Interim – Planning Guidance for the Handling of Solid Waste Contaminated with a Category A Infectious Substance

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INTERIM – PLANNING GUIDANCE FOR THE HANDLING OF SOLID WASTE CONTAMINATED WITH A CATEGORY A INFECTIOUS SUBSTANCE

What this is for: This Guidance is for safe handling of solid waste contaminated with a Category A infectious substance (henceforth, “contaminated waste”) and the proper management of inactivated Category A waste materials in the United States. An infectious substance meets Category A criteria if it is in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals upon exposure to the substance.

Who this is for: Local emergency medical services (EMS); hospital or healthcare facility personnel; public health officials; environmental officials; individuals and organizations involved in healthcare waste management and solid waste management operations; and Federal, State (or, in some jurisdictions, tribal or territorial), or local officials who have to handle, transport, or dispose of waste from a person with a suspected or known exposure to a Category A infectious substance. NOTE: Parts of this guidance may not apply to every State or hospital, depending on individual State or hospital plans in place.

How to use: Use these recommendations to: 1) identify handling considerations for contaminated waste for your locality; 2) develop a contaminated waste protocol or evaluate an existing protocol; 3) guide protection of worker health and safety; and 4) support the development of Category A waste management and response plans for contaminated and inactivated waste materials. This guidance does not address wastewater streams or provide instruction on decontamination measures, nor does it remove the obligation to comply with all applicable Federal, State, and local laws and regulations.

*NOTE: Wastewater treatment is regulated by the Environmental Protection Agency and State agencies and is outside the scope of this document. This document is also not intended to describe environmental cleaning and decontamination.

KEY POINTS

The handling of waste contaminated with a Category A infectious substance is regulated by several different regulatory agencies, including the U.S. Department of Transportation’s (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA) and the U.S. Department of Labor’s Occupational Safety and Health Administration (OSHA). This waste is also subject to State environmental and health regulations. The U.S. Environmental Protection Agency (EPA) generally does not regulate the medical waste itself; however, Federal regulations establish minimum criteria for the facilities that accept the waste for ultimate disposal. The U.S. Department of Health and Human Services’
(HHS) Centers for Disease Control and Prevention (CDC) and the Assistant Secretary for Preparedness and Response (ASPR) provide technical guidance.

- The DOT Hazardous Materials Regulations (HMR; 49 CFR parts 171-180) regulate waste contaminated (or suspected by the offeror\(^1\) to be contaminated) with any Category A infectious substance (such as Ebola virus, *Yersinia pestis*, or *Bacillus anthracis*). PHMSA is responsible for regulating and advancing the safe and secure transportation in commerce\(^2\) of hazardous materials across all modes of transportation.
- The solid waste generated in a local area (prior to hospital admission) or in the care of persons with suspected or known exposure to a Category A substance (henceforth, “contaminated waste”) is also subject to procedures set forth by Federal, State, and local regulations.\(^3\) OSHA issues standards and other requirements that outline principles for spills of blood and other potentially infectious materials at various worksites.
- Take steps to minimize the amount of contaminated waste generated. Contaminated waste may be physically separated, if practical, from other solid waste when it is generated. When mixed together, manage contaminated waste and other solid waste (e.g., other regulated medical waste) as contaminated waste.
- Contaminated waste may be inactivated on-site through the use of autoclave cycles or incinerators operating within permitted parameters. Other validated methods of treatment (e.g., chemical disinfection) may be necessary when operational constraints, such as those associated with patient care activities outside of fixed hospital facilities, preclude the use of autoclaves or incinerators. However, such alternative methods should be supported by objective data that demonstrate their effectiveness at inactivating waste and that are acceptable to appropriate regulatory authorities, including at the State and local levels. Users of these alternative methods should consider worker safety issues, as well as the potential for triggering other Federal environmental (e.g., under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA), safety, and health regulations.
- Contaminated waste may be safely transported off-site for inactivation, under a DOT special permit or with packaging meeting the regulatory requirements for Category A packaging under DOT/PHMSA, to a properly permitted medical waste handling facility employing either autoclaving technology or incineration.
- Contaminated waste that has been inactivated through an effective autoclave cycle or incinerated (and associated treatment residuals) is no longer infectious, does not pose a

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1. An offeror is a person who does either or both of the following: (1) performs or is responsible for performing, any pre-transportation function required under the HMR (49 CFR parts 171-180) for transportation of the hazardous material in commerce; and/or (2) tenders or makes the hazardous material available to a carrier for transportation in commerce. See 49 CFR § 171.8, [www.ecfr.gov/cgi-bin/textidx?SID=eaca6638e5842f4f8b4c4af079cc23ba8&m=true&node=pt49.2.171&rgn=div5#se49.2.171_18](www.ecfr.gov/cgi-bin/textidx?SID=eaca6638e5842f4f8b4c4af079cc23ba8&m=true&node=pt49.2.171&rgn=div5#se49.2.171_18).

2. Transportation of a hazardous material in a motor vehicle, aircraft, or vessel operated by a Federal, State, or local government employee solely for noncommercial Federal, State, or local government purposes is not considered to be “in commerce” and so is exempt from the HMR under 49 CFR § 171.1(d)(5).

3. In the case of an incident resulting from suspected or actual terrorism or other criminal activity, certain solid waste, including contaminated waste, may be considered evidence. (The Attorney General, generally acting through the FBI Director, will determine whether a particular situation will be treated as an actual terrorist incident.) The FBI has primary responsibility to conduct, direct, or oversee crime scenes, their security, and evidence management, through all phases of the response.
health risk, and is not considered to be regulated medical waste\textsuperscript{4} or a hazardous material\textsuperscript{5} under Federal and State laws or regulations. Therefore, such waste is no longer considered a Category A infectious substance and is not subject to the requirements of the HMR. However, residuals (e.g., ash from incineration) should be evaluated to determine whether they may be hazardous waste (e.g., ash can concentrate certain constituents such as toxic metals, if present in the original waste, or in other wastes incinerated at the same time) and be transported and disposed of in accordance with State and local regulations and standard protocols for hospital waste disposal. The ultimate disposal facility must meet Federal minimum criteria which are generally incorporated into waste and air permits. Note: Workers can still be injured by sharps, broken glass, or other items that, while sterile (i.e., not infectious) after autoclaving, can cause cuts or puncture wounds.

- Generally, contaminated waste that has been inactivated is considered medical waste subject to State regulations regarding its handling and management. However, the ultimate disposal facilities must meet minimum Federal requirements.\textsuperscript{6}

1. INTRODUCTION

Contaminated waste handling can be done safely. This guidance is intended to support that process.

Recent experiences with the handling of contaminated waste generated by patients with Ebola virus disease (either before or after hospital admission) demonstrated that there was a lack of universal understanding as to how to inactivate or dispose of contaminated solid waste and acceptance that these activities can be done safely. An infectious substance is Category A if it is in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals upon exposure to the substance.\textsuperscript{7} (See Appendix B for a list of Category A pathogens, based on United Nations guidelines for transporting infectious substances.) The Ebola virus is one such pathogen, given its ability to cause severe, often fatal, illness in humans.

\textsuperscript{4} A waste or reusable material, other than Category A, derived from medical treatment of humans or animals including diagnosis and immunization; or from biomedical research, including production and testing of biological products including production and testing of biological products (49 CFR §173.134(a)(5)). \textbf{Exceptions}: A material that is unlikely to cause disease in humans or animals; non-infectious biological materials from humans, animals or plants; a material containing neutralized or inactivated pathogens and no longer poses a health risk; or blood collected for transfusion or preparation of blood products sent for testing (unless believed to contain an infectious substance); laundry, medical equipment conforming to OSHA regulation 29 CFR §1910.1030; any waste or recyclable material other than regulated medical waste; or corpses, remains, and anatomical parts transported for internment, cremation or medical research (49 CFR §173.134(b)).

\textsuperscript{5} Per 49 CFR §171.8, “hazardous material” means a substance or material that the Secretary of Transportation has determined is capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and has designated as hazardous under section 5103 of Federal hazardous materials transportation law (49 U.S.C. section 5103). The term includes hazardous substances, hazardous wastes, marine pollutants, elevated temperature materials, materials designated as hazardous in the Hazardous Materials Table (see 49 CFR §172.101), and materials that meet the defining criteria for hazard classes and divisions in 49 CFR part 173.

\textsuperscript{6} This is a complex area and this guidance does not deal with all the potential jurisdictional issues. It is critical that a facility handling waste consult with State environmental and public health departments.

\textsuperscript{7} 49 CFR §173.134(a)(1)(i).
This Planning Guidance is the product of extensive Federal interagency coordination. It is intended to bridge gaps in understanding and to help local emergency medical services, emergency managers and leaders, hospitals, healthcare providers, environmental services workers, waste management companies and workers, and related stakeholders safely handle, inactivate, transport, and dispose of waste generated by, or resulting from the care of, persons with possible or definite exposure to a Category A infectious substance. The guidance provides key information about procedures and regulations regarding such waste and is supplemented by several appendices that provide additional resources, assist with decision making, and address questions and answers about contaminated waste.

This Guidance uses the terms “generator” and “offeror” throughout to refer to individuals or organizations associated with the creation and transportation of waste, respectively. Though these terms may seem interchangeable, it is important to note that each has its own definition and associated requirements. A “generator” is a person whose act or process produces (i.e., “generates”) a waste, regardless of the type of waste they produce.\(^8\) An “offeror,” under DOT’s HMR, is a person who performs or is responsible for performing any pre-transportation function required under the HMR for transportation of the hazardous material in commerce and/or who tenders or makes the hazardous material available to a carrier for transportation in commerce. See the Glossary of Terms in Appendix G for complete definitions.

**Determining Classification and Handling of Waste**

An infectious substance is a material known or reasonably suspected to contain a pathogen that could cause an infection. For Category A infectious substances, U.S. classification criteria and packaging requirements are consistent with international standards, which follow criteria developed by the United Nations Committee of Experts, working with the World Health Organization, CDC, medical professionals, microbiologists, transportation professionals, and packaging technical experts. The criteria are also consistent with the requirements contained in the 13th and 14th editions of the United Nations Recommendations for the Transport of Dangerous Goods, the 2005–2006 edition of the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air, and the International Maritime Organization Dangerous Goods Code.\(^9\)

For transportation under the HMR, it is the offeror’s responsibility to classify a hazardous material, which drives how the material must be packaged for transport. The hazardous material classification should be based on the known medical history or symptoms of the source patient, the endemic local conditions, and/or professional judgment. Proper hazardous material classification is critical, as it is the basis for subsequent actions.

Separately, for waste disposal under Federal and State environmental regulations, it is the generator’s responsibility to make a waste determination, which drives how and where the waste

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\(^8\) The term “generator” has a very specific meaning under the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations. See the definition of “generator” in Appendix G – Glossary of Terms.

will be inactivated (if necessary) and where the waste itself and any residuals (e.g., incinerator ash) resulting from waste treatment will be disposed.

When dealing with a known or suspected Category A infectious substance, the offeror or generator should consult with the group with the best knowledge of the situation in making the hazardous material classification and waste determination. For healthcare facilities, this group would include infectious disease personnel working in collaboration with relevant State and local public health and waste management authorities. In turn, local governments should engage State and local public health and waste management authorities to make these decisions in the most informed manner possible.

Regulating the Transport of Contaminated Waste

DOT’s HMR regulate an infectious substance as a hazardous material. The HMR apply to any material that DOT determines is capable of posing an unreasonable risk to health, safety, and property when transported in commerce. An infectious substance must conform to all applicable HMR requirements when offered for or actually transported by air, highway, rail, or water, but the overall handling of contaminated waste begins with the creation of the waste, includes waste transportation, and ends at final disposition. The sections below explain these three phases of handling in greater detail.

2. WASTE CREATION

Managing contaminated waste that is created by the patient before hospital admission or during medical treatment or transport requires a multi-pronged approach that includes proper classification (as mentioned above), appropriate storage (i.e., a secure location and segregation from other wastes), and steps to minimize the amount of waste generated.

Local Government and Facility Plans

The leadership for local governments and facilities that may or will need to manage contaminated waste should ensure they have a plan to address the entire waste lifecycle—from creation to final disposition. The plan should detail how waste management tasks (waste classification, waste minimization, segregation, storage, etc.) will be accomplished, and it should provide locality- or facility-specific procedures. Each plan should have input from appropriate State and local health and environmental departments, and it should primarily focus on the safety of the people who will handle, manage on-site treatment or package and transport for off-site treatment—or otherwise risk contact with—contaminated materials.

In governed localities where a person is suspected to have a Category A disease, the local public health authority is in the best position to assess whether items in the patient’s immediate environment pose a health risk. For example, when Category A diseases are transmitted through contact with infectious bodily fluids, sometimes hard, non-porous items such as furniture in a

person’s residence can be safely cleaned on-site using acceptable practices. When safe on-site decontamination is not possible, such as with porous items that are contaminated, these items become contaminated waste. The determination whether the items are contaminated waste or not is usually based on clinical assessment of the patient (e.g., whether the patient has a suspected or confirmed diagnosis of a disease caused by a Category A agent), and whether the items contain bodily fluids of a sufficient quantity that may pose a public health risk. The local public health authority, in conjunction with the State public health and environmental officials, need to direct the handling of contaminated waste. In some instances, the local health authorities may recommend the use of a crime scene/biohazard remediation company already under contract to process the environment or directly safely packaged contaminated waste from a patient’s home to the hospital for safe processing rather than initiating a separate contaminated waste transport contract.

### Managing large amounts of waste associated with patient care activities

Care of patients with Category A diseases can result in substantial amounts of waste. During the 2014 Ebola outbreak, patient care activities sometimes resulted in more than ten packages a day due to the amounts of personal protective equipment (PPE) required. Hospital protocols should consider and address limiting the amount of waste generated by keeping infectious and non-infectious wastes separate and bringing only essential items directly needed for care into the room. Doing so limits the volume of items in the contaminated area, thereby limiting the volume of items that will ultimately need inactivation and disposal. As an example, where possible, hospital staff can remove all outer wraps on pre-packaged kits or remove any internal packaging. Special attention should also be directed at protecting large items (e.g., mattresses) from gross contamination through the use of protective coverings. When care of the patient is complete, the protective covering is disposed of using the contaminated waste protocol. The mattress can then be terminally cleaned using your facility’s existing procedures.

Facilities should have protocols to package, store and transport waste. Such protocols may address:

- Using a pre-identified route to a secure storage location within the facility that serves as a secured waste holding area, either prior to inactivation on-site or for holding prior to transport for off-site inactivation.
- Transporting Category A waste from the point of generation within the generating facility to a secure holding area with the use of covered push carts or bins or other leak-proof containers to ensure that there is no release or spillage of the waste.
- If applicable, storing packed Category A waste containers prior to waste vendor transport. Holding areas for Category A waste storage should be separate from other waste, located on impermeable surfaces and provide protection and security against spillage, weather, putrescence, pest infestation and trespassers. The waste holding area should adequately

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accommodate the volume of packaged waste that may develop between waste transport vendor pickups (e.g., 24-hour, 48-hour, or 72-hour intervals) and should be secure at all times with access limited to authorized employees only. When contaminated waste and other solid waste (e.g., other regulated medical waste) are mixed together, manage the waste as contaminated waste.

In addition, local public health officials and facility staff should contain and package contaminated waste as close as possible to the point of generation. If this cannot be accomplished due to space limitations, specific protocols should be followed. Once primary waste containment has taken place, staff should refrain from opening containers to manipulate waste.

