Signage and Labeling/Color Coding	No extra cost	Wherever needed to convey hazard warning	Can be achieved with adjustments to current practice (Often already covered by Bloodborne Pathogens Standard)
Patient Scheduling and Intake	No extra cost	As established by employer's SOPs	Can be achieved with adjustments to current practice (cost of training is below)
Patient Transport Procedures	No extra cost	Per patient requiring transport	Settings where applicable would already follow appropriate procedures, or need simple adjustment to current practice

Table VI-9 Unit Cost Summary Table, continued			
Cost Category	**Cost**	**Frequency**	**Comments/Assumptions**
Upgrade and Maintenance of Existing Engineering Controls			
Upgrade Airborne Infection Isolation Room (AIIR)	$7,217	One time	Only necessary for existing AIIRs that are being used for isolation purpose
Annual Maintenance AIIR	$866	Annually	
Upgrade Autopsy Suite	$14,435	One time	
Annual Maintenance Autopsy Suite	$1,732	Annually	
Upgrade Biological Safety Cabinet (BSC)	$809	One time	Only necessary for existing BSCs that are being used for containment purposes
Annual Maintenance BSC	$97	Annually	
Personal Protective Equipment			
Disposable Gloves	$0.16	When employee interacts with new patient and when gloves become visibly soiled. Also handling of contaminated items (e.g., linens, biohazard waste, used medical equipment)	
Face Mask (e.g., Surgical Mask)	$0.13	When encounter a suspected or confirmed case of droplet transmissible disease, and when facemask is visibly soiled	For all HCWs and for patients with suspected or confirmed droplet transmissible diseases who can tolerate a facemask
N95 Respirator	$0.33	When encounter a suspected or confirmed case of airborne transmissible disease, during aerosol generating procedures, and when N95 respirator is visibly soiled	
Disposable Gown	$2.42	When employee is at risk of skin or clothes becoming contaminated. Also when working in an Airborne Infection Isolation Room	
Disposable Face Shield	$4.55	Mainly when employee potentially exposed to droplet spray and during aerosol-generating activities	
Safety glasses, goggles	$2.05	When employee potentially exposed to splashes or sprays. Also during aerosol-generating activities	

Table VI-9 Unit Cost Summary Table, continued			
Cost Category	**Cost**	**Frequency**	**Comments/Assumptions**
Respiratory Protection			
Written Plan Development	4-8 hours	One time, all employers whose employees wear respirators	Time varies depending on complexity of setting
Written Plan Review and Update	2-4 hours	Annually	Time varies depending on complexity of setting
Initial Medical Questionnaire, or Re-evaluation for change in working conditions			
Employee's time	15 minutes	Per employee completing a questionnaire	Only necessary when the employee is required to wear a respirator. If must travel off site then another 30 minutes of employee time plus $5
PLHCP's time	5 minutes	Per employee completing a questionnaire	
Followup Medical Examination (if needed)	$294.75	Per employee	Plus one hour of employee time. As needed from initial examination, or change in work conditions. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Additional Medical Re-evaluation	$138	Per employee	For new or worsening health condition. Plus 30 minutes employee time. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Respirator Fit Testing			
Manufacturer	30 minutes	Per employee	Cost represents employee time
In-house	$1.15	Per employee	Plus 30 minutes employee time plus 30 minutes tester's time.
Third party testing	$76.68	Per employee	Plus half hour employee time
Vaccines			
Influenza	$13.13	Annually	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel
MMR	$54.07	One time, if born after 1957 with no serologic immunity.	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel
Varicella	$181.10	One time, if no previous history of disease and no serologic immunity.	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel
Tdap	$39.31	One time if never vaccinated/ booster every 10 years	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel
Meningococcal	$111.83	One time, as needed	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel
Typhoid	$24.87	One time, as needed/ then booster every 5 years if vaccine Ty21a, booster every 2 years if vaccine ViCPS	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Inactivated Polio	$23.18	One time, as needed	Also 5 minutes of employee time and 5 minutes of PLHCP time. If must travel off site then another 30 minutes of employee time plus $5 travel

Table VI-9 Unit Cost Summary Table, continued			
Cost Category	**Cost**	**Frequency**	**Comments/Assumptions**
Medical Screening and Surveillance			
Pre-placement Health Inventory			
Employee's time	25 minutes	Per new employee	If must travel off site then another 30 minutes of employee time plus $5 travel costs
PLHCP's time	15 minutes	Per new employee	
TB Test (if required)	$43-$299	Per employee	Also 0.5 – 1.5 hours of employee time. Either one-step, two step, or IGRA test. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Full Pre-placement Physical (not required)	$175	Per employee	At employer's discretion. Also one hour employee time. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Medical Evaluation, Follow-up, and Medical Removal Protection			
Influenza			
Vaccination	$13.13	Per infected worker	If previously without vaccination
Zanamivir or Oseltamivir Medication	$57.52/$80.53	Per infected worker	Either medication can be recommended
Rapid Influenza Diagnostic Test	$105	Per infected worker	If needed
Latent Tuberculosis			
Chest X-ray	$44	Per infected worker	If indicated. Add 30 minutes of employee time to cost. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Initial PLHCP Examination	$138	Per infected worker	If needed. Add 30 minutes of employee time. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Isoniazid or Rifampin Drug Treatment	$2.70-$218.62	Per infected worker	Either medication can be recommended. 4-9 month period
Liver Injury Test	$1,105/$1,657	Per infected worker	Monthly Test. Either 6 or 9 months
Active Tuberculosis			
Initial Drug Treatment	$276.29	Per infected worker	8 weeks of all 4: isoniazid, rifampin, ethambutol, and pyrazinamide
Followup Drug Treatment- Isoniazid and Rifampin	$67.46/$236.10	Per infected worker	18 weeks: either daily or twice weekly doses
Hospitalization	$12,578/$42,237	Per suspected/confirmed case	4 to 8.3 days, including hospital tests/treatment. Also Medical Removal Protection Benefits during this time period plus an additional 3-4 weeks

Table VI-9 Unit Cost Summary Table, continued

Cost Category	Cost	Frequency	Comments/Assumptions
Medical Evaluation, Follow-up, and Medical Removal Protection			
MRSA			
Wound Culture Screening	$48.88-$181.69	Per infected worker	Up to 3 rounds of screening tests. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Abscess Draining	$329-$650	Per infected worker	Depending on complication of procedure. Also 60 to 90 minutes of employee time. If must travel off site then another 30 minutes of employee time plus $5 travel costs
Hospitalization (for serious cases)	$25,262-$62,051	Per infected worker	6 to 9 days of hospitalization, depending on complications. Also Medical Removal Protection Benefits during this time period
Drug Treatment	$9.43-47.04	Per infected worker	Various possible treatments, see text
Training			
Developing Training Materials	30 hours	One time	
Employee Training Time	2-3 hours	Annually	Both for initial training and annual refresher training
Record Keeping			
Medical Screening Record Keeping	25 minutes	Per employee	10 minutes to create employee file, 15 minutes for recording screening
Medical Record	5 minutes	Per medical record generated	Record of any medical evaluation
Vaccination Record	15 minutes	Per employee	Or 5 minutes if need to file employee declination form. Also 5 minutes each year for any annual vaccines
Respirator Fit Test Record	5 minutes	Per employee	
Exposure Incident Record	15 minutes	Per incident	In connection with exposure incident investigation

OSHA, Office of Regulatory Analysis. See text for sources.

D. Preliminary Estimates of Baseline Compliance Rates

Table VI-10, below, presents OSHA's preliminary estimates of current compliance with selected provisions of the regulatory framework for infectious diseases. OSHA described how it generated these preliminary estimates in the Introduction to this section of the SER Background Document.

Table VI-10

Preliminary Estimates of Current Compliance with Selected Provisions of the Conceptual Framework on Infectious Diseases

Question	Hospitals	Physicians' Offices	Dentists' Offices	Other Ambulatory Care Settings	Long Term Care & Nursing Homes	Home Healthcare Agencies	Laboratories	Other Occupational Settings
What percentage of establishments have a written infection control plan (WICP)?	94%	42%	54%	49%	90%	62%	90%	39%
What percentage of establishments review their ICP on an annual basis?	77%	16%	18%	34%	63%	49%	70%	12%
What percentage of establishments have implemented procedures to promptly identify patients with a range of suspected or confirmed infectious diseases?	81%	51%	28%	56%	79%	43%	62%	20%
What percentage of the time do workers practice proper hand hygiene?	58%	51%	66%	57%	56%	63%	80%	34%
What percentage of establishments with AIIRs maintain them so that they meet industry standards?	83%	--	--	--	--	--	--	--
What percentage of establishments that have biological safety cabinets have them certified at least annually?	91%	--	--	--	--	--	94%	--
What percentage of establishments that perform autopsies maintain autopsy suites to a level that meets industry standards?	83%	--	--	--	--	--	--	58%
What percentage of the time do workers with exposure to infectious patients or materials use appropriate PPE?	76%	46%	76%	54%	56%	58%	86%	35%
What percentage of the time do workers who are exposed to potential airborne transmissible infectious agents wear the appropriate respirators?	64%	29%	38%	33%	51%	57%	85%	26%
In settings where some or all workers are required to wear a respirator, what percentage of establishments provide fit testing to those workers prior to their initial use of a respirator?	84%	23%	36%	39%	41%	43%	86%	17%

Table VI-10, continued

Preliminary Estimates of Current Compliance with Selected Provisions of the Conceptual Framework on Infectious Diseases

