

# OSHA's Infectious Diseases Regulatory Framework

## Section 1: Scope

*This section delineates the worker tasks being considered for coverage.*

Occupational exposure of workers to contact, droplet, or airborne transmissible infectious agents during provision of direct patient care or performance of other covered tasks, as defined below, would be covered. Occupational exposure as defined in OSHA's Bloodborne Pathogens standard, 29 CFR 1910.1030, would not be covered.

## Section 2: Definitions

*This section explains the Agency's intended meaning of terms used in the body of this document. Examples given within a particular definition are intended to clarify the Agency's intent and do not represent an all-inclusive list.*

- **Accredited laboratory** – A laboratory that has successfully participated in a quality assurance program leading to a certification of competence administered by a governmental or private organization that tests and certifies laboratories.
- **Accrediting body** - An entity, separate and distinct from an organization that provides direct patient care and/or performs other covered tasks, that assesses whether organizations that provide direct patient care and/or perform other covered tasks meet a set of requirements deemed necessary to ensure the organization's quality of services.

## OSHA's Infectious Diseases Regulatory Framework

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- ***Administrative controls*** - Managerial measures that reduce the risk of transmission of, or infection by, infectious agents. Examples of administrative controls would include, but would not be limited to: promoting and providing vaccination; enforcing exclusion of ill employees from the workplace; setting up triage stations and separate areas for patients with suspected or confirmed infectious disease when they enter a healthcare facility; and assigning dedicated staff to minimize the number of employees exposed to those with a particular suspected or confirmed infectious disease.
- ***Airborne infection isolation area (AIIA)*** - An area (e.g., room, booth, tent, or other enclosure), other than a dedicated airborne infection isolation room (AIIR), that is maintained at negative pressure to adjacent areas in order to control the spread of an airborne-transmissible infectious agent(s) outside of the AIIA.
- ***Airborne infection isolation room (AIIR)*** - A negative pressure patient-care room, with special air handling capability that is used to isolate persons with a suspected or confirmed airborne-transmissible infectious disease.
- ***Airborne precautions*** - Infection control measures designed to prevent or minimize transmission of infectious agents that remain infectious over time and distance (e.g., between or across rooms; through ventilation systems) when suspended in the air.
- ***Assistant Secretary*** - The Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.
- ***Contact precautions*** - Infection control practices designed to prevent or minimize transmission of infectious agents spread by direct contact (i.e., infectious agent

## OSHA's Infectious Diseases Regulatory Framework

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transmission from one infected individual to another individual without a contaminated intermediate item, surface, or individual) or indirect contact (i.e., infectious agent transmission through a contaminated intermediate item, surface, or individual) with an item, surface, or individual contaminated with, such an agent(s).

- **Contaminated** - The presence or reasonably anticipated presence of an infectious agent(s) in or on an item, surface, or individual.
- **Contaminated material** - An item (e.g., specimen, tissue, culture, biomedical waste, laundry, instruments, equipment) or surface (e.g., countertop, bed frame, examination table, laboratory bench, floor) contaminated with an infectious agent(s).
- **Decontamination** - The use of physical, radiological, and/or chemical means to remove, inactivate, or destroy an infectious agent(s) on an item or surface to the point where the infectious agent(s) is no longer capable of transmitting infectious particles and the item or surface is rendered safe for handling, use, or disposal. Decontamination can encompass cleaning, disinfection, and sterilization.
- **Direct patient care** - Job duties that involve the provision of healthcare services with hands-on or face-to-face contact with patients. An employee provides direct patient care only if she or he acts under a license, certification, or registration to provide healthcare services within a legally permitted scope of practice, or if she or he acts under the supervision of a licensed/certified/registered employee. Employees who provide direct patient care would include, but would not be limited to, nurses, physicians, physical and occupational therapists, and other healthcare employees who care for patients, as well as employees such as paramedics or emergency responders. An employee who provides first

## OSHA's Infectious Diseases Regulatory Framework

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aid only is not considered to provide direct patient care. Pharmacists who are licensed/certified/registered to perform hands-on care are considered to be providing direct patient care only when they perform duties that involve hands-on contact with patients (e.g., administering vaccinations), and not when they perform duties that involve face-to-face contact only (e.g., dispensing medications). A pharmacist(s) would still fall under the scope of this regulatory framework if the pharmacist(s) has occupational exposure during the performance of other covered tasks.

- ***Droplet precautions*** - Infection control measures designed to prevent or minimize transmission of infectious agents spread through direct contact of droplets containing the infectious agent with an individual's respiratory or mucous membranes.
- ***Engineering controls*** - Measures that reduce, isolate, or remove the infectious agents' hazard from the workplace. Examples of engineering controls would include, but would not be limited to, AIIRs and physical barriers, such as sneeze guards.
- ***Exposure incident*** – A specific event in which an employee has been exposed to a suspected or confirmed source of an infectious agent(s), either without the benefit of the infection control practices employers would be required to implement, or where the infection control practices have not adequately protected the employee from the exposure. For example, during an exposure incident investigation, a PLHCP may conclude that an employee has been exposed to a suspected or confirmed source of an infectious agent and that proper implementation of the employer's infection control practices have not adequately protected the employee from the exposure.

