MedAccred Sterilization (STN)

Radiation and Ethylene Oxide Sterilization for Medical Device Manufacturing

Critical Manufacturing Processes for the Medical Device Industry
Mark Aubele – Staff Engineer STN

PRI, Senior Program Manager for Nondestructive Testing, Measurement & Inspection, Electronics & Aerospace Quality Systems

PRI, Staff Engineer MedAccred Sterilization Task Group

PRI, 16 years as the Senior Staff Engineer for Nondestructive Testing Task Group

PRI, Lead Auditor for NDT; Penetrant, Magnetic Particle, Ultrasonic, Radiography, Digital RT (DDA & CR), Eddy Current; also Etch and Aerospace Quality Systems

Nondestructive Testing College Level Instructor

39 Years experience as an NDT professional

20 Years inspecting various components in Aerospace, Nuclear, Construction & Fabrication

NAVSEA Examiner Certification in PT, MT and UT

Corporate Level 3’s across the board held at various times
Kim Patton – Becton, Dickinson & Co - Chair STN

- Bachelor of Science, Microbiology – 1988, Clemson University, Clemson SC
- WW Sterilization Program Manager, BD Corporate Shared Services
- Sterilization/Microbiology Subject Matter Expert with 25 years experience in Medical Device and Pharmaceutical technologies in FDA regulated industry
- Audit Program Manager, BD Sterilization
- Certified Lead Auditor - 13485: 2003
- AAMI – BD Primary Representative – WG02(Radiation) and WG08(Microbiology)
- AAMI - BD Alternate Representative - WG03(Moist heat), WG04(Biological Indicators), WG05(Sterilization Terminology) and Sterilization Standards Committee (SSC)
- ASTM – BD representative and committee member Dosimetry Workshop 2017
- GIPA – BD representative
- CIRMS – BD representative
- Green Belt Certified
Rod Parker – Stryker - Vice Chair STN

- Bachelor of Science in Medical Technology
- Master of Science in Biomedical Engineering
- Doctorate in Business

Began my career International Research and Development Corporation as a Clinical Pathology Supervisor and later with Miles Corporation as a Clinical Pathologist. Roles included numerous types of contract toxicology testing. Since joining Stryker I have been a Manager in Regulatory Affairs and Clinical Sciences before assuming the role of Senior Principal Scientist with Stryker Instruments Division of Stryker Corporation with a focus on our scientific assessments for sterilization and material compliance to US and International standards. I am based in Kalamazoo, MI.
Agenda

- What is MedAccred
- MedAccred Sterilization Task Group
- Audit Scope - Sterilization
- Industry sterilization recalls/issues
- Critical Technical (process) Audits using Subject Matter Experts
- Technical Standards Compliance
- Standardized Accreditation
- Supply Chain and OEM Requirements
- Non-conformances (NCR’s)
What is MedAccred?

- MedAccred is an industry managed approach to supplier quality oversight
- Provides a mechanism to identify the critical manufacturing processes used by the device industry and oversee the supply chain’s ability to meet these requirements through a surveillance and accreditation process
- Brings together technical experts from both Industry and Government to establish requirements for accreditation, conduct in-depth audits by subject matter experts and accredit Suppliers
- Results in a standardized approach to critical manufacturing process quality assurance and a reduction in redundant auditing throughout the industry
- Based on success of the aerospace program, Nadcap
What is the MedAccred Scope?

- An industry-managed audit and accreditation program that assures compliance to critical manufacturing processes and reduces risk to patient safety
- MedAccred is an audit tool for Medical Device OEMs to use to ensure appropriate oversight of their supply base while maintaining ultimate responsibility for device quality and compliance
- MedAccred program provides in-depth, critical process focused, technical audits conducted by industry recognized and approved Subject Matter Experts to ensure conformance and compliance with accepted industry/technical standards and OEM requirements
- Assesses effectiveness of suppliers’ Quality Management System (QMS) at the critical process level (e.g. PCBA, Heat Treating, Sterilization, Welding, etc.)
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Task Group Structure

