U.S. Department of Agriculture
Washington, D.C.

DEPARTMENTAL REGULATION	NUMBER: 9630-001
SUBJECT: **USDA Policies and Procedures on Biohazardous Waste Decontamination, Management, and Quality Controls at Laboratories and Technical Facilities**	DATE: June 18, 2009 OPI: Agricultural Research Service

1. PURPOSE

Decontamination, sterilization, and disinfection procedures in a research or diagnostic environment vary, depending on the capabilities of the facility and the biological hazards (biohazard) being handled. Existing Department of Agriculture (USDA) Department Manuals (DM) on Security Policies for Biosafety Level (BSL)-3 and Labs excluding BSL-3 (DM9610-1 and DM9610-2) do not address biohazardous waste decontamination, management and quality control. This manual should provide USDA-wide biosafety policies for biological waste management and quality control at USDA facilities, including general information on decontamination methods and technologies, methods for validating decontamination efforts, and information on security and employee safety issues.

2. SPECIAL INSTRUCTIONS

The policies and procedures described herein are subject to review on a 5-year basis unless conditions warrant earlier review.

3. STATEMENT OF POLICY

Biohazardous agents used at USDA facilities must be decontaminated prior to disposal or discharge. Decontamination and disposal of biohazardous wastes should be conducted in accordance with applicable USDA, Federal, State, local, facility and/or host nation environmental standards. General procedures for decontamination, destruction, and disposal are described in this Manual, but it may be necessary to use additional resources to identify and develop appropriate biohazardous waste management on a case-by-case basis.

a. The preferred methods of decontamination, destruction, and disposal of many infectious/etiologic agents, zoonotic agents, veterinary pathogens, and biohazards are steam sterilization (autoclaving), chemical inactivation with appropriate biocidal solutions, or incineration in an appropriately

permitted hospital/medical/infectious waste and/or pathological waste incinerator(s).

b. Infectious/etiologic agents or other biohazards awaiting decontamination, destruction, and disposal will be properly contained and labeled at the appropriate biosafety/biocontainment level according to the risk presented by the biohazard.

4. ABBREVIATIONS

BSL	Biosafety level
CDC	U.S. Centers for Disease Control
CFR	Code of Federal Regulations
DM	Departmental Manual
EPA	U.S. Environmental Protection Agency
FIRFA	Federal Insecticide, Fungicide, and Rodenticide Act
FDA	U.S. Food and Drug Administration
FRC	Federal Records Center
NARA	National Archives and Records Administration
OSHA	Occupational Safety and Health Administration
PPE	Personal Protective Equipment
PPQ	Plant Protection and Quarantine
SOP	Standard Operating Procedure(s)
UN	United Nations
USDA	U.S. Department of Agriculture
UV	Ultraviolet

5. DEFINITIONS

Antimicrobial - An agent that kills or suppresses the growth of microorganisms.

Antiseptic – A substance that prevents or arrests the growth or action of microorganisms, either by inhibiting their activity or destroying them.

Bioburden - The number and types of viable microorganisms with which an item is contaminated; also known as "bioload" or "microbial load."

Biocide - A chemical or physical agent that kills all living organisms, both micro and macro, as well as pathogenic and nonpathogenic microorganisms. *Microbiocide* specifies an agent that kills microorganisms. Because a *biocide* kills spores as well as vegetative cells, it is presumably a sterilizing agent.

Biohazard - an infectious agent, or hazardous biological agent, or part thereof, regardless of origin (naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance), that presents a real or potential risk to humans, animals or plants, either directly through infection, or indirectly through the disruption of the environment. Biohazards include certain types of recombinant DNA; organisms and viruses infectious to humans, animals or plants (e.g., parasites, viruses, bacteria, fungi, prions, and rickettsia); and biologically active agents (i.e.,, toxins, allergens, and venoms) that may cause disease in other living organisms or significantly affect the environment, community, commerce, or trade agreements.

Biohazard Incident – An incident that may include human exposure to an infectious, potentially infectious, or zoonotic agent; a release of a biohazard into the environment; escape of infected animals or vectors; biohazard spills outside of a primary containment device; loss or theft of biohazardous agents; or other loss of containment or equipment failure in conjunction with a biohazard which may lead to a release of a hazardous agent within the laboratory environment or outside the laboratory environment.

Biohazardous waste types: Waste items as described in section 7 of this manual generated at USDA facilities.

Biological Indicator (BI) – A standardized preparation of nonpathogenic (surrogate) microorganisms (in many cases bacterial endospores) that are highly resistant to specific sterilization methods. BIs are used during the sterilization process to provide additional evidence that the sterilization method was effective in achieving sterilization. BIs can be dried preparations on filter paper (spore strips), stainless steel coupons, or aluminum foil, or can be a combined unit consisting of a paper carrier of the BI and a vial of growth medium containing a pH indicator system.

Biological Toxin or Biotoxin – A broad range of substances, predominantly of natural origin but increasingly accessible by modern synthetic methods, that may cause death or severe incapacitation at relatively low exposure levels. Biological toxins include metabolites of living organisms, degradation products of dead

organisms, and materials rendered toxic by the metabolic activity of microorganisms.

Biosafety Level (BSL)- Four BSLs are described in the 5th edition of *Biosafety in Microbiology and Biomedical Laboratories*, published by the Centers for Disease Control (CDC) and the National Institutes of Health. These consist of increasingly protective combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed, the documented or suspected routes of infectious agent transmission, and the laboratory function or activity.

Common Carrier- A U.S. Department of Transportation licensed commercial carrier contracted to transport biohazardous waste.

Contamination – The introduction of microorganisms or biological toxins to items or surfaces, or into tissues or sterile material.

D-Value – The time required to inactivate 90% of the cell population or to reduce the microbial population to one-tenth of its original number (a one-logarithm reduction).

Decontamination – Disinfection or sterilization of articles contaminated with toxins or agents to make the articles safe for use or disposal.

Disinfectant – A chemical agent that eliminates a defined scope of pathogenic organisms, but not necessarily all microbial forms (e.g., bacterial endospores).

Disinfection – The selective elimination of certain undesirable microorganisms to prevent their transmission to a susceptible host.

Disinfestation – Extermination or destruction of insects, rodents, or other animal forms that transmit disease or are otherwise considered pests and that may be present on plants, animals, humans, or in their immediate environments.

Droplet nuclei – Particles of 5 μm diameters or less, that are formed by dehydration of airborne droplets and capable of air dispersal.

Etiologic agent – Any viable microorganism or its toxin that has the capacity to cause human disease.

F-value – The time in minutes required to kill all the spores in suspension at a temperature of 121°C (250°F). By calculating and converting the temperature-time equivalents of the F-value during the heating and cooling of the sterilization cycle and adding them together, the holding time at sterilization temperature may be reduced and the product subjected to less heating than otherwise would be required.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) – Provides the basis for regulation, sale, distribution, and use of pesticides in the United States. FIFRA authorizes the U.S. Environmental Protection Agency (EPA) to review and register pesticides for specified uses. EPA also has the authority to suspend or cancel the registration of a pesticide if subsequent information shows that its

continued use would pose unreasonable risks. Some key elements of FIFRA include:

- product licensing statutes that require the registration of pesticide products with the EPA before their manufacture, transport, and sale;
- registration based on a risk/benefit standard;
- strong authority to require data, and the authorization to issue Data Call-ins;
- regulation of pesticide use through labeling, packaging, composition, and disposal;
- emergency exemption authority that permits approval of unregistered uses of registered products on a time limited basis; and
- authorization to suspend or cancel a product's registration, including the appeals process, adjudicatory functions, etc.

Fomite(s) – Inanimate objects that may transmit infectious microorganisms, such as pens, eating utensils, equipment, combs, etc.

Fumigation – A means of decontaminating an enclosed space and the articles enclosed in that space by using a gas or vapor method. Usually the agent selected can inactivate bacterial endospores.

Germicide – An agent that destroys microorganisms, especially pathogenic organisms. As commonly used, the term is associated with the death of all disease-producing microorganisms, but it does not necessarily include the capability of destroying bacterial spores.

Infection – The establishment of a pathogenic microorganism within a susceptible host after transmission via a viable route and subsequent host invasion.

Pasteurization – A process developed by Louis Pasteur for heating milk, wine, or other liquids to 60° to 100°C (140° to 212°F) for approximately 30 minutes to significantly reduce or kill the number of pathogenic and spoilage organisms.

Prion(s) – Proteinaceous infectious particles that lack nucleic acids. They are thought to consist of an abnormal isoform of a normal cellular protein highly resistant to treatments (e.g., moderate heat, protein digesting enzymes, radiation, and formalin) that would inactivate typical proteins, viruses, or bacteria. Complete inactivation may not always be possible, but all attempts should be made to ensure that adequate decontamination is met. The World Health Organization's publication, "Infection Control Guidelines for Transmissible Spongiform Encephalopathies," provides internationally-accepted guidance on handling Prion disease agents; it is located at:

http://whqlibdoc.who.int/hq/2000/WHO_CDS_CSR_APH_2000.3.pdf).

Select Agent and/or Toxin - A biological agent or toxin listed in 7 CFR 331.3 (PPQ); 9 CFR 121.3 and 9 CFR 121.4 (VS); and 42 CFR 73.3 and 42 CFR 73.4 (CDC) (See "Overlap Select Agent and/or Toxin").

Source Reduction - The process of removing certain items and/or materials from a contaminated site for further treatment and reuse or disposal; cleaning items remaining on site prior to the main decontamination activity; and/or cleaning surfaces. The latter step is usually performed in conjunction with fumigation remedies. For cleanups that only involve the application of liquids to nonporous surfaces, this step may provide the main remediation activity. When effectively conducted, source reduction:

- Reduces the number of potentially contaminated items and/or materials present;
- Ensures that any material that might inhibit decontamination is removed; and
- Reduces high contamination levels before full decontamination.

Spaulding Classification – Strategy suggested by Dr. E. H. Spaulding in 1972 that divides medical devices into three infection risk categories (Critical, Semi-critical and Non critical), based on use and types of tissue they contact. To complement the categorization of medical and surgical devices, three levels of germicidal action (High, Intermediate, and Low) were developed to carry out disinfection strategies in healthcare settings.

Sterile – Free from living microorganisms.

Sterility Assurance Level (SAL) – The probability of a viable microorganism being present on a product unit after sterilization. SAL is normally expressed as 10-x. SAL of 10-6 is most often used for sterile devices and drugs.

Sterilization – A carefully monitored process that will assure that the probability of an item being contaminated by a microbe to be equal to or less than one in a million (10^{-6})

Toxin - See Biological Toxin

USDOT regulated medical waste or clinical waste or (bio) medical waste – Defined in 49 CFR § 173.134, means 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. Regulated medical waste or clinical waste or (bio) medical waste containing a Category A infectious substance must be classed as an infectious substance, and assigned to UN2814 or UN2900, as appropriate.

- **Category A, UN 2814**- Infectious substances affecting humans and animals: An infectious substance in a form capable of causing permanent

disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs.

- **Category B, UN 2900**- Infectious substances affecting animals only: An infectious substance that is not in a form generally capable of causing permanent disability of life-threatening or fatal disease in otherwise healthy humans and animals when exposure to it occurs.
- **Category B, UN 3373**- Biological substance transported for diagnostic or investigative purposes.
- **Regulated Medical Waste, UN 3291**- Waste or reusable material derived from medical treatment of an animal or human, or from biomedical research, which includes the production and testing of biological products.

Virucide – An agent that destroys or inactivates viruses to make them noninfective, especially a chemical substance used on living tissue. The word *virucide* is a misnomer because the ending "cide" means *kill,* and the virus by itself is not a living entity. Thus, we do not say a virus is killed, but that a virus is inactivated.

Z-value – A measure of the way the D-value changes with temperature for a particular organism. It may be considered the slope of the logarithm of the D-value against temperature and the number of degrees to change the D-value by a factor of 10. It is useful for comparing the death rate of spores with the destructive effect on the product over an equivalent temperature range.

6. PERSONNEL RESPONSIBLE FOR BIOHAZARDOUS WASTE MANAGEMENT

Areas of Responsibility

This section outlines individual responsibilities for implementation of biohazardous waste disposal policies and procedures.

a. Agency

(1) Administrator or Agency Head. The Administrator is responsible for ensuring agency compliance with USDA biohazardous waste policies and procedures, and designates the agency official (Deputy Administrator or equivalent) who will ensure compliance implementation.

(2) Deputy Administrators or equivalent. The Deputy Administrators ensure USDA biohazardous waste policies and procedures are implemented at all sub-agency levels, and designate an Agency Biosafety Officer or equivalent.