Question	Hospitals	Physicians' Offices	Dentists' Offices	Other Ambulatory Care Settings	Long Term Care & Nursing Homes	Home Healthcare Agencies	Laboratories	Other Occupational Settings
What percentage of establishments provide annual fit testing to workers who wear respirators?	61%	14%	16%	30%	29%	21%	57%	15%
What percentage of establishments provide medical clearance to affected workers before they are fit tested for or required to use a respirator in the workplace?	84%	20%	26%	26%	38%	27%	71%	15%
What percentage of facilities properly clean and disinfect surfaces in accordance with their ICP or other applicable guidelines?	71%	35%	51%	34%	47%	44%	71%	25%
What percentage of the time do employers document recognized occupational exposure incidents involving infectious agents not covered by OSHA's BBP standard?	82%	34%	30%	47%	64%	49%	85%	29%
What percentage of the time do employers generate medical records for workers with occupational exposure to infectious agents not covered by OSHA's BBP standard?	71%	21%	17%	31%	33%	31%	66%	30%
What percentage of establishments offer their workers the full complement of CDC/ACIP or CDC/NIH BMBL recommended vaccines?	85%	33%	30%	37%	42%	42%	72%	29%
What percentage of establishments make only the vaccines required by their applicable state level health department available to their workers?	60%	52%	51%	67%	77%	72%	72%	69%
What percentage of workers are provided a full physical and/or a verbal or written questionnaire as part of their medical screening prior to their placement?	70%	19%	13%	16%	51%	46%	47%	10%

Table VI-10, continued

Preliminary Estimates of Current Compliance with Selected Provisions of the Conceptual Framework on Infectious Diseases

Question	Hospitals	Physicians' Offices	Dentists' Offices	Other Ambulatory Care Settings	Long Term Care & Nursing Homes	Home Healthcare Agencies	Laboratories	Other Occupational Settings
What percentage of workers are provided pre-placement diagnostic testing as part of their medical screening prior to placement?	90%	28%	26%	41%	46%	45%	71%	17%
Where CDC/HICPAC guidelines recommend PEP such as medications, vaccines or immune globulins, please estimate what percentage of time employers provide the recommended PEP.	91%	48%	44%	62%	68%	66%	86%	32%
What percent of time do employers provide post-exposure testing?	88%	44%	45%	58%	68%	64%	86%	34%
When a worker has a known or suspected infectious disease, what percentage of the time dp employers restrict the worker's normal duties and assign alternative job duties?	77%	44%	45%	49%	60%	46%	66%	23%
When a worker has a known or suspected infectious disease, what percentage of employers direct the worker not to come to work?	59%	29%	35%	30%	48%	50%	49%	27%
Where establishments or employers direct employees with known or suspected infectious diseases not to come to work, what percentage of the time are those workers provided with their normal pay and benefits during the restricted time	84%	60%	65%	67%	63%	45%	72%	41%
What percentage of workers are provided with appropriate training?	84%	25%	33%	41%	72%	68%	87%	23%
What percentage of workers are currently being provided refresher training on infection control practices at least annually?	75%	18%	16%	24%	54%	50%	79%	14%

Source: ERG, 2013

Section VII. Description of Any Duplicative, Overlapping, or Conflicting Rules

The Regulatory Flexibility Act (RFA) requires that the Agency's "initial regulatory flexibility analysis . . . identif[y], to the extent practicable, [] all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule." 5 U.S.C. 603(b)(5). (Separately, the OSH Act does not apply to "working conditions" of workers with respect to which another federal agency has "exercise[d] statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health." 29 U.S.C. 653(b)(1).)

OSHA has not yet developed a proposed rule addressing occupational exposure to infectious diseases. However, as discussed in prior sections of the SER Background Document, OSHA has developed a regulatory framework showing its preliminary thinking on what a proposed rule would encompass. OSHA has identified several federal rules and guidelines that address infection control. Below, the Agency discusses whether these rules and guidelines would duplicate, overlap, or conflict with a rule as outlined in the regulatory framework.

The first set of federal rules or guidelines that OSHA identified are guidelines promulgated by CDC/HICPAC (CDC, 1998). The CDC/HICPAC guidelines include provisions for: identification and isolation of infectious cases; immunizations for vaccine-preventable diseases; standard and transmission-based precautions; training; PPE; management of healthcare workers' risk of exposure to infected persons, including post-exposure prophylaxis; and work restrictions for exposed or infected healthcare personnel (Bolyard et al., 1998; *see also, e.g.*, Siegel et al., 2007).

While the CDC/HICPAC guidelines present recommended practices for reducing the risk of infectious disease transmission to patients and workers, the guidelines are non-mandatory. Such non-mandatory guidelines do not constitute rules that would duplicate, overlap, or conflict with a rule as outlined in the regulatory framework. *Cf. Ensign-Bickford Co. v. OSHRC*, 717 F.2d 1419, 1421 (D.C. Cir. 1983) (agency regulates working conditions only if it "implements [a] regulatory apparatus"); *Marshall v. Northwest Orient Airlines, Inc.*, 574 F.2d 119 (2d Cir 1978) ("sister agency must actually be exercising a power to regulate safety conditions").

There also would be no conflict between a rule as outlined in the regulatory framework and the CDC/HICPAC guidelines because a rule as outlined in the regulatory framework would be performance-based and is, in fact, intended to assure that employers adopt and implement infection control practices consistent with the CDC/HICPAC guidelines. Such a rule would require employers having workers covered by the rule to develop, implement, and update SOPs that are consistent with recognized and generally accepted good infection control practices

relevant to their work setting. To determine whether SOPs are consistent with recognized and generally accepted good infection control practices, the employer would have to consider applicable regulations, such as state and local regulations, and current guidelines, such as the CDC/HICPAC guidelines. Moreover, in the absence of such regulations and guidelines, the employer would need to consider current guidance issued by professional organizations and accrediting bodies. As such, a rule as outlined in the regulatory framework would allow employers to incorporate appropriate CDC/HICPAC guidelines into their infection control programs. Therefore, OSHA concludes that the CDC/HICPAC guidelines would not duplicate, overlap, or conflict with such a rule.

The second set of federal rules or guidelines that OSHA identified are Centers for Medicare and Medicaid Services (CMS) regulations that condition a provider's participation in Medicare or Medicaid on the provider's implementation of an infection control program.[55] CMS interpretive guidelines say that, to meet this condition, providers should ensure that their infection control programs conform to nationally-recognized infection control practices and guidelines, such as the CDC/HICPAC guidelines.[56] CMS regulations do not cover providers that do not accept or collect payment through Medicare or Medicaid. However, they do cover health care providers that accept or collect payment through Medicare or Medicaid (which requires a certification, that involves an inspection covering infection control procedures as they affect patient safety in order to participate), including hospitals, nursing homes, home health care (of kinds covered by Medicare), hospices and ambulatory care facilities providing hospital-like services, such as ambulatory surgical centers and specialty clinics. The CMS regulations do not cover employers engaged in some other covered tasks that take place in facilities where direct patient care is not also provided, such as those that occur in research or production laboratories and death care facilities

A rule as outlined in the regulatory framework would not conflict with the CMS regulations. To the contrary, the joint effect of the CMS regulations and a new OSHA rule would improve the quality and implementation of infection control programs in a manner that the CMS regulations cannot do, and have not done, alone. The Joint Commission (a CMS-approved accreditation organization) recognizes the need to improve the quality and implementation of infection control programs. (See for example http://www.centerfortransforminghealthcare.org/assets/4/6/hand_hygiene_storyboard.pdf). Moreover, other evidence OSHA has examined thus far (some of which is discussed in Section III, above) indicates that, notwithstanding the CMS regulations, many employers receiving

[55]See, e.g., 42 CFR 482.42 (hospitals), 483.65 (long term care facilities), 483.470(l) (intermediate care facilities for individuals with intellectual disabilities), 485.62(b) (outpatient rehabilitation facilities).
[56]See, e.g., CMS State Operations Manual App. A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, App. PP - Guidance to Surveyors for Long Term Care Facilities, App. J - Guidance to Surveyors: Intermediate Care Facilities for Persons With Mental Retardation (CMS, 2013a).

Medicare and Medicaid funding are not fully conforming to nationally recognized infection control practices and guidelines.

OSHA has, at its disposal, enforcement mechanisms that CMS does not have. For example, OSHA can respond to complaints and conduct random unannounced inspections. On the other hand, the CMS regulations establish the terms of a contractual or quasi-contractual agreement between CMS and a provider. A provider agrees to implement an infection control program in exchange for the right to participate in Medicare and Medicaid. *Cf. Ensign-Bickford Co.*, 717 F.2d at 1421 n.3 (noting that the repercussions of violating a contractual agreement "stand[] in sharp contrast to the civil and criminal penalties provided for in the [OSH] Act"). Compliance with the CMS regulations is generally validated through periodic accreditation surveys of the employer's facility by CMS-approved accreditation organizations, including the Joint Commission, state survey agencies, and other organizations that specialize in accrediting various types of healthcare facilities (e.g., Accreditation Association for Ambulatory Health Care (AAAHC)).

The joint effect of OSHA and CMS enforcement can reasonably be expected to result in better compliance than either one alone. This conclusion is borne out by the joint effect of CMS's enforcement of its infection control regulations alongside OSHA's enforcement of its existing Bloodborne Pathogens standard – a regime that has been in place for over twenty years. As noted in Section III, the Bloodborne Pathogens standard, which has existed alongside the CMS regulations since its promulgation, led to significant declines in bloodborne diseases among healthcare workers.

A rule as outlined in the regulatory framework would also not conflict with the CMS regulations because such a rule, like the CMS regulations, would allow employers to incorporate into their infection control programs appropriate nationally-recognized infection control practices and guidelines, such as the CDC/HICPAC guidelines. Thus, such a rule would complement the CMS regulations and would be likely to improve overall compliance with infection control practices.

