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OSHA Docket Office
Docket No. OSHA-2010-0003
U.S. Department of Labor
Room N-2625
200 Constitution Avenue, NW
Washington, DC 20210

To Whom It May Concern:

The Society for Healthcare Epidemiology of America (SHEA) appreciates the opportunity to provide our response to OSHA's Request for Information (RFI) on occupational exposure to infectious agents in settings where healthcare is provided and healthcare related settings, as published in the May 6, 2010 *Federal Register*.

We are pleased to comment on behalf of our members and recognize there are a number of questions we cannot address directly but will share our perspective on what we believe reflects general practice among our members. We have urged SHEA members to respond to your inquiry recognizing that they are dedicated to the health and safety of both patients and healthcare personnel. The efforts to protect and prevent transmission of disease are closely intertwined as is the safety of all building occupants. We will address each section as we are able as an organization assessing employee health programs based on guidelines currently used by our members. Where it is not possible to respond we will indicate N/A (not-applicable).

Thank you for the opportunity to provide our input in response to OSHA's Request for Information (RFI) on occupational exposure to infectious agents. Your consideration of our comments is appreciated.

Sincerely,

Neil O. Fishman, MD
President, SHEA

OSHA Questions

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.

- a) 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, and average number of patients/clients); total number of employees (both direct care and administrative support).

SHEA response: SHEA members oversee infection prevention and control (IPC) programs in many care settings including those mentioned by OSHA. SHEA represents over 1,700 members who provide epidemiology services and infectious disease resources to employee health services in hospitals, health systems and other health care organizations such as affiliated clinics. Although each member responding will provide information that is available, SHEA has encouraged all organizations to respond to questions that apply. Emergency and laboratory services are typical of many of our hospitals except for small community or critical access hospitals. We will refer primarily to hospitals understanding that our members function in many other care-delivery sites within hospital systems or affiliated organizations.

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).

- a) 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.

SHEA response: See #1 - Individual facilities affiliated with hospital systems have been encouraged to respond according to their patient population and if any specific risks beyond the infectious agents addressed below for hospitals.

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.

- a) 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?

SHEA Response:

- a) In focusing on acute care hospitals in general, IPC programs consider several key principles in *determining who is at risk*:

(1) Hospitals are concerned about the health and safety of all occupants, whether patients, healthcare personnel, or visitors. Therefore elements of the IPC must include concern for airborne, *droplet and contact assessments for all, and much attention to environmental/engineering controls for the environment affecting ALL occupants.*

(2) A risk assessment in terms of the population served for types of communicable disease likely to be seen in the specific facility, using the reportable communicable disease entries published weekly from local and state agencies as well from CDC via the weekly MMWR. Therefore specific issues may vary by locale. The best example is *M. tuberculosis*, (MTB) since according to CDC guidelines some areas may have minimal risk and need not carry out TB testing nor develop respiratory protection programs. In addition, facilities work with local and state public health agencies to stay abreast of changes in the community prevalence of infectious diseases (e.g., seasonal increases in influenza prevalence; local or regional outbreaks of diarrheal disease in children).

(3) General risks for healthcare personnel (HCP). All hospital personnel whether they perform direct care or support services, are considered at some level of risk because of the basic principle *all patients are considered potentially infectious* so that *“Standard Precautions” apply to all* and all received basic education and training.

(4) Specific risks. The disease exposure risk for the most part is similar per direct worker for adult populations versus pediatric and neonatal populations. The risk assessment considers for example: suspected or known to have a communicable disease; type, frequency and length/intensity of procedures, degree of contact. For example, risks are higher for personnel working the emergency room evaluating patients with potential communicable disease (e.g., MTB) and could involve staff carrying out pulmonary procedures such as bronchoscopy. Some may consider employees colonized with a multi-drug resistant organism (MDRO) such as MRSA as occupational exposures, but it is very difficult to determine whether the colonization or infection was acquired on the job or from the community, since MRSA is so widespread in the community. IPC programs place major emphasis on prevention and routine use of Standard Precautions. The IPC programs address potential risks by department/procedures and indicate if specific additional personal protective equipment should be used in addition to Standard Precautions. *Members have been encouraged to share samples of the exposure assessments or exposure control plans used assessing newly hired staff and needs for specific job training.*

- b) How many of your total workers have a risk of exposure to such diseases during the performance of their job duties?
c) What proportion of your workforce does this represent?

- d) What are the job titles or classification(s) of these workers?

SHEA Response: We have encouraged members to submit appropriate information.

