# Managing Solid Waste Contaminated with a Category A Infectious Substance

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# **PREFACE**

Solid waste contaminated with infectious substances can be managed safely.<sup>1</sup>

In the United States, much of this waste comes from hospitals, other healthcare facilities, medical transportation operations, and laboratories, though people with certain infectious diseases may also generate such waste at home. Infectious waste is routinely treated, transported, and disposed of in ways that protect the health of the American public, the environment, and workers.

However, the 2014–2015 experiences with individuals with Ebola virus disease (EVD) in the United States tested the nation's capacity for managing solid waste contaminated with Ebola virus or other potentially highly infectious waste—classified as Category A infectious substances under the U.S. Department of Transportation's *Hazardous Materials Regulations* (HMR). The HMR classify an infectious substance (and solid waste containing it) as "Category A" if it is in a form (e.g., untreated) capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals upon exposure to the substance.<sup>2</sup> The HMR require certain safety measures, including special permits and packaging, for commercial transportation of materials contaminated with Category A infectious substances (referred to as "Category A waste" throughout this document). Challenges associated with managing Category A waste generated by U.S. patients with EVD—both before and during hospitalization—highlighted a lack of universal understanding about how to handle such waste, as well as poor acceptance of the fact that these activities can be done safely.

A product of extensive federal interagency coordination and stakeholder input, this guidance aims to prepare the nation to effectively manage Category A waste associated with infectious disease incidents. The guidance also aims to improve understanding of the safety of infectious waste management processes. It is intended to help government and non-governmental leaders, local emergency medical services, emergency managers, hospitals, healthcare providers, laboratories, environmental services workers, waste management companies and workers, and related stakeholders safely handle, inactivate, transport, and dispose of Category A waste. In addition to the HMR, the document discusses additional U.S. Department of Labor (DOL)/Occupational Safety and Health Administration (OSHA), U.S. Department of Health and Human Services (HHS)/Centers for Disease Control and Prevention (CDC), and U.S. Department of Agriculture (USDA) requirements, including federal select agent regulations of HHS/CDC at 42 CFR part 73 and USDA at 7 CFR part 331 and 9 CFR part 121, that may be relevant for waste management planning. The guidance is supplemented by several appendices that provide additional resources, assist with decision making, and address questions and answers about Category A waste.

<sup>1</sup> 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. For more information, see definition of "solid waste" in <u>Glossary of Terms</u>.

<sup>&</sup>lt;sup>2</sup> Hazardous Materials Regulations, 49 CFR § 173.134(a)(1)(i) (2013).

<sup>&</sup>lt;sup>3</sup> Parts of this guidance may not apply to every hospital, healthcare facility, or laboratory in every state. Contact state, local, tribal, and/or territorial officials to discuss your organization's waste management plans in order to prepare for an incident before one occurs. See the directory of state and territorial waste management programs in Appendix E – Directory of State and Territorial Waste Management Programs.

This guidance focuses on managing waste contaminated with the Category A infectious substances that affect humans. Appendix B – Infectious Agent Categorization provides a non-exhaustive list identifying, among other categorizations, common agents classified as Category A pathogens affecting humans. Medical care of a person suspected of or confirmed as having a disease caused by a Category A pathogen (i.e., germ) typically generates used healthcare products or linens that are classified as Category A waste. While this document chiefly addresses Category A waste associated with hospital care of infectious patients, it also recognizes that infected people may contaminate their homes, vehicles in which they travel, and other environments before they are hospitalized. Category A waste may also come from laboratories that work with UN 2814 Category A pathogens, including when they intentionally cultivate certain pathogens (a process known as "culturing") that are not considered Category A in other forms (e.g., in body fluids or tissues of an infected person). Where appropriate, this document addresses these additional, non-healthcare scenarios and settings from which Category A waste may arise.

Information in this guidance serves several purposes. As a whole, the document offers readers an overview of Category A waste management in the United States. The main component of this guidance addresses planning for Category A waste management activities, including considerations for developing, evaluating, and revising organizational (e.g., hospital) or jurisdictional (e.g., state, territorial, or local) plans. It is presented in sections that break down waste management activities according to responsibilities as waste is moved from its point of generation to its place of disposal. Several accompanying appendices provide users with information about pathogens classified as Category A infectious substances, decision making for waste treatment and disposal activities, communicating effectively about safe waste management and associated issues, and additional related resources. The included listing of acronyms and glossary of terms applies to the entire document. Unless otherwise noted, references to a particular appendix or section refer to parts of this document (and, in the electronic version, can be clicked to navigate to that information directly).

Note that this document intentionally repeats some information, particularly when waste management requires actions from multiple parties (e.g., overlapping responsibilities between waste generators and waste transporters). Information presented in the planning guidance is also intentionally repeated in the appendices to make it as accessible as possible for a wide variety of readers.

<sup>4</sup> This document is not intended to cover Category B infectious substances (UN 3373) nor Category A Infectious substances that affect animals only (UN 2900). Category A infectious substances that affect humans <u>and</u> animals are categorized as Category A Infectious substances, affecting humans (UN 2814).

<sup>&</sup>lt;sup>5</sup> <u>Appendix B – Infectious Agent Categorization</u> distinguishes these "cultures only" pathogens from other Category A pathogens.

# **ACRONYMS & GLOSSARY OF TERMS**

#### **ACRONYMS**

APHIS Animal and Plant Health Inspection Service

ASPR Administration for Strategic Preparedness and Response

BSAT Biological Select Agents and Toxins

CAA Clean Air Act

CBT Countering Biological Threats

CDC Centers for Disease Control and Prevention

c/o Cultures only

CFR Code of Federal Regulations

DHS U.S. Department of Homeland Security

DoD U.S. Department of Defense

DOE U.S. Department of Energy

DOL U.S. Department of Labor

DOT U.S. Department of Transportation

DTR Defense Transportation Regulation

EMS Emergency Medical Services

EMTALA Emergency Medical Treatment and Labor Act

EPA U.S. Environmental Protection Agency

EPCRA Emergency Planning and Community Right-to-Know Act

EVD Ebola virus disease

FBI Federal Bureau of Investigation

FDA Food and Drug Administration

FIFRA Federal Insecticide, Fungicide, and Rodenticide Act

HAZMAT Hazardous material

HAZWOPER Hazardous Waste Operations and Emergency Response

HBV Hepatitis B virus

HCIR Homeland and Critical Infrastructure Resilience

HFV Hemorrhagic fever virus

HHS U.S. Department of Health and Human Services

HICPAC Healthcare Infection Control Practices Advisory Committee

HIV Human immunodeficiency virus

HMIWI Hospital/medical/infectious waste incinerator

HMR Hazardous Materials Regulations

HW Hazardous waste

HWI Hazardous waste incinerator

ICAO International Civil Aviation Organization

IMDG International Maritime Organization Dangerous Goods Code

IV Intravenous

LDR Land Disposal Restriction

LEPC Local emergency planning committee

MMR Measles, mumps, and rubella

MPXV Monkeypox virus

N/A Not applicable

NETEC National Emerging Special Pathogens Training and Education Center

NESHAP National Emission Standards for Hazardous Air Pollutants

NIEHS National Institute of Environmental Health Sciences

NIOSH National Institute for Occupational Safety and Health

NSC National Security Council

NSPS National Special Pathogens System

OPIM Other potentially infectious materials

OSH Occupational Safety and Health

OSHA Occupational Safety and Health Administration

PHMSA Pipeline and Hazardous Materials Safety Administration

PPE Personal protective equipment

PUI Patient (or person) under investigation (i.e., for a disease)

RCRA Resource Conservation and Recovery Act

RESPTC Regional Ebola and Other Special Pathogens Treatment Center

RMW Regulated medical waste

SARS-CoV Severe Acute Respiratory Syndrome-associated coronavirus

SLTT State, local, tribal, and/or territorial

SP Special permit

TB Mycobacterium tuberculosis

Tdap Tetanus, diphtheria, and pertussis

TRACIE Technical Resources, Assistance Center, and Information Exchange

UN United Nations

USC United States Code

USG United States Government

USDA U.S. Department of Agriculture

WHO World Health Organization

#### **GLOSSARY OF TERMS**

Airborne transmission: One of the three main conventional routes of infectious disease transmission, which involves either airborne droplet nuclei (i.e., the infectious material left behind when liquid droplets containing infectious materials evaporate) or small particles in the respirable size range containing infectious agents. Once released from an infectious source, these small particles can stay suspended in the air for various amounts of time, depending on their size and various environmental factors, and travel a range of distances to a susceptible host (i.e., a person who does not have immunity to that specific pathogen. Larger particles settle (i.e., deposit) on environmental surfaces and other fomites. Some pathogens (i.e., germs) can remain viable in the air or on environmental surfaces and fomites for long periods of time. Infection can occur when the infectious particles enter the host, such as when they are breathed in from the air.

**Autoclave**: A sterilization machine that utilizes a standardized process involving saturated steam under pressure for a specified exposure time and at a specific temperature.

**Bioaerosol**: A suspension of airborne particles, generally comprised of microorganisms (e.g., bacteria, viruses) or materials of biological origin released from humans, animals, plants, soil, water, or other sources. Particles may range in size from very small to very large, and may include liquid droplets and materials left behind after such droplets evaporate (known as "droplet nuclei").

Biological Select Agents and Toxins (BSAT): See "Select agent."

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

Bloodborne Pathogens (BBP) standard: The Occupational Safety and Health Administration (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 applies to exposure to blood and 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, all body fluids in situations where it is difficult or impossible to differentiate between body fluids, any unfixed tissue or organ (other than intact skin) from a human (living or dead), and HIV-containing cell or tissue cultures, organ cultures, and HIV- or Hepatitis B virus (HBV)-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV. 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 the substance occurs. 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 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); shipments of select agents must be transported in accordance with federal select agent regulations. Infectious substances labeled "cultures only" in Appendix B – Infectious Agent Categorization are only considered Category A when a pathogen(s) is intentionally propagated, such as when a laboratory grows more of the pathogen for clinical diagnostic or biomedical research purposes. The other substances, such as Ebola virus (and other hemorrhagic fever viruses, HFVs) and variola virus (which causes smallpox), are considered Category A without being cultured.

**Category A waste**: Waste contaminated with a Category A infectious substance. This waste must be packaged and transported in accordance with the *Hazardous Materials Regulations* (HMR) or an applicable DOT special permit.

**Category B infectious substance**: An infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. Transport as Biological substance, Category B (United Nations (UN) 3373). See 49 CFR § 173.134(a)(1)(ii).

**Chemoprophylaxis**: Administration of medication before, during, or after possible or known exposure to a pathogen to prevent either infection or disease.

**Clean Air Act (CAA)**: The comprehensive federal law under the authority of which the U.S. Environmental Protection Agency (EPA) 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.

Contact transmission: One of the three main conventional routes of infectious disease transmission, which involves transfer of microorganisms from a source, such as an infected person, to a susceptible host, such as another person. Indirect contact transmission is when such transfer occurs through a contaminated intermediate object or person (i.e., a fomite). Direct contact transmission occurs when microorganisms are transferred without a contaminated intermediate object or person.

**Contaminated waste**: See "Category A waste," as these terms are used synonymously in the document. For clarity and differentiation, also refer to definitions for "Category B infectious substance" and "Regulated Medical Waste (RMW)."

**Disinfectant**: An antimicrobial product, typically in the form of a liquid or liquid-containing wipe that will make certain biological agents, such as bacteria or viruses, inactive. Such products should be a U.S Environmental Protection Agency (EPA)-registered disinfectant or one with microbial pathogen claims appropriate for the pathogen.<sup>6</sup> Although not covered in this document, this term can also apply to Food and Drug Administration (FDA)-regulated liquid products used specifically on critical devices.

**Droplet transmission**: The transfer of infectious agents by droplets traveling directly from a source, such as an infected person's respiratory tract, to susceptible mucous membranes of a recipient.

www.cdc.gov/vhf/ebola/prevention/cleaning-us-homes.html.

<sup>&</sup>lt;sup>6</sup> Such products are included in EPA's List L: EPA's Registered Antimicrobial Products that Meet the CDC Criteria for Use Against the Ebola Virus (see U.S. Environmental Protection Agency, "List L: EPA's Registered Antimicrobial Products that Meet the CDC Criteria for Use Against the Ebola Virus," last modified October 4, 2023, <a href="https://www.epa.gov/pesticide-registration/list-l-disinfectants-use-against-ebola-virus">www.epa.gov/pesticide-registration/list-l-disinfectants-use-against-ebola-virus</a>); U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Interim Guidance for U.S. Residence Decontamination for Ebola and Removal of Contaminated Waste," last modified August 5, 2015,

**Endemic**: The condition in which a particular disease is naturally present in a particular community, population, or geographic area.

**Fomite**: An object, item, or material (e.g., equipment, furniture, bedding, clothing) that can carry and spread pathogens.

Frontline healthcare facility: A healthcare facility that is prepared to rapidly identify and isolate patients who may have Ebola or other highly infectious diseases. Such a facility must be able to promptly inform: the hospital/facility infection control program; state and local public health agency; and an assessment hospital (which can receive and isolate patients under investigation for highly infectious diseases and care for such patients until a diagnosis can be made and until discharge or transfer is completed), or Regional Ebola and Other Special Pathogens Treatment Center (RESPETC) or state/jurisdiction treatment center (which can safely care for patients with highly infectious diseases in the event that a cluster of such patients overwhelms the RESPTC), as necessary, to arrange patient transfer. Frontline healthcare facilities are also responsible to provide stabilizing treatment, per the Emergency Medical Treatment and Labor Act (EMTALA) requirements. Frontline healthcare facilities are part of a tiered approached for managing suspected and confirmed cases of highly infectious diseases in the United States.

Generator: The person or persons whose act or process produces (i.e., generates) waste. This term generally provides a way to describe waste generators irrespective of what type of waste they produce (e.g., solid, liquid, semi-liquid, infectious, hazardous, etc.). However, this term has a specific meaning under the hazardous waste regulations of the *Resource Conservation and Recovery Act* (RCRA) subtitle C, and hazardous waste generators must adhere to specific requirements for both managing their hazardous waste on-site and ensuring proper management off-site. See the U.S. Environmental Protection Agency (EPA) <u>Hazardous Waste Generators page</u>. Despite sick patients' physiological processes generating waste (e.g., vomitus, feces), the term "generator" typically does not apply to such patients; instead, it applies to healthcare or medical transport organizations caring for and moving them, laboratories testing clinical samples obtained from them, environmental remediation companies cleaning their homes, or others whose activities result in creating the waste. *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 USC section 5103). The term includes hazardous substances, hazardous wastes, marine pollutants, elevated temperature materials (as defined at 49 CFR § 171.8), 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 *Hazardous Materials Regulations* (HMR). See 49 CFR § 171.8.

**Hazardous Materials Regulations (HMR)**: The U.S. Department of Transportation (DOT) regulations at 49 CFR parts 171-180.

**Hazardous waste**: A specific term defined in the *Resource Conservation and Recovery Act* (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 U.S. Environmental Protection Agency (EPA), specified in 40 CFR part 262.

**Hazardous Waste and Emergency Response Operations (HAZWOPER) standard:** The Occupational Safety and Health Administration (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.

**HAZMAT employee**: A person who, in the course of their employment directly affects hazardous materials transportation safety. This term includes a person, who during the course of employment: (1) loads, unloads, or handles hazardous materials; (2) designs, manufactures, fabricates, inspects, marks, maintains, reconditions, repairs, or tests a package, container, or packaging component that is represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce; (3) prepares hazardous materials for transportation; (4) is responsible for safety of transporting hazardous materials; or (5) operates a vehicle used to transport hazardous materials. See 49 CFR § 171.8.

**In 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. Transportation of a hazardous material in a motor vehicle, aircraft, or vessel operated by a federal or state, local, tribal, or territorial government employee solely for noncommercial federal or state, local, tribal, and/or territorial (SLTT) government purposes is not considered to be "in commerce" and so is exempt from the *Hazardous Materials Regulations* (HMR) under 49 CFR § 171.1(d)(5).

**Inactivated**: Having reached the point, through incineration, autoclaving, or other validated treatment, where the waste material is no longer infectious, does not pose an infection 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. This process can reduce large volumes of waste materials to ash and lessen toxic gaseous emissions. Residues or residuals (e.g., ash) from the combustion of hazardous waste are also potentially subject to *Resource Conservation and Recovery Act* (RCRA) regulations for disposal.

**Incinerator, hazardous waste (HWI)**: A type of combustor that is designed, operated, and permitted to burn hazardous waste. HWIs are subject to applicable federal and/or state, local, tribal, and/or territorial (SLTT) 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 (i.e., waste size and volume/weight throughput limits over a specified period of time, such as an hour) for HWIs is an important criterion to know before a biological incident occurs, as each HWI may be set up to accept different waste amounts and sizes.

**Incinerator, medical waste**: A type of incinerator that is designed, operated, and permitted to burn wastes produced by hospitals, veterinary facilities, and medical research facilities for the purpose of inactivating pathogens. These wastes include both infectious (i.e., red/biohazard bag) medical waste and non-infectious, general housekeeping waste. Hospital/medical/infectious waste incinerators are subject to applicable *Clean Air Act* requirements (40 CFR part 60). Waste feed capacity (i.e., waste size and volume/weight throughput limits over a specified period of time, such as an hour) for medical waste incinerators is an important criterion to know before a biological incident occurs, as each medical waste incinerator may be set up to accept different waste amounts and sizes.

**Infectious substance**: A material known or reasonably expected to contain a pathogen. *See also "Pathogen."* 

**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 as *Resource Conservation and Recovery Act* (RCRA) subtitle C landfills, are subject to different federal standards (40 CFR parts 264 and 265, subpart N) than non-hazardous waste landfills, which are often referred to as RCRA subtitle D landfills (40 CFR parts 257 and 258). In addition, state, local, tribal, and/or territorial (SLTT) 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 United States. U.S. Department of Labor (DOL)/Occupational Safety and Health Administration (OSHA) 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, and assist states in their efforts to assure safe and healthful working conditions through their own OSHA-approved State Plans. *See also "State Plan."* 

**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 *Hazardous Materials Regulations* (HMR) (49 CFR parts 171-180) for transportation of a 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 offeror 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 (i.e., a containment vessel for receiving and holding materials) and any other components or materials necessary for the receptacle to perform its containment function in conformance with the minimum packing requirements of the *Hazardous Materials Regulations* (HMR). See 49 CFR § 171.8.

**Pathogen**: A microorganism (including a bacterium, virus, parasite, or fungus) 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 or reduce exposure, including of the skin, eyes, face, head, extremities, respiratory tract, and mucous membranes, to hazardous substances (e.g., pathogens, chemicals, other materials) or other hazards (e.g., heat, electricity, sharps). See 29 CFR part 1910 subpart I.

**Prion**: a pathogenic agent that is able to cause abnormal folding of specific normal cellular proteins called "prion proteins," which are found most abundantly in the brain. This abnormal folding is associated with neurological disease in humans and animals. Prions are believed to made of protein (i.e., they are proteinaceous) and are highly resistant to all but the most destructive methods of inactivation. They require specific inactivation, disposal, and containment procedures.

**Regional Ebola and Other Special Pathogens Treatment Center (RESPTC)**: A specially-designated hospital, identified in partnership between the U.S. Department of Health and Human Services (HHS)/Administration for Strategic Preparedness and Response (ASPR), state and local public health

officials, and the hospital or healthcare system, that can be ready within eight hours to receive a patient with confirmed Ebola from its federal region, across the United States, or medically-evacuated from outside of the United States, as necessary. These hospitals have enhanced capacity to care for other highly infectious diseases and are part of a tiered approached for managing suspected and confirmed cases of such diseases in the United States.

**Regulated medical waste (RMW)**: A waste or reusable material derived from medical treatment of humans or animals including diagnosis and immunization; or from biomedical research, including production and testing of biological products. Regulated medical waste containing a Category A infectious substance must be classified as an infectious substance (either United Nations (UN) 2814, UN 2900, or UN 3549) and managed appropriately. See 49 CFR § 173.134(a)(5).

Exceptions to regulated medical waste include: 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; blood collected for transfusion or preparation of blood products sent for testing (unless believed to contain an infectious substance); laundry, medical equipment conforming to the Occupational Safety and Health Administration (OSHA) *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 at a college, hospital, or laboratory. See 49 CFR § 173.134(b).

**Residual**: A byproduct of waste treatment, such as ash left behind when waste materials are incinerated.

**Resource Conservation and Recovery Act (RCRA)**: The primary federal law governing the disposal of solid waste and hazardous waste. U.S. Environmental Protection Agency (EPA) regulations promulgated under the *Resource Conservation and Recovery* Act (RCRA) set standards for treating, storing, and disposing of hazardous waste.

**Select agent:** Also referred to as "biological select agents and toxins (BSAT)," a subset of biological agents and toxins that the U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) have determined have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. The current list of select agents and toxins can be found at 42 CFR §§ 73.3 and 73.4, 9 CFR §§ 121.3 and 121.4, and 7 CFR § 331.3, as well as at <a href="https://www.selectagents.gov">www.selectagents.gov</a>. See also 42 USC § 262a and 7 USC § 8401. <a href="https://www.selectagents.gov">Appendix B – Infectious Agent</a> <a href="https://www.selectagents.gov">Categorization</a> provides examples of HHS and USDA select agents and toxins. Note that while Category A infectious substances described in this document do not specifically include infectious nucleic acids, certain types of nucleic acid materials are regulated by the Federal Select Agents Program.

**Tier 1 select agent or toxin**: a subset of select agents and toxins that present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety.

**Sharps**: any objects, including needles, scalpels, lancets, and broken glass, that could cause needle sticks, puncture wounds, cuts or lacerations, or other such injuries to individuals who handle them or come into contact with them inadvertently (e.g., when they have not been properly disposed of in approved sharps containers).

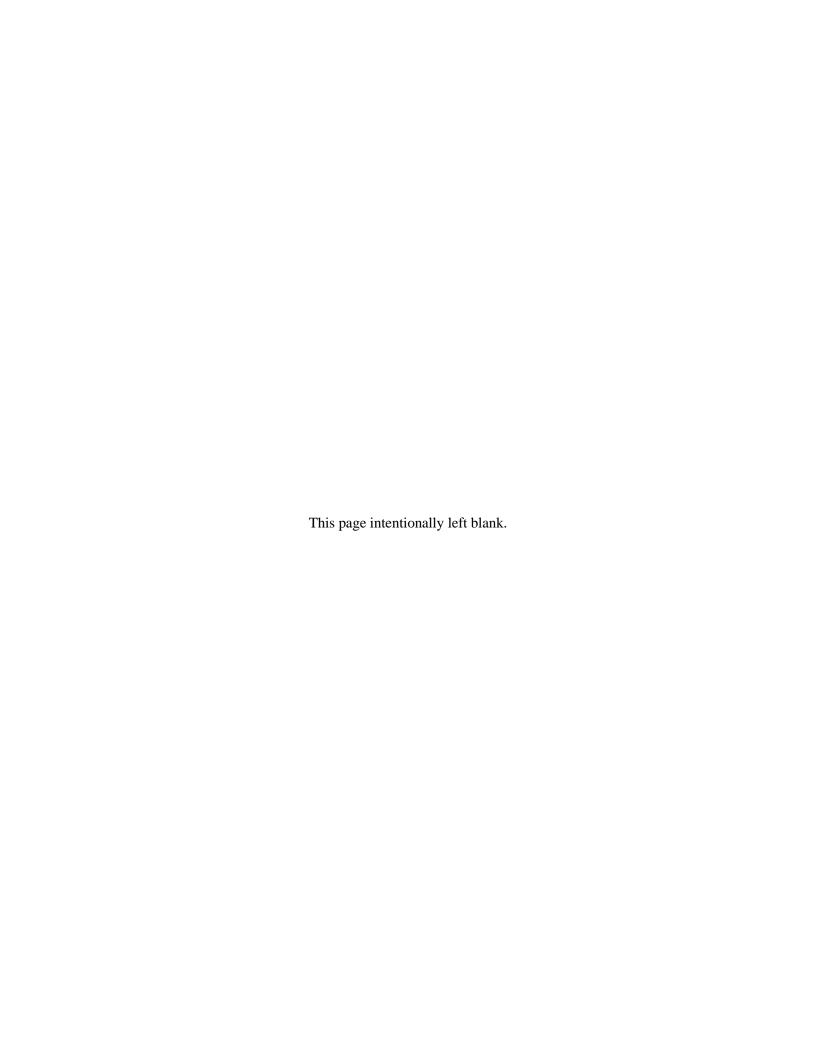
**Solid waste**: Any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, resulting from industrial, commercial, mining,

and agricultural operations, and from community activities, but does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to permits under the *National Pollutant Discharge Elimination System* at 33 USC § 1342, or source, special nuclear, or byproduct material as defined by the *Atomic Energy Act of 1954*, as amended (68 Stat. 923) [42 USC §§ 2011 et seq.]. Any garbage, 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. Certain materials are excluded from being defined as solid wastes, such as industrial point source discharges or domestic sewage. See *Resource Conservation and Recovery* Act (RCRA) 1004(27).