The third set of federal rules or guidelines that OSHA identified are a group of identical regulations for research that require the protection of human subjects and that were jointly promulgated by fifteen federal agencies, including HHS,[57] the Department of Veterans Affairs,[58] and the Environmental Protection Agency (EPA).[59] 56 FR 28003 (June 18, 1991). Pursuant to those regulations, when research involving human subjects is conducted, supported, or otherwise subject to regulation by a federal department or agency, an Institutional Review Board (IRB)

[57]45 CFR Pt. 46.
[58]38 CFR Pt. 16.
[59]40 CFR Pt. 26.

must review and approve the research and determine that the risks to the subjects are minimized.[60]

Unlike a rule as outlined in the regulatory framework, the regulations requiring the protection of human subjects do not necessarily require the protection of workers. That an individual protocol reviewed and approved by an IRB may address worker protection does not mean the regulations themselves address working conditions. Due to these factors, OSHA concludes that the regulations requiring the protection of human subjects would not duplicate, overlap, or conflict with a rule as outlined in the regulatory framework.

A rule as outlined in the regulatory framework would also not conflict with the regulations requiring the protection of human subjects because such a rule would permit employers conducting research on infection control practices to consider research protocols that are not consistent with recognized and generally accepted good infection control practices, provided those protocols have been approved by an IRB and adequately address worker protection as a component of the overall protection of the human subjects. A rule as outlined in the regulatory framework would therefore complement the regulations requiring the protection of human subjects.

The fourth set of federal rules or guidelines that OSHA identified are Department of Transportation (DOT) regulations that address the safe transport of hazardous materials, including infectious agents.[61] These requirements contain provisions regulating, among other things, the containerization, packaging, marking, labeling, and placarding of these materials.

The fifth set of federal rules or guidelines that OSHA identified are EPA regulations, promulgated pursuant to the Clean Air Act (42 U.S.C. 7401 *et seq.*), governing emissions from hospital/medical/infectious waste incinerators.[62] The regulations require that the training of incinerator operators cover, among other things, "work safety procedures."[63]

The sixth set of federal rules or guidelines that OSHA identified are EPA guidelines contained in its Guide for Infectious Waste Management. These guidelines address primarily decontamination, but also address several other areas, including packaging, storage, and transport of infectious waste, as well as disposal of treated waste (EPA, 1986).

OSHA concludes that there may be some duplication or overlap between the DOT regulations, and the EPA regulations and guidelines, and a rule as outlined in the regulatory framework. However, OSHA believes that, unlike these regulations and guidelines, an OSHA rule would

[60]*See, e.g.*, 45 CFR 46.101(a), 46.103(b), 46.109, 46.111(a).
[61]49 CFR Parts 171 through 180.
[62]40 CFR Pt. 60 Subpts. Ce, Ec; Pt. 62 Subpt. HHH
[63]40 CFR 60.53c

protect workers in a comprehensive manner. A rule as outlined in the regulatory framework would address, not only the training of workers, or the decontamination, transport, containerization, packaging, marking, labeling, and placarding of infectious agents, but myriad other means of protecting workers against the hazards associated with exposure to infectious agents (such as, the provision in the regulatory framework addressing the development and implementation of a written worker infection control plan designed to prevent or minimize the transmission of infectious agents to each worker).[64] The DOT regulations, and the EPA regulations and guidelines, also would not conflict with a rule as outlined in the regulatory framework because, again, such a rule would be performance-based.[65]

The final set of federal rules or guidelines that OSHA identified are existing OSHA standards, including: the Bloodborne Pathogens standard (29 CFR 1910.1030); the Respiratory Protection standard (29 CFR 1910.134); the Personal Protective Equipment standard (29 CFR 1910.132); and the Specifications for Accident Prevention Signs and Tags standard (29 CFR 1910.145). All of these existing standards would remain in place unless otherwise stated in a rule as outlined in the regulatory framework.[66]

The Agency believes that the Bloodborne Pathogens standard would not be duplicative, overlapping, or conflicting with a rule as outlined in the regulatory framework for the following reason: a rule as outlined in the regulatory framework addresses occupational exposure to infectious agents transmitted by contact, droplet and airborne routes other than occupational exposure as defined by the Bloodborne Pathogens standard. OSHA notes that an employer's implementation of a rule as outlined in the regulatory framework may be streamlined in light of the infection control procedures already required by the Bloodborne Pathogens standard.

OSHA believes that an Infectious Diseases rule would help assure that all employers comply with these diverse requirements as part of a comprehensive duty to protect workers from the hazards associated with exposure to infectious agents. If OSHA finds, through the rulemaking process, that some provisions of existing standards become duplicative, unclear, or confusing, it

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[64]While OSHA's authority to regulate working conditions is generally restricted by §4(b)(1) of the OSH Act, which states that "[n]othing in this Act shall apply to working conditions of employees with respect to which other Federal agencies . . . exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health," 29 U.S.C. 653(b)(1), the statutes authorizing the EPA regulations and the DOT regulations each contain a reverse-preemption provision. 42 U.S.C. 7610(a); 49 U.S.C. 5107(g)(2).

[65]OSHA notes, moreover, that the EPA guidelines are non-mandatory. As stated above, non-mandatory guidelines, such as the EPA guidelines, do not constitute rules that would duplicate, overlap, or conflict with a rule as outlined in the regulatory framework.

[66]For example, in OSHA's regulatory framework it is noted that:

> Infection control practices normally rely upon a multi-layered and overlapping strategy of employing engineering, work practice, administrative controls, and PPE. Therefore, OSHA would permit adherence to the required hierarchy of controls, such as that required in 29 CFR 1910.134(a)(1), to be modified in accordance with recognized and generally accepted good infection control practice.

may choose to modify the requirements of some existing standards or to modify a proposed Infectious Diseases standard. OSHA will seek comment during the SBAR process and throughout the rulemaking on provisions that may need to be modified.

Section VIII. Description of Regulatory Alternatives and Options

I. Introduction

Per Section 603(c) of the RFA, if OSHA proposes a rule based on its regulatory framework, it must, in its Initial Regulatory Flexibility Analysis, describe any significant alternatives to the proposed rule that accomplish the stated objective of the OSH Act to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions, 29 USC 651(b), and, at the same time, minimize any significant economic impact of the proposed rule on small entities. To this end, in Part II of this section, and pursuant to Section 609(b) of the RFA, OSHA asks SERs to suggest to the Panel alternatives to the regulatory framework that they believe would accomplish the OSH Act's protective purpose and minimize any significant economic impact on small entities. In Part II, OSHA also asks SERs to suggest to the Panel regulatory options associated with promulgating an infectious diseases standard. While these options are not alternatives for purposes of the RFA, OSHA believes that discussing these options at this stage will aid the rulemaking process.

Part III of this section describes regulatory alternatives to the regulatory framework that the Panel developed that would minimize the significant economic impact on small entities. To allow the SERs to fully understand these alternatives, OSHA provides the SERs with any preliminary determinations the Agency has made about whether the alternatives would accomplish the stated objective of the Act. OSHA asks SERs to comment on these alternatives and OSHA's preliminary determinations to help the Agency make an informed judgment about whether these alternatives would sufficiently protect employee health.

Part IV of this section examines regulatory options that OSHA is considering. OSHA asks SERs to comment on these options and OSHA's preliminary determinations about these options to help the Agency make an informed judgment about whether these options would sufficiently protect employee health.

II. OSHA Asks SERs to Suggest Alternatives and Options

As discussed in the issues paper attached to the SER Background Document, SERs are invited to suggest alternatives and options of their own choice, based on their view of what works and is needed in their kind of facility and what does not work or is unnecessary. The Panel is particularly interested in comments on whether portions of the regulatory framework would have significant costs, but little or no benefit, in a particular kind of facility. The Panel is also interested in comments from SERs indicating those provisions of the regulatory framework they do not already follow, why they do not follow those provisions, and the anticipated costs of

implementing those provisions.[67]

In addition, OSHA is interested in feedback from the SERs on the necessity and usefulness of individual provisions in the regulatory framework. To this end, OSHA asks SERs to respond to the following question:

- What provisions, if any, do you believe you would have to implement as a result of this potential rule that, in your opinion, would not improve worker safety?

Finally, the Agency is interested in the SERs' views on whether there are additional provisions, not contained in the regulatory framework, that are necessary in order to improve worker safety. To this end, OSHA asks SERs to respond to the following question:

- What, if any, additional provisions do you think should be added to the framework, and why?

In commenting on the rule's specific provisions, OSHA asks SERs to keep in mind that elimination of provisions in the regulatory framework would not impact requirements contained in existing standards. For example, as explained in Section IV, Description of the Important Components in the Regulatory framework, the Respiratory Protection standard (29 CFR 1910.134) generally applies to the use of respirators by workers performing tasks that would be covered by a rule as outlined in the regulatory framework. The applicability of, and costs associated with complying with, the Respiratory Protection standard do not depend on the inclusion in the regulatory framework of respiratory protection provisions. Moreover, OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) contains requirements related to the safe handling, processing, storage, transport, shipping and disposal of contaminated materials. The applicability of, and costs associated with complying with, the Bloodborne Pathogens standard do not depend on the inclusion of such provisions in the regulatory framework.

III. Alternatives to the Regulatory framework That Would Minimize Any Significant Economic Impact of the Proposed Rule on Small Entities

Alternative 1 would develop an infectious diseases rule that is specification-oriented rather than performance-oriented.

