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Ebola Preparedness (REP) Tool for Ebola Treatment Centers and Assessment Hospitals

THIS DRAFT TOOL MAY BE USED BY ELC APPLICANTS TO GUIDE DEVELOPMENT OF THEIR APPLICATION FOR FUNDING OPPORTUNITY “[DOMESTIC EBOLA SUPPLEMENT TO EPIDEMIOLOGY AND LABORATORY CAPACITY FOR INFECTIOUS DISEASES \(ELC\) – BUILDING AND STRENGTHENING EPIDEMIOLOGY, LABORATORY AND HEALTH INFORMATION SYSTEMS CAPACITY IN STATE AND LOCAL HEALTH DEPARTMENTS.](#)”

HEALTH DEPARTMENTS SHOULD CONSULT WITH CDC BEFORE USING THE TOOL TO CONDUCT FACILITY ASSESSMENTS.

Who this is for: Facilities that have been designated as or that are under consideration for designation as [Ebola assessment hospitals](#) and [Ebola treatment centers](#), and state and local health departments

What this is for: Tool to assess whether a designated hospital has appropriate infection prevention policies, procedures, and supplies in place to allow healthcare personnel (HCP) to provide safe care during the assessment and treatment of patients with suspected or confirmed Ebola virus disease (Ebola). The content included in the tool applies to both Ebola assessment hospitals and Ebola treatment centers, except where otherwise noted.

All U.S. acute healthcare facilities have an important role in preparing to identify, isolate, and evaluate patients with possible Ebola and promptly informing public health authorities. However, the roles and the preparations required to perform these tasks will differ by facility. Acute healthcare facilities can serve one of three roles: as a frontline healthcare facility, Ebola assessment hospital, or Ebola treatment center. In some cases, hospitals may serve simultaneously as an Ebola assessment hospital and an Ebola treatment center. Ebola assessment hospitals are facilities prepared to receive and isolate a patient with possible Ebola and care for the patient until a diagnosis of Ebola can be confirmed or ruled out and until discharge or transfer is completed. Ebola treatment centers are facilities that plan to care for and manage a patient with confirmed Ebola for the duration of the patient’s illness.

See <http://www.cdc.gov/vhf/ebola/hcp/us-hospital-preparedness.html> for more information including an outline of minimum recommended capabilities for assessment hospitals and treatment centers.

Summary of key differences between assessment hospitals and treatment centers:

- Protocol for Interfacility Transfer (Section A, Item 1)
- Staffing of Patient Care Team (Section B, Item 6)
- PPE Supply (Section E, Item 11)
- Management of Waste (Section I, Item 2)

This tool is designed to be used both by hospitals as a self-assessment tool for Ebola preparedness and by CDC’s Rapid Ebola Preparedness (REP) Teams and/or health departments to assist and support hospitals in their preparedness efforts.

How this is related to other guidance documents/purpose: This document is based on existing infection prevention [guidance](#) for U.S. Healthcare Settings in the evaluation and management of patients with suspected or confirmed Ebola. Because this guidance continues to evolve, hospitals and health departments are urged to consult the full guidance documents referenced within the tool to ensure they are following the most up-to-date recommendations.

Domains for Preparedness

- A. Pre-Hospital Transport Plans, Emergency Medical Services (EMS), Emergency Department (ED) Preparedness**
- B. Staffing of Patient Care Team**
- C. Patient Transport from Point(s) of Entry to Designated Ebola Treatment Area**
- D. Patient Placement**
- E. Personal Protective Equipment and Procedures for Donning and Doffing**
- F. Monitoring Healthcare Personnel and Managing Exposures**
- G. Laboratory Safety**
- H. Environmental Infection Control and Equipment Reprocessing**
- I. Management of Waste**
- J. Communications**
- K. Management of the Deceased**
- L. Special Populations**

A. Pre-Hospital Transport Plans, Emergency Medical Services (EMS), Emergency Department (ED) Preparedness

Refer to:

Emergency Department Evaluation and Management for Patients Who Present with Possible Ebola Virus Disease, at: <http://www.cdc.gov/vhf/ebola/hcp/ed-management-patients-possible-ebola.html>

Interim Guidance for Emergency Medical Services (EMS) Systems and 9-1-1 Public Safety Answering Points (PSAPs) for Management of Patient with Known or Suspected Ebola Virus Disease in the United States at:

<http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-emergency-medical-services-systems-911-public-safety-answering-points-management-patients-known-suspected-united-states.html>

EMS and initial transport into the facility

Elements to be assessed	Notes
<p>1. EMS provider(s) that will transport persons with suspected or confirmed Ebola to the facility for further evaluation have been identified.</p> <p>For Assessment hospitals, a protocol, developed in consultation with local and state EMS and public health officials, is in place to address patient transfer to a designated Ebola treatment center.</p>	
<p>2. EMS providers have protocols for:</p> <ul style="list-style-type: none"> • Safe transport of persons with suspected or confirmed Ebola, including PPE used by EMS personnel • Training of EMS providers in correct use of PPE and documentation of competency • Advance notification of the hospital and public health authorities • Cleaning and disinfection of the ambulance and potentially contaminated equipment • Disposal of used PPE and waste generated during transport 	
<p>3. The hospital has designated:</p> <ul style="list-style-type: none"> • Hospital personnel to meet the EMS provider on arrival to the hospital to: <ul style="list-style-type: none"> ○ Assume care of the patient ○ Assist EMS personnel with doffing PPE, if needed • Area where EMS personnel can doff their PPE • Area where EMS personnel can park their ambulance to perform decontamination 	