(3) Agency Biosafety Officer or equivalent. The Agency Biosafety Officer is responsible for ensuring adherence to all agency biohazardous waste policies and procedures, which includes reporting all biohazardous waste incidents to the designated Agency official.

b. Facility

(1) Center Director, Laboratory Chief or Director, or Research Leader or equivalent. The Center Director ensures the implementation of biohazardous waste policies and procedures at their facility or institute and also designates a Location Biosafety/Biosecurity/Quarantine Officer or equivalent.

(2) Location Biosafety/Biosecurity/Quarantine Officer(s) or equivalent. The Location Biosafety Officer(s) works with local line managers, scientists, and research personnel to ensure the facility is in compliance with agency and Department policy on biohazardous waste disposal. S/he reports all biohazardous waste incidents through Center or Location Management to the Agency Biosafety Officer or designated Agency Official.

(3) USDA Scientists and Research personnel. All USDA Scientists and Research personnel are responsible for:

- staying informed about hazardous biological agents in their work areas;
- adhering to biohazardous waste disposal policies and procedures; and
- Ensure that their employees are aware of hazards associated with biohazards or biohazardous waste(s) and are appropriately trained on the applicable regulations, standard operating procedures, emergency procedures, security and safety procedures.
- informing supervisors (or designee) and the Location Biosafety/Security/Quarantine Officer(s) of all biohazardous waste disposal incidents.

c. Development of Location Biohazard Waste Management Plan

(1) DR 4400-007, Biological Safety Program, dated May 19, 2006, (www.ocio.usda.gov/directives/doc/DR4400-007.htm) requires that affected personnel must be provided site-specific Biohazard Control Plans which contain specific information about biological hazards at their worksite.

(a) The Biohazard Control Plan must include provisions for the safe handling and disposal of hazardous biological agents, and can be incorporated into existing plans, such as the Chemical Hygiene Plan (Laboratory Safety) or Hazard Communication Plan--both mandated by the Occupational Safety and Health Administration (OSHA)--or the Biohazardous Control Plan.

(b) Whether it is incorporated into existing plans or exists as an independent document, the directives contained in the Biohazard Control Plan should be in accordance with the policy and procedures for decontamination, destruction, and disposal of hazardous waste as described in this Manual.

d. Biohazardous Waste Incident Reporting

All USDA scientists and research personnel are responsible for reporting any biohazardous waste incidents, regardless of severity, to their supervisor or designee and to the Location Biosafety Officer.

(1) The notification must be made by phone or in person.

(2) After investigating the circumstances that are reported, the Location Biosafety Officer will determine if a biohazardous waste incident has occurred.

(3) The Location Biosafety Officer is responsible for reporting biohazardous waste incidents to the appropriate line management and/or the Responsible Official for select agents and toxins. Line management is responsible for reporting the incident through the the normal management communication structure to the Agency Biosafety Officer or equivalent for incidents involving potential occupational exposure or illness, environmental release or a reportable incident involving a select agent.

(4) Once an investigation of the situation is complete, the supervisor will report the findings and corrective actions taken through the normal management communication structure.

(5) The Agency Biosafety Officer or equivalent is responsible for reporting any biohazardous waste incidents to the designated Agency official.

(6) Incidents related to select agents and toxins must be reported to the Agriculture Select Agent Program at 301-734-5960 (Or if registered with CDC Select Agent Program at 404-718-2000).

When responding to these incidents, the Responsible Official should follow the requirements of 7 CFR 331.19, 9 CFR 121.19 or 42 CFR 73.19- Notification of a theft, loss, or release.

7. TYPES OF BIOHAZARDOUS WASTE GENERATED AT USDA

USDA is composed of a number of agencies and offices. At least 6 agencies have diagnostic or research laboratories, animal research facilities, and containment greenhouse facilities. USDA diagnostic and research operations generate a range of biological waste products. The appropriate precautionary procedures and the most effective decontamination methods vary for different pathogens and waste streams, and the selection of any waste management method should only be done after a careful evaluation and risk assessment is performed. Various disinfection methods are described in subsequent sections of this document.

The following is a list of the many categories/types of biological waste generated in USDA facilities, but it is not comprehensive. Biological waste products not specified in this section are to be handled in a manner providing maximum protection to facility personnel, public health, U.S. Agriculture and to the environment.

All Federal, State, local, and facility regulations must be consulted and followed for the definition of biohazardous wastes and waste disposal.

a. Cultures, stocks of etiologic or infectious agents, and associated biologicals (including but not limited to all agents, whether designated as pathogens or not):

(1) Specimens from veterinary, diagnostic, regulatory, pathology, and research laboratories related to testing of products for animals, plants, food, soil, etc);
(2) Diagnostic sample cultures, including all inoculated media used to isolate or enumerate microorganisms regardless of final isolation result;
(3) Incubated food samples, including the initial dilution, recovery, or enrichment culture of the food sample;
(4) Quality control cultures;
(5) Disposable culture/Petri dishes;
(6) Devices used to manipulate specimens and devices used to transfer, inoculate, and mix cultures, including disposable and reusable items (reusable items include but are not limited to blender jars and blades, glass pipettes, scissors, knives, dilution bottles, ring slides, filter units, forceps, and funnels);
(7) Wastes from the production of biologicals;

(8) Waste water from containment greenhouses;
(9) All microorganisms constructed using rDNA; and
(10) Discarded live and attenuated vaccines.

b. Carcasses, body parts, and bedding from animals exposed to pathogens in research/diagnostics or that are used for diagnostics and may naturally harbor pathogens

c. Plant specimens or debris, seeds, or soil exposed to plant pathogens, infectious material, insects under a plant pest permit (PPQ 526), or plant materials and associated pests

d. All contaminated and uncontaminated sharps, including:

(1) Needles and syringes
(2) Scalpels, razors, and microtome blades
(3) Pasteur pipettes
(4) Slides and cover plates
(5) Broken glass

e. Laboratory wastes, including but not limited to:

(1) Specimen containers
(2) Histology samples and other fixed slides or wax embedded tissues
(3) Disposable personal protective equipment (gloves, lab coats, masks, and aprons)
(4) Contaminated culture containers (Petri dishes, flasks, cell culture flasks, pipette tips, disposable pipettes, vials, tubing, etc.)
(5) Towels, absorbent surface liners, or underpads
(6) Cell culture materials
(7) Test or diagnostic kits, enzyme-linked immunosorbent assay equipment, lateral flow devices, and spent pH test paper
(8) Disposable inoculating loops and needles, colony spreaders, and swabs
(9) Sample bags and collection and transport systems
(10) Filters and disposable filter units.

f. Human blood, blood products, and body fluids, including solidified blood and body fluids

g. Prions, including:

(1) Abnormal host proteins
(2) Transmissible Spongiform Encephalopathy agents
(3) Proteins resistant to moderate heat, digestion enzymes, radiation, and formalin

h. Biological toxins, including:

(1) Poisons of natural origin
(2) Poisons of natural origin synthetically produced
(3) Toxic metabolites of living organisms
(4) Degradation products of dead organisms
(5) Materials rendered toxic by the metabolic activity of microorganisms

i. Select Agents: All laboratories working with Select Agents must adhere to the requirements in 42 CFR part 73, 9 CFR part 121 and 7 CFR part 331, as well as the most current version of any and all relevant USDA manuals.

j. Multihazardous Waste: Waste with multiple type hazards including two or more of the following: radioactive, biohazardous agent(s), or hazardous chemical(s). If the multihazardous waste contains a biohazardous agent(s), inactivation of the biohazard(s) is usually the first step in the disposal process. After inactivation of the biohazard the waste will be treated as radioactive or hazardous chemical waste as appropriate. Contact your location Biosafety Officer and/or equivalent for appropriate inactivation methods.

8. BIOHAZARDOUS WASTE SEGREGATION, PACKAGING, LABELLING, AND COLLECTION

a. Biohazardous/infectious waste must be segregated from the general trash.

b. Packaging material must be selected that is appropriate for the type of waste handled (e.g., plastic bags for solid or semisolid infectious waste; puncture resistant containers for sharps; and bottles, flasks, or tanks for liquids).

c. Suitable containers must be used for the intended treatment, (e.g., incineration requires combustible containers). Suitable containers for sharps include; metal, rigid plastic, and heavy cardboard; containers that are compatible with selected treatment processes (NOTE: State and local regulations/requirements for sharps containers may vary).

d. Primary and secondary containment must be adequate to prevent release of biohazardous constituents into the environment.

e. Packaging containers/materials must maintain its integrity during storage and transportation.

f. Biohazardous/infectious waste or packaged biohazardous/infectious waste shall not be compacted using a trash compactor prior to decontamination.

g. Biohazardous waste Storage time should be minimized.

h. Biohazard bags should be sealed and containerized in leak-proof/puncture resistant secondary containment appropriate for treatment or transport. Autoclave Bags used in steam sterilization should be loosely closed during autoclaving to allow for steam circulation within the bag.

i. Liquid wastes must be in capped or tightly stoppered bottles or flasks and containerized in leak-proof/puncture resistant secondary containment as appropriate for transportation. Liquid waste vessels should never be tightly capped during steam sterilization (autoclaving).

j. The universal biological hazard symbol must be visible on infectious waste containers.

k. Appropriate labeling or color coding should be used to differentiate decontaminated from non-decontaminated waste.

l. Waste moved within the facility for treatment or storage may require additional packaging to preserve containment of the waste. This may be a rigid or semi-rigid container or double bagging.

m. Carts used to transfer wastes within a facility should be disinfected and cleaned frequently.

n. USDOT Regulated waste material to be transported offsite, on public access roads (or otherwise enter commerce), for decontamination shall be packaged, marked, labeled and shipped in compliance with USDOT hazardous materials regulations (49 CFR Parts171-180).

9. MECHANICAL METHODS FOR DECONTAMINATION OF BIOHAZARDOUS WASTE

The purpose of this section is to describe mechanical strategies used for decontaminating surfaces, items, and areas (laboratories, animal facilities, etc.). The basic goal of decontamination is to render an article safe for reuse or disposal. In order to eliminate the potential for environmental transmission of a biological agent under study/examination to a susceptible host, one or more of the requirements for environmental transmission must be disrupted. Environmental transmission can occur when the following requirements, also known as the "Chain of Transmission," include:

- Presence of agent

- Sufficient virulence of agent
- High numbers of agent
- Mechanism of transmission from environment to host
- Correct portal of entry
- Susceptible host

a. Mechanical decontamination involves measures to remove, but not necessarily neutralize, an agent. Cleaning is the removal of visible dirt and stains. This includes, but is not limited to:

(a) brushing or vacuuming with a HEPA vacuum
(b) washing or damp mopping with water containing a soap or detergent
(c) flushing water lines

b. Precleaning is routinely carried out if the risk of human or animal contact with pathogen-contaminated materials is high and subsequent decontamination is needed. In these cases, precleaning is essential to achieve proper disinfection or sterilization, because dirt and soil can shield microorganisms and can also interfere with the killing action of chemical germicides.

c. Many germicidal products are only effective on precleaned items.

d. Precleaning must be carried out carefully to avoid exposure to infectious agents.

e. Precleaning should only be conducted with materials chemically compatible with the germicides that will be subsequently applied. Because of this, it is common to use the same chemical germicide for precleaning and disinfection.

10. PHYSICAL METHODS FOR DECONTAMINATION OF BIOHAZARDOUS WASTE

The purpose of this section is to describe physical strategies used for decontaminating surfaces, items, and areas (laboratories, animal facilities, etc.). The basic goal of decontamination is to render an article safe for reuse or disposal. In order to eliminate the potential for environmental transmission of a biological agent under study to a susceptible host, one or more of the requirements for environmental transmission must be disrupted. Physical decontamination renders the agent harmless through physical means, such as heat, ionizing radiation, and ultraviolet (UV) radiation.

a. The most effective method of physical decontamination is steam sterilization (autoclaving). Steam sterilization under pressure is universally used in the conduct of biological research except when steam penetration or heat and moisture damage is a concern. Steam sterilization is considered one of the most dependable systems available for decontaminating laboratory waste and sterilizing laboratory glassware, media, and reagents.

Autoclaves are essentially steel pressure vessels that use pressurized steam, usually 15 PSI (1.05 kg/cm2), to achieve a chamber temperature of at least 121°C (250°F), which is effective at inactivating microorganisms and proteinaceous bacterial and plant toxins.
The critical factors in ensuring the reliability of this sterilization method are proper temperature and time and the complete replacement of the air with steam (i.e., no entrapment of air). Because of these factors, chamber pressurization requirements increase at higher geographic elevations.

