AUDITOR NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ AUDIT DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_

LOCATION/UNIT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

autoclave make and model (optional): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **Element Assessed** | **Response** | **Notes** |
| **Employee Competency**  |
| 1. All employees performing autoclave sterilization at the site have completed a competency? | [ ]  Yes[ ]  No |  |
| 1. Competency is on file?
 | [ ]  Yes[ ]  No |
| **Clean and Soiled Rooms**  |
| 3. Are there separate decontamination and clean rooms? | [ ]  Yes [ ]  No |  |
| 4. Is the autoclave in the clean room?  | [ ]  Yes[ ]  No[ ]  NA, all one room |
| 1. Does the room have unidirectional flow from contaminated to clean?
 | [ ]  Yes[ ]  No |
| 1. Supplies necessary for adherence to hand hygiene are readily accessible to healthcare personnel in areas where reprocessing occurs:
 |  |
| * 1. Soap, water, and paper towels
 | [ ]  Yes[ ]  No |
| * 1. Alcohol-based hand rub

  | [ ]  Yes[ ]  No |
| 1. Are decontamination and clean rooms free of dust, dirt, soil, and clutter?

NOTE: Specify concerns. | [ ]  Yes[ ]  No |
| 1. Are ceilings/ceiling tiles intact?
 | [ ]  Yes[ ]  No |
| 9. Are ceilings, floors, or walls free from water damage or mold?  | [ ]  Yes[ ]  No |
| **Instrument Cleaning and Inspection** |
| 10. Soiled items are pre-cleaned at the point of use prior to transport?  | [ ]  Yes[ ]  No[ ]  Unable to observe |  |
| 11. Soiled items are kept moist for transport (e.g. foam, gel, cleaning solution)? | [ ]  Yes[ ]  No[ ]  Unable to observe |
| 12. Contaminated items are properly contained during transport? | [ ]  Yes[ ]  No[ ]  Unable to observe |
| 13. Employee(s) correctly uses personal protective equipment?Specify concerns in the notes section. | [ ]  Yes[ ]  No[ ]  Unable to observe |
| 14. For manual cleaning, is fresh enzymatic solution prepared for each use and according to the manufacturer’s recommendations? NOTE: Review quality controls for ultrasonic cleaner and automated washer chemical dispensing. | [ ]  Yes[ ]  No[ ]  N/A, facility uses only mechanical cleaning. |  |
| 15. Are manufacturer’s instructions for cleaning, disinfection/sterilization immediately available? | [ ]  Yes[ ]  No |
| 16. Are items cleaned and lubricated (if indicated) properly? * Item soaked in the open position for at least 1-5 minutes
* Instruments are brushed below the level of the enzymatic solution
* All surfaces come in contact with the cleaning solution
* Rinsed in warm tap water
* Sprayed with a lubricant or dipped in lubricant (optional – may also occur in a washer/disinfector cycle)
* Air dried on a towel or chux in the open position
 | [ ]  Yes[ ]  No[ ]  N/A, facility uses only mechanical cleaning. |
| 17. Brushes should either be single use, disposable items or if reusable should be inspected for wear, cleaned after each use and disinfected or sterilized at least once a day.  | [ ]  Yes[ ]  No[ ]  N/A, facility uses only mechanical cleaning. |
| 18. For mechanical cleaning, are quality controls completed for ultrasonic and washer disinfectors/washer sterilizers? | [ ]  Yes[ ]  No[ ]  N/A, facility uses only manual cleaning. |

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| 19. Are instruments inspected after cleaning? If yes, what is verified? | [ ]  Yes, for adequate cleaning[ ]  Yes, for integrity and functionality[ ]  Yes, for cleaning, integrity and functionality[ ]  Not properly inspected |  |
| **Instrument Pouching and Wrapping** |
| 20. Are instruments pouched appropriately?* Pouch appropriate size for instruments
* Instruments are dry
* Sharp instruments are placed in tip protectors
* Instruments are in the open unlocked position
* Handles are closest to the peel area of the pouch
* Chemical indicator/ integrator is in pouch and visible
* Pouch is closed at the pre-fold line/perforation without any gaps
* If double pouching is utilized, the inner pouch is smaller than the outer pouch and not folded. Pouches are paper to paper and plastic to plastic.
 | [ ]  Yes[ ]  No | Indicate the number of pouches assessed: Indicate the number of pouches that were correct:  |
| 21. Are pouches and/or packs labeled and stored appropriately? * One step wrap or double layer wrap is appropriate in size and not cut
* Wrap secured with a maximum of three strips of steam indicator tape
* Alcohol based marker or gun label used
* Labeling on the plastic side of the pouch
* Wrapped packages: Label on outside wrap
* Include: date sterilized. Load number, initials, department if shared, sterilizer name/number if more than one autoclave
* Pouch/wrap integrity maintained
 | [ ]  Yes[ ]  No |  |
| 22. Are instrument trays prepared properly?* Curved tips are positioned in the same direction
* Cupped or concaved instruments are positioned to avoid water/condensation collection
* Chemical indicator/ integrator is in the tray
 | [ ]  Yes[ ]  No[ ]  Unable to observe |  |
| 23. If a rigid sterilization container system is used, are manufacturer’s written instructions for use regarding set preparation and assembly available? NOTE: Rigid container systems and medical devices must be tested and validated for preset standard steam sterilization cycles. See AAMI 13.10 *Periodic product quality assurance testing of rigid sterilization container systems* for additional details. | [ ]  Yes[ ]  No[ ]  NA, a rigid container system is not used  |  |
| **Autoclave** |
| 24. Is current autoclave policy and procedure available? NOTE: If no, skip to question 25. | [ ]  Yes[ ]  No |  |

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| 25. Has the policy/procedure been reviewed in the last year?  | [ ]  Yes[ ]  No[ ]  Unknown |  |
| 26. Are manufacturer’s instructions for the autoclave readily accessible? | [ ]  Yes[ ]  No |  |
| 27. Is there documentation that the autoclave has undergone preventive maintenance in the last year?  | [ ]  Yes[ ]  No |  |
| 28. Is documentation on the autoclave maintenance log maintained and up to date? (Routine maintenance) | [ ]  Yes[ ]  No |  |
| 29. Are pouches and wrapped packs appropriately placed in the autoclave?* Pouches: Lying flat with paper side down in a single layer or standing on edge with correct tray accessory all facing the same side
* Wrapped Packs: Solid trays positioned on edge or perpendicular. Perforated trays loaded with tray bottom down.
 | [ ]  Yes[ ]  No[ ]  Unable to observe |  |
| 30. Are chemical indicators read and documented after pouch/tray has gone through the sterilization cycle? NOTE: Rejected pouches shall be re-pouched with a new chemical indicator and run in the next autoclave load.  | [ ]  Yes[ ]  No |  |
| 31. Is biological indicator testing performed preferably daily, but at least weekly and with each load for implants? | [ ]  Yes[ ]  No |  |

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| 32. After sterilization, are pouches or packs stored in a designated clean area so that sterility is not compromised? * 8-10 inches from the floor
* 18-20 inches from the ceiling
* 2 inches from an outside wall
* Closed shelving/storage is preferred
* “First in, First out” stock rotation
 | [ ]  Yes[ ]  No |  |
| **Recall of Sterilized Items due to a Positive Biological Indicator** |
| 33. Is there a recall policy ad procedure available? NOTE: It should include the process to track sterilized instruments used on patents. If response is no, tool is complete. | [ ]  Yes[ ]  No |  |
| 34. Has the recall policy been reviewed in the last year?  | [ ]  Yes[ ]  No[ ]  Unknown |  |