WHAT IS A MEDACCRED® STERILIZATION AUDIT?

A MedAccred sterilization audit is an independent assessment of a sterilization facility's conformance to the sterilization standards for Ethylene Oxide - ISO 11135 and/or Radiation – 11137. The MedAccred sterilization audit also includes a full Quality Management Systems audit assessing conformance to ISO 13485 and 21 CFR 820.

The Sterilization Task Group was formed in 2014. A MedAccred Task Group consists of subject matter experts from OEMs, Contract Manufacturers, and Suppliers that is formed in a specific critical process technology area (e.g., Sterilization, Plastics Injection Molding, and Welding) who work collaboratively to develop detailed technical audit criteria, interview and approve auditors, review audit reports, and vote on accreditation decisions. Task Group members are typically the best in the world in their technology area.

The Sterilzation Task Group was created because:

- The ongoing struggles associated with the level of oversite necessary to satisfy the regulatory requirements, especially at the lower tiers of the supply chain
- The number of redundant audits being performed had become unmanageable and often added no value
- Many of the available auditors are strictly quality systems auditors and did not know how to audit the sterilization process to the required standards
- There was a need to have a consistent approach to addressing the quality issues associated with sterilization

MedAccred Sterilization Audit Criteria addresses every line item in the Sterilization and Quality standards which contributes to its robustness. As a continuous improvement activity, a gap analysis was performed by Subject Matter Experts (SMEs) from leading medical device companies and contract sterilizers. Evaluation criteria used during the gap analysis included: evidence, details of findings, independent oversight, nonconformances, sample size, auditor selection, training and oversight, procedures and standards.

MedAccred Sterilization Audit practices were found to be at least equivalent to MDSAP, 21 CFR Part 820, and Notified Body audits.

MedAccred Sterilization audits cover:

- Quality Management System elements
- Sterilization technology assessment
  - Conformance to regulatory requirements and guidance
  - Methodology to achieve compliance
- Equipment calibration and preventative maintenance
- Routine process controls
- Qualified personnel and training
- Process validation (IQ, OQ, PQ) – meeting industry and customer requirements

INDUSTRY SUPPORT

Subscribers:

- Baxter
- Becton Dickinson
- Boston Scientific
- Edwards Life-sciences
- Medtronic
- Philips
- Stryker
- W.L. Gore

Suppliers:

- Sterigenics
- Steri-tek
- Steris

Medical Device OEM Subscribing companies are utilizing MedAccred to reduce scope and frequency of the audits conducted at their Contract Sterilizers. Some are also eliminating their interval audits, unless there is a strong reason to go in, and others are building MedAccred into their procurement process and awarding new business to accredited suppliers.

AUDIT CRITERIA

MedAccred® Sterilization audit criteria is aligned with the following Sterilization industry standards:

1. **Radiation (Gamma, E-Beam, X-Ray)**
   - ANSI/AAMI/ISO 11137-1
   - ANSI/AAMI/ISO 11137-3
   - ASTM 51702
   - ASTM 51261
2. **Ethylene Oxide**
   - ANSI/AAMI/ISO 11135
   - AAMI TIR 14, 15
   - ISO 10993-7

COMMON NONCONFORMANCES FOUND DURING AN AUDIT

Sterilization NCRs were issued for failure to meet either ISO 11137 or ISO 11135 requirements.

- Failure to monitor temperature in the EO gas storage area, which could have resulted in an industrial accident
- Failure to specify dosimeter re-calibration frequency for batches extended past one year
- Failure to assess air flow in the aeration room during annual requalification
- Failure to assess process variability through replicate dose maps
- Ineffective CAPA system, repeat findings in dosimetry and product loading
- No initial IQ Report provided for review of Installation Qualification activities and documentation and thus no indication that the IQ was performed in accordance with 11137
- Verification of dosimeter calibration was not performed at the extremes and mid point of the calibration curve
- The adjusted results at wavelength 254 nm following a failure were not included in the documentation package for the spectrophotometer calibration

BENEFITS TO SUBSCRIBERS

- Enhances rigorous oversight of sterilization processes. Increases supply chain resiliency and quality within the sterilization process
- Provides greater visibility of the supply chain
- Improved capability to meet FDA purchasing control requirements. The sterilization audit does a deep dive into managing the purchasing function, especially from critical suppliers such as dosimetry, calibration, and sterilization gas
- Collaboration across many different medical device companies to improve:
  - Final product quality
  - Resource availability
  - Supplier oversight
  - Patient safety

The sterilization task group is collaborating to continue to have the most robust audit criteria. We only send the most expert auditors, which allows the industry to better place their resources, provide oversight to all tiers of the supply chain, and most importantly, improve patient safety with regard to infection risk.

BENEFITS TO SUPPLIERS

- Improves quality of the sterilization process through:
  - Significant focus on calibration compliance and adherence to preventive maintenance schedules
  - Focused review of original IQ/OQ and current re-qualifications
  - Technical and quality review of CAPA process, investigations and root cause analysis
  - Deep dive into on-the-job training, testing, and certifications, not limited to procedural read and understand
  - Large sample sizes based on a statistical calculation
  - Audits performed by real SMEs in sterilization provide value to suppliers
- Improves process control and process capability
- Potential to expand business within the growing medical device industry
- Reduction of customer (OEM) audits
  - Reducing the number of audits at contract sterilizers is the value proposition for those sterilizers
  - Sterilization and Quality Managers can feel confident that their sterilizers are audited by an SME in sterilization and quality; their own in-house sterilization experts are members of the task group and review and ballot each audit. The task group members own the audit, so they are involved and have the final decision on who is accredited

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