Sterile Processing Department Area Tracer

1. Review all Human Resource Department file expectations
   1. Personnel file expectations
   2. Personnel attire monitoring form
2. Review all logs kept in the department:
3. Perform inspections of Physical room included in the department
4. Review the following Patient care / department process tracer question / answer guide

Department File Expectations and Document Retention Guidelines

**Practice issue:** the manager should be able to produce these records within 15 minutes.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Record** | **Retention Period** | **Comments** |
| Mandatory | Current Primary source Verification of all required Licensure, Registration or Certification as per the job description | Most recent | These records are also mandatory for contract / agency / traveling staff |
| Initial Department orientation checklist | Keep permanently |
| Initial competency assessment [[1]](#footnote-1) (orientation skills checklist / flowsheet / record of completion) | Keep permanently |
| Any Performance Improvement Plans / Corrective Action notifications | Keep permanently | Not applicable |
| Optional | Resume obtained upon hire | If available |  |
| Keep hard copy in file if electronic records are not readily accessible | Current job description (only keep a copy in the file if it is not accessible online via intranet) |  |  |
| Annual Competency Validation  (not applicable for new-hires) | Keep permanently |  |
| Recent Mandatory education records [[2]](#footnote-2) | Keep permanently | Active CPR card is mandatory [[3]](#footnote-3) |
| Current job description | Keep permanently |  |
| Performance evaluations [[4]](#footnote-4) | Ensure ability to review if requested |  |

**Important point:** Files found to have missing orientation / competency checklists

All employees hired into positions in perioperative departments complete a department orientation, as evidenced by an orientation / competency checklist that is signed by the designated party responsible for ascertaining competence.

Unfortunately, due to instances of department relocations over a period of years, some longer-term employee files may be accidentally misplaced or destroyed. In instances where employees are missing their initial orientation / competency checklist, the following steps should be taken by department leadership:

1. Obtain the latest copy of the new employee orientation /competency checklist.
2. The contents should be reviewed by both the employee and the designated educator / leaders responsible for competency assessment.
3. Both the employee and leader should sign the document sections acknowledging competence, dating the document with the current date.
   1. Do NOT back-date the document to the employee’s date-of-hire.
4. If the employee’s position is involved in performance of procedural cases, include a case list report showing cases performed by the employee during the past fiscal year.
5. Retain this document in the department employee file along with the other mandatory employee records.

Attire Review:

Important! Review policy to become acquainted with expectations! Place tick marks per observations

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Expectation:** | **OR / Procedure area** | | **SPD** | | **Pre-Op & PACU** | |
| **Hair covering appropriate?** | **YES** | **YES** | **YES** | **NO** | **YES** | **NO** |
| **Earrings covered** | **YES** | **YES** | **YES** | **NO** | **YES** | **NO** |
| **Eyewear as needed?** | **YES** | **YES** | **YES** | **NO** | **YES** | **NO** |
| **Mask adorned appropriately?** | **YES** | **YES** | **YES** | **NO** | **YES** | **NO** |
| **Scrub attire appropriate?** | **YES** | **YES** | **YES** | **NO** | **YES** | **NO** |
| **Fingernails appropriate** | **YES** | **YES** | **YES** | **NO** | **YES** | **NO** |
| **Shoes coverings used as necessary?** | **YES** | **YES** | **YES** | **NO** | **YES** | **NO** |

Notes:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Review all logs kept in the department:

|  |  |  |  |
| --- | --- | --- | --- |
| **Log** | **Question** | **Answers** | **Findings** |
| Autoclave Steam Sterilizers | Daily Biological Indicator test | Bowie Dick test done before the sterilizer is used for the day | **Y/N** |
| Individual load testing | Biological indicator test done on each load sterilized | **Y/N** |
| Biological Indicator validation test | Test done to ensure the BI used in individual loads are valid | **Y/N** |
| Leak test | Test done weekly | **Y/N** |
| Low temperature sterilizers  (STERRAD, VPro) | Individual load testing | Biological indicator test | **Y/N** |
| Biological Indicator validation test | Test done to ensure the BI used in individual loads are valid | **Y/N** |
| High level disinfectors | Individual load testing | Test strip indicators done on each load sterilized | **Y/N** |
| Test strip validation | Test strips are checked for validation for use | **Y/N** |
| Cart washers | TOSI test | Done on each washer daily | **Y/N** |
| Ultrasonic washers | Cleaning indicator daily test | Test done daily to ensure cleaning efficacy | **Y/N** |
| Decontamination sink; Enzymatic Dosing system (AccusInQ) | Daily testing | TO include detergent dose and water temperature | **Y/N** |
| Endoscope flushing system (Scope Buddy) | Daily testing performed? | Flow validation test is to be done each day before use | **Y/N** |
| Eyewash station log | Weekly testing performed | Testing to be charted weekly | **Y/N** |
| Drying cabinet | No daily testing expectation; cleaning schedule should be in place | Cleaning schedule in place? | **Y/N** |
| Room temperature & humidity logs | Daily testing | Charted daily | **Y/N** |
| Positive / Negative air pressure logs | Daily testing | Charted daily | **Y/N** |

