Management of Positive Biological Indicator (BI) or Failed Sterilization Mode

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OBJECTIVES

To ensure an appropriate response to a failed BI or failed sterilization mode.

PRINCIPLES

Recall sterilization loads when:

- A load has failed to meet parameter requirements (chemical or mechanical).
- There is a positive Biological Indicator.
- There is doubt about the safety of released medical devices (e.g. process failure during any of the steps of reprocessing.)

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 and Operating Rooms.

ELEMENTS

1. Failed sterilization load
   - 1.1 Review parameters to determine whether this is an operator error versus sterilizer malfunction.
   - 1.2 For operator error (incorrect cycle, overloaded sterilizer, incorrect packaging, etc.), reprocess affected load only - monitor result.
   - 1.3 For sterilizer malfunction, remove sterilizer from service, post "DO NOT USE" sign on the door of the sterilizer, call Facilities Management & Engineering and reprocess affected load in alternate sterilizer.
   - 1.4 Document the failed load as per local procedures.
2. Positive Biological Indicator (BI)
   - 2.1 If the cause of the failed BI is immediately apparent (usually operator error) and confined to one load, the cause of the failure should be corrected, the BI repeated and the load quarantined until the second BI is read.
   - 2.2 If the second BI is positive, recall the positive BI load, and all loads that were processed in the sterilizer back to the last load with Negative BI result.

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2.3 Remove the affected sterilizer from service until the cause of the failure can be determined.

2.4 Reprocess all recalled items with fresh wrappers and integrators in a different sterilizer.

2.5 Ensure the staff member assigned to sterilization notifies the manager or designate.

2.6 Manager or designate will notify IPC personnel or designate.

2.7 Check documentation for load contents (ex. Daily Record Book)

2.8 Identify the supplies to be recalled by:

a) Date
b) Load number
c) Sterilizer number
d) Package name or contents
e) User department

2.9 Notify all stakeholders as soon as possible.

2.10 Retrieve all affected items.

2.11 File a recall report which contains the following information:

a) Date
b) The circumstances that prompted the recall procedure
c) The corrective action that has been taken to prevent a recurrence of the circumstances
d) The total numbers of supplies that were to be recalled
e) The number of supplies actually recalled

DEFINITIONS

None

REFERENCES

- Appendix A: Chemical Indicators: A Problem-Solving Flowchart
- Appendix B: Biological Indicators: A Problem-Solving Flowchart
- Appendix C: Bowie-Dick Test: A Problem-Solving Flowchart

- Non-Alberta Health Services Documents:
  - *Central Service Technical Manual*, 7th ed. IAHSCMM, Chicago, IL, USA. 2007.
  - *Reusable & Single-Use Medical Devices Standards*. (Government of Alberta-Alberta Health) (September 2019).
  - *Canadian Medical Device Reprocessing. (Canadian Standards Association)* (CAN/CSA Z314-18)

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VERSION HISTORY

Date	Action taken
September 2019	Initial approval
February 2020	Last updated
February 2023	Next revision date

