

GUIDE TO INFECTION PREVENTION FOR OUTPATIENT SETTINGS: MINIMUM EXPECTATIONS FOR SAFE CARE



National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion



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APPENDIX A: INFECTION PREVENTION CHECKLIST FOR OUTPATIENT SETTINGS

This checklist is a companion to the *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care* and is intended to assist in the assessment of infection control programs and practices in outpatient settings. The checklist should be used:

1. To ensure that the facility has appropriate infection prevention policies and procedures in place and supplies to allow healthcare personnel (HCP) to provide safe care.
2. To systematically assess personnel adherence to correct infection prevention practices. In order to complete the assessment, direct observation of infection control practices will be necessary.

Providers using this checklist should identify all procedures performed in their facility and refer to appropriate sections to conduct their evaluation. Certain sections may not apply (e.g., some settings may not perform sterilization or high-level disinfection). If the answer to any of the listed questions is No, efforts should be made to correct the practice, appropriately educate HCP (if applicable), and determine why the correct practice was not being performed. Consideration should also be made for determining the risk posed to patients by the deficient practice. Certain infection control lapses (e.g., re-use of syringes on more than one patient or to access a medication container that is used for subsequent patients; re-use of lancets) have resulted in bloodborne pathogen transmission and should be halted immediately. Identification of such lapses warrants immediate consultation with the state or local health department and appropriate notification and testing of potentially affected patients.

Overview

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Infection Control Domains for Gap Assessment

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- II. Infection Control Training and Competency
- III. Healthcare Personnel Safety
- IV. Surveillance and Disease Reporting
- V.a/b. Hand Hygiene
- VI.a/b. Personal Protective Equipment (PPE)
- VII.a/b. Injection Safety (if applicable)
- VIII.a/b. Respiratory Hygiene/Cough Etiquette
- IX.a/b. Point-of-Care Testing (if applicable)
- X.a/b. Environmental Cleaning
- XI.a/b. Device Reprocessing
- XII. Sterilization of Reusable Devices (if applicable)
- XIII. High-level Disinfection of Reusable Devices (if applicable)

Section 1: Facility Demographics

Questions	Details															
Is the facility licensed by the state?	☐ Yes ☐ No If yes, Date of last inspection: _____ Were any infection control deficiencies identified during last inspection? ☐ Yes ☐ No If Yes, ensure those elements are evaluated during the assessment.															
Is the facility certified by the Centers for Medicare & Medicaid Services (CMS)?	☐ Yes ☐ No If yes, Date of last inspection: _____ Were any infection control deficiencies identified during last inspection? ☐ Yes ☐ No If Yes, ensure those elements are evaluated during the assessment.															
Is the facility accredited?	☐ Yes ☐ No If yes, List the accreditation organization: ☐ Accreditation Association for Ambulatory Health Care (AAAHC) ☐ American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) ☐ American Osteopathic Association (AOA) ☐ The Joint Commission (TJC) ☐ Other (specify): _____ Date of last inspection: _____ Were any infection control deficiencies identified during last inspection? ☐ Yes ☐ No If Yes, ensure those elements are evaluated during the assessment.															
Is the facility affiliated with a hospital?	☐ Yes ☐ No If yes, consider engaging with the hospital infection prevention program for assistance in remediation of any identified lapses.															
Which procedures are performed by the facility? Select all that apply.	<table border="0"> <tbody> <tr> <td>☐ Chemotherapy</td><td>☐ Endoscopy</td><td>☐ Ear/Nose/Throat</td></tr> <tr> <td>☐ Imaging (MRI/CT)</td><td>☐ Immunizations</td><td>☐ OB/Gyn</td></tr> <tr> <td>☐ Ophthalmologic</td><td>☐ Orthopedic</td><td>☐ Pain remediation</td></tr> <tr> <td>☐ Plastic/reconstructive</td><td>☐ Podiatry</td><td>☐ Other (specify)</td></tr> <tr> <td colspan="3">_____</td></tr> </tbody> </table>	☐ Chemotherapy	☐ Endoscopy	☐ Ear/Nose/Throat	☐ Imaging (MRI/CT)	☐ Immunizations	☐ OB/Gyn	☐ Ophthalmologic	☐ Orthopedic	☐ Pain remediation	☐ Plastic/reconstructive	☐ Podiatry	☐ Other (specify)	_____		
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☐ Plastic/reconstructive	☐ Podiatry	☐ Other (specify)														