Some autoclaves use a steam-activated exhaust valve that remains open during the replacement of air by live steam until the steam triggers the valve to close. Others use a pre-cycle vacuum to remove air prior to steam introduction.

(1) There are three types of autoclave cycles:

(a) The gravity cycle is also known as the “Fast Exhaust” cycle, and is typically used to decontaminate or sterilize dry goods, glassware, etc. During this cycle, the chamber charges with steam and holds it at a set temperature for a set time; at the end of the cycle, the chamber returns quickly to atmospheric pressures.

(b) The pre-vacuum cycle is used for decontaminating porous materials, animal bedding, etc.; in this process, the autoclave chamber is partially evacuated before steam is introduced, which facilitates steam penetration throughout the load.

(c) The liquid cycle is also known as the “Slow exhaust” cycle. Steam is exhausted slowly at the end of the cycle to prevent sterilized liquids from boiling over; in this process, liquid containers must not be overfilled before autoclaving, or they will boil over and represent a hazard to the operator.

(2) The following procedures must be followed when preparing to place biohazardous materials in an autoclave.

(a) Materials that are to be decontaminated should be carried to the autoclave in closed, leak proof containers. Primary containers used during autoclaving include plastic autoclave bags, which are polypropylene bags used to contain materials during decontamination cycles within autoclaves. These bags, also known as "autoclavable bags", come in a wide variety of sizes, shapes and colors, and are available from many laboratory supply houses.

(b) Autoclave bags are usually placed in polypropylene or stainless steel pans during decontamination cycles to catch liquids that may drain out of the bag.

(c) Autoclave bags should be closed loosely during decontamination to allow steam to penetrate into the bag. It is essential for steam to come in contact with all areas of the load, and steam saturation is required for maximum heat transfer; air pockets or inadequate steam supply will result in incomplete sterilization.

(d) Water should be added to the materials that will be decontaminated to facilitate steam contact, but it is necessary to guard against creating infectious aerosols in the process. For safe handling, operators should trickle water down the sides of the container, instead of pouring water directly onto the material in the container or bag. In any case, 250-500 ml of water should be added to the interior of the autoclave bag to facilitate heat transfer to the material being decontaminated, unless the addition of water might create splashing that could facilitate the release of potentially infectious material from the bag.

(e) Autoclave bags that are filled in a laboratory should be temporarily placed inside another leak proof and puncture resistant container, which can then be taken to the autoclave. The autoclave bag should be removed from the container, decontaminated in the autoclave and discarded into the appropriate waste container in accordance with all facility policies and State and/or local regulations.

1 Secondary containers used during autoclaving can include plastic containers and steel containers.

2 Polypropylene is a durable, inexpensive plastic resin that is commonly used to contain material during autoclaving. Polypropylene plastic pans

with 6-12 inch sides can withstand autoclaving without melting and are preferred over polyethylene and polystyrene pans. When using polypropylene containers, extra processing time needs to be added to the autoclave decontamination cycle because polypropylene does not conduct heat as well as stainless steel.

3 Stainless steel containers are durable and come in a variety of sizes and shapes, and may reduce autoclave decontamination cycle processing time because stainless steel is a good conductor of heat. Durable stainless steel containers may be the optimal containers for autoclave decontamination when waste containment is mandatory.

(3) Only adequately-trained personnel should be permitted to operate an autoclave, and laboratory/program supervisors are responsible for providing and documenting autoclave operator training.

(a) Appropriate personal protective equipment is required, including a fully fastened lab coat, heat resistant gloves, eye protection, etc., particularly when unloading the autoclave. Local or area Safety, Health, and Environment staff should be consulted on the purchase of appropriate personal protective equipment.

(b) Autoclave operators should routinely inspect the autoclave components for proper operation, including inspections of autoclave door clamps and seals for signs of wear and damage.

(c) Autoclave operators should ensure that debris from the autoclave chamber floor drain has been removed; if the sieve is blocked with debris, a layer of air may form at the bottom of the autoclave, preventing sufficient heat transfer. If operators find a problem, they should promptly notify the laboratory/program supervisor who will facilitate the repair of the unit. **A DAMAGED AUTOCLAVE MUST NOT BE OPERATED UNTIL IT HAS BEEN PROPERLY REPAIRED.**

(4) Processing times starts after the autoclave is loaded and started and has reached normal operating conditions of 121^{o}C (250^{o}F) and pressures of 15 psi.

(a) Decontamination conditions vary with load type, load volume (loose packed or tightly packed), container type (polypropylene, glass, stainless steel), and the type of material to be decontaminated. Larger loads will typically require more time for complete decontamination.

(b) Sixty minutes are needed to decontaminate lab and medical waste, unless a shorter interval has proven effective by testing with biological indicators. Typically, additional time is required if polypropylene containers are used instead of stainless steel containers.

(c) Ninety minutes are recommended for the decontamination of waste in low sided polypropylene containers with bags half filled and loosely gathered.

(d) A longer processing time (120 minutes or more) may be needed if bags are tightly packed and do not readily permit steam penetration throughout the load.

(e) If the autoclave is equipped to operate at 132^{o}C (270^{o}F), it may be possible to reduce the processing time, if the shorter run times are validated using biological indicators. Typically BIs are placed in the center of the load.

(f) According to the EPA, "Infectious wastes from departments of health care facilities may be rendered noninfectious by subjecting the waste to autoclave temperatures of 121^{o}C (250^{o}F) and 15 minutes of prevacuum of 15 psi for the following dwell times when proper containers are used:"

EPA Recommended Decontamination Processing (Dwell) Times:

TRASH	60 Minutes
GLASSWARE	60 Minutes
LIQUIDS	60 Minutes / Gallon
ANIMAL CARCASSES	8 Hours
ANIMAL BEDDING	8 Hours

(5) At the end of a decontamination cycle, the operator must ensure that the pressure in the autoclave chamber is near zero before opening the door. Once this has been verified, the operator should slowly crack open the autoclave door (operator remaining behind the door) and allow the steam to gradually escape from within the

autoclave; opening the autoclave door too quickly may result in glassware breakage and/or steam burns. After materials inside the autoclave have been allowed to cool for 15-30 minutes, they can safely be removed from the autoclave by the operator in conjunction with appropriate PPE.

(6) Newer autoclave models are equipped with an internal printer that records temperature and pressure at pre-determined intervals throughout the autoclave cycle on a receipt-tape. The recorder tape should be removed and taped into the autoclave logbook as a permanent record of autoclave performance.

b. Ionizing Radiation is known as a cold sterilization process since sterilization can be achieved at room temperature. There are two technologies currently in use; electron-beam (E-beam) technology or γ-irradiation. Regardless of the method used, the primary means of inactivating organisms is to disrupt DNA chains by secondary energetic species (e.g., free radicals, electrons). The typical dose required for sterilization of bacterial spores is reported as 2.5 megarads.

(1) Gamma Irradiation: Gamma rays, emitted from cobalt-60, are similar in many ways to microwaves and Xrays. Ionizing energy produced by gamma rays penetrates deeply, making it a good fit for products with various densities and packaging types. Processing times tend to be longer as compared to Ebeam technology.

(2) E-beam radiation: a form of ionizing energy, is generally characterized by low penetration and high-dose rates. E-beam irradiation is similar to gamma processing in that it alters various chemical and molecular bonds on contact, including the reproductive cells of microorganisms. Beams produced for e-beam sterilization are concentrated, highly-charged streams of electrons generated by the acceleration and conversion of electricity. Typical medical device sterilization uses high-energy electrons, usually 10 million electron volts (10 MeV). This type of E-beam facility has a capacity comparable to a multimillion curie 60cobalt facility. Electron penetration into a product directly correlates to the energy of the electron and the density of the material to be sterilized. In general, E-beam irradiation performs best on low density, uniformly packaged products.

c. UV radiation is a form of non-ionizing radiation that has been used as an antimicrobial disinfectant for over 50 years, but its use as a surface and air disinfection method remains limited. The inactivation of microorganisms

from exposure to UV radiation is attributed to photobiochemical reactions that are induced within the microorganism.

(1) Germicidal lamps should have an output of least 40 microwatts per Cm^2 at 254 nanometers, and should be monitored frequently to ensure appropriate output. UV bulbs should be cleaned frequently to prevent dust accumulation.

(2) Cellular nucleic acids, DNA and RNA, particularly their pyrimidine bases are especially susceptible to UV radiation and its antimicrobial and mutagenic effects. UV induced damage is caused by the creation of nucleic acid dimers.

(3) Proteins are also affected by UV radiation, but they are typically less sensitive and exhibit a more varied level of damage when compared to nucleic acids.

c. Dry Heat/Incineration systems use high-temperature combustion to burn pathological and other medical wastes, and reduce the waste materials to non-combustible ash. A variety of incinerators can be used to incinerate research waste, but controlled air incinerators are most commonly used. Typically these incinerators have a dual chamber configuration that provides two sequential combustion processes, and a stack for venting combustion products/emissions.

(1) For effective incineration, the operator must ensure that the incinerator is in proper working order and that the incinerator is the proper type with a valid operation permit.

(2) Pathological waste or other medical waste is loaded into the primary or lower chamber, where the combustion process begins in an environment which has less than the stoichiometric amount of air required for combustion.

(3) Combustion air enters the primary chamber from beneath the incinerator hearth, below the burning bed of waste. This air is called primary or underfire air. In the primary (starved-air) chamber, the low air-to-fuel ratio dries and facilitates volatilization of the waste, and most of the residual carbon in the ash burns. In these conditions, combustion gas temperatures are a relatively low 760^o to 980°C ($1,400^o$ to 1,800°F).

(4) In the second stage, excess air is added to the volatile gases formed in the primary chamber, which completes the combustion. Secondary chamber temperatures are higher than primary chamber temperatures--typically 980^o to 1,095°C ($1,800^o$ to 2,000°F), and

sterilization of any remaining infectious particulates will occur within this chamber.

(5) Most modern incinerators include a scrubbing system or other pollution control systems after the secondary chamber to remove particulates and acid gases.

d. Alkaline hydrolysis is a process by which complex molecules are broken down into their constituent building blocks by the insertion of ions of water (H_2O), H+, and OH- between the atoms of the bonds that held those building bocks together. The process occurs in nature when animal tissues and carcasses are buried in soil of neutral or alkaline pH and in our small intestines after we eat.

Alkaline hydrolysis can also be used for disposing of waste biologic tissues and animal carcasses by subjecting the waste to strong alkali and heat under pressure. Alkali, in the form of either sodium or potassium hydroxide solution, or a mixture of both, is used at temperatures ranging from ~100ƒC to 180ƒC and higher for rapid dissolution and then hydrolysis of the proteins into small peptides and amino acids in the form of their sodium or potassium salts. Potassium hydroxide or mixtures of potassium hydroxide and sodium hydroxide are the preferred alkali solutions because of the instability of concentrated (50%) stock solutions of NaOH solutions at temperatures below 20ƒC . The result is a sterile liquid with high biological and chemical oxygen demand, and a crumbly, sterile solid resembling bone.

11. CHEMICAL METHODS FOR DECONTAMINATION OF BIOHAZARDOUS WASTE

The purpose of this section is to review the various chemical methods used for decontaminating biohazardous wastes or potentially contaminated surfaces. Chemical decontamination renders the agent harmless through the use of antimicrobial disinfectants or sterilants. Current technologies for chemical (antimicrobial) decontamination fall into three categories: liquids, foams and gels, and gases and vapors. Liquids are effective against many biological agents when applied to hard, nonporous surfaces, but they can cause corrosion to sensitive materials. Foams and gels are effective against certain biological contaminants, but some can pose a post-decontamination cleanup issue. Gases and vapor fumigants are effective for inactivating biological agents under controlled environments and conditions, but they involve complex, time-consuming, and expensive operations. Gases offer advantages in decontamination, but the quantities of certain gases required for room/area decontamination can create inherent safety hazards.

Chemical disinfectants are regulated by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and assigned to the following categories:

- Sterilizer or Sterilant - will destroy all microorganisms, including bacterial and fungal spores, on inanimate surfaces.
- Disinfectant - will destroy or irreversibly inactivate specific viruses, bacteria, and pathogenic fungi, but not bacterial spores.
- Hospital Disinfectant - shown to be effective against *S. aureus*, *S. choleresis* and *P. aeruginosa*. It may be effective against *M. tuberculosis*, pathogenic fungi or other viruses.
- Antiseptic - formulated for use on skin or tissue, and does not act as a disinfectant.

a. In 1972 Dr. Earl Spaulding classified chemical germicides by levels of disinfection (High, Intermediate and Low). Material Safety Data Sheets, Manufacturer Label Instructions & Claims and other manufacturer's product information should be available and thoroughly reviewed before using these products to ensure appropriate and safe application.