**Special permit**: A document issued by the U.S. Department of Transportation (DOT)/Pipeline and Hazardous Materials Safety Administration (PHMSA), or as otherwise prescribed in the *Hazardous Materials Regulations* (HMR), under the authority of 49 USC § 5117 permitting a person to perform a function that is not otherwise permitted under the HMR.

**State Plan**: An Occupational Safety and Health Administration (OSHA)-approved job safety and health program operated by an individual state or territory instead of federal OSHA. State Plans are monitored by OSHA and must be at least as effective as federal OSHA in protecting workers and in preventing work-related injuries, illnesses, and deaths. When this document was published, 28 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 workers. 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 the OSHA State Plans page.

**Validated**: A term used to describe a protocol or treatment cycle used for inactivating infectious materials (including waste) that has been shown to ensure the waste is no longer infectious. Validation often involves the use of biological indicators (e.g., *Bacillus* spore strips, 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 waste."* 



# PLANNING GUIDANCE FOR HANDLING SOLID WASTE CONTAMINATED WITH A CATEGORY A INFECTIOUS SUBSTANCE

# **KEY POINTS**

This section briefly summarizes key points in this planning guidance. It is meant to provide an overview of the document's recommendations for developing plans for managing solid waste contaminated with a Category A infectious substance (i.e., Category A waste). The remaining sections of the planning guidance provide important details about considerations for safe and effective waste management for which this summary is not a substitute.

- A Category A infectious substance is a material known or reasonably expected to contain a pathogen that is in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals who are exposed to it.
- Infectious waste, including materials contaminated with Category A infectious substances, can be managed safely.
- Leadership within healthcare facilities; laboratories; state, local, tribal, and/or territorial (SLTT<sup>7</sup>) governments; waste management companies; and other entities that may or will need to manage Category A waste should ensure their organizations have plans to address the entire waste lifecycle, from initial generation of the infectious waste to final disposition of any treated byproducts (residuals).
- Hospital care of a person infected with some pathogens classified as a Category A infectious substance, particularly Ebola or another hemorrhagic fever virus (HFV), can result in large volumes of potentially infectious waste, especially for diseases associated with severe illness and lengthy hospital stays.
- Outside of hospitals, people infected with some pathogens classified as Category A infectious substances, such as Ebola and other HFVs, may contaminate their homes, vehicles in which they travel, and other environments before they are hospitalized. Category A waste may also originate from laboratories (e.g., research, clinical) that work with Category A pathogens, particularly when they intentionally cultivate certain pathogens. Housing, care, and post-mortem management of animals infected with certain Category A pathogens also results in Category A waste.
- Every effort should be made to minimize the amount of Category A waste generated. Category A waste should be physically separated, if practical, from other solid waste at the point of origin.

<sup>&</sup>lt;sup>7</sup> Treatment, disposal and certain other waste management activities are typically regulated at the state or territorial level. However local and tribal governments may also have requirements that affect waste management activities within their jurisdictions. This guidance uses the "SLTT" acronym to describe state, local, tribal, and/or territorial requirements.

Similar considerations should be made for separating Category A waste from other, non-infectious hazardous materials.

- The U.S. Department of Transportation (DOT)/Pipeline and Hazardous Materials Safety Administration (PHMSA) regulates movement and certain other aspects related to management of Category A infectious substances, including waste that is known or suspected to be contaminated with them, through its *Hazardous Materials Regulations* (HMR). Additional federal and SLTT laws and regulations may apply to various aspects of waste management.
- Typically, the safest and best options for treating Category A waste so that it is no longer infectious—a process known as "inactivation"—are implemented on-site, where the waste is generated. Hospitals and laboratories often have on-site equipment that effectively inactivates waste when operated under validated (i.e., demonstrated to be effective) and permitted parameters. For example, autoclaves use saturated steam under pressure to heat materials to a high enough temperature for a long enough period of time to inactivate the pathogen(s) of concern in the waste. Medical incinerators with dual chambers burn materials at extremely high temperatures, leaving behind ash that is no longer infectious. Facilities without such equipment, SLTT governments responding to waste issues in the community, and others involved in waste management can also use portable autoclaves for waste inactivation. In specific circumstances, alternative treatment methods, including chemical disinfectants and alkaline hydrolysis digesters, may also be appropriate.
- When waste cannot be treated on-site, it must be sent off-site to special facilities typically operated by commercial waste management companies. These facilities, regulated and permitted by SLTT authorities, primarily use autoclaves and incinerators to treat waste on a larger scale than what most hospitals, laboratories, and other entities are capable of doing on-site.
- Before offering it for transportation, individuals and entities responsible for generating infectious waste must classify it appropriately, including as Category A waste when required under HMR requirements.
- Individuals and entities must classify waste as hazardous waste when required under *Resource Conservation and Recovery Act* (RCRA) requirements. These are set and enforced by the U.S. Environmental Protection Agency (EPA) or by states/territories authorized to implement the RCRA hazardous waste program in lieu of EPA.
- Category A waste may be safely transported off-site for inactivation in packaging meeting HMR requirements or the alternative packaging requirements of a DOT special permit. The HMR also require that waste transporters comply with certain labeling and paperwork (i.e., shipping papers) requirements. However, properly classifying (i.e., as Category A) and packaging waste begins at its point of origin.
- Management of waste that contains both a Category A infectious substance and certain other
  materials, such as those that are radioactive, must comply with regulations applicable to all
  substances in the waste. Such instances would need to be addressed on a case-by-case basis, and
  may require issuance of a special permit to address the unique combination of potentially
  hazardous materials.
- Waste that has been inactivated through an effective treatment method, along with any materials left over after treatment (i.e., residuals), is no longer infectious, poses no risk of infection, and is

not considered to be regulated medical waste (RMW) or a hazardous material<sup>8</sup> (unless other types of regulated hazardous materials, such as certain chemicals, are present) under federal or SLTT laws and regulations. Therefore, such waste is no longer considered a Category A infectious substance and is not subject to the requirements of the HMR for Category A infectious substances.

- Residuals, such as incinerator ash, must be evaluated to determine if the residual is still
  hazardous. Even though materials that have been properly incinerated are no longer infectious,
  ash may be categorized as hazardous waste due to its ability to concentrate certain toxic
  substances (e.g., metals) that may have been present in the original waste or in other waste
  incinerated at the same time.
- Residuals must be transported and disposed of in accordance with SLTT requirements and standard protocols for their disposal. Disposal options may vary depending on whether residuals contain hazardous materials. Disposal options also may need to consider requirements for managing inactivated waste that contains red bags, as the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens standard (29 CFR § 1910.1030) permits using red bags in lieu of biohazard labels to denote potentially infectious materials. As such, waste containing red bags typically cannot be disposed of with other municipal waste streams. Ultimate disposal facilities must meet federal requirements for environmental protection, which are generally incorporated into waste and air permits.
- Throughout the waste lifecycle, employers must protect workers from occupational exposure to pathogens, chemicals, other hazardous materials, and other hazards that could cause injury and illness. Even when handling waste materials that have been properly inactivated, workers can still be injured by sharps (e.g., needles, scalpels), broken glass, or other items that, even if non-infectious, can cause cuts or puncture wounds. A comprehensive worker protection program aims to eliminate hazards and implement engineering controls, safe work practices, administrative controls, and personal protective equipment (PPE) to prevent worker injuries and illnesses.
- At all stages of waste management, all involved parties should ensure effective communication
  with one another. For example, individuals and entities generating waste (referred to as "offerors"
  and "generators" in various contexts) must communicate with downstream waste transporters,
  treatment companies, and disposal facilities about the nature and content of the waste to help
  ensure safe, effective management of waste all the way to ultimate disposal.

# 1. Introduction

Infectious waste can be managed safely. This includes waste contaminated with a Category A infectious substance (herein, "Category A waste"), as defined in the Federal Government's *Hazardous Materials Regulations* (HMR) at 49 CFR parts 171-180. Section 2 – Category A Waste: What It Is And What It Is Not of this planning guidance and the Glossary of Terms further explain what is considered Category A waste.

In the United States, Category A waste typically comes from hospitals, other healthcare facilities, and laboratories. However, people with certain infectious diseases may also generate such waste at home or at

<sup>&</sup>lt;sup>8</sup> For more information, see definition of "hazardous material" in Glossary of Terms.

any place where they have been physically present. Particularly when incidents such as outbreaks of infectious diseases result in the generation of Category A waste, preparedness for managing that waste is critical to ensuring a safe and effective response. Planning efforts should involve healthcare systems (including hospitals and medical transport providers); waste management companies; state, local, tribal, and/or territorial (SLTT) governments; federal agencies; and other stakeholders who may participate or otherwise have interests in waste management activities during infectious diseases events—including isolated cases or clusters of cases, outbreaks, and epidemics.

This guidance addresses planning for Category A waste management activities, including considerations for developing, evaluating, and revising organizational (e.g., hospital or healthcare system) or jurisdictional (e.g., SLTT) plans (i.e., overarching strategies) and protocols (i.e., specific steps or actions). Following discussions of overarching planning considerations and governmental roles and responsibilities as they relate to Category A waste, the remaining sections of this guidance are structured around the waste lifecycle. They provide information for and describe responsibilities of those who generate, treat or inactivate, transport, and dispose of Category A waste. Lastly, a section on worker health and safety discusses protecting employees involved in waste management activities from initial generation to final disposition. The guidance is supplemented by several appendices that provide additional resources, assist with decision making, and address questions and answers about Category A waste.

# 2. CATEGORY A WASTE: WHAT IT IS AND WHAT IT IS NOT

Under the U.S. Department of Transportation (DOT) HMR, an infectious substance is classified as "Category A" if it is in a form (i.e., untreated) capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals upon exposure to the substance. This document refers to materials contaminated with Category A infectious substances as "Category A waste." Category A waste may be generated in the course of caring for a person with an infection caused by a pathogen that is considered to be a Category A infectious substance, from the home environment of such a person, and from laboratories working with Category A infectious substances. Appendix B – Infectious Agent Categorization provides examples of Category A infectious substances. Note that infectious substances labeled "cultures only" in the appendix are only considered Category A when a pathogen(s) is intentionally propagated, such as when a laboratory grows more of the pathogen for clinical diagnostic or biomedical research purposes. The other substances, such as Ebola virus (and other hemorrhagic fever viruses) and variola virus (which causes smallpox), are considered Category A without being cultured.

After proper treatment (as described in Section 6 – Waste Treatment Information and Responsibilities), waste is inactivated and therefore no longer contains pathogens capable of causing disease (i.e., is not infectious). After the treatment process, the waste no longer poses a health risk from biological agents and is not considered to be regulated medical waste (RMW)<sup>10</sup> or a hazardous material<sup>11</sup> (unless other types of regulated hazardous materials such as chemicals are present) under federal or SLTT laws and regulations. The same is true of byproducts associated with waste treatment (i.e., residuals), such as the ash left behind when Category A waste is incinerated. Therefore, such waste is no longer considered a Category A infectious substance and is not subject to the requirements of the HMR for Category A infectious

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<sup>&</sup>lt;sup>9</sup> Hazardous Materials Regulations, 49 CFR § 173.134(a)(1)(i) (2013).

<sup>&</sup>lt;sup>10</sup> For more information, see definition of "regulated medical waste" in Glossary of Terms.

<sup>&</sup>lt;sup>11</sup> For more information, see definition of "hazardous material" in Glossary of Terms.

substances. However, SLTT requirements may dictate disposal of certain residuals, including materials in red (i.e., biohazard) bags that have been autoclaved.

Waste or reusable materials from healthcare and laboratory operations, as well as from certain other activities, that are not considered Category A waste may be classified as RMW. Requirements for RMW vary among SLTT governments. However, whenever waste contains infectious substances other than those classified as Category A, this type of waste must be managed as Category B waste whenever the HMR also apply (e.g., during certain transportation activities). This document is not intended to cover routine transportation, treatment, or disposal of Category B waste (including RMW containing Category B infectious substances) or other non-infectious waste, except to the extent it addresses disposal of treated waste that once was Category A waste but is no longer infectious.

# 3. OVERARCHING PLANNING CONSIDERATIONS

Leadership within healthcare facilities, laboratories, SLTT governments, and other entities that may or will need to manage Category A waste should ensure their organizations have plans to address the entire waste lifecycle, from initial generation of the infectious waste to final disposition of any treated byproducts. Some organizations that will manage Category A waste at various points in its lifecycle may already have plans, such as security plans for hazardous materials transportation required by DOT under the HMR or waste management plans for hospital/medical/infectious waste incinerators required by the U.S. Environmental Protection Agency (EPA) under the *Resource Conservation and Recovery Act* (RCRA). Such existing plans may be modified to address management of Category A waste.

Waste management plans should detail how waste management tasks (classification, minimization, segregation, storage, treatment, disposal, terminal cleaning, etc.) will be accomplished, and they should provide jurisdiction- or facility-specific procedures. Each plan should incorporate input from appropriate SLTT health and environmental departments. Plans should focus on the safety of the people who will handle waste materials, including during on-site treatment, packaging, and transportation of waste for off-site treatment; the off-site treatment itself; and/or disposal of the waste. Potential exposures to pathogens, chemicals, other hazardous materials, and sharps in the waste must also be considered in this planning. Importantly, waste management plans also should consider ways to accurately and effectively communicate about exposure risks and vulnerabilities and measures for reducing or eliminating them.

#### **Facility Plans**

Hospitals, healthcare systems, clinical and research laboratories, and other facility-level plans should include protocols that reflect their capabilities for managing Category A waste. Facilities that intend to treat (i.e., inactivate) such waste on-site will plan differently than facilities that need to package, store, and transport waste off-site for treatment. For most facilities, protocols may address:

- Minimizing the amount of Category A waste generated. Category A waste should be physically separated, if practical, from other solid waste when it is generated. When mixed together with other solid waste, manage waste (e.g., other RMW) as Category A waste. Mixed waste streams that must be managed as Category A waste require significantly more resources (e.g., storage areas, packaging materials, transportation capacity under waste hauling contracts, disposal cost) than Category A waste streams that only contain Category A waste.
- Planning for the amount of Category A waste likely to be generated. Hospitals that will stabilize and transfer infectious patients to other facilities during infectious disease incidents (including isolated cases or outbreaks) may generate relatively little Category A waste. Facilities that anticipate managing seriously ill patients infected with Category A pathogens, such as those

- that are part of the national network of Regional Ebola and Other Special Pathogens Treatment Centers, should have sufficient on-site treatment capacity to inactivate the amount of Category A waste generated by their units, as appropriate for the unit's capacity. Such facilities should also plan ahead for the cost associated with generating, managing, and disposing of Category A waste, including directly in the course of patient care and in any supporting laboratory activities.
- Moving Category A waste within a facility. Use a pre-identified route from patient treatment areas (or, in laboratories and other facilities, areas where Category A waste is generated) to a secure storage location within the facility that serves as a waste holding area, either prior to inactivation on-site or for storage prior to transport for off-site inactivation. Transport Category A waste from the point of origin within the generating facility to a secure holding area with the use of covered push carts, bins, or other leak-proof containers to ensure that there is no release or spillage of the waste. Decontaminate the outside surfaces of all waste containers before moving them. Avoid high-traffic areas or divert other traffic while Category A waste is being moved through a particular area. Use designated elevators, such as freight elevators, if possible.
- Cleaning up spills. Develop spill clean-up protocols, assemble spill clean-up kits, and train staff on how to respond to and clean up spills consisting of blood, body fluids, and other potentially infectious or contaminated materials within the facility. Spill clean-up kits typically contain absorbent materials (such as clay cat litter or other absorbent granules), an appropriate disinfectant, and tools for clean-up (including of bulk materials). Spill clean-up kits may also include personal protective equipment (PPE) or other supplies workers may need to safely manage spills.
- Packaging waste for off-site treatment (if applicable). Section 6 Waste Transporter Information & Responsibilities discusses packaging requirements for Category A waste.
- Treating waste on-site (if applicable). <u>Section 7 Waste Treatment Information and Responsibilities</u> discusses Category A waste treatment.
- Storing packaged Category A waste containers prior to waste vendor transport. Facilities should comply with any additional SLTT requirements for storage time, temperature controls, and capacity. Emergency permits may be required for extended storage periods or to manage increased volumes of waste. Consider measures for separating the areas for Category A waste storage from other waste, locating the Category A wastes on impermeable/non-porous surfaces (i.e., floors without carpet, cracks, or gaps) and providing protection and security against spillage, weather, putrescence (i.e., rotting), pest infestation, trespassers, and theft. The waste holding area should adequately 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. Employers must also follow applicable U.S. Department of Labor (DOL)/OSHA requirements for signage and labeling (e.g., biohazard signs). See 29 CFR § 1910.1030(g).
- Transporting waste for off-site treatment. For any movement off-site, a detailed agreement or contract should be in place with an entity that holds (i.e., has party status to) a DOT/Pipeline and Hazardous Materials Safety Administration (PHMSA) special permit (SP). Facilities should have contingency plans, such as for extended waste storage, in the event that transportation infrastructure is compromised or a particular vendor is unable to immediately provide transportation services.
- Accepting waste from healthcare system partners. Smaller organizations, including ambulance services and other medical transport providers, may not have fixed facilities and equipment for properly managing Category A waste on their own. Category A waste generated in an ambulance transporting a patient to a hospital may need to be left at the hospital to be packaged or treated. (Medical transport providers and other entities outside of fixed facilities that may need to manage Category A waste should work with healthcare system partners, as appropriate, to plan for and safely conduct such activities.)

- Collaborating with SLTT public health and environmental agencies. Entities planning for Category A waste management activities should consider the extent to which pre-negotiated working relationships or partnerships may facilitate safe waste management activities. Facility leadership should work closely with SLTT health departments, environmental agencies, waste management regulators, and other appropriate entities and officials to ensure that their plans for managing waste do not conflict with any SLTT prohibitions related to the inactivation and disposal of Category A waste. Additionally, facilities and their waste management contractors should understand what requirements SLTT authorities may place on the transport of waste within their jurisdictions.
- **Protecting worker health and safety**, including by training staff. <u>Section 9</u> discusses worker health and safety considerations.
- Exercising waste management plans. Exercises, and broader infectious disease incident preparedness efforts, prepare teams (e.g., hospital and laboratory staffs) to respond effectively to the situations for which plans are developed, and help identify weaknesses in planning efforts before protocols must be implemented in response to real-world incidents.
- **Reviewing and updating plans.** As facility needs, regulatory requirements, and other factors change, facilities should regularly review and update their plans. Plans should also be updated to reflect lessons learned from exercises or real-world response activities.

#### **Jurisdictional Plans**

SLTT government plans should include protocols that reflect the types of waste management needs and challenges their jurisdictions may face. Plans may vary significantly depending on legal requirements, capabilities, and infrastructure within a particular SLTT jurisdiction, as well as the scenario(s) on which they are based. The presence of hospitals, laboratories, or other public facilities (e.g., airports, bus depots, and train and rail stations) that may generate Category A waste; accessibility of facilities to treat and dispose of waste; and other factors are likely to influence plans.

In developing waste management plans at the local level, governments may choose to utilize their existing local emergency planning committees (LEPCs). Established under the *Emergency Planning and Community Right-to-Know Act* (EPCRA), LEPCs develop emergency response plans, review those plans at least annually, and provide citizens with information about potential hazards specific to the community. To incorporate stakeholder input, LEPCs are comprised of

- Elected state and local officials.
- Police, fire, civil defense, and public health professionals.
- Environment, transportation, and hospital officials.
- Facility representatives.
- Representatives from community groups and the media.

The local public health authority, in conjunction with SLTT health and environmental officials, needs to direct the handling of Category A waste. The level of direction and support that waste generators require may vary significantly, depending on the generators' capabilities. For example, jurisdictions with treatment centers, including those designated as a *Level 1:Regional Ebola and Other Special Pathogens Treatment Center (RESPTC)* within the National Special Pathogen System (NSPS) or other specially trained and equipped facilities, may need to provide less intensive support to such well-prepared entities compared to jurisdictions planning for Category A waste management at other healthcare facilities. At a minimum, all jurisdictions should be prepared to manage Category A waste generated in residential settings.

In a locality where a person is known or suspected to have a disease caused by a pathogen that is classified as a Category A infectious substance, the SLTT public health authority is in the best position to assess environmental contamination in residential environments and provide guidance about how to manage waste associated with remediation activities. For example, when diseases caused by Category A infectious substances are transmitted through contact with infectious body fluids, hard, non-porous items such as furniture in a person's residence can often be safely cleaned on-site using acceptable practices. When safe, on-site decontamination is not possible, such as for porous items, contaminated items should be handled as Category A waste and packaged, transported, and treated off-site. The determination whether the items are Category A waste or not is usually based on a variety of factors, including clinical assessment of the patient (e.g., whether the patient has a suspected or confirmed diagnosis of a disease caused by a Category A infectious agent), the types of materials contaminated and what they were used for, and whether the items pose a public health risk. Section 5 – Waste Generator Information and Responsibilities provides more information about classifying waste.

For most jurisdictions, plans may address:

- Managing waste from residential environments. In some instances, the local health authorities may recommend the use of a biohazard/environmental remediation company already under contract to decontaminate the environment or transport safely packaged Category A waste from a patient's home to the hospital for safe processing. In other instances, they may initiate a separate Category A waste transport contract. Contractors must transport Category A waste in full compliance with the HMR or in compliance with a special permit, if applicable.
- Containing and packaging Category A waste as close as possible to the point of generation. If this cannot be accomplished due to space limitations, site-specific protocols should be followed. Once primary waste containment has taken place, staff should refrain from opening containers to manipulate waste unless handling is essential.
- Storing packaged Category A waste containers prior to waste vendor transport, if applicable. Localities should comply with any additional SLTT requirements for storage time, temperature control, and volume. Emergency permits may be required for extended storage periods or to manage increased volumes of waste. Consider measures for separating the areas for Category A waste storage from other waste, locating the Category A wastes on impermeable surfaces (i.e., non-concrete floors without carpet, cracks, or gaps) and providing protection and security against spillage, weather, putrescence, pest infestation, and trespassers. The waste holding area should adequately 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.
- Identifying routes for transporting Category A waste for off-site treatment. Previous incidents revealed that elected officials and their constituents were sometimes concerned about the transport of Category A waste through their communities—in a few instances, to the point of such officials prohibiting Category A waste from being transported along SLTT roadways. Identifying acceptable routes and transportation support protocols, such as law enforcement escorts, in advance of the need to move Category A waste will ensure that waste can be appropriately transported for off-site inactivation and disposal as needed.
- Coordinating with surrounding jurisdictions. Some SLTT governments may wish to align their plans and protocols for managing Category A waste to ensure consistency between

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<sup>&</sup>lt;sup>12</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Interim Guidance for U.S. Residence Decontamination for Ebola and Removal of Contaminated Waste," last modified March 2, 2015, www.cdc.gov/vhf/ebola/prevention/cleaning-us-homes.html.

- neighboring jurisdictions. Coordinating with surrounding jurisdictions may also allow for prenegotiation of mutual aid agreements that may be useful in the event that an infectious disease incident in a particular jurisdiction exceeds its capacity to respond without additional support.
- Collaborating with potential waste-generating organizations within the jurisdiction.

  Jurisdictions planning for Category A waste management activities should consider the extent to which pre-negotiated working relationships or partnerships may facilitate safe waste management actions. SLTT health and environmental officials may be involved in overseeing and coordinating collection, storage, inactivation, transportation, and disposal of waste generated within their jurisdictions. SLTT government agencies should communicate to facilities, medical transport providers, and waste management contractors about any requirements they may place on the transport of waste within their jurisdictions. SLTT government agencies should also engage potential waste-generating organizations within their jurisdictions, as appropriate, to plan ahead for the cost associated with generating, managing, and disposing of Category A waste, including materials resulting from patient transport, patient care, and other supporting/related activities.
- **Protecting worker health and safety**, including by training staff. <u>Section 9</u> discusses worker health and safety considerations.
- Exercising waste management plans and protocols. Exercises, including as part of broader infectious disease preparedness efforts, prepare teams (e.g., SLTT emergency responders, health and environmental officials) to respond effectively to the incidents for which plans and protocols are developed, and to help identify errors, threats, risks, weaknesses, and vulnerabilities in planning efforts before protocols must be implemented in response to real-world incidents.
- Reviewing and updating plans and protocols. As jurisdictional needs, regulatory requirements, and other factors change, SLTT governments should regularly review and update their plans and protocols. These should also be updated to reflect lessons learned from exercises or real-world response activities as well as risk, threat, and vulnerability assessments.

# 4. FEDERAL GOVERNMENT ROLES & RESPONSIBILITIES

Various aspects of managing Category A waste are regulated by several different agencies, including DOT/PHMSA and the DOL/OSHA. (Note: Category A waste is also subject to SLTT environmental and health regulations. There may also be overlap between requirements for managing Category A waste from laboratories and the federal select agent regulations of HHS/Centers for Disease Control and Prevention (CDC) at 42 CFR parts 72 and 73 and U.S. Department of Agriculture (USDA) at 7 CFR part 331 and 9 CFR part 121.) In addition, facilities that inactivate Category A waste on-site (i.e., at the point of generation) are subject to the DOT HMR requirements for packaging, handling, and transporting these wastes before inactivation occurs, as well as for training and certifying staff responsible for those activities.