## OSHA's Infectious Diseases Regulatory Framework

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- **Facemask** - A U.S. Food and Drug Administration (FDA) cleared facemask (e.g., an FDA cleared surgical, medical procedure, dental, laser, or isolation mask). Facemasks are not tight-fitting. They are used as a physical barrier to protect from hazards such as splashes, splatters, or sprays of large droplets of blood or body fluids.
- **Host employer** - An employer that controls the operation of a work setting (e.g., hospital, doctor's office, laboratory) in which (a) the employer's employees have occupational exposure during provision of direct patient care and/or performance of other covered tasks, and (b) contractors, vendors, and/or licensed independent practitioners with privileges perform work.
- **Infectious agent** – A biological agent (including viruses, bacteria, fungi, protozoa, parasites, and aberrant proteins known as prions) that can be transmitted by the contact, droplet or airborne routes and that is capable of causing adverse health effects in infected individuals.
- **Infectious agent hazard evaluation** - An assessment to determine the presence of suspected or confirmed sources of infectious agents to which employees have occupational exposure during provision of direct patient care and/or performance of other covered tasks. An effective hazard evaluation would anticipate a range of infectious agent hazards and be appropriately linked with standard and transmission-based precautions. Such an evaluation would need to be consistent with recognized and generally accepted good infection control practices (e.g., Centers for Disease Control and Prevention (CDC) guidelines). In a healthcare setting, such an evaluation would include an assessment of a patient's infectious status based upon symptoms reported at scheduling and intake/admittance, and/or a

## OSHA's Infectious Diseases Regulatory Framework

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healthcare provider's index of suspicion based upon the provider's interactions with the patient.

- ***Institutional review board*** - A body established within a public or private entity or agency that is registered with an appropriate federal agency and operates in accordance with applicable federal regulations on the protection of human subjects (e.g., see the Department of Health and Human Services regulations on the Protection of Human Subjects, 45 CFR Part 46).
- ***Medical surge*** - An increase in the number or types of patients that severely challenges or exceeds the normal medical infrastructure of an affected community and its ability to provide adequate medical evaluation and care. Events that could lead to a medical surge include: pandemics, epidemics, other public health emergencies, natural or man-made disasters, or mass casualty incidents.
- ***Occupational exposure*** - Exposure, which is or should be reasonably anticipated, to sources of infectious agents resulting from an employee's execution of job duties that involve the provision of direct patient care or the performance of other covered tasks.
- ***Other covered tasks*** - Job duties that do not involve direct patient care but still involve occupational exposure in settings where direct patient care is provided, or occupational exposure to contaminated materials originating from settings where direct patient care is provided or to human remains. ***Other covered tasks*** also include job duties that involve occupational exposure to contaminated materials in diagnostic, research or production facilities. Examples of ***other covered tasks*** would include, but would not be limited to: providing patient support services (e.g., triage reception, housekeeping, food services,

## OSHA's Infectious Diseases Regulatory Framework

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facility maintenance); handling, transporting, receiving or processing contaminated materials (e.g., laundering healthcare linens, transporting medical specimens, disposing of medical waste, reprocessing medical equipment); maintaining, servicing or repairing contaminated medical equipment; conducting autopsies (e.g., in medical examiners' offices); performing mortuary services; manipulating and analyzing cultures, specimens, and human remains containing infectious agents in diagnostic, research and production facilities; and dispensing medications and/or medical supplies in settings where direct patient care is provided.

- ***Patient transport*** - The movement of a patient within a facility, as well as, inter-facility transfer, or movement during pre-hospital emergency medical care.
- ***Personal protective equipment (PPE)*** - Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothing (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard would not be considered PPE.
- ***Physician or other licensed healthcare professional (PLHCP)*** - An individual whose legally permitted scope of practice (e.g., a license, certification, or registration) allows her or him to provide a particular healthcare service that would be required by a provision in a rule as outlined in this regulatory framework. A PLHCP could delegate performance of some of these services to other healthcare professionals, provided their legally permitted scope of practice allows them to perform the tasks assigned under the supervision of the PLHCP. For example, although certain healthcare services, such as those that require a definitive diagnosis or post-exposure management, would necessitate a PLHCP with a

## OSHA's Infectious Diseases Regulatory Framework

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particular level of licensure (e.g., a physician, physician's assistant, or nurse practitioner), that PLHCP may delegate to a nurse, such tasks as, obtaining a medical history and exposure incident details.

- ***Standard operating procedures (SOPs)*** - An organizational directive that establishes a standard course of action to accomplish a task or goal.
- ***Standard precautions*** – The minimum infection control practices that apply to all direct patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is provided.
- ***Transmission-based precautions*** - Infection control measures, used in addition to standard precautions that are designed to prevent or minimize transmission of infectious agents, based on the way the agent is transmitted. Categories include contact, droplet, and airborne precautions, or a combination of these precautions for infectious agents that can be transmitted by more than one route.
- ***Work practice controls*** - Measures designed to reduce the likelihood of transmission of infectious agents by specifying the manner of performing particular work tasks. Examples of work practice controls would include, but would not be limited to: performing tasks in a manner that minimizes generation of droplets or aerosols of infectious agents and practicing appropriate hand hygiene and respiratory hygiene/cough etiquette.



### Section 3: Worker Infection Control Plan (WICP)

*This section provides the overall framework for an infection control plan that all affected employers would be required to develop to protect their covered workers.*

- Each employer having an employee(s) with occupational exposure during provision of direct patient care and/or performance of other covered tasks would be required to develop and implement a written WICP designed to prevent or minimize the transmission of infectious agents to each employee.
- **Exposure determination.** Each employer who has an employee(s) with occupational exposure during provision of direct patient care and/or performance of other covered tasks would be required to prepare an exposure determination. The exposure determination would be required to be made without regard to the use of PPE and would be required to contain a list of all job classifications in which all or some of the employees in those job classifications have occupational exposure.
- **WICP elements.** The WICP would be required to contain at least the following elements:
  - The name and title of, and contact information for, the plan administrator responsible for WICP implementation and oversight (e.g., infection preventionist, occupational health professional, biosafety officer). If the designated plan administrator does not have the knowledge, skills, or training necessary to implement and oversee the plan effectively, then she or he would be required to consult with appropriate personnel who have such knowledge, skills or training to ensure that the WICP is implemented and overseen effectively;