<p>4. Entry point(s) for EMS are:</p> <ul style="list-style-type: none"> • Identified and have been communicated with EMS • Secured and free of any other patient or personnel traffic (e.g., using security escort) during patient entry and transport 	
ED Guidance for triage and isolation/initial management of patients under investigation	
Elements to be assessed	Notes
<p>5. ED triage personnel are trained in screening patients for Ebola by asking:</p> <ul style="list-style-type: none"> • Whether the patient has resided in or traveled to a country with widespread Ebola virus transmission or with cases in urban settings with uncertain control measures or had contact with an individual with confirmed Ebola within the previous 21 days • Whether patients with this history have experienced signs or symptoms compatible with Ebola 	
<p>6. ED personnel are trained in questioning EMS providers about possible risk factors for Ebola in patients being transported via ambulance to the hospital.</p>	
<p>7. Protocols are in place to immediately isolate patients who report a relevant exposure history and signs or symptoms consistent with Ebola.</p> <ul style="list-style-type: none"> • Patients are placed in a private room with in-room dedicated bathroom (or covered, bedside commode) away from other patient care areas. • Separate areas for donning and doffing of PPE are designated in proximity to the patient room • Hospital infection control program (and other appropriate staff) and health department are immediately notified 	
<p>8. Only essential HCP who have had appropriate training and documented competency in infection control, including PPE for Ebola, and have a designated role provide patient care in the ED.</p>	
<p>9. A log is maintained of all personnel who enter any potentially contaminated space in the Ebola treatment/assessment area and/or handle potentially infectious materials and includes sufficient information to assign exposure categories (e.g., high-risk, some risk, low-risk)¹ in order to apply movement and monitoring guidance to HCP (See Section F)</p>	

<p>10. All HCP who have contact with a patient while the patient is under investigation for Ebola use appropriate PPE based on the patient's clinical status.</p> <ul style="list-style-type: none"> • If the patient is exhibiting obvious bleeding, vomiting, copious diarrhea or a clinical condition that warrants invasive or aerosol-generating procedures (e.g., intubation, suctioning, active resuscitation), HCP wear PPE designated for the care of hospitalized patients with confirmed Ebola as outlined in Guidance on Personal Protective Equipment to be used by Healthcare Workers during Management of Patients with Ebola Virus Disease in U.S. Hospitals, including Procedures for Putting on (Donning) and Removing (Doffing). • If signs and symptoms such as bleeding, vomiting, diarrhea or conditions warranting invasive or aerosol-generating procedures are not present and the patient is clinically stable, HCP at a minimum wear PPE as outlined in Identify, Isolate, Inform: Emergency Department Evaluation and Management for Patients under Investigation (PUIs) for Ebola Virus Disease (EVD). 	
<p>11. All equipment used in the care of patients suspected to have Ebola is not used for the care of other patients until appropriate decontamination is performed.</p>	
<p>12. The hospital has protocols addressing:</p> <ul style="list-style-type: none"> • Collection and testing of laboratory specimens drawn in the ED for both Ebola and alternative diagnoses to support timely evaluation and medical care of the patient. • Environmental infection control of the treatment area in the ED • Management of waste generated in the ED 	

B. Staffing of Patient Care Team	
Elements to be assessed	Notes
1. A trained Patient Care Team has been pre-identified for management of the patient ² . Consider cross-training registered nurses or physicians to minimize number of staff with direct patient contact (e.g., phlebotomy, cleaning).	
2. Team members receive job-specific training and demonstrate competency on infection control practices, policies, and procedures for caring for a patient with Ebola (see Section E).	
3. Qualified, trained staff members are identified for obtaining, handling, processing and testing of specimens from the Ebola patient.	
4. Hospital has identified additional team members ³ involved in consultation but who should avoid entering the patient room (e.g., audio/video conferencing may be used to communicate with patients or team members in room).	
5. A schedule of staffing for patient care is created in advance of a patient’s arrival so that individuals on call are trained and have demonstrated competency, and can be quickly assembled when needed.	
6. Staffing schedules address the following considerations: <ul style="list-style-type: none"> • For Ebola assessment hospitals, staffing plans include a roster to manage up to 96 consecutive hours of clinical care. • For Ebola treatment hospitals, staffing plans include a roster to manage at least several weeks of clinical care. • Plans to minimize number of personnel in room • Adequate time to rest between shifts • On-call schedule for consultants to the patient care team 24 hrs/7 days/week • Maximum duration HCP can be providing direct patient care (e.g., 2–4 hours continuously) and maximum duration of an Ebola patient care unit shift (e.g., 8–12 hours) 	
7. Policies are in place for HCP movement, monitoring, and non-Ebola patient care responsibilities while serving on an Ebola patient care unit (see Section F).	

<p>8. Worker safety programs and policies are in place.</p> <ul style="list-style-type: none">• The hospital is in compliance with all federal and state occupational safety and health regulations applicable to reducing employee exposure to Ebola.• Hospital has designated individuals as site managers⁴ responsible for overseeing the implementation of precautions for healthcare workers and patient safety.• At least one manager is on-site at all times in the Ebola treatment unit when a patient is present.	
<p>9. A plan for ongoing support and evaluation of team members is in place, including process for HCP to provide feedback to leadership.</p>	
<p>10. Protocols are in place so that only direct patient care staff, wearing appropriate PPE, delivers meals to patients.</p>	

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C. Patient Transport from Point(s) of Entry to Designated Ebola Treatment or Assessment Area

Interim Guidance for Environmental Infection control in Hospitals for Ebola Virus:

<http://www.cdc.gov/vhf/ebola/hcp/environmental-infection-control-in-hospitals.html>

Elements to be assessed	Notes
1. Protocols are in place to transport the suspected or confirmed Ebola patient safely from the hospital point of entry or Emergency Department, via a pre-identified route that is secured and free of any other patient or personnel traffic (e.g., using security escort) during patient transport to pre-identified room	
2. Protocols are in place for transport personnel to wear appropriate personal protective equipment (PPE) during transport of Ebola patients. Such personnel must receive training and demonstrate competency on proper procedures for donning and doffing of PPE.	
3. Protocols are in place for patient to be transported in appropriate protective equipment to prevent leakage or spillage of body fluids, if needed.	
4. Protocols are in place to manage blood or body fluid spills during transport.	
5. Protocols are in place to manage cleaning and disinfection of reusable transportation equipment and potentially contaminated areas of the transportation route.	
6. Once patient is in the designated patient room/care area further movement of the patient within the hospital is limited.	
7. Protocols are in place for safe emergency evacuation of patient and staff members designated to work with patient, minimizing any possible exposures.	