1. Perform physical inspection of the department area:

|  |  |  |
| --- | --- | --- |
| Room: | Decontamination area | Answers |
| Air: | Humidity / temperature:   * What is the acceptable range? * How is it monitored, and on what frequency? * Actions to be taken when measures are out of acceptable range? | AAMI standards list humidity ranges of   * 30%-70% |
| Air | Pressures: Positive / Negative   * How is it monitored, and on what frequency? * Actions to be taken when measures are not complaint with expectations? | Y/N |
| Ceiling | * Clear of water stains / damage? * Air vents: dusty / dirty? | Y/N |
| Walls | * Intact? * Clear of dust / dirt / cobwebs? * Stored supplies kept within 18 inches of ceiling? * Eyewash station in place? * Fire alarms. Shut-off valves not blocked? | Y/N  Eyewash station to be checked weekly – ANSI Z358.1-2014 |
| Sinks | * No cleaning supplies kept in a cabinet under the sink? | Y/N |
| Detergents / cleaning solutions | * Any expired solutions? * Sufficient warning labels present on any solution re-packaged into a non-manufacturer-produced container? | Y/N |
| Doors | * Correct type of door (fire rating?) * Is door blocked from functioning   + Barriers blocking door; door jam in place to keep door from closing during a fire * Does the spring-hinged door close & latch as expected? | Y/N |
| Windows | * Intact? * Exterior: secure to prevent opening? * Interior: operating correctly? | Y/N |
| Floors | * Intact? | Y/N |
| Area care | * What is the room cleaning schedule? * How is cleaning monitored for completion? | Y/N |
| Staff | * Correct PPE / employee dress code expectations in place? | Y/N |

|  |  |  |
| --- | --- | --- |
| Room: | Tray preparation / sterilization area | Answers |
| Air: | Humidity / temperature:   * What is the acceptable range? * How is it monitored, and on what frequency? * Actions to be taken when measures are out of acceptable range? | AAMI standards list humidity ranges of   * 30%-70% |
| Air | Pressures: Positive / Negative   * How is it monitored, and on what frequency? * Actions to be taken when measures are not complaint with expectations? | Y/N |
| Ceiling | * Clear of water stains / damage? * Air vents: dusty / dirty? | Y/N |
| Walls | * Intact? * Clear of dust / dirt / cobwebs? * Stored supplies kept within 18 inches of ceiling? * Fire alarms. Shut-off valves not blocked? | Y/N |
| Doors | * Correct type of door (fire rating?) * Is door blocked from functioning   + Barriers blocking door; door jam in place to keep door from closing during a fire * Does the spring-hinged door close & latch as expected? | Y/N |
| Windows | * Intact? * Exterior: secure to prevent opening? * Interior: operating correctly? | Y/N |
| Floors | * Intact? | Y/N |
| Area care | * What is the room cleaning schedule? * How is cleaning monitored for completion? | Y/N |
| Staff | * Correct PPE / employee dress code expectations in place? | Y/N |

|  |  |  |
| --- | --- | --- |
| Room: | Case cart preparation / tray storage | Answers |
| Air: | Humidity / temperature:   * What is the acceptable range? * How is it monitored, and on what frequency? * Actions to be taken when measures are out of acceptable range? | AAMI standards list humidity ranges of   * 30%-70% |
| Air | Pressures: Positive / Negative   * How is it monitored, and on what frequency? * Actions to be taken when measures are not complaint with expectations? | Y/N |
| Ceiling | * Clear of water stains / damage? * Air vents: dusty / dirty? | Y/N |
| Walls | * Intact? * Clear of dust / dirt / cobwebs? * Stored supplies kept within 18 inches of ceiling? * Fire alarms. Shut-off valves not blocked? | Y/N |
| Doors | * Correct type of door (fire rating?) * Is door blocked from functioning   + Barriers blocking door; door jam in place to keep door from closing during a fire * Does the spring-hinged door close & latch as expected? | Y/N |
| Windows | * Intact? * Exterior: secure to prevent opening? * Interior: operating correctly? | Y/N |
| Floors | * Intact? | Y/N |
| Area care | * What is the room cleaning schedule? * How is cleaning monitored for completion? | Y/N |

