

Management of Non-Conformances in the Decontamination Process

1. Purpose

This procedure details the process for the recording, investigating and resolving non-conforming products/process found during the decontamination process.

2. Responsibilities

Management should ensure that this procedure is available and followed by all staff involved in the decontamination process. Management should ensure that staff are trained on this procedure. Management take any required action when there is a non-conformance confirmed.

3. Procedure

- record the details of the non-conforming product/process (see record form PRO 179-520R) and inform the User to decide the appropriate corrective actions;
- separate the non-conforming items, label as non-conforming items and control to prevent its unintended use;
- investigate the occurrence of non-conforming product/process to determine the cause;
- determine corrective and/or any preventative actions to be taken;
- monitor the actions to evaluate its effectiveness and arranges discussion at the annual management review meeting;
- record the preventative and corrective actions in the non-conformance record, sign and date when the action has been verified.