Section 2: Infection Control Program and Infrastructure

I. Infection Control Program and Infrastructure

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Written infection prevention policies and procedures are available, current, and based on evidence-based guidelines (e.g., CDC/HICPAC), regulations, or standards. <i>Note: Policies and procedures should be appropriate for the services provided by the facility and should extend beyond OSHA bloodborne pathogens training</i>	☐ Yes ☐ No	
B. Infection prevention policies and procedures are re-assessed at least annually or according to state or federal requirements, and updated if appropriate.	☐ Yes ☐ No	
C. At least one individual trained in infection prevention is employed by or regularly available (e.g., by contract) to manage the facility's infection control program. <i>Note: Examples of training may include: Successful completion of initial and/or recertification exams developed by the Certification Board for Infection Control & Epidemiology; participation in infection control courses organized by the state or recognized professional societies (e.g., APIC, SHEA).</i>	☐ Yes ☐ No	
D. Facility has system for early detection and management of potentially infectious persons at initial points of patient encounter. <i>Note: System may include taking a travel and occupational history, as appropriate, and elements described under respiratory hygiene/cough etiquette.</i>	☐ Yes ☐ No	

II. Infection Control Training and Competency

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Facility has a competency-based training program that provides job-specific training on infection prevention policies and procedures to healthcare personnel. <i>Note: This includes those employed by outside agencies and available by contract or on a volunteer basis to the facility.</i> <i>See sections below for more specific assessment of training related to: hand hygiene, personal protective equipment (PPE), injection safety, environmental cleaning, point-of-care testing, and device reprocessing.</i>	☐ Yes ☐ No	

III. Healthcare Personnel Safety

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Facility has an exposure control plan that is tailored to the specific requirements of the facility (e.g., addresses potential hazards posed by specific services provided by the facility). <i>Note: A model template, which includes a guide for creating an exposure control plan that meets the requirements of the OSHA Bloodborne Pathogens Standard is available at: https://www.osha.gov/Publications/osh3186.pdf</i>	☐ Yes ☐ No	
B. HCP for whom contact with blood or other potentially infectious material is anticipated are trained on the OSHA bloodborne pathogens standard upon hire and at least annually.	☐ Yes ☐ No	
C. Following an exposure event, post-exposure evaluation and follow-up, including prophylaxis as appropriate, are available at no cost to employee and are supervised by a licensed healthcare professional. <i>Note: An exposure incident refers to a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an individual's duties.</i>	☐ Yes ☐ No	
D. Facility tracks HCP exposure events and evaluates event data and develops/implements corrective action plans to reduce incidence of such events.	☐ Yes ☐ No	
E. Facility follows recommendations of the Advisory Committee on Immunization Practices (ACIP) for immunization of HCP, including offering Hepatitis B and influenza vaccination. <i>Note: Immunization of Health-Care Personnel: Recommendations of the ACIP available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm</i>	☐ Yes ☐ No	
F. All HCP receive baseline tuberculosis (TB) screening prior to placement; HCP receive repeat testing, if appropriate, based upon the facility-level risk assessment. <i>Note: For more information, facilities should refer to the Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005 available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=rr5417a1_e</i>	☐ Yes ☐ No	
G. If respirators are used, the facility has a respiratory protection program that details required worksite-specific procedures and elements for required respirator use, including provision of medical clearance, training, and fit testing as appropriate.	☐ Yes ☐ No ☐ Not applicable	

III. Healthcare Personnel Safety *(continued)*

Elements to be assessed	Assessment	Notes/Areas for Improvement
H. Facility has well-defined policies concerning contact of personnel with patients when personnel have potentially transmissible conditions. These policies include:	☐ Yes ☐ No	
i. Work-exclusion policies that encourage reporting of illnesses and do not penalize with loss of wages, benefits, or job status.	☐ Yes ☐ No	
ii. Education of personnel on prompt reporting of illness to supervisor.	☐ Yes ☐ No	

IV. Surveillance and Disease Reporting

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. An updated list of diseases reportable to the public health authority is readily available to all personnel.	☐ Yes ☐ No	
B. Facility can demonstrate knowledge of and compliance with mandatory reporting requirements for notifiable diseases, healthcare associated infections (as appropriate), and for potential outbreaks.	☐ Yes ☐ No	
C. Patients who have undergone procedures at the facility are educated regarding signs and symptoms of infection that may be associated with the procedure and instructed to notify the facility if such signs or symptoms occur.	☐ Yes ☐ No	

V.a. Hand Hygiene

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. All HCP are educated regarding appropriate indications for hand hygiene: i. Upon hire, prior to provision of care ii. Annually	☐ Yes ☐ No ☐ Yes ☐ No	
B. HCP are required to demonstrate competency with hand hygiene following each training.	☐ Yes ☐ No	
C. Facility routinely audits (monitors and documents) adherence to hand hygiene.	☐ Yes ☐ No	
D. Facility provides feedback from audits to personnel regarding their hand hygiene performance.	☐ Yes ☐ No	
E. Hand hygiene policies promote preferential use of alcohol-based hand rub over soap and water in most clinical situations. <i>Note: Soap and water should be used when hands are visibly soiled (e.g. blood, body fluids) and is also preferred after caring for a patient with known or suspected C. difficile or norovirus during an outbreak.</i>	☐ Yes ☐ No	

