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|  | | Environmental Health and Safety  STANDARD OPERATING GUIDELINE  AUTOCLAVE VALIDATION | | |
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1. *Purpose/Scope*
   1. This procedure is used to assess the efficiency and performance of autoclaves.
2. *Responsibilities*
   1. Each operating college/department has the primary responsibility for assuring proper use and validation of autoclave equipment in order to ensure efficiency of sterilization procedures.
3. *References*
   1. Biosign Steam-24 Biological Indicators Product Specification
4. *Definitions*
   1. Autoclave Validation: A quality assurance procedure used to ensure that the autoclave reaches adequate temperature for an adequate amount of holding time to sterilize biological agents and wastes.
   2. Biological Indicators: Will demonstrate that adequate temperature and holding time has been achieved in an autoclave; should be used during validation to ensure efficient sterilization. The most commonly used biological indicator is *Bacillus stearothermophius,* being the most resistant to steam autoclaving.
5. *Procedure*
   1. Each autoclave should be validated every 40 operating hours. See the “**Cumulative Time**” on the *Autoclave Operation Log* to determine when validation is necessary.
   2. Each time the autoclave is validated, the date of validation, pass/fail and other relevant information should be noted on the *Autoclave Validation Log*.
   3. When the cumulative time reaches 38-40 hours, a validation test must be performed. Wait for the next run of the autoclave, and follow the procedures as follows.
      1. Be sure to wear gloves, a lab coat, and any other necessary personal protective equipment (PPE) when working with biological agents and waste.
      2. Reference supplier instruction for the Getinge Biosign Steam-24 Biological Indicator.
      3. Make sure the Getinge Biosign Steam-24 indicators being used are not expired, and record the lot # and expiration date on the *Autoclave Validation Log.*
      4. Place Getinge Biosign Steam-24 indicator in the center of the load being sterilized/under the bag being autoclaved.
      5. Use another sample of the Getinge Biosign Steam-24 indicator **not autoclaved** as a control.
      6. Process load as per standard operating procedure.
         1. When autoclave cycle is complete, remove and incubate the indicator spores and the positive control as per supplier’s instructions. The Biosign Steam-24 Indicator should be incubated at 55 °C ±3 °C for 24 hours.
         2. After the 24 hour incubation period, look for a color change in the indicator media.
            1. A color change from **Red** to **Yellow** indicates positive growth **(failure).**
            2. No color change indicates no growth **(passing).**
      7. Check the positive control (sample not autoclaved) for color change to ensure the validity of results.
         1. If the test cannot be considered valid, the validation should be performed again with new indicators.
         2. If the test is determined valid, record the results and test parameters on the *Autoclave Operation Log* and *Autoclave Validation Log.*
         3. If the test **fails**, record the results and test parameters on the *Autoclave Operation Log* and *Autoclave Validation Log* and notify the area PI immediately.
         4. Label autoclave “Out of Service” until a **passing** validation test is achieved.
      8. Dispose of the used indicators and contaminated PPE as biological waste.
      9. Attachments
         1. *Autoclave Operation Log*
         2. *Autoclave Validation Log*

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