

TIP No. 006-0423 Waste Characterization of Silver Nitrate Application Sticks

- 1. **PURPOSE.** This document provides the rationale for characterizing used and unused silver nitrate applicator sticks as non-infectious, ignitable, and toxic hazardous waste (HW), which is identified by the U.S. Environmental Protection Agency (EPA) HW numbers D001 and D011.
- **2. REFERENCES.** See Appendix A for a list of reference information.

3. BACKGROUND

A. Product Description

Silver nitrate applicators (also referred to as STYPT-STIX, caustic pencils, or "sticks") cauterize blood vessels to stop superficial bleeding, remove warts, and remove excessive granulation and tissue around wounds. Dentists use them to heal oral ulcers. Veterinarians use them to stop bleeding of minor cuts, particularly those encountered when clipping the nails of dogs or cats. Silver nitrate sticks are prescription pharmaceutical products with national drug codes and expiration dates. Once the product expiration date elapses, all remaining sticks in the package require disposal.

An unused silver nitrate stick contains visible amounts of silver/potassium nitrate solid in the form of a match tip. Contact with body fluids or water activates the applicator tip. When in contact with fluids, a reaction of the oxidizer chemicals and the silver occurs, creating heat to cauterize/burn the tissues and form a scab containing silver. Once in contact with blood/fluids, the chemicals on the tip of the stick cauterize the wound and stop wound bleeding within seconds. Only the tip of the stick is actively used in treatment. One applicator with an estimated contact time of 10 to 30 seconds is sufficient for each application.

B. Composition

The silver nitrate applicator stick composition consists of a rigid wooden stick tipped with a solid comprised of a mixture of 75% Silver Nitrate and 25% Potassium Nitrate in a form that resembles a match tip. Silver nitrate serves as a caustic antiseptic and an astringent. Potassium nitrate serves as a topical antiseptic on mucous membranes.

C. U.S. Environmental Protection Agency (EPA) Waste Classifications

The EPA classifies silver concentrations greater than 5 milligrams per liter (mg/L), which is determined using the toxicity characteristic leaching procedure (TCLP), as HW in Title 40 Code of Federal Regulations (CFR) Part 261.24. The EPA HW number for silver is D011.

The EPA classifies an oxidizer as an ignitable HW in 40 CFR Part 261.21 and defines oxidizer as a substance such as a chlorate, permanganate, inorganic peroxide, or a nitrate, that yields oxygen readily to stimulate the combustion of organic matter. The EPA HW number for ignitability is D001.

4. UNUSED SILVER NITRATE APPLICATOR STICK WASTE CHARACTERIZATION

- **A. Ignitability**. The characteristic of ignitability was assessed using product safety data sheets (SDSs) from multiple manufacturers and the product package inserts. The product package inserts detailed material compositions of potassium nitrate and silver nitrate (both oxidizers). The SDSs described the unused products as oxidizers. Product SDSs instructed users to perform proper waste characterizations prior to disposal according to all Federal, State, and local regulations. An unused silver nitrate applicator stick is a strong irritant to skin and tissue and is an oxidizer, resulting in an ignitable HW characterization when disposed.
- **B. Toxicity**. The Defense Health Agency (DHA) Defense Centers for Public Health Aberdeen (DCPH-A) [formerly, the U.S. Army Public Health Center] conducted a waste characterization of unused silver nitrate sticks in April 2011. Five representative samples comprised of unused silver nitrate sticks were submitted to the DCPH-A Laboratory for silver analyses per the EPA mandated TCLP test. All five samples exceeded the TCLP limit of 5 milligrams per liter (mg/L) by an average of 55 times the 5 mg/L limit, indicating the unused sticks are HW for silver content.
- **C. Waste Characterization**. Unused silver nitrate sticks are both an ignitable HW (D001) and a toxic HW for silver content (D011). See section 6 for disposal options and regulatory considerations.

5. USED SILVER NITRATE APPLICATOR STICK WASTE CHARACTERIZATION

Used silver nitrate applicator sticks were assessed for HW and regulated medical waste (RMW) characteristics because they are used to treat wounds.

A. Treatment Duration

During treatment, the tip is partially depleted during the chemical reaction that occurs when in contact with body fluids. The DCPH-A interviewed doctors to determine the average contact time a silver nitrate applicator stick is used during treatment. The average contact time was 10 to 30 seconds for each application. Onsite treatment observations were also conducted to verify the accuracy of the interview responses. The validated range of 10 to 30 seconds was then used to develop a sampling strategy to evaluate used silver nitrate stick applicators for silver content.

B. Observed Treatment Process

Medical personnel do not submerge the wooden part of the stick directly into body fluids; only the tip is submerged into a wound. Any residual fluids that may drip onto the stick near the tip were in contact with the silver nitrate and potassium nitrate chemicals during treatment. The residual fluid dries in a matter of minutes due to the heat created from the chemical reaction of the silver/potassium nitrate solution. This chemical reaction provides antiseptic treatment and creates a scab on the wound, effectively stopping blood flow. A black, charred stain is left by the chemical reaction and should not be mistaken for residual fluid stains. Any residual fluid stains will look brown, not black. Appendix B provides a picture of the used stick—one with a residual stain and one without for comparison. Observed clinical treatment practices were approximately

30 seconds to 1 minute of application time. After application, visible amounts of silver/potassium nitrate solid remain on stick tip because the average treatment time does not deplete all the solid content. It takes approximately 5 minutes to deplete all solid content from the applicator stick.

C. Hazardous Waste Characterization

- (1) Oxidizer (D001 Ignitable Hazardous Waste). The silver/potassium nitrate solid in the stick tip is a strong irritant to skin and tissue and is an oxidizer. After application, visible amounts of silver/potassium nitrate solid remain on the tip of each stick because the average treatment time does not deplete all the solid content. This remaining solid silver/potassium nitrate is still classified as an oxidizer because it was not completely consumed during the treatment process. Thus, if visible material remains on the tip of the stick, it is classified as an EPA HW for ignitability (D001) due to the oxidizer component.
- (2) <u>Silver (D011 Toxic Hazardous Waste)</u>. In September 2011, the DCPH-A conducted a waste characterization sampling study of used silver nitrate sticks to determine the silver concentrations remaining on the sticks after treatment. The DCPH-A, Environmental Health Sciences Division (EHSD), Waste Management Branch devised a sampling plan and procedures to collect representative samples based on clinical treatment practices of approximately 30 seconds to 1 minute of application time. Current silver nitrate stick composition and medical use remains the same as in 2011. The silver nitrate applicator sticks were applied to a bleeding wound for approximately 1 minute each and then composited into sample containers. The DCPH-A Laboratory analyzed seven representative samples (approximately 115 sticks per sample) for TCLP silver concentrations. All sample results exceeded the EPA HW limit of 5 mg/L by an average of 40 times the limit; thus, indicating the used sticks are HW for silver content. The EPA HW number for silver is D011.