Vla. Personal Protective Equipment (PPE)

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. HCP who use PPE receive training on proper selection and use of PPE: i. Upon hire, prior to provision of care ii. Annually iii. When new equipment or protocols are introduced	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	
B. HCP are required to demonstrate competency with selection and use of PPE following each training.	☐ Yes ☐ No	
C. Facility routinely audits (monitors and documents) adherence to proper PPE selection and use.	☐ Yes ☐ No	
D. Facility provides feedback from audits to personnel regarding their performance with selection and use of PPE.	☐ Yes ☐ No	

VII.a. Injection Safety (This element does not include assessment of pharmacy/compounding practices)

If injectable medications are never prepared or administered at the facility check **O Not Applicable** here and skip to Section VIII.a. Respiratory Hygiene/Cough Etiquette.

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. HCP who prepare and/or administer parenteral medications receive training on safe injection practices: i. Upon hire, prior to being allowed to prepare and/or administer parenteral medications ii. Annually iii. When new equipment or protocols are introduced	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	
B. HCP are required to demonstrate competency with safe injection practices following each training.	☐ Yes ☐ No	
C. Facility routinely audits (monitors and documents) adherence to safe injection practices.	☐ Yes ☐ No	
D. Facility provides feedback from audits to personnel regarding their adherence to safe injection practices.	☐ Yes ☐ No	
E. Facility has policies and procedures to track HCP access to controlled substances to prevent narcotics theft/diversion. <i>Note: Policies and procedures should address: how data are reviewed, how facility would respond to unusual access patterns, how facility would assess risk to patients if tampering (alteration or substitution) is suspected or identified, and who the facility would contact if diversion is suspected or identified.</i>	☐ Yes ☐ No ☐ Not applicable (Facility does not prepare or administer controlled substances)	

VIII.a. Respiratory Hygiene/Cough Etiquette

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Facility has policies and procedures to contain respiratory secretions in persons who have signs and symptoms of a respiratory infection, beginning at point of entry to the facility and continuing through the duration of the visit. Policies include: i. Offering facemasks to coughing patients and other symptomatic persons upon entry to the facility, at a minimum, during periods of increased respiratory infection activity in the community. ii. Providing space in waiting rooms and encouraging persons with symptoms of respiratory infections to sit as far away from others as possible. <i>Note: If available, facilities may wish to place patients with symptoms of a respiratory infection in a separate area while waiting for care.</i>	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	
B. Facility educates HCP on the importance of infection prevention measures to contain respiratory secretions to prevent the spread of respiratory pathogens.	☐ Yes ☐ No	

IX.a. Point-of-Care Testing (e.g., blood glucose meters, INR monitor)

If point-of-care testing is never performed at the facility check **O Not Applicable** here and skip to section X.a. Environmental Cleaning.

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. HCP who perform point-of-care testing receive training on recommended practices: i. Upon hire, prior to being allowed to perform point-of-care testing ii. Annually iii. When new equipment or protocols are introduced	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	
B. HCP are required to demonstrate competency with recommended practices for point-of-care testing following each training.	☐ Yes ☐ No	
C. Facility routinely audits (monitors and documents) adherence to recommended practices during point-of-care testing.	☐ Yes ☐ No	
D. Facility provides feedback from audits to personnel regarding their adherence to recommended practices.	☐ Yes ☐ No	

X.a. Environmental Cleaning

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Facility has written policies and procedures for routine cleaning and disinfection of environmental surfaces, including identification of responsible personnel.	☐ Yes ☐ No	
B. Personnel who clean and disinfect patient care areas (e.g., environmental services, technicians, nurses) receive training on cleaning procedures: i. Upon hire, prior to being allowed to perform environmental cleaning ☐ Yes ☐ No ii. Annually ☐ Yes ☐ No iii. When new equipment or protocols are introduced ☐ Yes ☐ No <i>Note: If environmental cleaning is performed by contract personnel, facility should verify this is provided by contracting company.</i>		
C. HCP are required to demonstrate competency with environmental cleaning procedures following each training.	☐ Yes ☐ No	
D. Facility routinely audits (monitors and documents) adherence to cleaning and disinfection procedures, including using products in accordance with manufacturer's instructions (e.g., dilution, storage, shelf-life, contact time).	☐ Yes ☐ No	
E. Facility provides feedback from audits to personnel regarding their adherence to cleaning and disinfection procedures.	☐ Yes ☐ No	
F. Facility has a policy/procedure for decontamination of spills of blood or other body fluids.	☐ Yes ☐ No	