The regulatory framework is a flexible, performance-oriented approach that reflects what OSHA believes conscientious employers are already doing. Under this alternative, OSHA would

[67] Many employers who have provided comment to the Agency thus far have objected to the promulgation of a rule on the grounds that they already follow most of what OSHA would require. If this is the case, the costs of a rule for these particular employers would be minimal.

promulgate a specification-oriented standard (i.e., an approach that spells out exactly what employers must do to comply with the standard). Such a specification-oriented approach would provide less flexibility, but greater clarity, than a performance-oriented approach.

A rule as outlined in the regulatory framework would require affected employers to assess the infectious disease hazards present in their facilities, and develop and implement appropriate infection control plans that are relevant to those hazards. Infection control plans would also need to be consistent with recognized and generally accepted control practices, which OSHA recognizes, are generally contained in regulations and guidelines, such as the 2007 CDC/HICPAC guidelines (Siegel et al., 2007) and the BMBL guidelines (CDC/NIH, 2009). Therefore, under this possible approach, OSHA would require employers to consider applicable regulations and guidelines in developing their infection control plans. OSHA believes this possible approach offers employers a significant amount of flexibility, since development and implementation of an infection control plan would be dependent on the hazards present. For instance, the Agency believes it is unlikely that a podiatrist's office would need to develop and implement a respiratory protection program under the regulatory framework.

OSHA believes that, in promulgating a specification-oriented infectious diseases rule, the Agency would likely fail to anticipate all of the potential hazards, and, therefore, all of the necessary controls, for every type and every size of facility. As such, such a rule would under-protect workers to the extent the rule did not include specifications to address particular hazards. Similarly, a specification-oriented approach would likely result in requiring employers to implement some protective measures that are not applicable to their facilities.

While structuring an OSHA standard using performance-based language, such as the language presented in the regulatory framework, has distinct advantages, such a rule also is not without some drawbacks. Because the rule does not lay out explicit requirements for each type of affected firm, employers must develop and implement their own infection control plans. OSHA believes that the affected firms have sufficient familiarity with infection control practices to meet these requirements, but the Agency is interested in the views of the SERs.

Specifically, OSHA is interested in whether SERs would find it difficult to determine how a rule based on the regulatory framework would apply in their facilities, or how OSHA would enforce the performance-oriented provisions in the regulatory framework. OSHA is also interested if SERs think that OSHA should promulgate a specification-oriented standard that spells out exactly what employers must do to comply with each provision. OSHA also asks SERS to respond to the following questions:

- Do SERS find the performance-based approach outlined in the regulatory framework to be flexible?

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

Alternative 2 would rely on enforcement under the General Duty Clause.

OSHA would decide not to promulgate a new rule addressing occupational exposure to infectious diseases. Instead, OSHA would issue guidance on workplace exposures to infectious diseases recommending that employers follow current guidelines, such as those issued by the CDC, CDC/HICPAC, and NIH, and then attempt to protect workers exposed to infectious agents through enforcement of the OSH Act's General Duty Clause (29 USC 654(a)(1)). The General Duty Clause requires "[e]ach employer" to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees" (*id.*). To establish that an employer exposed its employees to infectious disease hazards in violation of the General Duty Clause, OSHA would need to establish, in part, that the hazard was recognized and that a feasible and useful method exists to correct the hazard. For example, OSHA would show that an employer had knowledge of, and would have followed, applicable federal, state and local regulations, and current guidelines.[68]

OSHA does not believe that this approach would adequately protect workers with occupational exposure to infectious diseases. A rule based on the regulatory framework would require employers to, among other things, develop and follow worker infection control plans, conduct medical surveillance, and provide medical removal protection benefits. Some elements of the regulatory framework go beyond what is addressed in current regulations and guidelines. OSHA believes that all of the provisions of the regulatory framework would work in concert to minimize the spread of infectious disease to workers; the use of enforcement actions under the

[68] *See, e.g.*, *Kelly Springfield Tire Co. v. Donovan*, 729 F.2d 317, 320-21 (5th Cir. 1984); *Georgia Elec. Co. v. Marshall*, 595 F.2d 309, 320-21 (5th Cir. 1979).

General Duty Clause would be a much less comprehensive approach to addressing workplace exposures to infectious diseases. Thus, the promulgation of a rule based on the regulatory framework would be more protective of employee health than enforcement based on the General Duty Clause. In addition, federal enforcement of the General Duty Clause would not necessarily protect employees in the 25 states and 2 U.S. Territories that operate their own OSHA-approved occupational safety and health plans; even though all state plan states have adopted statutory provisions that are comparable to the OSH Act's General Duty Clause, they were not required to do so, and need not enforce such statutory provisions to the same extent as federal OSHA. (State plans *do* need to promulgate standards that are at least as effective as standards promulgated by federal OSHA.) And finally, enforcement solely through the General Duty Clause is disfavored because it can impose heavy litigation burdens on both OSHA and employers.

Given the limitations associated with enforcement under the General Duty Clause, choosing this non-regulatory alternative would not do as much to accomplish the goals of the OSH Act as the promulgation of a comprehensive standard on workplace exposures to infectious diseases. Thus, OSHA does not believe this would be a desirable approach as long as there is a viable rulemaking alternative (see Section II, Legal Basis for an OSHA Standard Addressing Occupational Exposure to Infectious Diseases). OSHA welcomes comments from SERs on non-regulatory alternatives. In commenting on this issue, OSHA asks SERs to examine the preliminary conclusions OSHA made in Section III of this SER Background Document, Reasons Why Action by the Agency is Being Considered. For example, SERs may examine and comment on the evidence on which OSHA based its preliminary conclusions that: (1) there is a well-recognized risk to workers associated with exposure to infectious agents during the provision of direct patient care and/or performance of other covered tasks; (2) current infection control guidelines are non-mandatory, are not consistently and rigorously followed, and therefore are not sufficient to adequately reduce the risk of transmission of infectious agents to workers who provide direct patient care and/or perform other covered tasks; and (3) following recognized and generally accepted good infection control practices considerably reduces the risk of transmission of infectious agents to workers providing direct patient care and/or performing other covered tasks.

Alternative 3 would exempt very small entities (those with fewer than 20 workers) from all requirements of an infectious diseases rule.

Under this alternative, very small entities (i.e., entities with fewer than 20 workers) would be exempted from all requirements of an infectious diseases rule. Approximately 87 percent of the 637,000 entities that OSHA has preliminarily determined to be affected by a rule as outlined in the regulatory framework are very small establishments with fewer than 20 workers. Approximately 1.5 million of the estimated 9 million workers affected by a rule as outlined in the regulatory framework work in very small entities. Thus, exempting very small entities from

all requirements of an infectious diseases rule would result in only about 82,000 entities and 7.5 million workers remaining in the scope.

OSHA believes strongly that exempting workers based solely on the size of their employer's firm is inconsistent with the objectives of the OSH Act. Congress emphasized in the OSH Act, without reference to the size of individual firms, "every working man and woman" has a right to "safe and healthful working conditions." 29 USC 651(b). OSHA believes that exempting workplaces solely on the basis of size (number of workers) would not provide adequate protection to workers at very small establishments, as workers providing direct patient care and performing other covered tasks in very small establishments also face an elevated risk of occupational exposure to infectious diseases. Additionally, because of the overall shift in the delivery of healthcare services away from larger institutional settings to smaller settings or home healthcare, the Agency is concerned that exempting establishments solely on the basis of size would, over time, have an adverse effect on an increasing proportion of workers.

Alternative 4 would apply an infectious diseases rule to workers providing direct patient care, but not to workers performing other covered tasks.

Under this alternative, OSHA would restrict an infectious diseases rule to workers who have occupational exposure during the provision of direct patient care and not cover those workers with occupational exposure during performance of other covered tasks (as those terms are used in the regulatory framework). Based on the figures in the industry profile presented in Section V of this SER Background Document, OSHA calculates that this alternative would reduce the number of workers affected by such a rule by from about 9 to about 8 million workers: a reduction of approximately 1 million workers. About 500,000 of these one million workers would be employed at SBA defined small businesses. This alternative would reduce the number of affected workers employed at SBA defined small businesses from about 5.8 to about 5.3 million workers, which includes, among other employees described in the industry profile, a reduction of approximately: 69,000 employees at approximately 4,000 diagnostic laboratories, 19,000 medical waste and laundry handlers at approximately 6,000 establishments, and more than 54,000 morticians, medical examiners, and other health care service providers employed at approximately 11,000 morgues/mortuaries.

While the majority of workers with occupational exposure are engaged in direct patient care, there is also occupational exposure in workers performing other covered tasks, including, but not limited to: 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/or 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. While employers would face a cost burden in complying with a rule as outlined in the regulatory framework, OSHA believes, based on the evidence – particularly a number of studies it has thus far analyzed – that workers performing other covered tasks face a risk of infection because of their occupational exposure. For example, Henkel et al. (2012) reported that 11 laboratory-acquired infections with select agents[69] occurred in the U.S. between 2004 and 2011. In addition, at least ten laboratory-acquired Vaccinia infections were reported following occupational exposure to the virus (Byers, 2005, Lewis et al., 2006). And in another example, laundry workers who had contact with contaminated linen in a nursing home in Tennessee suffered the highest attack rate[70] of salmonellosis among the nursing home's workers despite having had no direct contact with infected patients (Standaert et al., 1994). Therefore, the Agency chose to include these workers in the regulatory framework.

Alternative 5 would exempt very small employers (those with fewer than 20 workers) from written documentation requirements.