(1) High-level disinfection kills vegetative microorganisms and inactivates viruses, but may not kill high numbers of bacterial spores. These disinfectants typically are capable of sterilization when the contact time is relatively long (e.g., 6 to 10 hours). As high-level disinfectants, they are used for relatively short periods of time (e.g.,, 10 to 30 minutes). In some cases these chemical germicides are potent sporicides that are classified by the Food and Drug Administration (FDA) as sterilants/disinfectants. They are formulated for use on medical devices, but not on environmental surfaces such as laboratory benches or floors.

(2) Intermediate-level disinfection kills vegetative microorganisms, including *Mycobacterium tuberculosis* and all fungi, and inactivates most viruses. Chemical germicides used in this procedure often correspond to EPA-approved "hospital disinfectants" that are also "tuberculocidal." They are used commonly in laboratories to disinfect laboratory benches, and are part of the inventory of detergent germicides used for housekeeping.

(3) Low-level disinfection kills most vegetative bacteria (except *M. tuberculosis*), some fungi, and inactivates some viruses. The EPA approves chemical germicides used in this procedure in the United States as "hospital disinfectants" or "sanitizers."

b. Common laboratory disinfectants include alcohols, aldeyhdes, chlorine compounds, iodine and iodophors, phenol and phenolic compounds, and quaternary ammoninum compounds

(1) Alcohols possess many desirable attributes for use as disinfectants or antimicrobials. Many alcohols have a cleansing action and have no residual effects, which can be advantageous in some applications. Their specific activity depends on concentration levels and disinfection conditions. Like many chemical disinfectants, the effectiveness of alcohol as a non-specific antimicrobial disinfectant stems from a range of combined toxic mechanisms, but its primary mode of action is through protein coagulation/denaturation.

(a) Alcohols are bactericidal as well as bacteriostatic against vegetative forms, and are also effective against fungi and lipid viruses, but are only moderately effective against nonlipid viruses, and are completely ineffective against bacterial spores.

(b) The most commonly used alcohols, ethanol and isopropanol, are most effective at concentrations of 70% in water; higher and lower concentrations are less effective because proteins are not denatured as readily in the absence of water, so alcohol solutions above 85% are ineffective for disinfection purposes.

(c) Alcohols are not recommended for use as a surface contact disinfectant because they evaporate quickly, which decreases contact time and impedes their penetration of organic matter.

(d) When disinfecting with alcohols, it is best to clean an object and then submerge it in alcohol for the recommended contact time.

(e) Because the most commonly used alcohols (methanol, ethanol, propanols, propanols and tert-butanol) have flashpoints lower than 15^{o}C (59^{o}F), proper precautions are essential when they are used as disinfectants; for instance, alcohols should never be used around a Bunsen burner or other open flame.

(2) Aldehydes—including formaldehyde in its gas state and glutaraldehyde in its liquid state—are both good disinfectants.

However, aldehydes are toxic, and their practical use in the laboratory for routine disinfection is limited.

(a) Aldehydes are active against vegetative bacteria (including mycobacteria), spores, fungi, and both enveloped and nonenveloped viruses. They remain active in the presence of protein, and their activity levels are only lessened slightly by natural or man-materials or detergents.

(b) Formaldehyde is available as a gas dissolved in a mixture of water and methanol, and as a 37% formaldehyde solution known as formalin. Dissolved in water, formaldehyde is active at 1-8% solutions, and can be used to decontaminate hard surfaces. However, formaldehyde is very irritating at low concentrations (0.1 to 5 ppm), and is classified as a probable carcinogen, so it is used only when necessary to disinfect hard surfaces.

(c) Gluteraldehyde is usually supplied as a 20% solution and requires activation by the addition of an alkaline agent prior to use. The activated product may be kept for about two weeks and should be discarded when turbid. Glutaraldehyde is toxic, irritating, and mutagenic, and should be used only when necessary (i.e., for the decontamination of endoscopes). It is essential to follow the manufacturer's guidance/label claims when using glutaraldehyde-based products, because there are many different formulations that have been designed for specific uses.

(3) Chlorine compounds: The most commonly used and generally effective chlorine based disinfectant is sodium hypochlorite (common household bleach). It is a strong oxidizing agent and therefore can be corrosive to metal. The presence of high concentrations of protein or other organic material can reduce the effectiveness of chlorine products, and dilute hypochlorite solution should be prepared daily to be maximally effective. There are more concentrated sodium hypochlorite solutions available for industrial use, and product information must be followed carefully to determine the proper dilution.

(a) A 1:50 dilution of 5.25% Sodium hypochlorite(e.g., Clorox® household bleach) with water, supplying 1000 ppm available chlorine is very effective as a general laboratory disinfectant.

(b) A 1:10 dilution supplying 5000 ppm available chlorine is effective against spills involving blood or other organic material.

(4) Iodine and iodophors are compounds in which the iodine is combined with a solubilizing or carrier agent. They serve as all-purpose disinfectants and have an action similar to that of chlorine products. Like chlorine compounds, the effectiveness of iodine compounds may be diminished in the presence of protein.

(a) The appropriate concentration for iodine-containing products to disinfect work surfaces is 75 ppm available iodine. Concentrations may be much higher for other purposes.

(b) Only those iodophors registered with EPA as hard-surface disinfectants should be used, and the manufacturer's instructions regarding proper dilution and product stability must be closely followed.

(c) Antiseptic iodophors are not suitable for disinfecting devices, environmental surfaces, or medical instruments.

(5) Phenolic compounds are active at concentrations of 0.2% to 3% against all forms of vegetative microorganisms, but are not active against spores, and have only limited effectiveness against nonlipid viruses. Most phenolics are active in the presence of large amounts of protein, but are inactivated to some extent by rubber, wood, and plastics. They are not compatible with cationic detergents. In the laboratory, they can be used to disinfect discard jars and surfaces. Many common disinfectants are based on phenol and should be used according to the manufacturer’s recommendations.

(a) Clear phenolics should be used at the highest recommended concentration.

(b) Dilutions should be prepared daily and diluted. Phenolics should not be stored for more than 24 hours.

(c) Precautions must be taken to protect skin and eyes from contact with phenolic substances.

(6) Quaternary ammoninum compounds are cationic detergents, active at concentrations of 0.1% - 2%, which are effective against vegetative bacteria, enveloped viruses, and some fungi. They are

less or not effective at inactivating mycobacteria, spores, and non-enveloped viruses, and are inactivated by protein and a variety of natural and plastic materials and soap. Because of this, their laboratory uses are limited; however, they are stable compounds and are non-corrosive to metals. They are usually used for cleaning surfaces and are used extensively in food hygiene laboratories because of their detergent nature. They are non-toxic and harmless to the skin and eyes.

c. Only a few gas and vapor chemical sterilants are widely used in biomedical and research institutions, and for other industrial sterilization applications. Gaseous sterilants can be broadly characterized by an alkylation or oxidizing mode of action, and gas/vapor sterilization is only achieved through the successful union of the sterilant and the sterilization process. Many of the gas/vapor methods have a fundamental process sequence of pre-conditioning (temperature, relative humidity, sterilant concentration etc), exposure, and sterilant removal.

(1) Only individuals who are well versed and well trained on the sterilization method, sterilant, and associated hazards should be permitted to conduct decontamination/sterilization operations using these agents. Certain gas-phase water disinfection systems involve the generation of gas onsite, using chemical or electrochemical processes that offer some advantages in terms of removing the requirement for the storage of compressed gases.

(2) Difficulties with some of these systems include measuring the efficiency of the gas-producing reaction, and establishing that the required contact time and concentration gradients are achieved.

(3) Chlorine dioxide (CD), a greenish-yellow gas, is an effective sterilant and powerful oxidizer even at low concentrations of 10–20 mg/L. The EPA registered CD under the FIFRA as a sterilizing agent in 1988. CD reacts with carbohydrates by oxidizing the primary hydroxyl groups to aldehydes and then to carboxylic acids. Oxidation occurs at the double bond with lipids. The effect on peptides and proteins is mainly oxidation, substitution, and addition reactions.

(a) The lethal activity of CD on spores is dependent on hydration of the spores for optimal activity—a relative humidity of 50% or higher is optimal for sterilization.

(b) CD is noncarcinogenic, nonflammable, does not deplete ozone, and is not associated with any serious human toxicity from either acute or chronic ingestion.

(c) CD is considered a mucous membrane irritant and inhalation of excessive amounts can result in pulmonary edema. The threshold limit value time-weighted average (the period of safe exposure during an 8-hour period) for CD is 0.1 parts per million, which is also the reported odor threshold.

(d) After an area is treated, CD can be converted to sodium sulfate using sodium thiosulfate.

(e) Because of the selective reactivity of CD, materials such as titanium, stainless steel, silicone rubber, ceramics, polyvinyl chloride, and polyethylene are unaffected by exposure to the gas. However, uncoated copper and aluminum are highly affected. In addition, certain formulations of polycarbonates and polyurethanes develop a marked change in color and tensile properties.

(4) Ethylene oxide (epoxyethane, ETO) is one of the most widely used alkylating sterilants by the research and biomedical communities. It is a flammable and explosive gas, and is classified as both a mutagen and a carcinogen. The microbicidal activity of ETO is caused by alkylation of sulfhydryl, amino, carboxy, phenolic, and hydroxyl groups in the spore or vegetative cell. The primary mechanism of its bactericidal and sporicidal activity is the reaction of ETO with nucleic acids. ETO is used because of its ability to inactivate most bacteria, molds, yeasts, and viruses, but its use is limited because of the many dangers mentioned. An EPA air permit is required to use ETO under certain circumstances because of air quality emission standards. ETO sterilization should only be conducted in strict compliance with the sterilizer manufacturer's operating guidelines.

(a) Four parameters affect the ability of ETO to sterilize products: temperature, concentration, humidity and time.

1 Most routine sterilization is conducted at 49^{o} to 60^{o}C (120^{o} to 140 ^{o}F), but sterilization of particularly heat sensitive materials is performed at 38^{o} to 40^{o}C (100^{o} to 105^{o}).

2 It has been determined that 450 mg/liter is the minimum ETO concentration required to achieve sterilization, but most ETO sterilizers use ETO concentrations of 600 -1,100 mg/liter.

3 A relative humidity of 45-75% must be maintained to achieve sterilization.

4 The amount of time required for sterilization is temperature dependent, taking less than 2 hours at 54°C (130°F) and over 5 hours at 38°C (100°F).

5 Since ETO penetrates into porous material and is absorbed strongly by rubber and many plastics, an appropriate aeration time is required; in most cases aeration times of 12 hours or more are utilized.

(5) Formaldehyde is widely used by the research and biomedical communities as a fumigant for buildings, rooms, and equipment, and has commonly been used as a gas/vapor decontaminant for enclosed areas. Formaldehyde acts as a decontaminant by denaturing proteins. It is capable of killing microorganisms and detoxifying *C. botulinum* toxin, but is not effective at inactivating prions, and a formaldehyde concentration of 0.6 g/ft3 is required to kill the rikettsial agent *Coxeilla burnetii*, the causative agent for Q fever.

(a) Ammonium carbonate/bicarbonate can be used to neutralize formaldehyde gas.

(b) Although formaldehyde vapor is explosive at concentrations between 7.0 and 73.0% by volume in air, these concentrations should not be reached if standard decontamination procedures (using 0.3–0.6 g/ft3 of paraformaldehyde in the presence of 60–90% relative humidity with a minimum contact time of 6 hours) are used.

(c) Although widely used and recommended as a surface and area sterilant, formaldehyde is a safety hazard because it is a carcinogen.

(d) Formaldehyde is also a powerful reducing agent, has limited penetrating ability, and is potentially explosive. Environmental release of formaldehyde is also highly regulated.

(e) Until 1991, paraformaldehyde was registered for decontamination of laboratories and experimental animal facilities. However, all registrations for this use and many

of the other uses described above were canceled due to nonpayment of registration maintenance fees by the manufacturer. Currently only those facilities that have applied and received a quarantine exemption from EPA can use paraformaldehyde for laboratory disinfection.

