Occupational Safety and Health Administration (OSHA)

Summary Report of
Stakeholder Meetings on
Occupational Exposure to Infectious Diseases

Washington, D.C.

July 29, 2011
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1 Introduction

This report summarizes key discussion points made during two informal stakeholder meetings that the Occupational Safety and Health Administration (OSHA) convened to solicit comments on a possible infectious disease standard. The two three-hour meetings were held on July 29, 2011, at the U.S. Department of Labor (DOL) Frances Perkins Building in Washington, D.C. The purpose of the meetings was to obtain information from stakeholders to explore the possible development of a standard to protect workers from occupational exposure to infectious agents in settings where they provide direct patient care or perform other covered tasks that also involve occupational exposure. These other covered tasks might include patient support services (e.g., housekeeping, facility maintenance); handling, transporting, receiving, or processing infectious items or wastes (e.g., transporting medical specimens, disposing of medical waste); conducting autopsies or performing mortuary services; and performing tasks in laboratories.

On May 6, 2010, OSHA published a Request for Information (RFI) titled “Infectious Diseases” (docket number OSHA-2010-0003). OSHA was interested in more accurately characterizing the nature and extent of occupationally acquired infectious diseases, as well as current strategies for mitigating the risk of occupational exposure to infectious agents. OSHA received more than 200 comments in response to the RFI. Based upon these responses and an ongoing review of current literature on this subject, OSHA is considering what action, if any, it should take to limit occupationally acquired infectious diseases. One action the agency is considering is the development of a program standard to control workers’ exposure to infectious agents.

In the course of its review, the agency determined that informal discussion with stakeholders would aid its further deliberations on how to proceed with respect to occupational exposure to infectious diseases. OSHA therefore announced stakeholder meetings in the Federal Register on July 5, 2011. The announcement explained that parties interested in attending and participating should register in advance.

Together, the two July 29, 2011 stakeholder meetings had 53 participants, representing, among others, hospitals, unions, public health organizations, government agencies, trade organizations, and industry. All participants were given the opportunity to provide verbal comments at the meetings. Non-participant members of the general public were also allowed to observe the meetings on a first-come, first-serve basis, as space permitted. Forty-three (43) people attended the two meetings as observers.

Eastern Research Group, Inc. (ERG) provided logistical support for the stakeholder meetings, and a technical writer from ERG attended the meetings and prepared this summary report. This report captures the main discussion points that stakeholders raised during the meetings, but is not a verbatim transcript of the meetings. Stakeholders’ remarks at the meetings do not represent the opinions of ERG or of OSHA.
2 Opening Remarks

During the opening remarks for both sessions, Dorothy Dougherty, Director, Directorate of Standards and Guidance, welcomed the stakeholders and opened the meeting. OSHA Assistant Secretary David Michaels (during the morning session) and OSHA Deputy Assistant Secretary Jordan Barab (during the afternoon session) then welcomed the stakeholders, provided brief remarks, and thanked the participants for their input. Following the Assistant Secretary’s and Deputy Assistant Secretary’s remarks, Ms. Dougherty highlighted the OSHA and DOL staff members who have contributed to the infectious diseases effort.

3 Purpose/Objectives

Andrew Levinson, Director, OSHA Office of Biological Hazards, thanked the stakeholders for their involvement in the infectious diseases issue. Mr. Levinson explained that the stakeholder meetings were being held as an extension of the May 2010 RFI, to which many of the meeting participants had previously responded with thoughtful comments.

Mr. Levinson discussed OSHA’s efforts to review the available literature and develop policy options for Assistant Secretary David Michaels to consider in addressing infectious diseases. The purpose of the stakeholder meetings was to discuss one of the potential options—a regulatory pathway. OSHA was petitioned to consider this option, and the Assistant Secretary will make the final decision. Mr. Levinson described OSHA’s traditional approach to a program standard, which follows the principle of “plan, train, do.” The planning element of this approach details the hazards and provides a framework that employers use to execute the training and implementation elements of a program standard. This approach allows for a large amount of flexibility—if something changes, employers can just adjust the plan and retrain their workers.

OSHA is also considering a vertical approach for a potential standard. Vertical standards apply to a particular group of workers where a hazard exists, while horizontal standards apply to any worker in any industry where the hazard exists. Vertical standards emphasize scope, and take into account the hazard and the specific workers and settings.

The potential standard that OSHA is considering would encompass all exposure pathways (e.g., contact, droplet, airborne), but would only cover contact transmissions that are not covered by the bloodborne pathogens (BBP) standard. For example, it would cover methicillin-resistant \textit{Staphylococcus aureus} (MRSA) but not hepatitis B. In developing such a standard, OSHA would review the Healthcare Infection Control Practices Advisory Committee’s (HICPAC) guidelines and extract programmatic and administrative elements for incorporation.