3. WASTE MANAGEMENT

Once a patient is suspected to have or has been diagnosed with an infection caused by one of the Category A Infectious substances (see Appendix B), the facility treating the patient should activate their Facility Emergency Waste Management Plan. This plan will indicate whether the facility will be using on-site inactivation (e.g., autoclaving, incineration, or other validated methods) or if it will need to follow all the necessary requirements for transporting the waste off-site for inactivation.\textsuperscript{12}

On-site Inactivation

Facilities may inactivate contaminated waste using an autoclave operating within permitted parameters.\textsuperscript{13} Use of an autoclave cycle heats materials to a high enough temperature for a long enough period of time to inactivate the organism(s) of concern in the waste. Such time/temperature/pressure conditions will ensure that the waste material is no longer infectious, does not pose a health risk, and is not considered regulated medical waste or a hazardous material under Federal law. The autoclaving should include a process control to show that the process performed effectively. For example, staff should check the autoclave cycles frequently with biological indicators (spores) as a quality assurance measure to show that the waste treatment

\begin{boxedtext}
\textbf{On-site Inactivation of Ebola-contaminated Waste}

When inactivating waste contaminated with the Ebola virus, an example autoclave cycle could include heating the material to 121°C (250°F) for at least 30 minutes. Such a treatment process uses more than enough heat and time to kill Category A infectious substances at least as susceptible as Ebola virus. However, some porous waste materials or other variations in load and packaging may require modifications to the operating procedures of the autoclave to achieve the necessary material temperatures prior to being held at the required temperature for 30 minutes.
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\textsuperscript{12} Waste that presents explosive hazards, e.g., batteries sealed containers, or oxygen cylinders, may require special handling.

\textsuperscript{13} Operators should validate that their waste inactivation procedures meet required performance standards, including achieving certain exposure time and temperature requirements, acceptable results on biological indicators or other test assays, and allowable concentration of certain pollutants or contaminants in any effluent or other by-product of the process.
cycles are achieving desired results. Hospitals without organic autoclave capability of sufficient capacity could consider portable industrial autoclaves which are available through waste management contractors. These portable autoclaves can be delivered to a critical location and can handle larger quantities of waste than usual hospital autoclaves.

Another method of on-site inactivation is incineration. Incinerators run at extremely high temperatures, well above the relatively low temperatures needed to kill most Category A organisms. Incineration would be the best method for large or bulky items, such as mattresses. Incineration that reduces waste to ash at any temperature kills Ebola virus. A waste management plan that considers on-site incineration should include a method for disposing of residuals. Residuals from Category A wastes that have been inactivated either through autoclaving as described above or through incineration are no longer infectious and should be disposed of in accordance with the applicable State and local regulations.

Other validated methods of waste treatment (e.g., chemical disinfection) may be necessary when operational constraints, such as those associated with patient care activities outside of fixed hospital facilities, preclude the use of autoclaves or incinerators. However, such alternative methods should be supported by objective data that demonstrate their effectiveness at inactivating waste and that are acceptable to appropriate regulatory authorities, including at the State and local levels. Users of these alternative methods may need to consider worker health and safety issues, as well as the potential for triggering other Federal environmental (e.g., under FIFRA), safety, and health regulations.

Additionally, inactivation or incineration of contaminated waste may be subject to State, local, and OSHA regulations. For instance, employers may be required to provide training and implement controls, including PPE, to protect workers operating autoclaves. (Worker safety and health is specifically addressed in Section 6, below.)

It is critical that staff handling Category A waste be made aware of the ultimate treatment method for the waste. Such training could be part of an overall waste management plan or a facility-specific training plan. Staff should be cognizant of the materials being sent for on-site inactivation since the operators of the on-site inactivation equipment will be unable to perform any waste segregation operations on waste streams from a healthcare setting involving Category A infectious substances. Materials that might cause problems with on-site inactivation processes (e.g., batteries or electronics) should be separated from the remaining waste at the point of generation, and staff can select alternate treatment/disposal pathways for such components. During an event, there should be routine communication among staff and the operators of on-site treatment to ensure they are following the best procedures for managing wastes.

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**Off-site Inactivation**

If Category A wastes cannot be inactivated on-site, then the wastes will need to be transported off-site. Off-site transportation requires additional steps and compliance with specific regulations as described in the next section. In most circumstances, off-site transportation will likely be for incineration. Incineration of contaminated waste may be subject to Federal, State, and/or local laws or regulations. Beyond the act of incinerating the waste (and disposing of the residuals), the transportation of the waste materials is subject to the HMR (discussed more in the next section). For any movement off-site, a detailed agreement or contract should be in place with an entity that has party status to a DOT/PHMSA special permit.\(^\text{15}\)

Facility and local government leadership, as well as waste transportation and treatment facilities, should work closely with State and local health departments, environmental agencies, and other appropriate entities and officials to ensure that the waste management plan does not conflict with any State statutory or regulatory prohibitions related to the inactivation and disposal of Category A infectious substances.

**4. MOVEMENT OF WASTE CONTAMINATED WITH A CATEGORY A INFECTIOUS SUBSTANCE IN TRANSPORTATION**

DOT/PHMSA regulates movement of hazardous materials across all modes of transportation through the HMR, which are designed to minimize the risks to life, property, and the environment during the transportation of hazardous materials. For Category A infectious substances, the HMR provide clear regulations for classification, packaging, and communication procedures that must be followed.\(^\text{16}\) DOT/PHMSA also has the authority to issue a special permit for transporting contaminated waste in a manner that deviates from conventional, established HMR methods (e.g., using alternate packaging).

**Category A Infectious Substance**

Pursuant to the HMR, the offeror has the responsibility of classifying a hazardous material. For example, once the offeror classifies the material as Category A waste, it must be classified as UN2814, a Category A infectious substance affecting humans.

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\(^{15}\) See Appendix C for more information.

\(^{16}\) See Appendix A link: “Department of Transportation Guidance for Transporting Ebola Contaminated Items, a Category A Infectious Substance.”
Inter- and Intrastate Movement

The HMR apply to the transportation of hazardous materials in interstate or intrastate commerce, which includes the movement of the hazardous material, as well as its loading, unloading, or storage. The HMR regulate materials that are suspected or known to be contaminated with a Category A infectious substance.

Selecting a Transporter

Materials that are suspected or known to be contaminated by Category A infectious substances may only be transported in two scenarios: in full compliance with classification and packaging requirements of the HMR, or under the terms of a special permit. During the 2014 Ebola outbreak, there was a relatively large quantity of contaminated waste generated when treating patients with known or suspected Category A diseases, the available packaging authorized under the regulations governing the transport of Category A infectious substances were intended for laboratory specimens and were not large enough to meet the need. Alternative packaging designs were needed to meet safety requirements and to accommodate the large volume of waste. DOT/PHMSA issued a special permit, DOT-SP 16279, which authorizes transportation of Ebola waste in the alternative packaging designs. Several transporters have been approved by DOT to use DOT-SP 16279, which requires training on the requirements of the special permit, including package preparation, closure, marking, documentation, and emergency response. PHMSA’s special permit search portal can provide a current list of transporters who are authorized to use DOT-SP 16279:


5. DISPOSITION OF WASTE

The ultimate disposition of waste, including any residuals from inactivation of such waste, depends on a number of factors, including the characterization of the waste and residuals, State regulations, and permit conditions for particular treatment/disposal facilities. As a general matter, under the Federal Resource Conservation and Recovery Act (RCRA) and the majority of State programs, waste is categorized as either “hazardous waste” or “nonhazardous (or solid) waste.” Importantly, the Federal hazardous waste regulations under the RCRA do not classify a waste as “hazardous” based on a waste’s infectious nature (though State hazardous waste regulations may differ from Federal regulations). However, the waste could still be hazardous as defined under RCRA regulations due to the nature of the contaminated material (e.g., presence of certain toxic metals or chemicals, such as solvents). This determination (i.e., hazardous versus non-hazardous) under the RCRA is independent of the presence or absence of infectious agents.

The requirements for hazardous waste management are based on Subtitle C of the RCRA and its implementing regulations beginning at 40 CFR part 260: once a waste is determined to meet the definition of a hazardous waste, it is subject to strict requirements “from cradle to grave” (i.e., from its point of generation to its ultimate disposal). Requirements for nonhazardous (or solid) waste are based on Subtitle D of the RCRA. Disposal of solid waste is primarily regulated at the State level; but there are minimum Federal criteria that solid waste facilities must meet. In
addition, many States have specific statutory or regulatory requirements for identification, treatment and disposal of medical waste.

Category A waste, once inactivated through autoclaving, incineration, or other validated methods, is no longer considered to be a Category A infectious substance or a regulated medical waste with respect to DOT’s HMR. It is anticipated that the inactivated material will not generally be subject to specific Federal RCRA hazardous waste regulations, but this determination should be made in particular if the waste contains toxic metals or chemical solvents. As solid wastes, the inactivated material may be subject to State regulations. Because some States have additional requirements for treated medical waste, including additional documentation or specific management requirements, facilities need to check with the State(s) in which they operate and comply with those regulations.

Since situations vary, this section outlines considerations for final disposition and planning by the location that could generate the waste and the facility that could receive the waste and/or residuals for ultimate disposal.

The first key consideration: Has the contaminated waste been properly treated to inactivate the pathogens?

If the Category A waste has been inactivated, then:
- The remaining waste is considered a solid waste. As described above, a hazardous waste determination should be made independently the fact that the waste has been inactivated. The waste may be subject to additional State solid waste regulations or State regulations for treated medical waste, including additional documentation or management requirements. Facilities must understand and comply with these requirements.
- The facility where the properly inactivated waste (or residuals) is located should:
  - Verify with its State or local regulatory official that the waste may be treated as a solid waste.
  - Confirm any State-specific solid waste or treated medical waste requirements with which the facility must comply. Verify that its usual solid waste treatment/disposal facility is properly permitted and able to handle the material, especially if there is a large volume.
  - Verify that the treatment/disposal facility’s management/ownership is willing to accept the waste.
  - Ensure that the generating facility understands and complies with any special conditions that may be imposed either by a permit or by the receiving facility.
  - Verify that the disposal facility properly received and processed the waste.

If the waste has not been inactivated (i.e., it remains contaminated waste), then:
- The contaminated waste generally requires special handling; disposal options are likely more limited.
- The facility generating the waste should:
  - Verify the “classification” of the waste (e.g., hazardous) with its State or local regulatory official.
Choose a facility permitted for such materials—e.g., medical waste incinerator, municipal waste combustor, hazardous waste (HW) combustor, other incinerator, autoclave, etc. Whether a particular facility may receive such material depends on its particular permit.

Understand and comply with any special conditions that may be imposed either by a permit or by the receiving facility.

Follow all conditions and packaging instructions of the DOT PHMSA special permit, or use appropriate packaging for Category A requirements and follow all packaging instructions prior to transport.

Verify that the treatment/disposal facility’s management/ownership is willing to accept the waste.

Verify that the disposal facility properly received and processed the waste.

Have a contingency plan in case the disposal facility is unavailable.

And verify that the disposal facility also has a contingency plan to handle disruptions.

Facilities must also appropriately manage residuals from treatment, meaning they must determine (either by testing or by knowledge) whether the residuals are a hazardous waste under the Federal regulations implementing the Resource Conservation and Recovery Act (RCRA) or the appropriate State regulations. If the residuals (including incinerator ash) are hazardous waste, then they must comply with all of the hazardous waste requirements, including disposal in a hazardous waste permitted unit. If they do not meet the definition of “hazardous,” then they may be disposed of in a solid waste disposal unit. If the waste was classified as RCRA hazardous waste at the beginning of the process, then the residuals including the ash remain hazardous waste and they must be tested for compliance with applicable treatment standards and then managed as a hazardous waste (i.e., sent to a subtitle C Treatment, Storage or Disposal (TSD) facility).

The diagram in Appendix D illustrates the path and key decisions in the treatment and the ultimate disposal of waste. The diagram shows the paths both for waste that may be inactivated on-site and for waste that cannot be treated on-site. In the first scenario, waste is treated on-site if it is appropriate, available, and allowable under State regulations. If the waste is no longer infectious, it is then transported to an off-site disposal facility permitted under State regulations to accept the waste (e.g., a RCRA subtitle D landfill, a municipal waste combustor). Any treatment residuals are also tested and disposed of appropriately (that is, assuming the residuals are not hazardous, they are disposed of in a subtitle D landfill or solid waste facility). If on-site treatment is performed but the treatment does not result in inactivation of the Category A waste, then the waste is either retreated on-site or sent off-site for treatment and disposal.

In the second scenario, no on-site treatment is available (or the on-site treatment has not been effective). The waste is thus managed in accordance with State medical waste requirements and DOT requirements for transportation (as well as any other appropriate requirements). The waste is sent to an off-site treatment facility permitted to accept this material, most likely a medical waste incinerator. The waste is treated (incinerated) and the residuals are tested. If the residuals do not meet the requirements for an RCRA hazardous waste, they may be disposed of in a solid
waste facility (e.g., RCRA Subtitle D landfill). If the residuals had tested as hazardous, then they would need to be managed as a hazardous waste and sent to a RCRA Subtitle C disposal facility.

6. PROTECTION OF WORKER HEALTH AND SAFETY

Protecting workers during handling, treatment, transport, or disposal of suspected or known Category A contaminated waste begins before the waste is generated, through anticipation, assessment, identification and planning for occupational exposure risk and appropriate control measures. The first and best strategy for protecting workers is to control the hazard at its source: if possible, minimize the amount of waste generated, and ensure plans are in place to deal with waste before generating it. Once waste is generated (i.e., the point of origin), implement protective measures that continue through final disposition of the waste. Under OSHA standards for bloodborne pathogens, personal protective equipment (PPE), and respiratory protection (i.e., respirators to prevent inhalation of infectious materials), as well as other OSHA requirements, employers must protect workers who handle contaminated waste.

A comprehensive protection program for waste workers relies on a hierarchy of engineering controls, administrative controls, and safer work practices; PPE; and training, medical exams, and other elements that OSHA standards require. This guidance provides general strategies for protecting workers, though employers must assess their work sites and the job duties of their workers to implement appropriate controls.

In all stages of the waste lifecycle, employers and workers should:

- Limit the number of workers who handle Category A waste to essential staff. For example, instruct and train healthcare workers generating contaminated waste during care of an infectious patient to package the waste properly instead of requiring an environmental services, waste collection, or waste hauling workers to also handle the waste.
- Whenever gloves are removed or changed, wash hands with soap and water for at least 20 seconds, or use alcohol-based hand rubs if soap and water are not immediately available. Always wash with soap and water if hands are visibly soiled.
- Avoid touching the face or other exposed parts of the body while wearing gloves or before washing/sanitizing bare hands.
- Change clothing and shower as soon as possible if work clothing becomes soiled.
- Discard soiled work clothing, and PPE with other contaminated waste.
- Wear dedicated washable footwear while on the job.
- Train workers to notify a supervisor immediately if exposed to potentially infectious material or waste on the job, including on work clothing or exposed skin or through mucous membranes (e.g., eyes, nose or mouth).
- Consider vaccination to protect workers from diseases for which a vaccine exists. Although OSHA’s Bloodborne Pathogens (BBP) standard at 29 CFR § 1910.1030 only

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18 For more detailed information on protection guidance for workers dealing with Category A contaminated waste, see www.osha.gov/Publications/OSHA_FS-3766.pdf.
requires the Hepatitis B vaccine series be made available to workers with occupational exposure, as defined in the standard, employers may consider offering additional vaccines to their workers.

