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 |  |