Mr. Levinson emphasized that the meeting should focus on four elements: 1) validation of major elements, 2) blind spots or errors in major elements, 3) areas with unintended consequences, and
4) issues associated with non-hospital settings (e.g., mortuary, ambulatory, long-term care, home health, laboratories).

4 Administration of the Meeting

Meeting facilitator Barbara Upston (of Management Consulting Associates) provided the stakeholders with an overview of the meeting format. The meeting format included a short presentation for each major element of the potential program standard OSHA is considering, followed by 30 minutes of stakeholder discussion. Ms. Upston explained that the meeting should be considered an informal forum to present comments, and informed the participants that they would not be allowed to read prepared statements (though they could submit prepared comments to OSHA for consideration). Ms. Upston also presented an overview of the agenda, including the specific questions that OSHA was asking the stakeholders to address. Participants introduced themselves by giving their names and organizations.

5 Points of Discussion

OSHA representatives sought specific information on the potential development of a program standard that would include the following sections: 1) the scope, application, costs, and availability; 2) Worker Infection Control Plans (WICPs) and methods of compliance; 3) medical screening, surveillance, and vaccination; and 4) communication of hazards and recordkeeping.

The following is a summary of the key stakeholder comments made during the meeting. Comments are grouped together by topic, without reference to the identity of the commenter.
5.1 Scope, Application, Costs, and Availability

A OSHA Statement

Thomas Nerad (OSHA) gave a brief presentation on the scope, application, costs, and availability sections of the potential program standard OSHA is considering. The program standard OSHA is considering would allow for flexibility, as there are continually emerging infectious agents. In the potential standard, OSHA would not provide a list of infectious agents, and employers would be responsible for determining the infectious agents of concern at their workplace.

Several potential definitions were discussed during Dr. Nerad’s presentation. The potential standard defines the term “occupational exposure” as reasonably anticipated contact with suspected or confirmed sources of infectious agents resulting from a worker’s performance of his/her duties. Such exposures could occur through the contact, droplet, and airborne routes of transmission. The potential standard also defines the term “infectious agent” as a biological agent capable of causing adverse health effects sufficient to require medical care.

The scope of the potential standard OSHA is considering would include occupational exposure to infectious agents in two circumstances: 1) during provision of direct patient care, for example, by doctors, nurses, paramedics, and emergency responders in settings such as hospitals, clinics, and medical facilities embedded in non-medical settings (e.g., schools, prisons); and 2) during the performance of other covered tasks (both on-site and off-site) with occupational exposure to infectious agents, including handling of infectious items in laboratories and healthcare laundries, and during maintenance and reprocessing of contaminated equipment.

The potential standard OSHA is considering would not replace existing regulations (e.g., the BBP standard would remain in effect). Workers would not incur any costs related to implementation of the potential standard’s requirements. Further, employers would be required to make all medical evaluations and procedures available to the worker at reasonable times and locations, and to provide training during work hours.

B Stakeholder Comments

Stakeholders made the following comments and recommendations regarding the scope, application, costs, and availability of a potential infectious diseases program standard:

- Need for an infectious agent standard: The primary stakeholder concern was whether OSHA needs to develop and implement a new standard specific to infectious agents. Some stakeholders urged OSHA to consider that many industries are already heavily regulated in this area, most notably the hospital industry, which must already implement regulations by the Centers for Medicare & Medicaid Services (CMS) and state agencies. Further, many industries, including hospitals, dental offices, blood centers, and similar
environments, are already covered under the BBP standard. By adhering to the Centers for Disease Control and Prevention (CDC) guidelines, industries are already required to address BBP and airborne transmissions in ways that go beyond potential OSHA requirements. These stakeholders requested that OSHA demonstrate why additional regulation is necessary given that these occupation scenarios do not involve a higher rate of infection compared to the general population. They felt that, even with OSHA’s promise of flexibility in the plan, implementation would be burdensome on facilities, with no added value.

Other stakeholders commented that a new standard is still necessary for those settings that are not as highly regulated. Further, consistency between guidance in multiple agencies (CDC, CMS) and private organizations is essential, and OSHA needs to be a leader because other organizations are not focused solely on protecting workers. OSHA needs to develop this rule, they said, within the context of worker protection.

Ms. Amanda Edens, Deputy Director, Directorate of Standards and Guidance, noted that OSHA has not decided whether a proposed standard will be developed. Unions petitioned OSHA to explore this issue in response to California OSHA’s (CalOSHA’s) standard and the H1N1 pandemic. Ms. Edens emphasized that a new standard is one of several ways for OSHA to address the petition.