## OSHA's Infectious Diseases Regulatory Framework

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- The name of the person(s) responsible for the daily management of the WICP;
- The exposure determination that would be required; and
- The SOPs that would be required.
- Each employer would be required to ensure that a copy of the WICP is provided and accessible to all of its workers. The WICP could be part of a larger document, such as one addressing overall infection control in the workplace (e.g., a plan that also addresses patient safety, or a Biosafety Plan for laboratories) provided that the larger plan addresses all elements of the WICP. If the WICP is incorporated into a larger document, it would have to be a cohesive entity by itself or there would have to be a guiding document which states the overall program goals and references the elements of the larger document that comprise the WICP.
- The WICP would be required to be reviewed and updated at least annually, and whenever necessary to reflect changes in occupational exposure resulting from:
  - New or modified job tasks and procedures;
  - New or revised job classifications;
  - Changes in technology, updated federal, state, local, and other infection control guidelines, updated vaccination recommendations, or other medical advances that prevent or minimize transmission of infectious agents; and
  - New or emerging infectious agents, or changes in community patterns of infectious diseases (e.g., emergence of an antibiotic resistant infectious agent, an outbreak or a change in prevalence of an infectious disease).

## OSHA's Infectious Diseases Regulatory Framework

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- During development and reviews of the WICP, the employer would be required to:
  - Solicit input from non-managerial workers with occupational exposure regarding the WICP's implementation and possible improvements; and
  - Establish and maintain records for each review and/or update of the WICP that include:
    - The name(s) of the person conducting the review;
    - The dates the review was conducted and completed;
    - The name(s) and work area(s) of workers involved; and
    - A summary of the conclusions of the review and a timeline for completion of action items.
  
- **Host employer potential duties with respect to contractors, vendors, and licensed independent practitioners with privileges.** Where occupational exposure exists, the host employer would be required to:
  - Ensure that contractors, vendors, and licensed independent practitioners with privileges, at a minimum, adhere to infection control practices consistent with the host employer's WICP. Contractors, vendors, and licensed practitioners with privileges may adhere to infection control practices that are more protective than those contained in the host employer's WICP.
  - Ensure that its WICP is followed by each of its employees, even when instructions from a contractor, vendor or licensed independent practitioner with privileges (as described above) are contrary to the host employer's WICP. However, the host employer would

## OSHA's Infectious Diseases Regulatory Framework

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be permitted to allow its employees to follow contrary instructions from a contractor, vendor or licensed independent practitioner with privileges (as described above) if the host employer is able to show that not following the contrary instructions would be a greater hazard to a patient(s) or an employee(s), or that following the contrary instructions is consistent with recognized and generally accepted good infection control practices; and

- Ensure that a copy of its WICP is provided and accessible to all contractors, vendors, and licensed independent practitioners with privileges.
- **Contractors, vendors, and licensed independent practitioners with privileges.**

Notwithstanding the host employer potential duties with respect to contractors, vendors, and licensed independent practitioners with privileges, employers that are contractors, vendors, and licensed practitioners with privileges would be obligated to comply with all components of a rule as outlined in the regulatory framework, including development and implementation of a written WICP.
- The WICP would be required to be made available to the Assistant Secretary, upon request, for examination and copying.

### **Section 4: Standard Operating Procedures Development and Implementation**

*This section describes the general considerations for, and sources that employers would be required to consider, in developing their SOPs. In addition, this section provides a list of SOPs that employers in all affected work settings would be required to develop as part of their WICPs,*

## OSHA's Infectious Diseases Regulatory Framework

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*and specific SOPs that employers with workers that provide direct patient or workers that perform other covered tasks would be required to develop.*

- **General Considerations.** The employer would generally (unless otherwise stated in this regulatory framework) be required to develop, implement, and update written SOPs that are consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered by employees during their job tasks.
  - In developing and updating SOPs, the employer would be required to consider applicable regulations (e.g., federal, state and local regulations) and current guidelines (e.g., those issued by the CDC and its Federal Advisory Committees, such as the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices, CDC/National Institutes of Health (NIH) Biosafety in Microbiological and Biomedical Laboratories guidance, and the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules); and
  - In the absence of such regulations and guidelines, the employer would be required to consider current guidance issued by professional organizations and accrediting bodies.
  - In the situation where the employer is conducting research on infection control practices, the employer would be allowed to consider research protocols not consistent with recognized and generally accepted good infection control practices, provided those protocols have been approved by an institutional review board and adequately address employee protection as a component of the overall protection of the human subjects.

## OSHA's Infectious Diseases Regulatory Framework

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- The employer would be required to develop, implement, and update written SOPs that are consistent with applicable requirements in Part 1910 (e.g., requirements contained in 29 CFR 1910.134, and 29 CFR 1910 Subpart I); and, if a recognized and generally accepted good infection control practice conflicts with an applicable requirement in Part 1910, the employer would be required to incorporate into its SOPs, and implement, the Part 1910 requirement.
- **All Affected Work Settings.** All employers' SOPs would be required to contain at least the following procedures:
  - **Infectious agent hazard evaluations.** Procedures to promptly identify suspected or confirmed sources of infectious agents that are present in the work setting by conducting timely infectious agent hazard evaluations.

**Note:** OSHA would not require infectious agent hazard evaluations to be written documents; OSHA would permit the evaluations to be incorporated into routine activities, such as triage;

- **Communication of hazard evaluation results.** Procedures to communicate the results of the infectious agent hazard evaluation and the status of any suspected or confirmed sources of infectious agents to the person(s) responsible for implementing worker protection precautions;
- **Hand hygiene.** Procedures to ensure that handwashing facilities are available and accessible, and for following recognized and generally accepted good infection control practices for hand hygiene.