Engineering Controls

The work environment should be designed to eliminate or otherwise reduce worker exposure to hazards. Engineering controls in waste operations serve as physical barriers between workers and pathogens, reducing the likelihood and amount of worker exposure to sources of infectious substances. Equipment that functions without worker actions (e.g., continuous operation of a negative-pressure ventilation system in areas where waste is handled) provides the best protection. Other engineering controls include using:

- Barriers (with windows or closed-circuit television monitors) between areas where waste processing equipment operates and where workers may control or observe the equipment.
- Needleless I.V. systems, retractable syringes, and other devices designed to prevent needlestick injuries. These systems protect healthcare and waste workers.
- Rigid containers to package waste, including puncture-proof containers for sharps. Packaging must meet the requirements of OSHA’s Bloodborne Pathogens standard and DOT’s HMR (or exceptions outlined in a special permit, if applicable).
- Equipment that ventilates outside the work area when treating contaminated waste.
- Suitable shelves, straps, or other equipment—especially in transport vehicles, where containers may move or shift—to secure stacked contaminated waste containers.

Safer Work Practices and Administrative Controls

Develop protocols for handling, transporting, treating, and disposing of waste that, when properly followed, reduce the likelihood of worker injury and illness. Train workers in how to perform their jobs safely, following appropriate work practices and administrative controls:

- Package waste in accordance with OSHA’s Bloodborne Pathogens standard, CDC guidelines, and DOT’s HMR. Proper packaging from the outset minimizes repackaging or additional handling. If DOT has issued a special permit for the waste, follow its provisions.
- To prevent toppling and spillage, place containers of waste as low as possible on dollies, hand trucks, or carts and when stacking (including in transport vehicles).
- Select waste processing techniques that minimize worker exposure to pathogens, including by minimizing the need for workers to handle waste (including in packaging).
- Incinerate or autoclave entire, unopened waste containers to eliminate exposure associated with handling and opening containers. For Category A waste, avoid reusable containers that must be emptied into an incinerator or autoclave and/or processed for reuse.
- Do not use open burning techniques, which could expose workers and other individuals to harmful air contaminants.
- Do not use waste management processes that involve shredding suspected or known contaminated waste, as these techniques may result in generation of bio-aerosols (aerosolized droplets containing infectious particles that can be inhaled). Shredders also
may become clogged or jammed by atypical, porous waste materials (e.g., linens, carpet, curtains, or other textiles) that must be discarded when decontamination is not possible.

- If workers use shredding equipment despite this guidance recommending otherwise, and if the shredding equipment becomes clogged, avoid entering clogged shredding machines to resolve mechanical problems. If a worker must do so, always ensure the machine is off, the worker correctly uses appropriate PPE, and the worker follows proper lockout/tagout procedures for controlling hazardous energy. To prevent worker exposure to infectious material in equipment that becomes clogged prior to completing treatment, use chemical decontamination methods prior to servicing equipment in addition to PPE.
- Handle inactivated, non-infectious waste as though it may continue to pose a hazard from sharps or other puncture injuries. In particular, autoclaved waste may contain needles, broken glass, and other hazards, even though these items are sterile after treatment (assuming use of an effective inactivation protocol).

Personal Protective Equipment

The OSHA PPE standard requires that employers assess the workplace, determine the presence of hazards, and then choose appropriate PPE to protect workers. Employers must select PPE that protects workers against infectious substances and other hazards to which they may be exposed. Depending on the route(s) of transmission of the pathogen of concern and the types of potential exposures associated with a worker’s job tasks, workers must wear PPE to help minimize exposure to pathogens via mucous membranes, broken skin, or through inhalation of bio-aerosols or airborne particles. For additional information about PPE, see the OSHA PPE standards at 29 CFR part 1910 subpart I.

Employers should also follow manufacturer instructions on product labels and Safety Data Sheets for EPA-registered disinfectants and other chemicals involved in waste management operations when selecting PPE for their workers (i.e., to ensure that PPE protects workers from chemical hazards posed by such disinfectants).

When workers may be exposed to infectious particles, employers must implement a respiratory protection program that complies with the OSHA Respiratory Protection standard. A comprehensive respiratory protection program includes properly selected respirators approved by the National Institute for Occupational Safety and Health (NIOSH), fit testing, and medical exams for workers who will use such equipment. Note that not all respirators or respirator cartridges used to protect workers against inhalation of infectious particles effectively protect them from exposure to certain chemicals used in waste packaging procedures or for cleaning and decontaminating equipment and surfaces.  

Workers must don (i.e., put on) and use PPE properly in order to achieve the intended protection and minimize the risk of infection. Workers should doff (i.e., remove) PPE in a way that avoids self-contamination. For example, avoid skin and mucous membrane contact with potentially

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19 Consult OSHA’s Respiratory Protection standard, as well as the manufacturer’s Safety Data Sheet for the specific chemical(s) that workers are using, to learn more about selecting an appropriate respirator to protect against chemical exposure. See www.osha.gov/SLTC/respiratoryprotection.
infectious materials contaminated with contact- and droplet-transmissible agents; only remove respirators after leaving work areas where air contaminants (e.g., airborne-transmissible agents) may be present. The order of PPE donning and doffing may vary depending on the infectious agent(s) of concern in the waste, the type of PPE a worker uses, the nature of the work tasks being performed, and which devices or garments are contaminated, among other factors. Refer to updated guidance from OSHA and CDC for the most current information about particular Category A infectious agents.

Worker Training

Employers must train workers about sources of exposure to infectious substances and appropriate precautions. All training provided to workers must be in a manner and language they can understand. Some types of work may necessitate that employers provide interactive training. For specific information about training requirements, see, among other OSHA regulations, the BBP standard at 29 CFR § 1910.1030. In general:

- Workers who may be exposed to items contaminated with Category A infectious substances prior to packaging must be trained to handle and appropriately package such materials.
- All facility personnel who may come in contact with packaged contaminated waste must be trained to handle the waste and/or containers of waste materials safely.
- Facility leadership should have a post-exposure plan in place for any personnel who inadvertently contact contaminated waste.

In addition, employers must train workers required to use PPE on what equipment is necessary, how to put it on and take it off safely and effectively, when and how they must use it, and how to dispose of the equipment (including frequency with which PPE must be disposed of and replaced). Practice and observation of workers in correct donning and doffing of PPE are critical infection control measures. This helps to ensure that PPE is used in ways that achieve the intended protection and that workers do not contact contaminated surfaces of PPE during or after removal. When respirators are needed to protect workers from inhalation exposures, employers also must train employees on how: a particular respirator should be positioned on the face; to set strap tension; to determine an acceptable fit; to achieve a proper seal between mask and the face; and perform regulated functions; as well as the respirator itself. Employees must receive hazmat general awareness, function specific, safety, and security awareness training and a fit check.

Hazardous Waste Operations and Emergency Response

Routine contaminated waste handling, transport, treatment, and disposal operations typically do not fall under OSHA’s Hazardous Waste Operations and Emergency Response (HAZWOPER) standard (29 CFR § 1910.120). However, HAZWOPER requirements may apply to incidents that release, or substantially threaten to release, a hazardous substance, including biological agents, into the environment, which may occur during a transportation accident involving contaminated waste.

Employers, such as those with contracts to transport contaminated waste under a DOT special permit, should be familiar with the provisions of the HAZWOPER standard, including paragraph
(q), and be prepared to comply, as needed. For emergency response operations that fall under HAZWOPER, employers must have a written emergency response plan with certain basic and critical elements. They must appropriately train workers who will respond to an emergency before participation in an actual incident, implement medical surveillance for workers potentially exposed to hazardous substances during work, maintain exposure records, and provide appropriate PPE to workers. Employers providing waste transportation services under a DOT special permit generally must have a spill response plan and provide hazardous materials training to workers, as required by 49 CFR § 172.704. Employers can plan and train for emergency response operations involving spills in a way that complies with the OSHA and DOT requirements at the same time.

Although not every employer’s operations fall under the scope of the HAZWOPER standard, developing emergency plans can ensure a safe, effective response when emergencies, including releases or substantial threats of releases of hazardous substances, do occur. Employers should evaluate their risk and develop plans for emergency events. Such plans should address worker safety and health considerations, State and local requirements, DOT/PHMSA training and security plan requirements, and the requirements of any DOT-issued special permits.
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APPENDIX A – ADDITIONAL RESOURCES

These documents are provided as supplemental resources to this guidance for the handling of solid waste contaminated with a Category A infectious substances. Some of the documents are general in nature, while others focus on management of waste associated with specific substances, including Ebola. The substance-specific resources are provided as examples of plans, procedures, and protocols, and may be adapted to the management of waste in future events involving Category A infectious substances.

Emergency Planning


Worker Health and Safety

- **Guidance on Personal Protective Equipment (PPE) to Be Used by Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola Who Are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE**, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2015.

Environmental Management/ Infection Control
Selected EPA-registered Disinfectants, Environmental Protection Agency, 2016.


Army Regulation 200-1: Environmental Protection and Enhancement, Department of the Army, U.S. Department of Defense, 2016. Note: This document was developed for use by U.S. Department of Defense facilities and personnel. Different regulatory requirements may apply in other settings.

Waste Management


Standing Operating Procedure No. EHE37-001: Ebola Virus Disease Waste Management in the Medical Treatment Facility, U.S. Army Public Health Command, Department of the Army, U.S. Department of Defense, 2016. Note: This document was developed for use by U.S. Department of Defense facilities and personnel. Different regulatory requirements may apply in other settings.

For Questions on:

• CDC guidance, contact 1-800-CDC-INFO (1-800-232-4636)
• DOT guidance or HMR requirements, contact DOT/PHMSA’s Hazardous Materials Information Center at 1-800-467-4922
• EPA guidance or solid waste issues or emergency response. Contact (202) 564-3850
• OSHA guidance, contact 1-800-321-OSHA (6742).

For Information about the National Ebola Training and Education Center (NETEC):

• Contact hpp@hhs.gov. In July 2015, HHS announced the funding of the National Ebola Training and Education Center (NETEC) (www.netec.org). The NETEC will help ensure that U.S. healthcare providers and facilities and healthcare waste management workers are prepared to safely identify, isolate, transport, and treat patients with Ebola and other emerging threats. The NETEC is a collaborative effort among HHS’ Office of the Assistant Secretary for Preparedness and Response (ASPR), the CDC, Emory University (Atlanta, Georgia), University of Nebraska Medical Center/Nebraska Medicine (Omaha, Nebraska), and Bellevue Hospital Center (New York City, New York) and will support further training of healthcare providers and facilities on strategies to manage Ebola and other emerging infectious diseases, including waste management.

For Information about the Technical Resources, Assistance Center, and Information Exchange (TRACIE):

• In 2015, HHS/ASPR created the Technical Resources, Assistance Center, and Information Exchange (TRACIE) (asprtracie.hhs.gov) to meet the needs of regional ASPR staff, healthcare coalitions, healthcare entities, healthcare providers, emergency managers, public health practitioners, and others working in disaster medicine, healthcare system preparedness, and public health emergency preparedness.
• ASPR TRACIE supports timely access to information and promising practices, identifies and remedies knowledge gaps, and includes a Topic Collection (asprtracie.hhs.gov/technical-resources) with resources and information regarding decontamination and waste management.
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APPENDIX B – EXAMPLES OF CATEGORY A INFECTIOUS SUBSTANCES

(UN2814, Infectious Substances Affecting Humans)

Note: The list below provides examples for guidance only. It is NOT an all-inclusive list. Designations of “cultures only” means that the substance is only considered “Category A” when a pathogen(s) is intentionally propagated; the term “cultures” does not include patient specimens collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

<table>
<thead>
<tr>
<th>Bacillus anthracis (cultures only)</th>
<th>Junin virus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brucella abortus (cultures only)</td>
<td>Kyasanur forest disease virus</td>
</tr>
<tr>
<td>Brucella melitensis (cultures only)</td>
<td>Lassa virus</td>
</tr>
<tr>
<td>Brucella suis (cultures only)</td>
<td>Machupo virus</td>
</tr>
<tr>
<td>Burkholderia mallei—Pseudomonas mallei—Glanders (cultures only)</td>
<td>Marburg virus</td>
</tr>
<tr>
<td>Burkholderia pseudomallei—Pseudomonas pseudomallei (cultures only)</td>
<td>Monkeypox virus</td>
</tr>
<tr>
<td>Chlamydia psittaci—avian strains (cultures only)</td>
<td>Mycobacterium tuberculosis (cultures only)</td>
</tr>
<tr>
<td>Clostridium botulinum (cultures only)</td>
<td>Nipah virus</td>
</tr>
<tr>
<td>Coccidioides immitis (cultures only)</td>
<td>Omsk hemorrhagic fever virus</td>
</tr>
<tr>
<td>Coxiella burnetti (cultures only)</td>
<td>Poliovirus (cultures only)</td>
</tr>
<tr>
<td>Crimean-Congo hemorrhagic fever virus</td>
<td>Rabies and other lyssaviruses (cultures only)</td>
</tr>
<tr>
<td>Dengue virus (cultures only)</td>
<td>Rickettsia prowazekii (cultures only)</td>
</tr>
<tr>
<td>Eastern equine encephalitis virus (cultures only)</td>
<td>Rickettsia rickettsia (cultures only)</td>
</tr>
<tr>
<td>Escherichia coli, verotoxigenic (cultures only)</td>
<td>Rift Valley fever virus (cultures only)</td>
</tr>
<tr>
<td>Ebola virus</td>
<td>Russian spring-summer encephalitis virus (cultures only)</td>
</tr>
<tr>
<td>Flexal virus</td>
<td>Sabia virus</td>
</tr>
<tr>
<td>Francisella tularensis (cultures only)</td>
<td>Shigella dysenteriae type I (cultures only)</td>
</tr>
<tr>
<td>Guanarito virus</td>
<td>Tick-borne encephalitis virus (cultures only)</td>
</tr>
<tr>
<td>Hantaan virus</td>
<td>Variola virus</td>
</tr>
<tr>
<td>Hantaviruses causing hemorrhagic fever with renal syndrome</td>
<td>Venezuelan equine encephalitis virus (cultures only)</td>
</tr>
<tr>
<td>Hendra virus</td>
<td>Vesicular stomatitis virus (cultures only)</td>
</tr>
<tr>
<td>Herpes B virus (cultures only)</td>
<td>West Nile virus (cultures only)</td>
</tr>
<tr>
<td>Human immunodeficiency virus (cultures only)</td>
<td>Yellow fever virus (cultures only)</td>
</tr>
<tr>
<td>Highly pathogenic avian influenza virus (cultures only)</td>
<td>Yersinia pestis (cultures only)</td>
</tr>
<tr>
<td>Japanese Encephalitis virus (cultures only)</td>
<td></td>
</tr>
</tbody>
</table>

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APPENDIX C – DECISION MATRIX FOR WASTE TREATMENT

To transport materials that are suspected or known to be contaminated with a Category A infectious substance, a special permit may be necessary. The special permit would allow for a variance of the HMR packaging requirements to handle the larger volume of contaminated waste generated during the treatment of patients.

In 2014, DOT/PHMSA issued a special permit (DOT-SP 16279) in response to the treatment of patients with Ebola virus disease in the United States and the subsequent accumulation of Ebola-contaminated wastes. The special permit provided packaging, operational, and safety controls to provide options for the safe transport of infectious substance (e.g., Ebola-contaminated waste).