Under this alternative, employers with fewer than 20 workers would not be subject to written documentation requirements. Per the regulatory framework, OSHA would require covered employers to have a written worker infection control plan (WICP), WICP review records, medical records, and exposure incident records. Therefore, this alternative would decrease the paperwork burden on very small employers. However, OSHA believes it would be virtually impossible to adequately train workers and assure they are routinely and rigorously implementing the employer's infection control plan without a written plan, as the written plan would contain all the Standard Operating Procedures (SOPs) that workers would need to follow to protect themselves.

Inadequate training would, in turn, lead to a higher degree of risk for these workers. It is also important for workers to have access to a written WICP so that workers can review SOPs for newly assigned procedures or review SOPs for their current activities. Finally, it is crucial to document exposure incidents to allow for adequate medical follow-up and contact tracing (i.e., tracing the line of exposure to other workers or patients who also may have had exposure or who may have been a source of exposure), and to update the WICP to account for new or emerging infectious agents or changes in community patterns of infectious diseases (e.g., emergence of an antibiotic resistant infectious agent, an outbreak, or a change in prevalence of an infectious disease).

[69] Pursuant to 42 USC 262a and 7 USC 8401, select agents and toxins are a subset of biological agents and toxins that HHS and the United States Department of Agriculture (USDA) have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. The current list of select agents and toxins can be found at 42 CFR §§ 73.3, 73.4; 9 CFR §§ 121.3, 121.4; and 7 CFR § 331.3.

[70] Attack rate is the number of workers infected with the infectious agent out of the total number of workers exposed to the infectious agent.

Moreover, OSHA believes that many employers of workers with occupational exposure have already developed and implemented infection control plans in their workplaces, as these actions are required for accreditation by the Joint Commission and other CMS approved accrediting agencies in order to receive funding through CMS. In addition, OSHA believes that many employers of workers that would be covered by a rule as outlined in the regulatory framework have already developed and implemented infection control plans in their workplaces to meet the requirements of the Bloodborne Pathogens standard, the recommendations of CDC/NIH's *Biosafety in Microbiological and Biomedical Laboratories*, and/or the recommendations of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. These existing infection control plans would only need to be expanded to include additional elements relevant to a rule as outlined in the regulatory framework. The amount of additional documentation that would be required under a rule as outlined in the regulatory framework would therefore be minimal for these workplaces.

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.

Under this alternative, employers would not be required to develop, implement, and update SOPs for contact precautions. The regulatory framework uses the term contact precautions to mean infection control practices designed to prevent or minimize transmission of infectious agents spread by direct contact (i.e., infectious agent transmission from one infected individual to another individual without a contaminated intermediate item or surface, or individual) or indirect contact (i.e., infectious agent transmission through a contaminated intermediate item or surface, or individual). If the Agency adopted this alternative, its approach would more closely align with that taken by the California Division of Occupational Safety and Health (Cal-OSHA), when it promulgated its Aerosol Transmissible Diseases standard in 2009 (California OSHA, 2009). The Cal-OSHA standard was promulgated to protect workers from exposure to droplet- and airborne-transmissible diseases, but not to contact-transmissible diseases. OSHA believes that Cal-OSHA's approach does not adequately protect workers because, based on the evidence the Agency has thus far analyzed, there are a number of contact-transmissible diseases that pose an elevated risk to workers who provide direct patient care and/or perform other covered tasks. Occupational exposure of workers to contact-transmissible infectious agents such as methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin resistant *Enterococcus* (VRE), is quite common in healthcare settings and is of concern to OSHA. In a recent publication on MRSA that reviewed 127 studies, for example, it was estimated that approximately 5 percent of healthcare workers are colonized with MRSA and 5 percent of these develop infections (Albrich & Harbarth, 2008). Based upon this and other peer-reviewed studies, it is OSHA's position that failing to cover contact-transmissible infectious agents in an infectious disease rule would not protect workers adequately.

Alternative 7 would exclude from an infectious diseases rule any requirement that employers make vaccinations available.

Under this alternative, employers would not be required to make vaccinations available to workers. The alternative would also eliminate the paperwork burden associated with recordkeeping requirements for vaccine administration and signed vaccine declination statements, and eliminate vaccination-related training that would be required by a rule as outlined in the regulatory framework. However, vaccination is generally considered an important component of an effective infection control program, as it protects inoculated workers from infections, lessens chances of outbreaks by minimizing transmission of infections from workers to other workers and patients, and may also lessen the duration and severity of infections, depending on the efficacy of the vaccine. The recommendations of CDC's Advisory Committee on Immunization Practices (ACIP) assert that "optimal use of recommended vaccines helps maintain immunity and safeguard [healthcare workers] from infection" (Shefer et al., 2011). Therefore, as in OSHA's Bloodborne Pathogens standard (§1910.1030), OSHA thinks it is important to require employers to make vaccinations available to workers.

Alternative 8 would exclude from an infectious diseases rule any requirement that employers provide medical removal protection benefits.

Under this alternative, employers would not be required to provide medical removal protection (MRP) benefits. Not incorporating such a provision in an infectious diseases rule would decrease employers' compliance costs, specifically, the cost of paying a worker's total normal earnings, and maintaining the worker's seniority, rights, and benefits, when the worker has been removed from his or her job or otherwise medically limited as a result of occupational exposure.

While OSHA has not calculated the total costs related to medical removal protection, the Agency believes that the costs will be minimal for most employers, especially because full implementation of the provisions in a rule as outlined in the regulatory framework would reduce the need for medical removal protection. The provisions of the regulatory framework are aimed at preventing or minimizing worker contact with potentially infectious agents and, if fully implemented, a rule as outlined in the regulatory framework would greatly reduce the number of occupationally-acquired infections in the workers covered. In addition, if OSHA required employers to provide MRP benefits, this would encourage worker participation in (and therefore increases the effectiveness of) any medical surveillance program that would be required, by ensuring that reporting symptoms or health conditions will not result in loss of job or pay. Without a requirement for MRP benefits, workers might be deterred from reporting signs and symptoms that could be indicative of infection and might work while sick (due to concerns about loss of pay or other such punitive consequences), potentially resulting in further infections to co-

workers and/or patients. Most occupationally acquired infectious diseases that would require extensive leave under a medical removal provision are seen relatively infrequently - especially since, under the regulatory framework, OSHA would not require MRP benefits for most workers who are removed from their jobs or otherwise medically limited as a result of occupational exposure to the common cold or influenza. Many employers would have no cases in any given year. However, OSHA seeks input on whether the MRP provision would have significant economic impacts on small or very small firms in the relatively uncommon circumstance of an employee being removed from the workplace because of a long-term serious illness.

Alternative 9 would only include initial training and training-as-needed in an infectious diseases rule.

Under this alternative, OSHA would not require employers to conduct annual training for workers. Under the regulatory framework, annual training would, at a minimum, include: information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of PPE; all of the SOPs developed as part of the WICP that are applicable to the worker's duties; and information on vaccine(s) that will be made available to the worker 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 will be offered at no cost and at reasonable times and places). Not including these provisions in an infectious diseases rule would decrease the burden for all employers. Research, however, shows that an effective training program, which includes annual training, is essential to ensuring that workers understand the hazards to which they are exposed and how employers must protect them from these hazards (Bolyard et al., 1998). Effective training can result in fewer injuries and illnesses, better morale, and lower insurance premiums, among other benefits. Inclusion of an annual training requirement reflects OSHA's belief that training is an essential part of every employer's safety and health program for protecting workers from injuries and illnesses (Bolyard et al., 1998), and that workers will not be adequately protected unless they regularly receive information about the safety and health aspects of their jobs. In its review of current scientific literature related to occupational exposure to infectious agents, OSHA found nearly 100 studies that supported the need for such training programs to ensure worker familiarity with general infection control practices, proper use of PPE, effective hand hygiene, and other methods for reducing occupational exposure (see, e.g., Aboumatar et al., 2012; Nichol et al., 2013; Chen et al., 2011).

Moreover, even if OSHA does not require annual training in an infectious diseases rule, this would not affect a requirement that employers conduct supplemental training that is tied to the employer's WICP. Under the regulatory framework, OSHA would require the employer to conduct supplemental training to address changes in the WICP. And, per the regulatory framework, OSHA would require the WICP to be reviewed and updated at least annually, and

whenever necessary to reflect various changes in occupational exposure. So given the regulatory framework's provisions for supplemental training, the alternative of not requiring annual training would not significantly limit the overall training burden on employers.

Alternative 10 would add additional time for small employers to phase-in compliance with an infectious diseases rule.

A phase-in of an infectious diseases rule would have several advantages in regards to potential impacts on small businesses. First, it would reduce the one-time initial costs of such a rule by spreading these costs out over time. A differential phase-in for smaller firms would also assist very small firms in developing and implementing a WICP specific to their workplace based upon the experience of larger firms. However a phase-in would also postpone the benefits of an infectious diseases rule.

IV. Regulatory Options Under Consideration

Option 1 would include in the scope of an infectious diseases rule workers who perform first aid only.

Under this option, workers who perform first aid only would be considered to provide direct patient care for the purposes of an infectious diseases rule. Inclusion of these workers would substantially increase the number of covered workers. However, OSHA believes the resulting increased burden on employers is unnecessary for reducing the health hazards posed by infectious diseases. First aid primarily involves attention to persons with conditions such as cardiac or respiratory arrest, small lacerations (cuts), insect stings and bites, poisonings, and burns, not attention to persons with infectious diseases. Moreover, OSHA believes that general public health measures are adequate to protect first aid workers from the types of infectious agents covered by a rule as outlined in the regulatory framework, and thus that it is not necessary to impose the burden of implementing and maintaining a comprehensive infection control plan for such workplace exposures.

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.

