Transmission Provider for performing any System Impact Study needed to evaluate the capability of the Transmission System to accommodate the proposed change and any additional costs resulting from such change. The Reseller shall remain liable for the performance of all obligations under the Service Agreement, except as specifically agreed to by the Transmission Provider and the Reseller through an amendment to the Service Agreement.

23.3 Information on Assignment or Transfer of Service:

In accordance with Section 4, all sales or assignments of capacity must be conducted through or otherwise posted on the Transmission Provider's OASIS on or before the date the reassigned service commences and are subject to Section 23.1. Resellers may also use the Transmission Provider's OASIS to post transmission capacity available for resale.

[FR Doc. 2010–10500 Filed 5–5–10; 8:45 am]
BILLING CODE 6717–01–C

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA–2010–0003]

RIN No. 1218–AC46

Infectious Diseases

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Request for information.

SUMMARY: OSHA requests information and comment on occupational exposure to infectious agents in settings where healthcare is provided, (*e.g.,* hospitals, outpatient clinics, clinics in schools and correctional facilities), and healthcare-related settings (*e.g.,* laboratories that handle potentially infectious biological materials, medical examiner offices and mortuaries). OSHA is interested in strategies that are being used in such healthcare and other healthcare-related work settings to mitigate the risk of occupationally-acquired infectious diseases. As such, OSHA would like to collect information and data on the facilities and the tasks potentially exposing workers to this risk; successful employee infection control programs; control methodologies being utilized (including engineering, work practice, and administrative controls and personal protective equipment); medical surveillance programs; and training. OSHA will use the information received in response to this request to determine what action, if any, the Agency may take to further limit the spread of occupationally-acquired infectious diseases in these types of settings.

DATES: Comments must be submitted by the following date:

Hard copy: Your comments must be submitted (postmarked or sent) by August 4, 2010.

Facsimile and electronic transmission: Your comments must be sent by August 4, 2010.

ADDRESSES: You may submit comments and additional materials by any of the following methods:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions:

Fax: If your submissions, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648; or

Mail, hand delivery, express mail, messenger or courier service: You must submit three copies of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2010–0003, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210. Deliveries (hand, express mail, messenger and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m.–4:45 p.m., EST.

Instructions: All submissions must include the Agency name and the OSHA docket number for this rulemaking (OSHA Docket No. OSHA–2010–0003). Submissions, including any personal information you provide, are placed in the public docket without change and may be made available online at *http://www.regulations.gov.*

Docket: To read or download submissions or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the

docket are listed in the *http://www.regulations.gov* index, however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office.

FOR FURTHER INFORMATION CONTACT:

Press Inquiries: Jennifer Ashley, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1999.

General and Technical Information: Andrew Levinson, Director, Office of Biological Hazards, OSHA Directorate of Standards and Guidance, Room N–3718, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC, 20210; telephone: (202) 693–2048.

SUPPLEMENTARY INFORMATION:

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I. Background

A. Introduction

In 2007, the healthcare and social assistance sector as a whole had 16.5 million employees.[1] Healthcare workplaces can range from small private practices of physicians to hospitals that employ thousands of workers. In addition, healthcare is increasingly being provided in other settings such as nursing homes, free-standing surgical and outpatient centers, emergency care clinics, patients' homes, and pre-hospitalization emergency care settings. Over the last 10 years, the number of healthcare workers (HCWs) (defined as healthcare professionals, technicians, and healthcare support workers, including those not directly providing patient care such as maintenance or laundry workers) has increased from 8.4 million in 1998, to approximately 11 million in 2008. In 1998, of the 8.4 million HCWs, 3.0 million were employed in hospitals and 5.4 million were employed outside of hospitals. In 2008, 3.6 million HCWs were employed in hospitals and 7.3 million outside of hospitals. Of the 7.3 million workers employed outside of hospitals, 2.1 million were employed by establishments not defined as part of the healthcare sector.[2] The increasing number of HCWs outside of hospital settings who are exposed to occupational injuries and illnesses likely has implications for risk management.

Depending on the setting and the job tasks, HCWs may be exposed to a number of occupational hazards including: Exposure to infectious agents, radiation and chemicals. The Bureau of Labor Statistics (BLS) reports that for 2008, the incidence of all occupational injury and illness (including musculo-skeletal disorders from slips and falls and lifting patients and equipment) in the healthcare sector as a whole was 5.6 cases per 100 full-time workers, in contrast to an average of 4.2 cases per 100 full-time workers for private industry overall.[3] Higher rates have been documented in hospitals, with an incidence rate for all injuries and illnesses of 7.6 per 100 full-time workers, and nursing homes, with an incidence rate for all injuries and illnesses of 8.4 per 100 full-time workers.

In addition to settings where healthcare is provided, there are other work settings where workers might be at increased risk for occupational exposure to infectious agents. Occupational exposure to infectious agents may occur in settings where healthcare is provided (*e.g.,* hospitals, clinics, some emergency response settings; clinics in schools or correctional facilities); and healthcare-related settings where there is increased potential for exposure to infectious agents due to the populations being served or the materials being handled (*e.g.,* drug treatment programs; laboratories that handle potentially infectious biological materials; medical examiners' and coroners' offices; and mortuaries). The purpose of this Request for Information (RFI) is to gather additional information on occupational exposure to infectious agents, how occupational exposure is being mitigated, and other types of work settings where there may be an increased risk of exposure. It should be noted that bloodborne pathogens (*e.g.,* HIV, hepatitis B), are already covered by OSHA's Bloodborne Pathogens standard (§ 1910.1030) and are not included in this RFI.

