Recommendations for manual batch labelling and manual tracking of instruments trays for Operating Suite

1. Introduction

The sterilisation of reusable medical devices requires the management of quality systems to validate the effectiveness of all stages of instrument reprocessing.

Appropriate management of quality systems ensures Queensland Health facilities can promptly respond to the recall of a “sterilised product”, tracking it from when it is dispatched from the Central Sterilizing Department (CSD) to receipt by the “user area”. This process provides facilities with the ability to link the steriliser cycle batch information of instrument trays being sterilised to the patients on which they are used. This quality process is imperative, especially those facilities that undertake high risk surgical procedures.

This recommendation can be achieved simply and cost effectively using a manual batch labelling system. Manual batch labelling for the tracking of instrument trays for the operating suite meets the requirements of Australian/New Zealand Standard 4187:2003 “Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities” (AS4187) and the Australian Council on Healthcare Standards. Manual batch labelling is performed using a batch label gun and piggy-back batch labels. There are a number of companies across Australia that now produce interchangeable batch label guns and piggy back batch labels.

The recommended practice for manual batch labelling and tray tracking systems is to be read in conjunction with Queensland Health Infection Control Guidelines and the CHRISP http://www.chrispgld.com/easi_sterilise/easi-sterilise.html resources which include the following Standard Operating Procedures and Workplace Skills Assessments;

- 2.5 Wrapping/Packaging/Labelling
- 3.1 Batching & Recording of Items prior to Sterilisation
- 3.2 Loading & Recording of Items for Steam Sterilisation
- 3.4 Releasing & Unloading a Sterilised Load

2. Product Recall

To facilitate the recall process as described in AS 4187 all items being reprocessed in a steriliser shall have:

- Batch and load information on each pack/tray/bundle
- Documented evidence of all items that have been through a sterilising process
- A process that allows for tracking/tracing proof of the sterilising process
- A process that assists in the recall of an item/load if required, and
- A process for the recording of load contents assists in compiling of statistical data on production volume
3. General Requirements

Implementation and Ongoing Management
To facilitate the implementation and ongoing management of a system that links steriliser batch information to a patient, a co-ordinated plan is required. The Quality Co-ordinator and Patient Safety Officers are resources that are available to assist the CSD and OT NUM’s with implementation and sustainability of the revised system.

Equipment Requirements
CSD
Batch labelling gun (some batch guns can be interchangeable between batch label products)
Piggy-Back Batch labels
Non-toxic solvent based pen

Operating Suite
Peri-operative medical record

4. Central Sterilising Department (CSD) Requirements

Labelling of all items to be sterilised is to be clear and precise for easy identification and recall if required. The minimum requirements for labelling of each wrapped item include:

- name of item and its identifying number
- signature or designated identification of person packing and wrapping the item,
- date item is wrapped

Following the wrapping of trays/items and prior to the sterilisation process, the items are to be placed on steriliser trolley awaiting batch labelling process

The following minimum Piggy-Back Batch label information is to be applied to each packaged item or tray prior to sterilisation using a batch gun and piggy-back batch labels (refer to figure 1):

- date
- steriliser number or code
- load number if more than 1 load for that day
- contents (optional)
- tray number (optional)
The piggy-back batch label is to be affixed to the external wrapping of each wrapped item.

The item/s are to be placed appropriately on the sterilising trolley. The piggy-back batch label should display the following information; cycle number, date and steriliser number. The load contents are then documented on the steriliser-recording log.

Once the steriliser is loaded and the cycle commenced, the responsible staff member completes the steriliser-recording log which includes the following information:

- Autoclave Number
- Responsible Person
- Sterilisation Date
- Batch Number Sticker
- The Run Type (Bowie Dick, Live etc)
- Cycle Pass/Fail
- Biological Indicator pass/fail (if required)

Once the sterilisation process has been completed, all items processed are checked to ensure that:

- batch/item information corresponds with load documentation
- external chemical indicators have changed
- Piggy-Back batch labels have not dislodged during sterilisation
• Items are not wet and packaging remains intact

Once the items are autoclaved, the parameters are to be checked for a pass by the responsible staff member and then released by an authorised person. The sterile stock is then allowed to cool, and then dispatched to the required destination. The autoclave perimeters printout is attached to the steriliser recording-log.

In the event of a failed load, the shift coordinator is to be notified and the items are to be documented as a “non-conformance” and returned to the Central Sterilisation Department for reprocessing.

5. Operating Suite Requirements

All reusable medical devices processed in CSD will have a piggy-back batch label such as the example in figure 1 attached to the external wrapping of the tray or item.

If sterile pack does not have a piggy-back batch label sticker attached to the wrapped tray/item, that tray or item is deemed to be un-sterile and must be returned to CSD for reprocessing (which includes cleaning and sterilisation).

For each tray that is to be opened for patient’s surgical procedure, the batch label is to be removed from the sterile pack, parameters checked and then placed into the patient’s peri-operative medical record.

6. Process Compliance

As part of quality management, CSD and OT should undertake regular process compliance checks as an integral part the department’s quality improvement system. This can be undertaken by conducting an audit of CSD and OT processes (refer to attachment 1). The audit results, along with strategies for areas requiring improvement must be fed back to staff and should be communicated to the facility’s relevant committees, e.g.

• Feedback to staff e.g. staff meetings/forums
• Departmental and Divisional meetings
• Infection Control Committee
• Risk Management Committee
• Quality Management Committee

7. Patient Recall or Look Back Investigation

All patient related sterilising incidents or near misses are to be recorded in PRIME, the Queensland Health clinical incident management system.

The reporting of a critical incident associated with a sterilising breach or incident that requires patient recall or look back investigations are to be managed in line with the Queensland Health Infection Control Guidelines: Guidelines for the investigation of critical incidents resulting in actual/suspected healthcare associated infection (Appendix P1).
References


Queensland Health, 2008. Centre for Healthcare Related Infection Surveillance and Prevention, Easi-Sterilise®,


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