

# Internal Audit

## 1. Purpose

Each internal audit is a snapshot of the quality of the documentation and processes used for the operational management and decontamination of reusable thermolabile flexible endoscopes. The internal audit examines on a given day how well the decontamination SOPs are being followed and on analysis of the findings identifies potential improvements.

## 2. Responsibilities

This procedure is managed and operated by the Endoscope Decontamination Unit Manager/User as defined in SHTM 2030 (normally the Unit Manager or Charge Nurse). Management take any required action when there is a non-conformance confirmed (SOP PRO 179-200).

## 3. Procedure

- plan the internal audit program, taking into consideration the status and importance of the processes and the area to be audited, as well as the results of previous audits;
- ensure the audit program covers and report on the following:
  - suitability of the medical devices, decontamination policies and operational processes with respect to current needs and any risk assessments;
  - previous audit reports (e.g. HIS, Health and safety and global rating scale);
  - the functional effectiveness of the medical devices and decontamination policies and their ability to meet objectives;
  - operational problems and actions taken;
  - complaints and reported incidents;
  - areas for improvement/changes needed;
  - training needs;
  - equipment maintenance, validation and commissioning;
  - working environment.
- analyse each internal audit, determine any significant trends and inform the annual management review meeting;
- ensure that any necessary corrections and corrective actions are taken without undue delay, to eliminate detected nonconformities and their causes;
- follow up any observations at the next audit as defined in the audit program;
- ensure that all records of the internal audits and their results are maintained.