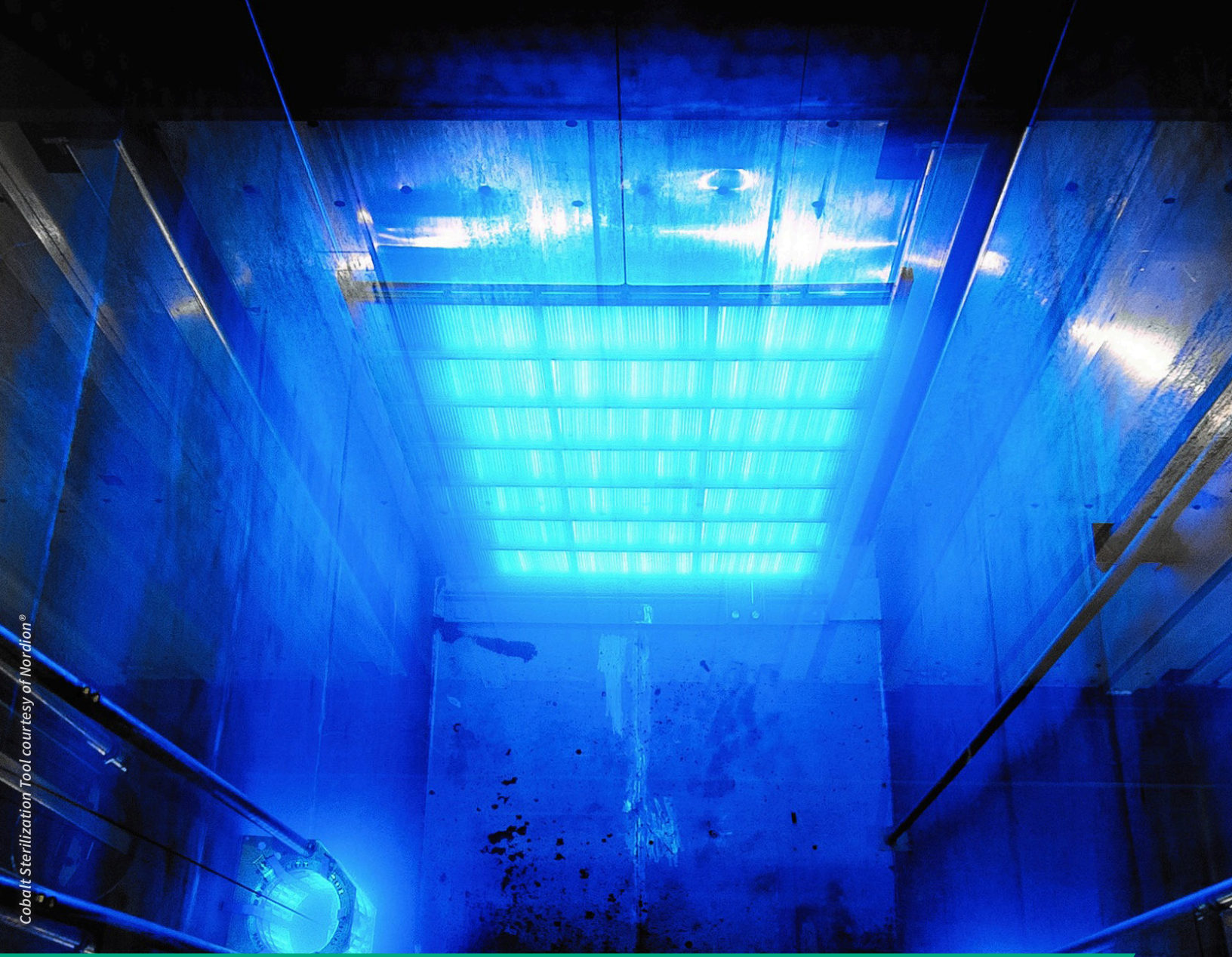


Cobalt Sterilization Tool courtesy of Nordion®



Pilot Study Report

MedAccred Accreditation and Audit Program for Contract Sterilizers

February 2025

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FDA is a member of the MDIC Case for Quality Collaborative Community (CfQcc). FDA staff participated in the development of the pilot study discussed in this report as subject matter experts. However, the contents of this report represent the views of the MDIC and do not necessarily represent the official views of, and are not an endorsement by, U.S. Food and Drug Administration (FDA)/Department of Health and Human Services (HHS) or the U.S. Government. The views, findings, and interpretations contained in this document do not constitute FDA guidance, position on this matter, or legally enforceable requirements.

About the MDIC Case for Quality Collaborative Community (CfQcc)

At MDIC, we unite in a shared mission to improve health and save lives by accelerating access to medical technologies. Through stakeholder collaboration, MDIC leads the way in advancing the scientific and technical foundations of medical device design, manufacturing, regulation, reimbursement and clinical integration. Founded in 2012 as a nonprofit, public-private partnership to elevate regulatory science, MDIC develops new approaches and tools for addressing shared challenges among medical device manufacturers, researchers, regulators, payers, patients, and health care providers. We deliver high impact work in the core areas of quality design and manufacturing, evidence generation, digital technology and transformation, and patient engagement. **To learn more and join us in our mission, visit [MDIC.org](https://www.mdic.org).**

The MDIC Case for Quality Collaborative Community, now named the Advancing Quality Excellence Collaborative Community, offers a unique opportunity for medical device stakeholders to work together to enhance device quality and patient safety.

Leveraging its unique convening platform, the AQEcc brings together manufacturers, healthcare providers, governmental agencies, third parties, industry associations, and other stakeholders to develop practices, tools, and metrics that promote product quality—from design and manufacturing to performance.

Through stakeholder collaboration, the AQEcc encourages regulatory best practices that align with these goals. Key initiatives include the Voluntary Improvement Program (VIP), SafeSpace, #makeCAPAcool – Risk-Management Framework, Accelerate Sustainable Capability Pilot, Championing a Culture of Quality Initiative, and various stakeholder events.

Get involved at [mdic.org/our-work/advancing-quality-excellence-collaborative-community-2/](https://www.mdic.org/our-work/advancing-quality-excellence-collaborative-community-2/)

About MedAccred

MedAccred is a medical device industry-managed, critical process supply chain oversight program that reduces risk to patient safety, assures quality products and verifies compliance with requirements. The program is administered by the Performance Review Institute.

OEM subscribers including Becton Dickinson, Boston Scientific, Edwards Lifesciences, Medtronic, Philips Healthcare, Stryker and now W.L Gore, fund and manage the accreditation program and determine audit criteria, interview and select auditors, and determine which suppliers are granted accreditation.

Learn more at www.p-r-i.org/medaccred

About PRI

The MedAccred program is administered by the Performance Review Institute (PRI), a not-for-profit trade association started in 1990. PRI is a global administrator of industry-managed critical process accreditation programs focused on improving process and product quality with collaboration among stakeholders in industries where safety and quality are shared goals.

Learn more at www.p-r-i.org

This report provides an overall summary analysis of the findings by the Medical Device Innovation Consortium (referenced herein as “MDIC”) following the evaluation of MedAccred’s Sterilization Audit and Accreditation Program of contract sterilizers as an acceptable audit approach that may be leveraged for regulatory purposes.

Introduction

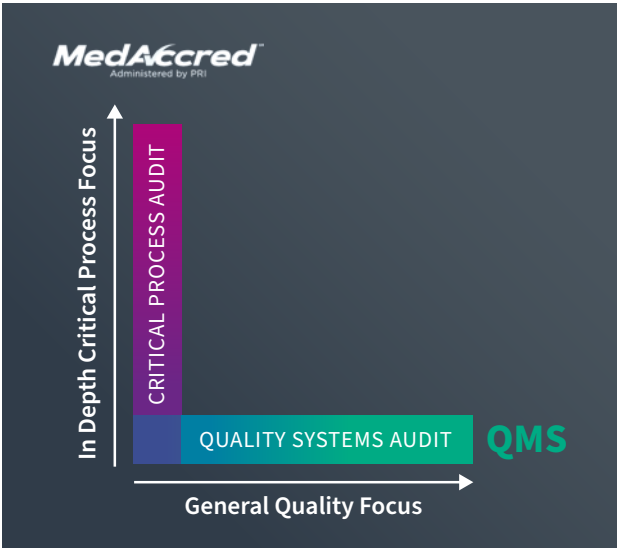
Background

A pilot study was conducted to evaluate the MedAccred’s Sterilization Audit and Accreditation Program for contract sterilizers by observing MedAccred sterilization audits, reviewing the resultant audit reports, and evaluating information for determining if the MedAccred Accreditation process is suitable for regulatory purposes. This final report is being issued to the U.S. Food and Drug Administration (also referenced herein as “FDA”) by MDIC to summarize the pilot and evaluation process and provide recommendations for consideration as part of their regulatory decision making.