## OSHA's Infectious Diseases Regulatory Framework

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- **Food and cosmetics.** Procedures for restricting eating, drinking, smoking, applying cosmetics or lip balm, handling contact lenses, and storage of food and drink to areas where there is no occupational exposure during provision of direct patient care and/or performance of other covered tasks. The procedures would be required to prohibit storage of food and drink in refrigerators or freezers that contain contaminated materials.
  
- **Engineering, administrative and work practice controls, and personal protective equipment (PPE).**
  - Procedures for the use of engineering, administrative and work practice controls in accordance with recognized and generally accepted good infection control practices;
  
  - Procedures to provide, make readily accessible, and ensure that each employee uses PPE (such as, but not limited to, gloves, gowns, laboratory coats, face shields, facemasks, and respirators) in accordance with recognized and generally accepted good infection control practices;

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

## OSHA's Infectious Diseases Regulatory Framework

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- Procedures for examining engineering controls on a regular schedule, and maintaining or replacing them to ensure their effectiveness; and
- Procedures involving occupational exposure that are performed in a manner that prevents or minimizes generation of infectious agents. Where generation of droplets or aerosols is necessary (e.g., sputum induction), OSHA would require the procedures to prevent or minimize transmission of infectious agents;
- **Decontamination.**
  - Procedures for the routine and targeted decontamination of all contaminated materials (i.e., contaminated items and/or surfaces) in the work setting that could be a source of occupational exposure; and
  - Procedures to ensure that contaminated equipment is inspected and decontaminated prior to servicing or shipping. If decontamination of such equipment or portions of such equipment is not feasible, OSHA would require that the procedures ensure that the equipment be labeled/color-coded;
- **Handling, containerization, transport, or disposal of contaminated materials.**
  - Procedures to ensure that contaminated materials that could be a source of occupational exposure are placed in a container that is labeled/color-coded and that prevents leakage, and that employee contact with the contaminated materials during collection, handling, processing, storage, transport, shipping or disposal is minimized or prevented; and



## OSHA's Infectious Diseases Regulatory Framework

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- Procedures to ensure that, if the contaminated materials could puncture the primary container, the primary container is placed within a secondary container that is puncture-resistant and prevents leakage. In such cases, OSHA would require that the procedures provide that the secondary container also be labeled/color-coded;
- **Occupational health services.** Procedures for the employer to provide occupational health services, including screening, surveillance, vaccinations and vaccination regimens (e.g., doses, intervals), post-exposure treatment and follow-up, and medical removal protection, that are consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered by employees during their job tasks, as would be required under section 5 (Medical screening, surveillance and vaccination);
- **Exposure incidents.** Procedures to investigate the circumstances surrounding each exposure incident, including determination of the cause of the incident, and whether existing policies, procedures, or training need to be revised to prevent future exposure incidents;
- **Signage and labeling/color-coding.** Procedures for the use of signage and labeling/color-coding to convey an appropriate hazard warning to employees throughout the employer's work settings. The procedures would also require the use of signage and labeling/color-coding to convey an appropriate hazard warning to employees outside the employer's work setting, when such employees may be exposed to contaminated materials originating from the employer's work setting (e.g.,

## OSHA's Infectious Diseases Regulatory Framework

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specimens, equipment, laundry) during collection, handling, processing, storage, transport, shipping, and disposal activities; and

- **Notification of occupational exposure during transfer, transport, shipping, or receipt of sources of infectious agents.** Employers that transfer, transport, ship, or receive sources of infectious agents (e.g., suspected or confirmed infectious individuals and/or contaminated materials) would be required to include procedures in their SOPs for notifying other employers whose employees have or had occupational exposure to such sources;
- **Direct patient care.** In addition to the SOPs that would be required for all affected work settings, employers whose employees provide direct patient care would be required to develop, implement, and update SOPs that contain at least the following procedures for those employees:
  - **Patient scheduling and intake/admittance.** For employers that conduct patient scheduling and intake/admittance, procedures to promptly identify individuals with suspected or confirmed infectious diseases in order to initiate appropriate infection control practices (e.g., precautionary isolation or segregation; and patient placement and/or transfer, including procedures guiding patient treatment or transfer outside of the facility);
  - Procedures for standard precautions;
  - Procedures for contact precautions;
  - Procedures for droplet precautions;

## OSHA's Infectious Diseases Regulatory Framework

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- Procedures for airborne precautions, including:
  - If the employer's healthcare setting does not have an available AIIR, the procedures for the temporary isolation and inter-facility transfer of an individual with a suspected or confirmed airborne-transmissible infectious disease. OSHA would require that these procedures include the methods the employer will use to: isolate the individual, to the extent feasible, until transfer or AIIR placement; limit occupational exposure to the individual; and transfer the individual, as soon as feasible after identification, to a facility with an available AIIR;  
  
**Note:** OSHA would not require transfer of the individual if: a transfer would be medically detrimental to the individual's health; it is not medically necessary for the individual to remain in the healthcare facility (e.g., it is appropriate to send the individual home); or an AIIR becomes available for isolation of the individual.
  - If the employer's healthcare setting has an AIIR, the procedures for ensuring proper AIIR operation. These would include procedures for ensuring that each AIIR, associated ducting, and filtration are constructed, operated, and maintained so that they maintain negative pressure, achieve sufficient air changes per hour, properly exhaust contaminated air, and function to prevent or minimize transmission of infectious agents, and for ensuring that, when in use, each AIIR is monitored daily for maintenance of negative pressure; and
  - The procedures for use of respiratory protection. These would include, but would not be limited to, procedures for use: when entering areas, rooms, or homes where individuals have been isolated; when transporting individuals with suspected or