D. Regulated Medical Waste Assessment

Visible stains can occur on the stick where the treatment tip joins the wooden stick (see Appendix B). The stains are dry within minutes of treatment and are not capable of caking or sloughing off the stick. To address concerns about the stains, the DCPH-A conducted an RMW assessment to determine whether the sticks require RMW management and treatment. The assessment involved a complete regulatory review (i.e., Occupational Safety and Health Administration (OSHA) and State RMW regulations), onsite treatment observations, and consultation with multiple microbiologists at DHA (previously U.S. Army Medical Command laboratories) and is detailed in this section. According to the DCPH-A RMW assessment, the used sticks are not RMW (also referred to as infectious waste) even if visible stains exist on the sticks because—

- No free-flowing, dripping, or saturated fluids remain on used silver nitrate sticks;
- No biohazardous growth is possible on the dry sticks or dry stains; and
- No state specifically classifies used silver nitrate sticks as infectious/RMW.
- (1) <u>The OSHA Bloodborne Pathogen Standard</u>. The OSHA Bloodborne Pathogen Standard, Title 29 CFR Part 1910, Section 1910.1030(b), is the regulatory reference most states

refer to when defining RMW. The DHA referenced this regulation when writing DHA Procedural Manual (DHA-PM) 6050.01, *Medical Logistics (MEDLOG) Regulated Medical Waste (RMW) Management*, which applies to all continental DHA medical treatment facilities (DHA 2021).

An OSHA Frequently Asked Question (FAQ) response clarifies that "regulated waste" (OSHA term for infectious waste/RMW) must be free-flowing fluids or be capable of releasing fluids or caked material upon compression (see Appendix C). The OSHA FAQ response states, "The Bloodborne Pathogens standard uses the term, "regulated waste," to refer to the following categories of waste which require special handling:

- (1) Liquid or semi-liquid blood or other potentially infectious materials (OPIM);
- (2) Items contaminated with blood or OPIM and which would release these substances in a liquid or semi-liquid state if compressed;
- (3) Items that are caked with dried blood or OPIM and are capable of releasing these materials during handling;
- (4) Contaminated sharps; and
- (5) Pathological and microbiological wastes containing blood or OPIM."

The OSHA Bloodborne Pathogen Preamble documents the regulatory discussions pertaining to how OSHA determined that anything infectious must be fluid or capable of releasing fluid when compressed. Appendix D provides an extract of this preamble. Appendix D gives a good description of the compression and fluid considerations with very insightful background into the classifications and risk considerations.

An extract from the past trial EPA Medical Waste Tracking Act, where the EPA set the definitions for RMW, is provided in Appendix E because the OSHA preamble in Appendix D refers to it. The Act uses the term "saturated and/or dripping" for the blood and bandages classification (Class 3) (Appendix E). This is the historical origin for the terminology "dripping or saturated."

- (2) <u>Laboratory Testing</u>. Upon request, the DCPH-A, EHSD, Waste Management Branch attempted to submit used sticks to two DHA medical microbiology labs to test for biohazardous growth as an investigational study. In both requests, microbiology personnel rejected the sticks from testing because they were too dry to support microbiological growth for biohazard testing purposes. Microbiologists cannot test for a pathogen without viable body fluids to swab for the test. Swabbing a dry stain on the stick will not support biohazardous growth on the culture medium. The lack of fluids for laboratory testing further indicates the inability for infectious growth on the sticks.
- (3) State Environmental RMW Regulatory Reviews. States classify RMW as a special classification of solid waste. The EPA does not regulate RMW treatment and disposal more stringently than other types of solid waste. States have the option to enact RMW regulations but are not required to meet any minimum Federal standards for RMW treatment and disposal. Consequently, a wide variety of RMW definitions and terms are in effect throughout the 50 States. The environmental regulations in many states do not address all facets of RMW generation from characterization, segregation, collection, packaging, transport, treatment, and disposal. Instead, multiple State government regulatory agencies including environment, public health, labor, and transportation regulate RMW generated in healthcare settings. However, Federal regulations do apply to worker protection when handling and transporting RMW. The

OSHA Bloodborne Pathogen Standard is applicable in all 50 States and is, therefore, the basis for determinations of what is an RMW generated in a healthcare setting. The DCPH-A conducted a comprehensive review of State RMW regulations and did not identify any State requirements that would classify the used silver nitrate sticks as RMW.

(4) Regulated Medical Waste Assessment Conclusion. Dried blood stains on the sticks are not RMW and require no RMW management because: (1) the stains are not fluid or caked in a way that meets the OSHA Blood Borne Pathogen, State, or DHA RMW regulations for an RMW; and (2) the dry, physical state of the sticks will not support biohazardous growth.

E. Used Silver Nitrate Applicator Sticks Waste Characterization

Used silver nitrate applicator sticks are both an ignitable HW (D001) and a toxic HW for silver content (D011) but are not an RMW. See section 6 for disposal options and regulatory considerations.

6. WASTE MANAGEMENT

A. EPA Pharmaceutical Rule (40 CFR Part 266 Subpart P)

On 22 February 2019, the EPA issued a new rule that establishes streamlined standards designed specifically for the healthcare sector. These standards will protect human health and the environment while bringing efficiencies and cost-savings to the sector. Subpart P must be adopted by all authorized states. The states were given time to adopt and incorporate this new rule into their State HW regulations. The EPA maintains a map to identify the states that have and have not yet adopted the new pharmaceutical rule. The map can be viewed at: https://www.epa.gov/hwgenerators/where-are-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075#tab-1.

B. Unused Silver Nitrate Applicator Sticks

If not already wrapped in sterile packaging, medical personnel should place the sticks into a sealable bag or container to prevent exposure to any liquids that could result in release of the silver/potassium nitrate solid on the stick tips. Collection in bags or tubes will prevent exposure to other incompatible pharmaceutical products that could also initiate a reaction.

(1) States Yet to Adopt the EPA Pharmaceutical Rule (40 CFR Part 266 Subpart P). Unused silver nitrate sticks are considered pharmaceutical products and may be eligible for inclusion in the Defense Logistics Agency (DLA)-approved pharmaceutical return to vendor program (reverse distribution) at your medical treatment facility (MTF) for monetary credit from the manufacturer. This program is subject to State-specific regulations and states may prohibit the returns of specific items. For more information on this program, contact the DCPH-A Waste Management Branch to evaluate applicable State regulations. If the unused sticks are not eligible for reverse distribution, manage them as ignitable and toxic HW with EPA HW numbers D001 and D011, respectively, in established HW satellite accumulation areas according to the requirements in 40 CFR Part 262.