D.Patient Placement

Elements to be assessed	Notes
<p>1. A private room with private bathroom (or covered bedside commode) and critical care capacity has been identified to accommodate a possible or confirmed Ebola patient. If feasible:</p> <ul style="list-style-type: none"> Negative pressure airborne infection isolation room (AIIR)⁵. 	
<p>2. Ebola patient room is physically separated from other patient care areas. Ideally, the room or unit is sealed or closed off to personnel not engaged as part of Ebola patient management team.</p>	
<p>3. A log is maintained of all personnel who enter any potentially contaminated space in the Ebola treatment/assessment area and/or handle potentially infectious materials and includes sufficient information to assign exposure categories (e.g., high-risk, some risk, low-risk)^{Error! Bookmark not defined.} in order to apply movement and monitoring guidance (See Section F)</p>	
<p>4. Ebola patient room incorporates a method of remote communication (e.g., intercom, video system, telemedicine equipment) for patient-staff communication, patient-family communication, and interdisciplinary rounds so that only essential personnel enter the room.</p>	
<p>5. Puncture-proof sealed sharps containers are located in room in close proximity to patient bed.</p>	
<p>6. Ebola patient room has dedicated and/or disposable patient care equipment⁶ that is not used for any other patients. Protocols are in place for reusable equipment (e.g., portable x-ray, dialysis machine⁷) to be cleaned and disinfected according to manufacturers' instructions by trained personnel wearing correct PPE.</p>	
<p>7. In close proximity to the patient room, these separate areas are designated:</p> <ul style="list-style-type: none"> HCP changing area⁸ Clean area⁹ PPE removal area¹⁰ 	

<p>8. PPE removal area is in proximity to patient room (e.g., anteroom or adjacent vacant patient room separate from clean area) and includes:</p> <ul style="list-style-type: none"> • Supplies for disinfection of PPE and washable footwear • Supplies for performing hand hygiene • Space to remove PPE • Place(s) for sitting¹¹ • Leak-proof waste container to discard PPE and area or containers designated to collect PPE for reprocessing (e.g., PAPRs) if applicable • Signs¹² • Full-length mirror (optional) 	
<p>9. Showers¹³ are available and in close proximity to PPE removal area for HCP to use following PPE removal protocol</p> <p>Note: HCP can leave PPE removal area wearing dedicated washable footwear that has been disinfected using an EPA-registered disinfectant wipe¹⁴ (wiping down complete external surface of the washable footwear) and scrubs.</p>	
<p>10. A designated area for waste storage has been identified that meets all applicable fire codes and principles of maintaining a clutter-free, secure environment</p>	
<p>11. A protocol has been developed to address a plan of care for the patient that incorporates family involvement:</p> <ul style="list-style-type: none"> • Maintain communication between patient and family • Identify an area for the family outside the Ebola unit if appropriate based on movement and monitoring guidance and in consultation with local health department 	

E. Personal Protective Equipment and Procedures for Donning and Doffing

Refer to: **Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing)**, at: <http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>

Identify, Isolate, Inform: Emergency Department Evaluation and Management for Patients Who Present with Possible Ebola Virus Disease, at: <http://www.cdc.gov/vhf/ebola/hcp/ed-management-patients-possible-ebola.html>

Elements to be assessed	Notes
1. Hospital has selected the PPE to be used by HCP to manage Ebola patients and has a protocol outlining procedures for use of the PPE. <u>(If hospital elects to use additional/different PPE from CDC recommendations, HCP are trained to ensure donning and doffing procedures are adjusted and practiced accordingly.)</u>	
2. Hospital is compliant with all elements of OSHA Respiratory Protection Standards, including respirator fit-testing, medical evaluation, and training of HCP.	
3. HCP caring for Ebola patients change into hospital scrubs or disposable garments and dedicated, washable footwear, if using.	
4. Healthcare personnel (HCP) on the Ebola Patient Care Team receive repeated training and are required to demonstrate competency through testing and assessment ¹⁵ on proper procedures for donning and doffing of PPE.	

<p>5. Assessment of person under investigation. All HCP who have contact with a patient while the patient is under investigation for Ebola use appropriate PPE based on the patient’s clinical status:</p> <ul style="list-style-type: none"> • If the patient is exhibiting obvious bleeding, vomiting, copious diarrhea or a clinical condition that warrants invasive or aerosol-generating procedures (e.g., intubation, suctioning, active resuscitation), PPE designated for the care of hospitalized patients with confirmed Ebola as outlined in Guidance on Personal Protective Equipment to be used by Healthcare Workers during Management of Patients with Ebola Virus Disease in U.S. Hospitals, including Procedures for Putting on (Donning) and Removing (Doffing). • If signs and symptoms such as bleeding, vomiting, diarrhea or conditions warranting invasive or aerosol-generating procedures are not present and the patient is clinically stable, HCP at a minimum wear PPE as outlined in Identify, Isolate, Inform: Emergency Department Evaluation and Management for Patients under Investigation (PUIs) for Ebola Virus Disease (EVD) 	
<p>6. Treatment of Confirmed Patient. Recommended PPE during management of hospitalized patients with confirmed Ebola is described in Guidance on Personal Protective Equipment to be used by Healthcare Workers during Management of Patients with Ebola Virus Disease in U.S. Hospitals, including Procedures for Putting on (Donning) and Removing (Doffing)</p>	<p>List PPE selected by the hospital for care of a patient with suspected or confirmed Ebola, including the specific make and model numbers for all components.</p>

<p>7. A policy is in place for trained observers to monitor for correct PPE use and adherence to donning/doffing protocols prior to entering and after leaving patient's room.</p> <ul style="list-style-type: none"> • Trained observer is a designated individual with the sole responsibility, during donning/doffing process, of ensuring quality control in all steps of the procedure. • Trained observer reads aloud each step of the procedure to HCP using a checklist, then visibly confirms and documents that each step has been completed correctly • HCP must engage/wait for a trained observer prior to PPE donning and doffing • Donning and doffing of PPE proceeds slowly and deliberately to ensure full-coverage and prevent self-contamination 	
<p>8. Recommended PPE for trained observers during observations of PPE doffing is described in Guidance on Personal Protective Equipment to be used by Healthcare Workers during Management of Patients with Ebola Virus Disease in U.S. Hospitals, including Procedures for Putting on (Donning) and Removing (Doffing)</p>	
<p>9. Hand hygiene is performed before donning and after doffing and disposing of gloves and at any time during doffing procedure when contamination of hands is suspected.</p>	
<p>10. Doffing procedure includes steps for disinfection of <u>visibly contaminated PPE</u> with EPA-registered disinfectant¹⁴ wipes or spray¹⁶ prior to removal and steps for <u>disinfection of gloved hands</u> with ABHR (ideally with touch-free dispensing system) or EPA-registered disinfectant¹⁴ wipe between each step in the doffing process.</p>	