The primary routes of infectious disease transmission in US healthcare settings are contact, droplet, and airborne. Contact transmission can be sub-divided into direct and indirect contact.[4] Direct contact transmission involves physical contact between an infected person and another person, and the physical transfer of microorganisms (*e.g.,* direct skin-to-skin contact). Indirect contact transmission occurs in situations where the physical transfer of microorganisms to a person comes from contact with a contaminated surface (*e.g.,* contaminated environmental surfaces, such as a door knob, inadequately cleaned patient-care instruments or equipment, such as an examination table or patient bed).

Droplets containing microorganisms are generated when an infected person coughs, sneezes, or talks, or during certain medical procedures, such as suctioning or endotracheal intubation. Transmission occurs when droplets generated in this way come into direct contact with the mucosal surfaces of the eyes, nose, or mouth of a susceptible individual.[5] Droplets are too large to be airborne for long periods of time, and droplet transmission does not occur through the air over long distances. However, some of the droplets expelled by the infected patient will desiccate (dry out) very quickly (less than 1–2 seconds) and form what are called droplet nuclei (residue from evaporated droplets). These small particles can remain suspended in air for long periods of time and travel significantly longer distances.

Airborne transmission occurs when infectious droplet nuclei or particles containing infectious agents that remain suspended in air, are inhaled, enter the respiratory tract and cause infection.[6] Since air currents can disperse these droplet nuclei or particles over long distances, airborne transmission does not require face-to-face contact with an infected individual. Airborne transmission only applies to those organisms that are capable of surviving and retaining infectivity for relatively long periods of time in airborne droplet nuclei or particles. Only a limited number of diseases are transmissible via the airborne route.

The major goal of infection control (IC) is to prevent transmission of infectious diseases to patients and HCWs. This fundamental approach is set forth in the guidelines of the Department of Health and Human Services (HHS) Centers for Disease Control and Prevention's (CDC) Healthcare Infection Control Practices Advisory Committee (HICPAC), a Federal advisory committee to CDC on the practice of health care infection control in U.S. healthcare facilities. The HICPAC guidelines include:

Identification and isolation of infectious cases; immunizations for vaccine-preventable diseases; standard and transmission-based precautions; training; personal protective equipment (PPE); management of HCWs' risk of exposure to infected persons, including post-exposure prophylaxis; and work restrictions for exposed or infected healthcare personnel.[7]

These recommendations have been endorsed by professional associations such as the Association for Professionals in Infection Control and Epidemiology (APIC),[8] the Society for Healthcare Epidemiology of America (SHEA),[9] and the Association of periOperative Registered Nurses (AORN).[10] OSHA is soliciting comment through this RFI on any other strategies that might be applied within healthcare or healthcare-related work settings to mitigate the risk of occupationally transmitted infectious diseases.

While the CDC/HICPAC guidelines present the recommended practices for reducing the risk of infectious disease transmission to patients and HCWs, the guidelines are non-mandatory. However, Centers for Medicare and Medicaid Services (CMS) mandates that in order for hospitals and other providers to receive certification and reimbursement through Medicare or Medicaid, the "facility must establish and maintain an Infection Control Program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection." [11] Similarly, the Joint Commission (formerly called the Joint Commission on Accreditation of Healthcare Organizations), a private not-for-profit organization that evaluates and accredits more than 17,000 healthcare organizations and programs in the United States, requires an effective Infection Prevention and Control Plan for accreditation.[12]

CDC/HICPAC has stated that "adherence to recommended infection control practices decreases transmission of infectious agents in healthcare settings." [13] While the infection control guidelines and requirements are widely recognized, day-to-day compliance, surveillance and oversight is left to each individual employer. Due to the continued prevalence of healthcare-associated infections (HAIs), particularly among patients,[14] and the emergence of new infectious diseases that affect both patients and HCWs [*e.g.,* severe acute respiratory syndrome (SARS), 2009 H1N1 pandemic influenza], compliance with routine infection control procedures is an increasingly important issue.

The lack of adherence to voluntary infection control procedures is of particular interest to OSHA. CDC/HICPAC states that "several observational studies have shown limited adherence to recommended practices by healthcare personnel." [15] It should be noted that these were small case studies which were not designed to be representative of healthcare settings in general. CDC/HICPAC has also noted that HCWs generally reported greater self-adherence to infection control practices than was actually reported in observational studies. Observed adherence to universal precautions (now part of standard precautions) ranged from 43% to 89%, with even greater variability reported for certain recommended infection control practices (*e.g.,* glove use).[16]

The World Health Organization (WHO) recognized the lack of compliance with hand hygiene and launched the *First Global Patient Safety Challenge* to achieve improvement in hand hygiene worldwide. In 2009, WHO issued hand hygiene guidelines that were based upon a thorough review of hundreds of manuscripts that dealt with the negative impact of non-compliance with hand hygiene on the transmission of infectious diseases in healthcare settings.[17] A second review that examined the results of 20 hospital-based studies published between 1977 and 2008, concluded that despite study limitations, most studies showed a temporal relation between improved hand hygiene practices and reduced infection and cross-contamination rates.[18]

A study of adherence to CDC recommended respiratory infection control practices examined 653 healthcare workers in primary care clinics and emergency departments of five medical centers and found significant gaps in compliance. There were shortcomings in overall personal and institutional use of CDC recommended practices, including deficiencies in posted alerts, patient masking and separation, hand hygiene, PPE use, staff training, and written procedures.[19] Another study, published in 2009, surveyed nurses and doctors from five medical facilities and documented the lack of compliance with both hand hygiene and respiratory protection guidelines. Although not necessarily representative of, or generalizable to, the healthcare industry, it is of interest that of those doctors that responded to the survey, only 8% of 177 reported using recommended respiratory protection and only 33% of 156 reported practicing recommended hand hygiene. In addition, of those nurses that responded to the survey, only 25% of 249 reported practicing appropriate respiratory precautions and only 43% of 266 reported practicing recommended hand hygiene measures.[20]

