

# INFECTION CONTROL PLAN OUTLINE FOR AMBULATORY SURGICAL FACILITIES

*The Pennsylvania Department of Health, Healthcare Associated Infection Prevention (HAIP) Division is providing the following outline to guide the creation or modification of an ambulatory surgical facility's (ASF's) infection control (IC) plan. This outline highlights the information that should be included in the IC plan. Content should be used as appropriate, and tailored to be specific to the facility.*

## 1. Introductory Statement / Purpose

- a. The reason for the plan, why it is necessary, and what it is intended to accomplish. Background and importance of an infection control plan, as indicated by the Pennsylvania's [Medical Care Availability and Reduction of Error \(MCARE\) Act of March 20, 2002](#).

## 2. Scope

- a. The plan applies to the whole infection prevention & control (IP&C) program.
- b. All healthcare personnel (HCP) are responsible for adhering to the plan, policies, and processes regardless of their position.

## 3. Facility Introduction / Description

- a. Ownership
  - i. Whether facility is part of a structure, corporation, has a parent hospital
  - ii. Individual, partnership, association, or a combination thereof
- b. Population(s) served
- c. Characteristics of HCP
- d. Services provided
- e. Geographic area
- f. Building characteristics
  - i. If owned or rented
  - ii. Building age
  - iii. Number of beds, operating rooms (ORs), procedure rooms
  - iv. Room types (e.g., patient bays, consult room with closeable door, etc.)
  - v. Availability of airborne infection isolation rooms (or AIIRs)

## 4. Infection Prevention & Control Program

- a. Leadership support for and empowerment of IP&C program, committee, and IP(s)
- b. Program structure and reporting (e.g., administrative reporting, data reporting)
- c. Infection preventionist (IP) title, background, credentials, training (e.g., [AORN](#), [APIC](#)), duties
  - i. Documentation of training that qualifies them to lead the IP&C program.

- ii. [Certification in Infection Control \(CIC\)](#)
- d. IP Characteristics
  - i. Number of IPs
    - 1. If the IP is part-time or the person fulfilling the role of IP also has other roles, how many hours per week are devoted to the IP&C program?
  - e. Administrative or clerical support for the program (e.g., administrative assistant to print and distribute ICC meeting packets, posters, newsletters, etc.)
  - f. Support for data management, extraction, etc. (e.g., dedicated computer for IP surveillance data files, report generation, medical records access, etc.)
  - g. Other resources allocated to the program
    - i. IP workstation
    - ii. Software (e.g., Microsoft Office, Microsoft Teams)
    - iii. Journal access
    - iv. Fee and time for initial IP training (e.g., APIC)
    - v. Continuing education
    - vi. Membership with professional organizations
    - vii. Support for certification
  - h. IC plan is a comprehensive document with high-level details about program elements.
    - i. No policy and procedure manuals should be submitted.
  - i. Related IP&C Program Documents: The Risk Assessment, Policies, And Procedures
    - i. There are a few companion documents to the IC plan. These are independent documents, which are related to and referenced in the IC plan. They should be submitted to the Department for plan review as individual attachments. They include the risk assessment and IP&C program policies and procedures.
    - ii. All documents – *including the overall plan*:
      - 1. Must comply with MCARE Law, and federal & state regulations
      - 2. Must align with the core / basic elements of IP&C
      - 3. Must have approval, effective, revision dates.
      - 4. Must demonstrate formal approval by facility ICC.
      - 5. Must be signed by ICC signatory/signatories.
      - 6. Should have clear and specific document title names.
      - 7. Must be submitted in acceptable formats (i.e., Word, PDF, Excel, etc.) – no scanned documents.
      - 8. Should be organized and structured, with headers.
      - 9. Must identify, reference, and align with specific nationally recognized guidelines and evidence-based practices (e.g., [Association for the Health Care Environment](#) (AHE), [American National Standards Institute](#))

(ANSI)/[Association for the Advancement of Medical Instrumentation](#) (AAMI), [Association of periOperative Registered Nurses](#) (AORN), [Association for Professionals in Infection Control and Epidemiology](#) (APIC), [American Society of Heating, Refrigerating and Air-Conditioning Engineers](#) (ASHRAE), [Centers for Disease Control & Prevention](#) (CDC), [Healthcare Sterile Processing Association](#) (HSPA), [Infectious Diseases Society of America](#) (IDSA), [Society for Healthcare Epidemiology of America](#) (SHEA), [World Health Organization](#) (WHO), etc.).