X.a. Environmental Cleaning (*continued*) – Operating room

For the purposes of this checklist, an operating room is defined as a patient care area that met the Facilities Guidelines Institute's (FGI) or American Institute of Architects' (AIA) criteria for an operating room when it was constructed or renovated. This is the same definition that is used in the National Healthcare Safety Network's Procedure-associated Module for the SSI Event (<http://www.cdc.gov/nhsn/pdfs/pscmanual/9pscscssicurrent.pdf>)

If the facility does not have an operating room check **O Not Applicable** here and skip to section XI.a. Device Reprocessing.

Elements to be assessed	Assessment	Notes/Areas for Improvement
G. Operating rooms are terminally cleaned after last procedure of the day.	☐ Yes ☐ No	
H. Facility routinely audits (monitors and documents) adherence to recommended infection control practices for surgical infection prevention including: i. Adherence to preoperative surgical scrub and hand hygiene ii. Appropriate use of surgical attire and drapes iii. Adherence to aseptic technique and sterile field iv. Proper ventilation requirements in surgical suites v. Minimization of traffic in the operating room vi. Adherence to cleaning and disinfection of environmental surfaces	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	
I. Facility provides feedback from audits to personnel regarding their adherence to surgical infection prevention practices.	☐ Yes ☐ No	

XI.a. Device Reprocessing

The following basic information allows for a general assessment of policies and procedures related to reprocessing of reusable medical devices. Outpatient facilities that are performing on-site sterilization or high-level disinfection of reusable medical devices should refer to the more detailed checklists in separate sections of this document devoted to those issues.

Categories of Medical Devices:

- **Critical items** (e.g., surgical instruments) are objects that enter sterile tissue or the vascular system and must be sterile prior to use (see Sterilization Section).
- **Semi-critical items** (e.g., endoscopes for upper endoscopy and colonoscopy, vaginal probes) are objects that contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection prior to reuse (see High-level Disinfection Section).
- **Non-critical items** (e.g., blood pressure cuffs) are objects that may come in contact with intact skin but not mucous membranes and should undergo cleaning and low- or intermediate-level disinfection depending on the nature and degree of contamination.

XI.a. Device Reprocessing (*continued*)

Single-use devices (SUDs) are labeled by the manufacturer for a single use and do not have reprocessing instructions. They may not be reprocessed for reuse except by entities which have complied with FDA regulatory requirements and have received FDA clearance to reprocess specific SUDs.

Note: Cleaning must always be performed prior to sterilization and disinfection

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Facility has policies and procedures to ensure that reusable medical devices are cleaned and reprocessed appropriately prior to use on another patient. <i>Note: This includes clear delineation of responsibility among HCP for cleaning and disinfection of equipment including, non-critical equipment, mobile devices, and other electronics (e.g., point-of-care devices) that might not be reprocessed in a centralized reprocessing area.</i>	☐ Yes ☐ No	
B. The individual(s) in charge of infection prevention at the facility is consulted whenever new devices or products will be purchased or introduced to ensure implementation of appropriate reprocessing policies and procedures.	☐ Yes ☐ No	
C. HCP responsible for reprocessing reusable medical devices receive hands-on training on proper selection and use of PPE and recommended steps for reprocessing assigned devices: i. Upon hire, prior to being allowed to reprocess devices ii. Annually iii. When new devices are introduced or policies/procedures change. <i>Note: If device reprocessing is performed by contract personnel, facility should verify this is provided by contracting company.</i>	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	
D. HCP are required to demonstrate competency with reprocessing procedures (i.e., correct technique is observed by trainer) following each training.	☐ Yes ☐ No	
E. Facility routinely audits (monitors and documents) adherence to reprocessing procedures.	☐ Yes ☐ No	
F. Facility provides feedback from audits to personnel regarding their adherence to reprocessing procedures.	☐ Yes ☐ No	
G. Facility has protocols to ensure that HCP can readily identify devices that have been properly reprocessed and are ready for patient use (e.g., tagging system, storage in designated area).	☐ Yes ☐ No	

Elements to be assessed	Assessment	Notes/Areas for Improvement
H. Facility has policies and procedures outlining facility response (i.e., risk assessment and recall of device) in the event of a reprocessing error or failure.	☐ Yes ☐ No	
I. Routine maintenance for reprocessing equipment (e.g., automated endoscope reprocessors, steam autoclave) is performed by qualified personnel in accordance with manufacturer instructions; confirm maintenance records are available.	☐ Yes ☐ No ☐ Not applicable (Reprocessing equipment is not used at the facility)	