# **Regulatory Requirements**

U.S. Department of Transportation

The DOT HMR (49 CFR parts 171-180) apply to waste contaminated (or suspected by the offeror<sup>13</sup> to be contaminated) with any Category A infectious substance. Appendix B – Infectious Agent Categorization

<sup>&</sup>lt;sup>13</sup> For more information, see definition of "offeror" in Glossary of Terms.

provides examples of Category A infectious substances.<sup>14</sup> As noted in <u>Section 2</u>, infectious substances labeled "cultures only" in the appendix are only considered Category A when a pathogen(s) is intentionally propagated. In these cases, the Category A infectious substance HMR apply to some laboratory-generated materials (i.e., cultures) but not to patient specimens that are not cultured nor to waste from patients. PHMSA is responsible for regulating and advancing the safe and secure transportation in commerce<sup>15</sup> of hazardous materials across all modes of transportation.

For Category A infectious substances in the United States, HMR classification criteria and packaging requirements are consistent with international standards, which follow criteria developed by the United Nations (UN) Subcommittee of Experts, working with the World Health Organization (WHO), CDC, medical professionals, microbiologists, transportation professionals, and packaging technical experts. The criteria are also consistent with the requirements contained in the 23<sup>rd</sup> edition of the *United Nations Recommendations for the Transport of Dangerous Goods*, the 2023–2024 edition of the International Civil Aviation Organization (ICAO) *Technical Instructions for the Safe Transport of Dangerous Goods by Air*, and the 41-22 edition of the International Maritime *Dangerous Goods Code*. <sup>16</sup>

Whenever transporting Category A waste involves steps that are not covered by the HMR, such as the use of alternative packaging materials, a special permit is required. DOT/PHMSA has the primary responsibility for the issuance of DOT special permits and approvals to the HMR.

The solid waste generated in a local area (e.g., in a residential environment prior to an infected person's hospital admission) or in the care of persons with suspected or known exposure to a Category A infectious substance and wastes from laboratories that are contaminated with Category A infectious substances from intentionally propagated pathogen cultures are also subject to procedures set forth by federal and SLTT requirements.<sup>17</sup> Wastes from non-Category A infectious substances must also be managed in ways that meet applicable federal and SLTT requirements.

#### U.S. Department of Labor/Occupational Safety and Health Administration

Throughout the waste lifecycle, DOL/OSHA requires employers to protect workers from workplace safety and health hazards. A variety of such hazards are associated with managing Category A waste, including pathogens and sharps in the waste itself and chemicals used to treat the waste and clean environments and equipment. OSHA standards for <u>bloodborne pathogens</u> (BBP, 29 CFR § 1910.1030), <u>PPE</u> (29 CFR 1910 subpart I), and <u>hazard communication</u> (29 CFR § 1910.1200), as well as other OSHA

<sup>&</sup>lt;sup>14</sup> The DOT HMR do not contain or reference a list of Category A infectious substances, and the list in <u>Appendix B</u> – <u>Infectious Agent Categorization</u> is provided as guidance only. In the case of a discrepancy between the examples provided and the criteria for Category A (see 173.134(a)(1)(i)), the criteria take precedence.

<sup>&</sup>lt;sup>15</sup> For more information, including governmental exemptions, see definition of "in commerce" in Glossary of Terms.

<sup>&</sup>lt;sup>16</sup> U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, *Transporting Infectious Substances Safely* (Washington, DC, 2022), <a href="www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-safely">www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-safely</a>.

<sup>&</sup>lt;sup>17</sup> In the case of an incident resulting from suspected or actual terrorism or other criminal activity, certain solid waste, including Category A waste, may be considered as evidence. (The Attorney General, generally acting through the Federal Bureau of Investigation (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.

requirements may apply during various waste management activities. <sup>18</sup> For additional information, see Section 9 – Protecting Worker Health and Safety of this guidance.

# U.S. Environmental Protection Agency

The EPA sets and enforces federal hazardous waste regulations under the RCRA. As a general matter, under RCRA and the majority of state and territorial 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 SLTT hazardous waste regulations may be more stringent or broader in scope than 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. Under EPA requirements, waste generators are responsible for determining if waste is hazardous waste.

# Federal Select Agent Program

Some agents are regulated by the HHS/CDC and USDA Federal Select Agent Program (7 CFR part 331, 9 CFR part 121, and 42 CFR part 73). These biological agents and toxins must be inactivated or destroyed before final disposal or, in most cases, prior to being transferred as outlined in Section 16 of the federal select agent regulations. Wastes generated during the treatment of patients infected with a select agent identified as a Category A infectious substance by the HMR (e.g., Ebola viruses, Marburg viruses, Lassa fever virus) are not subject to the federal select agent regulations as long as the material has been subjected to decontamination or a destruction procedure (See the exclusion provision 42 CFR §§ 73.3(d)(3) and 73.4(d)(3))).

#### **Non-Regulatory Activities**

#### U.S. Environmental Protection Agency

The EPA generally does not regulate medical waste itself. However, federal regulations establish minimum criteria for facilities that accept waste for ultimate disposal. See <u>Appendix A – Additional Resources</u> for further information.

#### U.S. Department of Health and Human Services

HHS/CDC and HHS/Administration for Strategic Preparedness and Response (ASPR) provide technical guidance for managing Category A waste. See <u>Appendix A – Additional Resources</u> for more information.

# 5. WASTE GENERATOR INFORMATION & RESPONSIBILITIES

Managing Category A waste at the point of generation requires a multi-pronged approach that includes waste minimization, proper classification, and appropriate storage (i.e., a secure location and segregation from other wastes). These considerations apply regardless of whether a person with an infection caused

<sup>&</sup>lt;sup>18</sup> Bloodborne Pathogens, 29 CFR § 1910.1030 (2012); Personal Protective Equipment, 29 CFR part 1910 subpart I (2016); Hazard Communication, 29 CFR § 1910.1200 (2013).

by a Category A agent creates waste in the residential environment before hospital admission, medical treatment or transport generates the Category A waste, or Category A waste results from laboratory work or other activities. The following information is critical for generators of waste. Additional information about managing waste at its point of generation can also be found in the appendices of this document, including Appendix D – Questions and Answers.

# **Waste Minimization and Segregation**

As described previously, take steps to minimize the amount of Category A waste generated. Category A waste may be physically separated, if practical, from other solid waste when it is generated, before the two waste streams have been mixed. When mixed together, manage Category A waste and other solid waste (e.g., other RMW) as Category A waste. Mixed waste streams that must be managed as Category A waste may require significantly more resources (e.g., packaging materials, storage areas, transportation capacity under waste hauling contracts) than Category A waste streams that only contain materials that actually need to be managed as Category A waste.

#### Managing Large Amounts of Waste Associated With Patient Care Activities

Care of patients known or suspected to have diseases caused by a Category A infectious substance can result in substantial amounts of waste. During the 2014 Ebola outbreak, patient care activities sometimes resulted in more than ten 30-55-gallon packages a day due to the amounts of PPE required for hospital staff. 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 a patient room. Doing so limits the volume of items in the contaminated area, thereby limiting the volume of items that will ultimately require 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 Category A waste protocol. The mattress can then be cleaned using the facility's existing procedures for terminal cleaning (i.e., for materials that do not need to be managed as Category A).

Regardless of whether Category A waste is generated in hospitals, laboratories, residences, ambulances, or other settings, it is critical that facility staff, emergency responders, remediation contractors, and others handling the waste be made aware of the ultimate treatment method for the waste and its implications for what types of materials can be processed safely. No matter whether waste will be inactivated on-site or transported for off-site inactivation, staff should be cognizant of the materials going into waste streams since the operators of downstream treatment equipment (e.g., autoclaves, incinerators) will be unable to segregate or separate materials within Category A waste. Materials that might cause problems with 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. Waste that presents explosive hazards (e.g., batteries, sealed containers or oxygen cylinders) may require special handling. During an incident resulting in Category A waste, there should be routine communication among staff and the operators of downstream treatment equipment to ensure they are following the optimal procedures for managing waste. Information and training on these considerations should be part of the overall waste management plan, both for facility- and jurisdiction-level plans.

#### **Determining Classification and Handling of Waste**

For transportation under the HMR, it is the offeror's responsibility to properly classify hazardous materials, including infectious substances. This classification determines how the material must be

packaged for transport. The offeror must ensure and arrange for training and testing in accordance with the requirements of the HMR for any employee classifying a hazardous material or performing any function subject to the requirements of the HMR.<sup>19</sup>

# Difference between the Terms "Offeror" and "Generator"

This document discusses individuals and entities who produce waste as "offerors" and "generators" in various contexts.

As defined in the <u>Glossary of Terms</u>, an offeror is a person who performs or is responsible for performing any pre-transportation function required under the HMR for transportation of a hazardous material in commerce and/or who tenders or makes the hazardous material available to a carrier for transportation in commerce.

A generator is a person 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.). Under RCRA subtitle C, 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.

In some instances, these terms may be interchangeable, as the same person or persons may generate and offer waste. However, this document also describes responsibilities specific to the offeror under the HMR and to the generator under RCRA regulations.

Hazardous material classification should involve consultation with the generator or the group with the best knowledge of the situation in which the waste was created. For healthcare facilities, this group would include infectious disease personnel working in collaboration with relevant SLTT public health, environmental, and/or waste management authorities. In turn, local governments should engage SLTT public health and waste management authorities to make these decisions in the most informed manner possible. Classification of an infectious substance is typically based on the source's (e.g., human, animal) medical history or symptoms (if applicable), laboratory processes that generated the material, endemic local conditions, and/or professional judgment concerning the individual circumstances of the source. When managing potentially infectious waste from patients, classification usually involves consideration of clinical assessment of the patient (e.g., whether the patient has a suspected or confirmed diagnosis of a disease caused by a Category A infectious agent) and whether the items pose a public health risk. Typically, anything that comes into contact with or that is contaminated with body fluids from patients with a disease caused by a Category A infectious substance (other than those designated as "cultures only" in Appendix B – Infectious Agent Categorization) is classified as Category A waste. However, this precautionary approach may increase the volume of waste that must be managed as Category A. In any case, once an offeror classifies a material as Category A waste, it must be classified as UN 2814, infectious substances, affecting humans, or as UN 3549, Medical waste, category A, affecting humans.

Separately from classification under the HMR, it is the generator's responsibility to make an accurate waste determination under RCRA.<sup>20</sup> Determinations as to whether waste is hazardous inform how and

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<sup>&</sup>lt;sup>19</sup> Hazardous Materials Regulations, 49 CFR § 172.702 (1996).

<sup>&</sup>lt;sup>20</sup> As mentioned elsewhere in the text, the RCRA hazardous waste regulations do not classify a waste as "hazardous" based on its infectious nature (though SLTT regulations may be more stringent or broader in scope). However, the waste could still be defined as RCRA hazardous due to the presence of certain toxic metals or other chemicals.

where the waste will be disposed and whether treatment under the RCRA *Land Disposal Restrictions* (LDRs) is necessary or otherwise required prior to disposal.

Consultation between waste offerors and generators, if separate and distinct from each other, helps to facilitate the waste's classification as a Category A substance under the HMR and/or as hazardous under the RCRA, as appropriate. Collaboration between offerors and generators also helps to ensure that waste can be effectively and efficiently managed.

There may be multiple steps in the waste lifecycle involving waste generators. For example, some off-site treatment facilities generate incinerator ash as part of waste treatment. As generators, they must make accurate determinations for any residuals and determine how and where that waste will be disposed.

Waste offerors and generators must also comply with applicable SLTT public health, environmental, waste management, and other regulations.

# Considerations for Waste Generators Planning to Ship Waste Off-Site for Inactivation

Waste generators who anticipate the possibility of sending waste off-site should plan in advance for its transportation. Under most circumstances, such planning should include a pre-arranged contract(s) with a qualified waste hauler(s) and protocols for properly packaging any waste to be transported off-site.

#### Arranging Waste Transportation

Most hospitals, laboratories, and other entities that generate Category A waste, including those that manage such waste as part of environmental remediation efforts in residential or other environments, should have detailed agreements or contracts in place with a waste hauler that holds (i.e., has party status to) a DOT/PHMSA special permit for the specific type of waste that will be moved. When making transportation arrangements, entities generating waste must ensure that any company considered for a contract has proper training, equipment, and supplies for safely handling Category A waste. Such companies must be able to comply with the HMR, including as discussed in Section 6 – Waste Transporter Information and Responsibilities.

Note that transportation of a hazardous material in a motor vehicle, aircraft, or vessel operated by a SLTT government employee solely for noncommercial federal or SLTT government purposes is not considered to be "in commerce" and so is exempt from the HMR under 49 CFR § 171.1(d)(5). Note, however, that when more stringent, agency-specific policies exist for a federal or SLTT department, agency, or organization, that department, agency, or organization must follow the more stringent requirement and comply with the HMR, as appropriate. For example, U.S. Department of Defense (DoD) personnel transporting Category A waste must follow *Defense Transportation Regulation* (DTR) 4500.9-R, Part II, Chapter 204. Similarly, SLTT personnel transporting waste must follow their own SLTT medical waste regulations.

Facilities inactivating waste on-site should also plan for managing the residuals, including materials that have been inactivated through autoclaving or ash from on-site incinerators. After proper treatment (as described in Section 7 – Waste Treatment Information and Responsibilities), waste no longer contains pathogens capable of causing disease (i.e., is not infectious), does not pose a health risk from biological agents, and is not considered to be RMW or a hazardous material<sup>21</sup> (unless other types of regulated

<sup>&</sup>lt;sup>21</sup> For more information, see definition of "hazardous material" in Glossary of Terms.

hazardous materials, such as chemicals, are present) under federal and SLTT laws and regulations. However, additional SLTT requirements may govern transportation and disposal of these types of materials.

All facilities relying on waste management companies to transport waste away from their on-site storage areas should maintain contingency plans, such as for extended waste storage, in the event that transportation infrastructure is compromised or a particular vendor is unable to provide transportation services on schedule.

#### Packaging Category A Waste

The HMR require that all hazardous materials are properly packaged and labeled by a properly trained person, according to the regulations' packaging requirements. Under special circumstances, the DOT may issue a special permit that allows for alternative packaging compared to what the HMR otherwise require. This packaging must be equal to or greater in safety to what the HMR require. When alternative packaging is needed (e.g., when required packaging is not feasible for large volumes of waste or when required packaging materials are not available for purchase on the market), DOT can issue a special permit.<sup>22</sup> Issued under the authority of 49 USC § 5117, special permits allow a person to perform a function that is not otherwise permitted under the HMR.

Although complying with the stowage and handling requirements of special permits is the responsibility of waste transporters (sometimes called "haulers" or "carriers"), proper waste packaging starts at the point of generation and in conjunction with hazardous materials classification (as required by the HMR), hazardous waste determinations (as required under the RCRA), and waste segregation, as described above. Facilities and jurisdictions planning for off-site transportation of waste should work with the waste management contractors they select to identify proper, HMR- or special permit-compliant packaging for the types of waste they anticipate generating or managing.

DOT provides guidance on <u>how to use the HMR</u>, which explains how to identify packaging requirements for infectious substances in the regulations. DOT also maintains a <u>searchable database</u> of special permits, which include specific packaging requirements. Question 6 in the

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<sup>&</sup>lt;sup>22</sup> In some cases, packaging manufacturers may be able to produce larger, non-bulk packages that meet the HMR requirements at 49 CFR § 178.609 or larger packaging that meets the requirements of 49 CFR subparts P and Q. The availability of such packaging may eliminate the need for a special permit.

Waste Transportation Questions & Answers section of <u>Appendix D – Questions and Answers</u> provides additional information about this topic.

It is critical for facilities and jurisdictions to train their workers on the requirements of proper packaging prior to the waste being generated. Specialized protocols for packaging Category A waste, including any packaging specifically approved through a special permit, may differ from the packaging requirements for RMW that healthcare workers use routinely. Employers must ensure that workers packaging waste at its point of generation can do so safely and in compliance with the HMR and OSHA's *Bloodborne Pathogens* (29 CFR § 1910.1030) and other standards. Particularly with respect to the HMR, working with a qualified waste transporter can help waste generators understand exactly what needs to be done to ensure compliance with applicable laws and regulations and to ensure the safety of their workers, the public, and the environment.

# 6. WASTE TRANSPORTER INFORMATION & RESPONSIBILITIES

Whenever Category A waste, as determined by an offeror, cannot be inactivated on-site, waste generators—including hospitals; laboratories; other types of facilities; environmental/biohazard remediation companies; and federal and SLTT government agencies not transporting the waste themselves in a non-commercial capacity—will need to work with a qualified transporter (sometimes called "haulers" or "carriers") to ship the waste off-site for treatment (i.e., inactivation) and ultimate disposal. Transporters must ensure that they comply with all DOT regulations, particularly the HMR, during the transportation of Category A wastes to protect the health and safety of their employees, the public, and the environment. This section discusses the general HMR requirements for transporters. Additional information is also available in the appendices of this document, including Appendix D — Questions and Answers.

As this guidance has explained, the HMR regulate infectious substances as hazardous materials. The HMR apply to transportation of any material that DOT determines is capable of posing an unreasonable risk to health, safety, and property when transported in commerce. DOT/PHMSA regulates movement of hazardous materials across all modes of transportation; and an infectious substance (e.g., Category A waste) must conform to all applicable HMR requirements when offered for, or actually transported by, air, highway, rail, or water.<sup>23</sup>

The HMR provide clear regulations for classification, packaging, and communication procedures for Category A infectious substances. Category A waste may only be transported in two scenarios: in full compliance with classification and packaging requirements of the HMR, or under the terms of a DOT special permit. The latter scenario allows for transportation the waste in a manner that deviates from conventional, established HMR methods (e.g., using alternative packaging). DOT maintains a <a href="maintains-searchable-database">searchable database</a> of special permits.

Although the overall management of Category A waste and best practices for complying with the HMR or a DOT special permit begin prior to the generation of the waste, the HMR primarily regulate waste

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<sup>&</sup>lt;sup>23</sup> U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, *Transporting Infectious Substances Safely* (Washington, DC, 2022), <a href="www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-safely">www.phmsa.dot.gov/transporting-infectious-substances-safely</a>.

transportation and storage. The HMR continue to apply throughout transportation and storage, until waste is no longer infectious (i.e., it has been inactivated).

#### **Interstate and Intrastate Movement**

The HMR apply to the transportation of hazardous materials in interstate (i.e., between states) or intrastate (i.e., within the same state) commerce, which includes the movement of the hazardous material, as well as its loading, unloading, or storage. This is a preemptive regulation that applies regardless of the state in which the waste originated or to which it travels.

SLTT governments may have additional requirements for infectious waste transportation. Transporters and others involved in managing Category A waste must comply with any applicable requirements in the jurisdictions in which they operate. Individual SLTT governments may have additional licensing or approval requirements for infectious waste transporters.

#### **Exemptions from Hazardous Materials Regulations**

For waste generated by patients in transportation, several exceptions may apply. The HMR do not apply to the patients themselves, but may apply to waste created during transport. Transportation of Category A waste as part of air ambulance operations is exempt from the HMR.<sup>24</sup> A similar exception applies to waste transported during motor vehicle ambulance operations under 49 CFR § 177.823(a)(3). After the patient exits the aircraft or motor vehicle, the waste is subject to the HMR. The HMR also provides exceptions for hazardous materials transported under the direct supervision of the DoD or the U.S. Department of Energy (DOE) for the purpose of national security, and for air transport by an aircraft under the exclusive direction and control of the government under 49 CFR § 173.7.<sup>25</sup>

If government employees transport the waste for destruction, the transportation would be excepted because the HMR do not apply to the transportation of hazardous materials in a motor vehicle, aircraft, or vessel operated by a government employee solely for noncommercial, government purposes. <sup>26</sup> If contractors transport the waste, the transportation would be subject to the HMR unless they qualify for one of the exceptions above. In most cases a contractor would need to apply for a special permit.

# Packaging, Labeling, and Shipping Papers

The HMR require that all hazardous materials, including Category A waste, are properly packaged and labeled according to the packaging requirements outlined in the regulations. All transporters must comply with the HMR. As stated above, wastes that are suspected or known to be contaminated by Category A infectious substances are a hazardous material. As such they may only be transported in two scenarios: in

<sup>&</sup>lt;sup>24</sup> Hazardous Materials Regulations, 49 CFR § 175.1(d) (2016).

<sup>&</sup>lt;sup>25</sup> An aircraft is under the exclusive direction and control of a government when the government exercises responsibility for: (1) Approving crew members and determining they are qualified to operate the aircraft; (2) Determining the airworthiness and directing maintenance of the aircraft; and (3) Dispatching the aircraft, including the times of departure, airports to be used, and type and amount of cargo to be carried. See Hazardous Materials Regulations, 49 CFR § 173.7(f) (2018).

<sup>&</sup>lt;sup>26</sup> Hazardous Materials Regulations, 49 CFR § 171.1(d)(5) (2018).

full compliance with classification and packaging requirements of the HMR, or under the terms of a special permit as outlined in this section.

Under special circumstances, DOT may issue a special permit that allows for alternative packaging compared to what the HMR require. Issued under the authority of 49 USC § 5117, special permits allow a person to perform a function that is not otherwise permitted under the HMR. With respect to packaging for Category A waste, packaging authorized under a special permit must be equal to or greater in safety to what the HMR would ordinarily require. Although complying with the stowage and handling requirements of special permits is the responsibility of waste transporters, proper waste packaging starts at the point of generation and in conjunction with hazardous waste classification (as required by the HMR) and hazardous materials determinations (as required under the RCRA) and waste segregation, as described in Section 5. Waste transporters should work with their clients (i.e., offerors of Category A waste) to ensure use of proper, HMR- or special permit-compliant packaging for the types of waste they have been contracted to transport. Transporters also should contact and work closely with DOT to ensure that all of the most current procedures are being followed.

DOT may make modifications to the special permit and may or may not approve transporters to use the special permit. If a transporter wishes to be party to the special permit, it must apply for party status with DOT before transporting any waste to which the special permit applies. DOT issues special permit party status letters to approved transporters. That status is usually granted for two years, but may vary under special circumstances. If a transporter chooses to have alternative packaging to what is in the current special permit, it may apply for its own special permit.

The HMR also require that all hazardous materials are accompanied by a shipping document that provides information on the type of hazardous material in the vehicle transporting it. A shipping document must accompany all Category A infectious substances being transported in commerce.

Transporters should work closely with SLTT health departments, environmental agencies, waste management regulators, and other appropriate entities and officials to ensure that their plans for managing waste do not conflict with any SLTT prohibitions related to the inactivation and disposal of Category A waste. Additionally, waste transporters and their clients (i.e., offerors of Category A waste) should understand what requirements SLTT authorities may place on the transport of waste within their jurisdictions.

# **Transporting Select Agents**

Select agents are a subset of biological agents and toxins that HHS and USDA have determined have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. The table in <u>Appendix B – Infectious Agent Categorization</u> includes select agents.

Importation and interstate shipment involving select agents is regulated by HHS and USDA through their select agent regulations (7 CFR part 331, 9 CFR part 121, and 42 CFR part 73). The Animal and Plant Health Inspection Service (APHIS)-CDC Form 2, *Request to Transfer Select Agents and Toxins*, is used to request prior authorization of a transfer of select agent from the Federal Select Agent Program.

# 7. WASTE TREATMENT INFORMATION & RESPONSIBILITIES

All facilities and jurisdictions planning for managing Category A waste should consider how any waste they generate and/or offer for transport will be treated (i.e., inactivated). A variety of options exist for waste inactivation, including autoclaving, incineration, and, in certain circumstances, chemical

alternatives. Depending on facility or jurisdiction capabilities, the volume of waste needing treatment, and other factors, these options may be deployed on-site (i.e., where the waste is generated) or off-site (e.g., at specialized waste management contractors' facilities). This section discusses considerations for several possible scenarios involving these treatment modalities in the context of both on- and off-site treatment. The tool in <u>Appendix C – Decision Matrix for Waste Treatment</u> also traces key decisions in the treatment and the ultimate disposal of waste, including for waste treated on-site and for waste that cannot be treated on-site.

Whenever possible, on-site treatment is highly recommended since off-site treatment may increase risk to staff, waste handlers, and the public due to the additional steps that need to be taken to package, transport, and inactivate the waste off-site. If a hospital, laboratory, or other facility has on-site treatment capabilities for inactivation, those processes should be validated and periodically tested to ensure they function properly—and will continue to do so during an infectious disease event that will result in Category A waste. Validation is the responsibility of the equipment operator and may be an SLTT requirement.

When on-site treatment is not an option, facilities and jurisdictions need to identify waste management contractors capable of transporting and treating waste off-site, ideally in advance of the need for such services. Section 5 discusses selecting a waste management contractor(s).

A waste management plan that considers on-site incineration should include a method for disposing of residuals (e.g., ash, autoclaved materials). Ultimately, management of residuals from an effective treatment operation should include testing the materials and making a determination about how and where such waste should be disposed. See the discussion of waste determinations in Section 5. Residuals from Category A wastes that have been fully inactivated either through autoclaving, incineration, or alternative methods described in this section are no longer infectious and should be disposed of in accordance with the applicable SLTT regulations. Section 8 – Final Disposal Information & Responsibilities discusses disposal in more detail.