10. Must be facility-specific

- a. Use of system plans or policies, if applicable – refer to the “Requirements for System Policy Submission” section of the “Infection Control Plan Submission Checklist”

11. Must be readily accessible to HCP (i.e., location where HCP can find these documents), including but not limited to:

- a. IC plan, risk assessment, and policies & procedures such as:
  - i. [Bloodborne pathogen](#) (BBP) exposure control plan/policy
  - ii. [Tuberculosis exposure control plan](#)/policy
  - iii. [Respiratory protection program plan](#)/policy
  - iv. Water management plan/policy
  - v. Surveillance plan/policy
- b. Manufacturer instructions for use (IFUs)
- iii. The IC plan and risk assessment are updated annually or sooner if needed.
- iv. Policies and procedures are updated annually or sooner if needed.
- v. Infection Prevention & Control Risk Assessment
  1. A risk assessment should be submitted along with the IC plan as an individual document, and there should be high-level details about the risk assessment in the plan.
    - a. Should include [specific, measurable, achievable, relevant, time-bound, goals](#) that are informed by the risk assessment
  2. Different from gap analysis, emergency preparedness [all-hazard](#) self-assessment, [infection control assessment and response](#) (ICAR) tool, [ICRA for construction](#), rounds checklists
  3. Responsible persons (e.g., IP in collaboration with infection control committee)
  4. Done annually, using:
    - a. Healthcare-associated infection (HAI) data
    - b. [State](#) and [national](#) HAI reports
    - c. Service registries
    - d. Data from accreditation bodies

- e. Data from similar healthcare facilities
  - f. Emerging diseases
  - g. Changes in community risks/problems, population(s), service line(s)
  - h. Regulatory / legal changes
  - i. Leadership / quality / regulatory / payor priorities and concerns
5. Process should consider potential risks to the following:
- a. Community (e.g., geography, rural/urban, weather, natural disasters, etc.)
  - b. Population served (e.g., age (geriatric/pediatric), characteristics, behaviors, health statistics, high risk, [multidrug-resistant organism](#) (MDRO) prevalence, etc.)
  - c. Facility (e.g., environment, structure, surfaces, age of utilities, OR high-efficiency particulate air (HEPA) filtration, multi-service building with shared systems, etc.)
  - d. Staff competency (e.g., processes or competency programs for cleaning, high-level disinfection (HLD), sterilization, etc.)
  - e. Services offered (e.g., treatments, procedure types (total joints/cardiovascular), invasive device placement/utilization, robotic surgery, low- or high-volume procedures, etc.)
  - f. [Staff immunity](#) (e.g., new hire health screening, communicable diseases immunization status, vaccine programs for influenza/COVID-19, etc.)
  - g. Patient care/Infection control practice compliance (e.g., hand hygiene; personal protective equipment (PPE); not isolating for MDROs; environmental cleaning & disinfection; injection/medication preparation, etc.)
  - h. Medical devices (e.g., selection, introduction and training, reuse of single-use items, devices with water reservoirs, handling & storage, cleaning, HLD, disinfection & sterilization requirements, etc.)
  - i. Facility type (e.g., orthopedic surgery center, pediatric dental surgery center, endoscopy center)
  - j. Patient safety (e.g., healthcare-associated infection trends, perioperative and day-of-procedure screening for signs & symptoms of infection, requirement for self-care or defined care provider, post-op, etc.)
6. Risks are listed and ranked according to criteria (e.g., probability, severity (should the risk occur), impact (to the patient or facility), facility preparedness to address the issues (should they arise)) and then scored accordingly utilizing a tool that permits this functionality. Highest-scored risks have associated SMARTIE goals in the plan (updated annually)
7. Inclusion of associated priorities in the IC plan

- vi. Policies and procedures provide a greater amount of detail than the plan. They help to provide evidence of plan implementation by outlining specific organizational rules, methods, strategies, processes, and steps to implement the plan.

## 5. Authority

- a. Describe the organized governing body (e.g., board of directors of ASF, hospital, corporation, etc.) or designated person, who has authority and responsibility for the program.
- b. Consideration should be given to facility bylaws, as this will determine how authority is delegated (e.g., from the medical executive committee, governing body, administrator, etc.)
- c. [Authority for oversight of the program should be given to the multidisciplinary infection control committee](#) (ICC).
- d. [Authority for the development, implementation, monitoring, and enforcement of the program should be given to the infection preventionist](#) (IP).

## 6. Multidisciplinary / Infection Control Committee

- a. Relationship with other committees (e.g., [quality assurance & performance improvement](#) (QAPI), patient safety, etc.)
- b. Identification of chair (and co-chair, where applicable) and their qualifications
- c. Membership: Consider including the title / position of the member and not their name. Should ideally include frontline HCP, in addition to leadership.
  - i. Medical staff: Could include the chief medical officer (CMO), medical director, infectious disease physician, or surgeon.
  - ii. Administration: Could include the chief executive officer (CEO), chief financial officer (CFO), chief nursing officer (CNO), director of nursing (DON), facility administrator, comptroller, or other members of the c-suite.
  - iii. Lab services: Could include the lab director, lab personnel, lab consultant (e.g., contracted lab director, supervisor, or microbiologist).
  - iv. Nursing staff: Could include the director of nursing (DON) if not filling the role of administration, nursing manager/supervisor, or staff nurse.
  - v. Pharmacy staff: Could include the pharmacy director, clinical pharmacist, or pharmacy consultant.
  - vi. Physical plant staff: Could include the facilities director, maintenance supervisor, heating, ventilation, and air conditioning (HVAC) technician, or physical plant consultant (e.g., contracted pharmacist, pharmacy tech, or director of pharmacy).
  - vii. Patient safety officer
    1. PSO can only serve exclusively as the PSO for ICC purposes (knowing that they may also hold another title for the facility).
  - viii. Infection control: Should include the facility IP (i.e., and not just a consultant). Could include the infectious disease (ID) physician, epidemiologist, IP, or infection control consultant.