## OSHA's Infectious Diseases Regulatory Framework

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confirmed infectious disease in an enclosed vehicle; during aerosol-generating procedures; during maintenance of air systems or equipment reasonably likely to contain airborne-transmissible infectious agents; and in any situations where the infectious agent hazard evaluation indicates that respiratory protection is necessary for employee protection. These would also include procedures to ensure that a facemask is not used to provide respiratory protection if the use of a respirator is required under 29 CFR 1910.134;

- Procedures for patient transport;
- **Medical surge procedures.** For employers that provide services in medical surge conditions, procedures for the implementation of temporary control measures for medical surge conditions. OSHA would require that these control measures include: work practices; decontamination; set-up, performance testing, and use of temporary engineering controls used to establish AIAs (where appropriate); and preparation for the appropriate use of PPE during such situations, including procedures for stockpiling necessary supplies and PPE; and
- Any other employee protection precautions necessary to address specific infectious diseases or circumstances.
- **Other covered tasks.** In addition to the SOPs that would be required for all affected work settings, employers whose employees perform other covered tasks would be required to develop, implement, and update SOPs that contain at least the following procedures for those employees:
  - Procedures for the handling and intake of contaminated materials;

## OSHA's Infectious Diseases Regulatory Framework

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- Procedures for the use of control measures necessary to prevent or minimize transmission of infectious agents;
- For diagnostic, research and production facilities, in addition to the other procedures that would be required for other covered tasks, procedures to implement standard microbiological practices and any special practices for handling infectious agent(s) of a specific biosafety level, including, as appropriate:
  - Engineering controls, such as biosafety cabinets, laboratory hoods, and other laboratory design and containment measures, which would need to be appropriately constructed, operated, and maintained (e.g., proper air flow, exhaust air filtration, double access doors, special design requirements for Biosafety Level 3 and 4 facilities); and
  - Measures necessary to address uncontrolled releases of infectious agents, including mitigation of such releases and prompt reporting of such incidents to appropriate authorities (e.g., federal, state, and local authorities); and
- Procedures covering any other employee protection precautions necessary to address specific infectious diseases or circumstances.
- The employer would be required to ensure that each employee follows the SOPs applicable to that employee's job duties.

### Section 5: Medical screening, surveillance and vaccination

*This section specifies, among other things, the medical screening, surveillance and vaccinations that would be required to be provided to workers who have occupational exposure, and the procedures that would be required to be followed after an exposure incident occurs.*

- **General.**
  - The employer would be required to make available medical screening, surveillance, and vaccinations to each employee who has occupational exposure during provision of direct patient care and/or performance of other covered tasks, and post-exposure evaluation and follow-up to each employee who has had an exposure incident.
  - The employer would be required to ensure that each medical evaluation and procedure is performed by, or under the supervision of, a PLHCP and that each laboratory test is conducted by an accredited laboratory.
  
- **Vaccinations.**
  - The types of vaccinations made available, and associated vaccination regimens (e.g., doses, intervals), would be required to be consistent with recognized and generally accepted good infection control practices relevant to the occupational exposures encountered during the job tasks of the employee.
    - The employer of an employee(s) in a research or production facility would be required to make available to that employee(s) any vaccination(s) specified in the employer's WICP, or determined by a PLHCP to be medically appropriate for a particular employee.

## OSHA's Infectious Diseases Regulatory Framework

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- The employer of an employee(s) in a work setting other than a research or production facility would be required to make available to that employee(s), at a minimum, the following vaccinations:
  - Influenza (Seasonal and Pandemic);
  - Measles, Mumps and Rubella (MMR);
  - Tetanus, Diphtheria, and Pertussis (Tdap);
  - Varicella; and
  - Any other vaccination(s) that is specified in the employer's WICP, or determined by a PLHCP to be medically appropriate for a particular employee (e.g., the meningococcal vaccine).
- The employer would be required to review and update the vaccination(s) specified in its WICP at least annually, and whenever necessary to reflect changes in occupational exposure.
- **Exception.** The employer would not need to make available a vaccination(s) to an employee with occupational exposure if the employer has documented that the employee's vaccination(s) is up-to-date, antibody testing has revealed that the employee is immune, or a vaccine(s) is contraindicated for medical reasons.
- The employer would be responsible for monitoring administration of a vaccination series until completion. Upon completion of the series, any further testing, (e.g., antibody titer) would be required to be made available in accordance with recognized and generally accepted good infection control practices.

## OSHA's Infectious Diseases Regulatory Framework

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- Vaccinations would be required to be made available after the employee has received the training that would be required, as appropriate, and prior to the initial assignment to a job with occupational exposure. Vaccinations that require a series of inoculations would be required to be started prior to initial assignment to a job with occupational exposure.
- If, after completing the training that would be required, the employee declines a vaccination(s) or decides not to complete a vaccination that requires a series of inoculations, the employer would be required to ensure that the employee signs a declination statement (see Attachment B of this regulatory framework).
- If the employee initially declines a vaccination(s) but, at a later date, decides to accept the vaccination(s), the employer would be required to make the vaccination(s) available at that time.
- Revaccination or booster dose(s) of a vaccine would be required to be made available for each employee with occupational exposure in accordance with recognized and generally accepted good infection control practices.
- **Medical Screening and Surveillance.** The employer would be required to ensure that a PLHCP determines the necessity and frequency of medical screening and surveillance of the employer's employees who have occupational exposure during provision of direct patient care and/or performance of other covered tasks. Based upon this determination, the employer would be required to make available confidential medical surveillance (e.g., tuberculosis testing) for each employee with occupational exposure. Where medical surveillance tests indicate the need for further medical evaluation and follow-up (e.g., to



## OSHA's Infectious Diseases Regulatory Framework

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determine the need for precautionary removal of an employee), the employee would be referred to a PLHCP for such services.