<p>11. Hospital maintains updated inventory of PPE supplies, including details on specific make and models of selected PPE</p> <p>Given current PPE shortages, hospitals may not be able to procure in advance the amount of PPE needed for the entire time period to care for an Ebola patient. CDC, in collaboration with state and local health departments, may facilitate the procurement of or provide additional PPE supplies.</p> <ul style="list-style-type: none"> • For assessment hospitals, at least a 4–5 day supply of PPE in stock • For treatment hospitals, at least a 7 day supply of PPE in stock 	<p>Document the number of days the hospitals can safely care for a patient with suspected or confirmed Ebola, based on current PPE inventory.</p>
<p>12. Hospital has plans in place for re-supplying PPE and alternative procedures if supply chain is interrupted. If barriers exist to procuring adequate supply of PPE, state health departments should be contacted to facilitate additional assistance¹⁷.</p>	

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F. Monitoring Healthcare Personnel and Managing Exposures

Refer to: Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure, at: <http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html>

Elements to be assessed	Notes
<p>1. Hospital has well-defined policies including:</p> <ul style="list-style-type: none"> • Work-exclusion policies that encourage reporting of illnesses and do not penalize with loss of wages, benefits, or job status • Education of personnel on prompt reporting of illness to supervisor and occupational health 	
<p>2. A log is maintained of all personnel who enter any potentially contaminated space in the Ebola treatment/assessment area and/or handle potentially infectious materials and includes sufficient information to assign exposure categories (e.g., high-risk, some risk, low-risk)^{Error! Bookmark not defined.} in order to apply movement and monitoring guidance</p>	
<p>3. Protocols¹⁸ for monitoring and restrictions of asymptomatic HCP are in place, according to the exposure category^{Error! Bookmark not defined.} of the HCP. HCP are monitored during patient care or period of time handling potentially infectious materials and during the 21 days after the last potential exposure.</p> <ul style="list-style-type: none"> • Direct, active monitoring is performed for HCP providing direct care to Ebola patients while wearing appropriate PPE, with no known breaches in infection control (“low-risk” exposure category) • Direct, active monitoring, with controlled movement, patient care restrictions, and potential public health orders, is performed for HCP providing direct care to Ebola patients in a healthcare facility where another HCP has been diagnosed with confirmed Ebola without an identified infection control breach, or where a breach is identified retrospectively (“high-risk” exposure category) 	
<p>4. Following a recognized Ebola exposure incident, protocols for post-exposure management, evaluation, and follow-up are in place¹⁹.</p>	

G. Laboratory Safety and Capacity

Refer to: **Guidance for U.S. Clinical Laboratories for Managing and Testing Routine Clinical Specimens When There is a Concern About Ebola Virus Disease** at: <http://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/index.html>

Elements to be assessed	Notes
<p>1. Protocols are in place for Ebola testing at the nearest Laboratory Response Network (LRN) laboratory capable of testing for Ebola.</p> <p>If the hospital chooses to use a commercial Ebola virus test, specimens are submitted to an LRN facility or CDC for definitive Ebola virus testing.</p>	
<p>2. The hospital is prepared to provide a minimum menu of testing²⁰ to ensure patient care is not compromised while patients undergo assessment. In the US, most persons under investigation for Ebola have had another etiology for their illness. Timely identification of these other etiologies is essential to appropriate patient care.</p>	
<p>3. A site-specific risk assessment²¹ has been performed to identify potential exposure risks and to mitigate these risks by implementing engineering controls, administrative and work practice controls, and use of appropriate personal protective equipment. The risk assessment considers the path of the sample throughout the laboratory and all work processes, procedures and tasks performed.</p>	
<p>4. Protocols are in place for handoff and placement of specimen tubes into appropriate container for transport to laboratory. Specimens are placed in a durable, leak-proof secondary container for transport within the hospital. The outside of specimen containers are disinfected with EPA-registered hospital disinfectant¹⁴ prior to removal from room.</p> <p>Note: Pneumatic tube system is NOT used for Ebola specimens.</p>	
<p>5. Personnel who manipulate primary patient specimens wear PPE as described in Guidance for U.S. Clinical Laboratories for Managing and Testing Routine Clinical Specimens When There is a Concern About Ebola Virus Disease AND use a certified Class II biosafety cabinet. Personnel have demonstrated competency in donning and doffing PPE.</p>	
<p>6. In addition to PPE, personnel who manipulate primary patient specimens use manufacturer-installed safety features for instruments that reduce the likelihood of exposure and to ensure additional protection.</p>	
<p>7. There is a designated area for laboratory personnel to safely doff PPE.</p>	

8. Protocols are in place for cleaning and disinfection of laboratory surfaces, management of blood and body fluid spills, and exposure of staff.	
9. A tracking system is in place for patient specimens that are transported to the laboratory.	
10. A policy is in place for safe storage and disposal of Ebola patient specimens.	