ix. Community member

1. Cannot be an agent, employee, or contractor of the health care facility

d. What constitutes a quorum?

e. Meeting frequency (must be at least quarterly)

- f. Duties of the committee (e.g., approving the infection control plan, risk assessment, policies; reviewing HAI and process surveillance; recommending and carrying out quality improvement activities and establishing subcommittees – for example, to evaluate new medical devices/supplies, hand hygiene compliance, etc.)

**7. Evidence-Based Strategies to Detect, Control, and Prevent Healthcare-Associated Infections**

- a. Consider breaking out into sections devoted to detection, control, and prevention (understanding that there can be some overlap)

b. Detection

i. Patient Screening

1. Use of screening checklists and written scripts by trained persons with screening duties
2. A means to identify (e.g., pre-operative phone call; assessment at time of admission) patients with:
  - a. Current signs or symptoms of infection
  - b. Current, history of, or recent exposure to a communicable disease (e.g., chickenpox, COVID-19, TB)
  - c. Current or history of colonization or infection with MDRO (e.g., [Candida auris](#) (*C. auris*), [Clostridioides difficile](#) (*C. diff*), [carbapenem-resistant Enterobacteriales](#) (CRE), [extended-spectrum beta-lactamases](#) (ESBL), [methicillin-resistant Staphylococcus aureus](#) (MRSA), [vancomycin-resistant Enterococci](#) (VRE), etc.)
  - d. Other infection control risks (e.g., transfer from another hospital or skilled nursing facility (SNF); recent prolonged hospital or intensive care unit (ICU) stay; transplant, dialysis, or immunocompromised patient; travel or healthcare received outside of the US; history of incarceration; intravenous (IV) drug use, etc.).
    - i. If identified, what is the mechanism for communicating this to other HCP (e.g., flag in an electronic medical record or paper chart, verbal report, etc.)?
    - ii. If identified, any other triggers that occur (e.g., order generated for a MRSA swab, order for [Transmission-Based Precautions](#), cancellation of nonemergent procedure, etc.)
3. Process and authority for the IP/DON to cancel/reschedule cases in collaboration with Medical Director, as needed.

4. Communication of lab results requiring initiation of Transmission-Based Precautions (TBPs)
- ii. Screening of Healthcare Personnel (HCP)
  1. [Employee Health](#)
    - a. Screening of new HCP
      - i. [Immunity status](#) (e.g., hepatitis B; measles, mumps, rubella (MMR); tetanus, diphtheria, and pertussis (Tdap); varicella titers, etc.)
      - ii. Vaccination history (e.g., coronavirus disease 2019 (COVID-19), influenza, etc.)
      - iii. Risk assessment for [tuberculosis](#) (TB)
      - iv. Assessment, exposure to other communicable diseases
    - b. Annual TB screening questionnaire
  2. A means to identify and notify HCP (e.g., staff, providers, contractors, students, volunteers) with current or recent exposure to a communicable disease (e.g., when receive a significant positive micro result, such as TB or *Neisseria meningitidis*)
  3. Education of HCP to report community exposure to communicable conditions as soon as known
  4. Means to detect and manage HCPs with conditions such as skin lesions on the hands, which may impact ability to perform hand hygiene, adhere to [Standard Precautions](#), etc.
  5. Established criteria for defining what constitutes a communicable disease exposure
  6. Work restrictions / exclusions for HCP who screen positive or meet criteria (e.g., in an exposure)
- iii. Surveillance
  1. Surveillance plan and methodology
    - a. Responsible person(s) and training (e.g., [National Healthcare Safety Network](#) (NHSN), [PA-Patient Safety Reporting System](#) (PA-PSRS))
      - i. Training upon hire and annually (e.g., NHSN [Outpatient Procedure Component](#) (OPC), NHSN [Patient Safety Component](#) (PSC), PA-PSRS [Acute Care User Manual](#), etc.)
      - ii. Consistent application of surveillance versus clinical criteria.
        1. [IP to determine if event meets surveillance criteria and report events meeting criteria, even if provider disagrees \(e.g., since patient is not diagnosed with a clinical infection\).](#)