The matrix below outlines key considerations for States to address future treatment of Category A-infected patients and to ensure that associated Category A-contaminated waste is properly inactivated and/or transported safely.

<table>
<thead>
<tr>
<th>1. Does the waste meet your State’s definition of a regulated medical waste?</th>
<th>Yes = move to 2.</th>
<th>No = dispose of as trash.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Is the waste properly classified as UN2814, Infectious Substance Affecting Humans, 6.2?</td>
<td>Yes = move to 3</td>
<td>No = dispose of according to the material’s classification and your State requirements (e.g. as regulated medical waste).</td>
</tr>
<tr>
<td>3. Does your facility have the capability to treat the waste on-site to the point of rendering the virus completely inactive (through autoclaving, or incineration, or other validated methods)?</td>
<td>Yes = inactivate on-site and dispose of treated material according to your State’s requirements.</td>
<td>No = move to 4.</td>
</tr>
<tr>
<td>4. Do you have packaging available to contain Category A waste that complies with the HMR (i.e., packaging for Category A infectious substances that meet the requirements of 49 CFR § 173.196)?</td>
<td>Yes = package the waste using the compliant Category A packaging.</td>
<td>No = move to 5.</td>
</tr>
<tr>
<td>5. Is the waste contaminated with Ebola?</td>
<td>Yes=move to 6. No= Contact PHMSA to discuss a special permit for waste transportation for Category A infectious substances other than Ebola. Currently, there is only a DOT Special Permit for Ebola.</td>
<td></td>
</tr>
<tr>
<td>6. DOT Special Permit 16279 provides alternative requirements for packaging and transporting Ebola waste. DOT/PHMSA’s special permits database contains records of the companies currently holding party status to DOT-SP 16279.</td>
<td>Yes = the company with party status to DOT-SP 16279 has authority to transport the waste under alternative requirements, and it has trained its staff in loading, transporting, and unloading the material at a disposal facility. Contact the company to discuss scheduling waste removal. Move to 7.</td>
<td>No = contact a company with party</td>
</tr>
</tbody>
</table>
Put “16279” in the “Special Permit” box and search to display all entities that have held party status.

Have you contracted with one of the companies listed as a party to DOT-SP 16279?

| 7. | Does your waste transportation contractor have access to a disposal or treatment facility where it can unload your waste? | status to DOT-SP 16279 to determine whether it is available to assist with handling your waste. If no companies respond affirmatively, contact DOT/PHMSA to discuss next steps.  

Yes = schedule transportation with your contractor, making sure to inform DOT of the planned movement of the waste and its arrival at the disposal site.  

No = work with your contractor to identify why it does not have access to a disposal facility. |

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21 You can reach DOT/PHMSA’s Hazardous Materials Information Center by phone at 1-800-467-4922.
APPENDIX D – DECISION TREE FOR TREATMENT AND DISPOSAL OF CATEGORY A INFECTIONOUS SUBSTANCES

Category A infectious substance is generated.

Is on-site treatment appropriate, available, and allowable under State regulations?

YES

Waste is appropriately treated to inactivate it on-site.

NO

Waste is transported as a Hazardous Material under DOT regulations to an off-site treatment facility.

Are waste/residuals determined to be no longer infectious (and nonhazardous under RCRA)?

YES

Noninfectious, nonhazardous waste and residuals are transported to an off-site disposal facility permitted to accept medical waste (e.g., RCRA Subtitle D landfill).

NO

Waste is treated off-site (e.g., medical waste incinerator).

Considerations
1. Known history and symptoms of source patient
2. Local endemic conditions
3. Local capabilities
4. Applicable Federal, State, and local regulations (e.g., DOT HMR, OSHA Bloodborne Pathogens, PPE, and Respiratory Protection standards, RCRA)

Note: If residuals are hazardous waste under RCRA, then the residuals are transported to a RCRA Subtitle C facility.
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APPENDIX E – QUESTIONS AND ANSWERS

This section provides answers and guidance to potential questions that may be posed by the public (including workers), the media, and stakeholders concerning the management of medical and infectious waste from the point-of-origin (e.g., healthcare facilities) to final disposal of the inactivated waste (e.g., in a landfill accepting incinerator ash or materials inactivated with an effective autoclave or other validated process).

This guidance is intended for use by local, State, Tribal, and Federal partners, including, but not limited to, public health, worker safety and health, environmental, and elected officials. The questions and answers/guidance are designed for use during an infectious disease outbreak or emergency, but may also be useful in addressing public/media inquiries related to routine medical and infectious waste issues, particularly relating to Category A infectious substance(s).

Each question has several parts to its answer:
- A *key message* that summarizes the most important information;
- A detailed *answer* that provides more in-depth information; and
- Selected *background/references* that supplement each answer.

Users of the document should note that the key messages are intended to highlight significant information related to each question, but the full answers may provide additional details not included or introduced in the key message.

The table below outlines questions and answers/guidance included in this section.

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<td></td>
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<td>12.</td>
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<td>13.</td>
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<td>4.</td>
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<td>2.</td>
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<td>3.</td>
<td>Are there any steps normally involved in treating medical waste that should be avoided during treatment and disposal of waste contaminated with Category A infectious substances?</td>
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<td>4.</td>
<td>What is my/my family’s risk of being exposed to infectious waste if it is processed or inactivated at facilities in my/our community?</td>
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<td>2.</td>
<td>Can burying inactivated waste in landfills affect crops or ground water supplies nearby?</td>
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**BACKGROUND QUESTIONS**

Acronyms used throughout this section:

- CDC: U.S. Centers for Disease Control and Prevention
- DOT: U.S. Department of Transportation
- EPA: U.S. Environmental Protection Agency
- HMR: Hazardous Materials Regulations
- ICAO: International Civil Aviation Organization
- IMDG: International Maritime Organization Dangerous Goods Code
- OSHA: U.S. Occupational Safety and Health Administration
- PPE: Personal protective equipment
- PHMSA: U.S. Pipeline and Hazardous Materials Safety Administration
- RCRA: Resource Conservation and Recovery Act
- RMW: Regulated medical waste
- UN: United Nations
- USDA: U.S. Department of Agriculture
- WHO: World Health Organization

1. **What is contaminated waste?**

**Key Message:** Contaminated waste is generated during patient care in a healthcare facility when there is a potential for pathogens (i.e., germs) to exist. These are materials such as needles, blood
soaked gauze pads, gloves or other personal protective equipment that may have blood or other bodily fluids on them that may contain pathogens.

**Answer:** Contaminated wastes are generated during patient care in a healthcare facility when there is a potential for pathogens (i.e., germs) to exist. These are materials such as needles, blood soaked gauze pads, gloves or other personal protective equipment that may have blood or other bodily fluids on them that may contain pathogens.

Contaminated wastes result from a variety of tasks, the most common of which is likely to be patient care activities in healthcare facilities, where needles/syringes, IV access devices, tubing, dressings, PPE, and other materials are used and become contaminated. However, laboratories and other facilities and worksites also generate waste that may be contaminated and managed as RMW. When generating waste in a healthcare or lab setting where infectious substances may be present it is a good idea to assume there are potential pathogens and dispose of them as RMW for proper inactivation prior to disposal.

RMW management is regulated at the State and local level. Once treated these materials are no longer infectious and are considered a solid waste subject to solid waste regulations.

**Background/References:**

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### 2. What is regulated medical waste?

**Key Message:** The DOT HMR define “regulated medical waste” (RMW) as a waste or reusable material derived from the medical treatment of an animal or human or from biomedical research. Category A RMW is fully regulated and must be transported in compliance with all requirements of the HMR, or a special permit, if applicable.

**Answer:** RMW, also called “clinical waste” or “biomedical waste,” means a waste derived from the medical treatment of an animal or human, including diagnosis and immunization, or from
biomedical research, including the production and testing of biological products. They consist of materials that are typically seen in a doctor’s office, healthcare setting, or research facility, like gloves, gowns and other personal protective equipment that could be covered in blood or bodily fluids.

RMW is a subcategory of infectious substances under DOT’s HMR, and is subject to requirements for proper packaging, emergency response and documentation. This helps ensure proper and safe transport of these regulated wastes every day.

RMW containing a Category A infectious substance must be classified as a Category A infectious substance for transportation purposes. It must be assigned the UN Identification Code for UN2814 - Infectious substances affecting humans, or UN2900 - Infectious substances affecting animals only, as appropriate. An infectious substance meets Category A criteria if it is in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals upon exposure to the substance.

Each State determines which generators of waste are subject to medical waste regulations in its jurisdiction.

Background/References:
  - RMW Definition. 49 CFR § 173.134(a)(5).

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3. **What is the composition of regulated medical waste?**

**Key Message:** RMW can consist of sharps, bulk blood and body fluids, microbiological wastes (e.g., cultures), anatomical and pathological wastes, and animals exposed to or infected with human pathogens and the waste from these animals. The proportion of each of these in the overall volume of RMW will vary.

**Answer:** RMW can consist of many types of materials. Some examples are sharps; bulk blood, body fluids, and other potentially infectious materials (i.e., as defined in the OSHA Bloodborne Pathogens standard, 29 CFR § 1910.1030) or items contaminated with these materials; anatomical and pathological wastes; microbiological wastes (e.g., cultures); and animals exposed to or infected with human pathogens and the waste from these animals.

**Background/References:**

4. **What is a Category A infectious substance?**

**Key Message:** The DOT HMR define a Category A infectious substance as material known or expected to carry germs in a form capable of causing life-threatening or deadly disease in humans or animals when exposure to it occurs.

**Answer:** A Category A infectious substance is a material, which is in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. For the purpose of the HMR, an infectious substance is a material known or reasonably expected to contain a pathogen. A pathogen is a microorganism (including bacteria, viruses, rickettsiae, parasites or fungi) or another agent, such as a proteinaceous infectious particle (prion) than can cause disease in humans or animals.

An infectious substance is regulated as a hazardous material under the HMR. The HMR apply to any material DOT determines is capable of posing an unreasonable risk to health, safety, and property when transported in commerce. Classification of an infectious substance is based on the patient’s or animal’s known medical history or symptoms, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal.

An infectious substance must conform to all applicable HMR requirements when offered for transportation or transported by air, highway, rail, or water, in commerce. The Ebola virus is an example of a Category A infectious substance. Refer to the CDC for guidance on handling these agents before transporting them (see [www.cdc.gov/vhf/ebola/healthcare-us/cleaning/waste-management.html](http://www.cdc.gov/vhf/ebola/healthcare-us/cleaning/waste-management.html)).

**Background/References:** The definition of a Category A infectious substance within 49 CFR § 173.134 is based on criteria developed by the UN Committee of Experts working with the WHO, CDC, medical professionals, microbiologists, transportation professionals, and packaging technical experts. The definition is consistent with the requirements of the UN Recommendations for the Transport of Dangerous Goods (UN Recommendations), the ICAO
Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions), and the IMDG.

- **Transporting Infectious Substances Safely.** Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.
- **Transporting Infectious Substances.** Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.
- **A Guide for Shipping Infectious Substances.** World Health Organization.

5. **Who determines if an infectious substance is “Category A”?**

**Key Message:** Under the DOT HMR, it is the offeror’s (the person who prepares, tenders, or makes the hazardous material available to a carrier for transportation in commerce) responsibility to classify a hazardous material for transportation.

**Answer:** Under the DOT HMR, it is the offeror’s (i.e., the person or entity generating the material) responsibility to classify a hazardous material for transportation. The classification of the waste should be based on the known medical risk factors or symptoms of the source patient, the endemic local conditions, and/or professional judgment. In healthcare facilities, the decision should be made by infectious disease personnel working in collaboration with relevant State and local public health and waste management authorities.

**Background/References:**

6. **What is waste treatment and disposal?**

**Key Message:** Waste treatment and disposal covers all of the steps in handling waste from the point it is generated to the final disposal of the waste itself and any residuals (e.g., incinerator ash) from the treatment. Waste treatment and disposal is governed by a combination of Federal and State laws and regulations.

**Answer:** Waste treatment and disposal covers all of the steps in handling waste from the point it is generated to the final disposal of the waste itself and any residuals (e.g., incinerator ash) from the treatment of the waste.

Waste treatment and disposal is governed by a combination of Federal, State, and local laws and regulations. The type and characteristics of the waste determine the treatment and disposal requirements. Facilities that generate contaminated waste should have a plan for how the waste will be managed. Each plan should have input from State and local health departments, and it should primarily focus on the safety of those who will handle or package (or otherwise risk
contact with) the contaminated waste material at the source as well as further down the waste handling process.

**Background/References:** State regulatory agencies provide guidance to facilities in their States about waste characterization and management.

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**7. Prior to treatment, why must waste contaminated with a Category A infectious substance(s) be handled differently than other waste, such as regular trash from a healthcare facility or other regulated medical waste?**

**Key Message:** Compared to regular trash or medical waste from a healthcare facility that is generally managed under State environmental regulations, waste contaminated with a Category A infectious substance must be handled more carefully so that persons are not exposed to the infectious substances in the waste. Contaminated waste can be handled safely. To accomplish this, local governments and facilities that may need to manage contaminated waste should have a plan to address all steps in the waste management cycle.

**Answer:** Waste contaminated with a Category A infectious substance must be handled more carefully so that persons are not exposed to the infectious substances in the waste. Contaminated waste can be handled safely. The leadership for local governments and facilities that may or will need to manage contaminated waste should ensure that they have a plan to address the entire waste cycle. Each plan should have input from State and local public health and environmental authorities, as appropriate, and comply with applicable regulations.

Regular trash or medical waste from healthcare facilities is generally managed under State environmental regulations. This waste does not typically pose the same level of risk as a Category A infectious substance; thus the requirements for handling these wastes are different.

Because of the hazards posed by Category A infectious substances, these materials have more stringent packaging requirements than other infectious substances and RMW. The transport of medical equipment, sharps, and used healthcare products (such as soiled absorbent pads or dressings, emesis pans, portable toilets; used PPE, including gowns, masks, gloves, goggles, face shields, respirators, booties, etc.; and byproducts of cleaning) contaminated or suspected of being contaminated with a Category A infectious substance must comply with the packaging requirements for infectious substances in the DOT HMR and, if applicable, the OSHA Bloodborne Pathogens standard.

The HMR regulate waste contaminated (or suspected by the offeror to be contaminated) with any Category A infectious substance (such as Ebola, plague, or anthrax). The DOT/PHMSA is responsible for regulating and ensuring the safe and secure movement of hazardous materials across all modes of transportation.

**Background/References:**
8. How do the government and the medical waste industry know that waste contaminated with a Category A infectious substance(s) can be handled safely?

**Key Message:** Workers handle RMW every day without incident. Requirements and procedures in place for routine waste handling are augmented by Federal, State, and local requirements for handling waste contaminated with Category A infectious substances. Complying with these requirements protects workers, public health, and the environment.

**Answer:** Workers handle RMW every day without incident. Employers of workers who handle contaminated waste are required to protect those workers from the hazards associated with their jobs, including Category A infectious substances in the waste. Complying with the requirements of Federal, State, and local agencies ensures waste can be handled safely. These requirements cover how the waste must be packaged, transported, inactivated, and disposed (e.g., EPA, DOT, and State/local requirements), as well as protections for workers handling the waste (e.g., OSHA and State/local requirements).