#### Waste inactivation methods

#### Autoclaving

Category A waste can be inactivated using an autoclave operating within permitted parameters as outlined by the manufacturer and validated by the operator. An autoclave uses saturated steam under pressure to heat materials to a high enough temperature for a long enough period of time to inactivate the pathogen(s) of concern in the waste. Such time and steam pressure 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 or SLTT requirements (unless other types of regulated hazardous materials, such as chemicals, are present). Some infectious agents (e.g., prions, spores, and pathogens within biofilms) are particularly stable in the environment and difficult to inactivate.

Autoclave operators should validate that their waste inactivation procedures meet required performance standards as outlined by the manufacturer or any applicable SLTT requirements and effectively inactivate pathogens of concern, including achieving certain exposure time and temperature requirements, acceptable results on biological indicators (e.g., *Bacillus* spore strips) or other test assays, and allowable concentration of certain pollutants or contaminants in any effluent or other by-product of the process. For example, staff should check the autoclave cycles frequently with validated biological indicators (such as commercially available spore-ampoule systems) placed in simulated locations to ensure adequate steam

penetration within the waste as a quality assurance measure to show that the waste treatment cycles are achieving desired results.<sup>27</sup>

Autoclave cycle parameters may also vary significantly depending on the types, conditions, and amounts of materials being autoclaved. For instance, frozen laboratory specimens or large volumes of liquid may require longer cycle times or changes to other autoclave settings. When autoclaving waste that has been packaged according to applicable requirements for Category A infectious substances (including certain alternative packagings allowed under a Special Permit), it may also be necessary to run multiple sequential autoclave cycles without opening the door, in order for waste to reach the desired conditions.

Many organizations require autoclaves to be inspected annually by professionals to ensure proper operation and maintenance. Autoclave operators should keep records that include details of all autoclave runs, biological indicator test results, maintenance, and repairs.

#### Incineration

Incineration is a thermal method of treatment using combustion to reduce waste to ash and flue gases. Medical incinerators with dual chambers run at extremely high temperatures, well above the relatively low temperatures needed to kill (i.e., inactivate) most Category A organisms. Incineration that reduces waste to ash at any temperature inactivates almost all infectious substances (except prions, as noted previously), including those classified as Category A. Combustion at or above 1,000°C/1,832°F is necessary to destroy prion infectivity.

Incineration, if available on-site and properly permitted, would be the best method for large or bulky items, such as mattresses (though consideration should be given to whether there are size limits for on-site incinerators) that may be associated with terminal (i.e., final) cleaning after hospital patient discharge or residential environmental remediation activities. Incinerator operators should be cognizant of large, bulky, porous items that are wet so as not to feed materials into the incinerator system in a way that impedes heat transfer into those large, wet items. It is crucial that large, wet items fed into the incinerators receive enough heat within the solid-phase residence time to boil off any absorbed water and combust prior to dropping into the ash collection system.

EPA regulates hospital/medical/infectious waste incinerators under the *Clean Air Act* (CAA). These facilities require permitting and specialized equipment for the combustion of the waste and the proper management of the remaining air or flue gases to ensure safe emissions. Considering the CAA's hospital/medical/infectious waste incinerator (HMIWI) regulations, it will be unlikely that hospitals would install incinerators in anticipation of managing Category A waste on-site. However, such facilities should work closely with the SLTT air permitting departments if they determine this is an option they would like to pursue. Commercial waste management companies in the United States continue to operate some incineration facilities capable of (i.e., with the capacity to and proper permits for) inactivating Category A waste.

#### Alternative Methods

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

<sup>&</sup>lt;sup>27</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Information on the Survivability of the Ebola Virus in Medical Waste," modified February 12, 2015, www.cdc.gov/vhf/ebola/healthcare-us/cleaning/ebola-virus-survivability.html.

facilities, preclude the use of autoclaves or incinerators. Chemical disinfection is commonly used for surface decontamination. When waste includes body parts, tissues, organs, or other such materials (i.e., anatomical waste) from humans or animals, alkaline hydrolysis digesters (i.e., tissue digesters) may be an appropriate alternative method. 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 SLTT levels. Users of these alternative methods may need to consider worker health and safety issues; the potential for triggering other federal environmental (e.g., under the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA)), safety, and health regulations; and the need to manage residuals from such methods.

#### Additional considerations

Activities and processes associated with inactivating Category A waste may be subject to other federal (e.g., OSHA) and SLTT requirements. For instance, employers may be required to provide training and implement controls, including PPE, to protect workers operating autoclaves. Employers may also need to take steps to protect workers who manage residuals from waste treatment processes, as these 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. Worker health and safety is specifically addressed in Section 9 – Protecting Worker Health and Safety.

It is critical that staff handling Category A waste be made aware of the ultimate treatment method for the waste. No matter whether waste will be inactivated on-site or transported for off-site inactivation, staff should be cognizant of the materials going into waste streams, as the operators of downstream treatment equipment (e.g., autoclaves, incinerators) will be unable to segregate or separate materials within Category A waste. Materials that might cause problems with 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. Waste that presents explosive hazards (e.g., batteries, sealed containers, or oxygen cylinders) may require special handling. During an event, there should be routine communication among staff and the operators of downstream treatment equipment to ensure they are following the best procedures for managing waste. Information and training on these considerations should be part of the overall waste management plan, both for facility- and jurisdiction-level plans.

#### **Considerations for On-Site Inactivation**

Facilities, including hospitals and laboratories, 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 most hospital autoclaves usually can. Challenges to these operations include resources for hooking up gas, water, and electrical supplies, as well as managing effluent (e.g., liquid discharge) from portable equipment. For example, in-line filters on the liquid exhaust may be suggested for some types of Category A waste. Care should be taken in the selection of an autoclave to ensure that

<sup>&</sup>lt;sup>28</sup> Ingrid H. Franke-Whittle, and Heribert Insam, "Treatment Alternatives of Slaughterhouse Wastes, and Their Effect on the Inactivation of Different Pathogens: A Review," *Critical Reviews in Microbiology* 39, no. 2 (2013): 139-151, <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3622235/">www.ncbi.nlm.nih.gov/pmc/articles/PMC3622235/</a>; World Health Organization, Global Healthcare Waste Project, "Non-Incineration Treatment and Disposal of Healthcare Waste," modified October 2016, <a href="https://www.who.int/water\_sanitation\_health/facilities/waste/module15.pdf">www.who.int/water\_sanitation\_health/facilities/waste/module15.pdf</a>.

the type of autoclave is appropriate for the waste and that all safety guidelines are followed. Treatment parameters for portable autoclaves should also be validated prior to use on particular wastes.

Facilities that have autoclave units intended for typical medical, laboratory, or other wastes should test surrogate waste in advance of an event to ensure that the parameters being used are sufficient for the potential change in waste streams (e.g., more PPE, different materials, etc.). These facilities should check to see if there are any prohibitions against their autoclave operation and discuss this with SLTT environmental or health department in the jurisdiction in which they operate. They should also ensure they have sufficient capacity to handle any increase in waste volume associated with an infectious disease event that results in Category A waste.

Whenever Category A waste is moved for inactivation within a facility, waste management plans should address how such movement will be accomplished. For example, identify a route from patient treatment areas (or, in laboratories and other facilities, areas where Category A waste is generated) to a secure storage location within the facility that serves as a waste holding area prior to inactivation on-site. If reusable carts are used to move the waste, plans should provide for setting up a decontamination area where the waste is transferred to the treatment system.

Hospitals that have in-unit (i.e., in special pathogen patient care areas) autoclaves should run and test equipment periodically if it is not in continuous use.

#### **Considerations for Off-site Inactivation**

It is highly recommended that Category A wastes be treated on-site whenever possible. 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.

Whenever Category A waste is moved for packaging and storage within a facility prior to being transported off-site for inactivation, waste management plans should address how such movement will be accomplished. For example, identify a route from patient treatment areas (or, in laboratories and other facilities, areas where Category A waste is generated) to a secure storage location within the facility that serves as a waste holding area prior to off-site transportation. If reusable carts are used to move the waste, plans should provide for setting up a decontamination area where the waste is transferred to the storage area.

## Packaging Requirements for Category A Wastes, Including DOT Special Permits

Packagings for Category A waste are almost exclusively designed to transport small samples between laboratories, and are not adequate to move large volumes of waste. In 2014, in order to facilitate movement of large volumes of Ebola contaminated waste, a Category A infectious substance, DOT issued a special permit to authorize alternative packagings, subject to additional operational controls. Packaging manufacturers may be able to produce larger non-bulk packages that meet the requirements of 49 CFR § 178.609 or make large packaging in accordance with 49 CFR subparts P and Q.

#### Autoclaving

Commercial autoclave processing facilities are typically permitted by the SLTT environmental or health department in the jurisdiction in which they operate. These facilities are required to have operating plans or permits that outline how the facility will operate and the types of wastes they are permitted to treat.

These plans should include controls to show that the waste is inactivated effectively. For example, staff should check the autoclave cycles frequently with biological indicators (e.g., *Bacillus* spore strips) as a quality assurance measure to show that the waste treatment cycles are achieving desired results.<sup>29</sup>

Considering that some of the packaging and waste streams being treated may be different than normal medical wastes, commercial processing facilities should test surrogate waste in advance of an event to ensure that the parameters being used are sufficient for the potential change in waste streams (i.e. more PPE, different materials etc.) and more robust packaging. Commercial facilities should not open containers to remove waste before processing the waste through the autoclave. However, containers must be loosely capped or vented and solid waste bags must be loosely packed and loosely closed during autoclaving for effective inactivation of infectious agents. Again, this may be different than the way the facility typically operates and the ability to safely and effectively process unopened containers should be tested in advance of accepting this type of waste. Commercial facilities should check to see if there are any prohibitions against their autoclave operations in their permit or operating plans and discuss this with SLTT environmental or health department in the jurisdiction in which they operate. Commercial facilities should also ensure they have sufficient capacity to handle the increase in volume associated with an infectious disease event that results in Category A waste. Facilities accepting this waste should also have a backup plan for the management of the waste in the event of an operational issue.

#### Incineration

In most circumstances, off-site transportation will likely be needed for incineration. Incineration of Category A waste is subject to applicable federal and/or SLTT laws and regulations.

Commercial incineration facilities are typically permitted by the SLTT environmental or health department. These facilities are required to have operating plans or permits that outline how the facility will operate and the types of wastes they are permitted to treat. These plans should include controls to show that the waste is inactivated effectively. For example, staff should check the incineration times, temperatures, and all appropriate air pollution control systems. Ash generated by these facilities is also subject to regulations to determine how any remaining residuals must be properly disposed of.

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 should be transported and disposed of in accordance with SLTT regulations and standard protocols for waste disposal. The ultimate disposal facility must meet federal minimum criteria, which are generally incorporated into waste and air permits.

#### Additional considerations

Commercial facilities accepting Category A waste for off-site treatment should have a backup plan for the management of such waste in the event of an operational issue, such as equipment failure at the treatment plant or delays in transporting residuals to disposal sites.

<sup>&</sup>lt;sup>29</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Information on the Survivability of the Ebola Virus in Medical Waste," modified February 12, 2015, www.cdc.gov/vhf/ebola/healthcare-us/cleaning/ebola-virus-survivability.html.

#### 8. FINAL DISPOSAL INFORMATION & RESPONSIBILITIES

The ultimate disposition of waste, including any residuals from inactivation of Category A waste, depends on a number of factors, including the characterization of the waste and residuals, SLTT laws and regulations, and permit conditions for particular treatment/disposal facilities. As Section 4 explained, as a general matter, under the RCRA and the majority of state/territorial 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 SLTT hazardous waste regulations may be more stringent or broader in scope than federal regulations). However, waste could still be hazardous as defined under RCRA regulations due to the nature of contaminating materials (e.g., presence of certain toxic metals or chemicals, such as solvents). Determination of waste as being hazardous versus non-hazardous under the RCRA is made independently of the presence or absence of infectious agents. Under EPA requirements, waste generators are responsible for determining if a particular waste is hazardous waste.

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/territorial level, but there are minimum federal criteria that solid waste facilities must meet in 40 CFR part 257 and federal criteria for municipal solid waste landfills in 40 CFR part 258. In addition, many states/territories have specific statutory or regulatory requirements for identification, treatment, and disposal of medical waste.

Items that were previously Category A waste, once inactivated through autoclaving, incineration, or other validated methods, are no longer considered to be Category A infectious substances under the HMR. Inactivated materials will not generally be subject to specific federal RCRA hazardous waste regulations. However, waste determinations for residuals should consider situations involving mixed materials (e.g., non-infectious solid waste with hazardous waste). As solid wastes, the inactivated material may be subject to SLTT regulations. As some states/territories have additional requirements for treated medical waste, including additional documentation or specific management requirements, facilities need to check with the SLTT governments for the jurisdictions in which they operate and comply with those regulations.

Since situations vary, this section outlines considerations for final disposition and planning by facilities and jurisdictions in which waste may be generated and facilities that will receive the waste and/or residuals for ultimate disposal.

In determining how to dispose of waste/residuals, consider whether the Category A waste been properly treated to inactivate pathogens it may have or was known to contain. Consult with the intended disposal facility's operator to determine waste analysis and acceptance procedures.

## **Inactivated Category A Waste Alone**

If other types of hazardous waste are not present and 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 of the fact that the waste has been inactivated. The waste may be subject to additional SLTT solid waste regulations or SLTT regulations for treated medical waste, including additional requirements for documentation, rendering the waste

unrecognizable, or other management steps. Facilities must understand and comply with these requirements.

- The facility where the properly inactivated waste (or residuals) is located should:
  - Verify with its SLTT regulatory official that the waste may be treated as a solid waste.
  - Confirm any SLTT-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 disposal facility's management/owner 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.

# Category A Waste that Has Not Been Inactivated

If the Category A waste has not been inactivated (i.e., it remains Category A waste), then:

- The Category A waste requires special handling in accordance with the HMR, as outlined in this guidance; disposal options are likely more limited.
- The entity generating the waste should:
  - Verify the classification of the waste (e.g., Category A, hazardous) with the appropriate SLTT regulatory official.
  - Choose a facility permitted for such materials (e.g., medical waste incinerator; hazardous waste incinerator, or HWI; HMIWI; other incinerator; or autoclave). Whether a particular facility may receive such material depends on its permit(s).
  - 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 under the HMR or applicable DOT/PHMSA special permit, including using appropriate packaging for Category A requirements and follow all packaging instructions prior to transport.
  - Verify that the disposal facility's management/owner is willing to accept the waste.
  - Have a contingency plan in case the disposal facility is unavailable.
  - Verify that the disposal facility also has a contingency plan to handle disruptions.
  - After shipping the waste, verify that the disposal facility properly received and processed the waste.

#### **Disposing of Treated Waste Residuals**

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 RCRA or the appropriate SLTT 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.<sup>30</sup> If the treatment residuals do not meet the definition of "hazardous," then they may be disposed of in accordance with applicable requirements for solid waste disposal.

The tool in Appendix C – Decision Matrix for Waste Treatment also traces key decisions in the treatment and the ultimate disposal of waste. The tool describes the paths both for waste that may be inactivated onsite 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 SLTT regulations. If the waste is no longer infectious and does not contain some other hazardous material, it is then transported to an off-site disposal facility permitted under SLTT regulations (typically at the state/territory level) 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). As mentioned previously, SLTT requirements may dictate disposal of certain residuals, including materials in red (i.e., biohazard) bags that have been autoclaved. If on-site treatment is performed but the treatment does not result in inactivation of the Category A waste, then the waste must be either retreated on-site or sent off-site for treatment and disposal. Other types of hazards present (e.g., mixed hazard wastes) may be either treated on-site or off-site.

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 SLTT 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, HMIWI, or HWI. The waste is treated (incinerated) and the residuals are tested. If the residuals do not meet the definition of a RCRA hazardous waste, they may be disposed of in a solid waste facility (e.g., RCRA subtitle D landfill). If the residuals test as hazardous, then they would need to be categorized and managed as a hazardous waste, which includes applicable RCRA treatment (distinct from inactivation, such as stabilization for toxic metals) followed by disposal at a permitted, RCRA subtitle C facility. Again, SLTT requirements may dictate disposal of certain residuals, including materials in red (i.e., biohazard) bags that have been autoclaved.

Ultimately, the key factor is that 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 that poses a health risk from the originating infectious substance. However, as discussed above, other factors need to be considered prior to ultimate disposal.

# 9. PROTECTING WORKER HEALTH AND SAFETY

Protecting workers during handling, transport, treatment, and disposal of Category A waste begins before the waste is generated, through anticipation, assessment, identification and planning for occupational

<sup>&</sup>lt;sup>30</sup> Under the RCRA, hazardous wastes are disposed of in carefully constructed units designed to protect the environment, including groundwater and surface water resources.

exposure risk and appropriate control measures. Remember that infectious agents in Category A waste are not the only hazards that may be present. Hazard assessments and control measures must also account for chemicals, radioactive materials, sharps, and other health and safety hazards to which workers may be exposed.

The first and best strategy for protecting workers is to control hazards at their sources: if possible, minimize the amount of waste generated, and ensure plans are in place to manage and contain 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. Control measures should be set that protect against all hazards present, including cases of mixed hazards. Under OSHA standards for bloodborne pathogens (29 CFR § 1910.1030), PPE (29 CFR part 1910 subpart I) including respiratory protection (29 CFR § 1910.134) (i.e., respirators to prevent inhalation of infectious materials), and hazard communication (29 CFR § 1910.1200), as well as other OSHA requirements, employers must protect workers who handle Category A waste.<sup>31</sup>

A comprehensive protection program for waste workers relies on a hierarchy of engineering controls, administrative controls, and safe 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 at various steps throughout the waste lifecycle. For example, instruct and train healthcare workers generating Category A waste during care of an infectious patient to package the waste properly (i.e., according to the HMR) instead of requiring environmental services workers to also handle the waste. In waste hauling and treatment operations, limit the number of staff who handle Category A waste.
- Whenever gloves are removed or changed, wash hands with soap and water for at least 20 seconds, or use alcohol-based hand rubs followed by hand-washing as soon as possible. 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.
- Wear dedicated work clothing while on the job. Change clothing and shower as soon as possible if work clothing becomes soiled.
- Discard soiled work clothing and PPE with other Category A waste.
- Wear dedicated, washable footwear while on the job.

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<sup>&</sup>lt;sup>31</sup> Bloodborne Pathogens, 29 CFR § 1910.1030 (2012); Personal Protective Equipment, 29 CFR part 1910 subpart I (2016); Hazard Communication, 29 CFR § 1910.1200 (2013). With some exceptions, OSHA's *Occupational Exposure to Hazardous Chemicals in Laboratories standard* (29 CFR § 1910.1450, 2012) supersedes, for laboratories, the requirements of all other OSHA health standards in 29 CFR 1910 subpart Z.

- 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 standard* (29 CFR § 1910.1030) only 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, such those for Hepatitis A; influenza; measles, mumps, and rubella (MMR); and tetanus, diphtheria, and pertussis (Tdap). Vaccine offerings should consider anticipated exposures based on hazard and risk assessment.
- Plan, train workers for, and be ready to implement emergency response procedures for incidents such as spills and potential exposures.
- Consider making chemoprophylaxis available to workers as part of post-exposure follow-up and care, as needed.

## **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:

- For healthcare (and, to some extent, laboratories):
  - o Barriers with windows or closed-circuit television monitors that minimize the need for workers to use PPE to enter patient care areas, thus minimizing total volume of waste.
  - Needleless IV systems, retractable syringes, and other devices designed to prevent needle stick injuries. These systems protect workers at the point of waste generation and downstream waste workers.
- For waste storage and transportation:
  - Rigid containers to transport waste off-site or within a facility, including puncture-proof
    containers for sharps. If reusable carts are used to move waste within a facility, such as a
    hospital or waste treatment plant, a decontamination area should also be set-up in the area
    where the waste is transferred to the treatment system.
  - o Puncture-proof, leak-proof, and tip-resistant containers for inactivated waste or on-site storage/disposal.
  - Packaging that meets the requirements of OSHA's *Bloodborne Pathogens standard* (29 CFR § 1910.1030) and DOT's HMR (or exceptions outlined in a special permit, if applicable).
  - O Suitable shelves, straps, or other equipment—especially in transport vehicles, where containers may move or shift—to secure stacked Category A waste containers.

- For waste treatment:
  - o Equipment that ventilates outside the work area when treating Category A waste.
  - o Barriers (with windows or closed-circuit television monitors) between areas where waste processing equipment operates and where workers may control or observe the equipment.

#### **Safe 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. Waste management facilities must train workers how to perform their jobs safely, including follow appropriate work practices and administrative controls:

- When utilizing onsite inactivation, develop a transportation and packaging plan that minimizes repacking and staff handling. If reusable carts are used, a decontamination area should be setup in the area where the waste is transferred to the treatment system.
- Package waste in accordance with OSHA's *Bloodborne Pathogens standard* (29 CFR § 1910.1030), <u>CDC guidelines</u>, and the 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).
- Secure waste containers to prevent them from tipping.
- 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 Category A 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.<sup>32</sup>

<sup>32</sup> U.S. Department of Labor/Occupational Safety and Health Administration, U.S. Department of Health and Human Services/Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health,

and U.S. Environmental Protection Agency, *Safe Handling, Treatment, Transport and Disposal of Ebola-Contaminated Waste*, FS-3766 (Washington, DC, 2016), <a href="www.osha.gov/Publications/OSHA\_FS-3766.pdf">www.osha.gov/Publications/OSHA\_FS-3766.pdf</a>.

- 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 that the machine is off, the worker correctly uses appropriate PPE, and the worker follows proper lockout/tag-out 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 appropriate 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 (e.g., chemicals). Note that some hazardous chemicals should not be autoclaved. Even though these items are sterile after treatment (assuming use of an effective inactivation protocol), they can still cause cuts, puncture wounds, or other injuries.

## **Personal Protective Equipment**

The OSHA *PPE standard* (29 CFR § 1910.132) 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. PPE selections should address hazards for specific workplaces and tasks, and may vary significantly for workers performing differing operations throughout the waste lifecycle.

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* (29 CFR part 1910 subpart I). Employer and workers may also consult OSHA's *PPE Selection Matrix for Occupational Exposure to Ebola Virus* for additional guidance on PPE for healthcare, laboratory, janitorial, and waste management workers who may be involved in waste management tasks.<sup>33</sup> Note that PPE may vary for Category A infectious substances associated with exposures and transmission mechanisms different than those anticipated with Ebola virus.

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). Employers must also comply with applicable provisions of OSHA's *Hazard Communication standard* (29 CFR § 1910.1200).

When workers may be exposed to aerosolized infectious particles, employers must implement a respiratory protection program that complies with the OSHA *Respiratory Protection standard* (29 CFR § 1910.134). 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

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<sup>&</sup>lt;sup>33</sup> U.S. Department of Labor, Occupational Safety and Health Administration, *PPE Selection Matrix for Occupational Exposure to Ebola Virus*, FS-3761 (Washington, DC, 2015), www.osha.gov/Publications/OSHA3761.pdf.

certain chemicals used in waste packaging procedures or for cleaning and decontaminating equipment and surfaces.<sup>34</sup>

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 infectious materials (i.e., those contaminated with infectious agents); only remove respirators after leaving work areas where air contaminants (e.g., airborne-transmissible or other potentially aerosolized agents) may be present. The order of donning and doffing of PPE items 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. Employers and workers should refer to updated guidance from OSHA and CDC for the most current information about recommended donning and doffing procedures for particular Category A infectious agents. Disposal procedures for single-use PPE items should help reduce the risk of self-contamination and, if possible, minimize the amount of Category A waste generated. Reusable PPE should be decontaminated or packaged for decontamination following task- or facility-specific procedures.

# **Worker Training**

General Occupational Safety and Health 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 *Bloodborne Pathogens standard* (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 Category A 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 are inadvertently exposed to Category A waste.

In addition, employers must train workers required to use PPE on what equipment is necessary, how to don and doff it 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 type of visual and interactive training helps to ensure that PPE is used in ways that achieve the intended protection and that workers do not come into contact with 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

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<sup>&</sup>lt;sup>34</sup> Consult OSHA's *Respiratory Protection standard* (29 CFR § 1910.134), 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: U.S. Department of Labor, Occupational Safety and Health Administration, "Respiratory Protection," last modified May 16, 2019, <a href="www.osha.gov/SLTC/respiratoryprotection">www.osha.gov/SLTC/respiratoryprotection</a>. Consider all respiratory hazards (biological, chemical, etc.) when selecting respirators to protect workers.

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 respirator fit check.

#### Hazardous Materials Training

DOT also requires HAZMAT employers to provide training for HAZMAT employees, in accordance with 49 CFR § 172.702 and 49 CFR § 172.704.<sup>35</sup> All HAZMAT employees who perform functions subject to the HMR must be provided with general awareness, function-specific, safety, and security awareness training within 90 days of new employment or a change in job function; recurrent training must be provided at least every three years.

## **Hazardous Waste Operations and Emergency Response**

Routine Category A 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 Category A waste.

Employers, such as those with contracts to transport Category A waste under a DOT special permit, should be familiar with the provisions of the *HAZWOPER standard* (29 CFR § 1910.120), including paragraph (q) for emergency response, and be prepared to comply with the standard, as needed. For emergency response operations that fall under the *HAZWOPER standard* (29 CFR § 1910.120), 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 OSHA and DOT requirements at the same time.