- **Approach considerations:**
  - *Vertical approach*—Stakeholders discussed the use of a vertical approach, especially in the context of K–12 schools. Schools are the biggest contributors of community outbreaks for such illnesses as tuberculosis (TB) and pertussis. Stakeholders noted the success of the BBP standard and recommended that OSHA consider a horizontal standard that would apply in all settings where the hazard was present. They also requested that OSHA identify the various populations to be covered by a new standard.
  - *Risk-based assessment approach*—Stakeholders discussed the inclusion of a risk-based assessment approach in a new standard. Some stakeholders commented that such an approach could address many of the stakeholder concerns, given that different settings have different infectious agents. For example, schools are concerned with viruses, while prisons are concerned about MRSA and BBPs. If OSHA uses a risk-based assessment approach, stakeholders said, it should provide specific tools to conduct the risk assessments (similar to CDC’s tools).
  - *Hazard assessment*—Stakeholders discussed requiring a hazard assessment in a new standard. Some stakeholders stated that OSHA should consider that not all organizations will be able to conduct hazard assessments well.
- **Cost/benefit analysis**—Stakeholders said that OSHA should consider providing impact, cost, and benefit information in conjunction with a new standard.

- **Other guidance**—Stakeholders recommended that OSHA refer to existing guidance for assistance if it develops a new standard. For example, CalOSHA’s Aerosol Transmissible Disease Standard would be a useful model.

  - **Not addressing specific infectious agents:** Stakeholders expressed concern over a new standard not addressing specific agents. This approach is too broad, they said, and would cause complications for employers. Employers may not have the proper resources to identify the infectious agents of concern specific to their facility. Stakeholders stated that, in the first responder setting (e.g., for police officers), the potential standard OSHA is considering would require that the facility research every conceivable disease and have vaccines for them, and that under this potential approach, every possible disease would require training, vaccinations, and reporting.

  - **Length of exposure:** Stakeholders felt that OSHA should consider the implications of exposure length (one continuous shift versus a single incident) if it develops a new standard (e.g., exposure length has implications for TB and MRSA).

  - **Defining populations:** Stakeholders recommended that OSHA specifically define the populations covered under a new standard. Specifically, OSHA should define the emergency responders included in a new standard (e.g., police, fire, emergency medical services).

  - **Non-traditional population considerations.** Stakeholders recommended that a new standard include anyone who is occupationally exposed to infectious agents. They mentioned several populations that are not traditionally considered healthcare workers:
    
    - **Flight attendants**—Flight attendants are trained in providing health care for crew and travelers, so they have direct contact with ill individuals. They often travel globally and could contribute to spreading illness, so including them in a new standard is crucial in preventing the spread of emerging diseases.

    - **Teachers**—Teachers are often in position to be first responders when children are ill.

    - **Correctional officers**—Correctional officers are often exposed to infectious agents without receiving medical care.

    - **Independent contractors**—OSHA protocol does not include independent contractors.
• Setting considerations:
  
  o Laboratories—Stakeholders asked whether OSHA intends for a new standard to apply only to laboratories for specimens related to patient care, or whether it would also include research laboratories. OSHA replied that the intent of the potential standard OSHA is considering is to cover any laboratory where workers are potentially exposed to infectious agents, including the full range of research facilities (e.g., biomedical, pharmaceutical, production).

  o Multiple worker types in one location—Stakeholders stated that some occupational settings contain workers of several types; a prison laundry, for example, can have laundry workers and security personnel. Therefore, stakeholders felt that OSHA should further specify which workers would be covered by a new standard.

  o Long-term and routine care—According to stakeholders, long-term care involves patient care over extended periods of time, sometimes (e.g., in the case of home health and skilled nursing care) outside the traditional hospital setting, and OSHA needs to determine what settings a new standard would encompass in its provisions for long-term and routine care.

  o Other residential care facilities—As well as long-term and routine care, stakeholders felt a new standard should address other types of residential care facilities (e.g., non-healthcare-related housing facilities, such as homeless shelters).

  o Dentist offices—Stakeholders noted that dentist offices are much different from hospital and doctor offices, with fewer airborne illnesses. OSHA should take these differences into account, they said, if it develops a new standard. Ms. Edens (OSHA) responded that the potential standard OSHA is considering would allow for flexibility and that dental offices would be required to develop a plan suitable for their work settings.

• Specific disease considerations:

  o Tuberculosis—Stakeholders recommended that OSHA consider developing a specific standard for TB (referring to CDC and the Mayo Clinic for guidance).

  o Zoonotic diseases—OSHA should include zoonotic diseases (i.e., diseases that are transmittable from animals to humans) and veterinarian clinics in a new standard, stakeholders said. OSHA replied that the potential standard OSHA is considering would not include zoonotic diseases for a variety of reasons, including the fact that the Healthcare Infection Control Practices Advisory Committee guidelines that OSHA is reviewing would not apply to those settings.
Shingles—Stakeholders requested that OSHA consider diseases such as shingles, which do not always produce symptoms in infected people.