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H. Environmental Infection Control and Equipment Reprocessing

Refer to: Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus, at:
<http://www.cdc.gov/vhf/ebola/hcp/environmental-infection-control-in-hospitals.html>

Elements to be assessed	Notes
<p>1. Facility selects approved EPA-registered hospital disinfectants¹⁴ with a label claim of potency <i>at least equivalent</i> to that for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus), and uses all cleaning and disinfecting products, including disposable wipes, in accordance with manufacturers' instructions (e.g., dilution, storage, shelf life, contact time).</p>	-
<p>2. Trained Ebola patient care team members have been designated to perform routine cleaning and disinfection of Ebola patient room surfaces. Consider having Environmental Services (EVS) staff perform only terminal cleaning to limit personnel with direct patient contact.</p>	.
<p>2. Protocols are in place for staff, including EVS personnel, to wear appropriate PPE to prevent exposure to Ebola virus during cleaning of the Ebola patient room and equipment²².</p> <ul style="list-style-type: none"> • Staff, including EVS personnel must have received job-specific training and demonstrated competency prior to performing duties 	
<p>4. Protocols are in place for monitoring of cleaning and disinfection procedures to ensure they are consistently and correctly performed.</p>	
<p>5. Materials to be used for cleaning and disinfection of Ebola patient room and equipment are disposable, for single-use only.</p>	
<p>6. Protocols are in place for environmental surfaces in Ebola patient care areas to be cleaned with a detergent and disinfected on a regular basis (e.g., at least daily), when spills occur, and when surfaces are visibly contaminated. Hospital promptly removes bulk spill matter, cleans and decontaminates spills of blood or other potentially infectious materials using appropriate EPA-registered hospital disinfectants¹⁴</p>	
<p>7. Protocols are in place for post-discharge cleaning and disinfection of the Ebola patient care areas, including visibly soiled areas, frequently touched surfaces, and floors in the Ebola patient care area.</p>	
<p>8. Ebola patient room has dedicated and/or disposable patient care equipment⁶ that is not used for any other patients. Protocols are in place for reusable equipment (e.g., portable x-ray, dialysis machine⁷) to be cleaned and disinfected according to manufacturers' instructions by trained personnel wearing correct PPE.</p>	

<p>9. Protocols are in place clearly delineating responsibility for cleaning and disinfection of reusable patient care equipment (how equipment should be cleaned and by whom).</p> <ul style="list-style-type: none"> • Protocols include documentation of cleaning on a log (who/when/how) 	
<p>10. HCP are trained to handle soiled textiles/linens with minimum agitation to avoid contamination of surfaces and persons.</p>	
<p>11. All linens used in the Ebola patient room are discarded into the waste stream and disposed of appropriately. These items are not reused.</p>	
<p>12. Food trays, dishes, and cutlery provided to the Ebola patient with meals are disposable, and are placed into the waste stream along with leftover food items for appropriate disposal.</p>	

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I. Management of Waste

Refer to: Ebola-associated Waste Management, at: <http://www.cdc.gov/vhf/ebola/hcp/medical-waste-management.html>

- Medical waste generated in the care of patients with known or suspected Ebola is subject to procedures set forth by local, state and federal regulations.
- Medical waste contaminated with Ebola virus is a Category A infectious substance regulated as a hazardous material under the U.S. Department of Transportation's (DOT's) Hazardous Materials Regulations (HMR; 49 CFR, Parts 171-180). For off-site commercial transport of Ebola-associated medical waste, strict compliance with the HMR is required. For more information on the HMR requirements see <http://phmsa.dot.gov/hazmat/transporting-infectious-substances>.

Safe Handling, Treatment, Transport and Disposal of Ebola-Contaminated Waste

https://www.osha.gov/Publications/OSHA_FS-3766.pdf

Elements to be assessed	Notes
<p>1. Handling and in-hospital management of waste generated through the care of patients with Ebola includes:</p> <ul style="list-style-type: none"> • Safe containment and packaging of waste should be performed as close as possible to the point of generation. • Limiting the number of personnel handling generated waste before and after primary containment. • Always using appropriate PPE and procedures for handling waste until onsite inactivation or transport away from the hospital for offsite inactivation. • Protocols to transport the waste via a direct, pre-identified route to the point of final storage. 	

<p>2. The hospital has waste management plan and protocols²³ in place</p> <ul style="list-style-type: none"> • To package and transport waste contaminated or suspected to be contaminated with Ebola virus in accordance with U.S. DOT Hazardous Materials Regulations (HMR, 49 C.F.R., Parts 171-180), state, and local regulations. • For waste contractor to inactivate potentially contaminated and contaminated waste onsite at the hospital or transport it offsite for inactivation. <p>During initial assessment, hospitals may consider sequestering medical waste until the patient’s Ebola test result becomes known. At that time, if the patient is confirmed to have Ebola, the hospital follows its pre-arranged protocol with a vendor capable of managing the waste as a Category A infectious substance; if Ebola is ruled out, waste can be handled according to procedures in compliance with local waste management ordinances.</p>	
<p>3. A designated waste management team²⁴ has been identified with job-specific training and documented competency on wearing appropriate PPE and on standardized procedures for waste handling.</p>	
<p>4. All necessary supplies for hand hygiene, cleaning and disinfection and packaging waste have been obtained. Supply list is referenced in Procedures of safe handling and management of Ebola-Associated Waste²⁵.</p>	
<p>5. Protocols are in place for the disposal of solid waste (e.g., medical equipment, sharps, linens, privacy curtains, used healthcare products and used PPE). All placement of receptacles and primary packaging by double-bagging of waste occurs in the patient’s room and is performed by the primary healthcare workers (i.e., doctors and nurses) wearing appropriate PPE.</p>	
<p>6. Protocols are in place for disposal of liquid waste (e.g., urine, diarrhea, vomit) that incorporate state and local regulations regarding pretreatment of liquid waste. While CDC does not recommend pretreatment, if this is required by state or local regulations, a chemical that does not pose a respiratory risk to the patient or staff is selected²⁶</p>	

<p>7. If waste is to be autoclaved, a protocol is in place to ensure appropriate waste autoclave procedures²⁷ are followed that will inactivate all infectious material, and a large capacity, dedicated autoclave²⁸ is available within the Ebola patient care unit or within close proximity to the Ebola patient care unit²⁹. If waste is not to be autoclaved, protocols are in place for disposal of non-autoclave, non-sharps waste³⁰.</p>	
<p>8. Protocols are in place for disposal of sharps waste³¹.</p>	
<p>9. Protocols are in place for the designated storage of packed, sealed Category A waste containers in an area separated from other waste, while awaiting transport by the facility waste contractor.</p>	
<p>10. The facility's waste contractor has been contacted and a plan is in place for the facility's waste contractor to request a special permit from the U.S. DOT²⁵.</p>	

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J. Communications	
Elements to be assessed	Notes
1. The hospital has a plan in place to inform and educate staff and patients of plans to care for Ebola patients	
2. The hospital has a process in place for dissemination of every new or changed plan, procedure, and protocol to appropriate groups within hospital to ensure understanding, proficiency, comfort among HCP	
3. The hospital has a plan in place to handle media inquiries related to Ebola patient care.	
4. The hospital has a plan in place for protecting the privacy of the Ebola patient and controlling and monitoring access of HCP to the Ebola patient record so that unauthorized access does not occur.	
5. A single staff member is designated as primary point of contact for communicating information to the designated public health department contact on a daily basis.	