Although not every employer's operations fall under the scope of the *HAZWOPER standard* (29 CFR § 1910.120), developing emergency plans can ensure a safe, effective response when emergencies, including releases, substantial threats of releases of, or potential exposures to, hazardous substances do occur. Employers should evaluate their risk and develop plans for emergency incidents. Such plans should address worker safety and health considerations, SLTT requirements, DOT/PHMSA training and security plan requirements, and the requirements of any DOT-issued special permits.

<sup>&</sup>lt;sup>35</sup> See 49 CFR § 171.8 for definitions of HAZMAT employer and HAZMAT employee.

# APPENDIX A – ADDITIONAL RESOURCES

These documents are provided as supplemental resources to this guidance for managing Category A waste.

#### **Waste Management**

- Managing Materials and Wastes for Homeland Security Incidents. U.S. Environmental Protection Agency, 2019.
- <u>Procedures for Safe Handling and Management of Ebola-Associated Waste</u>. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2014.
- U.S. Department of Labor, Occupational Safety and Health Administration; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; and U.S. Environmental Protection Agency. <u>Safe Handling, Treatment, Transport and Disposal</u> of <u>Ebola-Contaminated Waste</u>. FS-3766. Washington, DC, 2016.
- <u>Program Will Train First Responders and Hazardous Waste Workers on Infectious Disease Safety</u>, U.S. Department of Health and Human Services, National Institutes of Health, 2016.
- U.S. Department of Defense, Department of the Army, U.S. Army Public Health Command. <u>Technical Guide 197: Guide for Developing Integrated Solid Waste Management Plans at Army Installations</u>. Aberdeen Proving Ground, Maryland, 2013. This document was developed for use by U.S. Department of the Army facilities and personnel. Different regulatory requirements may apply in other settings.
- U.S. Department of Defense, Department of the Air Force. <u>Air Force Instruction 41-201, Clinical Engineering</u>. Arlington, Virginia, 2017. This document was developed for use by U.S. Department of the Air Force facilities and personnel. Different regulatory requirements may apply in other settings.
- U.S. Department of Defense, Department of the Air Force. <u>Air Force Instruction 44-108, Infection Control</u>. Arlington, Virginia, 2019. This document was developed for use by U.S. Department of the Air Force facilities and personnel. Different regulatory requirements may apply in other settings.

#### **Emergency Planning**

- U.S. Department of Homeland Security, Federal Emergency Management Agency. <u>Biological Incident Annex to the National Response Framework</u>. Washington, DC, 2017.
- U.S. Department of Homeland Security, Federal Emergency Management Agency. *National Response Framework (NRF)*. Washington, DC, 2016.

### **Worker Health and Safety**

Recommendations for the Selection and Use of Respirators and Protective Clothing for Protection
 <u>Against Biological Agents</u>, U.S. Department of Health and Human Services, Centers for Disease
 Control and Prevention, National Institute for Occupational Safety and Health, 2015.

- <u>Safety and Health Topics: Respiratory Protection</u>, U.S. Department of Labor, Occupational Safety and Health Administration, 2015.
- <u>Safety and Health Topics: Infectious Diseases</u>, U.S. Department of Labor, Occupational Safety and Health Administration, 2017.
- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health. <u>Biosafety in Microbiological and Biomedical Laboratories (BMBL)</u>, <u>5<sup>th</sup> edition</u>, edited by L. Casey Chosewood and Deborah E. Wilson. HHS Publication No. (CDC) 21-1112. Atlanta, Georgia, and Bethesda, Maryland, 2009.
- <u>Selecting, Evaluating, and Using Sharps Disposal Containers</u>, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, 2015.

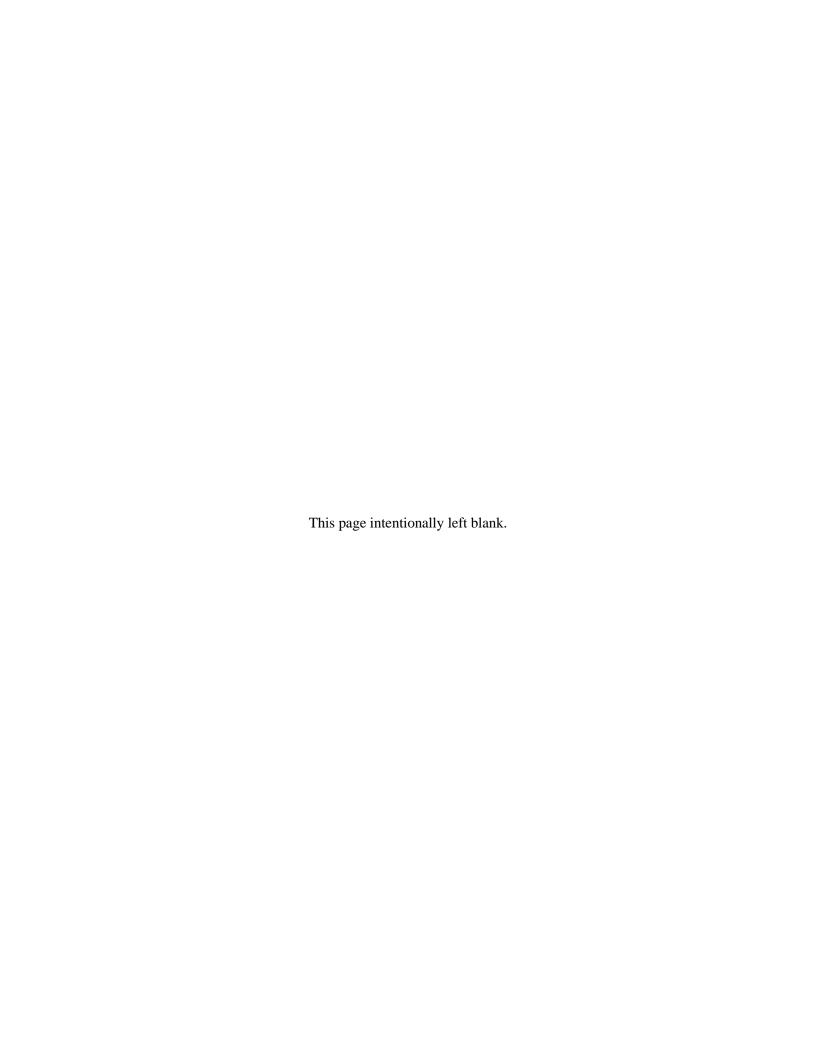
## **Environmental Management & Infection Control**

- Selected EPA-Registered Disinfectants, U.S. Environmental Protection Agency, 2016.
- <u>Information on Cleaning and Decontamination</u>, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2014.
- <u>Guideline for Disinfection and Sterilization in Healthcare Facilities</u>, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Healthcare Infection Control Practices Advisory Committee (HICPAC), 2008.
- <u>Guidelines for Environmental Infection Control in Healthcare Facilities</u>, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Healthcare Infection Control Practices Advisory Committee (HICPAC), 2003.
- <u>Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings</u>, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Healthcare Infection Control Practices Advisory Committee (HICPAC), 2007.
- Interim Guidance for U.S. Hospital Preparedness for Patients Under Investigation (PUIs) or with Confirmed Ebola Virus Disease (EVD): A Framework for a Tiered Approach and updated guidance on the appropriate use of Personal Protective Equipment (PPE), U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2018.
- <u>Guideline for Hand Hygiene in Health-Care Settings</u>, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Healthcare Infection Control Practices Advisory Committee (HICPAC), 2002.

## **For Further Information**

- From the U.S. Department of Transportation, including about the *Hazardous Materials Regulations* (HMR) requirements and guidance, contact the Pipeline and Hazardous Materials Safety Administration (PHMSA) Hazardous Materials Information Center at 1-800-467-4922.
- From U.S. Environmental Protection Agency (EPA) information on <u>solid and hazardous waste</u> or emergency response, visit www.epa.gov.

- From the Occupational Safety and Health Administration (OSHA), visit <a href="www.osha.gov">www.osha.gov</a> or contact 1-800-321-OSHA (6742).
- From the Centers for Disease Control and Prevention (CDC), visit <a href="www.cdc.gov">www.cdc.gov</a> or contact 1-800-CDC-INFO (1-800-232-4636).
- About the National Emerging Special Pathogens Training and Education Center (NETEC), visit <a href="www.netec.org">www.netec.org</a> or contact <a href="https://hpp@hhs.gov">hpp@hhs.gov</a>. The NETEC has helped 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 has been a collaboration between HHS' Administration for Strategic Preparedness and Response (ASPR) and CDC to support Emory University (Atlanta, Georgia), University of Nebraska Medical Center/Nebraska Medicine (Omaha, Nebraska), and NYC Health + Hospitals/Bellevue Hospital Center (New York City, New York) in training healthcare providers, personnel affiliated with facilities, patient evacuation providers, and other applicable personnel on strategies, including for waste management, to respond to Ebola and other emerging infectious diseases. NETEC offers support services to healthcare facilities and emergency medical services (EMS) providers to enhance their operational readiness. These services include readiness consultations, and on-site or web-based technical assistance to support them to prepare for, and respond to, Ebola and other special pathogen events.
- About the ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE), visit asprtracie.hhs.gov. In 2015, HHS/ASPR created the TRACIE 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 Topic Collections with resources and information regarding decontamination and waste management. The ASPR TRACIE provides personalized support and responses to requests for information and technical assistance. ASPR TRACIE responses to selected technical assistance requests are available on the ASPR TRACIE site, and can be located in the infectious disease subcategory.



# APPENDIX B – INFECTIOUS AGENT CATEGORIZATION

Several federal departments and agencies identify various biological agents and toxins in their regulations. This document is primarily concerned with Category A infectious substances (specifically, those affecting humans), as described in the U.S. Department of Transportation (DOT)/Pipeline and Hazardous Materials Safety Administration (PHMSA) *Hazardous Materials Regulations* (HMR) at 49 CFR parts 171-180. However, many Category A agents are also designated as select agents by the U.S. Department of Health and Human Services (HHS)/Centers for Disease Control and Prevention (CDC) and U.S. Department of Agriculture (USDA), which jointly regulate biological select agents and toxins (BSAT) at 42 CFR part 73 (for CDC) and 7 CFR part 331 and 9 CFR part 121 (for USDA).

This appendix cross-references common Category A agents under the HMR and select agents under the select agent regulations. This list is for guidance only; it is not all-inclusive.<sup>36</sup> Find the most current list of BSAT at www.selectagents.gov.

Designation of "cultures only" means that a Category A infectious 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.

See additional explanatory information in the notes following the table.

	Categ Subst	ory A ances	Select Agents		5
Agent	UN 2814 (Infectious substances affecting humans)	UN 2900 (Infectious substances affecting animals only)	HHS Select Agent	USDA Select Agent (animal pathogens)	USDA Select Agent (Plant Protection and Quarantine, PPQ)
Abrin			✓		
African horse sickness virus				✓	
African swine fever virus		✓		✓	
Avian influenza virus, highly pathogenic <sup>c</sup>	✓ c/o			✓	
Bacillus anthracis	✓ c/o		✓	✓	
Bacillus anthracis Pasteur strain			✓	✓	
Bacillus cereus Biovar anthracis*			✓		

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<sup>&</sup>lt;sup>36</sup> U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, *Transporting Infectious Substances Safely* (Washington, DC, 2022), <u>www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-safely</u>.

		gory A tances	Select Agents		S
Agent	UN 2814 (Infectious substances affecting humans)	UN 2900 (Infectious substances affecting animals only)	HHS Select Agent	USDA Select Agent (animal pathogens)	USDA Select Agent (Plant Protection and Quarantine, PPQ)
Botulinum neurotoxin producing species of <i>Clostridium</i> *			✓		
Botulinum neurotoxins*			✓		
Brucella abortus	√ c/o		✓	✓	
Brucella melitensis	√ c/o		✓	✓	
Brucella suis	√ c/o		✓	<b>✓</b>	
Burkholderia mallei*			✓	✓	
Burkholderia mallei— Pseudomonas mallei—Glanders	√ c/o				
Burkholderia pseudomallei*	√ c/o		✓	✓	
Chapare virus (South American hemorrhagic fever virus)			✓		
Chlamydia psittaci—avian strains	√ c/o				
Classical swine fever virus		√ c/o		✓	
Clostridium botulinum	√ c/o				
Coccidioides immitis	✓ c/o				
Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines)				<b>✓</b>	<b>✓</b>
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X <sub>1</sub> CCX <sub>2</sub> PACGX <sub>3</sub> X <sub>4</sub> X <sub>5</sub> X <sub>6</sub> CX <sub>7</sub> ) <sup>a</sup>			✓		
Coxiella burnetii	<b>√</b> c/o		✓		
Crimean-Congo hemorrhagic fever virus	✓		✓		
Dengue virus	√ c/o				
Diacetoxyscirpenol			✓		

		gory A tances	Select Agents		S
Agent	UN 2814 (Infectious substances affecting humans)	UN 2900 (Infectious substances affecting animals only)	HHS Select Agent	USDA Select Agent (animal pathogens)	USDA Select Agent (Plant Protection and Quarantine, PPQ)
Eastern Equine Encephalitis virus <sup>c</sup>	✓ c/o		✓		
Ebola virus*	✓		✓		
Escherichia coli, verotoxigenic	✓ c/o				
Flexal virus	✓				
Foot-and-mouth disease virus*		√ c/o		✓	
Francisella tularensis*	✓ c/o		✓		
Goat pox virus		√ c/o		✓	
Guanarito virus (South American hemorrhagic fever virus)	✓		✓		
Hantaan virus	✓				
Hantaviruses causing hemorrhagic fever with renal syndrome	✓				
Hendra virus	✓		✓	✓	
Herpes B virus	✓ c/o				
Human immunodeficiency virus	√ c/o				
Japanese Encephalitis virus	✓ c/o				
Junin virus (South American hemorrhagic fever virus)	✓		✓		
Kyasanur Forest disease virus	✓		✓		
Lassa fever virus	✓		<b>√</b>		
Lujo virus		<b>√</b>	✓		
Lumpy skin disease virus		c/o		✓	
Machupo virus (South American hemorrhagic fever virus)	✓		✓		
Marburg virus*	✓		✓		
Monkeypox virus (Clade I) <sup>c</sup>	✓ c/o		✓		

		gory A tances	Select Agents		S
Agent	UN 2814 (Infectious substances affecting humans)	UN 2900 (Infectious substances affecting animals only)	HHS Select Agent	USDA Select Agent (animal pathogens)	USDA Select Agent (Plant Protection and Quarantine, PPQ)
Mycobacterium tuberculosis	√ c/o				
Mycoplasma capricolum <sup>c</sup>				✓	
Mycoplasma mycoides <sup>c</sup>		√ c/o		✓	
Newcastle disease virus <sup>b, c</sup> (avian paramyxovirus serotype 1)		√ c/o		✓	
Nipah virus	✓		✓	✓	
Omsk hemorrhagic fever virus	✓		✓		
Peronosclerospora philippinensis (Peronosclerospora sacchari)					✓
Peste des petits ruminants virus		√ c/o		✓	
Poliovirus	√ c/o				
Rabies and other lyssaviruses	<b>√</b> c/o				
Ralstonia solanacearum					✓
Rathayibacter toxicus					✓
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)			✓		
Ricin			✓		
Rickettsia prowazekii	√ c/o		✓		
Rickettsia rickettsiia	√ c/o				
Rift Valley fever virus	√ c/o		✓	✓	
Rinderpest virus*		√ c/o		✓	
Russian spring-summer encephalitis virus	√ c/o				

		gory A tances	Select Agents		S
Agent	UN 2814 (Infectious substances affecting humans)	UN 2900 (Infectious substances affecting animals only)	HHS Select Agent	USDA Select Agent (animal pathogens)	USDA Select Agent (Plant Protection and Quarantine, PPQ)
Sabia virus (South American	✓		✓		
hemorrhagic fever virus) SARS-associated coronavirus					
(SARS-CoV)			✓		
SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors			<b>✓</b>		
Saxitoxin			✓		
Sclerophthora rayssiae					✓
Sheep pox virus		√ c/o		✓	
Shigella dysenteriae type I	✓ c/o				
Staphylococcal enterotoxins A,B,C,D,E subtypes			✓		
Swine vesicular disease virus		√ c/o		✓	
Synchytrium endobioticum					✓
T-2 toxin			✓		
Tetrodotoxin			✓		
Tick-borne encephalitis viruses	√ c/o				
Tick-borne encephalitis complex – Far Eastern subtype	√ c/o		✓		
Tick-borne encephalitis complex – Siberian subtype	√ c/o		✓		
Variola major virus (Smallpox virus)*	✓		✓		
Variola minor virus (Alastrim)*			✓		
Venezuelan equine encephalitis	<b>√</b>		✓	✓	
virus <sup>c</sup>	<i>c/o</i> ✓	<b>√</b>			
Vesicular stomatitis virus	c/o	c/o			

	Categ Subst		Select Agents		S
Agent	UN 2814 (Infectious substances affecting humans)	UN 2900 (Infectious substances affecting animals only)	HHS Select Agent	USDA Select Agent (animal pathogens)	USDA Select Agent (Plant Protection and Quarantine, PPQ)
West Nile virus	√ c/o				
Xanthomonas oryzae					✓
Yellow fever virus	✓ c/o				
Yersinia pestis*	√ c/o		✓		

*Note:* "c/o" = agents that are considered Category A as cultures only (i.e., only when they are intentionally propagated); UN = United Nations.

<sup>\*</sup> denotes a Tier 1 Select Agent, one of a subset of biological agents and toxins that present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety.

 $<sup>^{</sup>a}$  C = Cysteine residues are all present as disulfides, with the  $1^{st}$  and  $3^{rd}$  Cysteine, and the  $2^{nd}$  and  $4^{th}$  Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example, if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

<sup>&</sup>lt;sup>b</sup> A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

c Select agents that meet any of the following criteria are excluded from the requirements of the Select Agent Regulations at 7 CFR part 331, 9 CFR part 121, and 42 CFR part 73: Any low-pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus, West African (now referred to as Clade II) clade of Monkeypox viruses (MPXV) (see additional MPXV information in Appendix F-2), any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies *Mycoplasma capricolum* except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies *Mycoplasma mycoides* except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category.

# 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 U.S. Department of Transportation (DOT) special permit (SP) may be necessary. A special permit allows for a variance of the *Hazardous Materials Regulations* (HMR) packaging requirements to handle the larger volume of Category A waste generated during the treatment or transport of patients infected with pathogens (i.e., germs) classified as Category A infectious substances or during remediation of such individuals' contaminated residential environments.

The decision matrix below outlines key considerations for managing Category A waste, including where a DOT special permit(s) may be needed.

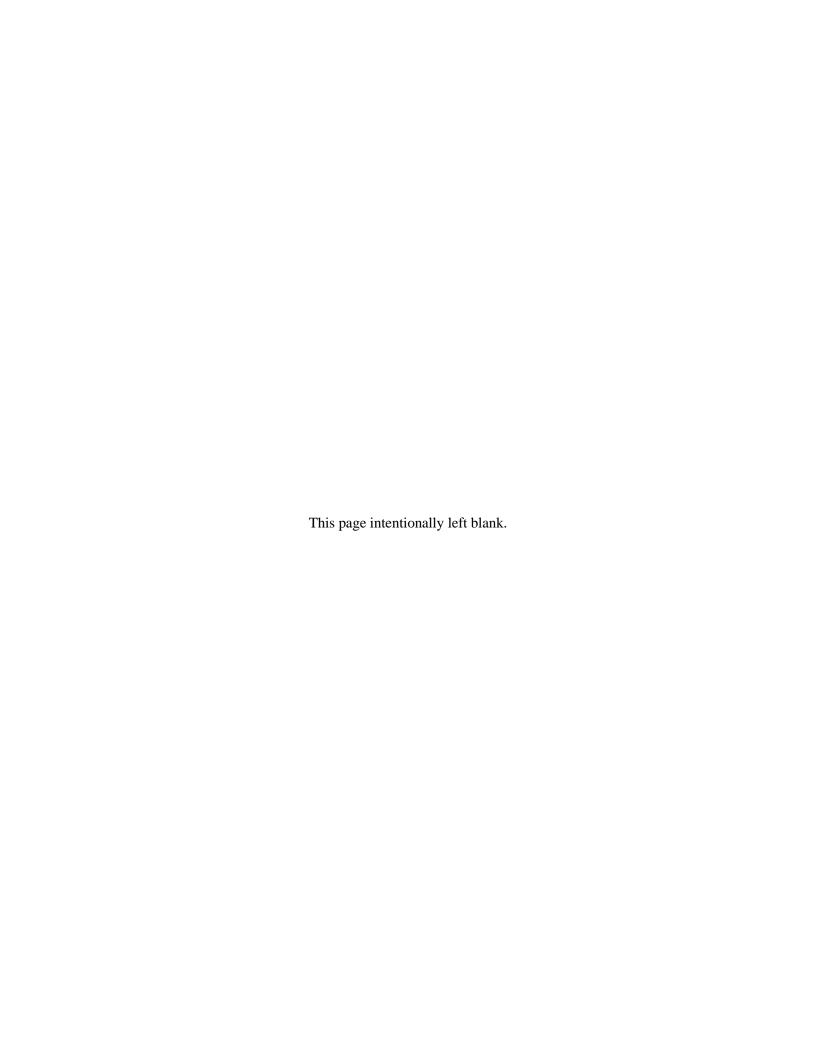
#	<b>Decision Point</b>	Recommended Action
1.	Does the incident resulting in waste involve	Yes = immediately contact the Federal
1.	suspected or actual terrorism or another criminal activity?	Bureau of Investigation (FBI), as certain solid waste, including Category A waste, may be considered as evidence. (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.  No = move to 2; there is no need to
		contact the FBI.
2.	Is the waste properly classified as United Nations (UN) 2814, Infectious substances, affecting humans,	Yes = move to 3.
	6.2 or UN 3549 Medical waste, category A, affecting humans?	No = dispose of according to the material's classification and state, local, tribal, and/or territorial (SLTT)
	For transportation under the HMR, it is the offeror's responsibility to classify hazardous materials, including infectious substances.	requirements (e.g., as regulated medical waste (RMW), hazardous waste, non-hazardous waste).
3.	Does your facility have the capability to treat the waste on-site to the point of rendering the agent	Yes = inactivate on-site, then move to 4.
	completely inactive (through autoclaving, or incineration, or other validated methods)? Is the onsite treatment capability allowable under SLTT requirements?	No = move to 5.
4.	Are residuals from treatment determined to be no longer infectious?	Yes = dispose of treated materials and/or residuals according to SLTT requirements. Waste that is not infectious but remains hazardous must be disposed of in a manner

#	<b>Decision Point</b>	Recommended Action
		appropriate for the hazardous nature of the waste (e.g., in compliance with <i>Resource Conservation and Recovery Act</i> (RCRA) and SLTT requirements).
		No = move to 5.
5.	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)?	Yes = package the waste using the compliant Category A packaging. Move to 8.
	6	No = move to 6. In the meantime, ensure that Category A wastes are stored appropriately.
6.	Has DOT issued a Special Permit that applies to the Category A infectious substance(s) contained in or contaminating the waste?	Yes = package the waste using the packaging detailed in the applicable Special Permit(s). Move to 7.
	Visit DOT's searchable database of special permits.	No or uncertain = contact DOT/PHMSA to discuss a special permit for waste transportation for the Category A infectious substance(s) in question.
7.	DOT special permits provide alternative requirements, such as for packaging and transporting waste contaminated with certain Category A infectious substances, under the HMR.  Have you contracted with one of the companies listed as a party to the applicable special permit(s)?	Yes = the company with party status to the applicable permit 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 8.
		No = contact a company with party status to the applicable special permit(s) to determine whether it is available to assist with handling your waste.
		Once you have contracted with a company, move to 8.

#	<b>Decision Point</b>	Recommended Action
		If no companies respond affirmatively, contact DOT/PHMSA to discuss next steps. <sup>37</sup>
8.	Does your waste transportation contractor have access to a disposal or treatment facility where it can unload your waste?	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.
	Off-site disposal facilities must be permitted to accept medical waste (i.e., RCRA subtitle D landfills).	No = work with your contractor to identify why it does not have access to a disposal facility.

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<sup>&</sup>lt;sup>37</sup> Reach DOT/PHMSA's Hazardous Materials Information Center by phone at 1-800-467-4922.



# **APPENDIX D – 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 or during patient transfer) 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 also intended for use by state, local, tribal, and/or territorial (SLTT) and federal partners, including, but not limited to, public health, worker safety and health, environmental protection, waste management, and elected officials.