Sterilization

Checklists
- Quality
- Radiation
- Ethylene Oxide

Task Group Members
- Chairperson, Kim Patton
- Vice-Chairperson, Rod Parker
- Secretary, (vacant)
- Representatives

Staff
- Staff Engineer, Mark Aubele
- Coordinator, Jennifer Kornrumpf
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- **Audit Checklists - Sterilization**
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AC8113 - Quality Audit Checklist

- Scope
- General Information
- Information
- Audit Contacts
- Quality Documents
- Facility General Tour
- Facility Management
- Quality Management Systems
- Management Responsibility
- Resource Management
- Production and Process Control
- Measurement Analysis and Improvement
- Risk Assessment Tools
AC8113/1 – Radiation Audit Scope

Scope
General Information
Installation Qualification (Gamma)
Operational Qualification (Gamma)
Performance Qualification (Product Dose Mapping) (Gamma)
Installation Qualification (E-Beam)
Operational Qualification (E-Beam)
Performance Qualification (Product Dose Mapping) (E-Beam)
Standard Operating Procedures (SOP) Product/Process Specifications
Routine Monitoring and Control
Dosimetry Systems Control
AC8113/2 – Ethylene Oxide Audit Scope

Scope
General Information
Facility General
Ethylene Oxide Sterilization Validation
Precondition
Sterilization
Aeration
Process Control Documentation
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Firm initiated local non-conformances for three instances of employee data manipulation/falsification at three different facilities; however, your firm failed to escalate the issue of dosimetric data manipulation/falsification

Your firm did not maintain documentation of written consent provided to your foreign contract manufacturers ((b)(4)) for the sub-contracting of (b)(4) irradiation services for the conduct of the (b)(4) sterilization processing of your firm’s blood lancets, as required in your Quality Contracts (Supply Agreements) with the foreign contract manufacturers.
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Critical Sterilization Process Audit

Benefits of MedAccred Sterilization Program

- Improves Supplier Quality by providing:
  - Consistent technical requirements leading to process discipline, greater operational efficiency and continuous improvement resulting in higher quality and lower overall cost
  - Consistent/standardized critical process accreditation accepted by the Medical Device Industry resulting in fewer redundant onsite audits by multiple OEM’s
  - An in-depth critical process audit that is compliant and consistent to accepted industry/technical standards and conducted by Subject Matter Experts
  - Greater visibility of the supply chain to all levels and sub-tiers that provide critical processes
  - Improved flow down of OEM requirements to sub-tier suppliers
Subject Matter Expert Conducted Audits

An in-depth critical process audit that is compliant and consistent to accepted industry/technical standards and conducted by Subject Matter Experts in sterilization

- Audit criteria are in depth and taken directly from accepted industry standards as well as complimented by OEM requirements where necessary
- Participating OEM’s accept the audit criteria; AC8113 (Quality); AC8113/1 (Radiation) and AC 8113/2 (Ethylene Oxide)
- Auditors are skilled and experienced sterilization industry experts and not quality generalists
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Technical Standards Compliance

- Consistent technical requirements that lead to process discipline, greater operational efficiency and continuous improvement.
  - Each audit is conducted to the same criteria
  - Removes variation from audit to audit caused in part by differing criteria
  - All audits conducted by highly qualified sterilization industry experts
  - All audits are reviewed PRI/MedAccred Staff Engineer
  - All audits and nonconformances are reviewed by the Sterilization Task Group; comprised of highly skilled and experienced Sterilization industry experts
Technical Standards Compliance

- AC8113 - Base Document / Quality Systems
  - ISO 13485
  - 21 CFR Part 820
- AC8113/1 - Radiation
  - ANSI/AAMI/ISO 11137-1
  - ANSI/AAMI/ISO 11137-3
  - TIR 29
- AC8113/2 – Ethylene Oxide
  - ANSI/AAMI/ISO 11135
  - AAMI TIR 14
  - ISO 10993-7
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Standardized Sterilization Accreditation