- b. Surveillance technologies and software – electronic surveillance system (e.g., data mining software, video surveillance), if available.
  - i. Manual data collection, if not
- c. HAI surveillance
  - i. Process for and means to review data and identify HAIs
    - 1. Methods and processes to follow an NHSN operative procedure and capture signs and symptoms of a surgical site infection (SSI) event after discharge from the facility, for the duration of the surveillance period (e.g., from the procedure date through 30 or 90 days, depending upon the procedure category)
    - 2. Methods and processes to identify infections other than the NHSN operative procedures identified in 7.b.iii.3.c.i.1 immediately above.
  - ii. [Continuous](#) monitoring of all HAIs for all services, procedures, infections, etc.
  - iii. Data sources
    - 1. Laboratory tests
    - 2. Radiology / imaging
    - 3. Antibiotic starts
    - 4. Readmissions
    - 5. Reports received from other ASFs or hospital IPs
    - 6. Post-discharge calls or surveys
    - 7. Patient self-reporting
    - 8. Surgeon letters, attestations, and line lists (e.g., [for physicians to report SSIs](#))
    - 9. Letters to outpatient surgery cases
    - 10. Environmental / unit rounds
  - d. A means to identify clusters of infection, or outbreaks
  - e. Surveillance related to [IC breaches](#)
  - f. MDRO surveillance
  - g. Accessibility of the surveillance plan by HCPs (i.e., location, education)
- iv. Reporting
  - 1. Describe the process to ensure that reporting is compliant with MCARE requirements.
    - a. All HAIs are deemed serious events, which must be reported within [24 hours](#) of occurrence, discovery, or confirmation.

- i. Not just SSIs (e.g., includes post-operative pneumonias; IV site infections; bloodstream infections (BSIs) following insertion of a central line, port, dialysis catheter; urinary tract infections (UTIs), etc.)
- b. Patients (and/or family, guardian, durable power of attorney (POA) as appropriate) must receive written notification of serious events within 7 days of occurrence, discovery, or confirmation.
- c. External reporting to the Department of Health (DOH), NHSN, PA-NEDSS, and PA-PSRS as appropriate
  - i. All ASFs must report all HAIs as serious events into PA-PSRS.
    1. Responsible person(s) and training (e.g., NHSN Outpatient Procedure Component, PA-PSRS for Acute Care Facilities)
    2. *For ASFs sharing a CMS Certification Number (CCN) with a parent hospital:* HAIs meeting NHSN Patient Safety Component criteria are reported into NHSN (i.e., in addition to PA-PSRS):
      - a. Responsible person(s) and training (i.e., NHSN)
      - b. Hospital outpatient departments (or HOPDs) should be mapped to standard CDC location descriptions for the parent hospital's NHSN OrgID using the Patient Safety Component manual - even if at a different geographical location and / or an entire building. NHSN considers these ASFs a department/location of the NHSN-enrolled hospital. Therefore, the ASF must be added as a location of the hospital and mapped, per Chapter 15 of the NSHN PSC Manual.
    3. Process / IC breaches in practice resulting in possible BBP exposure must be reported into PSRS and to PA DOH by calling 877-PA-HEALTH (or local health department if applicable).
      - a. Sterilizer failures
      - b. Drug diversion
      - c. Shared [glucometers](#) which are not handled, cleaned, or disinfected according to manufacturer IFUs and [nationally recognized guidelines](#)
  - ii. [Reportable diseases](#) are reported into the PA DOH [PA National Electronic Disease Surveillance System](#) (PA-NEDSS).
    1. Responsible persons and training (i.e., PA-NEDSS)

2. Notification of patient(s) (and/or family, guardian, durable POA as appropriate) and DOH
  3. Investigation of possible HCP or patient exposures
- d. Internal reporting
- i. Process for IPs to analyze and report data to ICC, up through QAPI, medical executive committee (MEC), and governing body
  - ii. Data dissemination to providers, managers, other HCP as needed (along with targets, actions for performance improvement, etc.)
- c. Prevention
- i. [Standard Precautions](#)
    1. Not equivalent to [Universal Precautions](#). Combines elements of Universal Precautions and Body Substance Isolation.
    2. All [elements](#) are referenced in the plan.
    3. [Hand hygiene](#)
      - a. Guidelines are followed (i.e., [CDC](#) or [WHO](#)).
      - b. Moments of hand hygiene / hand hygiene opportunities
      - c. Availability of alcohol-based hand rub (ABHR) and hand washing sinks
      - d. Education of HCP on the elements of hand hygiene upon hire, annually, and if changes / as needed
      - e. While an element of Standard Precautions, this major component should have its own section.
      - f. ABHR is the [preferred form of hand hygiene for most clinical situations](#).
        - i. Before touching a patient
        - ii. Before an aseptic task or procedure (e.g., placing an indwelling device) or when handling an invasive medical device
        - iii. Before moving from a soiled to a clean body site on the same patient
        - iv. After touching a patient
        - v. After touching a patient's immediate environment or surroundings
        - vi. After contact with blood, other potentially infectious material (OPIM), or contaminated surfaces
        - vii. After removing gloves
      - g. Soap & water should be used:
        - i. When hands are soiled (e.g., visible contamination with blood or OPIM)