In another recent study 292 HCWs were surveyed about their use of PPE for protection against influenza. These HCWs consisted of internal medicine house-staff, pulmonary/critical care fellows, faculty, respiratory therapists and nurses working in four ICU's in two large hospitals. The study found that only 63% of the HCWs surveyed were able to correctly identify appropriate PPE for influenza. The study's authors stated that of the respondents "nearly 40% of HCWs reported poor adherence with influenza PPE, and 53% reported that their colleagues often forget to use appropriate PPE." [21] The CDC initiated a similar investigation of possible occupationally-acquired 2009 H1N1 pandemic influenza, which was published in the April-May 2009 MMWR. In response to a solicitation from CDC, State health departments reported 48 cases of confirmed or probable cases of H1N1 infection in HCWs. Of the 48 cases, information on PPE use was available for 11 of the HCWs who were deemed to have probable or possible acquisition from a patient. Of these 11 HCWs who were infected, only 3 reported always using either a surgical mask or an N95 respirator when appropriate and none reported always following standard precautions (*e.g.*, use of gloves, gown, facemask) and airborne precautions (*e.g.*, use of a respirator).[22]

In its revised 2007 guidelines, CDC/HICPAC noted that "a recent review of the literature concluded that variations in organizational factors (*e.g.*, safety culture, policies and procedures, education and training) and individual factors (*e.g.*, knowledge, perceptions of risk, past experience) were determinants of adherence to infection control guidelines for protection against SARS and other respiratory pathogens." [23]

Several studies have found organizational factors to be the most significant predictor of safe work behaviors. A study by Gershon *et al.* of 1716 hospital-based HCWs, at three regional hospitals, found that those who perceived that their institution had a strong commitment to safety were almost three times more likely to be compliant with standard precautions than those who did not.[24] Similar results were found when a group of 350 HCWs from 28 State correctional facilities were surveyed.[25] In addition, a series of studies demonstrated that interventions targeted at improving

organizational support for worker safety and health, resulted in enhanced compliance with standard precautions. These studies were: a survey of 789 hospital-based HCWs at a large regional research medical center; a survey of 452 nurses employed at one large medical center; a review of behavioral interventions to improve infection control practices; a survey of 1135 HCWs at one large teaching hospital; and finally, a survey of 742 nurses at a 900-bed urban teaching hospital.[26 27 28 29 30] A study by Nichol *et al* sent 400 surveys to nurses in nine nursing units from two urban hospitals. Of these surveys, 177 were returned with responses. The study found that nurses used recommended facial protection (*e.g.*, respirators, surgical masks, and eye/face protection) when they felt that management made health and safety a high priority, took all reasonable steps to minimize hazards, encouraged employees' involvement in health and safety issues, and actively worked to protect employees.[31] Other studies in industrial settings have shown that safety culture has an important influence on implementation of training skills and knowledge.[32 33]

The lack of compliance with recommended infection control practices is also noted by the Institute of Medicine (IOM), a Congressionally-chartered independent, nonprofit organization that provides unbiased and authoritative advice to decision makers and the public. In 2009, the IOM issued a report entitled, *Respiratory protection for healthcare workers in the workplace against novel H1N1 influenza A: A letter report.* The report was requested by both CDC and OSHA, and concluded that:

> * * * although 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."[34]

The relationship between safety culture and compliance with recommended infection control guidance in some portions of the healthcare sector is not a newly recognized issue. A 1999 IOM report on medical errors in the healthcare sector emphasized the pivotal role of system failures and the benefits of a strong safety culture in the prevention of such errors. The report notes that a safety culture is created through: (1) The actions management takes to improve both patient and worker safety; (2) worker participation in safety planning; (3) the availability of appropriate protective equipment; (4) the influence of group norms regarding acceptable safety practices; and (5) the organization's socialization process for new personnel.[35] Similarly, CDC/HICPAC has noted that "several hospital-based studies have linked measures of safety culture with both employee adherence to safe practices and reduced exposures to blood and body fluids."[36] This evidence was cited by CDC/HICPAC as one of the primary reasons for updating its guidance in 2007.[37] CDC/HICPAC noted that organizational characteristics, including safety culture, influence healthcare personnel adherence to recommended infection control practices and, therefore, are important factors in preventing transmission of infectious agents. CDC/HICPAC further emphasized the need for administrative involvement in the development and support of IC programs.

Noncompliance with recommended infection control practices (*e.g.*, hand hygiene, and proper use of gloves, facemasks, and respirators) increases the risk of transmission of infectious diseases among patients and workers.[19 31 38] HHS notes that HAIs are among the leading causes of death in the United States, accounting for an estimated 1.7 million infections and 99,000 associated deaths in 2002.[39] The 2007 CDC/HICPAC guidelines note that infectious agents are also transmitted from HCWs to patients.[40]

More specifically, poor infection control practices have been implicated in both acquisition and transmission of methicillin-resistant *Staphylococcus aureus* (MRSA) by healthcare personnel.[41] Other studies have documented the nosocomial (hospital-acquired) transmission of adenovirus from patients to HCWs[42 43]; invasive Group A Strep (GAS) from a patient to an HCW[44]; *Clostridium difficile* infection from a patient to a nurse in an oncology ward[45]; and a norovirus outbreak in HCWs in a hospital.[46] Additionally, CDC/HICPAC has documented the occupational transmission of influenza in hospitals and nursing homes.[47] OSHA previously documented occupational exposure to tuberculosis (TB) in its notice "Occupational Exposure to Tuberculosis; Proposed Rule" (62 FR 54160–54308; October 17, 1997). Additionally, an investigation of the 2003 SARS outbreak in Toronto, Canada, described the nosocomial transmission of SARS at a hospital. The investigation found that 42.5% of the cases occurred among hospital employees.[48]