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.
- 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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	6. What is waste treatment and disposal?	53
	7. Prior to treatment, why must Category A waste be handled differently than other waste, such as regular trash from a healthcare facility or other regulated medical waste?	54
Background Questions & Answers	8. How do the government and the medical waste industry know that Category A waste can be handled safely?	55
	9. What is a pathogen?	56
	10. Which government agency(ies) is/are responsible for regulating medical waste?	57
	11. How are pathogens transmitted to people (or animals, if applicable)?	58
	12. What is the federal government doing to ensure that healthcare facilities; ambulances services; and waste transport, treatment, and disposal companies handle the waste safely and comply with applicable requirements?	59
	13. Who can I contact if I have questions about infectious waste, regulated medical waste, and Category A waste?	60

Category	Question	Page
Waste Generation	1. Where does Category A waste come from?	61
Questions & Answers	2. What can be done to reduce the amount of infectious	62
Questions & Answers	waste generated in the first place?	
	1. Who is responsible for properly identifying infectious	63
	waste that is transported between facilities?	
	2. Is my family at risk of being exposed to infectious	63
	waste if it is transported through my/our community?	
	3. If waste is inactivated, is there a risk to me or my	64
	family if it is transported through or disposed of in	
Waste Transportation	my/our community?	
Questions & Answers	4. Will I be notified if Category A waste is transported	65
Questions & Answers	through my community or processed or disposed of at a	
	facility near my home or business?	
	5. Is there a plan in place to handle emergencies that	65
	happen when transporting infectious waste, such as an	
	accident involving the truck carrying the waste?	
	6. Are there specific requirements for transporting	66
	Category A waste?	
	1. Should infectious waste be pre-treated with a	70
	disinfectant before it is sent from a facility for further	
	treatment and disposal?	
	2. What methods are used to inactivate infectious waste so	71
	that it is no longer infectious?	
Waste Treatment	3. How do waste treatment and disposal companies ensure	71
Questions & Answers	that the processes they use to inactivate infectious	
Questions & Answers	waste are effective?	
	4. Are there any steps normally involved in treating	72
	medical waste that should be avoided during treatment	
	and disposal of Category A waste?	
	5. What is my/my family's risk of being exposed to	73
	infectious waste if it is processed or inactivated at	
	facilities in my/our community?	
	1. Where does infectious waste end up after treatment?	74
	2. Can burying inactivated waste in landfills affect crops	75
	or ground water supplies nearby?	
	3. What requirements are in place to ensure air quality	76
	near incinerator facilities that process infectious waste?	
	4. Is there potential harm to other natural resources when	76
Waste Disposal	infectious waste is transported or inactivated or when	
	inactivated waste is disposed of properly?	
	5. Is the ash from incinerated Category A infectious	77
	substances hazardous, infectious, or dangerous?	
	6. Is waste that has been autoclaved (which means to	78
	sterilize by means of high-pressure saturated steam)	
	hazardous, infectious, or dangerous?	
	1. What are the risks to workers handling infectious waste	79
<b>Worker Protection</b>	before it is properly inactivated?	
	2. What specific tasks may lead to worker exposure to	79
	untreated infectious waste?	

Category	Question	Page
	3. What should employers do to protect workers involved	81
	in handling, transport, and treatment of infectious waste	
	and disposal of inactivated waste?	
	4. What can workers involved in handling, transport, and	83
	treatment of infectious waste and disposal of	
	inactivated waste do to protect themselves?	
	5. Is there training available on handling, transport, and	84
	treatment of infectious waste and disposal of	
	inactivated waste that I can get in advance to be sure I	
	am prepared to do my job?	

# **BACKGROUND QUESTIONS & ANSWERS**

### 1. What is Category A waste?

**Key Message:** "Category A waste" is a specific designation for waste contaminated with a Category A infectious substance.

**Answer:** "Category A waste" is a specific designation under the U.S. Department of Transportation (DOT) *Hazardous Materials Regulations* (HMR) for waste contaminated with a Category A infectious substance, meaning an infectious substance in a form capable of causing permanent disability or lifethreatening or fatal disease in otherwise healthy humans or animals when exposure to the substance occurs. See 49 CFR § 173.134(a)(1)(i) and the definitions of "Category A infectious substance" and "Category A waste" in the Glossary of Terms.

Such waste results from a variety of tasks, the most common of which is likely to be patient care activities in healthcare facilities and patient transportation operations. During these activities, needles/syringes, intravenous (IV) access devices, tubing, dressings, personal protective equipment (PPE), and other materials are used and become contaminated. Larger items, like bulk bedding materials and mattresses, may also constitute contaminated waste from patient care and residential settings.

Hospitals, laboratories, and other facilities and worksites also generate waste that may be contaminated with infectious substances that are not classified as Category A. Such waste is often managed as regulated medical waste (RMW). When generating waste in a healthcare, patient transport, or laboratory setting where infectious substances may be present follow the facility and SLTT requirements for proper waste disposal.

RMW management is regulated at the SLTT levels. Once treated, these materials are no longer infectious and are considered a solid waste subject to solid waste regulations if no other type of hazardous material (e.g., chemical) is present that falls under another hazardous waste regulation.

#### **Background/References:**

 RCRA Orientation Manual 2014, EPA530-F-11-003. U.S. Environmental Protection Agency, 2014.

- Anderson, Henry A. "Evolution of Environmental Epidemiologic Risk Assessment,"
   Environmental Health Perspectives 62 (1985): 389-392.
- Guidelines for Environmental Infection Control in Healthcare Facilities. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2003.
- Lauer, James L., Donald R. Battles, and Donald Vesley. "<u>Decontaminating Infectious Laboratory Waste by Autoclaving</u>." *Applied Environmental Microbiology* 44, no. 3 (1982): 690-694.

# 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 (SP), 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 body 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 United Nations (UN) Identification Number for UN 2814, Infectious substances, affecting humans; UN 2900, Infectious substances, affecting animals only; or UN 3549, Medical waste, category A, affecting humans, as appropriate.<sup>38</sup> 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.

SLTT governments determine which generators of waste are subject to medical waste regulations in their jurisdictions.

# **Background/References:**

 <u>Transporting Infectious Substances</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2008.

<sup>&</sup>lt;sup>38</sup> Hazardous Materials Regulations, Purpose and Use of Hazardous Materials Table, 49 CFR § 172.101 (1990).

- Guidelines for Environmental Infection Control in Healthcare Facilities. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2003.
- <u>Hazardous Materials Regulations</u>. 49 CFR parts 171-180. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.
  - o RMW Definition. 49 CFR § 173.134(a)(5).
  - Hazardous Materials Table entries for UN 2814, UN 2900, and UN 3549. 49 CFR § 172.101.
  - o Classification Criteria. 49 CFR § 173.134.
  - o Packaging Information. 49 CFR § 173.196.
  - o Packaging Testing Information. 49 CFR § 178.609.
- <u>UN Hazard Numbers Guidance on Regulations for the Transport of Infectious Substances.</u> World Health Organization, 2007.

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

**Key Message:** RMW can consist of sharps (e.g., needles, scalpels, lancets, and broken glass), 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 (e.g., needles, scalpels, lancets, and broken glass); bulk blood, body fluids, and other potentially infectious materials (i.e., as defined in the Occupational Safety and Health Administration (OSHA) *Bloodborne Pathogens (BBP)* 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.

While most RMW comes from healthcare facilities, including hospitals and doctors' offices, materials contaminated with blood or body fluids outside of traditional healthcare settings could also be considered RMW under some circumstances. For example, RMW may come from cleanup of public spaces that have been contaminated with blood or other body fluids.

# **Background/References:**

 <u>Bloodborne Pathogens</u>. 29 CFR § 1910.1030. U.S. Department of Labor, Occupational Safety and Health Administration.

## 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 pathogens (i.e., 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 (i.e., germ). A pathogen is a microorganism (including a bacterium, virus, parasite, or fungus) or another agent, such as a prion (i.e., a proteinaceous infectious particle) that 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 one example of a Category A infectious substance. <u>Appendix B – Infectious Agent Categorization</u> lists other Category A infectious substances.

**Background/References:** The definition of a Category A infectious substance within 49 CFR § 173.134 is based on criteria developed by the UN Subcommittee of Experts working with the World Health Organization (WHO), Centers for Disease Control and Prevention (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 International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions), and the International Maritime Dangerous Goods (IMDG) code.

- <u>Transporting Infectious Substances Safely</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2020.
- <u>Transporting Infectious Substances</u>. Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 2017.
- <u>Hazardous Materials Regulations</u>. 49 CFR parts 171-180. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.
- <u>Dangerous Goods Regulations, Division 6.2—Infectious Substances</u>, 58<sup>th</sup> ed. International Air Transport Association, 2017.
- Safe Management of Wastes from Health-Care Activities. World Health Organization, 2014.

• <u>Infection prevention and control guideline for Ebola and Marburg disease</u>. World Health Organization, 2023.

# 5. Who determines if an infectious substance is "Category A"?

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

**Answer:** Under the DOT HMR, it is the responsibility of the offeror (i.e., the person or entity generating the material) 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. The offeror should consult with the generator or the group with the best knowledge of the situation in making the hazardous material classification and waste determination. In healthcare facilities, the decision should be made by infectious disease personnel working in collaboration with relevant SLTT public health and waste management authorities. See the definitions of "offeror" and "generator" in the <u>Glossary of Terms</u>.

#### **Background/References:**

- Hazardous Materials Regulations. 49 CFR parts 171-180. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.
  - o Class 6, Division 6.2—Definitions and exceptions. 49 CFR 173.134.

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

**Key Message:** Waste treatment and disposal covers all of the steps in handling RMW, including Category A 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 SLTT laws and regulations. Whenever possible, all Category A waste should be inactivated on-site with an autoclave, incinerator, or similarly effective, validated technologies that comply with SLTT requirements.

**Answer:** Waste treatment and disposal covers all of the steps in regulated medical waste including 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 and SLTT 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 reflect input from appropriate SLTT 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. Whenever possible, Category A infectious waste should be inactivated on-site with an autoclave, incinerator, or similarly effective, validated technologies that comply with SLTT requirements.

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

7. Prior to treatment, why must Category A waste 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 RMW from a healthcare facility that is generally managed under SLTT environmental regulations, Category A waste must be handled more carefully so that persons are not exposed to the infectious substances in the waste. To accomplish this, entities that may need to manage contaminated waste should have a plan to address all steps in the waste management cycle.

**Answer:** Category A waste must be handled more carefully so that persons are not exposed to the infectious substances in the waste. Category A waste can be handled safely. The leadership for local governments, facilities, and other organizations 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 SLTT public health and environmental authorities, as appropriate, and comply with applicable regulations.

Regular trash or RMW from healthcare facilities is generally managed under SLTT 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 some Category A infectious substances (see <u>Appendix B – Infectious Agent Categorization</u> for examples), 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* (29 CFR § 1910.1030).

# **Background/References:**

- Are You Preparing Suspected Ebola Contaminated Waste for Transportation? U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- <u>Transporting Infectious Substances Safely</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- <u>Hazardous Materials Regulations</u>. 49 CFR parts 171-180. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.

- Bloodborne Pathogens. 29 CFR § 1910.1030 (2012). U.S. Department of Labor, Occupational Safety and Health Administration.
- 8. How do the government and the medical waste industry know that Category A waste can be handled safely?

**Key Message:** Workers handle RMW on a regular basis without incident. Requirements and procedures in place for routine waste handling are augmented by federal and SLTT requirements for handling Category A waste. Complying with these requirements protects workers, public health, and the environment.

**Answer:** Workers handle RMW on a regular basis 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 and SLTT agencies ensures waste can be handled safely. These requirements cover how the waste must be packaged, transported, inactivated, and disposed (e.g., U.S. Environmental Protection Agency, EPA; DOT; and SLTT requirements), as well as protections for workers handling the waste (e.g., OSHA and other SLTT 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* (29 CFR § 1910.1030). Using DOT-compliant packaging helps ensure that Category A waste 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 and SLTT 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 for the specific pathogen will ensure that the waste material is no longer infectious.

Peer-reviewed literature also provides accounts of waste generators safely and effectively managing Category A waste on-site, without having to transport theses 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 SLTT requirements. These wastes can be safe to dispose of at a sanitary landfill or solid waste incineration facility (or a waste-to-energy facility), as well. The facility/owner/operator will need to follow any SLTT rules or regulations.

#### **Background/References:**

- <u>Transporting Infectious Substances</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- Occupational Safety and Health Act. 29 CFR §§ 651 et seq. (1970). U.S. Department of Labor, Occupational Safety and Health Administration.
- <u>Bloodborne Pathogens</u>. 29 CFR § 1910.1030 (2012). U.S. Department of Labor, Occupational Safety and Health Administration.
- Lowe, John J., Shawn G. Gibbs, Shelly Schwedhelm, John Nguyen, and Philip W. Smith, "Nebraska Biocontainment Unit Perspective on Disposal of Ebola Medical Waste," American Journal of Infection Control 42, no. 12 (2014): 1256-1257.
- <u>Hazardous Materials Regulations</u>. 49 CFR parts 171-180. U.S. Department of Transportation,
   Pipeline and Hazardous Materials Safety Administration.
- <u>Information on the Survivability of the Ebola Virus in Medical Waste</u>. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2015.

#### 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 bacteria, viruses, fungi, prions, and parasites (e.g., protozoa, helminths, and nematodes). These agents may cause disease in susceptible plant, animal, or human hosts.

Also see the definition of "pathogen" in the Glossary of Terms.

# **Background/References:**

- Casadevall, Arturo, and Liise-Anne Pirofski. "What is a Pathogen?" Annals of Medicine 34, no. 1 (2002): 2-4.
- Casadevall, Arturo, and Liise-Anne Pirofski. "Microbiology: Ditch the Term Pathogen," Nature 516, no. 7530 (2014): 165-166.
- Casadevall, Arturo, and Liise-Anne Pirofski. "Q&A: What is a Pathogen? A Question That Begs a Point," BMC Microbiology 10 no. 6 (2012): 6-8.

# 10. Which government agency(ies) is/are responsible for regulating medical waste?

**Key Message:** Individual states and territories have the primary regulatory authority for the management and treatment of RMWs in the United States. SLTT regulations may differ from one another—some jurisdictions may be more stringent than others. Specific SLTT regulations are generally found in the SLTT solid waste or health department regulations. However, the DOT/Pipeline and Hazardous Materials Safety Administration (PHMSA), EPA, U.S. Department of Agriculture (USDA), and OSHA each have requirements that may affect RMW.

**Answer:** Since the late 1980s, individual states and territories have had the primary regulatory authority for the management and treatment of RMW in the United States. 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.

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

DOT/PHMSA, EPA, USDA, and OSHA each have requirements that also may affect RMW.

DOT: 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.

EPA: There are no specific EPA regulations under the federal *Resource Conservation and Recovery Act* (RCRA) for the treatment/inactivation and disposal of RMW. As noted above, medical waste is primarily regulated at the SLTT level. However, hospital infectious medical waste incinerators must meet specific standards set by EPA's *Clean Air Act* (CAA) regulations. In addition, solid waste landfills must meet minimum federal criteria set out in the RCRA subtitle D regulations and state/territorial permits and any hazardous waste treatment, storage or disposal facility must comply with the hazardous waste regulations and requirements in their permits.

CDC and USDA: The U.S. Department of Health and Human Services (HHS) regulates select agents and toxins under 42 CFR part 73; USDA regulates them under 7 CFR part 331 and 9 CFR part 121. The federal select agent regulations include controls for who (i.e., which labs) can possess, use, or transfer such agents and toxins. Waste generated during the treatment of patients infected with a select agent identified as a Category A infectious substance in the HMR and which must be managed as such (i.e., the agent is not designated as "cultures only") are not subject to the select agent regulations as long as the material has been subjected to decontamination or a destruction procedure (See the exclusion provision 42 CFR §§ 73.3(d)(3) and 73.4(d)(3)). The select agent regulations require that laboratory samples of select

<sup>&</sup>lt;sup>39</sup> Hazardous Materials Regulations, 49 CFR § 173.134(a)(5) (2013).

agents obtained as part of patient care (i.e., for clinical diagnostic purposes) must be inactivated or transferred for destruction within seven calendar days of the conclusion of patient care.

OSHA: OSHA sets standards and other requirements to protect workers from exposure to infectious materials. These include the *Bloodborne Pathogens* (29 CFR § 1910.1030), *PPE* (29 CFR 1910 subpart I), and *Respiratory Protection* (29 CFR § 1910.134) standards and the *General Duty Clause* of the *Occupational Safety and Health (OSH) Act of 1970*. The *Bloodborne Pathogens standard* (29 CFR § 1910.1030) 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:**

- <u>Transporting Infectious Substances</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- Occupational Safety and Health Act. 29 CFR §§ 651 et seq. (1970). U.S. Department of Labor Occupational Safety and Health Administration.
- Bloodborne Pathogens. 29 CFR § 1910.1030 (2012). U.S. Department of Labor, Occupational Safety and Health Administration.
- Personal Protective Equipment. 29 CFR § 1910.132 (2011). U.S. Department of Labor, Occupational Safety and Health Administration.
- Respiratory Protection. 29 CFR § 1910.134 (2011). U.S. Department of Labor, Occupational Safety and Health Administration.

#### 11. How are pathogens transmitted to people (or animals, if applicable)?

**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, modes or routes of transmission. These include contact (direct and indirect), droplet, and airborne transmission. Pathogens that can be transmitted from animals to humans are termed "zoonotic agents." 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:**

- Ostrowsky, Belinda. "Epidemiology of Healthcare-Associated Infections" in *Bennett and Brachman's Hospital Infections*, 6<sup>th</sup> edition, ed. William R. Jarvis, 1-20. Philadelphia, Pennsylvania: Lippincott Williams & Wilkins, 2014.
- 12. What is the federal government doing to ensure that healthcare facilities; ambulance services; 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 waste; and is working closely with healthcare facilities, waste transport and treatment companies, landfill operators, and SLTT 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 waste. Whenever possible, the safest and best options for inactivating Category A waste (e.g., using an autoclave, incinerator, or similarly effective validated technologies that comply with SLTT requirements) are implemented on-site. When on-site treatment is not possible, materials that are suspected or known to be contaminated with Category A infectious substances may only be transported (e.g., for off-site treatment) in two scenarios: in full compliance with classification and packaging requirements of the DOT HMR and the OSHA *Bloodborne Pathogens standard* (29 CFR § 1910.1030); or, under the terms of a special permit issued by DOT. As noted previously, "medical waste" is generally regulated by SLTT governments, as are most other non-hazardous solid wastes, such as municipal solid waste. For hazardous waste streams, EPA has authorized some territories and all but two states to implement some or all of the RCRA hazardous waste program, such that authorized State requirements apply in lieu of federal EPA requirements. In some cases, SLTT governments may impose requirements that are more stringent or go beyond the federal regulations so it is important to check for any SLTT requirements.

Because of the relatively large quantity of contaminated waste generated when treating patients who are known or suspected of having certain infectious diseases, including Ebola virus disease (EVD) and other hemorrhagic fever viruses (HFVs), the available packaging authorized under the regulations governing the transport of Category A infectious substances (intended for laboratory materials) may not be large enough to meet the need. In response to the 2014–2015 Ebola outbreak, 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. Special permits for other Category A agents may have different requirements that reflect specific characteristics of the waste, waste generation scenarios, packaging needs, or other considerations.

Federal agencies, including CDC, OSHA, HHS/Administration for Strategic Preparedness and Response (ASPR), EPA, and DOT, have been working closely with healthcare facilities, waste transport and treatment companies, landfill operators, and state/territorial/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:**

- <u>Transporting Infectious Substances</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- <u>Hazardous Materials Regulations</u>. 49 CFR parts 171-180. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.
- Occupational Safety and Health Act. 29 CFR §§ 651 et seq. (1970), U.S. Department of Labor, Occupational Safety and Health Administration.
- <u>Bloodborne Pathogens</u>. 29 CFR § 1910.1030 (2012). U.S. Department of Labor, Occupational Safety and Health Administration.

# 13. Who can I contact if I have questions about infectious waste, regulated medical waste, and Category A waste?

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

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

- Regarding CDC guidance, contact: by phone, 1-800-CDC-INFO (1-800-232-4636); by email, <u>CDCINFO@cdc.gov</u>; or by <u>web form</u>.
- Regarding DOT guidance or HMR requirements, contact: by phone, DOT/PHMSA's Hazardous Materials Information Center, 1-800-467-4922.
- Regarding EPA guidance on solid and hazardous waste issues, contact: by phone, 1-703-308-8895; or by web form.
- Regarding OSHA guidance and worker safety and health requirements, contact: by phone, 1-800-321-OSHA (1-800-321-6742); or <u>by web</u>.

#### **Background/References:**

• <u>Transporting Infectious Substances</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.

- <u>Links to Hazardous Waste Programs and U.S. State Environmental Agencies</u>. U.S. Environmental Protection Agency.
- <u>CDC website</u>. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.
- OSHA website. U.S. Department of Labor, Occupational Safety and Health Administration.

# WASTE GENERATION QUESTIONS & ANSWERS

## 1. Where does Category A waste come from?

**Key Message:** Category A waste is typically generated during patient care in a healthcare facility, during patient transport, in homes of individuals with certain infectious diseases, in laboratories analyzing or studying pathogens (i.e., germs), and from other activities involving pathogens (i.e., germs) classified as Category A infectious substances (see <u>Appendix B – Infectious Agent Categorization</u>). Category A waste may include materials such as needles, specimen tubes, blood-soaked gauze pads, gloves, other PPE, bedding, and other items may have blood or other pathogen-containing bodily fluids in/on them.

**Answer:** Category A waste results from a variety of tasks, the most common of which is likely to be patient care activities in healthcare facilities and patient transportation operations. During these activities, needles/syringes, IV access devices, tubing, dressings, PPE, and other materials are used and can become contaminated with Category A infectious substances. Larger items, like bulk bedding materials and mattresses, may also constitute Category A waste from patient care and residential settings.

Generally, contamination with Category A infectious substances comes from bodily fluids from a symptomatic person. However, workers in clinical and research laboratories and in other settings may generate Category A waste when they handle Category A infectious substances. <u>Appendix B – Infectious Agent Categorization</u> provides more information about how the ways in which certain substances are handled (e.g., intentional propagation or "culturing") affects their categorization.

- Guidelines for Environmental Infection Control in Healthcare Facilities. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2003.
- <u>Guideline for Disinfection and Sterilization in Healthcare Facilities</u>. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2008.
- WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies, Report of a WHO Consultation, Geneva, Switzerland, 23-26 March 1999. World Health Organization, 2000.
- Interim Guidance for U.S. Residence Decontamination for Ebola and Removal of Contaminated Waste, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2015.

- Medical Waste. U.S. Environmental Protection Agency, 2017.
- 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 some diseases caused by Category A infectious substances, including EVD, only persons who are symptomatic (have a fever), generate bodily fluids that pose a risk. Other Category A agents may be transmissible even if a person is not symptomatic. Correctly assessing the presence of symptoms, agent transmissibility, 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. Frequently, healthcare facilities can 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:**

 Interim Guidance for U.S. Residence Decontamination for Ebola and Removal of Contaminated Waste, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2015.

# WASTE TRANSPORTATION QUESTIONS & ANSWERS

1. Who is responsible for properly identifying 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 or a patient transporter) 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 or a patient transporter) assigns to the waste (e.g., Category A waste) will determine how it must be packaged and prepared for transportation.

#### **Background/References:**

- <u>Hazardous Materials Regulations</u>. 49 CFR parts 171-180. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.
  - o Class 6, Division 6.2—Definitions and exceptions. 49 CFR § 173.134.
- <u>Transporting Infectious Substances Safely</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- <u>Transporting Infectious Substances</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- 2. Is my family at risk of being exposed to <u>infectious</u> waste if it is transported through my/our community?

**Key Message:** When infectious substances are transported in compliance with DOT requirements, the risk to the public is minimized.

**Answer:** When infectious substances are transported in compliance with DOT requirements, the risk to the public is minimized. Waste is required to be packaged appropriately to protect people. Packaging requirements and other operational and safety controls are very robust and 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 RMW in the United States, 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. There has only been one reported instance of infections resulting from waste management activities, in which three medical waste treatment workers at a single facility in Washington contracted *Mycobacterium tuberculosis* (TB) on the job.

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 special permits that authorize holders to use a process for transporting certain Category A waste 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. As the special permits granted to date are specific to certain pathogens or groups of pathogens, additional, but likely similar, special permits would be needed for waste contaminated with other Category A infectious substances not yet covered by those permits.

- <u>Infectious Substance Special Permits</u>. Pipeline and Hazardous Materials Safety Administration,
   U.S. Department of Transportation, 2022,
- <u>Transporting Infectious Substances Safely</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- <u>Transporting Infectious Substances</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- Johnson, Kammy R., Christopher R. Braden, K. Lisa Cairns, Kimberly W. Field, A. Craig Colombel, Zhenhua Yang, Charles L. Woodley, Glenn P. Morlock, Angela M. Weber, A. Yvonne Boudreau, Thomas A. Bell, Ida M. Onorato, Sarah E. Valway, and Paul A. Stehr-Green. "Transmission of Mycobacterium Tuberculosis from Medical Waste." Journal of the American Medical Association 284, no. 13 (2000): 1683-1688.

# 3. If waste is <u>inactivated</u>, 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 unless other types of hazards are present (e.g., chemical).

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 unless other types of hazards are present (e.g., chemical). 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:**

- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health. *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 5<sup>th</sup> edition, edited by L. Casey Chosewood and Deborah E. Wilson. HHS Publication No. (CDC) 21-1112. Atlanta, Georgia, and Bethesda, Maryland, 2009.
- <u>Safe Management of Wastes from Health-Care Activities</u>. World Health Organization, 2014.
- 4. Will I be notified if Category A waste 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 some Category A infectious substances, the public may not be notified regarding the route or disposal of Category A waste. The DOT HMR include requirements for providing information to transporters and emergency responders. Special permits may also include such requirements.