- ii. For known or suspected *C. diff* diarrhea or norovirus, if determined by a multidisciplinary committee
  - iii. Before eating, preparing, or handling food
  - iv. Before and after using the restroom
  - h. Nail care
    - i. Artificial nails not permitted
      - 1. CDC Guidelines: if caring for patients at high risk.
      - 2. WHO Guidelines: all HCP
      - 3. In the perioperative setting
    - ii. Natural nail tip length:
      - 1. AORN Guidelines:  $\leq 2$  mm
      - 2. CDC Guidelines:  $< \frac{1}{4}$ "
  - i. Surgical hand antisepsis, if surgical procedure
    - i. No brush use for surgical hand rub/scrub
  - j. Lotion compatible with hand hygiene products
  - k. Hand hygiene [audits](#), with responsible persons, training, audit frequency, and immediate feedback given
  - l. Data reported back to ICC and disseminated to providers, managers, other HCP as needed (along with targets, actions for performance improvement, etc.)
4. PPE
- a. Availability of PPE
  - b. Education of HCP about PPE availability, [risk assessment](#), [donning and doffing](#), etc.
  - c. PPE adherence audits, with responsible persons, training, audit frequency, and immediate feedback given.
    - i. Data reported back to ICC and disseminated to providers, managers, and other HCP as needed (along with targets, actions for performance improvement, etc.)
  - d. Respiratory protection plan
    - i. Responsible person(s) and training
    - ii. Education on respirator use upon hire, annually, and as needed / if changes
    - iii. Medical clearance for respirator use
    - iv. Fit testing upon hire, annually, and as needed / if changes
      - 1. Alternative respirators (e.g., powered air purifying respirators (PAPRs))

- v. Accessibility of the respiratory protection plan (i.e., location)
5. [Respiratory hygiene / cough etiquette](#)
  - a. Education of patients, HCP, family, visitors
  - b. Availability of supplies (e.g., wastebaskets, masks, facial tissues, etc.)
  - c. Communication (e.g., signage at facility entrances, on units, etc.)
6. [Sharps safety](#) and [safe injection](#) practices
  - a. Needles and syringes are used for only one patient.
  - b. Rubber septums on medication vials are disinfected with alcohol prior to piercing.
  - c. Medications are entered with a new needle and new syringe, even while obtaining additional doses for the same patient.
  - d. Medication administration tubing and connectors are used for only one patient.
  - e. Multidose vials to be used on more than one patient do not enter the immediate patient treatment area.
  - f. Preparation of injections as close as possible to the time of administration to the patient (e.g., medications are drawn up immediately prior to / during each case, as opposed to pre-filling multiple syringes for multiple cases).
7. [Use of masks for injections into spinal / epidural spaces and lumbar punctures](#)
8. Handling of potentially contaminated equipment
  - a. [Cleaning and disinfection of patient-care items \(e.g., blood pressure \(BP\) cuffs, bedside commodes \(BSCs\), pumps, glucometers\)](#)
    - i. Frequency
    - ii. Responsible person(s) – who cleans what, and how they know (e.g., cleaning schedule)
    - iii. Education of HCP on manufacturer IFUs, use of appropriate hospital- and ICC-approved, [US Environmental Protection Agency \(EPA\)-registered disinfectant](#) (e.g., per EPA list), dwell time, PPE, etc.
    - iv. Competencies / validation and monitoring of cleaning practices
  - b. Labeling and disposing of regulated medical waste, hazardous materials
  - c. Soiled linens
9. [Cleaning and disinfection of the environment](#)
  - a. High-touch surfaces, congregate areas, OR / procedure rooms, etc.
  - b. [Frequency](#)

- c. Responsible person(s) – who cleans what, and how they know (e.g., cleaning schedule) – and training
  - i. Environmental services (EVS).
    - 1. In-house vs. contract service
    - 2. Credentialing (e.g., [Certified Healthcare Environmental Services Professional](#) (CHESP), [Certified Healthcare Environmental Services Technician](#) (CHEST))
  - d. Cleaning audits: responsible person, audit frequency, subjective / objective (i.e., visual observation vs. [objective monitoring](#) – fluorescent gel, adenosine triphosphate (ATP), culture, etc.), and immediate feedback given.
    - i. Data reported back to ICC and disseminated to EVS, providers, managers, and other HCP as needed (along with targets, actions for performance improvement, etc.).
- ii. Storage of Supplies and Equipment
  - 1. Means to identify
    - a. Clean vs. dirty
    - b. Clean vs. sterile
      - i. Frequently accessed clean supplies are stored separately from sterile supplies.
      - ii. Sterile supply
        - 1. Monitoring (e.g., temperature, humidity, air flow)
        - 2. Event-related sterility
          - a. Packaging inspected for moisture, tears, damage, integrity of package and seals
          - b. Rotation on shelf (first in, first out (FIFO))
        - 3. Traffic minimization (e.g., restricted access)
- iii. Sterile Processing (SP)
  - 1. Alignment with March 2022 revised ANSI/AAMI [ST91:2021, Flexible and Semi-Rigid Endoscope Processing in Health Care Facilities](#).
  - 2. Responsible person(s)
    - a. In-house vs. contract service
    - b. Credentialing and certification of technicians, endoscope reprocessors, instrument specialists, etc.
    - c. Competencies / validation (even if contracted service)
  - 3. Any transport (e.g., between buildings, campuses, etc.)