DOT regulates the design, manufacture, and certification of packaging used to contain and transport hazardous materials safely. Because of the hazards posed by Category A infectious substances, these materials have more stringent packaging requirements than other hazardous materials, including RMW. The transport of medical equipment, sharps, and used healthcare products (such as soiled absorbent pads or dressings, emesis pans, portable toilets; used PPE, including gowns, masks, gloves, goggles, face shields, respirators, booties, etc.; and byproducts of cleaning) contaminated or suspected of being contaminated with a Category A infectious substance must comply with the packaging requirements for infectious substances in the DOT HMR and, if applicable, the OSHA Bloodborne Pathogens standard. Using DOT-compliant packaging helps ensure that waste contaminated with a Category A infectious substance(s) can be handled safely throughout the transportation process.

The DOT HMR classify hazardous materials according to the nature and severity of the hazards they present. Higher risk hazardous materials must be transported to a waste treatment facility in packaging that satisfy a higher design standard and are tested to prove they can withstand the stresses of transportation. Packaging made to hold infectious substances are tested to a higher standard than others—they are designed to withstand a drop from a height of 30 feet, exposure to heavy rain, freezing temperatures, a 15-pound rod dropped on it from a height of three feet, and a three-foot drop onto an eight-inch rod.

With specific respect to waste treatment, Federal, State, and local governments have been working closely with manufacturers and users of waste treatment equipment, such as autoclaves, to ensure that treatment procedures are effective in inactivating (i.e., killing) pathogens,
including Category A infectious substances, in waste. Many States require manufacturers of medical waste autoclaves to provide data demonstrating its effectiveness for their equipment to guide its use.

Achieving sufficient time/temperature conditions (e.g., for Ebola virus, 121°C/250°F for at least 30 minutes) will ensure that the waste material is no longer infectious.

Peer-reviewed literature also provides accounts of waste generators safely and effectively managing waste contaminated with a Category A infectious substance on-site, without having to transport these wastes off-site for treatment. Once treated, these wastes can be disposed of as either a solid waste or RMW at an appropriately permitted facility, depending on State or local requirements. These wastes can be safe to dispose of at a sanitary landfill or solid waste incineration facility (or a Waste to Energy) as well. The facility/owner/operator will need to follow any State-specific rules or regulations.

**Background/References:**
- **Transporting Infectious Substances.** Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.

**9. What is a pathogen?**

**Key Message:** A pathogen in the broadest sense is anything that can produce an infectious disease.

**Answer:** A pathogen in the broadest sense is anything that can produce an infectious disease. Typically pathogens include prions, viruses, bacteria, fungi, and parasites (e.g., protozoa, helminths, nematodes, etc.). These agents may cause disease in susceptible plant, animal or human hosts.

**Background/References:**
10. Which government agency(ies) is/are responsible for regulating medical waste?

**Key Message:** Individual States have the primary regulatory authority for the management and treatment of RMWs in the US. State regulations may differ from one another—some States may be more stringent than others. Specific State regulations are generally found in the State solid waste or health department regulations. However, the DOT/PHMSA, EPA, USDA, and OSHA each have requirements that may affect RMW.

**Answer:** Since the late 1980s, individual States have had the primary regulatory authority for the management and treatment of RMWs in the US. This includes, but may not be limited to, waste identification processes/procedures and requirements for treatment or inactivation prior to ultimate disposal, as well as ultimate disposal requirements.

State regulations may differ from one another—some States may be more stringent than others. Specific State regulations are generally found in the State solid waste or health department regulations.

However, the DOT/PHMSA, EPA, USDA, and OSHA each have requirements that may affect RMW. Infectious substances can be safely transported throughout the process.

For the purpose of transportation, DOT defines RMW as “a waste or reusable material derived from the medical treatment of an animal or human, which includes diagnosis and immunization, or from biomedical research, which includes the production and testing of biological products.”

The DOT HMR apply to the transportation of hazardous materials in interstate or intrastate commerce, which includes the movement of the hazardous material, as well as its loading, unloading, or storage. The HMR regulate materials that are suspected or known to be contaminated with a Category A infectious substance, as well as other forms of RMW.

There are no specific EPA regulations under the Federal RCRA for the treatment/inactivation and disposal of RMW. As noted above, medical waste is primarily regulated by each State. However, hospital infections medical waste incinerators must meet a minimum standard set by the Federal Clean Air Act regulations. In addition, solid waste landfills must meet minimum Federal criteria set out in the RCRA Subtitle D regulations and State permits and any hazardous waste treatment, storage or disposal facility must comply with the hazardous waste regulations and requirements in their permits.

Select agents and toxins are regulated by the CDC under 42 CFR part 73 and USDA under 7 CFR part 331 and 9 CFR part 121. The Federal Select Agent Program regulations include controls for who (e.g., which labs) can possess, use, or transfer such agents. Generally, RMW, even if it contains select agents and toxins, is not subject to the CDC and USDA requirements or the Select Agent Regulations.

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23 U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 49 CFR § 173.134(a)(5)
OSHA sets standards and other requirements to protect workers from exposure to infectious materials. These include the Bloodborne Pathogens, PPE, and Respiratory Protection standards, and the General Duty Clause of the Occupational Safety and Health Act of 1970. The Bloodborne Pathogens standard includes requirements for packaging, labeling, and handling blood, certain body fluids, and other potentially infectious materials, and items contaminated with these materials.

As evidenced by these references, RMW is heavily regulated. Because of these tight regulations, thousands of pounds of these materials are safely transported throughout communities each day without incident.

**Background/References:**
- [Transporting Infectious Substances](#), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.

<table>
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<th>11. How are pathogens transmitted to people (or animals, if applicable)?</th>
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| **Key Message:** Pathogens can be spread in a variety of ways, including through direct contact; indirect contact with a contaminated environmental surface, equipment, or other item; droplets; ingestion; or exposure to aerosolized or airborne infectious material. Susceptible (i.e., persons without immunity or who are otherwise capable of getting a disease) individuals can be infected when they are exposed through one or more of these routes.

**Answer:** Transmission of pathogens can occur by a variety of ways, generally referred to as means or modes of transmission. These include contact (direct and indirect), droplet, and airborne transmission. Transmission of an agent to an individual is driven by what is known as the “chain of infection,” and is a complex process with many steps. If any one step or component of this chain is missing or broken, infection cannot occur. In short, all of the following must be present: presence of an infectious agent of sufficient virulence and concentration (i.e., enough agent capable of causing infection), presence of a reservoir (i.e., sources that normally harbor disease-causing organisms and thus serve as potential sources of disease), source or portal of exit from infected host, route of transmission, a susceptible host, and a portal of entry into the host.

**Background/References:**

12. What is the Federal government doing to ensure that healthcare facilities and waste transport, treatment, and disposal companies handle the waste safely and comply with applicable requirements?

Key Message: The Federal government has strict requirements for handling, transporting, treating, and disposing of Category A infectious waste; and is working closely with healthcare facilities, waste transport and treatment companies, landfill operators, and State/local agencies to ensure all parties involved in the waste cycle are prepared to handle infectious waste in a safe and effective manner.

Answer: The Federal government has strict requirements for handling, transporting, treating, and disposing of Category A infectious waste. Materials that are suspected or known to be contaminated with Category A infectious substances may only be transported in two scenarios: in full compliance with classification and packaging requirements of the DOT HMR and the OSHA Bloodborne Pathogens standard; or, under the terms of a special permit issued by DOT. As noted previously, “medical waste” is generally regulated by the States. For other waste streams, EPA has authorized most States to implement waste management programs that implement regulations promulgated under the Federal RCRA. In some cases, the States may impose requirements that are more stringent or go beyond the Federal regulations so it is important to check for any State and/or local requirements.

Because of the relatively large quantity of contaminated waste generated when treating patients with known or suspected to have certain infectious diseases, including Ebola virus disease, the available packaging authorized under the regulations governing the transport of Category A infectious substances may not be large enough to meet the need. DOT issued a special permit, SP 16279, authorizing transportation of Ebola infectious materials in alternative packaging designs that meet safety requirements and that can help accommodate the large volume of waste.

Federal agencies, including CDC, OSHA, EPA, and DOT, have been working closely with healthcare facilities, waste transport and treatment companies, landfill operators, and State/local agencies to ensure all parties involved in the waste cycle are prepared to handle Category A infectious waste in a safe and effective manner. These activities include visits to hospitals and other facilities by experts in infection control, patient care, waste handling, occupational health, and other subject matter areas; designation of certain facilities with higher-level patient care and waste handling capabilities; and outreach efforts to ensure that impacted parties are knowledgeable about requirements and procedures for safe waste handling.

Background/References:
13. Who can I contact if I have questions about infectious waste, regulated medical waste, and waste contaminated with a Category A infectious substance?

Key Message: Depending on the specific issue, a variety of Federal, State, and local agencies have authority over and provide information about managing waste, including waste contaminated with a Category A infectious substance. Members of the public can contact CDC, DOT, EPA, and OSHA, as well as the State/local agencies in their area with questions.

Answer: Depending on the specific issue, a variety of Federal, State, and local agencies have authority over and provide information about the handling, transport, treatment, and disposal of infectious waste and RMW, including waste contaminated with a Category A infectious substance. Members of the public can contact CDC, DOT, EPA, and OSHA, as well as the State/local agencies in their area with questions.

- Regarding CDC guidance, contact: by phone, 1-800-CDC-INFO (1-800-232-4636); by email, CDCINFO@cdc.gov; by web form, www.cdc.gov/dcs/ContactUs/Form.
- Regarding DOT guidance or HMR requirements, contact: by phone, DOT/PHMSA’s Hazardous Materials Information Center, 1-800-467-4922.
- Regarding EPA guidance or solid waste issues or emergency response, contact: by phone, 1-202-564-3850.

Background/References:
- Transporting Infectious Substances, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.
- State Medical Waste Programs and Regulations, U.S. Environmental Protection Agency.
- CDC Website, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.
- OSHA Website, Occupational Safety and Health Administration, U.S. Department of Labor.
GENERATION OF THE WASTE

Acronyms used throughout this section:
OPIM  Other potentially infectious materials
OSHA  U.S. Occupational Safety and Health Administration
PPE  Personal protective equipment
RMW  Regulated medical waste

1. Where does infectious Category A waste come from?

**Key Message:** Infectious Category A waste (or contaminated waste) are items in the immediate environment of a symptomatic person or generated during patient care in a healthcare facility when there is a potential for pathogens to exist. These are materials such as porous, fluid-drenched items in the home or needles, blood soaked gauze pads, gloves or other personal protective equipment that may have blood or other bodily fluids on them that may contain pathogens.

**Answer:** Contaminated wastes are items in the immediate environment of a symptomatic person or generated during patient care in a healthcare facility when there is a potential for pathogens to exist. These are materials such as porous, fluid-drenched items in the home or needles, blood soaked gauze pads, gloves or other personal protective equipment that may have blood or other bodily fluids on them that may contain pathogens. Generally, contaminated waste comes from bodily fluids from a symptomatic person. In facilities, contaminated waste results from a variety of tasks, the most common of which is likely to be patient care activities in healthcare facilities, where needles/syringes, tubing, dressings, PPE, and other materials are used and become contaminated. However, laboratories and other facilities also generate waste that may be infectious and managed as RMW. When generating waste in a healthcare or lab setting where infectious substances may be present it is a good idea to assume there are potential pathogens and dispose of them as RMW for proper inactivation/treatment prior to disposal. RMW management is regulated at the State and local level. Once inactivated these materials are no longer infectious and are considered a solid waste subject to solid waste regulations.

**Background/References:**
- State Medical Waste Programs and Regulations, U.S. Environmental Protection Agency.

2. What can be done to reduce the amount of infectious Category A waste generated in the first place?

**Key Message:** Healthcare facilities and other generators of infectious waste can reduce the amount of such waste they produce by ensuring that non-infectious waste is kept separate from infectious waste.
Answer: The local public health authority is often in the best position to assess whether items in the patient’s immediate environment are contaminated and pose a health risk. Generally, environmental contamination occurs when items come in contact with bodily fluids. In the case of most Category A infectious diseases, including Ebola, only persons who are symptomatic (have a fever), generate bodily fluids that pose a risk. Correctly assessing the presence of symptoms and actual contamination is paramount to preventing mischaracterization, especially for large, bulky household items.

In healthcare facilities, reducing the amount of infectious waste items may not be easily accomplished, depending on the patient care procedures. More importantly, healthcare facilities take steps to ensure that routine solid waste items are not co-mingled with RMW. Failure to prevent the co-mingling of these waste streams will result in increased expenses for treatment of larger volumes of RMWs.

One strategy for reducing the volume of RMW is to control the amount of material that becomes contaminated. Removing packaging and other unneeded materials from medical equipment before introducing it into a patient care area can help reduce the volume of waste that must be inactivated, transported, and disposed.

Background/References:

TREATMENT AT THE POINT OF ORIGIN

Acronyms used throughout this section:
- CFR: Code of Federal Regulations
- DOT: U.S. Department of Transportation
- FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act
- HMR: Hazardous Materials Regulations
- ICAO: International Civil Aviation Organization
- IMDG: International Maritime Organization Dangerous Goods Code
- OSHA: U.S. Occupational Safety and Health Administration
- PHMSA: U.S. Pipeline and Hazardous Materials Safety Administration
- RMW: Regulated medical waste
- SP: Special Permit

1. Should infectious waste be pre-treated with a disinfectant before it is sent from a facility for further treatment and disposal?

Key Message: Whenever feasible, inactivation of a Category A infectious substance should be achieved by autoclaving or incineration. However, other validated methods of waste treatment that involve chemical disinfection may be necessary when operational constraints, such as those associated with patient care activities outside of fixed hospital facilities, preclude the use of autoclaves or incinerators.
**Answer:** In general, pre-treatment of large volumes of RMW with a disinfectant prior to transporting it for inactivation at an off-site facility will not achieve the outcome desired (e.g., rendering the waste non-infectious) because only the outer surfaces of the waste will have contact with the disinfectant. Additionally, spraying disinfectant on waste requires unnecessary manipulation of the waste above and beyond the containment of the waste.

Facilities may inactivate contaminated waste using an autoclave operating within permitted parameters.\(^{24}\) Use an autoclave cycle that heats materials to a high enough temperate for a long enough period of time to inactivate the organism(s) of concern in the waste. Such a treatment process uses more than enough heat and time to kill Category A infectious substances at least as susceptible as Ebola virus. However, some porous waste materials or other variations in load and packaging may require modifications to the operating procedures of the autoclave to achieve the necessary material temperatures prior to being held at the required temperature for 30 minutes.

A facility may also use incineration. Incinerators run at extremely high temperatures, well above the temperature needed to kill most Category A agents. Incineration would be the best method for large or bulky items.

When operational constraints, such as those associated with patient care activities outside of fixed hospital facilities, preclude the use of autoclaves or incinerators, other validated methods of waste treatment (e.g., chemical disinfection) may be necessary. However, such alternative methods should be supported by objective data that demonstrate their effectiveness at inactivating waste and that are acceptable to appropriate regulatory authorities, including at the State and local levels. Importantly, these methods must achieve sufficient chemical contact with and penetration of the waste to inactivate the infectious substances it may contain. On-site testing of treated materials can demonstrate that a previously validated protocol continues to successfully inactivate infectious substances in waste materials for which it is used. Users of protocols for chemical inactivation also should consider worker health and safety issues, as well as the potential for triggering other Federal environmental (e.g., under FIFRA), safety, and health regulations.