Although HCW infections have been documented, published data on the prevalence of these infections is limited. Recently, the National Institute for Occupational Safety and Health (NIOSH) noted that a lack of occupational data in existing healthcare surveillance systems made tracking illnesses among HCWs difficult.[49] The healthcare sector puts forth substantial effort to track patient infections, but does not appear to match that effort with a systematic means for tracking occupationally acquired worker infections. A weak culture of worker safety in this sector may be a contributing factor to this issue.

B. History of Occupational Safety and Health Regulations Addressing Protection of Workers From Infectious Diseases

OSHA's past efforts to protect workers against occupationally acquired infectious diseases include the Bloodborne Pathogens standard (§ 1910.1030), promulgated in 1991. That standard requires a comprehensive programmatic approach to controlling transmission of bloodborne diseases. Following its promulgation, the incidence of Hepatitis B in HCWs dropped from more than 100 cases per 100,000 HCWs in 1991 to only 9.1 cases per 100,000 HCWs in 1995.[50] The standard was revised in 2001 in response to the Needlestick Safety and Prevention Act, Pub. L. 106–430. In general, the revisions require employers to evaluate and use safer medical devices (*e.g.*, needleless devices, sharps with engineered sharps injury protections), and to establish and maintain a sharps injury log for recording percutaneous injuries from contaminated sharps.

As a result of a marked increase in tuberculosis (TB) during the early 1990s, which included worker infections, OSHA initiated action to address occupational exposure to TB. A standard was proposed, but was later withdrawn. In part, the proposal was withdrawn because of healthcare facilities' increased adherence to CDC's TB guidelines and the subsequent decline in TB infection rates.[51] To assure continued protection of workers, OSHA addresses occupational exposure to TB through its TB compliance directive.[52] The directive utilizes the CDC guidelines as the recognized means for controlling TB exposure. When OSHA determines that a TB hazard exists in a facility, exposure control deficiencies may be cited under existing OSHA standards [*e.g.*, the Respiratory

Protection standard (§ 1910.134)] and the General Duty Clause [Section 5(a)(1) of the Occupational Safety and Health Act of 1970, Pub. L. 91–596 (OSH Act)]. The General Duty Clause requires employers 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."

California-OSHA (Cal-OSHA) recently promulgated an Aerosol Transmissible Diseases (ATD) Standard [53] to protect workers from exposure to infectious agents transmitted via the droplet or airborne routes. Following Federal OSHA's withdrawal of the TB proposal, Cal-OSHA developed its standard in response to concerns about TB, the 2003 SARS epidemic, and a potential influenza pandemic. The standard significantly expands protection of California workers against aerosol transmissible diseases (this term, as defined by Cal-OSHA, encompasses those diseases that can be transmitted by the droplet or airborne routes). It should be noted that the standard does not deal with occupational exposure to infectious agents that are transmitted primarily via the contact route (*e.g.*, MRSA, Group A strep, and noroviruses).

Existing OSHA standards that may be applicable to controlling occupational exposure to infectious agents, other than the bloodborne pathogens standard, include: The Respiratory Protection standard (§ 1910.134); the Personal Protective Equipment standard (§ 1910.132); and the Specifications for Accident Prevention Signs and Tags standard (§ 1910.145). OSHA is seeking information through this RFI on whether or not its existing standards and the voluntary guidelines issued by other organizations are effectively protecting workers from occupational exposure to infectious agents. If not, OSHA seeks comment on what measures might be appropriate for the Agency to take to protect workers against infectious diseases (*e.g.,* development of a proposed standard, issuance of guidelines, or other alternatives).

C. Summary

In summary, as a result of several factors raised in the preceding discussion, OSHA is seeking additional information to more fully evaluate worker exposures to infectious agents in healthcare and healthcare-related settings. We are particularly interested in additional data regarding indications in some studies that transmission of infectious diseases to both patients and HCWs may be occurring as a result of incomplete adherence to voluntary infection control measures in traditional healthcare facilities. Another concern is the movement of healthcare delivery from the traditional hospital setting, with its greater infrastructure and resources to effectively implement infection control measures, into more diverse and smaller workplace settings with less infrastructure and fewer resources, but with an expanding worker population.

Consequently, the Agency is seeking information to assist in its deliberation on these issues. OSHA is interested in more accurately characterizing the nature and extent of occupationally-acquired infectious diseases and the strategies that are currently being used to mitigate the risk of occupational exposure to infectious agents in healthcare and healthcare-related settings, including patient and non-patient settings and sites where healthcare is embedded within non-healthcare settings such as clinics in schools and correctional facilities. The information being sought includes: the types of facilities and workers incurring this risk; successful employer infection control programs; control methodologies being utilized (including engineering, administrative, and work practice controls, and the use of appropriate personal protective equipment); medical surveillance programs; and training programs. The information received in response to this notice will be carefully reviewed and will assist OSHA in determining the effectiveness of approaches currently being used to eliminate and minimize occupational exposure to infectious agents. Based upon its analysis of this information, OSHA will determine what action, if any, the Agency may take to address these issues.

II. Request for Data, Information and Comments

A. General

The following general information will assist OSHA in more fully understanding each commenter's submissions and the possible differences in their approaches to infection control. The answers to the questions will also help OSHA understand the risk of workers contracting various infectious diseases in different types of workplaces.