- a. Method (e.g., labeled, color-coded, nonporous, leakproof, rigid, puncture-resistant container; separation of clean / sterile and contaminated; cart, vehicular transport)
- b. Means to:
  - i. Maintain container / package integrity
  - ii. Monitor and maintain temperature / humidity within controlled conditions
4. Identify whether the facility reprocesses [single-use devices](#).
  - a. If done: internal policies and processes to request and evaluate a single-use device for reprocessing
  - b. Selection of US Food and Drug Administration (FDA)-registered, third-party reprocessor
  - c. Validated through documentation review, visit to the facility, and inspection of items prior to use.
5. Physical design
  - a. Unidirectional flow from dirty → clean
  - b. Two-room design to separate manual cleaning from disinfection / sterilization process as preferred
  - c. Three sinks preferred
    - i. Minimum of two sinks – or one sink with two separate basins
      1. Leak testing and manual cleaning
      2. Rinsing
  - d. Designated drying area
  - e. Physically separate area for endoscope storage (not in reprocessing space)
  - f. Restricted access, location pickup/drop-off
6. Monitoring (e.g., temperature, humidity, air flow)
7. [Water usage](#) in SP (e.g., distilled, sterile, critical water per IFUs and nationally recognized guidelines)
8. Accessibility of manufacturer IFUs (i.e., location)
9. [Spaulding Classification](#) (i.e., non-critical, semi-critical, critical)
10. Identification of reprocessing methods and equipment used
  - a. Point-of-use treatment (i.e., instruments kept moist so bioburden will not harden)
  - b. Delayed reprocessing protocols (i.e., extended soak for endoscopes not meeting time requirements)
  - c. Leak testing equipment

- d. Manual / automated cleaning (e.g., automatic endoscope reprocessors (AERs), washers/disinfectors, ultrasonic cleaners, etc.) with automated as supplement to manual
- e. Enhanced visual inspection and cleaning verification
  - i. Lighted magnification preferred
  - ii. Cleaning verification – high-risk endoscopes after each use
  - iii. Borescopic inspection (e.g., channels, distal tip, valve openings using borescope)
- f. High-level disinfection (e.g., endoscopes; ultrasound probes; respiratory and anesthesia equipment; laryngoscope blades, handles; laryngoscope mask airways (LMAs); specula; etc.)
  - i. Specialty HLD units (e.g., Trophon, TD 100)
  - ii. Identify what endoscopes are used and reprocessed at the facility.
    - 1. Endoscopes should be sterilized – if not possible, then HLD.
- g. Drying (e.g., of scopes prior to storage or reuse, using instrument air or a minimum of HEPA-filtered air)
- h. Sterilization (e.g., steam sterilization, chemical sterilants, vaporized hydrogen peroxide, etc.)
- i. Storage (i.e., internal channel drying cabinets preferred for endoscopes; or at a minimum, conventional cabinets with HEPA air; see Section [7.c.ii.1.b.ii](#) for sterile storage)
  - i. Multidisciplinary risk assessment regarding endoscope “hang time”
  - ii. Visual cue that item is “patient-ready”

#### 11. Quality assurance

- a. See Section [7.c.iii.10](#) for enhanced visual inspection, cleaning verification, drying verification.
- b. Mechanical monitoring of sterilization (e.g., using gauges, digital readings, printouts, etc.) for:
  - i. Time
  - ii. Temperature
  - iii. Pressure
  - iv. Humidity
  - v. Sterilizer concentration
- c. Internal / external chemical indicator (CI) for specific sterilization method with each package (including placement, type/class)

- d. Biological indicator (BI) for specific sterilization method – at a minimum, weekly and with implant loads (including placement, type/class)
- e. Bowie-Dick air-removal test for dynamic air-removal steam sterilizer cycle
  - i. Used for routine testing, each day the sterilizer is in operation
  - ii. Used for qualification testing:
    - 1. When sterilizer is first installed
    - 2. Any time sterilizer is moved
    - 3. Following a major sterilizer repair
- f. Daily quality control testing for endoscopic leak testing (i.e., to ensure adequate pressure output, so leaks are not missed)
- g. Documentation of time point-of-use treatment has been performed
- h. Testing of HLDs (e.g., for appropriate concentration, continued efficacy)
- i. Management of “high-risk” endoscopes (difficult to reprocess, most often associated with outbreaks, any other deemed by facility to be high-risk – e.g., used on transplant patients)
  - i. Risk assessment: high-risk scopes prioritized
- j. Load documentation
  - i. Sterilizer number
  - ii. Load number
  - iii. Operator ID / number
  - iv. Load contents
  - v. Exposure time and temperature (if not on sterilizer tape)
  - vi. Lot numbers and biological testing and control results
  - vii. Bowie-Dick test results, if applicable
  - viii. Response of the CI placed in the process challenge device (PCD), if applicable
  - ix. Reports of any inconclusive or nonresponsive CIs found later
- k. Process for sterilization failures (e.g., indicator, parameters not met, load failures, etc.)
  - i. Tracking of instruments
  - ii. Quarantine / recall of instruments
  - iii. Removal of sterilizer from use
  - iv. Investigation of cause
  - v. Notification of stakeholders
  - vi. Testing of sterilizers before return to use