Inactivation (e.g., through autoclaving or other validated methods) or incineration of contaminated waste at a facility may be subject to Federal, State, local, environmental, and OSHA regulation.

**Background/References:**


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\(^{24}\) Operators should validate that their waste inactivation procedures meet required performance standards, including achieving certain exposure time and temperature requirements, acceptable results on biological indicators or other test assays, and allowable concentration of certain pollutants or contaminants in any effluent or other by-product of the process.
**2. Are there specific requirements for packaging and labeling Category A waste for transportation?**

**Key Message:** Yes. The DOT HMR dictate requirements for transporting Category A infectious substances. Additionally, DOT/PHMSA issued a special permit (DOT-SP 16279) to enable the safe transport of Ebola-contaminated waste. Materials that are suspected or known to be contaminated by Category A infectious substances may only be transported in two scenarios: in full compliance with classification and packaging requirements of the HMR, or under the terms of a special permit.

**Answer:** Yes, DOT has developed specific requirements for packaging of Category A infectious substances listed under 49 CFR 173.196. Additionally, if these specific standards cannot be met entities can request a special permit that shows equivalent safety in transporting these materials. Such a special permit was developed and granted specifically for Category A infectious substance Ebola under DOT DP-16279. It specifically spells out how the waste must be packaged, marked and transported. It also requires specific documentation, called a shipping paper, to identify the key hazards in the event of an emergency to first responders. Additional information on the transportation of all general Category A substances can be found at: [phmsa.dot.gov/hazmat/transporting-infectious-substances](http://phmsa.dot.gov/hazmat/transporting-infectious-substances).

The DOT HMR regulate an infectious substance as a hazardous material. The HMR apply to any material that DOT determines is capable of posing an unreasonable risk to health, safety, and property when transported in commerce. An infectious substance must conform to all applicable HMR requirements when offered for or actually transported by air, highway, rail, or water, but the overall handling of contaminated waste begins with the creation of the waste, includes waste transportation, and ends at final disposition.

DOT/PHMSA regulates movement of hazardous materials across all modes of transportation through the HMR, which are designed to minimize the risks to life, property, and the environment during the transportation of hazardous materials. For Category A infectious substances, the HMR provide clear regulations for classification, packaging, and communication procedures that must be followed. DOT/PHMSA also has the authority to issue a special permit for transporting contaminated waste in a manner that deviates from conventional, established HMR methods (e.g., using alternate packaging).

Materials that are suspected or known to be contaminated by Category A infectious substances may only be transported in two scenarios: in full compliance with classification and packaging requirements of the HMR, or under the terms of a special permit. Because of the relatively large quantity of contaminated waste generated when treating patients with known or suspected Ebola virus disease, the available packaging authorized under the regulations governing the transport of

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Category A infectious substances were not large enough to meet the need. Alternative packaging designs were needed to meet safety requirements and to accommodate the large volume of waste. DOT/PHMSA issued a special permit, DOT-SP 16279, which authorizes transportation of these materials in the alternative packaging designs.

What is the correct packaging for a Category A infectious substance?
The specific requirements for authorized packaging and materials for transporting a Category A infectious substance are listed in 49 CFR § 173.196. In addition, each packaging must meet specific test standards in accordance with 49 CFR § 178.609.

In general, a Category A infectious substance must be triple packed in a:
(1) primary watertight receptacle,
(2) watertight secondary packaging, and
(3) rigid outer packaging.

Are there any additional HMR packaging requirements for a Category A infectious substance?
Yes, depending on the physical state and other characteristics of the material:
- Category A infectious substances shipped at ambient temperatures or higher must be packaged in accordance with 49 CFR § 173.196(b)(1);
- Category A infectious substances shipped refrigerated or frozen must be packaged in accordance with 49 CFR § 173.196(b)(2); and
- Category A infectious substances shipped in liquid nitrogen must be packaged in accordance with 49 CFR § 173.196(b)(3).

Must the shipment of a Category A infectious substance be accompanied by a shipping paper?
Yes, the shipping paper requirements identify key hazard communication information. The shipping paper must include the following:
- UN number and proper shipping name for the applicable Category A infectious substance—For Ebola, the shipping name is: “UN 2814, Infectious substances, affecting humans;”
- Hazard class: Division 6.2 (infectious);
- Packing group: N/A;
- Type and quantity of packaging; and
- Emergency response information (e.g., telephone number).

What information is required on the outside of the outer packaging?
The outer packaging must be marked with the UN identification number and proper shipping name (see above), and labeled with the black and white “INFECTIOUS SUBSTANCE” label that conforms to 49 CFR § 172.432.

The manufacturer who represents that the packaging is manufactured to meet a UN standard must mark it with the appropriate packaging standard markings. The markings must be durable, legible, and placed in a location as to be readily visible, in accordance with 49 CFR § 178.503(a).
Directional arrows to indicate the correct (upright) orientation of the closures of inner packagings that contain liquids must be used in accordance with 49 CFR § 172.312.

Are there additional requirements for specific modes of transportation?
Yes, all hazardous materials packagings intended for transportation by aircraft must comply with the general requirements for transporting hazardous materials by aircraft in 49 CFR § 173.27. When unloaded from an aircraft, each package, overpack, pallet, or unit load device containing a Class A infectious substance must be inspected for signs of leakage. If evidence of leakage is found, the cargo compartment hold where the substance was stowed must be disinfected and the incident must be reported by telephone within 12 hours to the National Response Center at 1-800-424-8802. (See 49 CFR §§ 175.630(c) and 171.15(b)(3)).

Shippers and carriers also have the option of using international standards and regulations, instead of the HMR, in accordance with the provisions in 49 CFR §§ 171.22-171.24.

For air transportation, the carrier may use the ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air.

For maritime transportation, the carrier may use the IMDG.

Background/References:
- **Transporting Infectious Substances.** Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.

**TRANSPORTATION ISSUES**

Acronyms used throughout this section:
- CFR    Code of Federal Regulations
- DOT    U.S. Department of Transportation
- HAZWOPER    Hazardous Waste Operations and Emergency Response
- HMR    Hazardous Materials Regulations
- OSHA    U.S. Occupational Safety and Health Administration
- PHMSA    U.S. Pipeline and Hazardous Materials Safety Administration
- PPE    Personal protective equipment
- RMW    Regulated medical waste
- SP    Special Permit
1. Who is responsible for infectious waste that is transported between facilities?

Key Message: The DOT's HMR require the offeror of infectious waste to classify the waste before it is transported between facilities. The classification that an offeror (e.g. a healthcare facility) assigns to the waste (e.g. a RMW containing a Category A infectious substance) will determine how it must be packaged and prepared for transportation.

Answer: The DOT’s HMR require the offeror of infectious waste to classify the waste before it is transported between facilities. The classification that an offeror (e.g. a healthcare facility) assigns to the waste (e.g. a RMW containing a Category A infectious substance) will determine how it must be packaged and prepared for transportation.

An offeror is a person who (i) performs, or is responsible for performing, any pre-transportation function required under the HMR for transportation of the hazardous material in commerce, or (ii) tenders or makes the hazardous material available to a carrier for transportation in commerce.27

When dealing with a known or suspected Category A infectious substance, the offeror should first talk to all the necessary people within their organization or in their plan, such as infection control specialists or relevant State or local public health officials, when making a decision if the waste is a Category A infectious substance. If they need to transport the waste off-site for inactivation/treatment, then they would work with the RMW transporter or waste management facility to properly prepare the waste for transport.

Background/References:

- **Transporting Infectious Substances Safely,** Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.
- **Transporting Infectious Substances,** Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.

2. Is my family at risk of being exposed to infectious waste if it is transported through my/our community?

Key Message: When infectious substances are transported in compliance with DOT requirements, there should be no risk to the public.

Answer: When infectious substances are transported in compliance with DOT requirements, there should be no risk to the public. Waste is required to be packaged appropriately to protect people. Packaging requirements and other operational and safety controls are very robust and

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mitigate the risk in transport of infectious waste that may be transported through your community. As described above, DOT has stringent regulations regarding the packaging and transportation of infectious substances.

With over 25 years of management of RMWs in the U.S., during which medical wastes have been transported to off-site waste treatment operations, there have been no reports of infections in communities linked to this transport.

In the 10 years of Category A infectious waste identification, there are no reports of infections in communities linked to Category A infectious waste transport.

**Background/References:** Packaging materials made to hold infectious substances are tested to a higher standard than others—they are designed to withstand a drop from a height of 30 feet, exposure to heavy rain, freezing temperatures, a 15-pound rod dropped on it from a height of three feet, and a three-foot drop onto an eight-inch rod. DOT/PHMSA has also issued a special permit, SP 16279, which authorized special permit holders to use a process for transporting Category A infectious substances that involves a combination of effective package designs and extensive operational controls related to packing, disinfectant, driver qualifications, notification to DOT, vehicle inspection, loading, attendance, and security plans.

- **US DOT-SP 16279.** Materials transported under US DOT-SP 16279 must meet provisions within the special permit. Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.
- **Transporting Infectious Substances Safely.** Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.
- **Transporting Infectious Substances.** Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.

### 3. If waste is inactivated, is there a risk to me or my family if it is transported through or disposed of in my/our community?

**Key Message:** Once the waste has been inactivated it is no longer infectious. There should be no risk to a community during the transport or ultimate disposal of the waste.

**Answer:** Once waste has been properly inactivated, it is no longer infectious and does not pose a health risk if it is transported through or disposed of in your community. Waste that has been inactivated in an effective autoclave cycle, or by incineration or another validated method contains no live infectious agents. The validated exposure conditions (e.g., to heat, steam, pressure, or certain chemicals) for inactivation will ensure that the waste material is no longer infectious and, as such, is not considered RMW or a hazardous material under Federal law.
Waste inactivated by autoclaving or, in circumstances where it is necessary, chemical methods, should include a process control to show that the protocol is performed effectively. For example, staff should check the autoclave cycles frequently for biological indicators (spores) as a quality assurance measure to show that the waste cycles are achieving desired results.

**Background/References:** None.

### 4. Will I be notified if waste contaminated with a Category A infectious substance(s) is transported through my community or processed or disposed of at a facility near my home or business?

**Key Message:** Due to security concerns related to the transportation of Category A infectious substances, the public may not be notified regarding the route or disposal of Category A waste. The DOT HMR and DOT-SP 16279 include requirements for providing information to transporters and emergency responders.

**Answer:** Due to security concerns related to the transportation of Category A infectious substances, the public may not be notified regarding the route or disposal of Category A waste. The DOT HMR and DOT-SP 16279 include requirements for providing information to transporters and emergency responders. DOT-SP 16279 requires shipping paperwork that describes the materials being transported. The SP also requires marking and labeling of packages to inform transporters and emergency responders about any potential hazards associated with the materials being transported. For more information regarding the required form and content of the hazard communications, please refer to DOT’s guidance on transporting infectious substances safely via the link below.

**Background/References:**
- **US DOT-SP 16279.** Materials transported under US DOT-SP 16279 must meet provisions within the special permit. Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.
- **Transporting Infectious Substances Safely.** Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.
- **Transporting Infectious Substances.** Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.

### 5. Is there a plan in place to handle emergencies that happen when transporting infectious waste, such as an accident involving the truck carrying the waste?

**Key Message:** Yes, RMW and other hazardous materials transportation companies are required to develop and implement emergency response plans when transporting any hazardous material. For example, for Ebola, the special permit required specific emergency response plans be in place prior to transporting the waste materials. DOT’s packaging requirements and other operational and safety controls are very robust.
**Answer:** Yes, RMW and other hazardous materials transportation companies are required to develop and implement emergency response plans when transporting any hazardous material. For example, for Ebola, the special permit required specific emergency response plans be in place prior to transporting the waste materials. DOT’s packaging requirements and other operational and safety controls are very robust. All carriers authorized to transport infectious waste under DOT-SP 16279 are required to have a written spill response plan that includes provisions for the decontamination of spilled materials and for PPE to be carried on the vehicle and used to protect its employees from contact with infectious materials in any form. These carriers are also required to develop and adhere to security plans that address personnel security, preventing unauthorized access, and security during movement of the infectious waste, as described in the regulations (49 CFR §§ 172.800-822).

Individuals or companies that offer infectious waste for transportation must develop and implement written security plans to address emergencies such as an accident. Security plans include an assessment of possible transportation security risks including personnel security, unauthorized access and *en route* security as well as a plan to address any identified risks. These plans are reviewed and updated or revised as needed.

**Background/References:**

**TREATMENT OF INFECTIOUS WASTE AT OFF-SITE FACILITY**

Acronyms used throughout this section:
- DOT U.S. Department of Transportation
- FIFRA Federal Insecticide, Fungicide, and Rodenticide Act
- HMR Hazardous Materials Regulations
- OSHA U.S. Occupational Safety and Health Administration
- RMW Regulated medical waste

1. **What methods are used to treat infectious waste so that it is no longer infectious?**
**Key Message:** Autoclaves or incinerators are most commonly used to inactivate contaminated waste. Once waste has been properly inactivated, it is no longer infectious or a Category A waste.

**Answer:** Facilities may inactivate contaminated waste using an autoclave operating within permitted parameters. Use an autoclave cycle that heats materials to a high enough temperature for a long enough period of time to inactivate the organism(s) of concern in the waste. Such time/temperature conditions will ensure that the waste material is no longer infectious, does not pose a health risk, and is not considered RMW or a hazardous material under Federal law.

A facility may also use incineration. Incinerators run at extremely high temperatures, well above the temperature needed to kill a Category A virus. Incineration would be the best method for large or bulky items. If a facility uses incineration, then its waste management plan should include a method for disposal of the residuals.

Inactivation (e.g., through autoclaving or other validated methods) or incineration of contaminated waste at a facility may be subject to Federal, State, and local regulations, including environmental and worker safety and health requirements.

Other methods of inactivation (e.g., chemical treatment) would need to consider worker health and safety issues as well as the potential for triggering other State or Federal regulations including environmental regulations under FIFRA.

**Background/References:**

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2. **How do waste treatment and disposal companies ensure that the processes they use to treat infectious waste are effective?**

**Key Message:** While methods for ensuring the effectiveness of waste treatment vary by process, large commercial autoclaves, tested to inactivate materials using specific time, temperature, and pressure for treatment have been shown to properly kill pathogens or viruses and incineration which reaches extremely high temperatures (well above those needed to inactivate any Category A infectious substance) have proven to be very effective.

**Answer:** Large commercial autoclaves, tested to inactivate materials using specific time, temperature, and pressure for treatment have been shown to properly kill pathogens or viruses and incineration which reaches extremely high temperatures (well above those needed to inactivate any Category A infectious substance) have proven to be very effective. Treatment facilities that use autoclaving should have protocols and operating requirements that include a

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28 Operators should validate that their waste inactivation procedures meet required performance standards, including achieving certain exposure time and temperature requirements, acceptable results on biological indicators or other test assays, and allowable concentration of certain pollutants or contaminants in any effluent or other by-product of the process.
process control step to ensure the effectiveness of their equipment. For example, autoclave cycles should be frequently checked using biological indicators (spores) as a quality assurance measure to ensure that the cycles are achieving the desired results.

Incineration is effective due to the very high temperatures used and the relatively low temperatures needed to inactivate a Category A infectious substance.

Other methods have not been standardized; thus, if a facility seeks to use, for example a chemical treatment, it is likely to be required to perform substantial testing and quality control to ensure inactivation. Facilities should verify requirements with their State/local health and/or environmental departments.