Note: Diseases spread through bloodborne pathogens are not encompassed by this RFI since a specific OSHA standard (Bloodborne Pathogens, § 1910.1030) addresses those diseases. OSHA encourages those with experience in non-traditional or non-healthcare work settings to respond to these questions.

1. Since healthcare is provided in a wide variety of settings (as previously described), OSHA is interested in being able to sort the responses received by the characteristics of the workplace about which each responding entity is providing information. As such, please describe the characteristics of the workplace to which you are referring. For example: type of workplace (*e.g.,* hospital, long-term care, physician/dentist office, emergency medical services); size (*e.g.,* number of hospital beds, number of residents, average number of patients/clients); total number of employees (both direct care and administrative support).

2. While OSHA is primarily concerned about worker exposure to infectious agents in traditional healthcare settings, the Agency recognizes that there are other settings where healthcare may be provided and where occupational exposure to infectious agents may be a significant concern (*e.g.,* drug treatment facilities, home health services, prison clinics, school clinics, and laboratories that handle potentially infectious biological materials). Please describe any other work settings with an increased risk for occupational exposure to infectious agents that OSHA should consider, including why they should be considered. Please describe the nature and extent to which occupational exposure to infectious agents is a significant concern. For example, to which infectious agents are workers in these settings exposed and how often are they exposed? Please describe any infection control measures that can be or are being used in these settings.

3. One of the most important steps in determining how to effectively protect workers from infectious diseases is identifying who is at risk of exposure. What recommendations do you have for how to determine which employees are potentially exposed to contact, droplet, and airborne transmissible diseases in the type of workplace about which you are responding? How many of your total workers have a risk of exposure to such diseases during the performance of their job duties? What proportion of your workforce does this represent? What are the job titles or classification(s) of these workers? What are the job duties of these workers? To which diseases are they exposed?

4. Workplaces vary in the types of infectious diseases and the number of infected individuals encountered. OSHA is interested in the types of diseases that your workplace encounters and how often they are encountered. Please describe your workplace's experience with infectious diseases over

the past ten years (*e.g.,* which diseases, how often).

5. OSHA is interested in data and information that will further assist in characterizing workers' occupational exposure to contact, droplet, and airborne transmissible infectious diseases.

(a) OSHA encourages the submission of your workplace or your industry's experience with these diseases and the impact of infectious diseases on your workers (*e.g.,* type and number of exposure incidents, occupationally-acquired infectious diseases, days of work missed, and fatalities).

(b) Please provide information about any database that collects and aggregates data on occupationally-acquired infectious diseases (*e.g.,* Federal, State, provider network, or academic).

(c) Please provide any additional information, including peer-reviewed studies, which addresses occupational exposure to infectious agents that you think OSHA should consider.

6. Infection control (IC) programs are currently the primary means of controlling occupational exposure to infectious agents. However, these programs are largely voluntary. OSHA is particularly interested in case studies that highlight experience in the implementation and effectiveness of IC programs in protecting workers against infectious diseases (*e.g.,* the extent to which employers are fully implementing and consistently following their written IC programs). For example, has your workplace had instances where a significant increase in infections (among either patients or workers) required more rigorous implementation of your IC program? If so, please describe any factors that contributed to the increase and what steps your workplace took to address the situation. Please provide any studies that demonstrate the difference in infection rates between situations where the IC program had lapsed and situations where rigorous implementation of control measures was instituted.

7. While OSHA has a Bloodborne Pathogens standard (§ 1910.1030), the Agency does not have a comprehensive standard that addresses occupational exposure to contact, droplet, and airborne transmissible diseases. The Agency has other standards [(*e.g.,* Respiratory Protection (§ 1910.134) and General Personal Protective Equipment (§ 1910.132)] that may apply and, in some situations, Section 5(a)(1) of the OSH Act (the General Duty Clause) would apply. OSHA is interested in commenters' insights regarding the adequacy of existing OSHA requirements to protect workers against occupational exposure to infectious agents.

8. California OSHA recently issued a standard for occupational exposure to "Aerosol" Transmissible Diseases that covers infectious diseases transmitted through the airborne and droplet routes. IC programs that are established in most healthcare settings address exposure to contact, droplet, and airborne transmissible diseases. Please explain whether the Agency's deliberations on occupational exposure to infectious diseases should focus on only droplet and airborne transmission or if contact transmissible diseases should also be included.

9. If the Agency pursues rulemaking and promulgates a standard, jurisdictions with OSHA-approved State plans will be required to cover workers who OSHA determines are at occupational risk for exposure to infectious agents, including public employees. State and local governments are defined very broadly, and would typically include such entities as a university hospital associated with a State university as well as public hospitals and health clinics. What public sector healthcare or healthcare-related workers are at increased risk for occupational exposure to infectious agents? Please describe conditions unique to any of these occupations that are not seen in the private sector. Please describe any other issues specific to OSHA-approved State plans that the Agency should consider.

B. Infection Prevention and Control Plan

10. CDC/HICPAC's *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* recommends an IC program for addressing the transmission of airborne and other infectious diseases. In certain settings, the Center for Medicare and Medicaid Services (CMS) and the Joint Commission require that healthcare facilities have such programs.

(a) If you are subject to the CMS or Joint Commission requirements or otherwise have an IC program, please provide information on the elements of this program (*e.g.,* early identification of infectious patients, implementation of transmission-based control measures, HCW training) and how the program works.

(b) If you are not subject to these requirements and do not have an IC program, how does your workplace address preventing contact, droplet and airborne transmissible infectious diseases?