3. Medication, bone / tissue, patient nutrition refrigerators and freezers
4. Policies and processes for managing construction
  - a. Construction planning, meetings
  - b. Infection control risk assessments for construction
  - c. Construction rounding
5. Pest control
- v. [SSI Prevention](#)
  1. Begins pre-operatively
    - a. Discussion of procedure with patient
    - b. Patient and family educated pre-operatively (see Section [7.viii.1](#))
    - c. Patient bathing (i.e., chlorhexidine gluconate (CHG) bathing, wipes), nasal decolonization
    - d. Pre-operative skin prep (e.g., hair removal, skin antiseptics)
  2. Perioperative
    - a. HCP hair coverage and hand hygiene (see Section [7.c.i.3.i](#))
    - b. Glucose management
    - c. Patient normothermia
    - d. Traffic control
- vi. [Linen Management](#)
  1. Use of Healthcare Laundry Accreditation Council (HLAC)-accredited laundry management contractors
    - a. Validated through review of documentation and visit to the facility
  2. Provision of surgical scrubs
  3. Storage and transport of clean, soiled linens
  4. Handling of clean, soiled linens
- vii. Personnel Practices
  1. Attire
  2. Jewelry
  3. Leave policies for HCP illness
- viii. Education
  1. [Education of patients, family, care providers, other visitors](#) begins preoperatively (i.e., for better understanding, retention, assessment of learning deficits, etc.)
    - a. Good hygiene and oral care practices pre- and postoperatively
      - i. Respiratory hygiene / cough etiquette
    - b. Nutrition that promotes wound healing

- i. Nutritional assessment
    - c. Glucose control
    - d. Smoking cessation
    - e. Patient hand hygiene
    - f. Preoperative bathing – including CHG bathing, if applicable
    - g. Post-operative care
      - i. Wound care (e.g., monitoring wound, stages of normal wound healing, etc.)
      - ii. Device care
      - iii. Signs and symptoms of infection
        1. When to notify provider and ASF
        2. Situations requiring an emergent office visit or visit to an emergency department (ED) (e.g., when surgeon is unavailable – wound dehiscence, high fever, nausea / vomiting, chills, redness / swelling at the site, etc.)
      - h. Disease acquisition and transmission
    2. Postoperative educational reinforcement of above concepts. Referrals to home care as appropriate.
    3. [Mandatory education for HCP \(including providers, contractors, vendors, students, and volunteers\)](#)
      - a. Upon hire (i.e., prior to providing patient care), annually, and as needed / if changes
      - b. On IP&C topics
        - i. Disease acquisition and transmission
        - ii. Employee health
        - iii. Standard Precautions (e.g., hand hygiene, PPE, etc.)
        - iv. BBPs and TB
        - v. Transmission-Based Precautions (TBPs)
        - vi. Cleaning, disinfection, sterilization
        - vii. Contents and location of IC plan
      - c. Competencies / validation
- ix. [Antimicrobial Stewardship](#)
  1. Antimicrobial stewardship program
  2. Antimicrobial stewardship committee
  3. Leadership commitment
  4. Education of HCP

5. Guidelines followed (e.g., [American Society of Health-System Pharmacists \(ASHP\)](#)/[IDSA](#)/[Surgical Infection Society \(SIS\)](#)/[SHEA](#), specialty-specific)
6. Antibiogram
7. MDRO surveillance (see Section [7.b.iii.1.fb.iii.1.f](#))
8. Intravenous (IV) to *per os* (PO) protocols
9. Pharmacy monitoring / auditing of antimicrobial utilization
10. Reporting of antibiotic use and resistance (e.g., to leadership, providers, nursing)

d. Control

i. [Transmission-Based Precautions](#)

1. Building characteristics (i.e., patient bays, consult rooms with closeable doors, availability of AIIRs, etc.)
2. Immediate patient placement in private location when need identified or until evaluated by IP / DON / physician (e.g., new onset of infectious process, failed COVID-19 screening)
3. Cohorting practices when private rooms are not available
4. Basic information on types (i.e., [Airborne](#), [Droplet](#), [Contact](#))
5. Indications for TBPs
6. Authority to initiate, discontinue TBPs
7. Communication (e.g., when transfer within or between facilities) and signage
  - a. Use of flags and signage to alert HCP
  - b. Verbal report
  - c. Written, standardized interfacility [infection control transfer forms](#)
8. How patients requiring [Airborne Precautions](#) (e.g., for suspected or confirmed chickenpox, TB, etc.) are managed if AIIR or private room with door unavailable
9. Education of HCP
10. Auditing of compliance: responsible person(s), training, audit frequency with immediately feedback given
  - a. Reporting of data back to ICC
  - b. Data dissemination to providers, managers, other HCP as needed (along with targets, actions for performance improvement, etc.)