States may require medical waste treatment companies to present data demonstrating effectiveness of waste treatment processes prior to receiving a permit to operate in a particular State. States may have oversight programs involving inspections of these operations on a periodic basis.

Background/References:

3. Are there any steps normally involved in treating medical waste that should be avoided during treatment and disposal of waste contaminated with Category A infectious substances?

Key Message: Employers of workers whose tasks involve treating and disposing of waste contaminated with a Category A infectious substance should ensure that their work practices minimize worker contact with the contaminated waste, prevent generation of potentially infectious aerosolized particles, and comply with all applicable public health and environmental requirements.

Answer: Employers of workers whose tasks involve treating and disposing of waste contaminated with a Category A infectious substance should ensure that their work practices minimize worker contact with the contaminated waste. For example, protocols should involve autoclaving or incinerating entire packages of waste rather than unpacking for loading into treatment equipment. Use of machines to move or load waste containers into processing equipment may also reduce direct worker contact with infectious waste.

Prevent generation of potentially infectious aerosolized particles by avoiding the use of procedures that result in sprays of droplets or air. For example, do not shred waste prior to treatment; and do not use high-pressure sprays of air, water, or chemicals to clean waste processing facilities and equipment.

There is only one report of a waste treatment worker’s occupationally-acquired infection due to poor aerosol control during laboratory waste shredding prior to treatment (See Johnson et al.
below). However, while this poorly controlled process released contaminated aerosols, the building’s ventilation design helped to prevent these aerosols from a larger release to the community.

Employers must comply with all applicable public health and environmental requirements, including those designed to ensure containment of treated waste disposed of in landfills.

**Background/References:**

**4. What is my/my family’s risk of being exposed to infectious waste if it is processed or inactivated at facilities in my/our community?**

**Key Message:** With Federal, State, and local regulations in place to safeguard public health and the environment, your and/or your family’s risk of being exposed to infectious waste, if processed or inactivated at facilities in your community, is extremely low.

**Answer:** Your and/or your family’s risk of being exposed to infectious waste if processed or inactivated at facilities in your community is extremely low. Federal, State, and, in some cases, local regulations work together to ensure that waste is managed in a manner that protects public health and the environment from the time the waste is generated through ultimate disposal. These regulations include DOT HMR requirements for classification, packaging and communications. Materials to be transported must be in full compliance with the HMR, or transported in compliance with a special permit.

**Background/References:**
DISPOSAL ISSUES

Acronyms used throughout this section:

- CFR: Code of Federal Regulations
- DOT: U.S. Department of Transportation
- HMR: Hazardous Materials Regulations
- OSHA: U.S. Occupational Safety and Health Administration
- RMW: Regulated medical waste

1. Where does infectious waste end up after treatment?

**Key Message:** Once an infectious waste has been properly inactivated (i.e., it is no longer infectious), it is considered a solid waste and is handled, transported, and disposed according to the regular protocols for solid waste management in the State. This generally means that the waste is sent to a municipal solid waste landfill or to a municipal waste combustor/incinerator.

**Answer:** Once an infectious waste has been properly inactivated (i.e., it is no longer infectious), it is considered a solid waste and is handled, transported, and disposed according to the regular protocols for solid waste management in the State. This generally means that the waste is sent to a municipal solid waste landfill or to a municipal waste combustor (otherwise known as a municipal waste incinerator).

A facility that has generated and then inactivated waste on-site through its normal processes, should verify with its State/local regulatory official that the waste may be treated as a solid waste, and verify that its “usual” solid waste disposal facility can handle the waste, especially if there is a large volume. The generating facility also should understand and comply with any special conditions that may be imposed by a permit, by the receiving facility, or by a State or local authority; and should verify that the disposal facility received and properly processed the waste.

**Background/References:**

2. Can burying inactivated waste in landfills affect crops or ground water supplies nearby?

**Key Message:** Burying inactivated waste in appropriately designed and operated landfills should ensure that the waste does not affect crops or ground water supplies nearby. Landfills are subject to minimum Federal criteria under Subtitle D of RCRA and to State regulations and permits, which can vary depending on the types of waste the landfill is permitted to receive. Design and operational requirements for landfills can include liners and groundwater monitoring systems. The critical protections provided by these requirements help ensure that putting waste in landfills does not affect crops or ground water supplies nearby.

**Answer:** Burying inactivated waste in appropriately designed and operated landfills should ensure that the waste does not affect crops or ground water supplies nearby. In particular, municipal solid waste landfills in the U.S. are designed to meet technical requirements to prevent groundwater contamination, such as using liners to keep contaminants out of the soil and groundwater. Municipal solid waste landfills are also subject to extensive groundwater monitoring requirements to ensure early detection and prompt remediation (i.e., clean-up) of any potential contamination before it can spread. Even after a municipal solid waste landfill ceases operating, strict closure and post-closure requirements help ensure it does not pose a health or environmental hazard.

**Background/References:**

3. What requirements are in place to ensure air quality near incinerator facilities that process infectious waste?

**Key Message:** Under requirements of the Clean Air Act, incinerator operators must monitor for and comply with limits for specific air pollutants.

**Answer:** Incinerator operators are subject to extensive requirements specified in permits issued under the Clean Air Act. Generally, they must monitor for and meet specific limits for specific air pollutants. The precise permit terms generally depend on the type of incinerator (e.g., medical waste incinerator, hazardous waste incinerator, municipal waste incinerator, etc.). However, it is important to remember that wastes are burned at extremely high temperatures in the incinerator and that these temperatures destroy the infectious substances.

**Background/References:**
4. Is there potential harm to other natural resources when infectious waste is transported or inactivated or when inactivated waste is disposed of properly?

**Key Message:** When infectious waste is transported, inactivated, and disposed following applicable Federal or State regulations (e.g., transported in compliance with the strict DOT HMR requirements), any risk to the environment and public health is generally mitigated (i.e., removed or minimized). Waste that has been properly inactivated is no longer infectious, and ultimate disposal facilities would manage this material as they do any other inactivated infectious waste today.

**Answer:** Regulatory requirements for transportation, treatment, and disposal address potential risks to human health and the environment. When waste is transported, inactivated, and disposed following applicable Federal or State regulations (e.g., transported in compliance with the strict DOT HMR requirements) any risk to the environment or public health is generally mitigated through the classification and packaging requirements and, if necessary, the issuance of special permits with appropriate conditions. Autoclaves and incinerators used to inactivate infectious waste generally operate under strict controls using protocols demonstrated to be effective to address potential risks. The ultimate disposal facility also operates under strict permit or regulatory conditions to ensure that waste placed there does not pose a risk to the surrounding environment. Waste that has been properly inactivated no longer has infectious substances and ultimately disposal facilities would manage this material as it does any other treated waste today.

**Background/References:**

5. Is the ash from incinerated Category A infectious substances hazardous, infectious, or dangerous?

**Key Message:** The ash remaining after waste is incinerated is not hazardous, infectious, or dangerous. Incinerators typically operate at temperatures much higher than required to inactivate Category A infectious agents.

**Answer:** The ash remaining after waste is incinerated is not hazardous, infectious, or dangerous. However, waste regulations generally consider this ash as a “new waste”; and the owner/operator must make a decision and classify that waste as either hazardous or non-hazardous. Incinerators typically operate at very high temperatures, much higher than required to inactivate Category A infectious agents. Incinerator operators are trained to operate the equipment to ensure full combustion of the wastes going into the incinerator.

Non-hazardous waste is managed under the State solid waste regulations. Such waste, including incinerator ash, can be disposed of safely in a sanitary landfill. Any hazardous waste generally must be managed under the State or Federal hazardous waste regulations.
6. Is waste that has been autoclaved (which means to sterilize by means of high pressure saturated steam) hazardous, infectious, or dangerous?

**Key Message:** Waste that has been autoclaved using an effective autoclave cycle is not infectious or hazardous and is generally not dangerous. However, sharps can still injure workers handling the waste.

**Answer:** Waste that has been autoclaved using an effective autoclave cycle is not infectious or hazardous and is generally not dangerous. However, sharps can still injure workers handling the waste.

A facility may inactivate contaminated waste using an autoclave and an effective waste cycle (i.e., heated to a temperature and for a length of time that has been demonstrated to permit full steam penetration of the waste). This process generally uses sufficient heat and time to kill the Category A infectious substance, although some porous waste materials may require modifications to the operating procedures of the autoclave to achieve the necessary material temperatures prior to being held at the required temperature. Many States require manufacturers of medical waste autoclaves to provide validation data for their equipment to guide its use.

Achieving validated time/temperature conditions will ensure that the waste material is no longer infectious and is not considered RMW or a hazardous material under Federal law.

Inactivation of contaminated waste at a facility may be subject to Federal, State, local, environmental, and OSHA regulation.

**Background/References:**


**WORKER PROTECTION**

Acronyms used throughout this section:

- CDC: U.S. Centers for Disease Control and Prevention
- CFR: Code of Federal Regulations
- DOT: U.S. Department of Transportation
- EPA: U.S. Environmental Protection Agency
- HAZWOPER: Hazardous Waste Operations and Emergency Response
- HIV: Human Immunodeficiency Virus
- HMR: Hazardous Materials Regulations
1. What are the risks to workers handling infectious waste before it is properly inactivated?

**Key Message:** Waste can be handled in a way that protects workers from exposure to infectious agents and other hazardous substances in the waste, as well as from injuries from sharps, broken glass, and other materials.

**Answer:** There are many possible hazards to workers involved in the handling, transport, treatment and disposal of infectious waste. Depending on the specific infectious agent(s) in the waste, workers may be exposed to pathogens through direct contact with the waste, contact of mucous membranes or broken skin with splashes or sprays of infectious material, or inhalation of bioaerosols containing infectious particles.

However, waste can be handled in a way that protects workers from exposure to infectious agents and other hazardous substances in the waste, as well as from injuries from sharps, broken glass, and other materials. Employers of workers who handle waste should use a combination of engineering and administrative controls, safer work practices, and PPE to prevent or minimize worker exposure to infectious agents and other hazardous substances in the waste they handle. These controls can also help prevent or reduce injuries from sharps.

Use of this hierarchy of controls for worker protection should be done in the context of a comprehensive infection prevention and control program. Using such controls is also generally part of compliance with OSHA requirements, the DOT HMR, and CDC and EPA guidance.

**Background/References:**

2. What specific tasks may lead to worker exposure to untreated infectious waste?

**Key Message:** Until waste is completely treated to inactivate or destroy any infectious material it may include, unprotected workers may be exposed to disease-causing agents (i.e., pathogens) during waste handling, transport, and treatment tasks. Using engineering controls, administrative controls and safer work practices, and PPE can help prevent worker exposure during these operations.

**Answer:** From the point of waste generation until the waste is completely treated in a way that fully inactivates or destroys any infectious material (e.g., pathogens, including Category A infectious substances agents such as Ebola) in the waste, unprotected workers may be at risk for occupational exposure to disease-causing agents (i.e., pathogens) during waste handling (e.g.,
bare-handed contact with waste in the container), transport, and treatment tasks. Depending on how a pathogen is transmitted, exposure may occur through direct contact of mucous membranes (e.g., mouth, eyes, nose) or broken skin with contaminated materials, splashes or sprays of infectious liquids or droplets to mucous membranes or broken skin, or inhalation of infectious aerosolized (i.e., bio-aerosols) or airborne (i.e., droplet nuclei) particles.

Workers may have direct contact with contaminated materials when collecting or packaging waste at the point of origin, handling waste during transport (particularly if it is not properly and securely packaged), manipulating waste during treatment (e.g., loading it into an autoclave or incinerator), and during other tasks that require handling of untreated waste materials. Needle sticks and other injuries (e.g., cuts or puncture wounds) from contaminated sharps in waste can cause worker infections.

Waste workers are at increased risk for exposure to splashes or sprays of infectious liquids or droplets and air that contains infectious aerosolized particles (i.e., bio-aerosols) when handling waste before packaging and during tasks that require additional manipulation of packaged waste. Correctly using appropriate controls can prevent or reduce these exposures. Though it is not a best practice to do so and may violate some States’ requirements, dumping packaged waste into an autoclave or incinerator that cannot accommodate or process an entire unopened container may present significant worker exposure hazards. Using high-pressure streams of air, water, or chemicals for cleaning and disinfection may also produce infectious splashes, sprays, or droplets, including aerosolized particles.

Waste worker exposure to airborne (i.e., droplet nuclei) particles may occur during any task that involves disturbing or moving waste or other potentially contaminated materials, as airborne-transmissible pathogens are spread when droplets containing infectious materials dry and leave behind infectious droplet nuclei that travel through the air. Although transmission of airborne-transmissible diseases is not as well understood as other routes of transmission, waste workers may be at less risk for exposure to airborne-transmissible agents than are other types of workers as these agents are thought to be spread by particles breathed out by infected individuals.

Even after waste is inactivated, employers and workers should be cautious of waste that may contain sharps (e.g., needles), broken glass, or other objects that pose cut or puncture hazards. See “Disposal Issues - Question 6” above for additional information.


### 3. What should employers do to protect workers involved in handling, transport, and treatment of infectious waste and disposal of inactivated waste?

**Key Message:** Employers should follow the requirements and guidance of CDC, DOT, EPA, OSHA, and any State/local agencies with authority over waste management, including worker safety and health. Implementing appropriate worker protections as part of a comprehensive infection prevention and control program will help ensure workers stay safe and healthy.

**Answer:** Employers should follow the requirements and guidance of CDC, DOT, EPA, OSHA, and any State/local agencies with authority over waste management, including worker safety and health. Implementing appropriate worker protections as part of a comprehensive infection prevention and control program will help ensure workers stay safe and healthy.

OSHA always requires employers to protect their workers from recognized safety and health hazards, which can vary among different worksites and operations. Depending on the specific infectious substances to which workers may be exposed, the work tasks they perform, and other potential hazards, employers may be required to comply with provisions of OSHA’s Bloodborne Pathogens, PPE, Respiratory Protection, and HAZWOPER standards and other requirements, including the General Duty Clause of the Occupational Safety and Health Act. These standards may require employers to provide training, PPE, and medical surveillance to workers; develop and implement hazard assessments, safety and health plans, and controls for worksite hazards; and maintain records of medical exams, worker exposures, and other data.

Employers should ensure that the controls they implement in their work practices—including engineering controls and administrative or work practice controls that govern how workers do certain tasks—are sufficient to prevent worker exposures to infectious agents and other hazards, as needed.

Employers must also comply with public health and environmental protection requirements of CDC (e.g., when handling Select Agents), DOT (e.g., when packaging and transporting infectious waste), and EPA (e.g., when treating or incinerating waste, and when disposing of treated waste products in landfills). State/local requirements may also apply.

Other things employers can do to protect their workers who must handle infectious waste include:

- Minimizing the generation of waste, including by separating regular trash from medical waste or other types of potentially infectious waste.
- Ensuring that all sharps, including needles and broken glass, are disposed of and stored in appropriate rigid, puncture-proof containers.
- Providing workers with facilities and supplies to wash their hands regularly and shower and change clothes, if necessary, before leaving the workplace.
- Minimizing the number of staff members required to handle infectious waste.

**Background/References:**
- [Transporting Infectious Substances](#). Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.
- [Hazardous Waste Generators](#). U.S. Environmental Protection Agency.
- [Medical Waste](#). U.S. Environmental Protection Agency.