- **Medical Evaluation and Follow-up.**

- Following a referral from a medical screening or surveillance program, the employer would be required to promptly make available to the employee(s) a confidential medical evaluation and appropriate follow-up.
- Following a report of an exposure incident, the employer would be required to investigate the incident and would be required to promptly make available to the exposed employee(s) a confidential post-exposure medical evaluation and appropriate follow-up, including at least the following elements:
  - Documentation of the route(s) of exposure and the circumstances under which the exposure incident occurred;
  - Identification and documentation of the source, unless the employer could establish that identification is not feasible or is prohibited by federal, state or local law;
  - Appropriate baseline testing of the exposed employee(s), after consent is obtained, for use in determining future seroconversion or infection;
  - Post-exposure prophylaxis and treatment appropriate to the infectious agent(s) of concern;
  - Counseling, as necessary;
  - Evaluation of reported illnesses that may be attributable to the exposure; and

## OSHA's Infectious Diseases Regulatory Framework

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- Recommendations, if any, for modifications or restrictions to the employee's job duties or for precautionary removal of the employee from the workplace.
- **Exposure incident records.** The employer would be required to establish and maintain records of exposure incident(s). The employer would not be obligated to establish and maintain records of exposure incident(s) that involve occupational exposure to the common cold or influenza, with one exception. In research and production facilities, the employer would be required to establish and maintain records of an exposure incident(s) involving infectious agents, including those that cause the common cold and influenza. Records would be required to include:
  - The date of the exposure incident(s), where feasible;
  - The work setting and the work task(s) being performed when the exposure incident(s) occurred;
  - The name(s) or any other identifier(s) (e.g., employee ID number(s)) of the employee(s) to which post-exposure evaluation and follow-up was made available;
  - The infectious agent(s) to which the employee(s) was exposed;
  - A description of any post-exposure evaluations and follow-ups that were performed, the results of those evaluations, and the dates on which they occurred; and
  - The date of contact and contact information for any other party who either notified the employer, or was notified by the employer, regarding the exposure incident(s).
- **Information Provided to the PLHCP.**

## OSHA's Infectious Diseases Regulatory Framework

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- The employer would be required to ensure that the PLHCP providing the employee's vaccination(s) is given a copy of a rule as outlined in the regulatory framework.
- The employer would be required to ensure that the PLHCP evaluating an employee after an exposure incident is provided the following information:
  - A copy of a rule as outlined in the regulatory framework;
  - A description of the exposed employee's duties as they relate to the exposure incident;
  - Documentation of the route(s) of exposure and circumstances under which exposure occurred; and
  - Other medical records regarding the exposure incident that are relevant to the appropriate treatment of the employee, including, but not limited to, the employee's vaccination status (for which the employer would be required to establish and maintain an accurate record).
- **PLHCP's Written Opinions.** The employer would be required to obtain and provide the employee with a copy of the evaluating PLHCP's written opinion(s) within 15 days of the completion of the evaluation.
  - All findings or diagnoses would be required to remain confidential between the PLHCP and the employee and not be included in the written report to the employer.
  - The written opinion for vaccination(s) that is provided to the employer would be required to be limited to whether a vaccination(s) is (are) indicated for an employee, and if the employee has received or refused such vaccination(s).

## OSHA's Infectious Diseases Regulatory Framework

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- The written opinion for the evaluation and follow-up for medical screening and surveillance that is provided to the employer would be required to be limited to the following information:
  - That the employee has been informed of the results of the evaluation; and
  - Recommendations, if any, for modifications or restrictions to the employee's job duties or for precautionary removal of the employee from the workplace.
- The written opinion for post-exposure evaluation and follow-up that is provided to the employer would be required to be limited to the following information:
  - That the employee has been informed of the results of the evaluation;
  - That the employee has been told about any medical conditions resulting from exposure to infectious agents that require further evaluation or treatment; and
  - Recommendations, if any, for modifications or restrictions to the employee's job duties or for precautionary removal of the employee from the workplace.
- **Medical Removal Protection.**
  - **Employee Restrictions or Removal.** The employer would be required to follow the PLHCP's recommendations concerning modifications or restrictions to an employee's job duties or precautionary removal of an employee from the workplace (e.g., to protect patients or co-workers).
  - **Medical Removal Protection Benefits.** When an employee has been removed from his or her job or otherwise medically limited as a result of an exposure incident, the employer would be required to pay the employee her or his total normal earnings, and

## OSHA's Infectious Diseases Regulatory Framework

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maintain the employee's seniority and all other employee rights and benefits, including the employee's right to his or her former job status.

- The employer would not be obligated to provide medical removal protection benefits to employees removed from their jobs or otherwise medically limited as a result of occupational exposure to the common cold or influenza, with one exception. In research and production facilities, if an employee is removed from her or his job or otherwise medically limited as a result of an exposure incident to any infectious agent with which she or he is working (including the common cold or influenza viruses), the employer would be required to provide medical removal protection benefits to the employee.
- The employer would be required to provide medical removal benefits until the employee is determined to be noninfectious or is otherwise able to return to normal duties, but provision of benefits would not need to exceed a period of 18 months.
- The employer's obligation to provide medical removal protection benefits to a removed or restricted employee would be required to be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly- or employer-funded compensation program, or from employment with another employer made possible by virtue of the employee's removal.