11. In most cases, an IC program is managed by an infection control preventionist or other designated person. For example, the CDC/HICPAC guidelines recommend that the IC program be managed by individuals with training in infection control. Who manages your program? What percentage of this individual's time is spent managing the IC program?

12. For the IC program(s) established in your workplace, please describe, in detail, the resource requirements and associated costs, if available, expended to initiate the program(s) and conduct the program(s) annually. Please estimate, in percentage terms where possible, the extent to which the components or elements in your program(s) are typical of those practiced throughout your industry.

13. In your industry, for the IC programs established in your workplace or for IC programs in other workplaces of which you are aware, are there any components or features that may present economic difficulties to small businesses? Please describe and characterize in detail these components and why they might present difficulties for small businesses.

14. Periodic evaluation of IC program effectiveness is recommended by CDC/HICPAC and required by the Joint Commission and CMS for most types of facilities under their jurisdiction. Please describe how your workplace or industry evaluates the effectiveness of its IC program, including the methods and criteria used. How often does your workplace evaluate its program? Please describe the results your program has achieved (*e.g.,* if there has been a decrease in patient and/or worker infections). Please describe any specific problems and/or successes that have been encountered in the implementation and operation of the program.

15. Most peer-reviewed literature evaluating IC programs focuses on protecting patients from contracting HAIs. While this body of evidence can be an indicator of worker exposure, OSHA is seeking data that more specifically address the occupational risk to workers. If your workplace has a system for tracking worker exposures or infections that may have been occupationally acquired, please share with us the following information:

(a) A description of the tracking system and how it works;

(b) The types of infection diseases encountered in your workplace and the number of exposures and/or infections tracked;

(c) Exposure/infection rates; and

(d) Any trend data.

C. Methods of Control

16. If your workplace has a process for early identification of patients or clients who may have an infectious disease, please explain how your workplace conveys information to workers about individuals who are confirmed or suspected of being infectious, so that proper precautions can be implemented. Please describe the degree of success with these procedures and whether you think that such procedures are likely to be effective in other healthcare or healthcare-related settings.

17. CDC/HICPAC, CMS, and the Joint Commission provide a variety of approaches that employers can implement to reduce or eliminate workers' exposure to infectious agents. For example, a well-structured IC program can include: immunizations for vaccine-preventable diseases, isolation precautions to prevent exposures to infectious agents, training, personal protective equipment, management of workers' risk of exposure to infected persons, including post exposure prophylaxis, and work restrictions for exposed or infected personnel. Please describe the types of problems/obstacles your workplace or industry encountered with implementing specific control measures. Please include a discussion of each control measure, the problem/obstacle encountered, the affected worker group, and any particularly effective solutions your workplace or industry has implemented to address the obstacle/problem.

18. When developing and implementing infection control measures in your workplace, are there any recommended controls that you have found to be ineffective or unnecessary in controlling infectious diseases? If so, please explain how you arrived at this conclusion.

19. Airborne infection isolation rooms (AIIRs) are recommended as one aspect of controlling certain airborne transmitted diseases (*e.g.,* TB, SARS). OSHA recognizes that most workplaces outside of hospitals do not have an AIIR and will transfer persons requiring airborne precautions to a facility with the necessary capabilities. If your workplace provides healthcare or other services to individuals requiring airborne precautions, how many of these patients/individuals has your workplace encountered in each of the last ten years? If individuals requiring airborne precautions must be transferred to another facility, please describe how your workplace identifies and isolates them while they are awaiting transfer. If your workplace provides extended care to these individuals (*e.g.,* a hospital), does it have sufficient AIIRs to isolate the number of infected individuals your workplace has handled at any one time? If not, how does your facility provide alternate means of isolation and how many additional AIIRs would be necessary to fully accommodate your normal patient load? Please describe how your workplace plans to address surge capacity in the event of an outbreak, epidemic, or pandemic. Please provide any additional information, including peer-reviewed studies, which addresses issues relevant to the use of AIIRs in your workplace or industry.

20. CDC/HICPAC's *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* addresses the need for a safety culture and its role in improving a workplace's IC program (*e.g.,* worker adherence to safe work practices). Please describe the policies and actions undertaken in your workplace or industry to develop and maintain a culture of worker safety. Please describe any means that have been particularly effective in fostering a safety culture and any problems or obstacles that have been encountered in developing and/or maintaining the safety culture.

21. Poor adherence to infection control measures (*e.g.,* failure to use necessary PPE or to follow recommended hand hygiene practices) can be one indicator of the breakdown of an IC program. Please describe what actions have been undertaken in your workplace or industry to assess and enforce adherence to infection control measures. What obstacles has your workplace encountered in maintaining adherence and are there any particularly successful ways you have found to maintain adherence (*e.g.,* training initiatives, worker incentives)? Please discuss any underlying factors that you feel may affect non-compliance with current infection control guidelines and standards in your facility.

22. The use of proper PPE is an essential component of an effective IC program. For example, CDC/HICPAC recommends that facemasks (*e.g.,* surgical masks) be worn by workers when droplet precautions are implemented and respirators be worn under certain circumstances when airborne precautions are in place. Please describe how your workplace determines when a facemask (*e.g.,* surgical mask) is used for worker protection and when a respirator is used for worker protection. How does your workplace determine which employees use a facemask and which use a respirator? If your workplace uses different types of respirators, please describe what types and when they are used.