Section 3: Direct Observation of Facility Practices

V.b. Hand hygiene

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Supplies necessary for adherence to hand hygiene (e.g., soap, water, paper towels, alcohol-based hand rub) are readily accessible to HCP in patient care areas.	☐ Yes ☐ No	
Hand hygiene is performed correctly:		
B. Before contact with the patient	☐ Yes ☐ No	
C. Before performing an aseptic task (e.g., insertion of IV or preparing an injection, administering eye drops)	☐ Yes ☐ No ☐ Not applicable	
D. After contact with the patient	☐ Yes ☐ No	
E. After contact with objects in the immediate vicinity of the patient	☐ Yes ☐ No	
F. After contact with blood, body fluids or contaminated surfaces	☐ Yes ☐ No	
G. After removing gloves	☐ Yes ☐ No	
H. When moving from a contaminated-body site to a clean-body site during patient care	☐ Yes ☐ No ☐ Not applicable	

VI.b. Personal Protective Equipment (PPE)

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Sufficient and appropriate PPE is available and readily accessible to HCP.	☐ Yes ☐ No	
PPE is used correctly:		
B. PPE, other than respirator, is removed and discarded prior to leaving the patient's room or care area. If a respirator is used, it is removed and discarded (or reprocessed if reusable) <u>after</u> leaving the patient room or care area and closing the door.	☐ Yes ☐ No	
C. Hand hygiene is performed immediately after removal of PPE.	☐ Yes ☐ No	
D. Gloves i. HCP wear gloves for potential contact with blood, body fluids, mucous membranes, non-intact skin, or contaminated equipment. ii. HCP <u>do not</u> wear the same pair of gloves for the care of more than one patient. iii. HCP <u>do not</u> wash gloves for the purpose of reuse.	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	
E. Gowns i. HCP wear gowns to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated. ii. HCP <u>do not</u> wear the same gown for the care of more than one patient.	☐ Yes ☐ No ☐ Not applicable ☐ Yes ☐ No ☐ Not applicable	
F. Facial protection i. HCP wear mouth, nose, and eye protection during procedures that are likely to generate splashes or sprays of blood or other body fluids.	☐ Yes ☐ No ☐ Not applicable	

VII.b. Injection safety (This element does not include assessment of pharmacy/compounding practices)

If injectable medications are never prepared or administered at the facility check **O Not Applicable** here and skip to Section VIII.b. Respiratory Hygiene/Cough Etiquette

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids or contaminated equipment.	☐ Yes ☐ No	
B. Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).	☐ Yes ☐ No	
C. The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	☐ Yes ☐ No	
D. Medication containers are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient.	☐ Yes ☐ No	
E. Single dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient.	☐ Yes ☐ No	
F. Medication administration tubing and connectors are used for only one patient.	☐ Yes ☐ No ☐ Not applicable (Facility does not use tubing or connectors)	
G. Multi-dose vials are dated by HCP when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. <i>Note: This is different from the expiration date printed on the vial.</i>	☐ Yes ☐ No ☐ Not applicable (Facility does not use multi-dose vials or discards them after single patient use)	
H. Multi-dose vials to be used for more than one patient are kept in a centralized medication area and <u>do not</u> enter the immediate patient treatment area (e.g., operating room, patient room/cubicle). <i>Note: If multi-dose vials enter the immediate patient treatment area they should be dedicated for single-patient use and discarded immediately after use.</i>	☐ Yes ☐ No ☐ Not applicable (Facility does not use multi-dose vials or discards them after single patient use)	
I. All sharps are disposed of in a puncture-resistant sharps container.	☐ Yes ☐ No	

VII.b. Injection safety (This element does not include assessment of pharmacy/compounding practices) *(continued)*

Elements to be assessed	Assessment	Notes/Areas for Improvement
J. Filled sharps containers are disposed of in accordance with state regulated medical waste rules.	☐ Yes ☐ No	
K. All controlled substances (e.g., Schedule II, III, IV, V drugs) are kept locked within a secure area.	☐ Yes ☐ No ☐ Not applicable (Controlled substances are not kept at the facility)	
L. HCP wear a facemask (e.g., surgical mask) when placing a catheter or injecting material into the epidural or subdural space (e.g., during myelogram, epidural or spinal anesthesia).	☐ Yes ☐ No ☐ Not applicable (Facility does not perform spinal injection procedures)	

VIII.b. Respiratory Hygiene/Cough Etiquette

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Facility: i. Posts signs at entrances with instructions to patients with symptoms of respiratory infection to: a. Inform HCP of symptoms of a respiratory infection when they first register for care, and b. Practice Respiratory Hygiene/Cough Etiquette (cover their mouths/noses when coughing or sneezing, use and dispose of tissues, and perform hand hygiene after hands have been covered with respiratory secretions). ii. Provides tissues and no-touch receptacles for disposal of tissues. iii. Provides resources for performing hand hygiene in or near waiting areas.	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	