K. Management of the Deceased

Refer to: Guidance for Safe Handling of Human Remains of Ebola Patients in U. S. Hospitals and Mortuaries, at: <http://www.cdc.gov/vhf/ebola/hcp/guidance-safe-handling-human-remains-ebola-patients-us-hospitals-mortuaries.html>

REVISIONS ARE IN PROGRESS AND WILL BE POSTED WHEN FINALIZED AT THE ABOVE LINK

DRAFT

L. Special Populations

Recommendations for Safely Performing Acute Hemodialysis in Patients with Ebola Virus Disease in U.S. Hospitals: <http://www.cdc.gov/vhf/ebola/hcp/guidance-dialysis.html>

Guidance for Screening and Caring for Pregnant Women with Ebola Virus Disease for Healthcare Providers in U.S. Hospitals: <http://www.cdc.gov/vhf/ebola/hcp/guidance-maternal-health.html>

Elements to be assessed	Notes
<p>1. Protocols are in place to address needs of special populations (e.g., pregnant women, infants, children, dialysis patients).</p>	
<p>3. The hospital has a plan for patient arrival at all entry points (e.g., labor and delivery, Emergency department, outpatient clinic, dialysis unit) and safe transport to the designated treatment area.</p> <ul style="list-style-type: none"> • Patients can be adequately screened for risk factors, and signs and symptoms at all entry points 	
<p>3. The hospital has a plan for delivery of care (e.g., staffing, equipment), including labor and delivery, dialysis, surgical intervention, as needed.</p>	
<p>4. Protocols are in place to address family involvement in pediatric and obstetric care:</p> <ul style="list-style-type: none"> • Maintain communication between patient and parents/guardian • Identify an area for the family outside the Ebola unit if appropriate based on movement and monitoring guidance and in consultation with local health department • Develop protocol specific for parent/child interaction 	

Endnotes

¹ For the full list of exposures under each risk category, refer to [the Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure](#)

High risk exposure includes any of the following:

- Percutaneous (e.g., needle stick) or mucous membrane exposure to blood or body fluids of a person with Ebola while the person was symptomatic
- Exposure to the blood or body fluids (including but not limited to feces, saliva, sweat, urine, vomit, and semen) of a person with Ebola while the person was symptomatic without [appropriate personal protective equipment \(PPE\)](#) (<http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>)
- Processing blood or body fluids of a person with Ebola while the person was symptomatic without [appropriate PPE](#) (<http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>) or standard biosafety precautions
- Direct contact with a dead body without [appropriate PPE](#) (<http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>) in a [country with widespread Ebola virus transmission](#) (<http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html>)
- Having lived in the immediate household and provided direct care to a person with Ebola while the person was symptomatic
- Healthcare workers taking care of Ebola patients in a U.S. facility where another healthcare worker has been diagnosed with confirmed Ebola without an identified breach in infection control. A similar determination would be made if an infection control breach is identified retrospectively during investigation of a confirmed case of Ebola in a healthcare worker

Some risk includes:

- Close contact in households, healthcare facilities, or community settings with a person with Ebola while the person was symptomatic
 - Close contact is defined as being for a prolonged period of time while not wearing [appropriate PPE](#) (<http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>) within approximately 3 feet (1 meter) of a person with Ebola while the person was symptomatic

Low (but not zero) risk exposure includes the following:

- Having brief direct contact (e.g., shaking hands), while not wearing [appropriate PPE](#) (<http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>), with a person with Ebola while the person was in the early stage of disease
- Brief proximity, such as being in the same room for a brief period of time, with a person with Ebola while the person was symptomatic
- In countries without widespread Ebola transmission, direct contact while using [appropriate PPE](#) (<http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>) with a person with Ebola while the person was symptomatic
- Traveled on an aircraft with a person with Ebola while the person was symptomatic
- Clinical laboratory workers who use appropriate PPE and follow biosafety precautions

No identifiable risk

- Laboratory workers in Biosafety Level 4 facilities are considered to have no identifiable risk.

² Examples of team members involved in direct patient care of Ebola patient as needed (not intended to be all-inclusive). Where possible, consider cross-training physician and/or nursing personnel on the Ebola treatment team to perform activities normally performed by other staff (e.g., respiratory therapist(s), transporters, X-ray technicians, environmental services) to minimize the number of personnel in contact with the patient:

- Critical care nurses (nurses with ED, OR, or pediatric expertise may be considered, depending on hospital and specific patient care needs)
- Critical care physicians (hospitalists with critical care experience may be considered)
- Anesthesiologist or other airway management specialist
- Obstetrician
- Neonatologist
- Respiratory therapist(s)
- Dialysis technician
- Transporters
- X-ray tech (avoid radiologic procedures as much as possible)

NOTE: Trainees (e.g., medical and nursing students) should **not** be permitted to participate in direct patient care or handling of potentially infected materials.

³ Examples of additional team members involved in consultation

- Infectious Diseases physician
- Nephrologist
- Nutritionist(s)
- Physical/occupational therapist(s)
- Laboratory technologist(s)
- Pharmacist
- Mental health specialist (to provide support to team members on an ongoing basis)
- Clinical studies specialist or research pharmacist (to oversee and manage documentation and communication with federal agencies re: experimental treatments)
- Infection preventionist(s)
- Palliative care
- Interpretive services
- Chaplain
- Ethics expert

NOTE: Trainees (e.g., medical and nursing students) could be included in consultation not involving direct patient care or handling of potentially infected materials as deemed appropriate by the hospital.

