

OSHA RFI Questions (verbatim from May 6 *Federal Register* notice)

A. General

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.
4. 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?
5. 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).
6. 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.
7. 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.
8. While OSHA has a Bloodborne Pathogens standard (Sec. 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 (Sec. 1910.134) and General Personal Protective Equipment (Sec. 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.
 9. 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.
 10. 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

11. 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?
12. 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?
13. 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.
14. 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.
15. 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.

16. 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

17. 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.
18. 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.
19. 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.
20. 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.
21. 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.

22. 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.
23. 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.
24. 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, 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. 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 personal protective properties of devices?
25. 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/should be used to address the special needs of HCWs with these conditions?

D. Vaccination and Post-Exposure Prophylaxis

26. In the Bloodborne Pathogens standard (Sec. 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?
27. The Bloodborne Pathogens standard (Sec. 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.

28. Post-exposure prophylaxis (PEP) and evaluation for bloodborne pathogen exposures, such as hepatitis B and HIV, are addressed in the Bloodborne Pathogens standard [Sec. 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.
29. 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.
30. 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

31. 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.
32. 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

33. 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.
34. The OSHA requirements for recording and reporting occupational injuries and illnesses contain an exemption for the common cold and flu (Sec. 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 Sec. 1904?

G. Economic Impacts and Benefits

35. 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.
36. 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.
37. 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

38. 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.
39. 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.