5.2 Worker Infection Control Plan (WICP) and Methods of Compliance

A OSHA Statement

Andrew Levinson (OSHA) gave a brief presentation on the WICP and the methods of compliance element of the potential program standard OSHA is considering. The first element of the WICP would be a written plan similar to other OSHA program standards; OSHA recognizes that employers have already taken steps to ensure worker safety, and stated that employers could integrate their WICPs with existing BBP or other infection control plans used for patient safety. Integrated plans would reduce employer burden while ensuring that workers are protected.

The second element of the WICP would include the individuals responsible for WICP oversight, implementation, and daily management. Management occurs on multiple levels, including the facility manager (oversight), the infectious control specialist (implementation), and the front line managers/supervisors (daily management).

Under the potential standard, each WICP would also include standard operating procedures (“SOPs”) that cover conducting infectious agent hazard analyses, communicating hazard(s), medical surveillance, and exposure incident investigations. The potential standard would also require that SOPs address OSHA’s typical hierarchy of controls: engineering, administrative, and work practice controls, and personal protection equipment (PPE).

The potential standard would also require SOPs to include other elements, depending on the setting. In direct patient care scenarios, SOPs would also include patient scheduling and intake; standard precautions; transmission-based precautions (contact, droplet, airborne); patient placement and transport; and medical surge procedures. In work settings where other covered tasks are performed, SOPs would also include handling and intake of contaminated materials, and implementing control measures. In laboratories, SOPs would also include implementing measures to address uncontrolled releases of infectious agents, and addressing standard and special microbiological practices. Mr. Levinson emphasized that under the potential standard, SOPs would not “reinvent the wheel,” and the purpose would be to focus on worker protection by incorporating programmatic and administrative elements into the SOPs to apply to specific settings.

In developing and updating SOPs, employers would be required to consider current applicable regulations and guidelines of other agencies (e.g., CDC) and organizations, and then tailor the relevant elements to their workplace. (For example, laboratories would be required to consider National Institutes of Health (NIH) guidelines on uncontrolled releases to extract programmatic and administrative elements that they can incorporate into their SOPs in their specific settings.)
OSHA recognizes that the field of infection prevention and control is a very dynamic, and the potential standard would therefore allow for flexibility during infection control research studies.

Employers would be required to make the WICP readily accessible to workers, and to review and update the WICP annually and as necessary. Employers would also be required to solicit workers’ input on the WICP, given that workers know what elements are effective for their particular work settings and tasks.

In regard to methods of compliance, employers would be required to implement the elements outlined in their WICPs. Employers would be required to ensure that hazard analyses are conducted, written SOPs are followed, appropriate controls are implemented, appropriate PPE is available and properly used, appropriate worksite cleaning and decontamination procedures are followed, and prompt exposure investigations are conducted. The potential standard would require that hazard analyses be functional and not unnecessarily complicated; employers would be required to implement prompt identification mechanisms, identifying possible exposure to suspected or confirmed infectious diseases at the earliest contact.

B Stakeholder Comments

Stakeholders provided the following comments and recommendations regarding WICPs and methods of compliance:

- Need for an infectious agent standard. Similar to the scope discussion, the primary point of discussion under this topic was whether OSHA needs to develop a new standard on infectious agents when facilities already have protection plans in place. Stakeholders emphasized the following points in opposition to developing a new standard:

  - **BBP standard**—A new standard on infectious agents would significantly overlap with the existing BBP standard. Hospitals are already in compliance with the BBP standard, with all major hospitals having an infection control plan in place. A new standard would cause duplicative efforts and incur unnecessary costs. A new standard would also cause unnecessary concern among employees and reduce worker flexibility. OSHA should consider incorporating infectious agents into the BBP standard.

  - **Existing plans**—In response to existing guidance (e.g., CDC guidelines, OSHA respirator use), many facilities already have written plans that address infectious agents (e.g., influenza, TB, unidentified infections). Most places have already implemented engineering controls and have trained and educated staff on practices to prevent the spread of infectious disease.
- No evidence of necessity—OSHA should demonstrate that current hospital practices are insufficient in protecting workers against infectious disease before implementing a new standard that would result in additional costs.

Other stakeholders responded to the above comments with the following points in support of developing a new standard:

- Mitigated costs—If facilities are already in compliance with other overlapping standards, then additional implementation costs would be minimal. Embedding a WICP into an existing plan (e.g., an existing infection control, biosafety or biosecurity plan that already covers 90 percent of the new requirements) would keep costs minimal. Further, a risk-based WICP allows employers to tailor their plans to their workplace; employers with lower risks do not need to develop complicated plans.