For more information contact
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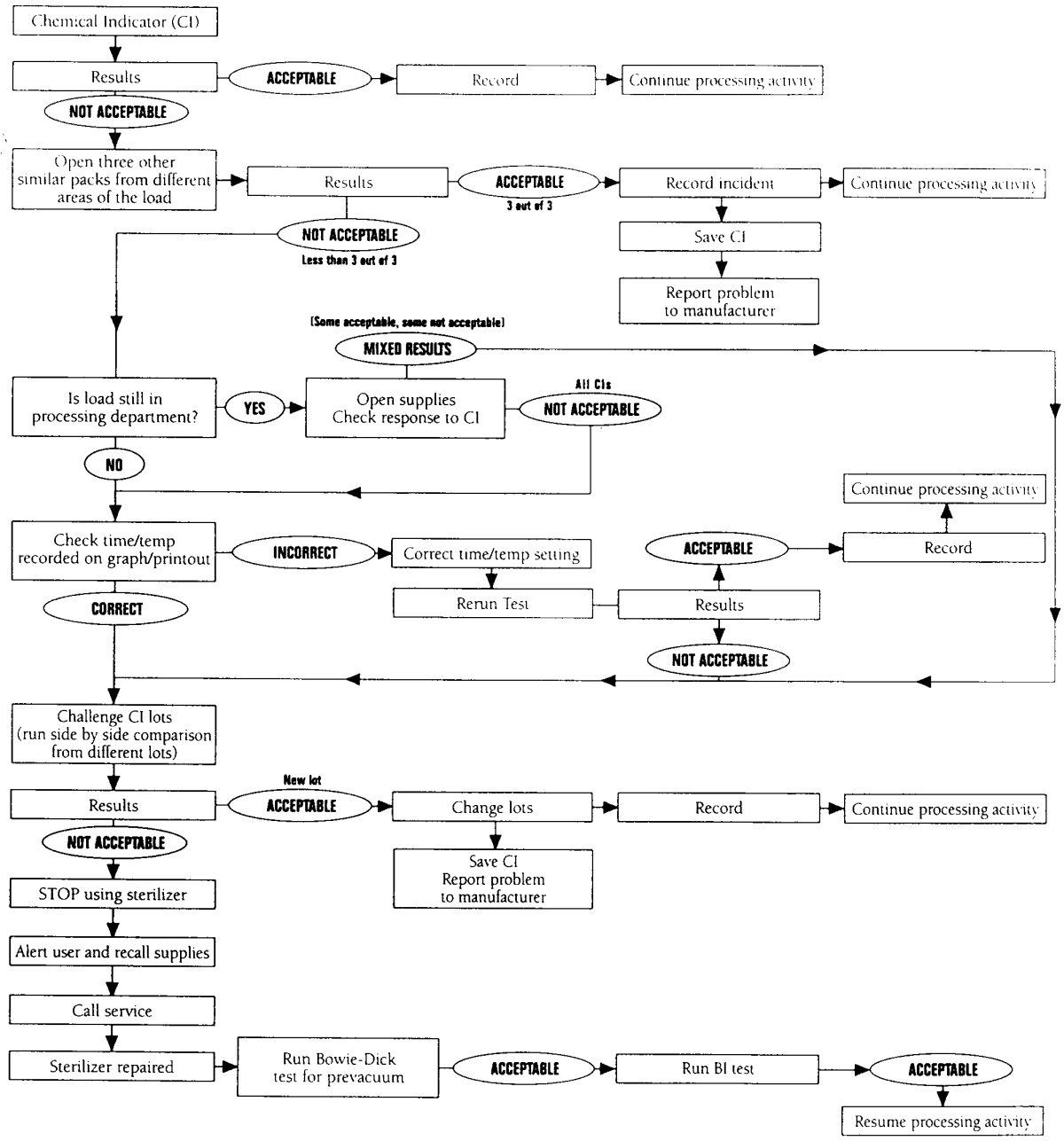
APPENDIX A

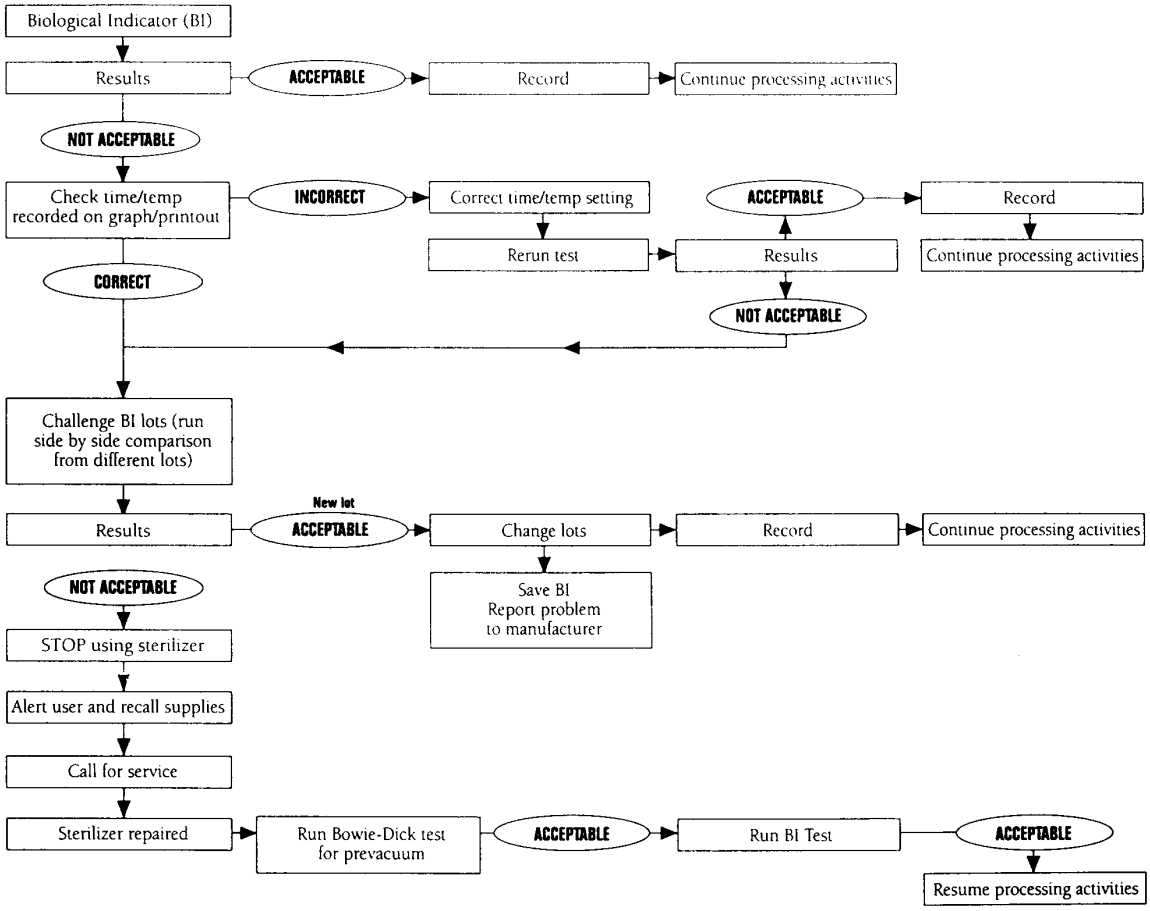
Chemical Indicators: A Problem Solving Flowchart