⁴ A site manager's sole responsibility is to ensure the safe and effective delivery of Ebola treatment. These individuals are responsible for all aspects of Ebola infection control including supply monitoring and evaluation with direct observation of care before, during, and after staff enter an isolation and treatment area.

⁵ Although Ebola virus is not airborne, placement of Ebola patient in AIIR room will provide additional protection in the event that an aerosol-generating procedure (AGP) is required.

⁶ Examples of dedicated or disposable patient care equipment: blood pressure monitoring devices, pulse oximeters, portable ultrasound device, or glucometer. Stethoscopes should not be used due to the nature of the PPE in use and the risk of HCP exposure from a contaminated stethoscope. Alternatives might include electronic or telephonic stethoscopes.

⁷ For more information on acute hemodialysis: <http://www.cdc.gov/vhf/ebola/hcp/guidance-dialysis.html>. A hemodialysis/CRRT machine should be dedicated for use on the patient and kept in the isolation room until terminal disinfection procedures are undertaken. All other dialysis-related supplies, including the dialyzer, should be disposed of after use in accordance with local, state, and federal regulations. Under no circumstances should a used dialyzer be reprocessed or reused. Read more on Ebola-Associated Waste Management: <http://www.cdc.gov/vhf/ebola/hcp/medical-waste-management.html>

⁸ HCP changing area is a designated area of HCP caring for Ebola patients to change from street clothes into hospital scrubs or disposable garments and dedicated, washable footwear, if using.

⁹ Clean area is a designated staging area outside Ebola patient room where clean PPE is stored and where HCP can don PPE prior to entering patient room. Examples of clean area space: nearby vacant room, demarcated area in hallway outside patient room.

¹⁰ PPE removal area is a designated area in proximity to patient's room which is separate from the clean area. Examples of PPE removal area space: anteroom or adjacent vacant patient room. If hallway outside patient room must be used as PPE removal area, physical barriers should be constructed to close the hallway to through traffic. Facility should make sure this complies with fire codes and restrict access to this hallway to essential personnel who are properly trained. Some PPE may be removed in a clearly designated area of patient room near the door, provided steps can be supervised by the trained observer (e.g., through window such that the HCP doffing PPE can still hear the instructions of the trained observer). This clearly designated area should not be used for any other purpose and the clean section of the PPE removal area should have gloves accessible.

¹¹ In PPE removal area, place for sitting should be easily cleaned/disinfected.

¹² Signs in PPE removal area should instructing HCP to wait for trained observer to support doffing of PPE and to remind HCP of slow and deliberate PPE removal.

¹³ Facilities should consider making showers available for use by healthcare workers after doffing of PPE

¹⁴ U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant with a label claim of potency at least equivalent to that for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus). For disinfectant wipes use a disposable wipe impregnated with an EPA-registered disinfectant.

¹⁵ Healthcare personnel are to be trained on all PPE recommended in the facility's protocols and repeatedly practice donning/doffing procedures before engaging in Ebola patient care. HCP are required to demonstrate competency in the use of PPE, including donning and doffing, through testing and assessment before engaging in Ebola patient care.

¹⁶ EPA-registered disinfectant spray can be used if facility conditions permit and regulations are followed, particularly on contaminated areas.

¹⁷ Considerations for U.S. Healthcare Facilities to Ensure Adequate Supplies of Personal Protective (PPE) for Ebola Preparedness: <http://www.cdc.gov/vhf/ebola/healthcare-us/ppe/supplies.html>

¹⁸ Protocols for monitoring HCP may include:

- Web-based or other system for HCP being monitored to report measured temperatures and symptoms consistent with Ebola, per hospital protocols.

- Specific individual(s) responsible for reviewing HCP monitoring data and actions to be taken if HCP does not comply with monitoring requirements.
- Protocol for HCP to follow for abnormal temperature and/or symptoms (with specific criteria to trigger the protocol: e.g., temperature $\geq 100.4^{\circ}\text{F}$ or 38°C ; symptoms including: severe headache, fatigue, muscle pain, vomiting, diarrhea, abdominal pain, or unexplained hemorrhage)

¹⁹ Protocols for post-exposure management, evaluation, and follow-up include:

- Safe exit from the patient care area and removal of PPE
- Decontamination of the exposed skin and/or mucous membranes
- Immediate contact of occupational health/supervisor for assessment and access to post-exposure management services for all appropriate pathogens (e.g., Human Immunodeficiency Virus, Hepatitis C, etc.).
- Appropriate monitoring and furlough of exposed HCP from direct patient care procedures for the 21 days following the exposure.
- Procedures for immediate notification and safe transport if fever or symptoms develop
- Testing procedures
- Early clinical management as appropriate (clarify options and procedures for accessing experimental therapies)

²⁰ Excerpted from full Guidance for U.S. Clinical Laboratories for Testing and Assessing Patients with Possible Ebola Virus Disease.

The clinician should determine specific testing according to the patient presentation and travel history.

Although the required laboratory testing for a PUI or a patient with EVD will likely vary, assessment and treatment facilities should consider how they might safely perform the following laboratory tests (if indicated) or, if unable to safely perform specific tests, identify alternative approaches to patient management (e.g. empiric treatments, alternative diagnostic strategies):

- A complete blood count (CBC), including differential, and platelet count
- Sodium, potassium, chloride, bicarbonate, calcium, blood urea nitrogen, creatinine, and glucose concentrations
- Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and total bilirubin
- Coagulation testing, specifically prothrombin time (PT), expressed as international normalized ratio (INR)
- Blood culture for bacterial pathogens (for information on automated or manual blood cultures, see “Laboratory Equipment” section on page 7 of this document).
- Malaria testing (smear or rapid tests)

Note: While not all facilities may have the capacity to definitively diagnose malaria, any facility capable of performing a complete blood count should be able to review the blood smear to provide an initial presumptive diagnosis regarding the presence or absence of malaria parasites. Facilities that do not have the capacity to perform definitive malaria testing on site should contact their state health department to facilitate the definitive

diagnosis; CDC and the state health departments can assist with providing a diagnosis of malaria in a timely fashion. More information can be found at CDC's malaria website .