**4. What can workers involved in handling, transport, and treatment of infectious waste and disposal of treated waste do to protect themselves?**

**Key Message:** Workers should make sure they are knowledgeable about their job tasks before attempting to perform them, and always follow the training and procedures provided to them by their employer.

**Answer:** Workers should make sure they are knowledgeable about their job tasks before attempting to perform them, and always follow the training and procedures provided to them by their employer.

While certain OSHA standards require employers to provide training to workers on how to do their jobs safely and healthfully, workers should seek information from their employers before starting a job or changing work tasks. Always correctly implement or use the engineering, administrative, and work practice controls required by the employer. Always correctly put on, use, and take off PPE required by the employer. Always follow the training provided by the employer.
Even if your employer does not require you to wear dedicated work clothing and footwear, it may be a good idea to shower and change your clothes and shoes after handling waste contaminated with a Category A infectious substance. This helps ensure that you do not spread infectious material outside of your workplace, including to your home and family members. Workers should also follow good hand-hygiene practices, including thoroughly washing their hands with soap and water or using an alcohol-based hand rub if running water is not immediately available.

**Background/References:**

**5. Is there training available on handling, transport, and treatment of infectious waste and disposal of treated waste that I can get in advance to be sure I am prepared to do my job?**

**Key Message:** Your employer may be required to provide you training on how to do your job safely and healthfully. Training may also be available to you through other sources not mentioned specifically in this document.

**Answer:** In many cases where workers are required to handle potentially infectious material, including waste contaminated with a Category A infectious substance, OSHA requires employers to provide training to workers on how to do your job safely and healthfully. For example, workers who may be exposed to Category A infectious substances that are also bloodborne pathogens (e.g., Ebola virus, HIV, Hepatitis) must receive initial training when they start their jobs and regular (e.g., annual) refresher training, including anytime new work tasks or exposures are introduced or tasks or exposures change. Though not all Category A infectious agents fall under OSHA’s Bloodborne Pathogens standards, employers may still be required to provide worker training as part of the agency’s requirements for PPE selection and use, hazardous waste operations and emergency response, or other mandates.

State/local agencies, including States that operate their own worker safety and health programs (OSHA State Plans), may have additional or more stringent requirements regarding worker training.

The NIEHS Worker Training Program has been working closely with government agencies, private-sector employers, and academic institutions to coordinate the development of worker training materials, particularly related to Ebola. Additional information about NIEHS programs and resources is available at [www.niehs.nih.gov](http://www.niehs.nih.gov).

The National Ebola Training and Education Center also provides information about preparedness and response to Ebola specifically, and provides employers with resources for training and preparing their workers [www.netec.org](http://www.netec.org).
Background/References:

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<td>(334) 271-7730</td>
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<td>(907) 269-7802</td>
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<td>501-661-2936</td>
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<td>(916) 558-1784</td>
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<td>Commonwealth of the Northern Mariana Islands</td>
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<td>(670) 664-8500</td>
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<td>(888) 424-4193</td>
<td><a href="http://www.ct.gov/deep/cwp/view.asp?a=2718&amp;q=325340&amp;deepNav_GID=1646">www.ct.gov/deep/cwp/view.asp?a=2718&amp;q=325340&amp;deepNav_GID=1646</a></td>
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<td>(302) 739-9403</td>
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<td>(202) 442-5955</td>
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<td>(850) 245-4277</td>
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<td>(404) 362-2692</td>
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<td>(502) 564-6716</td>
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<td>(505) 827-0197</td>
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<td>(503) 229-5696</td>
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<td>(787) 767-8181</td>
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<td>(801) 536-0200</td>
<td><a href="http://www.deq.utah.gov/ProgramsServices/programs/waste/solidwaste/">www.deq.utah.gov/ProgramsServices/programs/waste/solidwaste/</a></td>
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<td>West Virginia</td>
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<td>(304) 368-4420 ext. 79404</td>
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<td>(888) 936-7463</td>
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<td>(307) 777-7937</td>
<td><a href="http://deq.wyoming.gov/shwd/">deq.wyoming.gov/shwd/</a></td>
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Note: Additional State or territorial worker health and safety requirements may apply to the management of solid waste contaminated with a Category A infectious substance. The Occupational Safety and Health Administration (OSHA) covers most private sector employers and workers in all 50 states, the District of Columbia, and the other U.S. jurisdictions either directly through OSHA or through an OSHA-approved State Plan. State Plans are OSHA-approved job safety and health programs operated by individual states instead of federal OSHA. When this document was published, 26 states, Puerto Rico, and the Virgin Islands had OSHA-approved State Plans. Twenty-two State Plans (21 states and one U.S. territory) cover both private and state and local government workplaces. The remaining six State Plans (five states and one U.S. territory) cover state and local government workers only. For a complete list of OSHA-approved State Plans and information about worker safety and health requirements in each state, see: [www.osha.gov/dcsp/osp/index.html](http://www.osha.gov/dcsp/osp/index.html).
APPENDIX G – ACRONYMS & GLOSSARY OF TERMS

ACRONYMS

ASPR  Assistant Secretary for Preparedness and Response
CAA   Clean Air Act
CDC   U.S. Centers for Disease Control and Prevention
CFR   Code of Federal Regulations
DOT   U.S. Department of Transportation
EMS   Emergency Medical Services
EPA   U.S. Environmental Protection Agency
FIFRA Federal Insecticide, Fungicide, and Rodenticide Act
HAZWOPER Hazardous Waste Operations and Emergency Response
HHS   U.S. Department of Health and Human Services
HIV   Human Immunodeficiency Virus
HMR   Hazardous Materials Regulations
ICAO  International Civil Aviation Organization
IMDG  International Maritime Organization Dangerous Goods Code
NETEC National Ebola Training and Education Center
NIEHS U.S. National Institute for Environmental Health and Safety
NIOSH U.S. National Institute for Occupational Safety and Health
OPIM  Other potentially infectious materials
OSHA  U.S. Occupational Safety and Health Administration
PPE   Personal protective equipment
PHMSA U.S. Pipeline and Hazardous Materials Safety Administration
RCRA  Resource Conservation and Recovery Act
RMW   Regulated medical waste
SP    Special Permit
TRACIE Technical Resources, Assistance Center, and Information Exchange
UN    United Nations
USDA  U.S. Department of Agriculture
WHO   World Health Organization
GLOSSARY OF TERMS

Autoclave: A sterilization process that uses saturated steam under pressure for a specified exposure time and at a specific temperature.

Bioaerosol: Airborne particles released from animals or plants and bacteria, yeasts, molds, and viruses and their parts.

Bloodborne pathogens (BBP): Pathogenic microorganisms that are present in human blood (including human blood components and products made from human blood) and that can cause disease in humans.

Bloodborne Pathogens (BBP) standard: OSHA standard that requires employers to protect workers from occupational exposure to bloodborne pathogens (as defined above and including some Category A infectious substances). The standard also applies to exposure to other potentially infectious materials, including semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids, as well as any unfixed tissue or organ (other than intact skin) from a human (living or dead). See 29 CFR § 1019.1030.

Category A infectious substance: An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. See 49 CFR § 173.134(a)(1)(i). Note that Category A infectious substances described in this document and covered by the Hazardous Materials Regulations (HMR) at 49 CFR parts 171-180 should not be confused with the Category A select agents regulated by the Federal Select Agent program under 7 CFR part 331, 9 CFR part 121, and 42 CFR part 73 (although an infectious substance or agent may be both covered by the HMR and listed as a select agent). For additional information, see www.selectagents.gov and emergency.cdc.gov/bioterrorism/overview.asp.

Category A Waste: See “Contaminated waste.”

Clean Air Act (CAA): The comprehensive Federal law that regulates air emissions from stationary and mobile sources. Among other things, this law authorizes EPA to establish National Ambient Air Quality Standards to protect public health and public welfare and to regulate emissions of hazardous air pollutants.

Commerce: Trade or transportation in the jurisdiction of the United States within a single State; between a place in a State and a place outside of the State; that affects trade or transportation between a place in a State and place outside of the State; or on a United States-registered aircraft. See 49 CFR § 171.8.

Contaminated waste: Waste contaminated with a Category A infectious substance.
**Disinfection product:** A product that will make certain biological agents inactive. Specific to Ebola, such products would be an EPA-registered hospital disinfectant or one with the equivalent microbial pathogen claims that also have a label claim against a non-enveloped virus.29

**Endemic:** When a particular disease is usually present in a particular community, population, or geographic area.

**Generator:** The person or persons whose act or process produces (i.e., ‘generates’) a waste, and this term generally provides a way to describe waste generators irrespective of what type of waste they produce (e.g., solid, infectious, hazardous, etc.). However, this term has a very specific meaning under the hazardous waste regulations (RCRA subtitle C), and hazardous waste generators have specific requirements they must adhere to both for managing their hazardous waste on-site, as well as for ensuring proper management off-site. See [www.epa.gov/hwgenerators](http://www.epa.gov/hwgenerators). See also “Offeror.”

**Hazardous material:** A substance or material that the Secretary of Transportation has determined is capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and has designated as hazardous under section 5103 of Federal hazardous materials transportation law (49 U.S.C. section 5103). The term includes hazardous substances, hazardous wastes, marine pollutants, elevated temperature materials, materials designated as hazardous in the Hazardous Materials Table (see 49 CFR 172.101), and materials that meet the defining criteria for hazard classes and divisions in part 173 of the HMR. See 49 CFR § 171.8.

**Hazardous Materials Regulations (HMR):** The regulations at 49 CFR parts 171-180.

**Hazardous waste:** A specific term defined in the RCRA and implementing regulations. “Hazardous waste” is a subset of “solid waste” (where solid waste can be a liquid, semi-solid, solid, or contained gaseous material) that when improperly managed poses a serious threat to human health and the environment. There are specific regulatory definitions of “hazardous waste” with which waste generators should be familiar. For purposes of transportation, “hazardous waste” refers to any material that that is subject to the Hazardous Waste Manifest Requirements of the EPA specified in 40 CFR part 262.

**Hazardous Waste and Emergency Response Operations (HAZWOPER) standard:** The OSHA standard that requires employers to protect workers engaged in certain types of emergency response and recovery operations, including emergency response operations for releases of, or substantial threats of releases of, hazardous substances regardless of the location of the hazard. See 29 CFR § 1910.120.

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Inactivated: Having reached the point, through incineration or autoclaving, where the material is no longer infectious, does not pose a health risk, and is not considered to be a regulated medical waste or a hazardous material when transported in commerce.

Incineration: The combustion of waste primarily for destruction (i.e., disposal). This process can reduce large volumes of waste materials to ash and lessen toxic gaseous emissions. Residues (e.g., ash) from the combustion of hazardous waste are also potentially subject to RCRA regulation for disposal.

Incinerator, hazardous waste: A type of combustors that are designed, operated, and permitted to burn hazardous waste. These HWIs are subject to applicable Federal and/or State regulatory requirements pursuant to both the Resource Conservation and Recovery Act requirements (40 CFR parts 264, 265, and 266) and Clean Air Act standards (40 CFR part 63). Waste feed capacity for HWIs is an important criterion to know before a biological incident occurs, as each HWC may be set up to accept different waste amounts and sizes.

Incinerator, medical waste: A type of incinerators that are designed, operated, and permitted to burn wastes produced by hospitals, veterinary facilities, and medical research facilities. These wastes include both infectious ("red bag") medical wastes and non-infectious, general housekeeping wastes. Under the Clean Air Act, hospital/medical/infectious waste incinerators are subject to applicable requirements (40 CFR part 60).

Infectious substance: A material known or reasonably expected to contain a pathogen. A pathogen is a microorganism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion) that can cause disease in humans or animals. See 49 CFR § 173.134(a)(1).

Landfill: Disposal facilities in which wastes are placed in or on land. Regulatory requirements vary depending on the type of waste the landfill is permitted to receive. For example, hazardous waste landfills, often referred to RCRA Subtitle C landfills, are subject to different Federal standards (40 CFR parts 264 and 265, subpart N) than non-hazardous waste landfills often referred to as RCRA Subtitle D landfills (40 CFR parts 257 and 258). In addition, State requirements may apply in lieu of or in addition to the Federal standards.

Occupational Safety and Health (OSH) Act: The primary Federal law enacted to assure safe and healthful working conditions for workers in the U.S. Regulations promulgated under the OSH Act set standards for protecting workers from occupational safety and health hazards, require employers to maintain certain types of records, assist States in their efforts to assure safe and healthful working conditions through their own OSHA-approved State Plans.

Offeror: A person who does either or both of the following: (1) performs or is responsible for performing, any pre-transportation function required under the HMR (49 CFR parts 171-180) for transportation of the hazardous material in commerce; (2) tenders or makes the hazardous material available to a carrier for transportation in commerce. See 49 CFR § 171.8. See also “Generator.”
**Overpack:** An enclosure that is used by a single consignor to provide protection or convenience in handling of a package or to consolidate two or more packages. Overpack does not include a transport vehicle, freight container, or aircraft unit load device. Examples of overpacks are one or more packages: (1) placed or stacked onto a load board such as a pallet and secured by strapping, shrink wrapping, stretch wrapping, or other suitable means; or (2) placed in a protective outer packaging such as a box or crate. See 49 CFR § 171.8

**Packaging(s):** A receptacle and any other components or materials necessary for the receptacle to perform its containment function in conformance with the minimum packing requirements of this subchapter.

**Pathogen:** A microorganism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion) that can cause disease in humans or animals. See 49 CFR § 173.134(a)(1).

**Personal protective equipment (PPE):** Equipment worn to prevent exposure, including of the skin, eyes, face, head, extremities, respiratory tract, and mucous membranes, to hazardous substances (e.g., infectious agents, chemicals, and other materials). See 29 CFR part 1910 subpart I.

**Regulated medical waste (RMW):** A waste or reusable material, other than Category A, derived from medical treatment of humans or animals including diagnosis and immunization; or from biomedical research, including production and testing of biological products including production and testing of biological products. See 49 CFR § 173.134(a)(5)).

**Exceptions to regulated medical waste:** A material that is unlikely to cause disease in humans or animals; non-infectious biological materials from humans, animals or plants; a material containing neutralized or inactivated pathogens and no longer poses a health risk; or blood collected for transfusion or preparation of blood products sent for testing (unless believed to contain an infectious substance); laundry, medical equipment conforming to OSHA’s Bloodborne Pathogens standard (29 CFR § 1910.1030); any waste or recyclable material other than regulated medical waste; or corpses, remains, and anatomical parts transported for interment, cremation or medical research. See 49 CFR § 173.134(b)).


**Solid waste:** Any garbage or refuse, sludge from a wastewater treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, resulting from industrial, commercial, mining, and agricultural operations, and from community activities. Note that the definition of solid waste is not limited to wastes that are physically solid. Many solid wastes are liquid, semi-solid, or contained gaseous material. See 40 CFR part 261.
Special Permit: A document issued by PHMSA, or as otherwise prescribed in the HMR, under the authority of 49 U.S.C. section 5117 permitting a person to perform a function that is not otherwise permitted under the HMR.

Validated: A term used to describe a protocol or treatment cycle used for inactivating waste that has been shown to ensure the waste is no longer infectious. Validation often involves the use of biological indicators (e.g., spores, approved surrogate organisms or a culture-based method using the actual target organism) to demonstrate that potentially infectious substances have been exposed to sufficient heat, steam, pressure, or chemicals for a long enough period of time to ensure it is completely non-infectious. See also “Inactivated.”