- e) What are the job duties of these workers? To which diseases are they exposed?

SHEA Response: SHEA believes that exposure control plans typically reflect similar specific job titles or classifications developed for the OSHA Bloodborne standard (1910.1030) as well as CDC's Influenza vaccination recommendations - whether direct care, frequent contact or support services managing contaminated/used equipment. Disease exposures will reflect the community- whether airborne (e.g., MTB), large droplet (e.g. influenza, norovirus) or contact transmissible diseases (scabies, or various bacterial infections). IPC programs place major emphasis on prevention and routine use of Standard Precautions.

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).*

SHEA Response: We believe this question of “experience” is ambiguous and may be interpreted differently by some as meaning employees or patient admissions. For example, some may sum up the past 10 years of infectious disease classifications coded in medical records, others may use hospitals' copies of state-required forms for each type of recorded reportable disease sent to their local health department; yet others may use reportable disease logs for employees only, (OSHA Form 300A) as also reported to the local health department. Finally some may only report exposures to infectious diseases—not actual disease. *We have encouraged our members to clarify which database or list is being used when responding to this question.*

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*).

SHEA response: We again encouraged members to clarify the sources of the information they provide—since “experience” is ambiguous. The implication—though not stated explicitly - is that the data requested are from the OSHA Form 300A Database used to collect and report *occupationally-acquired disease*; some data submitted may be limited to just exposures and not disease outcomes.

- 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).

SHEA response: It is not clear whether OSHA is looking for any database – manual or electronic. Beyond the OSHA Form 300A that may be collected either way, other electronic systems include: (1) CDC’s NHSN module for healthcare personnel (HCP) exposures; (2) A number of commercial stand-alone databases for tracking sharps, immunization status/vaccination, etc.; (3) States and CDC publish reportable communicable diseases to local, state agencies—which are also reported by CDC in the weekly MMWR, but these are not specific to employees and encompass ALL reported diseases.

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

SHEA response: See member responses as well as the current “*CDC Infection Control in Healthcare Personnel Guideline 1998*”; CDC/HICPAC is currently in the process of updating this guideline. The literature in even the current version is replete with multiple citations of infectious agents for which prevention/treatment strategies are devised.

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*).

SHEA response:

We believe that OSHA has mischaracterized IC programs as “voluntary.” Hospitals, ambulatory care centers, other care-delivery sites and related entities understand these are mandated by CMS and any agency receiving deemed status from CMS in order to receive Medicare and Medicaid funds. Beyond reducing direct reimbursement, CMS hospitals not complying with its standards may risk loss of certification or even their license if CMS determines the facility has unsafe conditions related to life safety codes and infection control standards. Therefore CMS and other accrediting agencies enforcement affects both patient and HCP. It might be noted that HC facilities (e.g., outpatient clinics) operating under health plans still require such programs and survey periodically for reimbursement. The CMS IC standards and interpretative guidelines (IG) have become a community standard for many such clinics. We are **appending** the *very detailed Interpretative guidelines for the CMS IC standards* that address all aspects of an IPC program including the issue of protecting HCP.

- a) 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.

SHEA response: CDC Guidelines consider at the outset there may be clusters or outbreaks from time to time. Hospitals use the CDC Guidelines Transmission-based section recommendations that are outlined in Tier 1; that is, ensuring basic Standard Precautions are first implemented properly such as measuring adherence to hand hygiene protocols and use of barriers ensuring basic practices are at high rates of compliance, and determining the need to move to Tier II, i.e., taking additional steps to bring the outbreak under control even as the cause of the cluster or outbreak is investigated.

- b) 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.

SHEA response: The cause of the cluster or outbreak may not necessarily be characterized as a ‘lapse’ but may be from a single unexpected source from the environment identified during the investigation. The initial response will always be to take steps to protect patients and personnel in as cautious a manner as possible to stop further transmission until the cause is known. *Staff use both Isolation and MDRO guidelines and members have been encouraged to provide sample protocols.*

7. 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.

- a) OSHA is interested in commenter’s insights regarding the *adequacy of existing OSHA requirements* to protect workers against occupational exposure to infectious agents.