**Note:** OSHA's regulatory framework in no way is intended to preclude the employer from offering administrative or sick leave for medical removal of an

## OSHA's Infectious Diseases Regulatory Framework

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employee even when a rule as outlined in the regulatory framework would not require medical removal protection benefits.

- **Medical Records.**

- The employer would be required to establish and maintain an accurate record for each employee who has occupational exposure during provision of direct patient care and/or performance of other covered tasks, in accordance with 29 CFR 1910.1020.
- This record would be required to include:
  - The employee's name or any other employee identifier (e.g., employee ID number);
  - A copy of the employee's vaccination status for all vaccines that the employer would be required to offer, including the dates of all vaccinations, any medical records relative to the employee's ability to receive a vaccination(s) that would be required, and any vaccination declination statements signed by the employee;
  - A copy of all results of examinations, medical testing, and follow-up procedures that would be required;
  - A copy of the information provided to the PLHCP; and
  - The employer's copy of the PLHCP's written opinion.

- **Confidentiality.** The employer would be required to ensure that employee medical records are kept confidential and not disclosed or reported, without the employee's express written consent, to any person within or outside the workplace, except as would be required by OSHA or as may be required by law.

### Section 6: Training

*This section specifies the types and periods of training that employers would be required to provide to workers with occupational exposure to infectious agents.*

#### **Training.**

- The employer would be required to institute a training program and ensure each employee who has occupational exposure during provision of direct patient care and/or performance of other covered tasks participates in the program, and is provided training as follows:
  - Initially, prior to the time of assignment to tasks where occupational exposure may take place;
  - Annually thereafter, not to exceed 12 months from the previous training. If an employee(s) has received infectious diseases training in the 12 months preceding the effective date of the standard, OSHA would require the employer to provide training only to the extent that the previous training was deficient; and
  - Supplemental training to address specific deficiencies would be required to be provided when:
    - Changes, such as modification of tasks or procedures or institution of new tasks or procedures or control measures, affect the employee's occupational exposure. This training would be limited to addressing the changes;
    - Inadequacies in the employee's knowledge or work practices indicate that the employee has not retained the requisite understanding or skill; or

## OSHA's Infectious Diseases Regulatory Framework

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- Any other situation arises in which retraining is necessary to ensure employee protection from occupational exposure.
- The training program would be required to:
  - Be overseen or conducted by a person knowledgeable in the program's subject matter as it relates to the employees' workplace;
  - Consist of material appropriate in content and vocabulary to educational level, literacy, and language of employees; and
  - Provide an opportunity for interactive questions and answers with a person knowledgeable in the program's subject matter as it relates to the workplace.
- The initial training program would be required to contain, at a minimum, the following elements:
  - An accessible copy of a rule as outlined in the regulatory framework and an explanation of its contents;
  - A general explanation of the epidemiology and symptoms of common infectious diseases, including the signs and symptoms of infectious diseases that require further medical evaluation;
  - An explanation of the modes of transmission of infectious agents and applicable infection control procedures (e.g., standard and transmission-based precautions) so that the employee can recognize tasks and other activities that may involve occupational exposure and take precautionary measures;



## OSHA's Infectious Diseases Regulatory Framework

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- Information on vaccine(s) that would be required to be made available to the employee, including their efficacy, contraindications, likelihood and severity of possible adverse health effects, method of administration, the benefits of being vaccinated, and that the vaccines and vaccinations will be offered at no cost to the employee and at reasonable times and places;
- An explanation of the employer's WICP and the means by which the employee can obtain a copy of the written plan;
- Training on all of the SOPs developed as part of the WICP that are applicable to the employee's duties;
- An explanation of the use and limitations of engineering, work practice, and administrative controls; and
- Information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of personal protective equipment.
- The annual training program would be required to address, at a minimum, the following elements:
  - Information on the types, proper use, limitations, location, handling, decontamination, removal, and disposal of personal protective equipment;
  - All of the SOPs developed as part of the WICP that are applicable to the employee's duties; and
  - Information on vaccine(s) that would be required to be made available to the employee in the year of the training, including their efficacy, contraindications, likelihood and

severity of possible adverse health effects, method of administration, the benefits of being vaccinated, and that the vaccines and vaccinations would be required to be offered at no cost and at reasonable times and places.

### **Section 7: Recordkeeping**

*This section specifies the types of records that would be required to be retained by the employer, the retention period that would be required for each record, and the employer's potential obligation to make certain records available to the worker and OSHA upon request.*

- **Record maintenance.** The employer would be required to maintain the following records for the time periods specified:
  - Medical records for at least the duration of employment plus 30 years;
  - Exposure incident records for at least the duration of employment plus 30 years; and
  - WICP review records for three years.
  
- **Availability.**
  - Exposure incident records, the WICP, and the WICP review records would be required to be made available for examination and copying to workers and/or their representatives;
  - Medical records of each employee would be required to be provided, upon request, for examination and copying to the employee and to anyone having written consent of the employee; and

## OSHA's Infectious Diseases Regulatory Framework

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- The employer would be required to ensure that all records that would be required to be maintained be made available to the Assistant Secretary, upon request, for examination and copying.

### **Section 8: Cost and Availability**

*This section specifies that costs incurred by employee(s) would be compensable and that any activities that would be required of employees be conducted at a reasonable time and place.*

- **Cost.** OSHA would require that the implementation of all provisions outlined in this regulatory framework be at no cost to the employee(s) and that all employee time that would be spent complying with the provisions outlined in this regulatory framework, including time for training, medical evaluations/procedures, and reasonable travel time (as appropriate) be considered compensable time.
- **Availability.** OSHA would require that all medical evaluations and procedures (including vaccinations and post-exposure evaluation and follow-up) and any training be made available to the employee at reasonable times and places.