MedAccred is an industry managed, consensus-driven approach to ensuring critical manufacturing process quality throughout the medical device supply chain. The MedAccred program is administered by the Performance Review Institute (PRI) which provides consistent/standardized critical process accreditation accepted by the Medical Device Industry resulting in fewer redundant onsite audits by multiple Original Equipment Manufacturers (herein also referred to as “OEM”s) by conducting in-depth critical process audits that are compliant and consistent to accepted industry/technical standards and conducted by Subject Matter Experts while providing greater visibility of the supply chain to all levels and sub-tiers that provide critical processes, consistent with regulatory requirements (e.g., FDA, ISO 13485, MDD, etc.). The utilization of medical device industry-accepted and consistent technical requirements leads to process discipline, greater operational efficiency and continuous improvement resulting in higher quality and lower overall cost.

Audits are conducted on behalf of its subscribing OEM members using collaboratively created audit criteria. The accreditation is granted and accepted by the program’s subscribing OEM members. The audit criteria incorporate industry accepted performance standards and manufacturer specifications that meet the requirements of regulators. Process-focused and technical audits are conducted by industry approved and trained subject matter expert (SME) auditors, who have extensive process experience and knowledge.

The MedAccred sterilization audit is an independent process focused assessment of a contract sterilization facility’s conformance to the sterilization standards for Ethylene Oxide - ISO 11135 and/or Radiation (Gamma and E-beam) – ISO 11137. The MedAccred sterilization audit also includes a full



Quality Management Systems (also referred herein as “QMS”) audit assessing conformance to ISO 13485 (2016) and 21 CFR 820. Unlike traditional Quality Management System audits, as depicted in the illustration, the MedAccred audit is a thorough, vertical manufacturing process audit. A quality management system serves as the foundation, and a current valid QMS certification, such as ISO 13485, is required before scheduling a MedAccred Accreditation audit. The two types of audits together, both the Quality Management System and process audit, ensure that the highest product quality standards have been achieved.

The MedAccred Sterilization Audit and Accreditation Program, the subject of the conducted pilot study and this report, covered the following not all-inclusive audit elements as described in the *MedAccred Pilot Summary Report* attached in **Exhibit 1**:

- 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.

Procedural History & Legal Authority

FDA inspections of firms, such as contract sterilizers, are pursuant to Title 21-FOOD AND DRUGS, CHAPTER 9-FEDERAL FOOD, DRUG, AND COSMETIC ACT, SUBCHAPTER V-DRUGS AND DEVICES, Part A-Drugs and Devices, Section 21 USC 360: Registration of producers of drugs or devices, Subsection (h) Inspections.¹ Specific applicable extracted clauses pertaining to the inspection of sterilizer suppliers from §360 - Registration of producers of drugs or devices in the Act are as follows:

Subsection (h) Inspections -

“(1) In general

Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 374 of this title.

(2) Risk-based schedule for devices

(A) In general

The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the

¹ Title 21-FOOD AND DRUGS, CHAPTER 9-FEDERAL FOOD, DRUG, AND COSMETIC ACT; SUBCHAPTER V-DRUGS AND DEVICES; Part A-Drugs and Devices; Section 21 USC 360: Registration of producers of drugs or devices; Subsection (h); Inspections; <https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section360&num=0&edition=prelim>; Text contains those laws in effect on November 29, 2023.

manufacture, propagation, compounding, or processing of a device or devices (referred to in this subsection as "device establishments") in accordance with a risk-based schedule established by the Secretary.

(B) Factors and considerations

In establishing the risk-based schedule under subparagraph (A), the Secretary shall-

(i) apply, to the extent applicable for device establishments, the factors identified in paragraph (4); and

(ii) consider the participation of the device establishment, as applicable, in international device audit programs in which the United States participates or the United States recognizes for purposes of inspecting device establishments.

(4) Risk factors

In establishing a risk-based schedule under paragraph (2) or (3), the Secretary shall inspect establishments according to the known safety risks of such establishments, which shall be based on the following factors:

(A) The compliance history of the establishment.

(B) The record, history, and nature of recalls linked to the establishment.

(C) The inherent risk of the drug or device manufactured, prepared, propagated, compounded, or processed at the establishment.

(D) The inspection frequency and history of the establishment, including whether the establishment has been inspected pursuant to section 374 of this title within the last 4 years.

(E) Whether the establishment has been inspected by a foreign government or an agency of a foreign government recognized under section 384e of this title.

(F) The compliance history of establishments in the country or region in which the establishment is located that are subject to regulation under this chapter, including the history of violations related to products exported from such country or region that are subject to such regulation.

(G) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources."

Sterilizers of medical products, as they further process devices are defined as "establishments" and as such "required to be registered", are subject to the afore-referenced provisions of the Act.

High-level Summary of Pilot Study

Analysis of the pilot study reported results demonstrated that the MedAccred auditors were highly qualified, and the audit processes were thorough and comprehensive. Comparison of the MedAccred audit and regulatory inspectional elements were found to be at least equivalent, and in some areas more in-depth, than industry standards. MedAccred audit elements include, but are not limited to existence, adequacy, and compliance of the QMS; IQ/OQ/PQ, validation, and maintenance & calibration

of equipment; organization, qualification, and training of personnel; process validation; review and response to non-conformances; sampling plan; review and evidence of corrective actions; and verification of effectiveness.

Feedback from Sterilizers that participated in the pilot study indicated the audit was conducted as expected, there were no issues that were identified, and that the auditor was professional and congenial. Feedback from FDA observers indicated that though there were some early communication issues that were overcome (wi-fi connectivity, pre-access to documentation), ultimately the audit was thorough and covered all critical areas of EO and Radiation (Gamma and, or E-beam) sterilization processes.

The *Pilot Study Summary Report* of the results for the *MedAccred Sterilization Audit and Accreditation Program* appears in **Exhibit 1** of this report for reference and in-depth detail.

MDIC Findings

Based on the comprehensive review and analysis of the MedAccred Sterilization Audit and Accreditation Program (encompassing both full Process and Quality Management Systems (QMS) audits) during the conducted pilot study, MDIC finds the audit and accreditation program robust and comprehensive concerning the covered sterilization processes combined with a thorough evaluation of the Quality Management System (QMS) requirements.

The MedAccred Audit also presents a substantial benefit to suppliers by providing a comprehensive and thorough audit by auditors that are highly experienced with expertise in sterilization processes, technical elements, and applicable performance standards. Device manufacturers employing or sub-contracting critical processes, such as sterilization, may find value in leveraging the MedAccred audits in lieu of performing their own independent supplier audits, as appropriate, according to their established purchasing control requirements.

Of the nine participating sterilizers in this study, eight were granted MedAccred accreditation and one is pending verification of corrective actions.

MDIC considers that annual MedAccred Sterilization audits provide sustained oversight and adequate information that can be leveraged for regulatory purposes by the medical technology industry and regulators. The detailed summary report supporting these findings is attached herein as **Exhibit 1**.

Exhibit A

Pilot Study Summary Report

MedAccred Sterilization Audit and Accreditation Program

December 5, 2024

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Purpose

This pilot program was developed to evaluate the robustness of the MedAccred Sterilization Audit and Accreditation program of contract sterilizers and whether data from the audit may be leveraged to inform regulatory activities or decisions.

Background & Rationale

Description of MedAccred

MedAccred is an industry managed, consensus-driven approach to ensuring critical manufacturing process quality throughout the medical device supply chain, contract manufacturers, and sterilization providers.

