Policy on CSSD recall

1. **PURPOSE:**

   To describe the processes established by INODAYA Hospitals, Kakinada in the event of sterilization process failure and to enable rapid recall of all items suspected to be non-sterile

2. **SCOPE:**

   This procedure is applicable for product recall in the CSSD department.

3. **RESPONSIBILITY:**

   The CSSD Technician/Incharge is responsible for management of the sterilization activities.

4. **PROCEDURE:**

   4.1. The recall procedure includes:

   4.1.1. Sending a recall notice to the departments

   4.1.2. Identification of the persons or department for which the notice is intended

   4.1.3. Stating the batch information being recalled

   4.1.4. Include an area to record products and quantity of products to be returned in recall

   4.1.5. Include the action to be taken by persons receiving notice - e.g. return or hold by respective depts. to CSSD

4.1.6. After problem is corrected and a negative biological spores test is obtained, the CSSD incharge, after consultation with infection control coordinator, can allow the sterilizer be returned to operation.

4.2. A report is prepared and completed defining

4.2.1. The reason for recall

4.2.2. The total number of products recalled

4.2.3. The actual number located

4.2.4. Number of patients potentially exposed

4.2.5. The actions taken regarding patient involved

4.2.6. Where applicable, the actions taken to prevent this happening again

4.2.7. Sterilizing Cycle Records includes

a. Date of cycle
b. Steriliser code or number
c. Cycle or load number
d. Exposure time, temperature and pressure
e. Name/ID of loading operator
f. Name/ID of person authorizing release
g. Specific content of load and
h. Read out results of indicators used
    - Physical
    - Chemical

- Biological

4.3. Tracking labels and date of sterilization

All items must have a date of sterilization label or tracking label. This indicates that the item has been processed by CSSD and is for recall purposes in the event of a process failure. Some labels also have a colour indicator which changes from pink to brown when in contact with steam.

SUGGESTED PROTOCOL FOR MANAGEMENT OF POSITIVE BIOLOGICAL INDICATOR IN A STEAM STERILIZER

1. Take the sterilizer out of service. Notify area supervisor and infection control department.
2. Objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or the sterilization procedure is defective. As soon as possible, repeat biological indicator test in three consecutive sterilizer cycles. If additional spore tests remain positive, the items should be considered non sterile, and supplies processed since the last acceptable (negative) biological indicator should be recalled. The items from the suspect load(s) should be recalled and reprocessed.
3. Check to ensure the sterilizer was used correctly (e.g., verify correct time and temperature setting). If not, repeat using appropriate settings and recall and reprocess all inadequately processed items.

4. Check with hospital maintenance for irregularities (e.g., electrical) or changes in the hospital steam supply (i.e., from standard ≥97% steam, <3% moisture). Any abnormalities should be reported to the person who performs sterilizer maintenance (e.g., medical engineering, sterilizer manufacturer).
5. Check to ensure the correct biological indicator was used and appropriately interpreted. If not, repeat using appropriate settings.
6. If steps 1 through 5 resolve the problem If all three repeat biological indicators from three consecutive sterilizer cycles (step 2 above) are negative, put the sterilizer back in service.
7. If one or both biological indicators are positive, do one or more of the following until problem is resolved.
    A. Request an inspection of the equipment by sterilizer maintenance personnel.
    B. Have hospital maintenance inspects the steam supply lines.
    C. Discuss the abnormalities with the sterilizer manufacturer.
    D. Repeat the biological indicator using a different manufacturer's indicator.
8. If step 7 does not resolve the problem Close sterilizer down until the manufacturer can assure that it is operating properly. Retest at that time with biological indicators in three consecutive sterilizer cycles