Standard Operating Procedure

Operational & Performance Qualification of Pouches

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OBJECTIVES

- To provide guidance to Medical Device Reprocessing Area (MDRA) staff on how to perform testing of sealed pouches, verifying the heat sealer is producing an adequate seal, and that the sealed pouches will remain acceptable under MDRAs routine operational conditions.
- Testing shall be performed annually, or when there is a change in equipment or supplies, to demonstrate that the heat sealer and pouches will consistently produce an acceptable seal.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary) working within Medical Device Reprocessing Areas.

Note: Site specific procedures shall be developed and followed based on the specific equipment and products that are used.

ELEMENTS

Operational Qualification

1. Three test pouches shall be prepared according to the Manufacturer's instructions. Sample test pouches must be created to verify the seals made at the upper and lower temperature limits specified by the pouch Manufacturer's Instructions for Use (MIFUs), pouch integrity, and aseptic presentation.
2. These packages shall be assembled according to the site procedure and shall include the most challenging packages to be sealed (e.g., smallest, fullest, largest).
3. Seal and pouch integrity shall be evaluated and documented after the sealing operation, sterilization, storage, transportation, and distribution to the point of use to ensure that they pass accepted criteria.
   Accepted criteria shall include, but is not limited to,
   a) seal integrity: an intact seal
   b) the absence of:

i. wrinkles that extend across seal width
ii. package integrity: no puncture or tears
iii. channels or open seals

c) peelability: peelable without material rupture, delamination, separation, or degradation; and
d) evidence that:
   i. sterilization parameters are achieved inside the pouches verified by a chemical indicator, and
   ii. pouches are free of water
e) aseptic presentation: able to open and transfer the content without damage or contamination.

Performance Qualifications

1. A minimum of three batches or sets of sealed packages shall be assembled according to the site procedures and include variables such as time of day, operator, material (size, source, and lot), and package contents. The contents that present the greatest challenge (worst case) shall be included.
2. Multiple packages shall be prepared to accommodate for opening as packages are evaluated after sealing, sterilization and storage & distribution.
3. The documentation used during the qualification process shall be retained. The documentation shall include, but not limited to:
   a) identification of the operator
   b) time and date
   c) sterilization process, parameters, and cycle number; and
   d) the contents of the package
   e) heat sealing equipment used; and
   f) test outcomes
4. Three batches of test samples shall be exposed to the same sterilization process. The packages shall be evaluated before and after exposure to the sterilization process and after the expected worst-case handling, distribution, and storage conditions until the point of use, using accepted criteria from OQ. Results shall be documented.

DEFINITIONS

None

REFERENCES

- Non-Alberta Health Services Documents
  - Canadian Medical Device Reprocessing in all Health Care Settings (Canadian Standards Association) (CAN/CSA Z314-23)

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VERSION HISTORY

Date	Action taken
March 2023	Initial approval
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