- Renewed worker interest—A new standard would give workers an additional incentive to follow CMS and TJC standards and CDC guidelines.

- Value in universal requirements—A new standard would help ensure consistency in worker protection.

- Incentive for compliance—Implementing a new standard would ensure results (e.g., laws effect change).

- Improved community health—A new standard would refocus the issue on community health and saving lives.

- Good practices—A new standard would help health and safety officers identify good practices to prevent the spread of infectious diseases.

- OSHA should adopt or incorporate existing plans and procedures. Some stakeholders suggested that OSHA adopt or incorporate the following existing plans and procedures:

  - European Committee for Standardization (CEN)—The CEN bio-risk management standard is currently used in laboratories with infectious agents.

  - Institute of Medicine (IOM)—IOM guidelines include effective engineering controls that break the chain of transmission.

  - CDC—CDC-based protocols include communicable diseases and address all occupants of hospital facilities, including personnel.

  - Emergency Preparedness Response Plans—These plans typically use vertical approaches and address infectious agents.
- **Public health response**—Hospitals regularly assess public health threats (e.g., monitoring outbreaks).

- **Others**—Hospitals already have worksite cleaning and decontamination SOPs in place. Hospitals also have hand washing and PPE systems in place, though these processes are only adhered to 50 percent of the time.

- **No conflict with other standards**: If OSHA develops a new standard, stakeholders said, OSHA needs to ensure that the requirements do not conflict with existing standards, such as those by accreditation organizations and state agencies.

- **Non-hospital settings**: Stakeholders noted that non-traditional workplaces will benefit from a new standard. However, they said, OSHA needs to consider that settings outside the hospital do not have significant protocols in place to address infectious agents. When implementing a new standard, OSHA needs to keep in mind that non-hospital settings may require additional education and enforcement.

- **Small business concerns**: Some stakeholders were concerned about the ability of small businesses to comply with the WICP requirement given its complexity. Small businesses often rely on infection information from the healthcare industry and do not have the capability to conduct their own on-site analyses. OSHA should consider developing non-mandatory appendices, guidelines, and programs to help small businesses and other entities comply with the WICP requirement.

- **Employee participation**: Stakeholders recommended that OSHA encourage full employee participation in all elements of the WICP process, especially hazard assessments. Because workers are typically the ones who notice infectious disease at the workplace, their involvement would help protect the workplace. Employers will benefit from worker involvement and should not penalize workers for being sick.

- **Known versus unknown infectious agents**: Stakeholders urged OSHA to learn from the H1N1 pandemic by addressing the differences between known and quantifiable infectious agents and unknown agents. If OSHA develops a new standard, OSHA should handle them as separate issues.

- **Implementation issues**: Stakeholders said OSHA should consider the following implementation issues if it develops a new standard:

  - **Hierarchy of controls in the healthcare industry**—Stakeholders pointed out that the healthcare industry has a different hierarchy of controls compared to other industries. In the healthcare industry, engineering controls are not feasible in situations where infectious agents are not identified. Therefore, administrative controls and work
practices typically take precedent over engineering controls. OSHA needs to take this into account if it develops a new standard.

- *Airborne transmission*—OSHA needs to emphasize the importance of an exposure control plan when dealing with airborne transmissions, stakeholders said. Unlike transmissions that occur through physical contact with an agent, airborne transmissions are not always prevented through the use of technology and physical barriers. The airline industry has special considerations given the minimal ventilation in airplanes.

- *Risk screening*—Stakeholders advised OSHA to consider integrating a risk screening protocol in a new standard (to avoid unnecessary triage at the beginning of the assessment process).

5.3 Medical Screening, Surveillance, and Vaccination

A OSHA Statement

Christopher Brown (OSHA) gave a brief presentation on the medical screening, surveillance, and vaccination elements of the potential program standard OSHA is considering. Under the potential standard, employers would be required to make available medical screening, surveillance, and vaccinations to workers with occupational exposure. For instance, in the laboratory setting, employers would be required to make available vaccinations for specific infectious agents handled by workers, if available. Employers would be required to make the following vaccinations available: seasonal influenza and other vaccines and booster doses recommended by the CDC Advisory Committee on Immunization Practices (ACIP). Employers would also be required to provide vaccine-related training (e.g., on the benefits of vaccinations) prior to making vaccinations available to workers. Employers would not be required to make vaccinations available to workers who have already been vaccinated, have documented immunity (e.g., antibody titer), have a medical contraindication, or have chosen to sign a declination form. Employers would be required to perform post-exposure follow-up with workers, to provide information about a worker’s exposure to the worker’s physician or other licensed health care professional (PLCHP), to ensure confidentiality, and to follow PLCHP recommendations for restrictions and modifications to job duties. Employers would also be required to provide medical removal protection benefits for workers removed from their jobs or medically limited as a result of occupational exposure to an infectious disease. Although OSHA is considering including influenza in a potential standard’s vaccination requirements, influenza or the common cold would not be included in the requirements for post-exposure reporting or medical removal protection.
Stakeholders provided the following comments and recommendations regarding medical screening, surveillance, and vaccination:

- **Mandatory vaccinations as a condition of employment.** Stakeholders expressed concern over how a new standard would affect employer-mandated vaccinations as a condition of employment. Focusing on how OSHA should not include language that would keep employers from requiring vaccinations as a condition of employment, they discussed the following points:

  - *Hospitals*—In hospitals, public health concerns are the priority. Hospitals do have vaccination requirements as a condition of employment. Employees are also protected by measuring titer levels that indicate waning immunity. Variations in this requirement are community-specific.

  - *Biomedical research*—In the biomedical field, laboratory workers conducting virulent influenza research and surveillance must get vaccinated. Any worker who refuses the vaccination is prohibited from working in that facility. Such requirements are considered good practices.

  - *BBP standard and hepatitis B*—OSHA should refer to the BBP standard’s language on hepatitis B for guidance. Although the BBP standard does not make a hepatitis B vaccination a condition of employment, it includes careful wording about properly informing employees of the benefits of the vaccination and post-exposure evaluation through training.

  - *Legal issues and labor laws*—OSHA should consider the legal and labor implications of mandatory vaccines. For example, one stakeholder stated that employer may not terminate workers for refusing vaccinations, but may restrict access to certain facility locations and require the worker to change jobs.

Ms. Edens (OSHA) clarified that employers may make vaccinations a condition of employment; however, while the potential standard OSHA is considering would require that employers make vaccinations available, that potential standard would not require employees to get them. The potential standard OSHA is considering would require that employers record which employees declined the vaccination, and implement means to train employees on the benefits of vaccinations and the risks associated with declining them.
• Declination of vaccinations. Stakeholders offered the following recommendations and notes:
  
  o BBP standard and hepatitis B—A new standard should require an educational program similar to the practices found in the hepatitis B section of the BBP standard. The commenter’s BBP practices include an initial information sheet about the vaccination as well as further vaccination education if the worker refuses to get vaccinated. This approach allows the worker to make an informed and positive decision to get vaccinated.
  
  o Epidemiologist involvement—Most hospitals tend to require mandatory vaccinations. However, some hospitals do not do so. In this latter scenario, a worker who signs a declination form must meet with an epidemiologist to further discuss the implications of refusing the vaccine. This approach has proven to be effective.
  
  o Proof of immunity—Employees may decline a vaccination if they have been previously vaccinated. OSHA needs to address scenarios where new employees do not have records of past vaccinations.

• Medical removal considerations. Stakeholders made the following recommendations:
  
  o Vulnerable groups—OSHA should address medical removal concerns involving individuals with special vulnerabilities, such as pregnant workers.
  
  o Influenza exemption—OSHA should consider including seasonal influenza in the medical removal provisions. Regardless of whether the illness is due to non-occupational exposure, the purpose of a new standard is to prevent the spread of infectious disease.
  
  o Cost implications—OSHA should consider the cost and impact of medical removal when involving a large number of workers.

• Sick leave considerations. Stakeholders made the following recommendations:
  
  o Protecting workers—OSHA needs to include provisions that protect workers from reprisal for missing work due to illness. For example, flight attendants are severely disciplined for more than a few absences in a year.
  
  o Unpaid sick leave—Many workers come to work when they are sick because they do not receive paid sick leave, which contributes to the spread of infectious diseases. Requiring employers to provide vaccinations could help address this issue.
• **Vaccine considerations.** Stakeholders made the following recommendations:

  o **Efficacy**—OSHA should not assume that vaccines will be 100 percent effective, and should rigorously pursue other alternative preventive practices. Although vaccination is the preferred method of prevention, OSHA should also consider PPE requirements.

  o **Availability**—OSHA should consider vaccine availability issues that occurred during the H1N1 pandemic when supply of the vaccine could not meet the demand. If OSHA develops a new standard, OSHA should address situations where workers are required to be vaccinated but are not on the priority list.

  o **Emerging pathogens**—OSHA should address emerging pathogens in a new standard. Vaccinations will not be possible for all infectious agents.

  o **Investigational vaccines**—OSHA should address the use of investigational vaccines in a new standard. OSHA should consider availability and expense incurred with investigational vaccines.

  o **Employer responsibilities**—OSHA should address the extent of employer responsibility when providing vaccinations. For example, OSHA should consider whether employers are responsible for ensuring that workers receive all subsequent shots in a vaccination series.