Original date: September 2019
Revised: February 2020

APPENDIX B

Biological Indicators: A Problem Solving Flowchart



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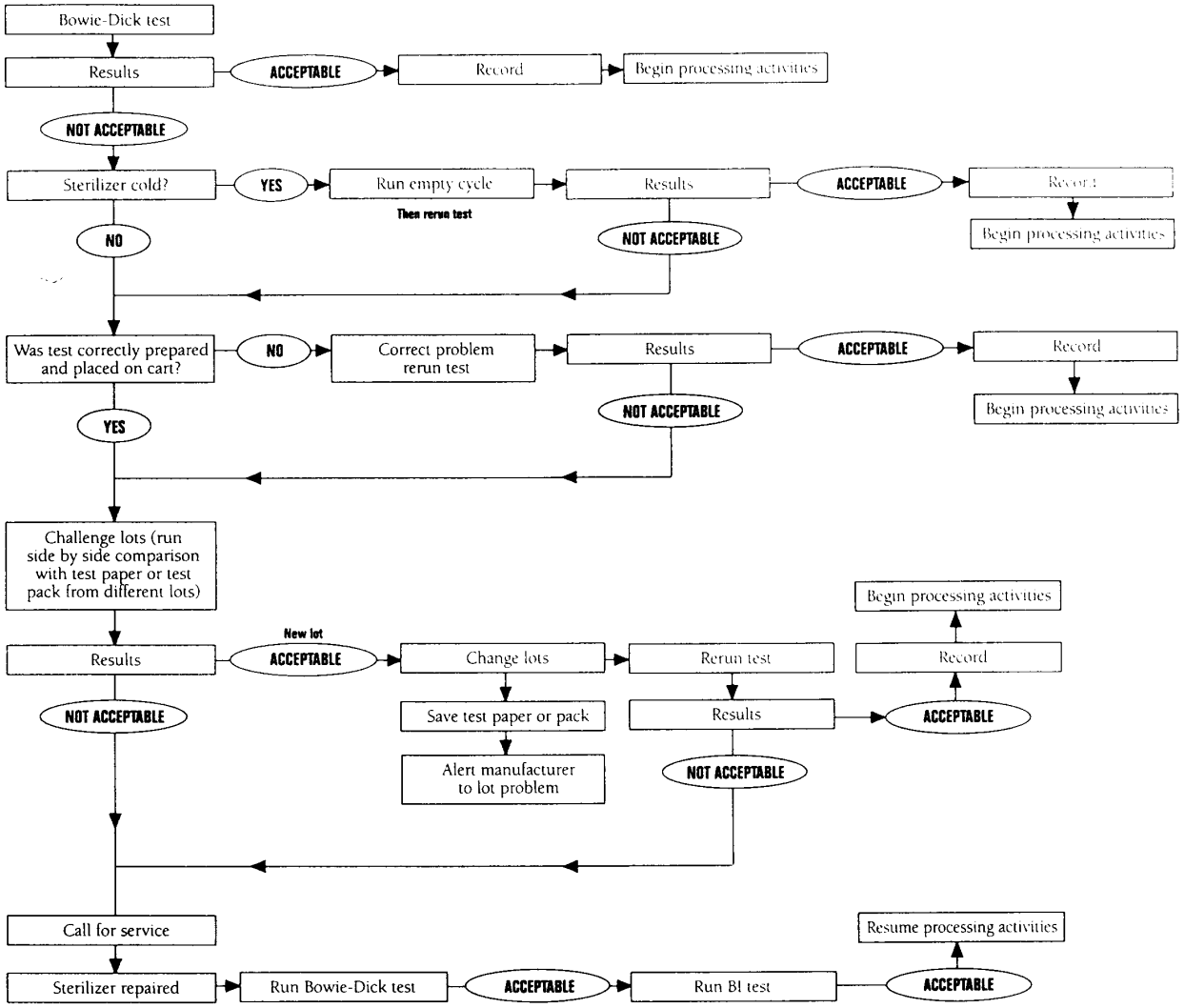
Alberta Health Services
Infection Prevention & Control

APPENDIX C

Bowie-Dick Test: A Problem Solving Flowchart



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