Under this option, in addition to tasks that would be covered by a rule as outlined in the regulatory framework, other tasks, such as tasks performed by teachers and prison guards would fall within the scope, even when these workers are not performing other covered tasks, as that

term is used in the regulatory framework. In addition, the scope would be expanded to include the tasks performed by flight attendants when they are working on airplanes.

Per the regulatory framework, OSHA would cover healthcare-related and certain other limited tasks, such as mortuary services and laboratory activities. Expanding the scope of an infectious diseases rule beyond the regulatory framework would greatly increase the number of employers that would be required to comply. Including prison guards, child daycare teachers, and elementary and secondary school teachers would add an additional 5 million workers to the scope of an infectious diseases rule and affect approximately 99,000 additional establishments. Adding flight attendants would result in coverage for approximately 88,000 more workers and 467 additional establishments.

The tasks that would be covered by a rule as outlined in the regulatory framework – unlike the typical duties of workers such as prison guards, teachers and flight attendants – would generally be subject to the standard and transmission-based precautions laid out in the CDC/HICPAC guidelines. Many of the programmatic elements contained in the regulatory framework are already in place for the tasks that would be covered by a rule as outlined in the regulatory framework, but that is not the case for tasks in this option. Development and implementation of these programmatic elements could be expensive for the employers affected by the option. Moreover, OSHA believes, based on the evidence it has thus far analyzed, that general public health measures are adequate to protect workers performing the tasks outlined in this option, and that it is not necessary to impose the burden of implementing and maintaining a comprehensive infection control plan for such workplace exposures.

Option 3 would define direct patient care to include all tasks performed by pharmacists that involve face-to-face contact.

In this option, the direct patient care definition would include all the tasks of pharmacists that involve face-to-face contact. Covering these additional tasks of pharmacists would increase the number of employers that would be required to comply with an infectious diseases rule, adding approximately 172,000 more workers to the scope of this rule and affecting approximately 72,000 additional establishments.

The regulatory framework defines direct patient care, in part, as job duties involving hands-on or face-to-face contact with patients. An exception for pharmacists in the regulatory framework states that pharmacists who provide hands-on care (e.g., administer vaccinations) provide direct patient care, while those who perform duties that involve face-to-face contact only (e.g., dispense medications) do not provide direct patient care. This option would eliminate this exception to the direct patient care definition.

OSHA believes, based on the evidence it has thus far analyzed, that general public health measures are adequate to protect pharmacists who neither provide direct patient care nor perform other covered tasks, as those terms are used in the regulatory framework, and that the cost of implementing and maintaining a comprehensive infection control plan for the tasks of all pharmacists would impose an unreasonable burden on employers. However, OSHA will continue to examine these job tasks carefully, and may explore ways to specifically address the infectious disease hazards that may be associated with the tasks of this job classification in the future. The Agency is seeking input on whether it should cover these tasks.

Option 4 would add increased specificity to the exposure determination that could be required.

This option would require the exposure determination to contain a list of all job classifications *and job tasks* in which all or some of the workers have occupational exposure. Under the regulatory framework, the employer would provide a list of job classifications for the exposure determination, but would not need to prepare a list of job tasks. OSHA believes that including a list of tasks workers perform where occupational exposure occurs would impose an unnecessary paperwork burden on employers.

Moreover, while the Agency expects that some employers may choose to add an additional list of tasks and procedures for the job classifications identified, at this time OSHA does not believe that it should require this increased specificity. Such specificity may lead to over-reliance on a list of specific tasks that may be incomplete when developing training programs, selecting PPE, and implementing other requirements of an infectious diseases rule, particularly considering the difficulty associated with anticipating all tasks that may be required as part of workers providing direct patient care and/or performing other covered tasks. OSHA recognizes that the nature of treating patients and completing tasks related to healthcare is dynamic, and that developing lists of specific job tasks associated with job classifications may be counterproductive and may result in a lower level of protection for workers.

The Agency is seeking input on the amount of time employers anticipate it would take to develop lists of all job classifications and specific job tasks with occupational exposure, as well as the utility of such an undertaking.

Option 5 would require written documentation for infectious agent hazard evaluations.

Under this option, employers would be required to document infectious agent hazard evaluations. Per the regulatory framework, OSHA would require employers to conduct, but not necessarily document, these evaluations (which the regulatory framework defines as assessments to determine the presence of suspected or confirmed sources of infectious agents to which workers

have occupational exposure during provision of direct patient care and/or performance of other covered tasks). Under the regulatory framework, OSHA would require employers to develop, implement, and update 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. In the regulatory framework, OSHA thus envisions an ongoing process meant to ensure that workers are continually protected from hazards that may change frequently due to the variety of infectious agents circulating in the community, the types of patients a facility receives, and other factors. The regulatory framework provides further that infectious agent hazard evaluations may be incorporated into routine activities, such as triage.

OSHA believes that requiring employers to document infectious agent hazard evaluations would increase both the paperwork burden, through additional requirements for written documentation and recordkeeping, and the cost, through time required to achieve compliance for employers. Further, the Agency believes that a documentation requirement would not advance (and might even detract from) OSHA's goal in the regulatory framework that occupational exposure to infectious agent hazards be continually evaluated in an ongoing fashion. Finally, OSHA believes that the recordkeeping provisions that are currently in the regulatory framework would sufficiently protect workers. For example, per the regulatory framework, OSHA would require employers to keep exposure incident records, which would allow the employer to document elements such as the work setting and work task(s) being performed when the exposure incident(s) occurred, which would, in turn, allow the employer to focus efforts on decreasing or eliminating specific circumstances or routes of exposures that caused the incident(s).

OSHA believes that requiring employers to keep infectious agent hazard evaluations in written form would not greatly improve protection of workers beyond what would be achieved with the recordkeeping provisions that are currently in the regulatory framework.

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).

Under this option, adherence by hospitals to the required hierarchy of controls as required in 29 CFR 1910.134(a)(1), would not be modified in accordance with recognized and generally accepted good infection control practices. This option, therefore, would require hospital employers to prevent or minimize airborne transmission of infectious agents in their work settings by first installing and employing effective engineering controls, i.e., an appropriate numbers of AIIRs, based on expected demand for airborne isolation.

OSHA recognizes that infection control practices normally rely upon a multi-layered and overlapping strategy of employing engineering, work practice and administrative controls, and

PPE. Therefore, in the regulatory framework, OSHA notes that the Agency would permit adherence to the required hierarchy of controls, such as that required by 29 CFR 1910.134(a)(1), to be modified in accordance with recognized and generally accepted good infection control practices.

OSHA's review of the scientific literature suggests that, when maintained and used properly, using AIIRs is an effective method for controlling the spread of airborne infectious agents (see, e.g., Parvez et al., 2010; Roberts et al., 2006; Saravia et al., 2007; Stroud et al., 1995). On the other hand, OSHA believes that workers will be adequately protected through compliance with a requirement that employers must develop, implement, and update airborne precautions that are consistent with recognized and generally accepted good infection control practices relevant to their work settings. Moreover, per section IV of the regulatory framework (Standard Operating Procedures Development and Implementation), OSHA would require employers that provide services in medical surge conditions to develop, implement, and update procedures for the implementation of temporary control measures, including the use of temporary engineering controls used to establish temporary airborne infection isolation areas, or AIIAs[71], where appropriate. This provision, if promulgated, would provide additional protection.

Option 7 would require all employers to provide medical removal protection benefits for common cold and influenza.

This option would apply medical removal protection (MRP) benefits to all infectious diseases, including influenza and the common cold. Per the regulatory framework, OSHA would require employers to pay a worker's total normal earnings, and maintain the worker's seniority, rights, and benefits, when the worker has been removed from his or her job or otherwise medically limited as a result of occupational exposure, but would not generally require employers to provide these benefits when a worker is removed from his or her job or otherwise medically limited as a result of occupational exposure to the common cold or influenza.

Requiring employers to provide MRP benefits encourages worker participation in (and therefore increases the effectiveness of) the medical surveillance program that would be required by an infectious diseases rule by ensuring that reporting symptoms or health conditions will not result in loss of job or pay. The expansion of MRP benefits to cover influenza and the common cold would likely reduce additional infections in coworkers and/or patients. Moreover, exclusion of the common cold and influenza, frequent occupational exposure to both of which is supported by scientific evidence, could deter workers from reporting signs and symptoms consistent with cold

[71] An AIIA is an area (e.g., room, booth, tent, or other enclosure), other than a dedicated airborne infection isolation room (AIIR), that is maintained at negative pressure to adjacent areas in order to control the spread of an airborne-transmissible infectious agent(s) outside of the AIIA.

or influenza (e.g., cough, runny nose, sneezing, sore throat, muscle aches, tiredness) that may also be indicative of infection with other, potentially more serious, agents.

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.

Under this option, employers would be required 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. CDC encourages patients to ask or remind HCWs to wash their hands (CDC, 2010b). Wu et al. (2013) found that patients were willing to participate in such initiatives to improve hand hygiene among HCWs; and McGuckin et al. (2004) found that, when patients asked HCWs to use soap or hand sanitizer products, HCWs washed or sanitized their hands about 4.7 times more per day compared with HCWs not asked about hand hygiene by patients in the study. This option would not only ensure placement of visual reminders to HCWs and workers performing other covered tasks to use proper hand hygiene, but would also help to promote a general culture of good hand hygiene for organizations by incorporating patient awareness and possible resulting action(s). However, printed signs would create additional compliance costs for employers, and represent an increased paperwork burden. OSHA invites stakeholder comment about the efficacy and cost of this option.