SHEA response:

SHEA believes that OSHA’s existing standards are more than adequate since there are so many other protections addressed in detail in CDC and CMS guidelines. We see the Respiratory Protection standard requirements adequate to the extent there is a requirement for respirators and the Personal Protective Equipment standard as duplicative to the detailed CDC and CMS guidelines. A few comments follow:

(1) Although hospitals and other entities follow the OSHA Bloodborne Pathogen standard carefully, we believe the high level of efficacy of the HBV vaccine had an enormous impact on the reduction of HBV. Hospitals addressed the prevention of all bloodborne infections, continuing to follow CDC guidelines related to sharps devices and other barriers such as glove use during the early years of HIV detection, prevention and management of

exposures—developing what was then termed “Universal Precautions” to benefit both patient and worker. We acknowledge the impact of OSHA’s standard but believe its impact was felt in many areas in which accessibility to HBV vaccination was less feasible. We also acknowledge the value of OSHA’s attention to regular review of current safety devices, but also believe the current attention by CDC and CMS to increase focus on injection safety in all care settings is an important focus today.

(2) CDC TB guidelines address respiratory protection as part of the overall risk assessment per facility types. The Guideline continues to be the key resource to hospitals and when directed to use N95s or related PPE it does follow the OSHA Respiratory Protection program guidance as appropriate. Such OSHA guidance was referenced by the CMS requirement outlined in the CMS Infection Control Interpretive Guideline (IC IG) **appended**. Hospitals also view the General Duty clause as comparable to CMS’s mandate for a ‘safe and sanitary’ environment which can apply if a Life Safety code or infection control issue is deemed to be an “immediate harm” concern.

(3) Hospitals and outpatient facilities are focused very much on reducing healthcare-associated infection (HAI) among their respective patients out of concern for patient and family safety. HAI can also lead to reduced payment from CMS for HAIs classified as Hospital-acquired Conditions (HACs), or reduced income in the future for value based purchasing (VBP) known also as ‘pay for performance’ programs. All the efforts using *CDC Guidelines* and other resources from CDC and AHRQ that are focusing on a safety culture are leading to increased reductions of HAIs. *It is critical to understand that the successes with patients cannot be separated from the benefits to HCP. Hand hygiene and use of barrier precautions for patients necessarily prevents transmission to workers, well beyond these specific pathogens and infections (Bloodborne pathogens and TB).*

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.
 - a) 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.*

SHEA response: We frankly did not understand the need or justification for California’s ATD standard given the studies that were examined by OSHA and stakeholders that did not demonstrate that the TB rate in HCP was any higher than the general population. CDC droplet precautions (See Isolation guidelines) are implemented to prevent exposures to all—especially to HCP, and enforced by other agencies during various types of surveys. Contact transmission – the most common mode – is equally important and a great deal of education and training time is spent on prevention; as noted previously this is already enforced by various agencies. We believe that current CDC guidelines, enforced by other agencies are adequate and another standard would be duplicative and burdensome for healthcare facilities.

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.

SHEA response: Contracts made with local universities for rotations of trainees through hospital training already include same requirements for health assessment (e.g., showing proof of HBV vaccination) as well as training to reduce occupational exposure. Further, there really are no situations unique to government employees that are not also seen in the private sector.

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.

SHEA Response: Infection Prevention and Control programs are very comprehensive and each key element – including occupational health issues – must meet the very detailed requirement of the CMS IC IG. The IC IG requires the program to be based on CDC's evidence-based guidelines. We have encouraged members to submit selected samples of protocols touching on specific issues.

- 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?

SHEA response: NA

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?

SHEA response: We expect many responses to this question based on facility size, since, for example the same person directs both IPC and Employee Health programs in many smaller facilities. We have encouraged members to submit appropriate information on these specific issues.

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.

SHEA response: We have encouraged members to submit comments, as feasible, since some will have their own laboratories, vaccination programs etc., while others may have either access limitations or fewer resources need to contract with outside laboratories, occupational health and safety clinics or local health departments.

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.

SHEA response: Although this does not apply to hospitals generally, we do have concern for the burden of a duplicative standard for small community and critical access hospitals that do comply with CDC guidelines and are surveyed by CMS and other accrediting agencies.

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.

- a) 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?

SHEA response: CMS and accrediting agencies call for a minimum of annual and/or periodic evaluations that involve risk reassessments or needed changes due to organizational programs affecting surveillance goals and strategies. Many also provide quarterly reviews of trends and issues to their Board of Trustees via quality, safety or infection control committees based on measurable performance improvement outcomes.

- b) 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.

SHEA response: The trends reported to hospital Boards of Trustees from quality, safety or infection control committees are based on measurable performance improvement outcomes, *including explicit employee health measures*. It should be noted again, that the successes on reducing HAIs necessarily lead to lowered exposure risks to employees. At a national level, rates of HAI reported to the CDC's NHSN have shown overall improvement over the past decades. *We have encouraged members to submit samples of successes of reduced HAIs, understanding the direct impact on HCP health as well.*

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.