IX.b. Point-of-Care Testing (e.g., blood glucose meters, INR monitor)

If point-of-care testing is never performed at the facility check **O Not Applicable** here and skip to Section X.b. Environmental Cleaning

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. New single-use, auto-disabling lancing device is used for each patient. <i>Note: Lancet holder devices are not suitable for multi-patient use.</i>	☐ Yes ☐ No ☐ Not applicable	
B. If used for more than one patient, the point-of-care blood testing meter is cleaned and disinfected after every use according to manufacturer's instructions. <i>Note: If the manufacturer does not provide instructions for cleaning and disinfection, then the testing meter should not be used for >1 patient.</i>	☐ Yes ☐ No ☐ Not applicable	

X.b. Environmental Cleaning

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Supplies necessary for appropriate cleaning and disinfection procedures (e.g., EPA-registered disinfectants) are available. <i>Note: If environmental services are performed by contract personnel, facility should verify that appropriate EPA-registered products are provided by contracting company</i>	☐ Yes ☐ No	
B. High-touch surfaces in rooms where surgical or other invasive procedures (e.g., endoscopy, spinal injections) are performed are cleaned and then disinfected with an EPA-registered disinfectant after each procedure.	☐ Yes ☐ No ☐ Not applicable	
C. Cleaners and disinfectants are used in accordance with manufacturer's instructions (e.g., dilution, storage, shelf-life, contact time).	☐ Yes ☐ No	
D. HCP engaged in environmental cleaning wear appropriate PPE to prevent exposure to infectious agents or chemicals (PPE can include gloves, gowns, masks, and eye protection). <i>Note: The exact type of correct PPE depends on infectious or chemical agent and anticipated type of exposure.</i>	☐ Yes ☐ No	

XI.b. Device Reprocessing

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Policies, procedures, and manufacturer reprocessing instructions for reusable medical devices used in the facility are available in the reprocessing area(s).	☐ Yes ☐ No	
B. Reusable medical devices are cleaned, reprocessed (disinfection or sterilization) and maintained according to the manufacturer instructions. <i>Note: If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use.</i>	☐ Yes ☐ No	
C. Single-use devices are discarded after use and not used for more than one patient unless they have been appropriately reprocessed as described in the note below. <i>Note: If the facility elects to reuse single-use devices, these devices must be reprocessed prior to reuse by a third-party reprocessor that it is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. The facility should have documentation from the third party reprocessor confirming this is the case.</i>	☐ Yes ☐ No	
D. Reprocessing area: i. Adequate space is allotted for reprocessing activities. ii. A workflow pattern is followed such that devices clearly flow from high contamination areas to clean/sterile areas (i.e., there is clear separation between soiled and clean workspaces).	☐ Yes ☐ No ☐ Yes ☐ No	
E Adequate time for reprocessing is allowed to ensure adherence to all steps recommended by the device manufacturer, including drying and proper storage. <i>Note: Facilities should have an adequate supply of instruments for the volume of procedures performed and should schedule procedures to allow sufficient time for all reprocessing steps.</i>	☐ Yes ☐ No	
F. HCP engaged in device reprocessing wear appropriate PPE to prevent exposure to infectious agents or chemicals (PPE can include gloves, gowns, masks, and eye protection). <i>Note: The exact type of correct PPE depends on infectious or chemical agent and anticipated type of exposure.</i>	☐ Yes ☐ No	
G. Medical devices are stored in a manner to protect from damage and contamination.	☐ Yes ☐ No	

XII. Sterilization of Reusable Devices

If all device sterilization is performed off-site, complete elements M-O below and check Not Applicable for the remaining elements in this section.

If sterilization of reusable devices is never performed (either at the facility or off-site) check **O Not Applicable** here and skip to Section XIII.