## OSHA's Infectious Diseases Regulatory Framework

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Attachment A – Common Infectious Agents and Their Modes of Transmission in Healthcare Settings (An appendix of this nature would be non-mandatory).

An appendix to a rule as outlined in the regulatory framework could contain a list of common diseases and infectious agents categorized by whether occupational exposure to the disease or agent typically requires contact, droplet or airborne precautions, as indicated below. This list represents scientific knowledge at the time this regulatory framework was written. However, there may be less common or new/emerging infectious diseases not reflected in this appendix. Additionally, continuing research on infectious diseases may impact how standard and transmission-based precautions are applied to the control of a particular disease.

To obtain current scientific information, employers should consult authoritative sources (e.g., CDC guidelines, state and local health department guidelines, medical journals, professional societies) on infectious diseases.

### **Infectious Agents/Diseases Requiring Contact Precautions**

*Clostridium difficile*

Diphtheria cutaneous

Hepatitis A

Human metapneumovirus

Norovirus

Parainfluenza virus, in infants and young children

Respiratory syncytial virus (RSV), in infants, young children or immunocompromised adults

Rotavirus

Staphylococcal disease (including diseases caused by methicillin-resistant *Staphylococcus aureus* [MRSA])

Major skin, wound or burn

Scalded skin syndrome

Vancomycin-resistant *Enterococcus* (VRE)

Any other disease for which public health guidelines recommend contact precautions

### **Infectious Agents/Diseases Requiring Droplet Precautions**

Diphtheria pharyngeal

Epiglottitis, due to *Haemophilus influenzae* type b

*Haemophilus influenzae* Serotype b (Hib) disease/*Haemophilus influenzae* serotype b -- Infants and children

Influenza, human (typical seasonal variations)/influenza viruses

Meningitis

*Haemophilus influenzae*, type b known or suspected

*Neisseria meningitidis* (meningococcal) known or suspected

Meningococcal disease sepsis, pneumonia (see also meningitis)

Mumps (infectious parotitis)/Mumps virus

Mycoplasmal pneumonia

Parvovirus B19 infection (erythema infectiosum)

Pertussis (whooping cough)

## OSHA's Infectious Diseases Regulatory Framework

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Pharyngitis in infants and young children/Adenovirus, Orthomyxoviridae, Epstein-Barr virus, Herpes simplex virus,

Pneumonia

Adenovirus

Haemophilus influenzae Serotype b, infants and children

Meningococcal

*Mycoplasma*, primary atypical

*Streptococcus* Group A

Pneumonic plague/*Yersinia pestis*

Rubella virus infection (German measles)/Rubella virus

Severe acute respiratory syndrome (SARS)

Streptococcal disease (group A streptococcus)

Skin, wound or burn, Major

Pharyngitis in infants and young children

Pneumonia

Scarlet fever in infants and young children

Serious invasive disease

Viral hemorrhagic fevers due to Lassa, Ebola, Marburg, Crimean-Congo fever viruses (airborne precautions may be required for aerosol-generating procedures)

Any other disease for which public health guidelines recommend droplet precautions

### **Infectious Agents/Diseases Requiring Airborne Precautions**

Aerosolizable spore-containing powder or other substance that is capable of causing serious human disease, e.g. Anthrax/*Bacillus anthracis*

Varicella disease (chickenpox, shingles)/Varicella zoster and Herpes zoster viruses, disseminated disease in any patient. Localized disease in immunocompromised patient until disseminated infection ruled out

Measles (rubeola)/Measles virus

Monkeypox/Monkeypox virus

Novel or unknown infectious agents

Severe acute respiratory syndrome (SARS)

Smallpox (variola)/Variola virus

Tuberculosis (TB)/*Mycobacterium tuberculosis* -- Extrapulmonary, draining lesion; Pulmonary or laryngeal disease, confirmed; Pulmonary or laryngeal disease, suspected

Any other disease for which public health guidelines recommend airborne precautions.

## OSHA’s Infectious Diseases Regulatory Framework

Attachment B – Vaccine Declination (An appendix of this nature would be mandatory)

**OSHA would require employers to use a vaccination declination statement, like the one below, for workers who decline vaccination(s).**

### VACCINE DECLINATION

I understand that in the course of doing my work, I am at risk of exposure to infectious agents that cause diseases. There are vaccines to protect against some of these diseases. My employer has given me the opportunity to be vaccinated against some/all of the infectious agents listed in the table below. These vaccines have been offered to me at no cost to myself.

However, as I have indicated in the table below, I have decided not to receive some or all of the offered vaccination(s) at this time. I understand that by not receiving the vaccination(s), I continue to be at risk of being infected, and that some of these infections may be very serious.

I can change my mind at any time and ask to be vaccinated at no cost to myself if in the future I continue be at risk of exposure to the infectious agents at work.

Infectious Agent(s) To Which I Am At Risk of Exposure At Work, and Vaccines that Have Been Offered to Me for Protection Against Infection From The Agent(s)

Infectious agent	Worker at risk of occupational exposure to agent (Employer initials in boxes that apply)		Vaccine	Worker offered vaccine (Worker initials in boxes that apply)		Worker declined vaccine (Worker initials in boxes that apply)
	Yes	No		Yes	No	
Influenza virus			Influenza			
Mumps virus, Measles virus, and/or Rubella virus			MMR			
Chickenpox virus			Varicella			
<i>Clostridium tetani</i> , <i>Corynebacterium diphtheriae</i> , and/or <i>Bordetella pertussis</i>			Tetanus, Diphtheria, and Pertussis (Tdap)			
<i>Other (specify)</i>						

\_\_\_\_\_  
Worker’s Name (Printed)

\_\_\_\_\_  
Worker signature

\_\_\_\_\_  
Date