SHEA response: We have encouraged members to submit samples of tracking systems which typically involve both infection preventionists, medical staff, admissions personnel, employee health and in increasingly frequent electronic methods of alerts to employees regarding proper precautions to avoid exposures.

C. Methods of Control

16. If your workplace has a process for *early identification of patients or clients* who may have an infectious disease:

- a) 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.

SHEA response: We have encouraged members to submit samples of early detection and communication of patients needing specific levels of precaution according to the CDC guideline- *similar to # 15.*

- b) 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.

SHEA response: We have encouraged members to submit samples of early detection and communication of patients needing specific levels of precaution according to the CDC guideline.

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.

- a) 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.

SHEA response: We have encouraged members to submit samples of solutions for greater efficiency of protocols affecting workers. Barriers may include lack of vaccine for example during past influenza seasons as well due to the delay in developing and production of 2009 H1N1 vaccine.

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.

SHEA response: We have encouraged members to submit examples of such situations if identified. SHEA believes the use of the *CDC guidelines provide sufficient flexibility to identify and use the most effective controls for the given situation. These are based on science and require the appropriate application as needed.*

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.

- a) 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?

SHEA response: We have encouraged members to respond with their experiences as information is available, knowing it may be difficult to sort out reported TB patients transferred from other facilities such as LTC.

- b) 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 *and* 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?

SHEA response: We have encouraged members to provide this information as it applies, e.g., LTC agreement with their facility.

- c) 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.

SHEA response: We have encouraged members to provide this information as it applies. SHEA is aware and proud of the detailed plans members have developed in preparing for Pandemic Influenza plans over many years, and knows that much attention has been placed on the importance of AIIRs when planning for surge capacity, considering temporary anterooms and use of HEPA or negative air machine to generate negative pressure in the room.

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).

- a) 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.

SHEA response:

(1) We increasingly recognize the critical importance of developing a safety culture involving teams working together for a common goal of HAI reduction in patients and reduced exposures and transmission to patients and workers alike. There are many examples across the country. For example, AHRQ is supporting the work carried out by AHA's HRET to emulate the Michigan Keystone success in nearly all states. Dramatic reduction of HAI means are the result of HCP working together to minimize—even eliminate infections in patients, *but also reduce the risk of HCP exposure through primarily high rates of compliance with hand hygiene and proper use of barriers*. The Keystone initiative is based on regular input and measurement of the safety culture among the staff in the care unit—not limited to ICUs. This is the basis for the frequent reference to “checklists.” The use of checklists raises an awareness of “doing the right thing all of the time” and translates into overall concern for each other’s safety—whether use of barriers as well as safe use of devices. We encourage our members to share their own similar successes. (2) Hospitals have Safety Management programs that also aim to foster a safety culture focused on the Environment of Care (EC). Much time and work is spent in our organizations on facility-wide performance measures and improvement. These programs include reduction of safety risks, reporting systems addressing occupational illness and actions that will prevent or even eliminate all types of safety

risks, including for example, sharps injuries. The Joint Commission focuses heavily on hospitals' safety programs that engage the employee in a culture of safety.

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.

- a) Please describe what actions have been undertaken in your workplace or industry to *assess and enforce adherence to infection control measures*.
- b) 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)?
- c) Please discuss any underlying factors that you feel may affect non-compliance with current infection control guidelines and standards in your facility.

SHEA response: Members have been encouraged to provide this information as it applies. In general, hand hygiene is not only the number one step in all "checklists" used to reduce HAIs, but is closely monitored as a major quality measure in organizations as they strive as part of their safety culture to demonstrate high rates of adherence. Hospitals follow CDC Hand Hygiene Guidelines. CMS and accrediting bodies place great focus on hand hygiene as well and closely observe actual practice on scheduled and non-scheduled surveys. Organizations are creative in their methods to aim for 100% adherence for both patient and worker protection. A major tool in this effort is the increased availability of alcohol-based hand rubs as well as well-placed sinks. *Members have been encouraged to provide additional examples.*

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.

- a) 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.
- b) How does your workplace determine which employees use a facemask and which use a respirator?
- c) If your workplace uses different types of respirators, please describe what types and when they are used.

SHEA response: We understand and have encouraged compliance with OSHA's respiratory protection standard as it applies and is recommended in the CDC guidelines.