1. Review the following Patient care / department process tracer question / answer guide

* Interview staff about equipment operations
* Review applicable quality / safety expectations as specified by equipment IFUs:

| **Equipment** | **Description** | **Questions** | **Answers** |
| --- | --- | --- | --- |
| Autoclaves / Sterilizers | Steam sterilizer used for trays of instruments | Daily testing performed: | Bowie-Dick test; chemical indicator test performed each day the sterilizer is to be used to ensure effective air removal in the system, necessary to ensure sterilization. This test releases the device for use |
| Actions taken when daily test fails: | Actions to include:   * Re-perform test * Contact facilities / repair personnel * Restrict device from use until acceptable results achieved |
| Individual load testing performed: | Biological indicators are spores used in each load to demonstrate sterility effectiveness |
| Actions taken when daily test fails: | Actions to include:   * Re-perform test * Contact facilities / repair personnel   Restrict device from use until acceptable results achieved |
| Where testing results logged? | Review log for completion of all sections |
| How are biological indicator lots validated? | BIs tested in the incubator for validity |
| Low temperature sterilizer | Sterilizes using low temp products, i.e. hydrogen peroxide; example: STERRAD, Vpro, STERIS System 1E | Individual load testing performed: | Biological indicators are spores used in each load to demonstrate sterility effectiveness |
| Actions taken when daily test fails: | Actions to include:   * Re-perform test * Contact facilities / repair personnel   Restrict device from use until acceptable results achieved |
| Where testing results logged? | Review log for completion of all sections |
| How are biological indicator lots validated? |  |
| Ethelyne Oxide sterilizer (EtO) | Low temp sterilizer that eradicates organisms on cellular level; the ultimate sterilizer | EtO monitor in place? | Monitors EtO environmental levels |
| High-level disinfector (HLD);   * Endoscope reprocessors * TEE probe reprocessors * Endocavity ultrasound (GUS devices) | Low-temp device which kills all bacteria but not spores (sterilization kills spores); used for endoscopes & TEE probes where HLD is approved per IFU | Individual load testing performed: | Test strip indicators are used in each load to demonstrate disinfection effectiveness |
| Actions taken when daily test fails: | Actions to include:   * Re-perform test * Contact facilities / repair personnel * Restrict device from use until acceptable results achieved |
| Where testing results logged? | Review log for completion of all sections |
| Instrument Washers | Device used to wash, rinse and decontaminate multiple trays / baskets of instruments per-hour | Daily test performed using TOSI test | TOSI test (Test Object Surgical Instrument) is a blood-soil device which identifies whether the washer is truly washing bioburden from instruments |
| Actions taken when daily test fails: | Actions to include:   * Re-perform test * Contact facilities / repair personnel   Restrict device from use until acceptable results achieved |
| Where testing results logged? | Review log for completion of all sections |
| Cart Washers | Large washer used to wash case carts after use; some cart washers are also able to wash instruments | Daily TOSI test only performed on cart washers that double as instrument washers | Follow the TOSI test regimen as is done with Instrument washers |
| Ultrasonic washer | Device using ultrasonic sound waves to vibrate water to dislodge bioburden from lumens / challenging crevices | Daily testing performed using Cleaning indicator | Cleaning Indicator test performed each day to ensure cleaning efficacy |
| Actions taken when daily test fails: | Actions to include:   * Re-perform test * Contact facilities / repair personnel * Restrict device from use until acceptable results achieved |
| Where testing results logged? | Review log for completion of all sections |
| Sinks | Decontamination area sink | How is the sink used to decontaminate instruments? | * Sinks have a water fill-level that must be attained before use * Detergent dosing per gallon of water should be listed and described by staff |
| * What PPE is used while using the decontamination sink? * Is it readily available? | * Gloves * Gown * Face shield / eye protection |
| Enzymatic dosing system (ex: Accu-sInQ) | Dosing system in Decontamination area that controls the dose of instrument detergent used during cleaning and water temperature | Daily testing performed? | * Testing should include detergent dose and water temperature verification * Verify device arrangement to detergent cannot splash staff when emitting from the device |
| Actions taken when daily test fails: | Actions to include:   * Re-perform test * Contact facilities / repair personnel * Restrict device from use until acceptable results achieved |
| Where testing results logged? | * Review log for completion of all sections |
| Endoscope flushing system | Device that provides hands-free consistent flushing of endoscope channels | Daily testing performed? | Flow validation test is to be done each day before use to validate proper system operation. |
| Actions taken when daily test fails: | Actions to include:   * Re-perform test * Contact facilities / repair personnel   Restrict device from use until acceptable results achieved |
| Where testing results logged? | Review log for completion of all sections |
| Drying cabinet | Used to dry endoscopes in expedited manner to retain disinfected state | What is the cleaning schedule for the cabinet? | No minimum / maximum time is mandated; but a cleaning schedule should be in place |
| Peel-Packed Instruments | Instruments packaged individually in sealed package for ease-of-retrieval of a singular instrument versus opening a surgical tray full of may instruments | Is the package the correct size? | The package should extend only 1 inch beyond the size of the instrument |
| Is the package intact? | * No perforations * Seal closing the pack is intact * No pen writing directly on paper part of the package |
| Sterility indicator in place? | Sterility indicator should be easily visible in clear plastic front of the package |
| Instrument free of bioburden / tape? | Identification tape should be cleanly applied with no corrosion or tape residue which inhibits ability to sterilize |
| Hinged instruments open? | Instrument stringers and rubber tip protectors should be in place to keep hinged instruments from closing during sterilization, thus thwarting ability for the closed surface to be sterilized |
| Instrument is reusable? | Ensure the instrument is not single-use / disposable. |
| Instrument trays | Metallic trays used to sterilize large numbers of surgical instruments | Instrument free of bioburden / tape? | Identification tape should be cleanly applied with no corrosion or tape residue which inhibits ability to sterilize |
| Sterility indicators in place? | Indicators inside surgical trays should be placed in multiple areas that present a challenge for steam to reach. |
| Genesis containers | Rigid container designed to maintain sterility of surgical instruments without needing to be covered in Blue Wrap | Is the tray filter in place? | The paper compression gasket seal in place in the bottom of the container maintains sterility. |
| Sterilization wrapped trays | Large sheets of wrap used to provide a sterile barrier for instrument trays | Is one sheet of wrap used, or two? | Instrument trays should be double-wrapped |
| Instrument free of bioburden / tape? | Identification tape should be cleanly applied with no corrosion or tape residue which inhibits ability to sterilize |
| Sterility indicators in place? | Indicators inside surgical trays should be placed in multiple areas that present a challenge for steam to reach. |