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Appendix A – SBA Definitions of Small Entities for all Affected Industries at the Six-Digit NAICS Level

Table A-1. SBA Definitions of Small Entities for all Affected Industries at the Six-Digit NAICS Level					
NAICS code	NAICS industry	SBA Definition - Revenue	SBA Definition - Employees	SBA Definition - Other	SBA Definition Converted To Employees
	Local Government Entities			Population <50,000	
	Non-Profits			Not dominant in their field	
221100	Electric Power Generation, Transmission and Distribution			4 million megawatt hours	500
221200	Natural Gas Distribution		500		500
221310	Water Supply and Irrigation Systems	$25,500,000			500
221320	Sewage Treatment Facilities	$19,000,000			100
221330	Steam and Air-Conditioning Supply	$14,000,000			20
311100	Animal Food Manufacturing		500		500
311200	Grain and Oilseed Milling		500		500
311300	Sugar and Confectionery Product Manufacturing		500		500
311400	Fruit and Vegetable Preserving and Specialty Food		500		500
311500	Dairy Product Manufacturing		500		500
311600	Animal Slaughtering and Processing		500		500
311700	Seafood Product Preparation and Packaging		500		500
311800	Bakeries and Tortilla Manufacturing		500		500
311900	Other Food Manufacturing		500		500
312100	Beverage Manufacturing		500		500
312200	Tobacco Manufacturing		500		500
313100	Fiber, Yarn, and Thread Mills		500		500
313200	Fabric Mills		1,000		1,000
313300	Textile and Fabric Finishing and Fabric Coating		1,000		1,000
314100	Textile Furnishings Mills		500		500
314900	Other Textile Product Mills		500		500
315100	Apparel Knitting Mills		500		500
315200	Cut and Sew Apparel Manufacturing		500		500
315900	Apparel Accessories and Other Apparel		500		500
316100	Leather and Hide Tanning and Finishing		500		500
316200	Footwear Manufacturing		1,000		1,000
316900	Other Leather and Allied Product Manufacturing		500		500
321100	Sawmills and Wood Preservation		500		500
321200	Veneer, Plywood, and Engineered Wood Product Manufacturing		500		500
321900	Other Wood Product Manufacturing		500		500
322100	Pulp, Paper, and Paperboard Mills		750		750
322200	Converted Paper Product Manufacturing		500		500
323100	Printing and Related Support Activities		500		500
324100	Petroleum and Coal Products Manufacturing		1,500		1,500
325100	Basic Chemical Manufacturing		1,000		1,000
325200	Resin, Synthetic Rubber, and Artificial Synthetic Fibers and Filaments Manufacturing		750		750

Table A-1. SBA Definitions of Small Entities for all Affected Indiustries at the Six-Digit NAICS Level, continued					
NAICS code	NAICS industry	SBA Definition - Revenue	SBA Definition - Employees	SBA Definition - Other	SBA Definition Converted To Employees
325300	Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing		1,000		1,000
325400	Pharmaceutical and Medicine Manufacturing		750		750
325500	Paint, Coating, and Adhesive Manufacturing		500		500
325600	Soap, Cleaning Compound, and Toilet Preparation Manufacturing		750		750
325900	Other Chemical Product and Preparation Manufacturing		500		500
326100	Plastics Product Manufacturing		500		500
326200	Rubber Product Manufacturing		1,000		1,000
327100	Clay Product and Refractory Manufacturing		750		750
327200	Glass and Glass Product Manufacturing		1,000		1,000
327300	Cement and Concrete Product Manufacturing		750		750
327400	Lime and Gypsum Product Manufacturing		500		500
327900	Other Nonmetallic Mineral Product Manufacturing		500		500
331100	Iron and Steel Mills and Ferroalloy Manufacturing		1,000		1,000
331200	Steel Product Manufacturing from Purchased Steel		1,000		1,000
331300	Alumina and Aluminum Production and Processing		1,000		1,000
331400	Nonferrous Metal (except Aluminum) Production and Processing		1,000		1,000
331500	Foundries		500		500
332100	Forging and Stamping		500		500
332200	Cutlery and Handtool Manufacturing		500		500
332300	Architectural and Structural Metals Manufacturing		500		500
332400	Boiler, Tank, and Shipping Container Manufacturing		500		500
332500	Hardware Manufacturing		500		500
332600	Spring and Wire Product Manufacturing		500		500
332700	Machine Shops; Turned Product; and Screw, Nut, and Bolt Manufacturing		500		500
332800	Coating, Engraving, Heat Treating, and Allied		750		750
332900	Other Fabricated Metal Product Manufacturing		500		500
333100	Agriculture, Construction, and Mining Machinery Manufacturing		500		500
333200	Industrial Machinery Manufacturing		500		500
333300	Commercial and Service Industry Machinery		500		500
333400	Ventilation, Heating, Air-Conditioning, and		500		500
333500	Metalworking Machinery Manufacturing		500		500
333600	Engine, Turbine, and Power Transmission Equipment Manufacturing		1,000		1,000
333900	Other General Purpose Machinery Manufacturing		500		500
334100	Computer and Peripheral Equipment Manufacturing		1,000		1,000
334200	Communications Equipment Manufacturing		1,000		1,000
334300	Audio and Video Equipment Manufacturing		750		750

Table A-1. SBA Definitions of Small Entities for all Affected Indiustries at the Six-Digit NAICS Level, continued					
NAICS code	NAICS industry	SBA Definition - Revenue	SBA Definition - Employees	SBA Definition - Other	SBA Definition Converted To Employees
334400	Semiconductor and Other Electronic Component Manufacturing		750		750
334500	Navigational, Measuring, Electromedical, and Control Instruments Manufacturing		500		500
334600	Manufacturing and Reproducing Magnetic and Optical Media		500		500
335100	Electric Lighting Equipment Manufacturing		1,000		1,000
335200	Household Appliance Manufacturing		750		750
335300	Electrical Equipment Manufacturing		750		750
335900	Other Electrical Equipment and Component Manufacturing		500		500
336100	Motor Vehicle Manufacturing		1,000		1,000
336200	Motor Vehicle Body and Trailer Manufacturing		1,000		1,000
336300	Motor Vehicle Parts Manufacturing		500		500
336400	Aerospace Product and Parts Manufacturing		1,500		1,500
336500	Railroad Rolling Stock Manufacturing		1,000		1,000
336600	Ship and Boat Building		1,000		1,000
336900	Other Transportation Equipment Manufacturing		500		500
337100	Household and Institutional Furniture and Kitchen Cabinet Manufacturing		500		500
337200	Office Furniture (including Fixtures) Manufacturing		500		500
337900	Other Furniture Related Product Manufacturing		500		500
339100	Medical Equipment and Supplies Manufacturing		500		500
339900	Other Miscellaneous Manufacturing		500		500
423400	Professional and Commercial Equipment and Supplies Merchant Wholesalers		100		100
446110	Pharmacies and Drug Stores	$25,500,000			100
452900	Other General Merchandise Stores	$27,000,000			500
454111	Electronic Shopping	$30,000,000			100
454113	Mail-Order Houses	$35,500,000			500
485991	Special Needs Transportation	$7,000,000			100
485999	All Other Transit and Ground Passenger Transportation				500
511200	Software Publishers	$25,000,000			100
523110	Investment Banking and Securities Dealing	$7,000,000			20
523120	Securities Brokerage	$7,000,000			20
523130	Commodity Contracts Dealing	$7,000,000			10
523140	Commodity Contracts Brokerage	$7,000,000			20
524113	Direct Life Insurance Carriers	$7,000,000			10
524114	Direct Health and Medical Insurance Carriers	$7,000,000			20
524126	Direct Property and Casualty Insurance Carriers		1,500		1,500
524127	Direct Title Insurance Carriers	$7,000,000			100

Table A-1. SBA Definitions of Small Entities for all Affected Indiustries at the Six-Digit NAICS Level, continued					
NAICS code	NAICS industry	SBA Definition - Revenue	SBA Definition - Employees	SBA Definition - Other	SBA Definition Converted To Employees
524128	Other Direct Insurance (except Life, Health, and Medical) Carriers	$7,000,000			20
524130	Reinsurance Carriers	$7,000,000			20
524200	Agencies, Brokerages, and Other Insurance Related Activities	$7,000,000			100
525910	Open-End Investment Funds	$7,000,000			500
525930	Real Estate Investment Trusts	$7,000,000			10
525990	Other Financial Vehicles	$7,000,000			20
531110	Lessors of Residential Buildings and Dwellings	$7,000,000			100
531120	Lessors of Nonresidential Buildings (except Miniwarehouses)	$7,000,000			20
531130	Lessors of Miniwarehouses and Self-Storage Units	$25,500,000			500
531190	Lessors of Other Real Estate Property	$7,000,000			100
531311	Residential Property Managers	$2,000,000			20
531312	Nonresidential Property Managers	$2,000,000			20
531320	Offices of Real Estate Appraisers	$2,000,000			20
531390	Other Activities Related to Real Estate	$2,000,000			10
532291	Home Health Equipment Rental	$7,000,000			100
532490	Other Commercial and Industrial Machinery and Equipment Rental and Leasing	$7,000,000			100
541380	Testing Laboratories	$12,000,000			100
541710	Research & Development in Physical Engineering and Life Sciences		500		500
551111	Offices of Bank Holding Companies	$7,000,000			100
551112	Offices of Other Holding Companies	$7,000,000			100
551114	Offices	$7,000,000			500
561100	Office Administrative Services	$7,000,000			100
561200	Facilities Support Services	$35,500,000			500
561310	Employment Placement Agencies	$7,000,000			100
561320	Temporary Help Services	$13,500,000			500
561330	Professional Employer Organizations	$13,500,000			500
561611	Investigation Services	$12,500,000			500
561612	Security Guards and Patrol Services	$18,500,000			500
561900	Other Support Services	$7,000,000			100
562100	Waste Collection	$12,500,000			100
562211	Hazardous Waste Treatment and Disposal	$12,500,000			100
562212	Solid Waste Landfill	$12,500,000			100
562213	Solid Waste Combustors and Incinerators	$12,500,000			500
562219	Other Nonhazardous Waste Treatment and Disposal	$12,500,000			100
562910	Remediation Services	$14,000,000			100
562920	Materials Recovery Facilities	$12,500,000			100
562991	Septic Tank and Related Services	$7,000,000			100
562998	Services	$7,000,000			100

