Steam Sterilization Failure and Recall Policy

In this facility a sterilization failure is considered to have occurred when:

- an incorrect sterilization time or temperature is used to sterilize devices
- the set sterilization time or temperature not met by the sterilizer
    - cycle stops before completion or sterilizer fails to reach temperature
- a positive/failed biological indicator is detected at any time during the incubation of the test.
    - sterilized test BI vials which change colour are considered to have failed—control tests should change colour
- failed internal or external chemical indicators are found—either in just one package or in multiple packages
    - failure is shown by the indicators not changing colour or by only partially changing colour
- non-sterile medical device(s) are released for use—either it was not noticed that they had not been through a sterilization cycle or that the sterilization cycle had failed and devices were used before the failure was detected
- wet packages are found after the sterilization load is finished even after they are allowed to cool in the sterilizer—either one package or multiple packages

Steps to take

1. In the event of sterilization failure notify _____ (manager or medical director)
2. Consult the Sterilization Failure and Recall Checklist. Follow directions on the checklist and complete all required documentation.
3. Immediately retrieve and quarantine all packages of medical devices which are involved with the failure. These devices will be reprocessed/re-sterilized after the sterilizer is repaired and/or confirmed to be working properly. Consult sterilization load records and the Failure and Recall Form to determine which packages must be recalled.
4. Document the steps taken during recall on the Sterilization Failure and Recall Checklist.
5. Retain all sterilization load records involved in a recall process.
6. Retain the completed Sterilization Failure and Recall Checklist and keep with sterilization records.