Accreditation by MedAccred:

- Provides consistent/standardized critical process accreditation accepted by the Medical Device Industry resulting in fewer redundant onsite audits by multiple OEMs
- Assures in-depth critical process audits that are compliant and consistent to accepted industry/technical standards and conducted by Subject Matter Experts
- Provides greater visibility of the supply chain to all levels and sub-tiers that provide critical processes, consistent with regulatory requirements (e.g. FDA, ISO 13485, MDD, etc.)
- Improves flow down of OEM requirements to sub-tier suppliers
- Medical device industry-accepted and consistent technical requirements leading to process discipline, greater operational efficiency and continuous improvement resulting in higher quality and lower overall cost

For sterilization providers, MedAccred provides a complementary approach to oversight by industry customers and existing supplier management programs. The annual audits performed by MedAccred provide more consistent and in-depth evaluation of critical processes and quality systems, resulting in greater confidence and assurance of product sterility and patient safety. A MedAccred Sterilization audit encompasses both full Process and Quality Management Systems (QMS) audits ([Reference Appendix 5](#)).

Rationale

Ensuring appropriate oversight of sterilization providers is a challenge in the current, complex global environment, MedAccred helps improve or augment the limited resources of original equipment manufacturers (OEMs) and regulatory bodies.

Dr. William Maisel, Director, Office of Product Evaluation and Quality, CDRH, Chief Medical Officer, FDA, and team voiced FDA's strong support during a meeting on February 10, 2022 with MedAccred and proposed a path forward to potentially leverage information from the MedAccred Sterilization audits for regulatory purposes.* There is potential to use data provided by the MedAccred audits and the MedAccred

*Note: FDA will not relinquish its right to inspect in accordance with Section 704(a) of the Food, Drug and Cosmetic Act

Accreditation to inform inspection planning and better utilize FDA resources based on risk. This would enable FDA to use its resources to “cover the landscape” effectively.¹

The proposed path forward was to conduct a pilot to evaluate the MedAccred Sterilization Audit and Accreditation Program by observing MedAccred sterilization audits and reviewing the resultant audit reports. A final report issued to FDA through the MDIC will summarize the audit and evaluation process and provide recommendations for implementation.

MedAccred Audit Procedure

Roles of participants

1. Performance Review Institute (PRI) administers the MedAccred program on behalf of the medical device industry. As a Not for profit, PRI brings OEMs and suppliers together to provide industry experts to oversee the process, schedule audits, contract auditors, resolve audit nonconformances, and publish program documents.
2. Medical Device OEM Subscribers manage the program, develop program requirements, determine all audit criteria, provide subject matter experts (SMEs) to participate on task groups, review program operations, interview and select auditors, have full access to audit findings, and determine who is granted MedAccred Accreditation.
3. Suppliers contribute to the development of audit criteria, support the operation of the task group, initiate audits, and provide subject matter expertise.

Sterilization Task Group

1. The sterilization task group is made up of sterilization and sterility assurance experts in the industry from medical device manufacturers, pharmaceuticals, and contract sterilizers. These experts have been at the top of their profession for many years, participating in standards development organizations (e.g., AAMI, ASTM), publications, and leading their respective companies.
2. The Task Group is responsible for: defining the MedAccred Sterilization accreditation scope and audit duration; development of audit criteria; auditor selection, training, and consistency; the audit process, including audit review and accreditation decisions; addressing auditee appeals; developing metrics and taking action based on review of metrics as appropriate; and defining specific process control changes that require notification and Task Group review. The development of metrics will be defined by the task group once a statistically valid number of audits have been performed.

¹ FDA’s Resiliency Roadmap for FDA’s Inspectional Oversight (May 2021)

3. The MedAccred Sterilization Task Group ([Table 1](#) below) is currently composed of the following individuals and companies:
 - a. Medical Device/Pharma Manufacturers. OEM – MedAccred Subscriber Sterilization SMEs
 - b. MedAccred Sterilization Staff Engineer/Auditor SME
 - c. Sterilization Supplier SMEs

Table 1. MedAccred Sterilization Task Group Members (at the time of the pilot study)

First Name	Last Name	Company	Title	MedAccred Role
Kim	Patton	PRI-MedAccred	Lead Sterilization Technologies Engineer	Staff Engineer/Auditor
Lisa	Foster	PRI-MedAccred	Consultant	Auditor
John	Williams	Medtronic	Sterility Assurance Director	Subscriber (Chair)
Mike	Sadowski	Baxter	Director, Sterile Manufacture Support	Subscriber (Vice Chair)
Denise	Cleghorn	Boston Scientific	Sr. Radiation Sterilization Engineer	Subscriber
Erick	Gustin	Stryker	Global Director, Sterilization & Microbiology	Subscriber
Steven	Seamons	Edwards Lifesciences	Principal Sterilization Engineer	Subscriber
Karla	Martinez Rojas	Philips	Manager, Supplier QA – Global Quality	Subscriber
Christophe	Deneux	BD	Sr. Director, Sterility Assurance	Subscriber
John	Logar	Johnson & Johnson	Sr. Director, Sterility Assurance	Participating Manufacturer
Michael	Ezzo	Steris	Sr. Director Qty & Reg Compliance, AST	Contract Sterilizer
Scott	Beard	Steris	VP, AST Quality Operations	Contract Sterilizer
Aaron	DeMent	Sterigenics	VP, Sterilization Technologies	Contract Sterilizer
Chris	Eustace	Sterigenics	VP, Global QA	Contract Sterilizer
Larry	Nichols	Steri-Tek	CEO	Contract Sterilizer

Sterilization Audit Program

A MedAccred Sterilization audit encompasses both full Process and Quality Management Systems (QMS) audits. The audit verifies that a supplier has the critical process capability to comply with state-of-the-art technical standards (sterilization) and QMS standards. The auditors verify that the sterilization facility has the necessary equipment and qualified personnel along with appropriate capability for monitoring and controlling the process.

1. The MedAccred audits cover:
 - a. Quality Management System elements (See [Appendix 5](#))
 - b. Sterilization technical assessment using ISO and ASTM sterilization standards and guidelines as well as other guidance documents (Reference [Appendix 5](#))
 - c. Conformance to regulatory requirements and guidance
 - d. Methodology to achieve compliance
 - e. Equipment calibration and preventative maintenance

- f. Routine process controls
 - g. Qualified personnel and training
 - h. Process validation – meeting industry (See [Appendix 5](#))) and customer requirements
2. The sterilization task group performed a qualitative assessment of audit practices in general to assess and compare the MedAccred audit practices. Based on this review, the MedAccred audit was felt to be at least equal to or more rigorous than other auditing bodies for the following practices reviewed (see [Appendix 1](#)):
- a. Recording audit data
 - b. Sampling plans
 - c. Review and response to nonconformances
 - d. Corrective actions
 - e. Evidence
 - f. Verification of effectiveness
 - g. Certification or accreditation
 - h. Close-out requirements

Auditor Selection

MedAccred auditors are recognized industry Subject Matter Experts that are hand selected, interviewed and trained by members of the MedAccred sterilization task group (STN) and must have the following qualifications:

1. Possession of a Bachelor degree in a scientific field
2. Minimum of 3 years hands-on Sterilization work experience in Ethylene Oxide or Radiation (Gamma &/or Electron Beam)
3. Significant knowledge of the Standards as they relate to Sterilization including ISO and ASTM
4. Minimum of 5 years auditing experience (not necessarily sterilization)
5. Quality Assurance System experience (primarily ISO 13485 or 21CFR820)
6. Willingness to travel extensively
7. Any other pertinent data such as research conducted, leadership positions, etc.
8. The following are not currently required, but strongly encouraged by the task group and staff engineer:
 - a. Certified Industrial Sterilization Specialist (CISS) certification
 - b. Engagement in sterilization standards through AAMI or other mirror groups
 - c. Society for Sterility Assurance Professionals – learning framework, profile and continuous learning
9. Auditors are required to complete a minimum of 2 training audits with a designated training auditor prior to being considered as an approved auditor.