(6) Vapor Phase Hydrogen Peroxide (VPHP) has been emerging as a viable alternative for sterilizing biomedical devices and for some industrial applications. Because of its low toxicity, VPHP can provide rapid, low-temperature decontamination that is less hazardous to workers compared to most of the other decontaminants discussed in this section. VPHP can be utilized to decontaminate or sterilize items and equipment that cannot withstand the higher temperatures required in steam sterilization and dry heat. The hydroxyl radical, a strong oxidant, is believed to have microbicidal activity by attacking membrane lipids, DNA, and other essential cell components. The hydrogen peroxide vapor is unstable and degrades through a catalytic process to the nontoxic residues of water vapor and oxygen.

(a) In this cold sterilization process, 35% liquid hydrogen peroxide (300,000 ppm) is vaporized to yield 700–1200 ppm.

(b) Small rooms, biological safety cabinets, or other small enclosures (up to 7500 ft^3) that can be effectively sealed can be sterilized with existing portable equipment.

(c) Non-portable generating equipment that can decontaminate larger spaces is available, but the initial purchase of one of these systems can be costly.

(7) Propylene oxide (epoxy propane) is an alkylating agent that is widely used for industrial applications such as the deinfestation and sterilization of agricultural products, including spices, nuts, and other food products. Propylene oxide hydrolyzes in the presence of moisture to form nontoxic propylene glycol. Propylene glycol vapor is odorless, tasteless, and nonirritating to the respiratory mucosa. The microbicidal mode of action of propylene oxide is the alkylation of DNA guanines, which results in single-strand breaks. β-propiolactone (BPL) is approximately 4000 times more active than ETO and 25 times more effective than formaldehyde. The microbiological activity of BPL is caused by alkylation of DNA.

(a) Although propylene oxide is similar in activity to ETO and uses similar equipment and cycles, use of this decontaminant is limited because BPL lacks the ability to penetrate material, requires a longer processing time, and is carcinogenic in mice.

(8) Methyl Bromide is a broad spectrum fumigant used to control insects, weeds, rodents, and pathogens. A colorless and odorless gas at room temperature, methyl bromide is normally applied as a liquid under pressure that vaporizes upon release at the point of application. Methyl bromide is produced by direct bromination of methane and by the hydrobromination of methanol. In the United States, methyl bromide is used primarily as a soil fumigant, but it can also be used as a disinfectant, rodenticide, methylating agent, wool degreaser, and in ionization chambers. Methyl bromide is applied into loose soil under plastic sheets or used in space fumigation under tarpaulins, and is also applied to a variety of agricultural commodities in specially designed fumigation chambers.

(a) Worker exposure may result from leaks in the plastic sheets or the tarpaulin, or from failure to allow adequate time for the methyl bromide to dissipate following fumigation.

(b) The use of methyl bromide as a pesticide is currently being phased out in the United States and all other countries, because of significant scientific evidence that using methyl bromide contributes to the destruction of the ozone layer.

(c) The use of methyl bromide was completely phased out in 2005, with the exception of certain preshipment and quarantine uses, and other critical uses where no other technically or economically feasible alternatives are available.

12. BIOHAZARDOUS WASTE DECONTAMINATION PROCESS VALIDATION

Validation of the decontamination process ensures that agents of potential harm to human, animal or plant health will be killed or inactivated prior to disposal or release into the environment. Written procedures are needed to document process validation, provide proof of compliance with relevant performance standards, and ensure ongoing process performance. Each decontamination process should be appropriately validated for the agent(s) to be treated, regardless of the type of process.

a. Equipment calibration, maintenance and process validation

(1) Autoclaves are a common means of decontamination in USDA facilities. Validation of effectiveness includes monitoring temperature, pressure and cycle duration time for each cycle and providing periodic decontamination challenges (quality assurance), i.e., use of biological indicators.

(a) Autoclaves performance must be verified prior to initial use and maintained to assure that the temperature sensing system is accurate, uniform and stable. Annual rechecks/validation of operation is required.

(b) Validation of autoclave temperature and pressure using thermocouples placed in various locations of the autoclave chamber should be performed annually to assess the temperature uniformity and gauge accuracy. Perform verifications for temperature and time daily using appropriate chemical indicators.

(c) Routinely conduct sterility validations using biological indicators (i.e., spore vials or strips). Use a microorganism that has a proven resistance to steam sterilization, such as *Geobacillus stearothermophillus*. Validation frequency should be determined by autoclave usage and load types; weekly or bimonthly for each load type is typically preferred.

(d) Some laboratories may choose to conduct more frequent autoclave monitoring/validation using biological and chemical indicators.

(e) Laboratory/research programs that use a particular autoclave should maintain a logbook to record autoclave usage. The logbook should be available for inspection by USDA safety representatives and other authorities. The log should contain the following information:

- date of treatment
- quantity and type of waste autoclaved
- method/condition of treatment
- name of autoclave operator

(f) Quality assurance for autoclaves also includes:

1 ensuring that the appropriate containers are being selected for the waste that is being decontaminated

2 providing odor control when necessary

3 providing personnel training for the operation of an autoclave

(2) Hot air sterilizing ovens, other heat sterilizing equipment and rendering processes should be validated for intended use. The same general principles involved with autoclave process validation can be used with these types of equipment as well.

(3) Incineration processes used for burning medical and veterinary pathological waste ensure that most biological agents do not survive the process. Risk assessments should be done to ensure that the type of incineration process selected meets acceptable criteria for the target agent:

(4) Vapor and gas systems should be calibrated and the process validated before use. The validation should include verification of efficacy and uniformity across the area to be treated (room or chamber). Annual performance checks should be performed. Each run should monitor the relevant parameters (Temperature, Relative Humidity, Vapor/Gas concentration) and verified for effectiveness using biological indicators, recommended by the equipment manufacturer. Biological indicators should be utilized to verify the effectiveness of ethylene oxide, formaldehyde (*Bacillus atrophaeus* and/or *Geobacillus stearothermophillus*), or vaporized Hydrogen Peroxide processes (*Geobacillus stearothermophillus)*.

(5) Ionizing Radiation treatment. Should be validated using the biological indicator, *Bacillus pumilus.* The appropriate load size must be considered to assure that radiation penetration is achieved. Penetration is dependant on the technology used (i. e., Gamma radiation or E Beam) and size, volume and density of the load.

(6) Alkaline Hydrolysis. This method used primarily for carcass disposal/decontamination may utilize a similar validation process to steam sterilization. Each run should monitor the relevant parameters such as time, temperature, pressure, and alkalinity. In many cases Standard biological indicators used for steam sterilization could be used. The process results in the formation of an alkaline (pH 10.3-11.5) aqueous residue with a high BOD (biological oxygen demand, 50.000-75.000 mg/l) and a higher COD (chemical oxygen demand, up to 100.000 mg/l).

(7) Chemical Disinfectants. EPA and the states (usually that state's agriculture office) register or license pesticides for use in the United States. EPA receives its authority to register pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). More than 5000 antimicrobial products are currently registered with the U.S. Environmental Protection Agency (EPA) and sold in the marketplace. Nearly 60% of antimicrobial products are registered to control infectious microorganisms in hospitals and other health care environments. Additional guidance needed for antimicrobials can be found in the links for efficacy test guidelines, antimicrobial policy questions, and other antimicrobial guidance. See specific antimicrobial laws and guidance documents below:

(a) Registration Policy Documents - list of policy and guidance documents to assist in registering or understanding antimicrobial products (http://www.epa.gov/oppad001/regpolicy.htm

(b) Disinfectant Technical Science Section (DIS/TSS) Documents - for determining efficacy data requirements, label claims, and in some cases testing requirements (http://www.epa.gov/oppad001/sciencepolicy.htm)

b. Chemical process validation indicators

(1) Chemical color change indicators for steam autoclaves change color after being exposed to normal autoclave operating temperatures of 121^{o}C (250^{o}F) for a few minutes, and provide a quick visual reference for heat penetration inside the load. Chemical indicators should be positioned near the center of each load, and toward the bottom front of the autoclave. Most chemical indicators can only be used to verify that the autoclave has reached normal operating temperature for decontamination, 121^{o}C (250^{o}F). Chemical indicators alone are not designed or intended to prove that organisms are actually killed during a decontamination cycle.

Chemical indicators are manufactured by many companies and come in a wide variety of sizes, shapes, and colors. They can be purchased from the manufacturers of sterilization equipment, biosafety suppliers and lab supply distributors. In addition to chemical indicators for steam sterilization, a variety of chemical indicators (color change) are available to monitor other decontamination processes, such as vaporized Hydrogen Peroxide, formaldehyde, etc. These indicators will verify exposure/concentration of decontaminating agent(s); however

additional indicators should also be employed to verify the effectiveness of the process.

(2) Tape indicators are adhesive backed paper tape with heat sensitive, chemical indicator markings. Commonly used heat sensitive markings include diagonal stripes (autoclave tape), and/or the word "sterile." These markings only appear when the tape has been exposed to normal autoclave decontamination temperatures. Tape indicators can only be used to verify that the autoclave is reaching normal operating temperatures for decontamination, 121^{o}C (250^{o}F); they have no time factor. Tape indicators alone are not designed or intended to prove that organisms have actually been killed.

Tape indicators should be used on all material decontaminated by autoclaving to show that the material has been processed. A three to four inch length of autoclave tape placed on the outside of the autoclave pan, bag, or individual container is sufficient for visual inspection by the operator.

c. Biological process indicators

Biological indicator systems are designed to demonstrate that a decontamination method is capable of killing microorganisms that have shown resistance to that particular method. For example *Geobacillus stearothermophilus* spores have typically been used to monitor the effectiveness of steam sterilization equipment (autoclaves).

Typical biological indicator systems used to validate steam sterilization consist of a vial with spore strips or a small glass ampoule of growth medium with spores and indicator dye. The manufacturers' instructions for use must be followed when using biological indicators for validations.

d. Physical indicators of process validation should be included in the protocols to validate sterilization processes. These include:

- thermocouples
- maximum registry thermometers
- temperature recorders, and
- time-temperature sensors and software.

e. Quality controls for sterilization process validation include the following:

(1) Each run or process should be traceable back to equipment or process by date, time, operator, and run identifier. This provides verification that each run was performed with equipment that was properly calibrated and maintained.

(2) Data should be maintained to ensure the effective verification of each process.

(3) Working thermometers, thermocouples or other equipment used for calibrations and verifications of decontamination/sterilization process should be calibrated traceable to recognized national or international calibration units against a national or international reference thermometer.

(4) Environmental monitoring of equipment or work areas by swabbing the work areas and testing for the analyte(s) or contaminant of interest will ensure that treatments are effective.

(5) Equipment maintenance records and run logs should be maintained to document maintenance, malfunctions and routine use.

(6) Documentation of run or load information and effectiveness of treatments should be maintained. Records should be retained according to Federal, State and local regulation or requirements, as well as facility or program requirements.

13. USDA PROCEDURES FOR PROTECTING EMPLOYEES FROM BIOHAZARDOUS WASTE

Biohazardous waste operations can be divided into four major categories: generation, packaging, transport, and disposal. Supervisors should perform a Job Hazard Analysis of all new tasks or new biohazard associated with biohazardous waste related operations to assess whether these tasks can be safely executed by new or existing employees. The Job Hazard Analysis should be performed in accordance with guidance provided by OSHA at www.osha.gov, including Bulletin 3071, Job Hazard Analysis. A Job Hazard Analysis identifies high-risk tasks, analyzes the tasks to identify hazards, and determines methods to control the hazards.

Biological Risk Assessment is similar to Job Hazard Analysis, but is focused on biological hazards. Section II, "Biological Risk Assessment," in the 5th edition of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) outlines an approach for conducting a biological risk assessment, which includes:

- identifying agent hazards
- identifying lab procedure hazards
- determining appropriate biosafety levels
- evaluating staff safety proficiency
- reviewing the risk assessment with subject matter experts as appropriate.

The BMBL should be referenced for complete details http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm. The following table is a sample Job Hazard Analysis format that can be used to assess all the risks of a task before initiation.

Job Hazard Analysis Format Table

JOB HAZARD ANALYSIS (JHA)		Date:	New JHA Revised JHA
			Page _____of _____
Task Overview:			
Task Elements:			
Personal Protective Equipment:			
Tools and Equipment:			
OCCUPATIONAL HEALTH CONCERNS			
Chemical Agents:	**Physical Agents:**	**Biological Agents:**	
Activity/Sequence of Job Steps	**Potential Hazards/ Injury sources**	**Safe Action or Procedure**	

a. Biohazardous waste generation. Generation of biohazardous waste may result from a number of activities, including but not limited to animal necropsy, potentially-infectious sample collection, sample preparation, sample analysis, animal waste collection, infectious article collection (e.g., contaminated laundry), infectious waste receptacle collection (e.g., waste sharps containers), spill clean-up, and mechanical equipment operation.

b. Biohazardous waste packaging. Once biohazardous waste is generated, it may need to be packaged or otherwise contained in preparation for disposal. The packaging process may involve a number of activities, including but not limited to moving, containing, packaging and/or decontamination/disinfection of biohazardous waste/waste containers, and cleaning up spills.