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Devices are thoroughly cleaned according to manufacturer instructions and visually inspected for residual soil prior to sterilization. <i>Note: Cleaning may be manual (i.e., using friction) and/or mechanical (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizers).</i> <i>Ensure appropriately sized cleaning brushes are selected for cleaning device channels and lumens.</i>	☐ Yes ☐ No ☐ Not applicable	
B. Cleaning is performed as soon as practical after use (e.g., at the point of use) to prevent soiled materials from becoming dried onto devices.	☐ Yes ☐ No ☐ Not applicable	
C. Enzymatic cleaner or detergent is used for cleaning and discarded according to manufacturer's instructions (typically after each use).	☐ Yes ☐ No ☐ Not applicable	
D. Cleaning brushes are disposable or, if reusable, cleaned and high-level disinfected or sterilized (per manufacturer's instructions) after use.	☐ Yes ☐ No ☐ Not applicable	
E. After cleaning, instruments are appropriately wrapped/ packaged for sterilization (e.g., package system selected is compatible with the sterilization process being performed, items are placed correctly into the basket, shelf or cart of the sterilizer so as not to impede the penetration of the sterilant, hinged instruments are open, instruments are disassembled if indicated by the manufacturer).	☐ Yes ☐ No ☐ Not applicable	
F. A chemical indicator (process indicator) is placed correctly in the instrument packs in every load.	☐ Yes ☐ No ☐ Not applicable	
G. A biological indicator, intended specifically for the type and cycle parameters of the sterilizer, is used at least weekly for each sterilizer and with every load containing implantable items.	☐ Yes ☐ No ☐ Not applicable	

XII. Sterilization of Reusable Devices *(continued)*

Elements to be assessed	Assessment	Notes/Areas for Improvement
H. For dynamic air removal-type sterilizers (e.g., prevacuum steam sterilizer), an air removal test (Bowie-Dick test) is performed in an empty dynamic-air removal sterilizer each day the sterilizer is used to verify efficacy of air removal.	☐ Yes ☐ No ☐ Not applicable	
I. Sterile packs are labeled with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and, if applicable, the expiration date.	☐ Yes ☐ No ☐ Not applicable	
J. Sterilization logs are current and include results from each load.	☐ Yes ☐ No ☐ Not applicable	
K. Immediate-use steam sterilization, if performed, is only done in circumstances in which routine sterilization procedures cannot be performed.	☐ Yes ☐ No ☐ Not applicable	
L. Instruments that undergo immediate-use steam sterilization are used immediately and not stored.	☐ Yes ☐ No ☐ Not applicable	
M. After sterilization, medical devices are stored so that sterility is not compromised.	☐ Yes ☐ No ☐ Not applicable	
N. Sterile packages are inspected for integrity and compromised packages are reprocessed prior to use.	☐ Yes ☐ No ☐ Not applicable	
O. The facility has a process to perform initial cleaning of devices (to prevent soiled materials from becoming dried onto devices) prior to transport to the off-site reprocessing facility.	☐ Yes ☐ No ☐ Not applicable	

XIII. High-Level Disinfection of Reusable Devices

If all high-level disinfection is performed off-site, complete elements L-N below and check **Not Applicable** for the remaining elements in this section.

If high-level disinfection of reusable devices is never performed (either at the facility or off-site) check **Not Applicable** here.

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Flexible endoscopes are inspected for damage and leak tested as part of each reprocessing cycle. Any device that fails the leak test is removed from clinical use and repaired.	☐ Yes ☐ No ☐ Not applicable	

XIII. High-Level Disinfection of Reusable Devices (*continued*)

Elements to be assessed	Assessment	Notes/Areas for Improvement
B. Devices are thoroughly cleaned according to manufacturer instructions and visually inspected for residual soil prior to high-level disinfection. <i>Note: Cleaning may be manual (i.e., using friction) and/or mechanical (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizers).</i> <i>Ensure appropriately sized cleaning brushes are selected for cleaning device channels and lumens.</i>	☐ Yes ☐ No ☐ Not applicable	
C. Cleaning is performed as soon as practical after use (e.g., at the point of use) to prevent soiled materials from becoming dried onto instruments.	☐ Yes ☐ No ☐ Not applicable	
D. Enzymatic cleaner or detergent is used and discarded according to manufacturer instructions (typically after each use).	☐ Yes ☐ No ☐ Not applicable	
E. Cleaning brushes are disposable or, if reusable, cleaned and high-level disinfected or sterilized (per manufacturer instructions) after use.	☐ Yes ☐ No ☐ Not applicable	
F. For chemicals used in high-level disinfection, manufacturer instructions are followed for: i. Preparation ii. Testing for appropriate concentration, and iii. Replacement (i.e., upon expiration or loss of efficacy)	☐ Yes ☐ No ☐ Not applicable ☐ Yes ☐ No ☐ Not applicable ☐ Yes ☐ No ☐ Not applicable	
G. If automated reprocessing equipment (e.g. automated endoscope reprocessor) is used, proper connectors are used to assure that channels and lumens are appropriately disinfected.	☐ Yes ☐ No ☐ Not applicable	
H. Devices are disinfected for the appropriate length of time as specified by manufacturer instructions.	☐ Yes ☐ No ☐ Not applicable	
I. Devices are disinfected at the appropriate temperature as specified by manufacturer instructions.	☐ Yes ☐ No ☐ Not applicable	
J. After high-level disinfection, devices are appropriately rinsed as specified by the manufacturer.	☐ Yes ☐ No ☐ Not applicable	