Audit Criteria Elements

The audit criteria have been developed over the last 10 years by the MedAccred sterilization task group. The current checklists are Revision C delta 3. Continuous improvement of the checklists is the responsibility of the MedAccred task group and MedAccred staff engineer. It is updated whenever there are standards revisions, new standards, or new guidance that the task group has determined to be industry standard.

Sterilization Standards, Quality Systems standards and guidance documents provided key elements of the audit criteria listed below: (Reference [Appendix 5](#))

1. General:
 - a. Standard Operating Procedures (SOP) Product / Process Specifications
 - b. Routine Monitoring and Control
 - c. Calibration and preventive maintenance
 - d. Sterilization monitoring devices, controls and equipment (Dosimetry, Biological indicators, sensors, spectrophotometers, thickness gauges, etc.)
 - e. Proper storage, handling and monitoring
2. Gamma:
 - a. Installation Qualification (IQ)
 - b. Operating Irradiator and Conveyor System, Containers, Verification of Installation, etc.
 - c. Operational Qualification (OQ), replenishments, change control
 - d. Irradiation Container Qualification Grid, Dose Mapping, Process Interruption Testing, transitioning, multiple densities, etc.
 - e. Performance Qualification (Product Dose Mapping) (PQ)
 - f. Loading Pattern, Monitoring Locations/Equivalent Dose Zones/calculation ratios/Dose Uniformity Ratio, etc.
3. E-Beam:
 - a. Installation Qualification (IQ)
 - b. Containers, Maintenance & Calibrations, Beam Inputs (e.g., Energy, Pulse repetition rate, Scan frequency, Scan width, Scan magnet current, etc.), etc.
 - c. Operational Qualification (OQ)
 - d. Qualification Grid, Impact of Edge Effects, Interruption Testing, etc.
 - e. Performance Qualification (Product Dose Mapping) (PQ)
 - f. Loading Pattern, Dose Mapping, Scan Horn & Product Distance, Product Orientation, Monitoring Locations/Equivalent Dose Zones/Dose Uniformity Ratio, etc.
4. Ethylene Oxide (EO):
 - a. Facility – General
 - b. Sterilant Storage, Sterilizer Equipment Characterization, etc.
 - c. Ethylene Oxide Sterilization Validation
 - d. IQ, OQ, PQ
 - e. Sensor Calibration, RH Sensors, Circulation System, Process Deviation Alarms, Product-loading Patterns, etc.

- f. Precondition
 - g. Pattern of Air Circulation, Temperature & Humidity Sensor Placement, Water Quality Evaluation, etc.
 - h. Sterilization chamber – EO concentration, pressure, temperature, humidity
 - i. Preventative Maintenance
 - j. Aeration
 - k. Temperature & Humidity Sensors, etc.
 - l. Process Control Documentation
 - m. Process Extremes, Sterilant Pressure, Aeration Process, Preconditioning, etc
5. Sterilization standards for methodology to achieve compliance to the requirements:
- a. ASTM E61 standards
 - b. Guidance documents from industry organizations (CIRMS, Panel)
6. Quality Systems – (Reference Appendix 5) – covers all the key elements of a rigorous QS audit:
- a. Quality Documents
 - b. Facility - General Tour
 - c. Facility Management
 - d. Quality Management Systems
 - Management Review
 - e. Management Responsibility
 - f. Resource Management
 - Training
 - g. Production and Process Control
 - Process Tracking, Traceability, Unloading of Product, Calibration, Maintenance, Software, Purchasing Controls
 - h. Measurement Analysis and Improvement
 - Non-conforming Process & Product, Internal Audits, CAPA Process
 - Feedback, complaints
 - i. Risk Assessment Tools
 - Procedure, Process, Outputs

Audit Process

MedAccred technical process audits are very different from Quality Systems audits, but the combination of the two audits result in a significant improvement in the final product quality and repeatability of the process. This fresh approach to optimizing quality in critical manufacturing processes is expected to result in reducing redundant industry audits, supply chain resiliency, improving final product quality and most importantly patient safety. A MedAccred audit is a robust sampling of the special process requirements (sterilization) inclusive of the QMS elements as the underlying support. Not only is the existence and adequacy of the QMS and Technical programs confirmed, but evidence is required to verify compliance to the requirements.

Audit process summary:

1. Pre-Audit
 - a. As a highly recommended practice, the Auditee should upload self-audit to eAuditNet a minimum of 30 days prior to the audit
 - b. Auditee must complete a facility information form
 - c. Auditee must upload all procedures to a shared folder for preparation
2. Audit
 - a. Desk audit / preparation day
 - b. Opening Meeting
 - c. Tour
 - d. Job Audits (collection of evidence for compliance)
 - e. Daily summary
 - f. Closing Meeting
3. Post Audit
 - a. Non-conformance Response (NCR) and Resolution Process with Staff Engineer Subject Matter Expert (SME)
 - b. Task group review of the Audit and Accreditation decision
 - c. Accreditation issued to the supplier
4. Timeline ([Table 2](#) below)

Table 2. Audit Process Timeline

Audit Response Timeline and Follow-up	
Auditor to submit audit report into eAuditNet (eAN)	3 business days after the end of the audit
Staff Engineer review of audit	3 calendar days after audit submittal for SE review
NO NCR's - Auditee review and complete feedback in EAN	3 calendar days after audit submittal for Auditee review
NCRs - Auditee review, response to NCs and audit feedback in EAN	21 calendar days after audit submittal for Auditee review
Review cycles for response	4 review cycles are allowed - after 6 the audit will be considered for failure ballot
Additional cycle responses	7 calendar days after request for additional information
Staff engineer review and disposition	14 calendar days after submittal of audit for SE review
Task group review of audit package and ballot for accreditation (to include any of the following: (Verification of Corrective Actions (VCA), failure, accreditation)	7 calendar days after audit submittal for Task Group review
Task group consideration for audit ballot for failure	30 days cumulative delinquency from response due date

Accreditation Process (see [Figure 1](#) below)

1. After all NCRs are closed and the Subscribers in the task group vote by ballot to accredit the supplier facility, the audit status will be updated to Accredited, a certificate will be issued, and the company added to the MedAccred on-line QML in eAuditNet.
2. The accreditation length is 12 months.
3. To maintain accreditation, reaccreditation audits must be scheduled annually and successfully completed.

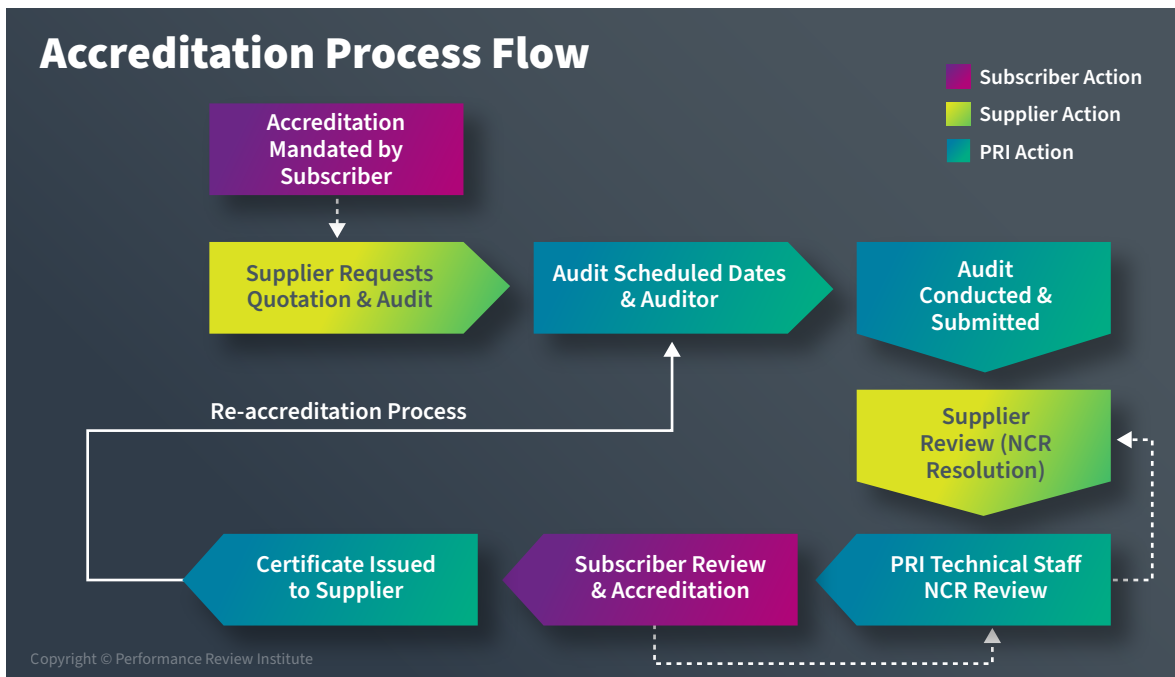


Figure 1. Accreditation Process Accreditation Flow

MDIC MedAccred Sterilization Pilot Operations

Scope:

The scope of the pilot included three sterilization modalities: Ethylene Oxide, Gamma Radiation and Electron Beam radiation. There were multiple suppliers, auditors, and observers as part of the pilot as well.