(1) If the disposal/treatment unit is located within the containment area, little or no packaging may be required.

(2) If the disposal/treatment unit is located outside the containment area (whether onsite or offsite), the waste will need to be packaged (if small articles) or contained (if liquid or bulk solid materials) in accordance with Section 15 - Security.

(3) The exterior of the package or container will then need to be disinfected prior to removal from the containment area using a disinfectant appropriate for the biological agent(s).

c. Biohazardous waste transport. Whether the biohazardous waste is to be disposed onsite or offsite, the waste will need to be taken to a treatment site. The activities associated with transport include, but are not limited to, collecting biohazardous waste containers and/or articles, placing the waste/waste containers/biohazardous articles in vehicles, driving transport vehicles, pushing hand carts, guiding self-propelled equipment, cleaning up spills, decontaminating items, and unloading waste/waste containers/biohazardous articles into disposal units.

(1) The treatment site may be a nearby autoclave within the work area, and transport may simply involve transporting the leak proof, sharp resistant waste container to the decontamination/treatment unit for processing.

(2) If the disposal unit is located outside the work area or laboratory, whether onsite or offsite, the packaged or contained waste will need to be transported in a secure manner to avoid releasing the biological agent(s) to the environment. Check with federal, state and local requirements applicable to waste packaging or containers for transport.

d. When biohazardous waste is delivered to the disposal site, the waste may be staged temporarily prior to processing.

(1) If the disposal site is offsite, and the waste is transported in relatively small packages or containers which are sealed and disinfected, then temporary staging should pose few risks as long as the staging site is secured.

(2) In some cases, as with necropsy or pathological waste, the material may need to be placed in controlled environments (cold/freezer rooms or refrigerators) prior to decontamination and final disposal.

(3) If the packages or containers are unsealed in the staging area, the area must meet appropriate biocontainment standards according to the risk and planned manipulations, and disposal unit operators must use appropriate practices and protective equipment.

e. Biohazardous waste disposal. Tasks associated with biohazardous waste disposal may include, but are not limited to, moving waste items, loading waste items into treatment units, using heavy equipment or forklifts,

operating disposal units, disinfecting premises and equipment, disposing of treatment by-products and sampling media, and cleaning up spills.

(1) The disposal process will pose few risks if the packages or containers are disposed of with the waste and the seals remain unbroken, assuming the disposal process meets biocontainment standards.

(2) If the packages or containers are unsealed prior to disposal, then the disposal facility must meet appropriate biocontainment standards according to the risk and planned manipulations, and disposal unit operators must use appropriate practices and protective equipment.

f. Physical hazards of biohazardous waste operations:

(1) Potential physical hazards while performing the tasks discussed in the previous section include ergonomic issues associated with heavy lifting and associated body strains; temperature extremes; slips, trips, and falls; contact with sharps; contact with poisonous plants, animals, and/or insects, including animal bites; injury from mechanical equipment; electrical noise hazards; explosions; and compressed gases.

(2) The potential consequences of unmitigated physical hazards include strains, sprains, fractures, loss of limbs, death, lacerations, contusions, electrocution, burns, hearing loss, blindness, hypothermia, heat stress, and skin irritation.

g. Chemical hazards of biohazardous waste operations

(1) Potential chemical hazards during biohazardous waste operations could arise from chemicals used during sample preparation and analysis, decontamination, spill clean-up, equipment operation, and waste treatment.

(2) Chemical exposures can occur by dermal contact, absorption through mucous membranes, injection, inhalation, or ingestion.

(3) The consequences of such exposures vary depending on chemical type and concentration, how it was used, and environmental conditions during its use. Possible effects of chemical exposure include burns, poisoning, acute symptoms, cancer, reproductive effects, mutations, birth defects, death, environmental contamination, fire and explosion.

(4) Chemical suppliers are required to provide Material Safety Data Sheets (MSDS) for the materials they sell, which contain information about how to prevent and treat specific chemical exposures; these should be reviewed prior to using the chemical.

h. Biological hazards of biohazardous waste operations. Biological hazards are likely to be present during biohazardous waste operations. The severity of the hazard depends on the specific agent, the concentration of the agent in the exposure medium, the health of the exposed individual, route of transmission, and many other factors.

(1) Exposure can occur through dermal contact, mucous membrane absorption, injection, inhalation, or ingestion, and can result in infection, intoxication, or transmission of infection to others hosts via fomites or other routes.

(2) Depending on the agent, an infection with a human or zoonotic pathogen, or intoxication by a biological toxin, can cause varying levels of morbidity and mortality.

(3) Released agricultural pathogens which are not transmitted to humans may cause economic, trade and environmental impacts if transmitted to a susceptible host.

i. Radiation (ionizing/non-ionizing) hazards of biohazardous waste operations. Ionizing radiation refers to alpha, beta, gamma, and neutral particles that can cause tissue damage by the ionization of cellular components. Non-ionizing radiation refers to UV, visible light, infrared, and microwaves that cause injury to tissue by thermal or photochemical means. Radiation hazards may be encountered during any phase of biohazardous waste operations if radiation sources are present in the work area, the waste or as part of the decontamination operation.

(1) Exposure to radiation can occur through dermal exposure, inhalation, or ingestion, depending on the type of radiation, the proximity to the source, and the duration of exposure.

(2) Radiation exposure in humans can result in cancer, reproductive effects, burns, and death.

j. Hazard controls for biohazardous waste. Hazard controls can be grouped into three categories: 1) engineering controls; 2) administrative controls; and 3) personal protective equipment (PPE). In general, engineering controls are preferred to administrative controls or PPE because engineering controls are typically mechanized or structural, and therefore less subject to failure due to human error.

A detailed Job Hazard Analysis must be performed by a person experienced in hazard analysis for each biohazardous waste disposal operation task prior to initiating the task in order to select the appropriate hazard controls for each situation.

(1) Engineering Controls include:

(a) designing the facility, equipment, or process to remove the hazard
(b) substituting a hazard with a non or lesser hazard
(c) enclosing the hazard using physical barriers
(d) isolating the hazard with interlocks, machine guards, or other means
(e) removing or redirecting the hazard with local or exhaust ventilation.

(2) Engineering controls that can be used to control the hazards associated with biohazardous waste disposal operations include:

(a) biological safety cabinets;
(b) air locks and directional airflow;
(c) chemical fume hoods;
(d) process containment (glove boxes);
(e) ergonomic equipment;
(f) assistive devices (remote operations); and
(g) protective barriers (enclosed containers, safety centrifuge cup).

A summary of practices, engineering controls and facilities (secondary barriers) may be found in the HHS (CDC/NIH) publication, Biosafety in Microbiology and Biomedical Laboratories (BMBL), 5th edition located at http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm Recommended sections are Section IV, Table 1 "Summary of recommended biosafety levels for infectious agents" and Section V, Table 1 "Summary of recommended biosafety levels for activities in which experimentally or naturally infected vertebrate animals are used.

Additional guidance on engineering controls and facilities may be found in Chapters 7, 9, and 10 of The ARS Facilities Design Standard, Manual 242.1 -ARS.

(3) Administrative controls include:

(a) safe work practices

(b) written standard operating procedures (SOPs),
(c) work permits
(d) exposure time limitations
(e) environmental monitoring
(f) alarms, signs, and warnings
(g) the buddy system
(h) training.

(4) Some specific administrative controls applicable to the hazards identified for biohazardous waste disposal operations include:

(a) Restricted access areas
(b) Security features (door locks, electronic entry devices)
(c) Shower-out facilities and contaminant reduction zones (containment or max containment facilities)
(d) SOPs
(e) Training
(f) Signage

(3) Personal Protective Equipment

Personal Protective Equipment (PPE) is a type of primary barrier worn by the employee, and should only be used if engineering and administrative controls do not provide sufficient protection. PPE includes gloves, lab coats, coveralls, gowns, shoe covers, boots, respirators, face shields, safety glasses, goggles, and hearing protection. The sections referenced within the BMBL 5th edition provided in section 13, j(2)g of this manual provide guidance on PPE appropriate to the various biosafety levels (BSL) and animal biosafety levels (ABSL).

PPE must be carefully selected based on the specific hazards and conditions identified in the Job Hazard Analysis. Comfort should also be considered to ensure maximum compliance with PPE requirements. Below is a list of PPE categories with associated selection considerations which may be applicable to biohazardous waste disposal operations.

(a) Head protection – hard hats should be used in the presence of operational heavy equipment, or if the possibility exists that falling objects could strike and injure employees or visitors at the worksite. Chemical-resistant head coverings are recommended if the potential exists for dermal contact with skin irritants; if so, PPE providing head protection must prevent dermal contact with the hazardous substance.

(b) Eye protection – Appropriate eye protection (safety goggles, glasses, and face shield) must be worn if chemicals, pathogens, dust, particles, or flying objects may be present. The material and type of the eye protection must be carefully selected to ensure resistance to the specific hazards at the worksite.

(c) Hand protection – gloves must be selected based on the expected hazard. Many safety equipment suppliers have charts showing recommended hand protection for various hazards; material should be selected to ensure the gloves will not be compromised by tears or otherwise damaged upon contact with the hazardous substance.

(d) Respiratory protection – the respirator must be selected based on the type and concentration of the breathing hazard, the fit-test results for the wearer, and suitability for the task. Employees wearing respirators must be enrolled in a Respiratory Protection Program in accordance with OSHA requirements.

(e) Foot protection – foot protection must be selected based on the type of hazard. Steel-toed or similar shoes are required where heavy items may fall, and additional protection is required when metal drums are handled. Boot or shoe covers may be required to prevent tracking of contaminants from one area to another, and must be slip resistant and impervious to damage from chemical hazards. In laboratory environments, open toed-shoes (sandals, etc.) shall not be worn by employees or visitors.

(f) Hearing protection – hearing protection must be selected based on the noise level at the worksite and in accordance with OSHA standards.

(g) Skin/clothing protection – protective clothing must be selected based on a risk assessment which considers the type of work to be performed, the nature of the hazards to be encountered, and resistance to break through/penetration of biological hazards or chemical hazards in the worksite. All protective clothing is either disposed of in the work area or decontaminated and laundered by the institution or decontaminated at the facility and laundered by a vendor/contractor who has been made aware of any potential risks. Home laundering of protective clothing is prohibited.

(4) Medical monitoring and other medical issues

Section VII of BMBL, "Occupational Health and Immunoprophylaxis," discusses occupational health/medical monitoring in detail. This section provides a summary of the BMBL information as it pertains to biohazardous waste issues. The BMBL should be consulted for complete guidance on these issues.

As discussed earlier in this section, each job task should undergo a Job Hazard Analysis. The analysis will identify specific risks, some of which may require the services of a occupational health provider. These medical services must comply with OSHA regulations, patient confidentiality laws (i.e. HIPPA), and the Americans with Disabilities Act of 1990. Occupational medical services may be provided through in-house, contracted or community based professionals, as long as the service is readily available and allows timely and appropriate medical evaluation and treatment. The medical provider must be knowledgeable about the nature of potential health risks in the biohazardous waste work environment and have access to expert consultation.

Medical support services for USDA facilities should be evaluated annually. Joint annual reviews of occupational injury and illness reports by healthcare providers and environmental health and safety representatives can facilitate the revision of exposure prevention strategies to minimize the occupational health hazards that cannot be eliminated.

(a) Preplacement Medical Evaluations should be considered for workers who may be exposed to human pathogens, zoonotic pathogens, toxins, hazardous chemicals, physical hazards and ionizing radiation during the course of their work.

(b) Healthcare providers should be cognizant of potential hazards associated with biohazardous waste handling or decontamination operations.

(c) Information from the job hazard analysis and individual history that should be obtained by the occupational health providers should include:
- a description of the requirements for the position;
- potential health hazards present in the work environment;

- worker's previous and ongoing medical problems;
- current medications;
- allergies to medicines, animals, and other environmental proteins;
- prior immunizations; and
- pre-existing medical records, if needed.

(d) Healthcare provider responsibilities include the following:

- identify needed medical services based on job requirements.
- Provide fitness for duty examinations/consultation
- evaluate individual's vulnerability to exposure to potential job-related hazards (e.g.,, immunodeficient workers, workers of reproductive age)
- establish optional serologic documentation that individual workers have pre-existing immunity to specific infections
- evaluate clearance for respirator use, if applicable.