- (2) States that Adopted the EPA Pharmaceutical Rule (40 CFR Part 266 Subpart P). Send potentially creditable HW pharmaceuticals for reverse distribution to the DLA-approved reverse distribution contractor. A package of unused silver nitrate sticks is a Potentially Creditable HW Pharmaceutical, which is defined as a prescription HW pharmaceutical that has a reasonable expectation to receive manufacturer credit and is—
 - 1. In original manufacturer packaging (except pharmaceuticals that were subject to a recall):
 - 2. Undispensed; and
 - 3. Unexpired or less than 1 year past expiration date.

Accumulation time is regulated indirectly by the definition of "potentially creditable HW pharmaceuticals" in 40 CFR Part 266.500, which requires that a prescription HW pharmaceutical be unexpired or less than 1 year past the expiration date. No container management standards or labeling requirements are established for potentially creditable HW pharmaceuticals; however, the silver nitrate sticks should be managed to prevent access to liquids and incompatible products. Military treatment facilities must retain delivery confirmation and any applicable shipping papers to the reverse distribution company for 3 years from the date of shipment. If the DLA-contracted reverse distribution company deems the item to be non-creditable, manage it accordingly as a non-creditable HW Pharmaceutical according to the requirements of 40 CFR Part 266 Subpart P (see section 6C below for HW Management guidance).

C. <u>Used</u> Silver Nitrate Applicator Sticks

All used silver nitrate sticks (applied to a wound) must be processed for HW treatment and disposal through the DLA Disposition Services. The DLA Disposition Services will accept used silver nitrate sticks with a signed certification statement declaring the waste is not an OSHA biohazard or a State infectious/medical waste. The certification statement may be signed by a knowledgeable staff member such as the Infection Control Officer, Environmental Science and Engineering Officer, Clinical Staff Members, etc. Appendix F provides an example certification statement. Medical personnel should place used sticks into a sealable bag or container to prevent exposure to any liquids that could result in additional release of the remaining silver/potassium nitrate solid on the stick tips. Collection in bags or tubes will also prevent direct handling by DLA waste managers and contractors and should eliminate any concerns with the stains. Consult with your Installation Environmental Office pertaining to the regulatory requirements detailed below for your State.

(1) States Yet to Adopt the EPA Pharmaceutical Rule (40 CFR Part 266 Subpart P). Accumulate and manage used silver nitrate sticks as ignitable (D001) and toxic (D011) HW in established satellite accumulation areas, according to the requirements in 40 CFR Part 262, to address both the silver and the oxidizer characteristics. Segregate to prevent contact with liquids or incompatible substances. Accumulate no more than 55 gallons of waste silver nitrate sticks in closed, compatible containers that are labeled with the words "Hazardous Waste" and marked to indicate the hazards of this waste (i.e., toxicity and ignitability) according to methods specified in 40 CFR Part 262.

(2) States that Adopted the EPA Pharmaceutical Rule (40 CFR Part 266 Subpart P).

A used silver nitrate stick is considered a Non-creditable HW Pharmaceutical, which is a prescription HW pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a non-prescription HW pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This waste must be accumulated and managed for HW treatment and disposal through the DLA Disposition Services according to the requirements in 40 CFR Part 266 Subpart P. The characteristics of ignitability (D001) and toxicity (D011) must be considered when accumulating and commingling this waste in containers with other non-creditable HW pharmaceuticals to prevent contact with liquids or incompatible pharmaceuticals. Waste silver nitrate sticks must be accumulated in compatible, closed containers. Each container must be labeled or marked with the phrase "Hazardous Waste Pharmaceuticals." Waste accumulation must not exceed 1 year and must be demonstrated according to methods specified in 40 CFR Part 266.502(f).

7. POINT OF CONTACT

For additional information, contact the DHA DCPH-A, EHSD, Waste Management Branch at 410-436-3651.

Dated: April 2023

Prepared By: DHA DCPH-A, EHSD Waste Management Branch

Appendix A

References

Code of Federal Regulations, "Bloodborne Pathogens," Title 29, Part 1910, Section 1910.1030(b).

Code of Federal Regulations, "Identification and Listing of Hazardous Waste," Title 40, Part 261.

Code of Federal Regulations, "Standards Applicable to Generators of Hazardous Waste," Title 40, Part 262.

Code of Federal Regulations, "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine," Title 40, Part 266, Subpart P. https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075

Department of Defense. 2019. 4160.21, Volume 2, incorporating Change 3, *Defense Materiel Disposition: Property Disposal and Reclamation.*

DHA. 2021. Procedural Manual 6050.01, *Medical Logistics (MEDLOG) Regulated Medical Waste (RMW) Management.*

EPA. Health and Environmental Agencies of U.S. States and Territories. https://www.epa.gov/home/health-and-environmental-agencies-us-states-and-territories

EPA. Links to Hazardous Waste Programs and U.S. State Environmental Agencies. https://www.epa.gov/hwgenerators/links-hazardous-waste-programs-and-us-state-environmental-agencies

EPA. Medical Waste. https://www.epa.gov/rcra/medical-waste

MEDCOM. 2017. Regulation 40-35, Regulated Medical Waste.

OSHA. Bloodborne Pathogen Standard, Frequently Asked Questions, Regulated Waste, Question and Answer 36. (See Appendix C) https://www.osha.gov/laws-regs/standardinterpretations/1993-02-01-0

State Medical Waste Regulations

Alabama

Department of Environmental Management, Land Division, Medical Waste

Program, Division 17

Regulation: ADEM Administrative Code Rule 335-17

https://adem.alabama.gov/alEnviroRegLaws/files/Division17.pdf

Alaska

Department of Environmental Conservation, Solid Waste

Management Regulation: Title 18 AAC 60.030 https://dec.alaska.gov/commish/regulations/

Arizona

Department of Environmental Quality, Solid Waste Management

Regulation: Title 18 Article 14, Biohazardous Medical Waste and Discarded Drugs,

R18-13-1401

http://www.azdeq.gov/environ/waste/solid/rules.html

Arkansas

Department of Health, Management of Medical Waste

Regulation: Rules and Regulations Pertaining to the Management of Medical Waste from Generators and Health Care Related Facilities https://www.healthy.arkansas.gov/programs-services/topics/medical-waste-program

California

Department of Health Services, Medical Waste Management Program Regulation: California Health and Safety Code, Sections 117600-118360 https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/MedicalWaste.aspx

Colorado

Department of Public Health and Environment, Hazardous Materials and Waste Management

Regulation: 6 CCR 1007-2; Part 1 Regulations Pertaining to Solid Waste Sites and Facilities, Section 13 Infectious Waste Disposal https://www.colorado.gov/pacific/cdphe/solid-waste-regulations

Medical and pharmaceutical waste guidance for Health Care Facilities

https://www.colorado.gov/pacific/cdphe/medical-and-pharmaceutical-waste-guidance

Connecticut

Department of Environmental Protection, Regulations for Solid Waste Management: Chapter 446d, Section 22a-209b and 209c https://portal.ct.gov/DEEP/Waste-Management-and-Disposal/Solid-Waste/Solid-Waste-Home#Statutes