Pilot Guiding Principles:

1. Perform Sterilization audits according to MedAccred program requirements as defined in MedAccred Program document PD1300 and Sterilization Audit Criteria AC8113 developed and approved by the MedAccred Sterilization Task Group and Management Council.
2. FDA CDRH and ORA representatives to, at a minimum, witness one pilot in each MedAccred modality (three total): Ethylene Oxide, Gamma, and E-Beam

3. MedAccred Subscriber company representatives may observe audits if agreed to by pilot audit company.

Once pilot audits are complete, submit a final summary report to MDIC Case for Quality Collaborative Community Steering Committee for review.

Eligibility and Participation:

1. Eligibility:

a. Audit Observer Eligibility:

- i. MedAccred Subscribing company representatives
- ii. FDA representatives and inspectors
- iii. Observers may not influence the audit. Their role is to review the audit process and provide feedback post-audit

b. Audit Company Requirements:

- i. Firms in good standing with FDA
- ii. Eligible: Firms with Voluntary Action Indicated (VAI) or No Action Indicated (NAI)
- iii. Not eligible: Firms currently classified as Official Action Indicated (OAI)
- iv. Firms with EO, Gamma Radiation, or E-Beam Radiation capability
- v. Valid ISO 13485 Certificate
- vi. Availability and staff to host a 3-4 day audit which shall be pre-announced

2. Participation Expectations:

a. Audit Observers:

- i. The purpose of the observation audit is to review the MedAccred audit process.
- ii. The MedAccred auditor is solely responsible for conducting the audit per MedAccred requirements
- iii. No influence to the selection of job audits
- iv. Remain with the auditor
- v. Refrain from discussing the audit process or results with the Auditor while the audit is being conducted
- vi. The observation is not to be used to simultaneously assess the Auditee or their processes per regulatory or Subscriber-specific requirements
- vii. Observers shall not provide interpretations of compliance to MedAccred requirements during the audit
- viii. Audit observers to be provided access to the audit criteria and auditee procedures

b. Observer Feedback:

- i. Pilot Audit Observers will be asked to provide their feedback on the MedAccred audit process following the completion of each audit. (See Appendix 3)

- ii. Observer feedback will be incorporated into the pilot report generated by MDIC (not attributable).

Shared Commitments:

1. Audit administration:
 - a. MedAccred to manage sterilization audit details and include the MedAccred Sterilization Task Group in audit review.
 - b. MedAccred Sterilization Technologies Engineer is responsible for:
 - i. Coordinating audit plan/schedule
 - ii. Assigning auditors
 - iii. Audit review and NCR resolution (ensuring NCRs are properly closed out according to Task Group expectations)
 - iv. Compiling a summary report of all the evaluation audits to be shared with MDIC CfQ Steering Committee
 - v. Auditor training
2. MDIC to review audit plan
3. MedAccred to share Audit Criteria with FDA (NOTE: Confidential - not subject to FOI)
4. FDA will provide observers for and a review report of a minimum of three audits

Pilot Process Activities and Expectations

1. Pilot Process Flow and Timeline: (see Table 3 below)
 - a. Month 1
 - i. MedAccred, FDA, and MDIC align on objectives/goals/milestones.
 - ii. Develop audit plan (identify audit companies and locations)
 - iii. Determine the type of aggregate audit information required by FDA
 - b. Months 2-5
 - i. Conduct nine MedAccred Sterilization audits with three of the nine witnessed by FDA
 - ii. Develop mechanism to share aggregate data with FDA
 - c. Month 6
 - i. Review audit results and create summary report
 - ii. Submit final summary report to MDIC CfQ Steering Committee

Table 3. MedAccred Sterilization Pilot Audit Schedule and Sites

	Company	Mode	Dates - 2023	Auditor(s)	FDA Observers
1	Supplier 1	E-Beam	Feb. 15-16	Auditor 1	2
2	Supplier 2	Gamma	Feb. 23 - 24	Auditor 1 (Lead) Auditor Trainee 1	2
3	Supplier 3	Ethylene Oxide	Feb. 28- Mar 1	Auditor 1 (Lead) Auditor Trainee 2	1
4	Supplier 4	Ethylene Oxide	March 29 - 30	Auditor 1	1
5	Supplier 5	E-Beam	April 11 - 12	Auditor 2	3
6	Supplier 6	Ethylene Oxide	April 18 - 19	Auditor 3	3
7,8	Supplier 7, 8 (Main and Satellite Facility)	Gamma E-Beam	April 18 - 20	Auditor 1	3
9	Supplier 9	Ethylene Oxide	May 3-4	Auditor 1	0

Summary & Conclusion

The pilot has achieved the stated objectives for nine audits in a 12-week time period (February – May, 2023), observed by a minimum of one FDA representative for each of the three Sterilization modalities. This objective was exceeded by having between 1–3 FDA representatives observe eight of nine pilot audits. The pilot was performed according to MedAccred program policies, procedures and principles and included sterilization audit criteria evaluations for EO, Gamma, and E-Beam.

There were three different MedAccred Sterilization auditors and three different supplier companies who participated in the pilot. The audits were observed by FDA CDRH and ORA (11 different observers). The pilot also included two training audits where the MedAccred auditor trainees observed and participated in the audit process. One of the auditor trainees went on to complete their first solo audit as part of the pilot.

At this time, there are eight of nine pilot facilities that have achieved MedAccred Accreditation; There is one audit that is pending response following a VCA audit (Verification of Corrective Actions). The VCA included a review of the remaining items that were not available at the time of the audit, which includes annual preventive maintenance (PM), internal audit, management review and customer records.

Through the pilot process it was observed during the audits, and upon review of audits, that there were a couple of trends in the findings:

1. Resources & Training - Resources and training-related nonconformances were clearly identified in four of nine audits (44%). Training went hand in hand with that issue. The recent turnover to a new Quality Manager occurred in six of nine audits (67%). Some were within the same company, though in a different role. While others were new to the company and to sterilization.
2. Legacy or Original Validations - Legacy validations are from original equipment installation and typically before there were standards for the process or equipment (prior to 1995, not required). Original validations were performed at installation of equipment whenever that occurred. It is not unusual for legacy validations and even original validations to be difficult to locate if no one has asked for them before. There were three of nine audits (33%) with an identified issue, one of which was resolved during the audit.