Mr. Levinson (OSHA) commented that OSHA is considering including the CDC’s Advisory Committee on Immunization Practices’ (ACIP) recommendations for healthcare workers and laboratory workers in the potential standard.

• **Exposure considerations.** Stakeholders made the following recommendations:

  o **Occupational versus non-occupational exposure**—OSHA should address how employers determine whether there is occupational exposure to an infectious disease.

  o **Unknown exposures**—Employers cannot always be aware of exposures. OSHA should emphasize that workers need to be adequately trained and provided with resources and PPE no matter what the exposure scenario.

  o **Preventing unnecessary concern**—Some facilities have an internal risk assessment group that evaluates exposure situations and determines whether a significant exposure has occurred. OSHA should consider this approach if it develops a new standard to prevent unnecessary concern at the workplace.

  o **Screening**—OSHA should emphasize the importance of screening, vaccinating, and training new workers in a new standard. Employers should be required to
immediately screen, vaccinate, and train new employees when they first start the job to avoid exposure to infectious agents.

- **Need for an infectious agent standard**: Stakeholders noted that the medical screening, surveillance, and vaccination elements of the potential standard OSHA is considering are already in place in most healthcare facilities.

- **HIPAA considerations**: Stakeholders felt that OSHA should consider HIPAA rules and worker privacy if it develops a new standard. HIPAA requirements preclude employers asking existing employees about any medical conditions. To ensure protection of all workers, OSHA should require that worker training covers issues affecting immunocompromised workers.

- **Non-traditional populations**: Stakeholders asked that OSHA include workers who handle garbage in the vaccination requirement.

- **Small businesses**: Stakeholders argued that OSHA should consider what providing vaccinations will cost small businesses, especially if vaccinations have a low efficacy rate (e.g., only 40 percent).

### 5.4 Communication of Hazards and Recordkeeping

#### A OSHA Statement

Sharon Carr (OSHA) gave a brief presentation on the hazard-communication and recordkeeping elements of the potential program standard OSHA is considering. Under the potential standard, employers would ensure that appropriate signage and labeling conveys warnings on infectious agent hazards to all on-site and off-site workers (e.g., medical waste handlers) who could be exposed. Examples of signage and labeling that would be required under the potential standard include: signs on patient doors and airborne infection isolation rooms and areas; hand washing signs and posters; and biohazard labels and posters. When training employees, employers would be required to consider all work tasks that involve occupational exposure to infectious agents. Employers would be required to provide training for each covered worker initially (prior to assignment to tasks with occupational exposure), annually thereafter, and on a supplemental basis (e.g., when changes in tasks, procedures, or control measures affect occupational exposure or when the worker’s knowledge or actions indicate a need for additional training). Employers would be required to ensure that workers are trained by people knowledgeable about the subject matter, and that the content and vocabulary of the training is appropriate to the worker’s language, literacy, and education level. During the training, employers would be required to provide workers with an opportunity for interactive questions and answers. Required training would include an explanation of: the signs, symptoms, and modes of transmission, of infectious diseases; vaccination information about infectious diseases; the WICP; all SOPs applicable to the
worker’s tasks; the use and limitations of control measures and PPE used to prevent or minimize exposure. Employers would also be required to maintain medical records, exposure incident records, and WICP review records. Employers would be required to ensure that medical records are kept confidential. Employers would also be required to make exposure incident records, the WICP, and WICP review records available to workers and their representatives.

B Stakeholder Comments

Stakeholders provided the following comments and recommendations regarding communication of hazards and recordkeeping:

- Training. Stakeholders emphasized the importance of training and discussed several issues that OSHA should consider:
  - Risk assessment—Given the number of potential infectious agents, training workers on all potential infectious agents would be impractical. Employers would benefit from conducting risk assessments to identify the infectious agents of concern in their work place.
  - Novel infectious agents—OSHA should provide employers with a default protocol for providing training on novel agents. Employers should follow standard precautions until a diagnosis is determined.
  - Reporting—Workers should be trained on how to report an exposure incident and to whom to report the incident.
  - Interactive questions—Employers should ensure that a knowledgeable person is available to answer worker questions at the time of training. Given that training can be conducted online (which is frustrating for some workers), the knowledgeable person must be available to workers during training regardless of implementation methods.
  - Pandemics—Under the potential standard OSHA is considering, employers would be required to provide training for each worker upon initial start date, annually, and on a supplemental basis. OSHA should also consider requiring training during a pandemic event.
  - Integration with other occupational health areas—Employers should consider integrating infectious agent signage and training with other areas of occupational health to streamline and consolidate educational efforts.