Delaware

Department of Natural Resources, Division of Air and Waste Management Regulations Governing Solid Waste: Section 11, Special Wastes Management https://dnrec.alpha.delaware.gov/waste-hazardous/management/infectious/

Florida

Department of Environmental Protection, Department of Health Regulation: FAC 64E-16, Biomedical Waste http://www.doh.state.fl.us/environment/community/biomedical/index.html

Georgia

Department of Natural Resources, Environmental Protection Division Regulation: Chapter 391-3-4-.15, Solid Waste Management, Biomedical Waste http://rules.sos.state.ga.us/gac/391-3-4

Hawaii

Department of Health

Regulation: Title 11, Chapter 104.1, Management and Disposal of Infectious Waste https://health.hawaii.gov/opppd/department-of-health-administrative-rules-title-11/

Idaho

Department of Health and Welfare

Rule: IDAPA 16.03.14, Rules and Minimum Standards for Hospitals in Idaho https://adminrules.idaho.gov/rules/current/16/160314.pdf

Illinois

Environmental Protection Agency

Rule: Title 35 IAC, Subtitle M: Biological Materials, Chapter I: Pollution Control Board, Subchapter b: Potentially Infectious Materials, Parts 1420-1422 https://pcb.illinois.gov/SLR/IPCBandIEPAEnvironmentalRegulationsTitle35

Indiana

State Department of Health

Regulation: IAC 16-41-16, Communicable Disease: Treatment of Infectious Waste http://iga.in.gov/legislative/laws/2018/ic/titles/016#16-41-16-4
https://www.in.gov/idem/waste/solid-waste/infectious-waste/

Iowa

Department of Natural Resources

Regulation: IAC 567-100, Chapter 100, Environmental Protection

Commission, Definitions, Forms and Rules of Practice https://www.iowadnr.gov/Environmental-Protection/Land-

Quality/Solid-Waste/Solid-Waste-Policy-Rules

Kansas

Medical Services Waste Division of Health and Environment, Bureau of Waste Management

Regulation: KAR Article 29, Part 2, Standards for Management of

Solid Waste, Chapter 28-29-27 Medical Services Waste https://www.kdhe.ks.gov/660/Statutes-Regulations

Kentucky

Division of Waste Management

Regulation: Kentucky Department for Environmental Protection, Division

of Waste Management, Title 401, Chapter 49:005(1)(78)

https://apps.legislature.ky.gov/law/kar/titles/401/049/005/

https://eec.ky.gov/Environmental-Protection/Waste/solid-

waste/Pages/default.aspx

https://eec.ky.gov/Environmental-Protection/Waste/recycling-and-local-

assistance/Pages/medical-waste.aspx

Louisiana

Office of Public Heath

Regulation: Title 51, Public Health Sanitary Code, Part XXVII Management of Refuse, Infectious Waste, Medical Waste and

Potentially Infectious Medical Waste

https://deq.louisiana.gov/faq/category/7

https://www.doa.la.gov/doa/osr/louisiana-administrative-code/

Maine

Department of Environmental Protection

Bureau of Remediation and Waste Management

Regulation: Title 06-096 Chapter 900, Biomedical Waste

Management Rules

https://www.maine.gov/sos/cec/rules/06/chaps06.htm

Maryland

Department of Health and Mental Hygiene, Department of Environment Regulation: COMAR Title 10.06.06, Communicable

Disease Prevention - Handling, Treatment and Disposal of

Controlled Hazardous Substances,

COMAR Titles 26.13.11, 26.13.12 and 26.13.13

http://www.dsd.state.md.us/COMAR/ComarHome.html

Massachusetts

Department of Public Health, Community Sanitation Program
Regulation: 105 CMR 480.000, Minimum Requirements for the Management
of Medical or Biological Waste (State Sanitary Code Chapter VIII)
https://www.mass.gov/lists/medical-waste-community-sanitation

Michigan

Department of Environmental Quality

Regulation: Part 138 Sections 333.13801-325.1549, Medical

Waste Regulatory Act

https://www.michigan.gov/egle/about/organization/materials-

management/medical-waste-regulatory-program

Minnesota

Pollution Control Agency

Regulation: Minnesota Administrative Rule Parts 7035.9100-9150

https://www.revisor.mn.gov/rules/?id=7035&view=chapter

Mississippi

State Department of Health

Regulation: "Adopted Standards for the Regulation of Medical Waste" in Health Care Facilities Licensed by the State Department of Health" https://www.mdeq.ms.gov/land/waste-division/solid-waste-management-programs/special-waste-management-guidelines/

Missouri

Department of Natural Resources, Division of Environmental Quality Regulation: 10 CSR 80-7, Infectious Waste Management http://www.sos.mo.gov/adrules/csr/current/10csr/10csr.asp

Montana

Department of Environmental Quality

Regulation: Montana Code, Title 75-10-1001 Infectious Waste Management Act https://leg.mt.gov/bills/mca/title 0750/chapter 0100/part 0100/sections index.html

Nebraska

Department of Environmental Quality, Waste Management Division Regulation: Title 132 Chapter 13.004, Rules and Regulations Pertaining to Solid Waste Management, Special Wastes: http://dee.ne.gov/RuleAndR.nsf/Title 132.xsp

Nevada

Division of Environmental Protection, Bureau of Waste Management Limited Regulation: Management of Special Waste NAC 444.589, NAC 444, and NAC 444.662: https://www.leg.state.nv.us/nac/nac-444.html

New Hampshire

Department of Environmental Services, Solid Waste Management Bureau Regulation: Chapter Env-Sw 904, Infectious Wastes

https://www.des.nh.gov/rules-and-regulatory/administrative-rules https://www.des.nh.gov/rules-and-regulatory/administrative-rules?keys=infectious+waste&purpose=&subcategory=Solid+Waste

New Jersey

Department of Environmental Protection, Division of Solid and Hazardous Waste Regulation: NJAC 7:26-3A, Regulated Medical Wastes https://www.state.ni.us/dep/dshw/resource/rules.htm

New Mexico

Environment Department, Solid Waste Bureau Regulation: Title 20 NMAC, Chapter 9, 20.9.2.7 I(5) Definitions and 20.9.8.13 Special Waste Requirements, Infectious Waste https://www.srca.nm.gov/nmac-home/nmac-titles/title-20-environmental-protection/

New York

Department of Health

Regulation: NYCRR Title 10, Part 70, Regulated Medical Waste

https://regs.health.ny.gov/ New York State Guidance:

http://www.health.ny.gov/facilities/waste/

North Carolina

Department of Environment and Natural Resources, Division of Waste Management Regulation: 15A NCAC 13B .1200, Medical Waste Management https://deq.nc.gov/about/divisions/waste-management/solid-waste-section/special-wastes-and-alternative-handling/medical-waste