(1) The CDC TB Guidelines recommend a risk assessment and if the criteria are met, the hospitals must implement worker TB evaluation as well as institute a full respiratory protection program. Members may indicate how they determine the *number of HCP trained* and fitted for a N95 and training on fit checking. A number of facilities use other types of respiratory protections (e.g. PAPRs).

(2) The CDC Guideline for H1N1 pandemic in 2009 led to a far greater number of HCP requiring similar education, fit-testing, and training on fit-checking given the changes in assignments that may occur. N95s were given priority to staff performing procedures generating short range aerosols, given wide-spread limited supplies. If an organization had sufficient respirators they were used in accordance with the CDC guidelines.

(3) SHEA fully expects hospitals will comply during the upcoming flu season with the CDC guidance for use of facemasks for routine care, and N95s for the listed procedures generating short range aerosols. Members may supply additional details according to their supplies.

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, 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.

a) *Is there a need for a more rigorous certification/approval process for facemasks and additional independent verification of personal protective properties of devices?*

SHEA response: It would be of value to have a single standard for facemask performance. However, while we are aware of the cited IOM report, we are also well aware of related information on testing facemasks and respirators shared at subsequent IOM panels and NIOSH workshops addressing both. The challenge of using aerosolized saline as a particle surrogate for aerosolized human mucous was noted many times and studies indicate the differences between measuring penetration results in laboratory studies versus outcomes in real work settings. Efficacy of current facemasks is evidenced by the lack of reported failures in settings where these are routinely used as PPE (e.g., meningitis). FDA participates in this scientific effort and should likely be queried by OSHA on this issue.

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.*

a) 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?

SHEA response: As OSHA is aware, there are many privacy and confidentiality issues that must be considered. Therefore hospitals are very conscientious in assessing employees' lab results during pre-employment protocols, and in general, provide – in these situations – additional one-on-one counseling sessions on the importance of

understanding and adhering to Standard Precautions. Employee health makes accommodation as much as possible for injured workers but there is no known “safe” unit in hospitals for assignment since as noted earlier, a basic issue is realizing all patients are potentially infectious and means that many asymptomatic patients may be incubating and exposing others with an infectious disease agent such as influenza or varicella. In addition to Standard Precautions, such employees are urged to always report potential exposures so that the employee can be assessed, tested and received appropriate prophylaxis. *Members have been encouraged to provide additional examples of their procedures.*

D. Vaccination and Post-Exposure Prophylaxis

25. 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.

- a) What vaccinations, other than hepatitis B, do you consider to be necessary to protect workers from occupational exposure to infectious agents?
- b) Who should receive these vaccinations, and why?
- c) Does your workplace offer vaccines other than the hepatitis B vaccine to workers and how do you determine who is offered these vaccines?

SHEA response: The guidelines do indicate the importance of these vaccines – many of which are childhood vaccines required by school systems – others are boosters such as Tdap. A very recent publication [Wei SC, et al. *Clin Infectious Dis Aug 1: 2010; 51(3):315-321*] demonstrated the effectiveness of Tdap in protecting against pertussis in a school, even in an outbreak setting. Most employee health policies require a thorough immunization history and for some infections they require testing for antibody to not only HBV but others-such as varicella if they do not have proof of immunity. This applies to all personnel. Depending on availability some hospitals may administer the vaccines or are referred to local public health for vaccinations if the individual is lacking immunity. SHEA encourages its members to follow ACIP guidelines for HCP vaccination – these are currently being updated. As noted earlier, CDC/HICPAC is currently in the process of updating the “*CDC Infection Control in Healthcare Personnel Guideline*.” CMS also surveys for this under IC IG.

26. 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).

- a) 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.

SHEA response: See #25. Yes, as a matter of policy, hospitals maintain immunization records of prior and/or current immunization. For example, in most hospitals if a worker upon new-hire does not have a particular immunization such as rubella, and the expectation is that all employees must have it as a condition of employment, an interview with the hospital epidemiologist or designated staff is required to ensure there is sufficient understanding that the worker is placing him/herself at risk.

27. 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.

- a) 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.

SHEA response: Hospitals rely very much on assessing the worker for vaccine-preventable diseases, including influenza. Hospitals follow CDC guidelines for the proper treatment or post exposure prophylaxis (PEP) depending on the type of infectious agent exposure.

28. In some instances, a vaccine may be available for a disease but a worker may decline vaccination.

- a) Please describe procedures in your workplace that ensure workers who have *declined vaccination have access to necessary PEP.*

SHEA response: See # 26-#27. Hospitals offer appropriate PEP to any employee regardless of vaccine status.