- Consistent/standardized critical process accreditation accepted by the Medical Device Industry resulting in fewer redundant onsite audits by multiple OEM’s.
  - Each audit is conducted to the same criteria; AC8113 (Quality); AC8113/1 (Radiation) and AC 8113/2 (Ethylene Oxide)
  - Removes variation from audit to audit caused in part by differing criteria
  - One audit can replace a multitude of OEM’s requirements resulting in fewer redundant audits being conducted
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Visibility of the Supply Chain

Greater visibility of the supply chain to all levels and sub-tiers that provide critical processes

- Audits are conducted/stored in eAuditNet which creates a permanent record for all Subscribing OEM’s to use as a tool to monitor their supply chain
- Audits are conducted/stored in eAuditNet which creates a permanent record for suppliers to view their own audits and utilize as a tool for process improvement
Flow Down of OEM Requirements

- Improved flow down of OEM requirements to sub-tier suppliers
  - Audit criteria are in depth and taken directly from accepted industry standards as well as complimented by OEM requirements where necessary
  - Criteria of an OEM is not necessarily only in their document, rather, critical criteria can be located in the audit criteria (Checklists)
  - Participating OEM’s accept the audit criteria; AC8113 (Quality); AC8113/1 (Radiation) and AC 8113/2 (Ethylene Oxide). So one criteria fits all.
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Non-conformances (2 Audits)

Document and documentation issues (AC8113)

Paragraph 4.4.2 Requirement: Records of processing changes for documents include identification of all affected documents

“Affected documents for ECR changes are not identified”.

Paragraph 9.3.7 Requirement: Risk Assessment documentation of actions taken

“Identified a high risk area and actions taken were not recorded”.

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Non-conformances (2 Audits)

Flow and handling of material (AC8113)

Paragraph 3.4.1 Requirement: Is the facility layout such that the flow and handling of material is controlled?

“Product was witnessed in the “processed” area that, per Procedure XXXX, Rev 7, Warehouse and Inventory Management, section; “Storage by Exception” was not stored or labeled as required”.

“Paragraph 3.4.1 Requirement: Is the facility layout such that the flow and handling of material is controlled?

Procedure XXXX, Rev 7, paragraph 1.6, in regards to stacking of product, states; “Unless otherwise specified by the customer, double or triple stacking of product is acceptable. The issue is, that same customer’s product was double stacked and there was a placard on the material that stated “do not double stack”. This constitutes “otherwise specified”, therefore the procedure is not strictly being followed”.

MEDMARC. Treated Fairly
Non-conformances (2 Audits)

Other Quality Issues (AC8113)

Paragraph 7.14.9 Requirement: Does the system lock-out after pre-defined incorrect access attempts?

“System must lock-out after pre-defined incorrect access attempts. The issue is that the ScanTrac system does not lock out the individual attempting access”.

Paragraph 8.8.2 & 8.8.3 Requirement: Review internal audit findings, corrective actions, implementation, and effectivity

“Procedure 00003, Rev 12, Internal Audit Process; requires the completion of all QMS elements in a 24 month period. The audit criteria requires that this activity be completed in a 12 month period”.

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Non-conformances (2 Audits)

Radiation Process Issues (AC8113/1)

Paragraph 11.8 Requirement: Dosimeter batch re-calibration performed per specified frequency

“There is no specified frequency for batch re-calibration per procedure”.

Paragraph 11.9 Requirement: Are UV filters employed on light fixtures where film dosimeters are used and read?

“UV filters are not utilized on light fixtures where dosimeters are used and read as required by the audit criteria”.

Paragraph 9.2.8 Requirement: Verification that processing parameters were met?

“In Procedure XXXX, Rev 13, Attachment C; the Spectrophotometer model and serial numbers do not match”.
Non-conformances (2 Audits)

Ethylene Oxide Process Issues (AC8113/2)

Paragraph 3.1 Requirement: Sterilant stored in accordance with vendor specification (< 30 C)

“Sterilant must stored in accordance with vendor specifications (<30 C); however storage is in an enclosed outside area for ventilation, but not temperature controlled”.

Paragraph 7.2 Requirement: correct type and number of successful runs per current requirements conducted

“Airflow for aeration chamber was not assessed in the most recent recommissioning (qualification)”.

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Questions?

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