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

- <u>Transporting Infectious Substances Safely</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- <u>Transporting Infectious Substances</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- <u>Hazardous Materials Regulations</u>. 49 CFR parts 171-180. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.
- 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. For example, all carriers authorized to transport infectious waste under 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 must respond to any release or suspected release from a package that occurs during transportation. 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). Security plans must be made available to an authorized official of the DOT or U.S. Department of Homeland Security (DHS).

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 by DOT/PHMSA and updated or revised as needed.

#### **Background/References:**

- <u>Transporting Infectious Substances</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- <u>Hazardous Materials Regulations</u>. 49 CFR parts 171-180. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.
- Occupational Safety and Health Act. 29 CFR §§ 651 et seq. (1970), U.S. Department of Labor, Occupational Safety and Health Administration.
- Bloodborne Pathogens. 29 CFR § 1910.1030 (2012). U.S. Department of Labor, Occupational Safety and Health Administration.
- OSHA Hazardous Waste Operations and Emergency Response standard. 29 CFR § 1910.120 (2013), U.S. Department of Labor, Occupational Safety and Health Administration.
- <u>Security Plans</u>. 49 CFR Part 172, Subpart I (2024). U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.

#### 6. Are there specific requirements for transporting Category A waste?

**Key Message:** Yes, The DOT HMR dictate requirements for transporting Category A infectious substances. DOT/PHMSA-issued special permits also allow for the safe transport of waste contaminated with certain Category A infectious substances. 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. SLTT

governments may have additional requirements for infectious waste transportation so facilities need to check with the jurisdictions in which they operate.

**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. For example, SP 16279, originally issued in 2014, authorizes the safe transportation of certain Ebola-contaminated medical waste for disposal. 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 on DOT's <u>Transporting Infectious Substances Overview page</u>.

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, 40 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 (see <u>Appendix B – Infectious Agent Categorization</u>), 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 EVD, the available packaging authorized under the regulations governing the transport of Category A infectious substances were not large enough to meet the need. Alternative packaging designs, authorized under SP 16279, were needed to meet safety requirements and to accommodate the large volume of waste.

The DOT 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 health care facility or a patient transporter) 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.<sup>41</sup>

<sup>&</sup>lt;sup>40</sup> U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, *Transporting Infectious Substances Safely* (Washington, DC, 2022), <a href="www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-safely">www.phmsa.dot.gov/transporting-infectious-substances-safely</a>.

<sup>&</sup>lt;sup>41</sup> Hazardous Materials Regulations, 49 CFR § 171.8.

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 SLTT 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.

#### 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:

- primary watertight receptacle;
- watertight secondary packaging; and
- 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 identification number and proper shipping name for the applicable Category A infectious substance. Include the UN identification number and proper shipping name in the format: "UN 2814, Infectious substances, affecting humans (Name of substance)" or "UN 3549, Medical waste, category A, affecting humans";
- Hazard class: Division 6.2 (infectious substance);
- 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 Category 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 §§ 175.630I 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 §§ 171.22-171.26.

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 Code.

- Special Permit 16279. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2014. Materials transported under SP 16279 must meet provisions within the special permit. The requirements for packaging and labeling of Category A infectious substances in transport can be found in 49 CFR § 173.196.
- <u>Transporting Infectious Substances Safely</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- <u>Transporting Infectious Substances</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- <u>Hazardous Materials Regulations</u>. 49 CFR parts 171-180. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.

# WASTE TREATMENT QUESTIONS & ANSWERS

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, Category A waste should be inactivated on-site (i.e., wherever the waste was generated) 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 Category A waste or other 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. Adding disinfectant also poses an additional hazard to healthcare worker because of exposure to chemicals, increased weight of bagged waste, and increased volume of liquid in bagged waste.

When operated within permitted parameters and according to validated protocols, autoclaving and incineration methods that are typically used at off-site treatment facilities can effectively inactivate waste without requiring pre-treatment. Unless otherwise specified, the packaging and transportation requirements in the HMR or, if applicable, a DOT Special Permit are intended to allow for safe transportation of waste for such treatment without the need for pre-treatment.

- <u>Information on the Survivability of the Ebola Virus in Medical Waste</u>. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2015.
- <u>Hazardous Materials Regulations</u>. 49 CFR parts 171-180. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.
- <u>List L: EPA's Registered Antimicrobial Products that Meet the CDC Criteria for Use Against the Ebola Virus.</u> U.S. Environmental Protection Agency.
- <u>List J: Registered Antimicrobial Products for Medical Waste Treatment</u>. U.S. Environmental Protection Agency.
- Franke-Whittle, Ingrid H., and Heribert Insam. "<u>Treatment Alternatives of Slaughterhouse</u>
   Wastes, and Their Effect on the Inactivation of Different Pathogens: A Review." Critical Reviews
   in Microbiology 39, no. 2 (2013): 139-151.
- Non-Incineration Treatment and Disposal of Healthcare Waste. Global Healthcare Waste Project, World Health Organization, 2017.

#### 2. 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. <sup>42</sup> 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. Medical incinerators with dual chambers run at temperatures well above the temperature needed to inactivate most Category A pathogens. Prions may be an exception to this general statement. Parameters should be tailored to the specific materials to be incinerated. 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 or SLTT regulations, including environmental and worker safety and health requirements.

Other methods of inactivation (e.g., chemical treatment, alkaline hydrolysis digesters) would need to consider worker health and safety issues as well as the potential for triggering other federal or SLTT regulations, including environmental regulations under the *Federal Insecticide*, *Fungicide*, *and Rodenticide Act* (FIFRA).

# **Background/References:**

• <u>Information on the Survivability of the Ebola Virus in Medical Waste</u>, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2015.

3. 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

<sup>&</sup>lt;sup>42</sup> 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.

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. Medical incinerators with dual chambers reach extremely high temperatures (well above those needed to inactivate any Category A infectious substance). These treatment methods have proven to be very effective. Treatment facilities that use autoclaving should have protocols and operating requirements that include a process control step to ensure the effectiveness of their equipment. For example, autoclave cycles should be frequently checked using biological indicators (e.g., *Bacillus* spore strips) 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 most Category A infectious substances. One exception may be prions which are extremely difficult to disinfect, requiring specialized treatments (e.g., combustion temperatures at or above 1,000°C/1,832°F) for complete inactivation.

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 SLTT health and/or environmental departments.

States/territories 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/territory. States/territories may have oversight programs involving inspections of these operations on a periodic basis.

#### **Background/References:**

- <u>Information on the Survivability of the Ebola Virus in Medical Waste</u>, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2015.
- 4. Are there any steps normally involved in treating medical waste that should be avoided during treatment and disposal of Category A waste?

**Key Message:** Employers of workers whose tasks involve treating and disposing of Category A waste 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 Category A waste 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:**

- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. <u>Stericycle, Inc. Health Hazard Evaluation</u> <u>Report</u>, by Angela M. Weber, Yvonne Boudreau, and Vincent D. Mortimer. HETA 98-0027-2709. Cincinnati, Ohio, 1998.
- Weber, Angela M., Yvonne Boudreau, and Vincent D. Mortimer. "A Tuberculosis Outbreak among Medical Waste Workers." Journal of the American Biological Safety Association 5, no. 2 (2000): 70-88.
- Johnson, Kammy R., Christopher R. Braden, K. Lisa Cairns, Kimberly W. Field, A. Craig Colombel, Zhenhua Yang, Charles L. Woodley, Glenn P. Morlock, Angela M. Weber, A. Yvonne Boudreau, Thomas A. Bell, Ida M. Onorato, Sarah E. Valway, and Paul A. Stehr-Green. "Transmission of Mycobacterium Tuberculosis from Medical Waste." Journal of the American Medical Association (JAMA) 284, no. 13 (2000): 1683-1688.
- 5. 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 and SLTT 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 and SLTT 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:**

Johnson, Kammy R., Christopher R. Braden, K. Lisa Cairns, Kimberly W. Field, A. Craig Colombel, Zhenhua Yang, Charles L. Woodley, Glenn P. Morlock, Angela M. Weber, A. Yvonne Boudreau, Thomas A. Bell, Ida M. Onorato, Sarah E. Valway, and Paul A. Stehr-Green. "<u>Transmission of Mycobacterium Tuberculosis from Medical Waste</u>." *Journal of the American Medical Association (JAMA)* 284, no. 13 (2000): 1683-1688.

- Keene, John H. "<u>Medical Waste: A Minimal Hazard</u>." Infection Control & Hospital Epidemiology 12, no. 11 (1991): 682-685.
- Phillips, G., "<u>Microbiological Aspects of Clinical Wastes</u>," *Journal of Hospital Infection*, 41, no. 1 (1999): 1-6.
- Rutala, William A., and David J. Weber. "<u>Infectious Waste—Mismatch Between Science and Policy.</u>" *New England Journal of Medicine* 325, no. 8 (1991): 578-582.
- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. <u>Stericycle, Inc. Health Hazard Evaluation</u> <u>Report</u>, by Angela M. Weber, Yvonne Boudreau, and Vincent D. Mortimer. HETA 98-0027-2709. Cincinnati, Ohio, 1998.
- Weber, Angela M., Yvonne Boudreau, and Vincent D. Mortimer. "A Tuberculosis Outbreak among Medical Waste Workers." Journal of the American Biological Safety Association 5, no. 2 (2000): 70-88.
- <u>Hazardous Materials Regulations</u>. 49 CFR parts 171-180. U.S. Department of Transportation,
   Pipeline and Hazardous Materials Safety Administration.

# WASTE DISPOSAL QUESTIONS & ANSWERS

#### 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/territory. 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/territory. 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). However, SLTT requirements may dictate disposal of certain residuals, including materials in red (i.e., biohazard) bags that have been autoclaved. If waste is determined to be hazardous under RCRA, however, it will need to be managed according to applicable hazardous waste requirements. This may include further treatment to address constituents in the waste (e.g., toxic metals, chemical contaminants), followed by disposal at a hazardous waste-permitted facility.

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 treated waste may be managed as a solid waste, and

also verify that the selected 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 SLTT authority; and should verify that the disposal facility received and properly processed the waste.

#### **Background/References:**

- Environmental Health Management Systems, Inc., Spectrum, and New York State Department of Health. <u>Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment</u> <u>Technologies</u>, by N.S. Slavik, E. Krisiunas, and I. Salkin. TR 112222. Palo Alto, California, 1998.
- <u>Criteria for Municipal Solid Waste Landfills</u>. 40 CFR part 258, subtitle D of *Resource Conservation and Recovery Act* (RCRA), Design Criteria, 128. U.S. Environmental Protection Agency, 1988.

## 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 remains contained and does not affect crops or ground water supplies nearby. Landfills are subject to minimum federal criteria under subtitle D of RCRA and to state/territorial 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 ground water 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 United States are designed to meet technical requirements to prevent ground water contamination, such as using liners to keep contaminants out of the soil and ground water. Municipal solid waste landfills are also subject to extensive ground water 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:**

<u>Criteria for Municipal Solid Waste Landfills</u>. 40 CFR part 258, subtitle D of *Resource Conservation and Recovery Act* (RCRA), Design Criteria, 128. U.S. Environmental Protection Agency, 1988.

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

**Key Message:** Under EPA's CAA requirements, 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 CAA. 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 infectious substances.

#### **Background/References:**

- Hospital/Medical/Infectious Waste Incinerators: Promulgated Amendments to the Federal Plan to Implement Standards of Performance for Existing Facilities and Promulgated Amendments to the New Source Performance Standards. U.S. Environmental Protection Agency, 2015.
- Environmental Health Management Systems, Inc., Spectrum, and New York State Department of Health. <u>Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment</u> <u>Technologies</u>, by N.S. Slavik, E. Krisiunas, and I. Salkin. TR 112222. Palo Alto, California, 1998.
- Clean Air Act Guidelines and Standards for Waste Management. U.S. Environmental Protection Agency, 2016. Includes information on National Emission Standards for Hazardous Air Pollutants (NESHAP); New Source Performance Standards; and Waste Incineration Rules – Clean Air Act (CAA) Section 129.
- 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, state/territorial 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.

**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, state/territorial 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.

#### **Background/References:**

- <u>Criteria for Municipal Solid Waste Landfills</u>. 40 CFR part 258, subtitle D of *Resource Conservation and Recovery Act* (RCRA), Design Criteria, 128. U.S. Environmental Protection Agency, 1988.
- <u>Hazardous Materials Regulations</u>. 49 CFR parts 171-180. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.
- 5. Is the ash from incinerated Category A infectious substances hazardous, infectious, or dangerous?

**Key Message:** The ash remaining after waste is incinerated is typically no longer infectious. Incinerators operate at temperatures much higher than required to inactivate most Category A infectious agents.

**Answer:** For most Category A waste, the ash remaining after it is incinerated is not infectious and no longer poses the risks associated with the Category A infectious substance. In rare cases, waste known to or suspected of containing prions may require additional treatment to ensure complete destruction of the prion.

Incinerator ash, as with other industrial wastes, nevertheless should be evaluated to ensure that appropriate storage and disposal requirements are identified and complied with. For example, although this ash may no longer be infectious, it could contain other toxic constituents (e.g., heavy metals) depending upon what materials were combusted, and the owner/operator should evaluate the ash as is the standard procedure prior to storage and ultimate disposal. Incinerators typically operate at very high temperatures, much higher than required to inactivate most 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 federal or SLTT hazardous waste regulations.

- Hazardous Waste Generators. U.S. Environmental Protection Agency, 2019.
- Clean Air Act Guidelines and Standards for Waste Management. U.S. Environmental Protection Agency, 2016. Includes information on National Emission Standards for Hazardous Air Pollutants (NESHAP); New Source Performance Standards; and Waste Incineration Rules – Clean Air Act (CAA) Section 129.

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 (or cycles) is not infectious and is generally not dangerous. Note that special combination inactivation treatments (usually alkaline chemicals along with stringent autoclave conditions) are needed for prions. However, sharps can still injure workers handling the waste.

**Answer:** Waste that has been autoclaved using an effective autoclave cycle (or cycles) is not infectious and is generally not dangerous. Note that special combination inactivation treatments (usually alkaline chemicals along with stringent autoclave conditions) are needed for prions. 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 substances, 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. Some infectious agents (e.g., prions, spores, and pathogens within biofilms) are particularly stable in the environment and difficult to inactivate. In particular, specialized inactivation procedures (such as high alkaline conditions plus lengthy times/high temperature autoclave cycles) are required for effective prion inactivation. 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:**

■ <u>Information on the Survivability of the Ebola Virus in Medical Waste</u>. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2015.

# WORKER PROTECTION QUESTIONS & ANSWERS

#### 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, safe 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:**

- U.S. Department of Labor, Occupational Safety and Health Administration; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; and U.S. Environmental Protection Agency. <u>Safe Handling</u>, <u>Treatment, Transport and Disposal of Ebola-Contaminated Waste</u>. FS-3766. Washington, DC, 2016.
- Hazardous Materials Regulations. 49 CFR parts 171-180. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration.

#### 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 safe 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) 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 generating, 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. Avoid dumping packaged waste into an autoclave or incinerator that cannot accommodate or process an entire unopened container, as this 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.

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.

**Background/References:** Under the OSHA *Bloodborne Pathogens*, *PPE*, and *Respiratory Protection* standards and other OSHA requirements, employers must protect workers who handle infectious waste from exposure to infectious agents, including Category A infectious substances, in the waste they handle.

Waste worker protection guidance from OSHA, the National Institute for Occupational Safety and Health (NIOSH), and EPA provides more detailed information about waste worker job tasks that may lead to occupational exposure, and methods for controlling potential exposures.

- U.S. Department of Labor, Occupational Safety and Health Administration; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; and U.S. Environmental Protection Agency. <u>Safe Handling</u>, <u>Treatment, Transport and Disposal of Ebola-Contaminated Waste</u>. FS-3766. Washington, DC, 2016.
- Occupational Safety and Health Act. 29 CFR §§ 651 et seq. (1970), U.S. Department of Labor, Occupational Safety and Health Administration.
- <u>Bloodborne Pathogens</u>. 29 CFR § 1910.1030 (2012). U.S. Department of Labor, Occupational Safety and Health Administration.

- Personal Protective Equipment. 29 CFR § 1910.132 (2011). U.S. Department of Labor, Occupational Safety and Health Administration.
- Respiratory Protection. 29 CFR § 1910.134 (2011). U.S. Department of Labor, Occupational Safety and Health Administration.
- 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, HHS/ASPR 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 SLTT 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* (29 CFR § 1910.1030), *PPE* (29 CFR 1910 subpart I), *Respiratory Protection* (29 CFR § 1910.134), and *HAZWOPER* (29 CFR § 1910.120) standards and other requirements, including the *General Duty Clause* of the *OSH 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 possessing 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). SLTT 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.

- U.S. Department of Labor, Occupational Safety and Health Administration; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; and U.S. Environmental Protection Agency. <u>Safe Handling</u>, <u>Treatment, Transport and Disposal of Ebola-Contaminated Waste</u>. FS-3766. Washington, DC, 2016.
- U.S. Department of Labor, Occupational Safety and Health Administration. <u>PPE Selection Matrix</u> for Occupational Exposure to Ebola Virus. FS-3761. Washington, DC, 2015.
- Occupational Safety and Health Act. 29 CFR §§ 651 et seq. (1970), U.S. Department of Labor, Occupational Safety and Health Administration.
- <u>Bloodborne Pathogens</u>. 29 CFR § 1910.1030 (2012). U.S. Department of Labor, Occupational Safety and Health Administration.
- Personal Protective Equipment. 29 CFR § 1910.132 (2011). U.S. Department of Labor, Occupational Safety and Health Administration.
- Respiratory Protection. 29 CFR § 1910.134 (2011). U.S. Department of Labor, Occupational Safety and Health Administration.
- Hazardous Waste Operations and Emergency Response. 29 CFR § 1910.120 (2013), U.S. Department of Labor, Occupational Safety and Health Administration.
- <u>Transporting Infectious Substances</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- Environmental Health Management Systems, Inc., Spectrum, and New York State Department of Health. <u>Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment</u> <u>Technologies</u>, by N.S. Slavik, E. Krisiunas, and I. Salkin. TR 112222. Palo Alto, California, 1998.
- Hazardous Waste Generators. U.S. Environmental Protection Agency, 2019.
- Medical Waste. U.S. Environmental Protection Agency, 2017.
- <u>Select Agent Regulations</u>. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; and U.S. Department of Agriculture; 2017.

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 Category A waste. 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. An alcohol-based hand rub does not replace washing with soap and water, but rather is used as an adjunct to routine hand washing.

- U.S. Department of Labor, Occupational Safety and Health Administration; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; and U.S. Environmental Protection Agency. <u>Safe Handling</u>. <u>Treatment, Transport and Disposal of Ebola-Contaminated Waste</u>. FS-3766. Washington, DC, 2016.
- U.S. Department of Labor, Occupational Safety and Health Administration. <u>PPE Selection Matrix</u> for Occupational Exposure to Ebola Virus. FS-3761. Washington, DC, 2015.
- U.S. Department of Health and Human Services, Food and Drug Administration. "Safety and <u>Effectiveness of Consumer Antiseptics</u>; Topical Antimicrobial Drug Products for Over-the-<u>Counter Human Use</u>." Federal Register 81 (September 6, 2016): 61106-61130.
- U.S. Department of Health and Human Services, Food and Drug Administration. "Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use." Federal Register 82 (December 20, 2017): 60474-60503.
- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Healthcare Infection Control Practices Advisory Committee (HICPAC). "Guideline for Hand Hygiene in Health-Care Settings," Morbidity and Mortality Weekly Report, MMWR 51, RR-16 (2002): 1-48.

- World Health Organization. *Guidelines on Hand Hygiene in Healthcare*. Geneva, Switzerland: World Health Organization, 2009.
- Aurora B. Le, Selin Hoboy, Anne Germain, Hal Miller, Richard Thompson, Jocelyn J. Herstein, Katelyn C. Jelden, Elizabeth L. Beam, Shawn G. Gibbs, and John J. Lowe, "A pilot survey of the US medical waste industry to determine training needs for safely handling highly infectious waste," *American Journal of Infection Control* 46, no. 2 (2018): 133–138.
- 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 Category A waste, 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 () 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 standard* (29 CFR § 1910.1030), 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.

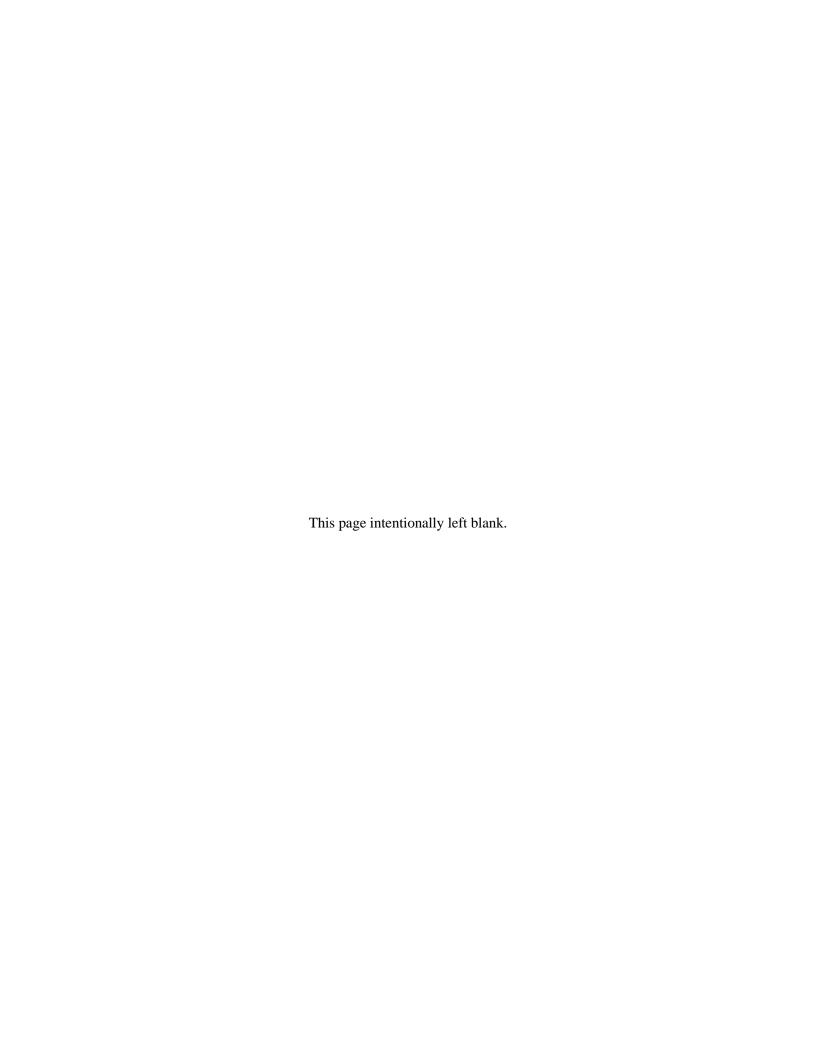
State/local agencies, including States that operate their own worker safety and health programs (OSHA State Plans), may have additional or more stringent requirements regarding worker training.

The National Institute of Environmental Health Sciences (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 related to hazardous materials management is available on the NIEHS <a href="https://hazmat.com/hazmatchangement">https://hazmatchangement.com/hazmatcha

The NETEC also provides <u>information</u> about preparedness and response to Ebola specifically and provides employers with resources for training and preparing their workers.

- Occupational Safety and Health Act. 29 CFR §§ 651 et seq. (1970), U.S. Department of Labor, Occupational Safety and Health Administration.
- <u>Bloodborne Pathogens</u>. 29 CFR § 1910.1030 (2012). U.S. Department of Labor, Occupational Safety and Health Administration.
- Personal Protective Equipment. 29 CFR § 1910.132 (2011). U.S. Department of Labor, Occupational Safety and Health Administration.

- Respiratory Protection. 29 CFR § 1910.134 (2011). U.S. Department of Labor, Occupational Safety and Health Administration.
- Hazardous Waste Operations and Emergency Response. 29 CFR § 1910.120 (2013), U.S.
   Department of Labor, Occupational Safety and Health Administration.