North Dakota

State Department of Health, Division of Waste Management, Regulation: NDC Chapter 33-20-12, Regulated Infectious Waste https://www.ndlegis.gov/information/acdata/html/33-20.html https://deq.nd.gov/WM/InfectiousWaste/

Ohio

State Environmental Protection Agency
Division of Solid and Infectious Waste Management
Regulation: OAC Chapter 3745-27, Solid and Infectious
Waste Regulations
https://codes.ohio.gov/ohio-administrative-code/chapter-3745-27

Oklahoma

Regulated Medical Waste Environmental and Natural Resources Oklahoma Environmental Quality Code Title 252.515-1-2 and 252.515-23 https://www.deq.ok.gov/asd/rules-and-regulations/

Oregon

Department of Environmental Quality, Land Quality Regulation: Title 36 ORS 459.386-459.405 https://oregon.public.law/statutes/ors_chapter_459

Pennsylvania

Department of Environmental Protection, Bureau of Waste Management Regulation: Title 25 PAC 271.1 and Title 25 PAC 284 http://www.pacode.com/secure/data/025/chapter284/chap284toc.html

Puerto Rico

Environmental Quality Board
Regulation for the Management of Non-Hazardous Solid Waste,
Chapter V, Rule 580
http://www.temasactuales.com/assets/pdf/gratis/RegIDSNP.pdf

Rhode Island

Environmental Protection Bureau, Office of Land Revitalization and Sustainable Materials Management, Medical Waste Regulations (250-RICR-140-15-1)

https://rules.sos.ri.gov/regulations/part/250-140-15-1

South Carolina

Department of Health and Environmental Control, Land and Waste Management Regulation: R 61-105 Infectious Waste Management https://scdhec.gov/environment/land-management/infectious-waste-regulation-overview

South Dakota

Department of Environment and Natural Resources

Regulation: Article 74:27:07:01, Definition of Medical Waste

https://danr.sd.gov/Environment/WasteManagement/SolidWaste/

MedicalWaste.aspx

https://sdlegislature.gov/Rules/Administrative/27300 https://sdlegislature.gov/Rules/Administrative/27401

Tennessee

Department of Environment and Conservation, Division of Solid Waste Management

Regulation: Chapter 0400-11-01, Solid Waste Processing and Disposal,

Rule 0400-11-01-.01 and Rule 0400-11-01-.04

https://publications.tnsosfiles.com/rules/0400/0400-11/0400-11.htm

Texas

Texas Commission on Environmental Quality, Municipal Solid Waste Division

Regulation: Title 30, Chapter 326, Medical Waste Management

https://www.tceq.texas.gov/permitting/waste_permits/msw_permits/med

waste/medwaste

https://texreg.sos.state.tx.us/public/readtac%24ext.ViewTAC?

tac view=4&ti=30&pt=1&ch=326

Utah

Department of Environmental Quality, Waste Management and Radiation Control

Regulation: UAC R315-316, Infectious Waste Requirements

https://deg.utah.gov/waste-management-and-radiation-control/solid-

waste-documents-solid-waste-program

https://rules.utah.gov/publicat/code rtf/r315-316.rtf

Vermont

Department of Environmental Conservation, Waste Management and

Prevention Division

Guidance Document: "Procedure Addressing Regulated Medical Waste

Definitions and the Handling and Treatment of Regulated Medical Waste"

https://dec.vermont.gov/content/safe-disposal-sharps

https://dec.vermont.gov/sites/dec/files/wmp/SolidWaste/Documents/R

egulatedMedicalWasteProcedures2018.pdf

Virginia

Department of Environmental Quality, Waste Management Board

Regulation: Title 9 VAC 20-120, Regulated Medical Waste

Management Regulations

https://law.lis.virginia.gov/admincode/title9/agency20/chapter120/

Washington

Department of Health

Regulation: RCW Title 79, Chapter 70.95K

http://apps.leg.wa.gov/RCW/default.aspx?cite=70.95K

West Virginia

Department of Health and Human Resources, Public Health, Environmental Health Services, Infectious Medical Waste and Disease Control Regulation: CSR Title 64-56, Infectious Medical Wastes https://oehs.wvdhhr.org/phs/infectious-medical-waste-disease-control/

https://apps.sos.wv.gov/adlaw/csr/rule.aspx?rule=64-56

Wisconsin

Department of Natural Resources, Waste Management Program Regulation: WAC 287.07(7)(c)1c and 299.51(1)(b), Medical Waste Management https://dnr.wisconsin.gov/topic/HealthWaste/Infectious.html https://dnr.wisconsin.gov/topic/HealthWaste/Laws.html

Wyoming

Department of Environmental Quality, Solid and Hazardous Waste Division Additional Guidance: Medical Waste Treatment Document https://deq.wyoming.gov/shwd/inspection-and-compliance/

Appendix B Used Silver Nitrate Applicator Stick Pictures



Defense Centers for Public Health – Aberdeen (formerly APHC), EHSD photo Figure B-1. Used Stick Tip with No Residual Fluid Stain



Defense Centers for Public Health – Aberdeen (formerly APHC), EHSD photo Figure B-2. Used Stick with Stain Next to Stick with No Stain

Appendix C

Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Frequently Asked Questions Extract Regulated Waste

02/01/1993 - Most frequently asked questions concerning the bloodborne pathogens standard.

Page 1 of 1

Regulated Waste

Q36. What does OSHA mean by the term "regulated waste"?

A36. The Bloodborne Pathogens standard uses the term, "regulated waste," to refer to the following categories of waste which require special handling: (1) liquid or semi-liquid blood or OPIM; (2) items contaminated with blood or OPIM and which would release these substances in a liquid or semi-liquid state if compressed; (3) items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; (4) contaminated sharps; and (5) pathological and microbiological wastes containing blood or OPIM.

https://www.osha.gov/laws-regs/standardinterpretations/1993-02-01-0

Appendix D

Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Final Rule Preamble Extract

Section 9 - IX. Summary and Explanation of the Standard

Page 1 of 2

"Regulated Waste" was called "Infectious Waste" in the proposal. "Infectious Waste" was defined as blood and blood products, contaminated sharps, pathological wastes, and microbiological wastes. In this final standard, the analogous term "regulated waste" has been defined as: 1) liquid or semi-liquid blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; 3) items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; 4) contaminated sharps; and 5) pathological and microbiological wastes containing blood or other potentially infectious materials. Based upon the collected information, OSHA has concluded that these items are generally recognized as presenting a hazard of disease transmission and as such, warrant special handling.