ii. BBP Exposure Control Plan

1. Engineering Controls
  - a. Sharps safety devices (e.g., safer medical devices, self-sheathing needles)

- i. HCP using sharps safety devices participate in their evaluation and selection
    - b. Sharps disposal containers (e.g., labeled, color-coded, leakproof, rigid) availability and replacement when  $\frac{3}{4}$  full
  2. Work Practice Controls
    - a. No smoking, eating, drinking
    - b. No applying cosmetics / lip balm
    - c. No handling contact lenses
    - d. No food / beverages in refrigerators or other areas where blood or OPIM are present
    - e. No recapping, bending, or breaking of needles
    - f. No pipetting
    - g. Neutral zones in OR – no passing of sharps
    - h. Immediately place used sharps in a sharps disposal container.
  3. BBP exposure follow-up protocols
    - a. In the event of a BBP exposure
      - i. Staffing support
      - ii. First aid
      - iii. Who to contact
      - iv. What to do / steps to take
      - v. Availability of post-exposure prophylaxis as soon as possible (i.e., within [2 hours](#)), if indicated for the exposure
      - vi. Testing of source, exposed HCP
      - vii. Availability of hepatitis B vaccine and hepatitis B immunoglobulin (HBIG), if indicated for the exposure
      - viii. Additional follow-up, as appropriate
      - ix. Investigation of cause(s), reeducation as needed, process changes as indicated
    4. Cleaning and disinfection of blood spills and OPIM
    5. Education of HCP upon hire, annually, and as needed / if changes
    6. Accessibility of BBP exposure control plan (i.e., location)
    7. Monitoring of sharps injuries, needlesticks
      - a. Reporting of data back to ICC
      - b. Data usage to assist with product selection, risk mitigation
  - iii. [Outbreak Investigation](#)
    1. Policies and procedures describing how HCP will recognize an outbreak

2. Steps taken by HCP in the event that an outbreak is suspected or detected
  3. Identification of person(s) who will lead the investigation, verification of diagnosis, case finding, characterization of cases (e.g., person, place, time), hypothesis formulation, testing (e.g., point prevalence)
  - iv. Breaches in IC Practice
    1. Identification of breaches in IC practice
    2. Investigation of IC practice breaches
    3. Notification of patients (and/or family, guardian, durable POA as appropriate), providers, agencies as appropriate
  - v. TB Exposure Control Plan
    1. Employee health (see Section [7.b.ii.1](#))
    2. Aligns with current CDC recommendations
      - a. Treatment of latent TB in new converters and those never treated in the past
    3. Education of HCP upon hire, annually, and as needed / if changes
    4. Accessibility of TB exposure control plan (i.e., location)
    5. TB monitoring (e.g., TB conversions)
      - a. Reporting of data back to ICC
  - vi. Communicable Disease Exposure Management
    1. Notification
    2. Availability of prophylaxis and process for distribution
    3. Process for HCP exposures (see Section [7.b.ii.2](#))
  - vii. HCP MDRO Exposure Management
    1. Following evidence-based CDC and OSHA guidelines for the evaluation and management of unprotected exposures (if follow-up care or testing is warranted)
    2. Emphasis on investigation of causes, documentation, reporting, QI
8. **Compliance Monitoring**
- a. Targeted priorities (e.g., hand hygiene, PPE, TBPs, cleaning, sterilization, etc.)
  - b. Responsible person(s) and training
  - c. Enforcement of compliance
    - i. Disciplinary process up to and including termination for addressing ongoing noncompliance
  - d. Environment of care monitoring
  - e. Monitoring of work practice safety
  - f. Rounding with immediate feedback given
  - g. Data summary and analysis

- i. Data to inform annual risk assessment and quality improvement activities
  - h. Reporting of data back to ICC
  - i. Data dissemination to providers, managers, other HCP as needed (along with targets, actions for performance improvement, etc.)
9. **Quality Assurance and Performance Improvement (QAPI)**
- a. Assist with development and review of policies, procedures
  - b. Review of data summaries and analysis
  - c. Creation, implementation, and usage of improvement activities, plans, tools, bundles, etc.
10. **Distribution of DOH advisories and PA Patient Safety Authority's Patient Safety Journal**
- a. Evidence of distribution of DOH advisories and PA Patient Safety Authority's rolling online journal articles/advisories and the annual print/digital Patient Safety Journal to HCP (location, method of distribution).

This outline was created by the Pennsylvania Department of Health (Department), Bureau of Epidemiology Healthcare Associated Infection Prevention (HAIP) Division for PA healthcare facilities to reference as they develop their infection control plans for submission to the Department. The Department respectfully requests that prior to using this document or its content in any manner for other purposes, such as by other entities, that written permission be given by the Department: [RA-DHHA1@pa.gov](mailto:RA-DHHA1@pa.gov).