# APPENDIX E – DIRECTORY OF STATE AND TERRITORIAL WASTE MANAGEMENT PROGRAMS

State	Agency with waste program management responsibility	Agency phone number	Agency website
Alabama	Alabama Department of Environmental Management Land Division	(334) 271-7730	adem.alabama.gov/programs/land/default. cnt
Alaska	Alaska Department of Environmental Conservation	(907) 269-7802	dec.alaska.gov/eh/solid-waste/
American Samoa	American Samoa Environmental Protection Agency	(684) 633-2304	www.epa.as.gov/hazardous-materials
Arizona	Arizona Department of Environmental Quality	(602) 771-4136	www.azdeq.gov/biohazardous-medical- waste
Arkansas	Arkansas Department of Health	(501) 661-2936	www.healthy.arkansas.gov/programs- services/topics/medical-waste-program
California	California Department of Public Health	(916) 558-1784	www.cdph.ca.gov/Programs/CEH/DRSE M/Pages/EMB/MedicalWaste/MedicalWaste.aspx
Colorado	Colorado Department of Public Health and Environment	(303) 692-3320	www.colorado.gov/pacific/cdphe/medical waste
Commonwealth of the Northern Mariana Islands	Bureau of Environmental and Coastal Quality, Division of Environmental Quality	(670) 664-8500	deq.gov.mp/sec.asp?secID=11
Connecticut	Department of Energy & Environmental Protection Waste Management Division	(888) 424-4193	www.ct.gov/deep/cwp/view.asp?a=2718 &q=325340&deepNav_GID=1646
Delaware	Delaware Department of Natural Resources and Environmental Control	(302) 739-9403	regulations.delaware.gov/AdminCode/title7/1000/1300/1301.shtml#TopOfPage
District of Columbia	Department of Health	(202) 442-5955	doh.dc.gov/
	Department of Public Works	(202) 673-6833	dpw.dc.gov/
Florida	Florida Department of Environmental Protection Florida Department of	(850) 245-8705 (850) 245-4277	www.dep.state.fl.us/waste/  www.floridahealth.gov/Environmental-
Georgia	Health Georgia Department of Natural Resources	(404) 362-2692	Health/biomedical-waste/index.html epd.georgia.gov/solid-waste
Guam	Guam Environmental Protection Agency	(671) 300-4751	epa.guam.gov/programs/solid-waste/
Hawaii	Hawaii Department of Health, Division of Environmental Health	(808) 586-4226	health.hawaii.gov/shwb/solid-waste/

State	Agency with waste program management responsibility	Agency phone number	Agency website
Idaho	Idaho Department of Environmental Quality Waste Management Division	(208) 373-0121	www.deq.idaho.gov/waste-mgmt- remediation/solid-waste/medical-waste/
Illinois	Illinois Environmental Protection Agency	(217) 524-3289	www.epa.illinois.gov/topics/waste- management/waste-disposal/special- waste/pimw/index
Indiana	Indiana State Department of Health	(317) 233-1325	www.in.gov/isdh/25513.htm www.in.gov/legislative/ic/code/title16/ar4 1/ch16.html
Iowa	Iowa Department of Natural Resources, Solid Waste Division	(515) 281-5918	www.iowadnr.gov/InsideDNR/Regulatory Land/SolidWaste.aspx
Kansas	Kansas Department of Health and Environment	(785) 296-1500	www.kdheks.gov/waste/techguide/sw00- 01.pdf
Kentucky	Kentucky Energy and Environment Cabinet, Department for Environmental Protection	(502) 564-6716	waste.ky.gov/RLA/Pages/medical waste. aspx
Louisiana	Louisiana Department of Environmental Quality Louisiana Department of	(225) 219-5337 (225) 342-8959	www.doa.la.gov/pages/default.aspx  new.dhh.louisiana.gov/index.cfm/page/61
	Health	(223) 342 0)3)	0
Maine	Maine Department of Environmental Protection	(207) 287-7718	www.maine.gov/dep/waste/biomedical/index.html
Maryland	Maryland Department of the Environment, Hazardous Waste Program	(410) 537-3314	www.dsd.state.md.us/comar/subtitle_chap ters/26 Chapters.aspx
Massachusetts	Executive Office of Health and Human Services, Department of Public Health	(617) 573-1600	www.mass.gov/eohhs/gov/departments/dp h/programs/environmental-health/comm- sanitation/medical-waste.html
	Massachusetts Executive Office of Energy and Environmental Affairs, Department of Environmental Protection	(617) 626-1000	www.mass.gov/eea/agencies/massdep/rec ycle/hazardous/infectious-waste-disposal- and-transport.html
Michigan	Michigan Department of Environmental Quality	(517) 284-6588	www.michigan.gov/deq/0,4561,7-135- 3312 4123 4119,00.html
Minnesota	Minnesota Pollution Control Agency	(651) 296-6300	www.pca.state.mn.us/waste/health-care- industry
Mississippi	Mississippi Department of Environmental Quality	(601) 961-5171	www.deq.state.ms.us/mdeq.nsf/pdf/SW_MDEQMedicalWasteFactSheet/\$File/MedWasteFactSheet.pdf
	Mississippi State Department of Health	(601) 576-7400	www.msdh.state.ms.us/msdhsite/index.cf m/30,116,83,pdf/licensureinfecreg.pdf
Missouri	Missouri Department of Natural Resources	(573) 751-5401	www.sos.mo.gov/cmsimages/adrules/csr/current/10csr/10c80-7.pdf
	Missouri Department of Health and Senior Services	(573) 751-6400	s1.sos.mo.gov/cmsimages/adrules/csr/curr ent/19csr/19c30-20.pdf

State	Agency with waste program management responsibility	Agency phone number	Agency website
Montana	Montana Department of Environmental Quality	(406) 444-2544	deq.mt.gov/twr/Programs/solidwaste
Nebraska	Nebraska Department of Environment and Energy	(402) 471-2186	www.deq.state.ne.us/ 86256873006009 CB.nsf/0/AA506C2EEE983E308625696 D005855BE
Nevada	Nevada Division of Environmental Protection	Carson City: (775) 687-4670 Las Vegas: (702) 486-2850	ndep.nv.gov/land/waste/solid- waste/special-waste-management
New Hampshire	New Hampshire Department of Environmental Services	(603) 271-2919	www.des.nh.gov/waste/solid-waste
New Jersey	New Jersey Department of Environmental Protection	(609) 633-1418	www.nj.gov/dep/dshw/rrtp/rmw.htm
New Mexico	New Mexico Environment Department, Solid Waste Bureau	(505) 827-0197	www.env.nm.gov/solid-waste/
New York	New York Department of Environmental Conservation	(518) 402-8792	www.dec.ny.gov/chemical/8789.html
North Carolina	North Carolina Department of Environment and Natural Resources, Division of Waste Management	(919) 707-8200	deq.nc.gov/about/divisions/waste- management/waste-management-permit- guidance/solid-waste-section/medical- waste
North Dakota	North Dakota Department of Environmental Quality	(701) 328-5164	deq.nd.gov/WM/InfectiousWaste/
Ohio	Ohio Environmental Protection Agency	(614) 644-3020	www.epa.ohio.gov/dmwm/Home/Infectio usWaste.aspx
Oklahoma	Oklahoma Department of Environmental Quality	(405) 702-0100	www.deq.ok.gov/divisions/lpd/
Oregon	Oregon Department of Environmental Quality	(503) 229-5696	www.oregon.gov/deq/hazards-and- cleanup/hw/pages/infectious-waste.aspx
Pennsylvania	Pennsylvania Department of Environmental Protection	(717) 783-2388	www.dep.pa.gov/Business/Land/Waste/S olidWaste/MunicipalWaste/Regulated- Medical-Chemotherapeutic- Waste/Pages/default.aspx
Puerto Rico	Junta de Calidad Ambiental (Environmental Quality Board)	(787) 767-8181	hwww.pr.gov
Rhode Island	Rhode Island Department of Environmental Management, Office of Waste Management	(401) 222-2797	www.dem.ri.gov/programs/wastemanage ment/facilities/medical-waste.php
South Carolina	South Carolina Department of Health and Environmental Control, Division of Waste Management	(803) 898-3432	www.scdhec.gov/Environment/LW/Infect iousWaste/
South Dakota	South Dakota Department of Environment and Natural Resources	(605) 773-3153	danr.sd.gov/Environment/WasteManagem ent/SolidWaste/MedicalWaste.aspx

State	Agency with waste program management responsibility	Agency phone number	Agency website
Tennessee	Tennessee Department of Environment & Conservation, Division of Solid and Hazardous Waste Management	(615) 532-0780	www.tn.gov/environment/program- areas/solid-waste/hazardous-waste- management/medical-waste.html
Texas	Texas Commission on Environmental Quality	(512) 239-6413	www.tceq.texas.gov/permitting/waste_permits/msw_permits/medwaste
U.S. Virgin Islands	Department of Planning and Natural Resources	(340) 774-3320 ext. 5215	dpnr.vi.gov/environmental- protection/solid-waste-management- program/
Utah	Utah Department of Environmental Quality Division of Solid and Hazardous Waste	(801) 536-0200	deq.utah.gov/division-waste- management-radiation-control
Vermont	Vermont Agency of Natural Resources Waste Management Division	(802) 828-1138	anr.vermont.gov/index.php
Virginia	Virginia Department of Environmental Quality	(804) 698-4000	www.deq.virginia.gov/permits/waste/med ical-waste
Washington	Washington Department of Ecology	(360) 407-6700	ecology.wa.gov
West Virginia	Office of Environmental Health Services Public Health Sanitation Division	(304) 368-4420 ext. 79404	oehs.wvdhhr.org/phs/infectious-medical- waste-disease-control
Wisconsin	Wisconsin Department of Natural Resources	(888) 936-7463	dnr.wi.gov/topic/healthwaste/infectious.ht ml
Wyoming	Wyoming Department of Environmental Quality	(307) 777-7937	deq.wyoming.gov/shwd/

Note: Additional state, local, tribal, and/or territorial (SLTT) worker health and safety requirements may apply to the management of solid Category A waste, including requirements of various OSHA State Plans.

# APPENDIX F – PATHOGEN-SPECIFIC INFORMATION

This appendix describes information specific to individual pathogens that are classified as Category A infectious substances (see <u>Appendix B – Infectious Agent Categorization</u> for additional information). This appendix may be expanded or revised to provide additional pathogen-specific guidance for new and emerging infectious diseases.

For each pathogen, the appendix provides information about classification and requirements under the U.S. Department of Transportation (DOT) *Hazardous Materials Regulations* (HMR) (including any DOT/Pipeline and Hazardous Materials Safety Administration special permits issued under its authority), inactivation, and environmental surface disinfection.

# F-1. EBOLA (EBOLA VIRUS) AND MARBURG (MARBURG VIRUS)

#### **Summary**

Ebola virus	
Classification	Category A, always (until inactivated)
DOT Special Permit (SP) issued?	Yes, SP 16279
Packaging	Consult SP 16279 from the DOT/PHMSA
	database, or package in accordance with
	requirements for Category A infectious substances
	found in 49 CFR § 173.196
Shipping Name	• For Ebola: United Nations (UN) 2814,
	Infectious substances, affecting humans (Ebola
	waste), 6.2
	• For Marburg: United Nations (UN) 2814,
	Infectious substances, affecting humans
	(Marburg waste), 6.2
<b>Inactivation methods (must be validated)</b>	Autoclaving, incineration, chemical
Autoclaving	Validated cycle that reaches ≥121°C/250°F for
	≥30 minutes; time and temperature depend on
	type, state, and volume of material
Incineration	Cycle must reduce materials to ash
Chemical	When required by operational considerations
	outside of fixed facilities; support effectiveness
	with objective data
Disinfectant(s)	• For Ebola, use an EPA-registered disinfectant on <u>List L</u> , or any product on <u>List Q</u> (emerging viral pathogen claim) if List L products are unavailable.
	• For Marburg, use an EPA-registered disinfectant on List Q (emerging viral pathogen claim).

#### Classification

Both Ebola and Marburg viruses are always considered a Category A infectious substance, regardless of whether or not they are cultured. They must be managed accordingly under the HMR.

#### **Special Permit**

SP 16279 provides alternative requirements for packaging and transporting Ebola or Marburg waste. The DOT/Pipeline and Hazardous Materials Safety Administration (PHMSA) <u>special permits database</u> contains records of the companies currently holding party status to SP 16279. To view the SP and entities that have held party status to it, enter "16279" in the "Special Permit Number" box and click "Search" on the search page.

#### Inactivation

Both Ebola and Marburg viruses should typically be inactivated through autoclaving or incineration. 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. Alternative methods should be supported by objective data that demonstrate their effectiveness at inactivating Ebola- or Marburg-contaminated waste.

When autoclaving Ebola- or Marburg-contaminated waste, achieving sufficient time/temperature conditions will ensure that waste materials are no longer infectious. For Ebola or Marburg viruses, the waste should reach 121°C/250°F for at least 30 minutes. As described in other sections of this document, using biological indicators (e.g., *Bacillus* spore strips) can ensure adequate time, temperature, and heat/steam penetration to inactivate infectious Ebola or Marburg virus particles in the waste.

Incinerators operate at extremely high temperatures, well above the relatively low temperatures actually required to inactivate Ebola or Marburg virus. Incineration that reduces waste to ash at any temperature inactivates both Ebola and Marburg virus. Incineration, if available on-site and properly permitted, would be the best method for large or bulky items, such as mattresses (though consideration should be given to whether there are size limits for incinerators) that may be associated with terminal (i.e., final) cleaning after hospital patient discharge or residential environmental remediation activities.

#### **Environmental Surface Disinfection**

For disinfecting environmental surfaces contaminated with Ebola virus, use an EPA-registered disinfectant on <u>List L</u>, or any product on <u>List Q</u> (emerging viral pathogen claim) if <u>List L</u> products are unavailable. For Marburg virus, use an EPA-registered disinfectant on <u>List Q</u> (emerging viral pathogen claim). Follow the manufacturer's directions for concentration, contact time, and care and handling. Consult EPA with questions.

#### **Shipping Paper Requirements**

The HMR's shipping paper requirements identify key hazard communication information. Under the HMR, shipping papers must include:

- UN identification number and proper shipping name for the applicable Category A infectious substance.
  - o For Ebola, include the UN identification number and proper shipping name: "UN 2814, Infectious substances, affecting humans (Ebola waste), 6.2;"

- o For Marburg, include the UN identification number and proper shipping name: "UN 2814, Infectious substances, affecting humans (Marburg waste), 6.2;"
- Hazard class: Division 6.2 (infectious substance);
- Packing group: N/A;
- Type and quantity of packaging; and
- Emergency response information (e.g., telephone number).

#### **Additional Resources**

- <u>Ebola Concept of Operations (ConOps) Planning Template</u>. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2015.
- Interim Guidance for Emergency Medical Services (EMS) Systems and 9-1-1 Emergency
   Communications Centers/Public Safety Answering Points (ECC/PSAPs) for Management of
   Patients Suspected to have Selected Viral Hemorrhagic Fevers in the United States. U.S.
   Department of Health and Human Services, Centers for Disease Control and Prevention, 2023.
- Emerging Viral Pathogens Policy. U.S. Environmental Protection Agency, 2022.
- <u>Marburg (Marburg Virus Disease)</u>, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2023.
- <u>Ebola (Ebola Disease)</u>, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2023.

#### Waste Management

- Are You Preparing Suspected Ebola Contaminated Waste For Transportation? Poster. U.S.
   Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.
- <u>Infection Prevention and Control Recommendations for Patients in U.S. Hospitals who are Suspected or Confirmed to have Selected Viral Hemorrhagic Fevers (VHF)</u>. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2023.
- U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration "Packaging and Handling Ebola Virus Contaminated Infectious Waste for Transportation to <u>Disposal Sites.</u>" Federal Register 79, no. 210 (October 30, 2014): 64646.
- <u>Guidance for Collection, Transport, and Submission of Specimens for Ebola Virus Testing</u>. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2015.
- <u>Infectious Substance Special Permits</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2022.

#### Worker Safety and Health

Guidance on Personal Protective Equipment (PPE) in U.S. Healthcare Settings during Management
of Patients Confirmed to have Selected Viral Hemorrhagic Fevers or Patients Suspected to have
Selected Viral Hemorrhagic Fevers who are Clinically Unstable or Have Bleeding, Vomiting, or
Diarrhea. U.S. Department of Health and Human Services, Centers for Disease Control and
Prevention, 2023.

- U.S. Department of Labor, Occupational Safety and Health Administration. *PPE Selection Matrix for Occupational Exposure to Ebola Virus*. FS-3761. Washington, DC, 2015.
- <u>Safety and Health Topics: Ebola</u>. U.S. Department of Labor, Occupational Safety and Health Administration, 2014.
- U.S. Department of Labor, Occupational Safety and Health Administration; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; and U.S. Environmental Protection Agency. <u>Safe Handling</u>, <u>Treatment, Transport and Disposal of Ebola-Contaminated Waste</u>. FS-3766. Washington, DC, 2016.

Environmental Management & Infection Control

- <u>Information on the Survivability of the Ebola Virus in Medical Waste</u>. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2015.
- Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus. U.S.
  Department of Health and Human Services, Centers for Disease Control and Prevention,
  2015. Guidance for Decontamination and Removal of Ebolavirus-Contaminated Waste for U.S.
  Residence. U.S. Department of Health and Human Services, Centers for Disease Control and
  Prevention, 2023.

# F-2. MPOX (MONKEYPOX VIRUS)

## **Summary**

Previous studies have defined two distinct Monkeypox virus (MPXV) clades, Clade I (formerly known as *Congo Basin*) and Clade II (formerly known as *West African*), with unique disease manifestations (i.e., how disease presents in people, the severity of its effects, and how readily it spreads). Both clades cause mpox in humans. Human disease associated with Clade II MPXV infection is typically less severe and associated with less human-to-human transmission compared to infections with Clade I MPXV. <sup>43</sup> Because of this, recommendations for managing waste contaminated with MPXV have differed primarily based on the clade of the virus. However, the U.S. healthcare and public health systems' experience in managing domestic cases of Clade II MPXV since 2022—including some patients with severe illness—suggests that approaches used to safely manage healthcare-generated waste contaminated with Clade II MPXV can be applied to the management of most healthcare-generated waste contaminated with Clade I MPXV, as well. Thus, waste management approaches should consider the type of materials requiring safe disposal. Most MPXV materials can be managed as Regulated Medical Waste (RMW); however, MPXV Clade I viral cultures (i.e., materials containing or contaminated with intentionally propagated virus) must be managed in accordance with the HMR requirements for Category A infectious substances, as described below.

<sup>&</sup>lt;sup>43</sup> Christina L. Hutson, Victoria A. Olson, Darin S. Carroll, Jason A. Abel, Christine M. Hughes, Zachary H. Braden, Sonja Weiss et al., "A prairie dog animal model of systemic orthopoxvirus disease using West African and Congo Basin strains of monkeypox virus," *Journal of General Virology* 90, no. 2 (2009): 323–333.

Monkeypox virus		
Classification	MPXV Clade I Viral cultures or materials contaminated with cultured MPXV Clade I virus  Category A, always (until	Materials other than MPXV Clade I viral cultures or those contaminated with cultured MPXV Clade I virus  Regulated Medical Waste (RMW) <sup>44</sup>
DOT Special Permit (SP) issued?	inactivated) <sup>44</sup> None issued as of publication of this document. See PHMSA's <u>Infectious</u>	No, not required unless using a packaging not currently authorized
Do also sime	Substance Special Permit website for status.	by the HMR.
Packaging	Package in accordance with requirements for Category A infectious substances found in 49 CFR § 173.196.	Package in accordance with applicable regulations for RMW found in 49 CFR § 173.197.
Shipping Name	UN 2814, Infectious substances, affecting humans (Monkeypox virus waste), 6.2	UN 3291, Regulated medical waste, n.o.s., 6.2
Inactivation methods (must be validated)	Autoclaving, incineration, chemical	Treat and/or dispose of such waste in accordance with applicable SLTT
Autoclaving	Validated cycle that reaches ≥121°C/250°F for ≥30 minutes; time and temperature depend on type, state, and volume of material	laws and regulations for RMW.
Incineration	Cycle must reduce materials to ash	
Chemical	When required by operational considerations outside of fixed facilities; support effectiveness with objective data	
Disinfectant(s)	U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant with an emerging viral pathogen label claim or any product on List Q with an emerging pathogen label claim.	

## Classification

Clade I MPXV is considered a Category A infectious substance whenever it is cultured and, in that form, must be managed accordingly under the HMR.

However, the U.S. Government (USG) does not consider either clade of MPXV in other forms (i.e., not cultured), nor cultures of Clade II MPXV, as meeting the definition of a Category A infectious substance under the HMR. Waste contaminated with MPXV should be managed as RMW unless the waste contains, or is contaminated with infectious materials from, Clade I MPXV cultures.

Note that categorization of MPXV under the HMR is different from select agent status under the federal select agent regulations. Clade I MPXV remains on the U.S. Department of Health and Human Services

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<sup>&</sup>lt;sup>44</sup> <u>Safety Advisory Notice—Classification of MPXV Diagnostic Samples and Waste</u>. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 2024.

(HHS) select agent list and is subject to applicable HHS/Centers for Disease Control and Prevention (CDC) requirements at 42 CFR parts 72 and 73. Clade II MPXV is excluded from the federal select agent regulations at 42 CFR parts 72 and 73. Neither clade is regulated by the U.S. Department of Agriculture (USDA) at 7 CFR part 331 and 9 CFR part 121, as they are not agricultural select agents.

Offerors classifying waste materials for transportation under the HMR should do so based on their knowledge of the contents of the waste. However, individuals or entities assessing their responsibilities under the federal select agent regulations should rely on the results of molecular assays or genetic sequencing of samples (i.e., from known or suspected mpox patients whose care results in the generation of waste) to determine the clade of virus, as requirements of the federal select agent regulations apply differently between clades, as noted above.

# **Special Permit**

At the time this document was published, no active DOT special permit was relevant to packaging and transporting MPXV-containing or -contaminated waste.

Prior to this document's publication, which reflects the USG assessment that, except for Clade I MPXV in culture form, MPXV (i.e., Clade II in all forms and Clade I when not in culture form) does not meet the definition of a Category A infectious substance, a special permit would have been needed to allow for the transportation of bulk waste materials containing or contaminated with Clade I MPXV, regardless of the form (i.e., cultures or otherwise), when such materials could not otherwise be packaged according to requirements specified in the HMR. To address this issue while the USG considered appropriate measures for safe and effective management of waste resulting from the care of patients infected with Clade I MPXV, in the event that such a case is identified in the United States, DOT issued SP 21707 in January 2024. From that time until March 11, 2024, when DOT issued a safety advisory notice on the classification of MPXV diagnostic samples and waste, SP 21707 was needed to allow for the transportation of Clade I MPXV-contaminated medical waste for disposal under the HMR. The permit addressed alternative packagings and certain operational (e.g., safety and security) controls for transporting such waste. However, as described above, the USG has since determined that, except for waste containing cultures of Clade I MPXV or contaminated with cultured Clade I MPXV, MPXV does not meet the definition of a Category A infectious substance and, thus, waste containing or contaminated with the virus can be managed as RMW.

In the future, if a special permit is needed and one is issued, the <u>Infectious Substance Special Permit website</u> will be updated with the permit information.

To learn more about the DOT/PHMSA special permits process, including the <u>application process</u>, visit the <u>Special Permits Overview page</u>. The DOT/PHMSA <u>special permits database provides</u> more information on specific permits and holders of party status. View and search for special permits from that page.

#### Inactivation

Waste containing viral cultures of Clade I MPXV, or otherwise contaminated with cultured Clade I MPXV, should typically be inactivated through autoclaving or incineration.

When autoclaving waste containing viral cultures of Clade I MPXV, or otherwise contaminated with cultured Clade I MPXV, achieving sufficient time/temperature conditions will ensure that waste materials are no longer infectious. The waste should reach 121°C/250°F for at least 30 minutes. As described in other sections of this document, using biological indicators (e.g., *Bacillus* spore strips) can ensure

adequate time, temperature, and heat/steam penetration to inactivate infectious MPXV particles in the waste. Although the types of materials expected to make up waste streams containing or contaminated with cultured Clade I MPXV may be generally limited to laboratory supplies and equipment, the composition of waste still affects conditions necessary in the inactivation process to ensure waste materials are no longer infectious.

Incinerators operate at extremely high temperatures, well above the relatively low temperatures actually required to inactivate MPXV. Incineration that reduces waste to ash at any temperature inactivates MPXV. Incineration, if available on-site and properly permitted, would be the best method for large or bulky items in instances in which they need to be managed as materials contaminated with a Category A infectious substance (though consideration should be given to whether there are size limits for on-site incinerators).

This guidance does not apply to inactivation of waste that does not meet the definition of a Category A infectious substance. Such waste should be treated and disposed of in accordance with applicable SLTT laws and regulations for RMW.

#### **Environmental Surface Disinfection**

For disinfecting environmental surfaces contaminated with MPXV, regardless of clade, use an EPA-registered disinfectant on <u>List Q</u> (an emerging viral pathogen claim). Follow the manufacturer's directions for concentration, contact time, and care and handling. Consult EPA with questions.

#### **Shipping Paper Requirements**

The HMR's shipping paper requirements identify key hazard communication information.

Under the HMR, shipping papers for waste contaminated with MPXV must include:

- UN identification number and proper shipping name for the applicable waste stream:
  - o For Category A infectious substances (i.e., waste containing or contaminated with cultured MPXV), include "UN 2814, Infectious substances, affecting humans (Monkeypox virus waste), 6.2."
  - o For RMW (i.e., waste other than viral cultures or those contaminated with cultured virus), include "UN3291, Regulated medical waste, n.o.s., 6.2"
- Hazard class: Division 6.2 (infectious substance);
- Packing group:
  - o For Category A infectious substances: does not apply;
  - o For RMW: II;
- Type and quantity of packaging; and
- Emergency response information (e.g., telephone number).

For more information on packing and marking RMW, see "Packing and Marking of Category B Infectious Substances" in the DOT/PHMSA "Transporting Infectious Substances Safely" publication.

#### **Additional Resources**

- Mpox. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2024.
- Emerging Viral Pathogens Policy. U.S. Environmental Protection Agency, 2022.