During the hearings, CDC/NIOSH testified:

The categories of items that we consider as potentially infectious and that should be handled in a special manner include microbiological waste, bulk blood or body fluid, contaminated blood, sharps or pathological waste, materials that contain those particular items would be defined by the CDC as infectious waste. (Ms. Polder - CDC/NIOSH, Tr. 9/14/89, p.54)

CDC explains their position further in their written comment, stating:

... As a related point of information, CDC considers it important to use the CDC definition of infectious waste, which has been adopted by OSHA in this proposed rule, in preference to the definition of medical waste adopted by EPA and used in the Medical Waste Tracking Act. The CDC definition is based on the epidemiology of disease transmission, whereas other definitions are much broader and include articles that should not require special handling. (CDC/NIOSH, Ex. 20-634)

With regard to EPA and their definition of wastes requiring special handling, some commenters expressed opinions similar to CDC and discouraged adoption of EPA's Medical Waste Tracking Act (MWTA) definition (e.g., APIC - Indiana, Ex. 20-139; McLeod Regional Medical Center, Ex. 20-527; Meadville Medical Center Ex. 20-624). However, other participants recommended that the MWTA definition be incorporated into the final standard (e.g. ADA, Ex. 20-665; Support Systems International, Ex. 20-1149). On a more general level, comments were also received which simply encouraged OSHA to assure that the final regulation's definition of "infectious waste" does not conflict with EPA's definition (e.g., AHA, Ex. 20-352; Tucson Medical Center, Ex. 20-141; Hospital of St. Raphael, Ex. 20-289).

In their comment on the proposal, EPA states:

The proposed OSHA definition appears to be fairly consistent with the wastestreams EPA regulates in 40 CFR Part 259, if the term "microbiological wastes" corresponds to Class 1 wastes in 40 CFR 259.30(a)(1) ("Cultures and stocks of infectious agents...."). EPA's rules also may cover a broader range of wastes, but generally do not refer to them as "infectious wastes" due to the wastes' widely varying infective capability. (EPA, Ex. 20-991)

Reviewing 40 CFR Part 259 reveals that microbiological wastes, as OSHA has defined them in this final regulation, would fall under Class 1 since the presence of blood or other potentially infectious materials is, under universal precautions, assumed to indicate the presence of a disease-causing bloodbome pathogen. EPA goes on to remark that their rules may cover a broader range of wastes. OSHA does not feel that this presents a conflict of definitions since the wastes regulated under this rule are a subset of those regulated by EPA. The Agency has concluded that the wastes covered under this standard warrant special handling and are in accordance with both CDC and EPA definitions. Therefore, these categories of waste have been retained in this regulation with modifications adopted in response to public comment.

Several participants commented on the ability of medical waste to transmit disease (e.g., Good Samaritan Hospital, Ex. 20-1230; Anaheim Medical Center, Ex. 20-45; Lewis-Gale Hospital, Ex. 20-871). In conjunction with this, a number of commenters raised the issue of the necessity of regulating the handling of certain components of the medical wastestream such as blood-stained bandages which could fall under the proposed definition but which they felt posed no threat of disease transmission (e.g., Palomar Pomerado Hospital, Ex. 20-1260; Rowan Memorial Hospital, Ex. 20-629; Community Hospital of Chula Vista, Ex. 20-761). Reviewing the record, it was noted that very little information is available on the potential for contracting disease as a result of contacting medical waste. The primary basis for comments that medical waste is no more infectious than household waste seems to be several German studies conducted in the early to mid-1980's comparing bacterial load of hospital wastes which are usually collected daily with that of household waste that was up to 7-days old (Exs. 286C; 286T; 286W). The Agency does not intend to debate the merits of these studies and has not conducted original research in this area. Hence, OSHA cannot offer a more definitive determination of the "infectiousness" of these materials. To eliminate the implication that OSHA has determined the "infectiousness" of certain medical wastes, the aforementioned waste categories have been grouped under the term 'Regulated Waste' rather than 'Infectious Waste."

Non-sharp waste, such as bandages, can be contaminated with widely varying amounts of blood or other potentially infectious materials, ranging from a single drop to complete saturation. The proposal contained no specific reference to how blood-contaminated non-sharp waste was to be differentiated and handled but simply stated that blood and blood products were to be treated as infectious waste. During the informal public hearings, the Agency solicited information from participants regarding what criteria were currently being utilized to determine which of these types of wastes were treated as "infectious" and which wastes were placed into the general waste stream. Responses to this inquiry were widely divergent, ranging from considering only blood-saturated items as infectious waste (Nassau-Suffolk Hospital Council, Inc., Tr. 11/14/89, pp.466-467) to "red-bagging" all items contaminated with blood or body fluids (Baptist Medical Center Montclair, Tr. 9/19/89, p.98; Laura Williams - SEIU, Tr. 10/17/89, pp.66-67). In addition, several interested parties requested that OSHA clarify what wastes were encompassed by the phrase "blood and blood products" (e.g., Greater New York Hospital Association, Tr. 11/14/89, p.316; APIC -Greater Los Angeles, Ex. 20-213). It became obvious to the Agency that no generally-accepted criteria was being applied by those involved to classify which bloodcontaminated non-sharp waste required special handling. Therefore, an easy-to-use, acceptable minimal benchmark would have to be developed to assure consistent compliance and enforcement in this area. A number of commenters offered suggestions as to what this benchmark should be. The majority of commenters who considered this issue suggested that only bulk blood be considered infectious waste (e.g., AHA, Ex. 20-352; Middle Tennessee Medical Center Inc., Ex. 20-105; Arizona Hospital Association, Ex. 20-69). The difficulty with this approach is that there is little agreement on how much blood constitutes "bulk blood." Some commenters recommended actual volume amounts of blood ranging from greater than 10 ml to more than 100 ml of blood (e.g., Kalispell Regional Hospital, Ex. 20-1212; Virginia Mason Hospital, Ex. 20-569; Providence Memorial Hospital, Ex. 20-744). The Agency has concluded that such a determination would be difficult to judge since the visual characteristics of a specific quantity of blood would vary based on the type and size of substrate on which it appeared. For example, 10 ml of blood on a bed sheet would appear as a spot while the same amount on a cotton ball would likely cause saturation and dripping. Suggestions offered by other participants included bulk blood and items heavily saturated with blood or which drip and splash (e.g., Redlands Community Hospital, Ex. 20-692; Mills-Peninsula Hospitals, Ex. 20-701; St. Anthony Hospital Systems, Ex. 20-221); waste heavily contaminated with blood (Cleveland Clinic Foundation, Ex. 20-563); blood soaked items - not blood stained items (e.g., Nassau-Suffolk Hospital Council, Inc, Tr. 11/14/89, p. 46); only

Section 9 - IX. Summary and Explanation of the Standard

Page 2 of 2

bulk amounts of liquid or semi-liquid blood (i.e. pourable or ability to flow), excluding dried blood (e.g., APIC - Indiana, Ex. 20-139; APIC - Greater Omaha, Ex.20-943); and blood that readily separates from the solid portion of waste under ambient temperature and pressure (Paradise Valley Hospital, Ex. 20-217). The record indicates that a large number of commenters feel that bulk blood should be classified as infectious waste. Moreover, "bulk" blood seems to be generally associated with the ability to pour or flow. During the hearings, Ms. Polder of the CDC stated:

... [I]n terms of blood, we really feel that the only type of blood that you need to be concerned about, in terms of transmission of disease, is bulk blood, or bulk fluids that may contain blood which means essentially liquids.... In terms of items that are contaminated with blood that may be dry or may be wet, but are contained in a material such as gauze or a bandage, the risk of transmission of a pathogen to a susceptible host is extremely unlikely, and therefore, that type of waste can be handled like any other waste that is collected in the community, that may be contaminated in the same fashion. (Tr. 9/14/89, p.92)

Consequently, this physical characteristic (i.e., the ability to pour, flow, drip, etc.) has been adopted as one of the attributes of waste being regulated under this chandred

Comments such as those submitted by APIC - Greater Omaha Area and Paradise Valley Hospital make it apparent that in some circumstances solid waste is capable of generating bulk (i.e. liquid or semi-liquid) blood (Exs. 20-943; 20-217). While an item which is freely dripping blood or other potentially infectious materials obviously falls into this category, some items may adequately contain these materials when in a static state yet liberate them when compressed. During accumulation of waste in a container, the weight of items toward the top of the container naturally compress those items beneath. Wastes may also be purposefully compacted in order to increase the amount of waste which can be placed into a single container. This compression could generate potentially infectious liquids which would then accumulate at the bottom of the container. If the container's barrier capability is compromised, these materials would be released, presenting an exposure and/or contamination hazard. An EPA guidance document addressing EPA's Medical Waste Tracking Act states:

... Only those fibrous items that are completely saturated with blood (or would drip with blood if squeezed), or non-fibrous items that have enough blood present that they are dripping, are regulated medical waste.... (Ex.224, Attachment A)

Both the EPA document and the statement by Ms. Polder of the CDC indicate that blood or other potentially infectious materials which are contained in non-sharp contaminated waste, such as bandages, do not become a concern until these liquids are liberated from the substrate. The ability of the substrate to contain these substances is the deciding factor as to their proper handling and disposal. OSHA has therefore concluded that items contaminated with blood or other potentially infectious materials which would release these substances in a liquid or semi-liquid state if compressed should be considered regulated waste.

Dried blood or other potentially infectious materials could also pose a problem if these dried materials are released from a contaminated item during handling. A study by Bond et. al. (Ex. 20-634) showed hepatitis B virus could remain viable in dried material for up to seven days. Furthermore, CDC recognizes the potential for disease transmission by dried blood. In their 1989 document, Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers, CDC recommends to law enforcement personnel:

Airborne particles of dried blood may be generated when a stain is scraped. It is recommended that protective masks and eyewear or face shields be worn by laboratory or evidence technicians when removing blood stain for laboratory analysis. (Ex. 15)

Based on this prolonged viability and potential for infection, items that are heavily contaminated or "caked" with dried blood or other potentially infectious materials have been included in those situations where such dried materials could flake or fall off of the item during handling.

In summary, the category "blood and blood products" contained in the proposal has been more specifically delineated in the final standard to read: 1) liquid or semi-liquid blood or other potentially infectious materials; 2) items contaminated with blood or other potentially infectious materials which would release these substances in a liquid or semi-liquid state if compressed; and 3) items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling. This expansion and clarification provides easily-recognized criteria for determining OSHA's intent as to those wastes it considers, at a minimum, to require special handling.

Very little comment was received about the remaining three categories of (infectious) regulated waste. Marion Memorial Hospital appeared to be referring to sharps that have not been contaminated by bloodborne pathogens when they stated that many sharps are utilized in hospitals that are never exposed to a patient (Ex. 20-1269). In consideration of those circumstances in which contamination of a sharp by bloodborne pathogens is known not to exist, the term "sharps" has been revised to "contaminated sharps" in the final standard to clarify that, for the purposes of this standard, sharps which are contaminated with blood or other potentially infectious materials are the items with which OSHA is concerned. However, it should be noted that other local, State, and Federal agencies (e.g., EPA) may have more expansive regulations regarding sharps and their disposal based upon factors such as transmission of diseases other than bloodborne diseases, aesthetic concerns, or the physical puncture hazard of sharps in general.

https://www.federalregister.gov/citation/56-FR-64004, pages 64104-64106

Appendix E

Medical Waste Tracking Act Federal Register Extract

Federal Register / Vol. 54, No. 56 / Friday, March 24, 1989 / Rules and Regulations

12337

to participate. Congress did not establish a "no less stringent" standard for these States. EPA will identify those States that elect to opt out in a later Federal Register notice.

3. Other States

States not mentioned above may elect to participate in the demonstration program. The Governor of a State electing to participate must petition EPA by April 24, 1989 to be included on the list of Covered States. The definition of "State" in RCRA section 1004(31) includes the several States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands. EPA interprets the term "Governor" to include the Governor in any of the several States, or the equivalent head of the executive branch of the government for those other governmental entities. The Act specifies that EPA must determine whether to include a petitioning State in the program within 30 days of receipt of the petition (RCRA section 11001(c)). American Samoa has already petitioned to be included in the program, and EPA will make a determination regarding American Samoa and any other potitionin States after the 30 day period.

The Agency is planning to publish the final list of Covered States in the Federal Register shortly after the April 24, 1989, opt-out/petition-in deadline.

D. Subpart D—Regulated Medical Waste

Section 11002 of RCRA requires EPA to develop and promulgate a list of medical wastes to be tracked under the demonstration progran. The statute provides the basic components of the list by identifying five waste types that must be included: (1) Cultures and stocks of infectious agents and associated biologicals; (2) pathological

waste; (3) human blood and blood products: (4) used sharps (e.g., syringes, needles, and surgical blades); and (5) contaminated animal carcasses. The statute also identifies five additional waste types that EPA is authorized to exclude from the demonstration program if the Agency determines that mismanagement of such wastes would not pose a substantial threat to human health or the environment; (6) surgery or autopsy waste; (7) laboratory wastes; (8) dialysis wastes; (9) discarded medical equipment; and (10) isolation wastes. The Act also gives EPA authority to add other medical wastes to the list if the Agency determines that such wastes may pose a substantial threat to human health or the environment.

The Act's designation of two different "universes" of medical waste originates, in part, from EPA's Guide for Infectious Waste Management (1986). In that document, the Agency identified two universes of medical waste: "infectious" medical waste and "miscellaneous contaminated wastes." The first universe, "infectious" medical wastes. included those wastes listed in the Act as waste types l, 2, 3, 4, 5, and 10. The Agency, at the time, believed that all of these wastes should be specially managed. The second universe included those wastes listed in the Act as waste types 6, 7, 8, and 9. EPA recognized that, depending on the specific characteristics of the "miscellaneous contaminated wastes," they could be handled appropriately as "infectious" medical wastes or noninfectious medical wastes based on the determination of a responsible infection control practitioner.