Appendix 1: Audit Practices Review

Audit Practices	MedAccred	MDSAP	FDA	Notified Body (Example)
<p>Recording of audit data</p>	<p>Objective evidence requirements are given in the audit criteria and evidence audited is recorded in the audit report.</p> <p>Inspectional Objectives:</p> <ol style="list-style-type: none"> 1. Does the quality management system documentation include: [ISO 13485: 4.2.1] 2. Documented statements of a quality policy and quality objectives? 3. A quality manual 4. Documented procedures and records required by this International Standard? 5. Documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes? 6. Other documentation specified by applicable regulatory requirements? 7. The quality manual shall outline the structure of the documentation used in the quality management system and include scope of QMS and identify with rationale those items excluded from scope. 8. Does top management ensure that the quality policy: is implemented. QP is posted. Is applicable to the purpose of the organization? 9. Ensuring that processes needed for the quality management system are documented? Reporting to top management on the effectiveness of the quality management system and any need for improvement? Ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization? 10. Does the organization document procedures for management review? 	<p>Requirements and suggested evidence for review is documented in the MDSAP manual</p>	<p>Guidance in QSIT</p> <p>Use both Top-down and Bottom-up approach to review records/ evidence of inspection objectives</p> <p>Inspectional Objectives:</p> <ol style="list-style-type: none"> 1. Verify that a quality policy, management review and quality audit procedures, quality plan, and quality system procedures and instructions have been defined and documented. 2. Verify that a quality policy and objectives have been implemented. 3. Review the firm's established organizational structure to confirm that it includes provisions for responsibilities, authorities and necessary resources. 4. Confirm that a management representative has been appointed. Evaluate the purview of the management representative. 5. Verify that management reviews, including a review of the suitability and effectiveness of the quality system, are being conducted. 6. Verify that quality audits, including re-audits of deficient matters, of the quality system are being conducted 7. Evaluate whether management with executive responsibility ensures that an adequate and effective quality system has been established and maintained. 	<p>Records of an assessment include the agenda as well as the hand written notes taken throughout the assessment. These notes are then entered into a report template and used as objective evidence of what was reviewed including what records reviewed and any relevant discussions. Recording includes the title, document number, revision, dates etc. along with statements for compliance or noncompliance</p>

Audit Practices	MedAccred	MDSAP	FDA	Notified Body (Example)
Sampling plan	<p>Six sigma stat. at 95% confidence level Sampling Plan (Equation 1) to be used when determining the number of records to review when indicated in the audit point. The sample size is determined using the Discrete data sample size. For all population sizes determine sample size by: (ex. Batch records)</p> <p>Equation 1</p> $\text{Infinite} = n / 1 + (n / N)$ <p>n= minimum sample size N = population size P = estimate of the proportion of the population or process that is defective Δ = level of precision desired from the sample (express as decimal or percentage) 1.96 = 95% confidence level (fixed z score value)</p>	<p>No set sample size</p>	<p>Binomial 95% Confidence level (11 samples) - critical device can be at 99% (15 samples)</p> <p>Select the table based upon how sure you want to be about what is observed. For example, if you are reviewing Device History Records of a life supporting device, you may choose to use Table 2 (99% Confidence). You may choose to use Table 1 (95% Confidence) for the review of Device History Records regarding a device with lower risk.</p> <p>Select a sample size. If the population of records to be sampled is small (approximately thirty or less), you may choose to review all of the records.</p>	<p>The assessment covers all aspects of the QMS as indicated in the agenda. Span of time is from previous assessment to current and priority is given to changes/new products or processes. No requirement for a certain number of CAPA/NC etc.. to be reviewed. It is often driven by the volume of records, a small company may only have 2 CAPAs so we sample 100% where a big company has hundreds. The process is to then get a list and select those that seem most interesting and try to ensure you hit several topics. This sampling then can drive towards what complaints, NCs and other quality objects are reviewed</p>
Review of NCs	<p>Staff engineer and Subject Matter Expert review and final review through the Sterilization Task group where SMEs review and vote. This is part of the accreditation process. No items can remain open.</p>	<p>MDSAP AS F0015.1.001. Assessor or APM issues nonconformance, reviews action plan, specifies modality(s) for review of implementation and effectiveness, reviews evidence, and when closed APM sends letter of closure, if escalation is necessary the APM notifies Technical Review team for review and decision</p>	<p>Review by district supervisor</p>	<p>Previously issued minor NCs are closed during the next assessment for QMS audits. Major NCs have a shorter turn time. Microbiology minor NCs are closed in one year via a remote review of the actions taken since micro audits are only once every two years. The review of NCs looks for actions taken, were they done, in a timely manner, is there an effectiveness check? If not effective what additional actions were taken, including ensuring the correct root cause was identified. Objective evidence of all actions is required. Major NCs have different rules and can include pulling of a certificate and/or notification to other agencies depending on severity and class of device</p>

Audit Practices	MedAccred	MDSAP	FDA	Notified Body (Example)
Response to NC	<p>A response with corrective actions is required in 21 calendar days with additional follow up</p> <p>Once a response is overdue by 30 days then it becomes a failed accreditation attempt. The task group can determine to extend time.</p>	<p>MDSAP procedure AU P0027.005</p> <p>D0 (audit end date) +15 calendar days: Recommended due date for the manufacturer to provide a remediation plan (including for each nonconformity: the outcome of the investigation of the nonconformity and its cause(s); the planned correction; and the planned corrective action).</p> <p>D0+30 calendar days: Recommended due date for the manufacturer to provide evidence of implementation of the remediation actions addressing any grade 4 or 5 nonconformity</p>	Initial response is 15 days	<p>Minor NCs require a written response within 30 days. Majors require a quicker response – maybe 10 days. The written response is reviewed and either accepted or rejected. If rejected the assessor must specifically state why and return the response to the client. Major NCs require a second assessment, typically remote but can be onsite if warranted</p>
Corrective Actions	Same as review of NCs	Same as Review of NC's	District office review and acceptance	Auditor reviews and accepts

Audit Practices	MedAccred	MDSAP	FDA	Notified Body (Example)
Evidence of corrective actions	Require hard evidence to close out nonconformities and achieve accreditation	Determined by Auditor and/or Audit Planner and specified to auditee	Require hard evidence to close out nonconformities	Objective evidence in the form of records, revised procedures, training records, reports etc are reviewed and deemed to either meet the agreed upon actions or not. If not the NC cannot be closed and additional work is required. For minors this is recorded and the deadline extended in the system. Majors have a different set of requirements again based on the severity and class of device
Verification of Effectiveness	Performed at next audit if still open	Determined by Auditor and/or Audit Planner and specified to auditee	Followed up at next inspection	NCs may be closed if the effectiveness check is ongoing and takes additional time (trending etc.) but during the next assessment these will (should be) reviewed to ensure completion. If an assessor finds an effectiveness check that demonstrates originally agreed upon actions were not effective they can issue a new NC in the system
Certificate	Certificate is issued			Certificate issued
Requirements for Close out	Membership balloting for acceptance of audit and corrective actions, if any		District office accepts responses, no written confirmation, no Warning Letter	If the assessor reviews the records provided and finds all is completed as agreed upon, including effectiveness check the NC is formally closed in the system.

Appendix 2: Auditee Feedback – Auditor Evaluation

The following feedback was provided by the Auditees regarding the performance of the MedAccred Auditor. These are standard Auditee Feedback questions that every audited company responds to.

Auditee Feedback - Auditor Evaluation Questions

Questions	Company								
	1	2	3	4	5	6	7	8	9
Did the auditor contact you at least three weeks prior to the audit to discuss the audit plan?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Did the auditor conduct an opening meeting to discuss the audit agenda and confirm the audit scope?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was this meeting effective?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	N/A
Was it evident that the auditor reviewed/utilized the self-audit that was submitted prior to the audit?	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Did the auditor conduct a daily debriefing to review nonconformances and to discuss the audit progress?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Were these meetings effective?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Did the auditor clearly and effectively explain each nonconformance and provide the auditee with a draft written or electronic document detailing all nonconformances and observations? (Indicate N/A if there were no nonconformances)	No	Yes	Yes	N/A	Yes	Yes	Yes	Yes	Yes
Did the auditor act in a professional and business-like manner?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Did the auditor conduct a closing meeting to discuss any issues and to explain all nonconformances?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was this meeting effective?	Yes	Yes	N/A	Yes	Yes	Yes	Yes	Yes	Yes
Did the auditor provide a review of the eAuditNet process and timeframe for responding to nonconformances?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was this review effective?	No	Yes	N/A	Yes	Yes	Yes	Yes	Yes	N/A
Was the communication between the auditor and the Auditee clear enough to prevent language barriers from impacting the audit results?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Did the auditor use time effectively to complete the audit?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was the auditor on-site a sufficient amount of time to conduct a thorough audit?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was the auditor consistent in their application of requirements as compared to previous audits?	N/A	Yes	Yes	N/A	Yes	Yes	Yes	N/A	N/A
Did the auditor demonstrate appropriate technical knowledge for the process(es) reviewed?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
May PRI share your feedback with the auditor? (If there are limitations to what may be shared, please add a note describing the restriction.)	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Auditee Feedback – Auditor Evaluation – Overall Comments