XIII. High-Level Disinfection of Reusable Devices *(continued)*

Elements to be assessed	Assessment	Notes/Areas for Improvement
K. Devices are dried thoroughly prior to reuse. <i>Note: For lumened instruments (e.g., endoscopes) this includes flushing all channels with alcohol and forcing air through channels.</i>	☐ Yes ☐ No ☐ Not applicable	
L. After high-level disinfection, devices are stored in a manner to protect from damage or contamination. <i>Note: Endoscopes should be hung in a vertical position.</i>	☐ Yes ☐ No ☐ Not applicable	
M. Facility maintains a log for each endoscopy procedure which includes: patient's name and medical record number (if available), procedure, date, endoscopist, system used to reprocess the endoscope (if more than one system could be used in the reprocessing area), and serial number or other identifier of the endoscope used.	☐ Yes ☐ No ☐ Not applicable	
N. The facility has a process to perform initial cleaning of devices (to prevent soiled materials from becoming dried onto devices) prior to transport to the off-site reprocessing facility.	☐ Yes ☐ No ☐ Not applicable	

Section 4: Infection Control Guidelines and Other Resources

- General Infection Prevention
 - ☐ CDC/HICPAC Guidelines and recommendations:
http://www.cdc.gov/HAI/prevent/prevent_pubs.html
- Healthcare Personnel Safety
 - ☐ Guideline for Infection Control in Healthcare Personnel: <http://www.cdc.gov/hicpac/pdf/InfectControl98.pdf>
 - ☐ Immunization of HealthCare Personnel: <http://www.cdc.gov/vaccines/spec-grps/hcw.htm>
 - ☐ Occupational Safety & Health Administration (OSHA) Bloodborne Pathogens and Needlestick Prevention Standard: <http://www.osha.gov/SLTC/bloodbornepathogens/index.html>
 - ☐ OSHA Respiratory Protection Standard: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&p_table=STANDARDS
 - ☐ OSHA Respirator Fit Testing: https://www.osha.gov/video/respiratory_protection/fittesting_transcript.html

- Hand Hygiene
 - ❑ Guideline for Hand Hygiene in Healthcare Settings: <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>
 - ❑ Hand Hygiene in Healthcare Settings: <http://www.cdc.gov/handhygiene/>
 - ❑ Examples of tools that can be used to conduct a formal audit of hand hygiene practices:
 - http://www.jointcommission.org/assets/1/18/hh_monograph.pdf
 - <http://compepi.cs.uiowa.edu/index.php/Research/IScrub>
- Personal Protective Equipment
 - ❑ 2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>
 - ❑ Guidance for the Selection and Use of Personal Protective Equipment in Healthcare Settings: <http://www.cdc.gov/HAI/prevent/ppe.html>
- Injection Safety
 - ❑ 2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>
 - ❑ CDC Injection Safety Web Materials: <http://www.cdc.gov/injectionsafety/>
 - ❑ CDC training video and related Safe Injection Practices Campaign materials: <http://www.oneandonlycampaign.org/>
- Respiratory Hygiene/Cough Etiquette
 - ❑ 2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>
 - ❑ Recommendations for preventing the spread of influenza: <http://www.cdc.gov/flu/professionals/infectioncontrol/>
- Environmental Cleaning
 - ❑ Guidelines for Environmental Infection Control in Healthcare Facilities: http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf
 - ❑ Options for Evaluating Environmental Infection Control: <http://www.cdc.gov/HAI/toolkits/Evaluating-Environmental-Cleaning.html>
- Equipment Reprocessing
 - ❑ Guideline for Disinfection and Sterilization in Healthcare Facilities: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
 - ❑ FDA regulations on reprocessing of single-use devices: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434>

- Point-of-Care Testing
 - ❑ Infection Prevention during Blood Glucose Monitoring and Insulin Administration: <http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>
 - ❑ Frequently Asked Questions (FAQs) regarding Assisted Blood Glucose Monitoring and Insulin Administration: http://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html
- Resources to assist with evaluation and response to breaches in infection control
 - ❑ Patel PR, Srinivasan A, Perz JF. Developing a broader approach to management of infection control breaches in health care settings. Am J Infect Control. 2008 Dec;36(10);685-90
 - ❑ Steps for Evaluating an Infection Control Breach: http://www.cdc.gov/hai/outbreaks/steps_for_eval_IC_breach.html
 - ❑ Patient Notification Toolkit: <http://www.cdc.gov/injectionsafety/pntoolkit/index.html>
- Antibiotic Stewardship
 - ❑ Get Smart Programs & Observances: <http://www.cdc.gov/getsmart/>