23. NIOSH regulates the testing and certification of respiratory protective equipment, has established minimum performance standards, and conducts independent testing and verification of all respirators prior to certification. The Food and Drug Administration (FDA) approval process for facemasks does not have established minimum performance standards and allows manufacturer submitted data. As noted in a 2009 IOM report,[54] a 2008 study that examined the filter performance of nine different types of facemasks using the sodium chloride NIOSH challenge test, found wide variation in penetration (4 percent to 90 percent) of smaller aerosol particles.[55] Therefore, the protective properties of different manufacturers' facemasks may vary. Is there a need for a more rigorous certification/approval process for facemasks and additional independent verification of the personal protective properties of these devices?

24. Some HCWs have medical conditions or are receiving treatments that impair their ability to resist infection. These HCWs may be unable to develop protective immune responses after vaccination. What is your workplace or industry doing to educate its workers about these conditions? What approaches are being used or should be used to address the special needs of HCWs with these conditions?

D. Vaccination and Post-Exposure Prophylaxis

25. In the Bloodborne Pathogens standard (§ 1910.1030), OSHA requires that hepatitis B vaccinations be made available to employees occupationally exposed to blood or other body fluids. It should be noted that while employers are required to offer the vaccine, employees are permitted to decline it. CDC/ACIP recommends a number of other vaccines for various groups of HCWs including: influenza (both seasonal and the 2009 H1N1); measles, mumps, rubella (MMR); varicella; tetanus, diphtheria, pertussis (Td/Tdap); and meningococcal vaccines. What vaccinations, other than hepatitis B, do you consider to be necessary to protect workers from occupational exposure to infectious agents? Who should receive these vaccinations, and why? Does your workplace offer vaccines other than the hepatitis B vaccine to workers and how do you determine who is offered these vaccines?

26. The Bloodborne Pathogens standard (§ 1910.1030) requires that employers follow certain administrative and recordkeeping procedures (*e.g.,* signing a declination statement; placing

an employee's vaccination status in his/her medical record). Does your workplace or industry use similar administrative and recordkeeping procedures for vaccines other than hepatitis B? If not, please describe what administrative and recordkeeping procedures are or should be used.

27. Post-exposure prophylaxis (PEP) and evaluation for bloodborne pathogen exposures, such as hepatitis B and HIV, are addressed in the Bloodborne Pathogens standard [§ 1910.1030(f)]. OSHA is interested in post-exposure evaluation and PEP for other infectious diseases. Please describe the current PEP and evaluation practices in your workplace. For what infectious agent exposures should workers be provided with PEP and/or evaluation? Please describe the disease, its associated PEP, and the PEP efficacy.

28. In some instances, a vaccine may be available for a disease but a worker may decline vaccination. Please describe procedures in your workplace that ensure workers who have declined vaccination have access to necessary PEP.

29. In order to appropriately evaluate the health status of a worker, some basic health information is needed. CDC/HICPAC recommends a personnel health service program for infection control that includes a number of components including: pre-placement evaluations, evaluation and treatment of exposure-related illnesses, and work restriction or work-exclusion policies for exposed HCWs. OSHA is interested in the prevalence, content and efficacy of such personnel health service programs.

(a) What should be included in a pre-placement medical evaluation for a worker who will be exposed to infectious agents? Please describe the possible components of the medical history and physical exam and specific tests (*e.g.,* TB skin test, spirometry, blood tests). How are pre-placement medical evaluations of workers addressed in your workplace? What do these evaluations include? If pre-placement medical evaluations are used in your workplace, have they been effective, and what metrics are used to evaluate effectiveness? Give the rationale, including references if available.

(b) What type of ongoing medical surveillance or periodic medical evaluations should be provided for exposed workers? Please describe the possible components of such surveillance or evaluations. How often should periodic medical evaluations be conducted? In what situations should medical evaluations or surveillance be performed (*e.g.,* return-to-work, fitness for duty)? How are periodic medical evaluations addressed in your workplace?

(c) In your State, are there State laws that apply to pre-placement and periodic medical evaluations of exposed workers? If so, what are they?

(d) Please describe the administrative procedures used by your workplace to evaluate and treat workers who have been occupationally exposed and/or infected (*e.g.,* who do they notify of the exposure/infection). How are the costs for treatment and follow-up (*e.g.,* visits to physician, lab tests) handled in your workplace? If a worker is put on restrictions or excluded from work due to a work-related infectious exposure or illness, how are the worker's salary, benefits, and seniority handled by your workplace?

E. Communication of Hazards

30. Training is generally considered a necessary component of an effective IC program in order to assure that workers understand the hazards they are exposed to and the proper methods of protection. Please describe how your workplace assures that workers are adequately trained in the use of infection control measures, including how your workplace assesses if a worker has been adequately trained. Please describe the contribution of training and education to improving adherence to your IC program. Please describe the format used by your workplace to conduct training (*e.g.,* computer-based, written material, interactive classes, hands-on practice, other) and whether you have found some more effective than others. Please describe what role, if any, knowledge and/or competency assessment plays in your workplace training program.

31. Both initial and periodic worker training are recognized as important components of an effective IC program. Initial training provides information that workers need to protect themselves against exposures to hazards while periodic training refreshes worker knowledge, reinforces the importance of the IC program and provides a means of introducing new information and procedures.

(a) What information should be included in initial training for workers who may be exposed to infectious agents? What is the best format for providing initial training to these workers (*e.g.,* specifying a minimum number of hours of training, specifying training content based on job tasks, specifying that training be adequate to demonstrate specified competencies, by a combination of these methods or by some other method)?

(b) How frequently does your workplace provide workers with refresher training on its IC program? What information should be included in periodic refresher training for workers who may be exposed to infectious agents? What is the best format for providing periodic training to these workers (*e.g.,* specifying a minimum number of hours of training, specifying training content based on job tasks, specifying that training be adequate to demonstrate specified competencies, by a combination of these methods or by some other method)? Should refresher training be provided based on lack of competency, or be provided at regular time intervals regardless of demonstrated competency?

