Standardization of expiring dates for sterilized of medical devices

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Introduction:

Presently, we have been following several approaches for processing medical device (MD) that bring about the need for palpable and well established standardization methods regarding efficiency and safety of MD processed in CSSD.

To establish the expiring dates of sterilized MD, we must take into consideration all stages of processing itself that precedes storage.

Objective: Describing the main parameters for determining the expiring dates and shelf life of sterilized of MD.

Results:

- Physical place to store of MD require:

study of the amount of devices that are handled there;

furniture and equipment used for storage.

- Advise single place with limited access.
- The ideal conditions for storage are: a restricted area;

sealed windows; a clean environment with temperature control by a thermo hygrometer and cabinets that can be easily seen and reached so batches can be efficiently controlled.

- It is mandatory to respect the single characteristics of each model and those of the sterile barrier system itself to ensure success and safety when storing MD.

Discuss:

- The expiring date of a sterilization process is closely associated to the **"related event"** meaning that if a package is stored under proper control conditions, it is considered to be sterile if it is also incorruptible and dry.
- It is mandatory to identify the expiring date of a sterile barrier system.
- Proper storing conditions are the biggest challenge for CSSD managers in Brazil especially in places where operations are not continuous. Many products expire before they are ever used.

Conclusion: To determine proper sterilization expiration dates and shelf life, each institution must have appropriate facilities, processes, flows, inputs and storage of its MD. Also, it is mandatory that each process cycle is validated so that it complies with good practices according to individual institutional policies.

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