- Reporting and recordkeeping. Stakeholders emphasized the importance of reporting and recordkeeping and discussed several issues that OSHA should consider:
- **Defining exposure incidents**—OSHA should define what constitutes an exposure incident to ensure accuracy and consistency in recordkeeping. OSHA should clarify whether an exposure incident is defined as an initial exposure to an infectious agent or as an outcome—i.e., a diagnosed infection. (For example, CDC defines an incident as one that requires post-exposure care or prophylactics.) OSHA also needs to address exposures and specific reporting requirements in industrial versus research settings. OSHA should also make compilations of exposure information accessible on OSHA 300 Logs.

- **Underreporting**—An occupational study by the University of Virginia has indicated underreporting of injuries and illnesses. Often employees view exposure incidents (e.g., blood splatters) as “part of the job.” Employers should investigate new ways to ensure that employees report exposure incidents.

- **Over-reporting**—Employees in the lower-paying positions of the healthcare system do not have adequate medical literacy to understand germ theory. These employees may have an irrational fear of exposure and may report false symptoms. Training is essential to ensure legitimate reporting.

- **Worker communication**—To ensure a safe work environment, employers must encourage workers to communicate to upper management and report any exposure incidents.

- **Trends**—WICPs should be considered living documents and modified over time in response to trends in record patterns. Recordkeeping on OSHA 300 Logs will help guide WICPs by showing trends of hazards and identifying the populations that are getting infected. Employers should ensure that these logs are maintained and monitored according to OSHA requirements.

- **Difficulty obtaining medical records**: Some stakeholders commented that obtaining medical records is difficult for those outside the medical industry. Stakeholders recommended that OSHA provide guidance on how to obtain medical records from PLHCPs or allow document retrieval attempts to count as compliance if employers cannot obtain the required records.

- **Multilingual workforce**: Stakeholders expressed concern over training a multilingual workforce on infectious agents. OSHA should provide guidance on how to address these language differences when providing training. Ms. Edens (OSHA) suggested that employers look to current training practices for other aspects of the worker’s job on how to address this issue.
• Program evaluation: OSHA should use science-based methods to evaluate illness prevention, said stakeholders. In addition to illness data, OSHA should analyze illness prevention practices (e.g., PPE use) to provide a comprehensive evaluation.

5.5 Additional Discussion

Stakeholders provided the following additional comments and recommendations:

• Need for an infectious agent standard: Some stakeholders emphasized the importance of a standard to prevent epidemics from occurring. Others reiterated their concern that a standard would be unnecessary and discussed the following points:

  o Infectious disease rates—In contrast to the BBP scenario, in which workers had higher rates of BBP-related infections than the general population, OSHA has not shown that workers have higher rates of infection due to the infectious agents a new standard would cover.

  o Nontraditional settings—Stakeholders asked whether a new standard would add significant protection to healthcare providers in all settings or only in nontraditional settings where there is not enough regulation.

  o Effectiveness of a WICP—Stakeholders expressed concern about supporting a new standard without evidence-based proof that a WICP effectively reduce incidents of infectious disease.

• Additional elements for consideration: Stakeholders made the following suggestions:

  o Focus on education—The primary focus of a new standard should be education and reducing risk, not enforcement.

  o WICP audits—OSHA should require employers to conduct audits as mechanisms for continuous improvement.

  o Infectious agent panels—Employers should establish panels to evaluate health care concerns and identify issues in their particular workplace.

  o Knowledgeable staff—Employers should employ more staff members who are knowledgeable about infectious agents.

  o Work with other agencies—OSHA should work with other agencies and federal colleagues (e.g., ACIP) to encourage federal-wide implementation that expands beyond OSHA’s jurisdiction.
- **BBP standard considerations**—If a new standard is implemented, OSHA should consider the implications of integrating an infectious agent plan with an existing BBP plan. Standards are modified over time, which could cause complications.

- **Medical waste**—OSHA should address medical waste exposures in a new standard. Workers could be exposed to infectious agents during onsite and offsite handling and transport of medical waste, and first responders could be exposed during emergency situations involving spills.

OSHA also received written comment submissions for the docket from representatives of the Biotechnology Industry Association, the Transport Workers Association, and Occupational Health Consultants.

### 6 Wrap-Up and Next Steps

Mr. Levinson informed the stakeholders that next steps include discussions with OSHA Assistant Secretary David Michaels and other relevant federal agencies (e.g., the U.S. Department of Health and Human Services) to present them with the feedback obtained from these meetings. Mr. Levinson emphasized that OSHA is an evidence-based agency and will use solid evidence in moving forward in this process. Mr. Levinson also stressed that the development of a program standard is only one action that OSHA is considering to control worker exposure to infectious agents. OSHA will inform stakeholders of the Assistant Secretary’s decision on how OSHA will proceed with respect to occupational exposure to infectious diseases. Mr. Levinson concluded the meeting by thanking the stakeholders for their participation.