Clearly, one of the most controversial aspects of EPA's guidance document has been its inclusion of isolation wastes (waste type 10 in the Act) in the first universe of "infectious" medical wastes.

The health care community, medical professionals, and public health officials have strongly criticized this aspect of the guidance document stating that, except under special circumstances, isolation wastes are unlikely to pose a significant hazard to human health or the environment. Thus, EPA believes that Congress, in formulating the statutory list of medical wastes subject to the demonstration program, relied on the basic format of the original waste listing as set forth in the 1986 guidance document (i.e., separating the universe of medical waste into "infectious" and "miscellaneous contaminated waste" categories). However, EPA also believes that Congress concurred with prevailing scientific opinion concerning the relative threat posed by isolation patient waste (listed in the EPA guidance document as an infectious waste category) and designated this as a category that the Administrator may exclude from the demonstration program based on the authority of section 11002(b).

In today's rule, medical wastes to be tracked under the demonstration program are referred to as "regulated medical waste." Regulated medical waste is a subset of medical waste which, in turn, is a subset of "solid waste" as defined in RCRA section 1004. This relationship is illustrated in Figure 1. The term "regulated medical waste" includes the list of medical wastes, as determined by EPA, and certain mixtures of these wastes with other types of wastes. This section of the Preamble discusses the criteria used to define or designate medical waste as "regulated medical waste," explains the content and rationale behind the regulatory listing of regulated medical waste, and describes the conditions under which waste classes may be exempted from regulation.

BILLING CODE 6560-50-M

MWTA was clearly intended to address this type of degradation.

Intravenous bags are being included in this category because they may continue to resemble blood bags even after certain treatment processes. Although intravenous bags may not have come into contact with any pathogenic microorganisms, the aesthetic degradation of the environment caused when they are mismanaged warrants their inclusion in the demonstration tracking program. EPA is using the authority under RCRA section 11002(a)(11) to list these items, and is including these items in this part of the regulation for convenience.

Class 3 also includes items that are saturated and/or dripping with human blood or that were saturated and/or dripping but have since dried. These wastes are aesthetically objectionable and, while they may present low potential for causing adverse health effects, in certain instances they pose a potential health threat if mishandled in the presence of other waste material such as sharps. This concern should only be present if the blood is in liquid form. Items with large quantities of dried blood are not likely to transmit disease. The blood is generally not present in a form (i.e., liquid) likely to pose a significant hazard to the persons handling the waste, but blood-caked items may still cause environmental (aesthetic) degradation, so these items are included in Class 3 as described above.

d. Class 4—Used Sharps. EPA's regulatory description of Class 4, used sharps, is based on section 11002 (a)(4), and reads as follows:

Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, test tubes, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.

Sharps, with the exception of certain glassware, as explained below, are universally recognized as requiring stringent regulation under this program, given the unique bio and physical hazards as well as environmental degradation problems associated with used sharps (unused sharps are addressed in a separate class). The statutory waste type description has been modified slightly to clarify that sharps generated in care of both humans and animals are covered. It also includes the word "treatment" to cover

sharps generated from the preparation of human and animal remains for burial or cremation. Syringes are included under this class regardless of whether a needle is attached because EPA believes that this interpretation is consistent with the intent of Congress under the Medical Waste Tracking Act to minimize further improper disposal of aesthetically offensive medical wastes in the natural environment. Blood vials and culture dishes, which may also meet the descriptions of Waste Classes 3 and 1. respectively, were included in this class because the packaging requirements for sharps are more protective of waste handlers. Needles with attached tubing are included because of the physical and biohazard that may be present with the needle.

EPA has included in Class 4 certain wastes from RCRA section 11002(a)(7). These wastes are slides and cover slips that were in contact with infectious agents. In general, laboratory glassware that was not in contact with infectious agents does not pose the same kinds of aesthetic concerns as other sharps and is already adequately managed as general refuse. Therefore, only slides and cover slips that were in contact with infectious agents are listed in Class 4.

Finally, because the physical and aesthetic concerns are independent of the nature of medical service provided, EPA interprets Class 4 to cover sharps used in veterinary services as well as human patient care.

e. Class 5—Animal waste. EPA's description of Class 5 is based on section 11002(a)(5), and reads as follows:

Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.

Two modifications were made to the statutory language to clarify the wastes included in this class. First, the phrase "known to have been" was added to emphasize that only wastes from animals known to have been exposed to infectious agents during research are regulated medical waste. Without this phrase, it would be difficult for generators to identify accurately those wastes that should be regulated, which would make both compliance with and enforcement of this regulation problematic. This definition does not include household pets, farm animals, or wastes from farm animals unless they were exposed to infectious agents during research, production of

biologicals, or testing of pharmaceuticals.

The second clarification includes veterinary hospitals as an example of a research facility. This was suggested by attendees at EPA's medical waste meetings, because such facilities may generate contaminated animal waste. Wastes generated by general veterinary practices (e.g., small animals) are not covered in Class 5. However, the reader should note that sharps from veterinary services are covered under Class 4.

As guidance in determining what organisms are "infectious agents", the reader may use those agents identified in Classes 2 through 4 of the CDC's Classification of Etiologic Agents on the Basis of Hazard (July, 1974, available in the docket). Because EPA's definition of "infectious agent" in § 259.10 is limited to those organisms that cause disease or adverse health impacts in humans, only animal wastes potentially posing a hazard to human health are covered in Class 5.

f. Class 8—Isolation wastes. EPA's regulatory description of this class is identical to section 11002(a)(10) in all but one respect, and reads as follows:

Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.

Although the statute refers to "communicable diseases" generally, the Agency believes that only certain highly communicable diseases should be included in the demonstration program. Health care professionals recommend that the scope of this class be limited to only those specific diseases that are sufficiently communicable to pose a potential threat to public health (for example, diseases caused by those agents listed in Classification 4 by the CDC in Classification of Etiologic Agents on the Basis of Hazard (1974)).

The Agency considered regulating all wastes from isolation patients, but concluded that many of the waste items are already covered under other waste classes, and that regulating all wastes from isolation patients would needlessly subject large amounts of waste to handling and packaging according to the requirements of the tracking program even though the large majority of such waste would be neither infectious nor aesthetically objectionable. For example, health care facilities have the option of assessing which isolation wastes, in addition to those required by these regulations, should be managed as regulated medical waste. EPA requests

Appendix F Example Certification Statement for DLA Disposition Services

| Office Symbol | Date |
|---|------|
| MEMORANDUM FOR RECORD | |
| SUBJECT: Silver Nitrate Applicator Stick Waste | |
| I certify the waste silver nitrate sticks are neither an OSHA regulated biohazard waste nor a State infectious/regulated medical waste. | |
| | |
| Name Title | |
| | |
| | |
| | |
| | |
| | |
| | |