Overall Comments	
1	Overall, the auditor seemed effective enough and conducted a thorough audit. We did find the entire audit process to be cumbersome, confusing and time consuming. From the start, instructions were not entirely clear, and the resources to help navigate the website were hard to sift through. It seems like the resources were slightly outdated- the screenshots did not match what I was seeing on my browser. Additionally, much time went into this audit; 2 days for checklists and share folder prep, 1 day for desktop audit and additional requests, and 2 days for the onsite audit. This is even without the self-audit task that I was unable to complete, and the additional time spent on follow-up requests. 5 days is a long time to dedicate to an audit. This would be more acceptable if our customers accepted MedAccred audits. Currently, our customers that partner with MedAccred still audit us. Their audits are only 1-2 days each, but all of those combined with this 5 day MedAccred audit commitment makes it seem like MedAccred is not a beneficial certificate to have at this point. Additionally, our other facility has mentioned that it took them over a year to be issued a new MedAccred certificate. They were told it was due to a lack of staff, but our company had to answer to customers constantly questioning why our certificate was expired. Our customers noted that it seemed unprofessional for our certificate to be this late. I hope this isn't an issue in the future.
2	The audit was conducted as expected and there were no issues that were identified. The auditor was professional and congenial.
3	The audit process with MedAccred is always smooth and easy to follow and that continued again this year even with the addition of the FDA observers.
4	I felt that the auditor represented the MedAccred program professionally and did not let the presence of the FDA auditors change in approach to the audit or potential findings.

Appendix 3: FDA Observer Feedback

FDA Observer Surveys

The following questions were asked as part of the survey to each FDA observer. All responses were answered “yes” by FDA observers except for one audit where Question 3. (audit length) was answered “No”. That feedback is below and concerned with the intermittent wi-fi at that particular audit.

1. Did the **audit structure** (Audit Preparation, Agenda, Scope, Opening Meeting, NCR Identification/Communication, etc.) meet your expectations?
2. Did the **audit criteria cover** all key quality system and technical elements of the supplier’s process?
3. Was the **audit length (# of audit hours)** sufficient to cover the key quality system and technical elements in the supplier’s process?
4. Did the **audit as a whole** meet the expectations of the FDA?

Supplier Audit #	1	2	3	4	5	6	7	8	9
FDA Observer Evaluation Responses (11 Observer Aggregate)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
1. Did the audit structure (Audit Preparation, Agenda, Scope, Opening Meeting, NCR Identification/Communication, etc.) meet your expectations?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Did the audit criteria cover all key quality system and technical elements of the supplier’s process?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3. Was the audit length (# of audit hours) sufficient to cover the key quality system and technical elements in the supplier’s process?	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
4. Did the audit as a whole meet the expectations of the FDA?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Comments provided by FDA observers

1. It would be beneficial to be informed of any follow ups and the final decision regarding the audit. There were still some open items for the audit, so it would be nice to see how those issues were resolved.
2. I appreciated the thoroughness of the audit
3. Regarding the No answer and additional comments
 - a. Wifi: To prevent audit delays and loss of audit notes, it is important to define if the company that is being audited is responsible for providing a stable and reliable wifi connection or auditor should have a 5G Wifi router at hand as an additional tool to perform the audit, especially if the auditor relies on an online system to perform the audit.
 - b. Hardcopy: The documentation reviewed during the audit was provided only in hardcopies, which was something that I had [not] seen in a while. I don’t know if the use of a small screen

laptop or the need to use an online platform to perform the audit where the cause, but in my opinion, these documents could have been reviewed digitally. [The site] did have a large screen, with multiple access, that was only used in the opening and closing. Another option would be to have a large screen laptop or have two monitors provided by the company that is being audit so the auditor could go easily through the document in one screen and make notes on the online platform on the other screen.

- c. Evidence: I noticed a couple situations during the walk thru audit where the auditor asked questions and got only verbal feedback from the company. In my opinion, any audit questions raised during the audit should be documented with supporting evidence.
 - d. Audit preparation: I did not have access to the audit preparation, making it difficult to observe how the selected documentation was chosen.
4. I thought the audit was thorough and covered all critical areas of an EO sterilization process. The audit consisted of two auditors and there were a lot of documents reviewed and long days. The next two audits I will be observing will involve only one auditor. I look forward to seeing how detailed the audits will be with one auditor.

Both auditors demonstrated their knowledge on EO sterilization during the audit and the two minor nonconformances were appropriate. It would be helpful to know more of the pre-audit activities and the documents reviewed during the pre-audit process. I was impressed with the MedAccred audit.

5. The audit was detailed and thorough. It was good to be able to witness how two auditors might work together to complete the audit. It went very smoothly.

I'd like to recommend the observers get access to the audit report, post audit. This will give us an idea how the reports may look like and the information that is typically included on the reports. Further, having had the opportunity to observe, we can appreciate the report out that much more because we have something to compare it to.

It was difficult to observe at times, as the records were being provided hard copy.

It might also be beneficial for the observers to get access of the records that the auditor requests as part of the desk audit that is performed prior to the audit. Further, SharePoint or OneDrive access should be set up for the observers as it is for the auditors.

6. This site was new. A good opportunity for us to witness how this is handled. FDA comes across these situations from time to time as well. Will the observers have a chance to attend the follow-up audit once they have processing reports to share so the audit can be completed? Will this be done virtually? Is there a process in place that defines how these situations are handled. How are these scenarios typically handled?
- The audit was thorough and detailed.
 - Would appreciate the opportunity to review the audit report.
 - Two nonconformance's were identified during the audit. Would like the opportunity to see the process how those nonconformances get addressed.
 - Recommend SharePoint/OneDrive access be given to the auditors prior to audit. This will help the

observers keep track of the discussions and give them an opportunity to review the information alongside the auditor.

- Sometimes records are provided in binders or hard copy which makes it hard for the observers to review alongside the auditor. However, it has been helpful to follow the conversation and the detailed questions asked by the auditor. It also helps understanding the checklist and/or reviewing the checklist ahead of time.

Also, to consider:

- Could we get a walkthrough of the “e audit net” (I think that’s what it is called). This is where all the subscribers can access the data reports.
 - Also, it would be great if we can review the report that comes out of these audits we are observing.
7. Overall, the audit was conducted well, in an organized and logical approach. The structure was easy to follow from the observer’s point of view, and the auditor ensured that we stayed on track as the two day audit progressed. Additionally, some of the more major technical issues such as validation gaps were given high priority as expected. My only additional feedback would be regarding the usage of the software to guide the audit. It appeared that although the software was a great tool, and had laid out the necessary items to be captured during the audit, the software would glitch periodically and often required manual intervention to ensure important notes had been captured. This could be due to the wireless signal at the facility, but it did disrupt the flow of the audit when this occurred.

Post-pilot study follow-up questions asked to FDA observers

1. How would you leverage MedAccred sterilization audits?
 - Pre-Market Approval - The MedAccred audits could help determine whether or not an auditee would need to receive an FDA inspection prior to pre-market approval.
 - Purchasing Controls - MedAccred could be used to identify if suppliers are meeting the requirements. It could be leveraged as a supplement for supporting purchasing controls.
 - Knowing that MedAccred audits are conducted annually is helpful. FDA inspections don't occur as often.
2. What additional information to a MedAccred sterilizer certification would help demonstrate compliance?
 - To be able to fully leverage the MedAccred program, FDA would expect to see the same level of audit details as they do for the MDSAP audit review process. It ensures that the manufacturers are fully meeting the requirements.
3. Would you find that leveraging MedAccred audits would aid in risk based work planning?
 - The level of access to the full MedAccred audit report would impact a risk-based approach.
4. Other Comments/Questions?
 - Will MedAccred be looking into developing an X-Ray Sterilization program?
Answer: The X-Ray audit criteria is still being developed and should be available within the next few months