F. Recordkeeping

32. Please describe the worker health surveillance system used in your workplace. Does the system include tracking of occupational exposures to infectious agents and/or occupationally-acquired infectious diseases? Please describe the procedures used by your workplace to determine whether an infectious disease is considered to have been occupationally-acquired. How is the worker health surveillance information collected under the system used in your IC program? Please describe the factors that affect the successful implementation of such surveillance systems.

33. The OSHA requirements for recording and reporting occupational injuries and illnesses contain an exemption for the common cold and flu (§ 1904.5(b)(2)(viii)). However, the Agency has determined that, if certain criteria are met, occupationally-acquired 2009 H1N1 pandemic influenza is recordable (OSHA Directive CPL–02–02–075). As OSHA more broadly considers the issue of occupational exposure to infectious agents, what are the implications, if any, for the Agency's existing recording and reporting requirements under § 1904?

G. Economic Impacts and Benefits

As part of the Agency's consideration of occupational exposure to infectious agents, OSHA is interested in the costs, economic impacts, and benefits of related practices to prevent such exposure. OSHA is also interested in the benefits of such practices in terms of reduced deaths, illnesses, and compromised operations (*i.e.,* infirm personnel, quarantined or disabled units, unexpected reallocation of resources). The following questions will

provide OSHA with needed economic impact and benefits information.

34. As the Agency considers possible actions to address the prevention and control of infectious diseases (*e.g.,* prospective standards or guidelines), what are the potential economic impacts associated with the promulgation of a standard specific to the hazards of infectious diseases? Describe these impacts in terms of benefits from the reduction of incidents and illnesses; effects on revenue and profit; and any other relevant impact measure. If you have any estimates of the costs of controlling infectious disease hazards, please provide them.

35. What changes, if any, in market conditions would reasonably be expected to result from issuing a comprehensive infectious diseases standard? Describe any changes in market structure or concentration, and any effects on services, that would reasonably be expected from issuing such a standard.

36. What are the potential benefits of more widespread compliance with infection control guidelines? How can OSHA best assure such compliance takes place?

H. Impacts on Small Entities

As part of the Agency's consideration of occupational exposure to infectious agents, OSHA is concerned whether its actions will have a significant economic impact on a substantial number of small entities. If the Agency pursues development of a standard and the standard has such impacts, OSHA is required to develop a regulatory flexibility analysis and assemble a Small Business Regulatory Enforcement Fairness Act (SBREFA) Panel prior to publishing a proposal. Regardless of the significance of the impacts, OSHA seeks ways of minimizing the burdens on small businesses consistent with OSHA's statutory and regulatory requirements and objectives.

37. How many, and what type of small firms, or other small entities, have infectious disease hazards, and what percentage of their industry (NAICS code) do these entities comprise? Please specify the types of infectious diseases encountered.

38. How, and to what extent, would small entities in your industry be affected by a potential comprehensive OSHA infectious diseases standard regulating occupational exposure to infectious agents? Do special circumstances exist that make controlling infectious diseases more difficult or more costly for small entities than for large entities? Describe these circumstances.

III. Public Participation

You may submit comments in response to this document by (1) hard copy, (2) fax transmission (facsimile), or (3) electronically through the Federal Rulemaking Portal. Because of security-related problems, there may be a significant delay in the receipt of comments by regular mail. Contact the OSHA Docket Office at (202) 693–2350 for information about security procedures concerning the delivery of materials by express delivery, hand delivery and messenger service.

All comments and submissions are available for inspection and copying at the OSHA Docket Office at the above address. Comments and submissions are also available at *http://www.regulations.gov* . OSHA cautions you about submitting personal information such as social security numbers and birth dates. Contact the OSHA Docket Office at (202) 693–2350 for information about accessing materials in the docket.

Electronic copies of this **Federal Register** notice, as well as news releases and other relevant documents, are available at OSHA's Web page: *http://www.osha.gov/index.html.*

Authority and Signature

This document was prepared under the direction of David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor. It is issued pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), 29 CFR 1911, and Secretary's Order 5–2007 (72 FR 31160).

Signed at Washington, DC, this 30th day of April, 2010.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Footnotes:

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[FR Doc. 2010–10694 Filed 5–5–10; 8:45 am]

BILLING CODE 4510–26–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2008–0155; FRL–9144–8]

Approval and Promulgation of State Implementation Plans: Oregon

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of Oregon, Department of Environmental Quality (ODEQ). These revisions pertain to the Clean Air Act (CAA) section 110(a)(1) maintenance plans prepared by ODEQ to maintain the 8-hour national ambient air quality standard (NAAQS) for ozone in the Portland portion of the Portland/Vancouver Air Quality Maintenance Area (Pdx/Van AQMA) and the Salem-Keizer Area Transportation Study (SKATS) air quality area. The 110(a)(1) maintenance plans for this area meet CAA requirements and demonstrate that each of the above mentioned areas will be able to remain in attainment for the 1997 and 2008 8-hour ozone NAAQS through 2015. As SKATS appears to be significantly impacted by emissions from the Portland area, an approved plan for the Pdx/Van AQMA is one of the control strategies for SKATS air quality area. Therefore, EPA is proposing to approve the section 110(a)(1) plans for the Portland portion of the Pdx/Van AQMA and the SKATS area at the same time.

Additionally, the EPA is proposing to approve SIP revisions submitted by ODEQ that phase out the State's Vehicle Inspection Program (VIP) enhanced BAR–31 test, and eliminate the Gas Cap Pressure Test and the Evaporative Purge Tests.

DATES: Written comments must be received on or before June 7, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–