Table A-1. SBA Definitions of Small Entities for all Affected Indiustries at the Six-Digit NAICS Level, continued					
NAICS code	NAICS industry	SBA Definition - Revenue	SBA Definition - Employees	SBA Definition - Other	SBA Definition Converted To Employees
611100	Elementary and Secondary Embedded clinics in schools, Privately owned	$7,000,000			100
611200	Junior colleges, Privately owned	$7,000,000			100
611300	Colleges, universities, and professional Embedded clinics in schools, Privately owned	$7,000,000			100
611400	Business Embedded clinics in schools and computer and management training, Privately owned	$7,000,000			100
611511	Cosmetology and Barber Schools Embedded clinics in schools, Privately owned	$7,000,000			100
611512	Flight Training Embedded clinics in schools, Privately owned	$25,500,000			500
611513	Apprenticeship Training Embedded clinics in schools, Privately owned	$7,000,000			100
611519	Other Technical and Trade Schools Embedded clinics in schools, Privately owned	$7,000,000			100
611610	Fine Arts Schools Embedded clinics in schools, Privately owned	$7,000,000			500
611620	Sports and Recreation Instruction Embedded clinics in schools, Privately owned	$7,000,000			500
611699	All Other Miscellaneous Schools and Instruction Embedded clinics in schools, Privately owned	$7,000,000			100
611700	Educational Support Services, Privately owned	$7,000,000			100
621111	Offices of Physicians (except Mental Health Specialists)	$10,000,000			100
621112	Offices of Physicians, Mental Health Specialists	$10,000,000			500
621200	Offices of Dentists	$7,000,000			100
621310	Offices of Chiropractors	$7,000,000			500
621320	Offices of Optometrists	$7,000,000			100
621390	Offices of All Other Health Practitioners	$7,000,000			500
621500	Medical and Diagnostic Laboratories	$13,500,000			100
621600	Home Health Care Services	$13,500,000			500
621910	Ambulance Services	$7,000,000			100
621990	All Other Ambulatory Health Care Services	$10,000,000			100
622100	General Medical and Surgical Hospitals, Privately owned	$34,500,000			500
622200	Psychiatric and Substance Abuse Hospitals, Privately owned	$34,500,000			500
622300	Specialty hospitals, Privately owned	$34,500,000			500
623100	Nursing Care Facilities	$13,500,000			500
623210	Residential Mental Retardation Facilities	$10,000,000			500
623220	Residential Mental Health and Substance Abuse Facilities	$7,000,000			500

Table A-1. SBA Definitions of Small Entities for all Affected Indiustries at the Six-Digit NAICS Level, continued					
NAICS code	NAICS industry	SBA Definition - Revenue	SBA Definition - Employees	SBA Definition - Other	SBA Definition Converted To Employees
623311	Continuing Care Retirement Communities	$13,500,000			500
623312	Homes for the Elderly	$7,000,000			500
623900	Other Residential Care Facilities	$7,000,000			500
624110	Child and Youth Services	$7,000,000			500
624120	Services for the Elderly and Persons with Disabilities	$7,000,000			500
624190	Other Individual and Family Services	$7,000,000			100
624230	Emergency and Other Relief Services	$7,000,000			20
624300	Vocational Rehabilitation Services	$7,000,000			500
624400	Child Day Care Services	$7,000,000			500
711200	Spectator Sports	$7,000,000			100
711300	Promoters of Performing Arts, Sports, and Similar Events	$7,000,000			100
713110	Amusement and Theme Parks	$7,000,000			100
713120	Amusement Arcades	$7,000,000			500
713200	Gambling Industries	$7,000,000			100
713910	Golf Courses and Country Clubs	$7,000,000			100
713920	Skiing Facilities	$7,000,000			500
713930	Marinas	$7,000,000			100
713940	Fitness and Recreational Sports Centers	$7,000,000			500
713950	Bowling Centers	$7,000,000			500
713990	All Other Amusement and Recreation Industries	$7,000,000			500
721199	All Other Traveler Accommodation	$7,000,000			500
721300	Rooming and Boarding Houses	$7,000,000			500
812191	Diet and Weight Reducing Centers	$19,000,000			500
812199	Other Personal Care Services	$7,000,000			500
812210	Funeral Homes and Funeral Services	$7,000,000			100
812220	Cemeteries and Crematories	$19,000,000			500
813100	Religious Organizations	$7,000,000			100

Notes: For those industries with a revenue criterion OSHA calculated the average revenue for each employment size class in the Census data, and found the largest size class where average revenue is less than the SBA definition. All non-profits were considered SBA entities for purposes OSHA's analysis. All governmental entities were considered not to be SBA entities.
Source: SBA, 2010.

Appendix B – Regulatory framework Crosswalk with Published Infection Control Guidelines/Regulations

Although OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) protects workers from occupational exposure to bloodborne pathogens, there are no other mandatory federal standards that protect workers from occupational exposure to the various infectious agents to which they may be exposed. However, infection prevention and control is a recognized and generally accepted practice in the healthcare industry, and, to this end, numerous non-mandatory guidelines on infection prevention and control provide recommendations for the protection of patients and workers from infectious agents.

Despite these recommendations, the focus of infection control practices, in general, has been on the protection of patients, with the common understanding that by reducing the transmission of infectious agents from healthcare workers to patients and between patients, the overall risk of exposure to healthcare workers would likely be reduced as well. Thus, the Centers for Medicare and Medicaid (CMS), as well as non-governmental organizations (e.g., CMS-approved accreditation organizations such as the Joint Commission), rely on recognized and generally accepted good infection prevention and control guidelines in developing their own programs

The Agency has been developing an extensive crosswalk comparing the provisions of the regulatory framework with existing guidelines and regulations for infectious disease prevention and control in workplaces where workers provide direct patient care and/or perform other covered tasks (as those terms are defined in the regulatory framework). The crosswalk currently contains 39 documents, and OSHA is working to analyze additional guidelines and regulations for inclusion. See List of Guidelines and Regulations OSHA Has Thus Far Analyzed, directly below this discussion.

OSHA concludes, based on the comparison it has thus far done, that many provisions in the regulatory framework are consistent with recommended infection control practices described in the crosswalk documents. For example, both the regulatory framework and infection control practices described in the 2007 *CDC/HICPAC Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* (Item 29 in the crosswalk), emphasize standard and transmission-based precautions to reduce the risk of transmission of infectious agents. Moreover, the 2007 guidelines contain infection control practices applicable to healthcare facilities (e.g., acute care hospitals, home care settings, and ambulatory care settings), which are addressed by the regulatory framework. The documents in the crosswalk also cover such diverse settings as behavioral health settings, dentists' offices, laboratories and funeral homes (Items 7, 12, 14, 22, 24, 25, 30, 32, 36, 37), which are also addressed by the regulatory framework.

The CDC guidelines have been widely accepted and incorporated into healthcare facilities' infection prevention and control programs. For example, the majority of employers that would be subject to a rule as outlined in the regulatory framework are also subject to CMS regulations (Items 16 thru 23 in crosswalk). These regulations condition a provider's participation in Medicare or Medicaid on the provider's implementation of an infection control program. Pursuant to CMS interpretive guidelines, to meet this condition, providers should ensure that their infection control programs conform to recognized and generally accepted infectious control practices and guidelines, such as the CDC/HICPAC guidelines. See, e.g., CMS State Operations Manual App. A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, App. PP - Guidance to Surveyors for Long Term Care Facilities, App. J - Guidance to Surveyors: Intermediate Care Facilities for Persons With Mental Retardation. Furthermore, compliance with the CMS regulations is generally validated through periodic accreditation surveys of facilities by CMS-approved accreditation organizations, including The Joint Commission (TJC), a private not-for-profit organization that evaluates and accredits more than 20,000 healthcare organizations and programs in the United States. Consistent with these interpretive guidelines, many of the infection prevention and control practices TJC requires to be adopted for accreditation (Items 31 thru 36 of the crosswalk) vary based on healthcare setting, but those practices closely follow the 2007 CDC/HICPAC guidelines.

Finally, OSHA believes that many employers not directly subject to the CMS regulations are familiar with, and may have adopted, infection control programs that are consistent with the regulations and guidelines in the crosswalk, again, because these guidelines and regulations are widely accepted means of addressing infectious agent hazards. Moreover, OSHA believes that a large number of employers of workers performing other covered tasks, as that term is defined in the regulatory framework (for example, employers of workers performing maintenance and housekeeping in health care settings), work in facilities that are subject to the CMS regulations.

OSHA emphasizes that the crosswalk in this SER Background Document does not represent the universe of relevant guidelines and regulations addressing infection prevention and control. OSHA is in the process of compiling and analyzing other relevant guidelines and regulations issued by entities such as state licensing boards, trade associations, and credentialing agencies. However, because OSHA wants to ensure that it examines a representative number of relevant documents, OSHA requests that any guidelines or regulations addressing infection prevention and control that are not listed in the crosswalk be submitted by the regulated community to OSHA for analysis.

List of Guidelines and Regulations OSHA Has Thus Far Analyzed

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