(e) Periodic medical evaluations or medical clearances targeted to job requirements may be warranted for respirator use or for workers with substantial risk of exposure to infectious agents to detect pre-clinical or sub-clinical evidence for an occupationally acquired infection. Refer to previous section for information related to healthcare provider capabilities, information for healthcare provider, and healthcare provider responsibilities.

(f) Medical support for occupational illnesses and injuries should be provided in the following circumstances:

- to any worker experiencing symptoms they suspect may be related to infectious agents, toxins or other biohazards in their work area.
- to workers or visitors to worksites containing biohazards who experience unexplained illness

(g) Healthcare providers must possess the following attributes:

- a working understanding of the biohazards present in the workplace
- an ability to identify subtle evidence of infection and atypical presentations
- an ability to maintain close working relationship with employee's research or clinical program
- a willingness to interact closely with employee and the employee's supervisor to facilitate adequate medical management and recordkeeping.

(h) Employees are responsible for reporting all occupational injuries, including exposures to biological hazards, to the appropriate supervisor/line management and medical support services providers

(i) Employers are responsible for the following:

- Preparing emergency response plan in advance (see Section 13 (j)(6) "Emergency Response" for additional information)
- Training employees on biohazard response plans
- Providing all necessary tools and equipment to execute biohazard response plans
- Providing wound-cleansing facilities and first aid supplies near work area
- Eliminating barriers to medical evaluation and treatment
- Maintaining SOPs near work areas that include printed summaries of recommended medical responses to specific exposures that can be used to guide immediate responses in the work place and for the reference of the facility treating the injured worker
- Consider collecting and storing a serum specimen prior to the initiation of work when occupational exposure to human or zoonotic pathogens is a risk. The sample can be used to establish baseline sero-reactivity, should additional blood samples be collected for serological testing subsequent to a recognized or suspected exposure.
- Providing applicable workers' compensation claim form(s) with instructions for completion
- Obtaining a description of accidents or incidents,
- Confirming the circumstances of injuries or exposures
- Distributing report to all other relevant parties, such as the safety professional.
- Evaluating initial job hazard analysis/risk assessments and modify procedures if necessary to prevent recurrence of the incident.

(j) Healthcare provider(s) are responsible for:

1 providing descriptions of the injury, including:

- identification of potential infectious agent or biohazard.

- mechanism and route of exposure (percutaneous, splash to mucous membranes or skin, aerosol, etc.)
- the time and place of the incident
- personal protective equipment used at the time of the injury
- prior first aid provided (e.g.,, nature and duration of cleaning and other aid, time that lapsed from exposure to treatment)
- aspects of the worker's personal medical history relevant to risk of infection or complications from treatment

2 Repeating first aid if the initial adequacy is in question

3 Using appropriate barrier precautions to avoid exposure to infectious agents and toxins

4 Administering post-exposure prophylaxis, if applicable

5 Consulting with subject matter experts if needed

6 carefully explaining the clinical risk assessment and treatment decision process

7 Addressing the worker's questions

8 Providing relevant, preprinted educational materials if available

9 Providing prompt treatment

10 Providing treatment plan for employee to follow

11 Performing post-exposure serologic testing if appropriate, and ensuring tests are administered at appropriate time intervals after exposure

12 Compare post-exposure serologic testing with baseline and over time, as appropriate.

(5) Vaccines

Section VII of BMBL, "Occupational Health and Immunoprophylaxis," discusses immunoprophylaxis (vaccines) in detail. This section summarizes information from the BMBL as it applies to biohazardous waste issues.

(a) This section applies to employees who are occupationally exposed to infectious agents

(b) Employers have the following responsibilities for ensuring their employees are properly vaccinated:

1 In accordance with the Advisory Committee on Immunization Practices, provide commercial vaccines on a voluntary basis to workers occupationally exposed to infectious agents (recommendations found at www.cdc.gov).

2 Provide current, applicable vaccine information statements whenever a vaccine is administered.

3 Evaluate each worker's immunization history for completeness and currency at the time of employment and re-evaluate when the individual is assigned job responsibilities with a new biohazard.

4 Consider using vaccines or immune serum preparations that are investigational or as an off-label use only when occupational exposure to highly pathogenic agents is possible and no commercial vaccine is available; this must be accompanied by adequate informed consent and in accordance with Investigational New Drug protocols.

(6) Emergency Response

In order to ensure adequate post-exposure emergency response, an emergency response plan must be developed in advance of an emergency. The emergency response plan should include the following exposure-specific information:

- Appropriate first aid
- Potential post-exposure prophylaxis options, applicability, and limitations
- Recommended diagnostic tests
- Sources of expert medical evaluation

- Procedures for exposures that occur outside of regular work hours

These protocols should be distributed to potential healthcare providers (e.g., local hospital emergency departments). In some cases, the protocols should be reviewed with state and community public health departments.

(7) Training

(a) Training may take the form of individual instruction, group seminars, audiovisual presentations, handout material, or any other format that communicates safe handling and hazard awareness to the employee.

(b) Prospective workers should be educated about the biohazards to which they may be occupationally exposed, the types of exposures that place their health at risk, the nature and significance of such risks, the appropriate first aid and follow up for potential exposures, and how to report exposures or suspected exposures.

(c) This information should be reinforced annually, as well as at the time of any significant change in job responsibility and following recognized and suspected exposures.

(d) Emergency incident training and drills should be provided on a regular basis for all affected employees. The training should include the contents and use of the Emergency Response Plan.

(e) Training must be provided at the time of an employee's initial assignment to a work area where known biohazards are present, and prior to an assignment involving new exposure situations. Employees must receive periodic refresher information and training as new information becomes available.

(f) All training must be documented.

14. ENVIRONMENTAL DISPOSAL CONSIDERATIONS FOR BIOHAZARDOUS WASTE

The purpose of this section is to provide information on environmental regulatory issues as they relate to the disposal of biohazardous waste. Many different activities within USDA generate biohazardous waste. Some of the components in

these wastes can be detrimental to human health, livestock (animals), plants and/or the environment if not properly managed.

It is USDA policy to follow all Federal, State, or local laws and regulations regarding biohazardous waste. If standards vary, the more stringent requirement should apply.

a. Responsibilities

(1) Laboratory managers and supervisors are responsible for proper biohazardous waste disposal procedures and for training employees in these procedures.

(2) All laboratory employees are responsible for following proper biohazardous waste disposal procedures.

(3) The EPA does not generally regulate biohazardous waste. Exceptions include Clean Air Act regulations for medical waste incinerators and chemical treatment systems, biotechnology products such as bioremediation microorganisms regulated under the Toxic Substance Control Act, and biopesticides regulated under FIFRA.

(4) Although there are no Federal EPA requirements for the management and disposal of biohazardous waste, most States do regulate biohazardous waste streams. Additionally, States with EPA approved programs have authority over medical waste incinerators, chemical treatment systems, etc. There are a number of waste categories (i.e., sharps, cultures and stocks, animal wastes, etc.) and treatment, destruction, and disposal methods vary for each.

(a) The State's Department of Natural Resources Office should be contacted to obtain current requirements prior to making any decision on the manner in which biohazardous waste will be disposed.

(b) Prior to generating waste, the waste generator must determine if a feasible disposal path exists for the proposed waste stream. No wastes should be generated until a disposal path has been identified and developed.

(c) Biohazardous waste streams containing a chemical and/or radiological component are considered multiple-hazard wastes. Such wastes must be treated to eliminate the biohazard prior to disposal. After treatment, the waste

must be managed pursuant to the regulations that apply to its non-biological component. For example, a waste containing a biohazardous component and a Resource Conservation and Recovery Act (RCRA) regulated constituent must be managed as a RCRA hazardous waste.

(5) Local Authorities: Biohazardous waste that has been rendered noninfectious may qualify for disposal at the local landfill or Publicly Owned Treatment Works. Waste generators should contact local authorities to discuss and seek approval for this action. All verbal approvals obtained from local authorities should be documented in a follow up letter that details the types of wastes to be disposed, processes that will be utilized to render the material noninfectious, quality control practices, etc.

b. Waste Minimization

(1) Pollution prevention and waste minimization procedures should be incorporated wherever feasible. An effective biohazardous waste program protects workers and the environment and can result in cost savings from waste reduction or prevention. Personnel should diligently investigate and pursue opportunities to use materials with a lower biohazard level or alternative procedures to reduce the material handling and disposal requirements. These practices will reduce biohazardous waste steams and ensure that biohazardous wastes are handled and treated appropriately.

(2) A primary means of reducing biohazardous waste is to ensure that it is separated from general waste, which should occur at the point of generation.

(a) Biohazardous waste should be placed directly into "biological hazard" labeled or color coded containers or plastic bags clearly identifiable and distinguishable from the general solid waste stream.

(b) Temporary markings or a second container or bag should be used if the waste is to be decontaminated prior to disposal.

c. Additional Information

There are many sources of information available regarding biohazardous waste disposal, including Federal and State guidelines regarding the disposal of biohazardous waste, which can be found at www.epa.gov/epaoswer/other/medical/#two

15. SECURITY PARAMETERS FOR BIOHAZARDOUS WASTE

This section sets policy and procedure to ensure appropriate levels of protection for securing and safeguarding biohazardous waste during its generation and packaging, transport (either on or off-site), storage (either on or off-site) and scheduled destruction. This section also details protection levels required in accordance with potential consequences, and ensures effective security planning and coordination between the government and local authorities in the proper disposal of biohazardous waste. This section does not cover incidents resulting from declared agricultural emergencies.

a. Disposal sites

The design of disposal sites varies, depending on the type of biohazardous waste, so it is necessary to refer to all relevant Federal, State, local, and facility regulations to ensure regulatory compliance when selecting a site for biohazardous waste disposal.

(1) On-site disposal area, or location: A designated area within the property of a given USDA facility properly designed to store, handle and dispose of biohazardous waste.

(2) Off-site disposal area, or location: A commercial facility that is properly permitted to receive, store, handle, and dispose of biohazardous waste.

b. Common Carrier and Transportation Vehicles

Biohazardous waste should be transported in closed leak-proof trucks or dumpsters. Secondary containment may be needed as well, depending on the type of biohazardous waste being transported.

(1) Vehicles used for transporting Category A and Category B biohazardous waste (see Definitions) should be in good mechanical condition and strong enough to carry the load without difficulty. If vehicles do not have a closed body, the body should be covered with a tarpaulin. Vehicle selection should include, but not be limited to:

- Transporting infected carcasses.
- Transporting infected live animals.
- Transporting clinical and diagnostic cultures.

(2) Vehicles should be properly marked with the appropriate UN identifier. Additional labeling and placards as noted below should be in accordance with 49 CFR 172.323 and 49 CFR 172.432, if the

vehicle will travel on public access roads or otherwise enter commerce.

- Biohazard- See Figure 1
- Infectious Substance- See Figure 2

(3) Unless provided by the common carrier, the shipper should provide all required shipping labels and placards in accordance with 49 CFR 172.505- Providing and affixing placards: Highway.

(4) Common carrier drivers should have a valid state driver's license appropriate for the type of vehicle commissioned to transport biohazardous waste, and/or a Commercial Driver License (CDL) for operating vehicles that require a CDL.

(5) Common carrier should be licensed or certified/permitted to transport biohazardous waste.

c. Additional common carrier responsibilities

(1) The common carrier is responsible and liable for the safe transport and accountability of the biohazardous waste once the carrier has accepted the biohazardous waste from the shipper of record.

(2) Acceptance includes the signature receipt of the hazardous waste manifest *[49 CFR 172, Subpart C, §172.205(c)(2)]*.

(3) Unless approved by USDA, the common carrier of record should not transfer the biohazardous waste to another common carrier for transport.

(4) Upon delivery to the designated receiving facility, the receiving facility becomes responsible for disposing of the biohazardous waste accepted from the common carrier of record. Note that USDA is still liable for the waste from cradle to grave, so it is prudent for USDA to confirm that the receiving facility is disposing of USDA's biohazardous waste in compliance with relevant laws and regulations.

(5) Acceptance includes the signature receipt of the hazardous waste manifest *[49 CFR 172, Subpart C, §172.205(d)(2)]*.