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).
(1)How are pre-placement medical evaluations of workers addressed in your workplace?
(2)What do these evaluations include?

(3) 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.

SHEA response: Hospitals generally follow CDC Guidelines for Infection Control in Healthcare Personnel and include in their pre-placement programs a medical history and physical exam. Elements include, for example, past infectious disease history, exposures, vaccines and tests for TB (if appropriate per CDC TB guidelines), vaccine titers, overall health and fitness for the job being sought.

- 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?

SHEA response: As noted several times, comprehensive IPC programs involve surveillance by IPs and or employee health to ensure follow-up recommended treatment or testing following exposure assessments. They also attend closely to the “return to work” policies and procedures to ensure it is safe for employees to return.

- 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?

SHEA response: We have encouraged members to provide any state-specific regulations.

- 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).

SHEA response: Members have been encouraged to provide selected examples of procedure algorithms used to communicate with workers and others regarding exposures, where to go for care and treatment, education and even worker and family counseling.

- e) 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?

SHEA response: Members have been encouraged to provide selected samples of policies addressing interactions with human resources issues for time off, return to work, and any workman compensation processes.

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.

- a) 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.
- b) 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.
- c) Please describe what role, if any, knowledge and/or competency assessment plays in your workplace training program.

SHEA response: Members have been encouraged to provide selected samples of policies addressing creative efforts for education such as use of observations and “teachable moments” during Environmental Rounds. Selected procedures may include department-specific requirement for competency training.

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?

SHEA response: Hospitals following CDC guidelines routinely offer initial and at least annual training on infectious disease beyond MTB and Bloodborne infections. We have encouraged members to provide selected samples of policies addressing policies for education and training.

- c) 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)?

SHEA response: Hospitals following CDC guidelines routinely offer initial and at least annual training on infectious disease beyond MTB and Bloodborne infection. Members have been encouraged to provide selected samples of policies addressing policies for education.

- d) Should refresher training be provided based on lack of competency, or be provided at regular time intervals regardless of demonstrated competency?

SHEA response: Hospitals following CDC guidelines routinely offer latest updates using recent evidenced based information to ensure the latest available information is given to employees. *We have encouraged members to provide relevant examples.*

F. Recordkeeping

32. Please describe the worker health surveillance system used in your workplace.
- a) Does the system include tracking of occupational exposures to infectious agents and/or occupationally-acquired infectious diseases?
 - b) Please describe the procedures used by your workplace to determine whether an infectious disease is considered to have been occupationally-acquired.
 - c) 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.

SHEA response: Hospitals following CDC guidelines investigate each reported exposure using the latest information and updates from CDC to determine for each specific disease, definitions and circumstances to assess whether the exposure was an occupational or community based exposure. As indicated throughout this document, following these CDC guidelines, employees are tracked with appropriate follow-up using testing as needed.

33. 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).

SHEA response: SHEA notes that the criteria appear to refer to initial reporting of individual cases during the beginning of a pandemic. Now that H1N1 is incorporated into the seasonal influenza vaccine, it would appear that this exemption would continue – since CDC has its Sentinel Surveillance systems for measuring cases in offices and emergency room. However it does put new emphasis on the importance of seasonal vaccination.

- a) 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?

SHEA response: We are concerned with an increased burden of reporting infectious agents (for example MRSA) when it is very difficult to distinguish colonization much less occupational versus acquisition in the community. There is serious concern over conflicts among agencies regarding the implications of OSHA requiring additional reporting of infections not typically required for report by states or backed up by evidence or for which PEP is effective.

G. Economic Impacts and Benefits

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?*

- a) 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.

SHEA response: Given review of responses on the earlier question, it should be clear that SHEA does not see any additional gain from a highly redundant standard and the burden of documenting elements for yet another agency.

35. What changes, if any, in market conditions would reasonably be expected to result from issuing a comprehensive infectious diseases standard?

- a) Describe any changes in market structure or concentration, and any effects on services, that would reasonably be expected from issuing such a standard.

SHEA response: *Increased costs that would take resources from other effective programs due primarily to differences in methods of documentation and reporting when we have yet to see a clearly identified problem that requires one more agency to monitor programs that appear to be well guided by other agencies.*

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

SHEA response: SHEA does not believe OSHA has demonstrated a specific problem that would permit development of a measure that would provide specific improvements over existing employee health programs, given their close relationships with IPC programs.

H. Impacts on Small Entities

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.

SHEA response: NA

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.

SHEA response: NA