- Influenza virus testing*
- Respiratory Syncytial Virus (RSV) and other respiratory virus testing*+
- Rapid group A strep testing on throat swabs
- Urinalysis

Ebola treatment hospitals should be able to provide the above tests, as well as additional testing required to manage a patient with EVD.

*Negative results when using point of care rapid diagnostics on respiratory specimens from older children and adults do not exclude infection because of their lower sensitivity compared with molecular assays. However, rapid RSV antigen testing in smaller children has been shown to be effective.

+ Molecular assays for numerous respiratory viruses are often available as multiplex assays and may aid in diagnosis of common respiratory infections

²¹ Some items for clinical laboratories to focus on during their site-specific risk assessment should include:

- Specimen management and transport, including the path of the sample through the laboratory particularly avoiding transport through high-traffic areas or pneumatic tube systems
- Equipment hazards (e.g., the potential for creating aerosols, sprays, splashes of the specimen when performing testing and using equipment)
- Biological Safety Cabinet certification, operation and safe work practices
- Decontamination procedures, including spill response, and methods for decontaminating equipment (see page 9)
- Infectious waste management
- Laboratory design
 - Laboratories that have open room designs should consider the risk of exposure to workers present in the area but not directly involved with testing of a particular sample
 - Some recommended measures to minimize the risk of laboratory transmission when testing specimens from PUIs include: limiting the number of staff engaged in testing, evaluating and segregating equipment used for testing, and performing testing in a dedicated space
- Engineering controls and safety equipment
- Laboratory communication protocols
- Laboratory entry and exit procedures
- PPE selection and use
- Facility ventilation and filtration
- Employee medical surveillance and exposure response
- Safe sharps handling
- Personnel safety training and competencies

Additional information on conducting a risk assessment can be found in the CLSI Document M29-A4 "*Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition*".

"*Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories*", MMWR, January 6, 2012/61(01);1-101 available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/su6101a1.htm>

²² PPE and required training for personnel performing cleaning and disinfection is the same as for providers performing direct patient care.

²³ Protocol for management of waste generated requires documentation of disposal of waste.

²⁴ Staff responsibilities for bagging and packaging waste, autoclaving waste (where appropriate), storing waste, and transporting packaged waste for removal from facility are clearly delineated.

²⁵ Supplies for Hand Hygiene, Cleaning and Disinfection, and Packaging Waste

- Leak-proof labeled biohazard bags: The film bags must have a minimum film thickness of 1.5 mils (0.0015 inch) and be 175 liters or smaller (46 gallons). Reference U.S. Department of Transportation (DOT) HMR requirements
- Approved sharps waste container
- Waste container in patient's room
- Transport cart
- Absorbent disposable towels
- EPA-registered hospital disinfectant for use against the Ebola virus ◦Select a hospital grade disinfectant available as wipe, spray, pull-top, or refill bottles (depending on application) with a label claim for one of the non-enveloped viruses (e.g., norovirus, rotavirus, adenovirus, poliovirus) to disinfect hospital environmental surfaces.
- Disposable cleaning cloths
- Alcohol-based hand rub (ABHR) that is at least 60% alcohol
- Rigid outer receptacle that conforms to U.S. DOT HMR requirements for transport of Category A DOT waste provided by approved waste vendor
 - Note: Outer package must be either a rigid United Nations Standard- or DOT-approved non-bulk packaging. If the outer packaging is fabricated from fiberboard, it must be a minimum of triple wall and contain a 6 mil polyethylene liner. Reference DOT Guidance for Preparing Packages of Ebola Contaminated Waste for Transportation and Disposal.
 - Waste should be packaged with an installed liner provided by the waste vendor.
 - Absorbent material sufficient to absorb potential free liquid (if any) should be placed in the bottom of the rigid outer packaging or the liner of the fiberboard outer packaging.

²⁶ Primary handling of liquid waste should occur in the patient's room and be performed by the primary healthcare workers (i.e., doctors and nurses) wearing recommended PPE as designated in the guidance for hospitals (<http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>).

- Pour waste, avoiding splashing by pouring from a low level, into the toilet.
- Close the lid first, and then flush toilet.
- Clean and disinfect flush handles, toilet seat, and lid surfaces with EPA-registered hospital disinfectant/cleaner.
- Discard cleaning cloths in biohazard bags.
- Discard emesis and portable toileting containers as solid waste

²⁷ Waste autoclave protocol requires that biological indicator, intended specifically for the type and cycle parameters of the sterilizer, is used. Autoclave parameters, including autoclave pressure, time, and liquid cycle are specified. Logs are maintained with documentation from each cycle.

²⁸ A 40+ or 70+ cu ft autoclave can hold large, trash sized autoclavable biohazard bags. Bags must be special autoclavable bags to avoid plastic melting in autoclave.

²⁹ For autoclave within close proximity to the Ebola patient care unit, identify safe means of waste transport to the autoclave.

³⁰ Non-autoclaved, non-sharps solid waste is:

- Placed into primary medical waste bags (1.5 mil—ASTM tested)
- EPA-registered hospital disinfectant¹² is added to sufficiently cover the surface of the materials in the bag.
- The bag is securely tied.
- The outside of the bag is disinfected with an EPA-registered hospital disinfectant.¹²
- The disinfected primary bag is placed into a second medical waste bag that is also securely tied and disinfected.

Double-bagged waste is placed into appropriate Category A waste packaging according to manufacturer's instructions and in a manner that prevents external contamination of the final container.

³¹ Disposal of sharps:

- Placed in appropriate disposable sharps containers and close container.
- Containers should not be filled beyond two-thirds full to allow safe closure.
- For onsite inactivation, add sufficient volume of water (according to validated procedures).
- For offsite inactivation, add EPA-registered hospital disinfectant is added to the sharps container prior to disposal.
- Sharps containers ready for disposal are sealed and placed into primary medical waste bags (1.5 mil—ASTM tested).
- The bag is securely tied.
- The outside of the bag is disinfected with an EPA-registered hospital disinfectant.¹²
- The disinfected primary bag is placed into a second medical waste bag that is also securely tied and disinfected.

Double-bagged waste is placed into appropriate Category A waste packaging according to manufacturer's instructions and in a manner that prevents external contamination of the final container.