(6) Unless approved by USDA, the receiving facility of record should not transfer the biohazardous waste to another facility for disposal.

d. Additional security precautions during transport

(1) In compliance with Department of Transportation (DOT) regulations, the USDA location and the transporter of the biohazardous waste (if different entity than USDA location) must develop and implement a security plan if the following types or quantities of hazardous materials will be transported *[49 CFR 172, Subpart I, §172.800]*:

(a) hazardous material in an amount that must be placarded in accordance with the Hazardous Materials Regulations;

(b) hazardous material in a bulk packaging having a capacity equal to or greater than 13,248 L (3,500 gallons) for liquids or gases or more than 13.24 cubic meters (468 cubic feet) for solids; or

(c) select agents or toxins regulated by the CDC under 42 CFR Part 73, or USDA under 9 CFR Part 121 *[49 CFR Part 172, Subpart I, §172.800(6)]*. USDA facilities generating biohazardous or medical waste containing select agents and toxins shall need to develop a transportation security facility plan.

(2) At a minimum, a security plan must include provisions for the following elements *[49 CFR Part 172, Subpart I, §172.802]*:

(a) Personnel security;
(b) Preventing unauthorized access; and
(c) En-route security

DOT's pamphlet, "Hazardous Materials Transportation Enhanced Security Requirements, DHM50-0030-0903," has additional information on this topic.

The security plan must be in writing and must be retained for as long as it remains in effect. The security plan must be revised as necessary to reflect changing circumstances. When applicable, transportation security plans developed under Sections 15(d)(1)(c) and 15(g) must be submitted to the USDA Animal and Plant Health Inspection Service or CDC Select Agent Program(s) for approval.

(3) A means of communication should be established between the transport driver, and the originating and receiving stations, including radios, cell phones, or similar devices. The transport driver and the originating and receiving stations will be provided with all relevant contact numbers. If transportation of the

biohazardous waste to the receiving station exceeds one (1) day, or in the event of an unplanned layover exceeding one (1) day, the transport driver should make contact with the originating station and receiving station at least every eight (8) hours.

(4) Unless pre-arranged, stops and overnight layovers should not be permitted. In the event of an unanticipated layover (i.e., vehicle breakdown, weather, traffic incident, etc.), the transporting vehicle should be secured to prevent unwanted intrusions. The driver should report any delay to the point of contact at the originating station and receiving station, and should remain with the vehicle until the vehicle is transported to a safe location and properly secured. Local law enforcement should be advised of the nature of the cargo that is being temporarily secured.

e. USDA On-site Storage and Disposal Security Requirements

All transportation of biohazardous waste generated at USDA facilities must be conducted in compliance with all Federal, State, local, and facility regulations, including all applicable DOT regulations. Each laboratory must obtain and comply with the regulations for its location. The importation or interstate movement of infested or potentially infested plant material requires an APHIS PPQ 526 Plant Pest Permit. The permit conditions will include information about proper packaging, transport, and sterilization procedures.

(1) Movement and handling of biohazardous waste should be kept to a minimum, and disposal preparation should be done as outlined in Sections 10, 11 and 12. The use of mechanical loading devices which may rupture packaged wastes should be avoided.

(2) All bags containing biohazardous waste should be properly labeled in accordance with Section 15(b)(2).

(3) Animal bedding, manure and/or mixture should be bagged in bio-degradable material in order to establish a numerical account for manifesting.

(4) A transfer/chain-of-custody form (see Figure 3 for sample document) should be prepared to document the biohazardous waste product that is being disposed. Laboratory should maintain a logbook to record chain-of-custody events.

(5) An accurate, current inventory for each biohazardous product must be maintained if held in short-term or long-term storage.

(6) USDA worksites and locations must establish a designated storage area for biohazardous waste that is not disposed of immediately. Such storage areas must be adequately secured to prevent theft or release of biohazardous waste material. Packaging integrity, storage temperature, storage duration, and storage location should be evaluated to ensure that the delay in treatment will not create potentially hazardous conditions.

(a) Temporary storage shelters should have secondary containment provisions for liquid waste or waste susceptible to leakage, such as concrete curbing or similar impervious barriers to prevent release to the environment.

(b) The packaging should deter rodents and vermin, and should be strong enough to block or mitigate the emission of any unpleasant odors that might develop.

(c) Storage site location and security should also be assessed to ensure they meet established requirements for biohazardous waste.

(d) Biohazardous waste held in storage for more that one (1) day should be physically checked daily, and verified against the inventory log, for each day in storage.

(e) The locking devices will also be checked daily.

(f) Long-term and short-term storage areas should be properly identified with applicable labels similar to the requirements of OSHA Subpart Z Section 1910.1030(g)-Communication of hazards to employees.

(7) Prior to destruction, an inventory should be conducted to ensure that all biohazardous waste has been accounted for.

(8) USDA facilities that have remote disposal sites (i.e., incinerators) within the facility property should secure and transport biohazardous waste in properly maintained vehicles.

(9) USDA laboratories utilizing on-site disposal areas should have an emergency response plan in place to appropriately address incidents involving theft, loss, or release of biohazardous waste scheduled for destruction.

(10) All documentation records related to the transportation and disposal of biohazardous waste at USDA on-site locations Records

must be retired to FRC 5 years after completion of shipment to an offsite disposal/treatment facility. Agencies should consider maintaining infectious medical waste records for "longer periods of time, such as 15 years with subsequent transfer to NARA for storage as permanent records (e.g. Waste containing environmentally stable agents or that have a hazardous waste component and could be a continuing concern in the event that the waste is improperly disposed of by the receiving site). Generators should also review State and local regulations to ensure they do not have more stringent requirements.

f. Non-USDA Off-site Storage and Disposal Security Requirements

All transportation of biohazardous waste generated at USDA facilities must be conducted in compliance with all Federal, State, local, and facility regulations, including all applicable USDOT regulations. Each laboratory must obtain and comply with the regulations for its location.

(1) Prior to any interstate transport of biohazardous waste to an off-site disposal location, the facility/Location Environmental or Biosafety Specialist/Officer should notify and coordinate with state and local transportation authorities to verify any transport restrictions and obtain any necessary permit requirements. Such transport should have a pre-established primary route and secondary route in the event of inclement weather or traffic incidents.

(2) Disposal site should be a properly licensed/certified organization and permitted to handle the type of biohazardous waste being transported.

(3) Disposal preparation should be done as outlined in Sections 9 through 11 of this document.

(4) All bags containing biohazardous waste should be properly labeled in accordance with Section 15(b)(2). In addition, animal bedding, manure and/or mixture should be bagged in bio-degradable material in order to establish a numerical account for manifesting.

(5) All biohazardous waste should be placed into appropriate USDOT rigid or semi-rigid containers before transport off-site.

(6) A transfer/chain-of-custody form (see Figure 3 for sample document) should be prepared to document the biohazardous waste product that is being disposed. The laboratory should maintain a logbook to record chain-of-custody events.

(7) A shipment manifest should be prepared for animal carcasses and/or live animals scheduled for disposal. Manifests should include type of biohazardous waste, quantity (quantity should not be by volume or weight), method of disposal (see Sections 9, 10, and 11), date of departure/arrival, and signature of authorizing USDA agent. Manifests should accompany the biohazardous waste. When applicable, shipment manifests should be in accordance with 49 CFR 172.205 "Hazardous waste manifest".

(8) In the event that the disposal cannot be performed at the scheduled time and there is a delay of more than one (1) day, the off-site disposal facility must provide a secured location for transport vehicles, freezers, or other means of storage until the disposal is complete.

(a) Such storage areas, whether a truck yard, room, trailer, freezer, or refrigerator, must have appropriate locking devices to secure the material.

(b) Biohazardous waste held in storage for more than one (1) day should be physically checked daily, and verified against the inventory log or shipping manifest for each day in storage. In addition, the locking devices should be checked daily.

(c) Long-term and short-term storage areas should be properly identified with applicable labels similar to the requirements of OSHA Subpart Z Section 1910.1030(g)-Communication of hazards to employees.

(d) If treatment cannot be accomplished on the day the waste is generated, packaging integrity, storage temperature, storage duration, and storage location should be evaluated to ensure that the delay in treatment will not create potentially hazardous conditions.

1 Temporary storage shelters should have secondary containment provisions for liquid waste or waste susceptible to leakage, such as concrete curbing or similar impervious barriers to prevent release to the environment.

2 The packaging should deter rodents and vermin, and should be strong enough to block or mitigate the emission of any unpleasant odors that might develop.

3 Storage site location and security should also be assessed to ensure they meet established requirements for biohazardous waste.

(9) Prior to destruction, an inventory should be conducted to ensure that all biohazardous wastes have been accounted for.

(10) A USDA agent should witness each disposal event to certify that it was completed in compliance with all relevant agreements, regulations, etc.

(11) All documentation records related to the transportation and disposal of biohazardous waste utilizing USDA off-site disposal locations should be prepared and retained in accordance with DOT 49 CFR 172, Subpart C- Shipping Paper. Records must be retired to FRC 5 years after completion of shipment to an offsite disposal/treatment facility. Agencies should consider maintaining infectious medical waste records for "longer periods of time, such as 15 years with subsequent transfer to NARA for storage as permanent records (e.g. Waste containing environmentally stable agents or that have a hazardous waste component and could be a continuing concern in the event that the waste is improperly disposed of by the receiving site). Generators should also review State and local regulations to ensure they do not have more stringent requirements.

g. USDA Facilities that Possess, Use, and Transfer Select Agents and Toxins

The following security requirements apply to those USDA facilities that generate biological waste deriving from select agents and toxins whether for on-site or off-site disposal.

(1) Security of select agents and toxins shall comply with 7 CFR Part 331.11, 9 CFR Part 121.11 and 42 CFR Part 73.11.

(2) Storage, transfer, transportation, and disposal of select agents and toxins shall comply with 7 CFR Part 331.11/16/17; 9 CFR Part 121.11/16/17; and 42 CFR Part 73.11/16/17. Storage, transfer, and transportation of select agents and toxins to an off-site unregistered entity shall require prior approval of the Agriculture Select Agent Program (telephone number (301) 734-5960).

(3) Emergency response plans for biohazardous waste involving select agents and toxins shall comply with 7 CFR 331.14, 9 CFR 121.14 or 42 CFR 73.14.

(4) All documentation related to select agents and toxins shall comply with 7 CFR 331.17(c), 9 CFR 121.17(c), and 42 CFR 73.17(c).

h. Emergency Response Plans

To ensure the safety of the general public and the environment the shipper should develop emergency response plans.

(1) USDA utilizing on-site disposal areas should have in-place an emergency response plan to address incidents involving theft, loss or release of a biohazardous waste scheduled for destruction.

(2) USDA laboratories utilizing off-site disposal areas requiring the transportation of biohazardous waste scheduled for destruction via common carrier should provide emergency response information in accordance with 49 CFR 172, Subpart G- Emergency Response Information. The emergency response information should be coordinated with the transportation security plan as outlined in 49 CFR 171, Subpart I-Security Plans.

FIGURE 1. BIOHAZARD LABEL [49 CFR 172.323]

FIGURE 2. INFECTIOUS SUBSTANCE LABEL [49 CFR 172.432]

FIGURE 3. SAMPLE TRANSFER AND CHAIN OF CUSTODY FORM

Section 1

USDA Facility	Instructions: • All external (inter-entity) transfers are required to have a Transfer/Chain of Custody Form completed prior to movement and filed in the facility logbook. Receiving organization is required to sign and FAX/return 1 copy to USDA once biohazardous waste is received and disposed. • All internal (intra-entity) transfers are required to have a Transfer/Chain of Custody Form completed and filed in the facility logbook. • Transfer/Chain of Custody Form is required to be signed by the Responsible Official (RO) and Principal Investigator (PI).								
Biohazardous [infectious substances] Waste _____ Signature of Responsible Official _____ Signature of Principal Investigator	Transfer		Received		Type of Transfer		Location Code ST- Storage LS- Lab to Storage SFD- Storage to Facility Disposal SOD- Storage to Off-site Disposal O- Other (explain)	Number of Primary Containers/Animals Use for internal and external transfers. ********** If transfer exceeds 8 actions use second form.	Remarks
	Date	Time	Date	Time	Internal☑	External☑			
1)						☐		☐☐☐☐☐	
2)						☐		☐☐☐☐☐	
3)						☐		☐☐☐☐☐	
4)						☐		☐☐☐☐☐	
5)						☐		☐☐☐☐☐	
6)						☐		☐☐☐☐☐	
7)						☐		☐☐☐☐☐	
8)						☐		☐☐☐☐☐	

Section 2: External (inter-entity) Shipping and Receiving Information (Check ☑ appropriate box)

Authorization/Ship to:		Authorization/Ship to: ☐	Received From: ☐	
		Organization: RO Signature: _____ Date:	Organization: Signature: _____ Date:	

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