1. Processes: Interview department staff concerning the processes described below:

| **Sterile Processing Department Survey Tracer** | |
| --- | --- |
| **Questions** | **Answers** |
| **Central Sterile / Receiving:** |  |
| Where are department & hospital policies & procedures kept? | On the Intranet under Administrative policies |
| Sending inpatient unit: describe the process of sending used surgical instruments to Sterile Processing Department: | Instruments transported to the Sterile Processing Department should have enzymatic spray applied to prevent bioburden from hardening on / inside the instruments |
| ***Decontamination area:*** |  |
| How do employees know how to clean different types of instruments? | * Have staff describe process * Match stated cleaning process to random product IFU |
| How are vendor loaner trays handled? | Have staff describe process; is cleanliness/sterility ensured as are owned trays? |
| Describe the use of equipment in Decontam area?   * How do employees know the equipment is functioning correctly? * Actions taken when equipment is malfunctioning * How to approach handling a situation that they have never encountered before | Actions should match IFUs  Staff can always contact their supervisor if they are uncertain about appropriate actions to be taken |
| Where is the nearest eyewash station? | Have staff locate the station |
| Where is the Chemical Spill kit   * What chemicals would require spill kit use? | Have staff locate  Check IFUs for spill kit necessity |
| ***Tray Assembly area:*** |  |
| Describe the process of assembling trays; how are employees informed when tray contents change? | Have staff describe process |
| How do employees know the washed instruments are indeed clean? | Have staff describe process |
| What is the process for dealing with an incomplete tray? | Have staff describe process |
| ***Sterilization:*** |  |
| Describe the different types of sterilizers used in the department. | Have staff describe equipment types |
| How does the employee know which instrument needs which type of sterilizer? | Have staff describe process |
| How does the employee know the sterilizers are indeed working correctly? | * Biological control tests * Biological load tests * Strip indicators |
| Wet loads:   * What is a “wet load” * How are “wet loads” handled? | “Wet loads” are items removed from an autoclave that have visible dampness / moisture.  Wet loads must be re-processed |
| Where are trays stored? How does the employee know where trays are located? | Have staff describe process |
| How does an employee know if a tray has been placed on a case cart, or has not been returned from the OR? | Have staff describe process |
| Describe performance improvement and quality measures that are actively being measured. | Staff can identify Quality Board listing numerous quality measures |

1. See directive in instances where initial competency assessment / orientation checklist is found to be missing [↑](#footnote-ref-1)
2. Research education that is mandatory to be kept up-to-date for the staff member to be allowed to work clinically. [↑](#footnote-ref-2)
3. Lurie Children’s policy Resuscitation Certification policy mandates that staff whose job description mandates CPR training cannot work clinically without an active CPR card. They must be suspended from the schedule until proof of active CPR training can be provided to the manager [↑](#footnote-ref-3)
4. If performance evaluations are kept online, ensure access is established so evals inspectors can be verify

   completion [↑](#footnote-ref-4)