Appendix 4: Nonconformance, Root Cause, Results & Trends

Supplier	NC	Detail	Root Cause	Results / Actions	Status
1	2 minor	<p>There was 1 QMS NC for handling product related to a complaint</p> <p>There was 1 technical NC for not assessing reproducibility of the process</p>	<p>Complaint Handling and Customer Feedback does not include specific instructions on how to handle customer product if it is still on-site when the complaint is issued.</p> <p>Auditor Interpretation for technical NC: Insufficient understanding of the requirements of the standard for determination of variability of process</p> <p>Trends: None</p>	<p>Revise SOP "Complaint Handling and Customer Feedback" to clarify how to handle complaint-related product still in supplier's possession. Section 4.2.6 revised to add: " any customer product related to a complaint is still on-site when the complaint is made, the order associated with the product will be placed on hold as appropriate. The order will remain on hold until the customer provides product disposition."</p> <p>Radiation Services Manager reviewed the finding and wrote a memo using the data collected during the OQ process showing graphs and a table with the max, min, and mean to show variability. In this memo, there are also calculations for the standard deviation and coefficient of data to allow for reproducibility.</p>	<p>Verification of Corrective Actions Audit (VCA) was performed on Nov 1st to complete review of records not available previously. The response from the supplier is pending. The audit report is under review.</p>
2	3 major, 1 minor	<p>There was a major finding in the QMS system related to ineffective CAPAs for product movement and dosimeter placement, 1 major for systemic production deviations - Procedures exist and are adequate but compliance is not being achieved (6.1.1.c). 1 major technical for not being able to provide IQ for review. The minor was for not following procedure for calibration of dosimeters</p>	<ol style="list-style-type: none"> Delays in the CAPA process may result in repeat occurrence of issues, due to corrective actions not being implemented in a timely manner. Resource Challenges due to changes in key positions prioritizing training for QA tasks that emphasized daily activities with fewer resources focused to continue to progress deficiencies. QA Technician was unable to assist with Deficiencies due to inability to consistently access the appropriate software system. Change in both GM and QAM caused a gap in knowledge of the location of the requested paperwork. Root cause of the finding is that it can be difficult to achieve the target doses in a production irradiator. <p>Trends: Legacy Validation Resources & Training</p>		

Supplier	NC	Detail	Root Cause	Results / Actions	Status
3	2 minor	<p>There was 1 minor for missing pages in legacy IQ/OQ validations</p> <p>There was 1 minor for a missing internal audit report</p>	<p>As legacy validations, no root cause was defined for the NC</p> <p>Site Internal Audit closing meeting was conducted by the lead auditor on 20-Dec-2022. The official audit report was not sent to location management until 01-March-2023. At the time of the audit, QB was unable to provide a memo with rationale for the delay, impact and planned completion date as per stated in G-WI-AUD-001.</p> <p>Trend: Legacy validations</p>	<p>All the legacy validations were reviewed for completeness corrections made where appropriate</p> <p>The audit report was received by the facility at the end of the audit</p>	Accredited
4	0	N/A	N/A	N/A	Accredited
5	1 minor	There was 1 minor for untimely CAPA initiation	<p>Follow-up of tasks were not completed as required due to lack of trained personnel to handle workload within the facility. Challenges related to COVID-19 and turnover from 4th Quarter 2021 resulting in understaffing during 1st and 2nd quarter of 2022 have contributed to delays in completion of tasks related to CAPAs. Due to understaffing of Validation Coordinators, the QA Manager could not oversee all tasks performed by the new QA Technician. Availability of trained resources was identified as a critical need to eliminate the possibility for future occurrences. The lack of trained resources contributed to the issues noted in the audit findings.</p> <p>Trend: Resources & Training</p>	<p>Training provided to QA Techs and QAM regarding initiation and completion of CAPAs.</p> <p>Training provided to facility management team regarding completion of Investigation sections of CAPAs.</p> <p>CAPA tasks provided as evidence of completion. Evidence of training will be attached when completed.</p> <p>For two months after actions are completed, all new Audit NCs and any associated CAPAs will be reviewed to ensure any necessary Audit NC/CAPAs are being completed on time. A summary of all CAPAs initiated after the action items are completed will be attached as evidence of completion.</p> <p>All corrective actions are complete and attached to the audit report</p>	Accredited

Supplier	NC	Detail	Root Cause	Results / Actions	Status
6	2 minor	<p>There was 1 minor QMS issue related to confirmation of training and software access and not addressing root cause.</p> <p>There was another minor technical NC in that an equivalency study was performed and a final report was not written to close it out.</p>	<p>Records associated with the minor nonconformance found by MedAccred were verified; The root cause to NCR 3882 was due to new Customer Service Manager (CSM) not having access to the Customer Monitoring System nor training on the process, however, the CAPA 7040 did not confirm the new CSM was provided access to customer monitoring software.</p> <p>The non-compliance from the audit is for the dose map and the study carried out in 2011 for the validation of equivalence in the irradiators. This analysis was performed and is acceptable, however it is necessary to attend to the documentation.</p> <p>Trend : Resources & Training Legacy Validation - resolved on-site</p>	<p>The training of the new Customer Service Manager was completed correctly, however access was delayed due to limited licenses and user change, this had no adverse impact because upon receiving access to CRM, the customer complaint was processed and resolved. Confirmed training and access.</p> <p>In compliance with ISO 11137-1:2006 9.2, the OQ dose map made In 2011 showed sufficient output data Information to determine the dose distribution and variation in the San Diego irradiators. The non-conformity is being addressed by documenting in a Report the data and analysis collected during the execution of the test “TP-170” completed in 2011. The report has been reviewed and found acceptable.</p>	Accredited
7	1 minor	<p>There was 1 minor for incomplete documentation for a calibration of spectrophotometers. There was a failed value and the repeat value was not included. It was not caught during review.</p>	<p>Employee misinterpretation of the work instruction requirement for the calibration and subsequent documentation review</p> <p>Trend: None</p>	<p>Awareness training complete – 03-May-2023; Recalibration records for the identified equipment – 09-May-2023; Retrospective review summary complete – 11-May-2023; Instructor led training expected for effectiveness – 02-Jun-2023</p>	Accredited
8	1 minor	<p>There was 1 minor that was technical in that high levels of variability in a PQ were not properly addressed in documentation.</p>	<p>Oversight by the document author and users, that the data evaluation per procedure X should be completed per the instructions in procedure Y.</p> <p>Oversight of the author of procedure Y to require Corporate radiation group evaluation of a discrepancy that can be resolved by the local Quality and/or Operations Management.</p>	<p>PQ will be amended, specifically, to indicate that the selection of maximum dose position was appropriately selected by facility management according to section 5.2 requirements, and that a review was conducted by the Corporate radiation group on May 12, 2023 which confirmed placements to be accurate.</p> <p>Work instruction, Dose Mapping Data Analysis and Presentation Tools and Gamma Irradiator Performance Qualification (Product Dose Mapping) will be reviewed and updated appropriately for clarification of facility management responsibility to contact Corporate radiation group when their evaluation of product and run data results in discrepancies.</p>	Accredited

Supplier	NC	Detail	Root Cause	Results / Actions	Status
9	1 major, 1 minor	<p>There was 1 major deemed systemic relating to timeliness of review; one of which would require taking the equipment out of service, which did not happen.</p> <p>There was 1 minor because there was not a “performed by” name on the PMs for 4 out of 8 reviewed.</p>	<p>Root cause of this nonconformance is attributed to resource constraints with the facility’s quality and validation department. Increasing validation projects and staffing issues, have led to an increased workload for the facility’s sole validation coordinator and the need for the facility QAM to assist with some validation coordinator functions.</p> <p>The root cause of this nonconformity was due to an oversight that occurred during new employee training - trainer failed to confirm that the trainee selected the correct eSignature Type</p> <p>Trend: Resources & Training</p>	<p>An action taken at the beginning of 2023 to help with completing profiles earlier and to give more facility oversight into the process, was to add the 12th month for Chamber requalifications to the Calibration At-a-Glance Schedule. This action gives more visibility to facility management regarding requal, with the goal being to help complete requals within the 12th month and use the 13th month in the unlikely event of requalification re-execution due to failures.</p> <p>QAM retraining on Annual Profile work instructions to help re-enforce the requirement to have reviews completed within 14 working days of the ESPED statistical analysis report time stamping or by the end of the 13-month since the last profile.</p> <p>Official onboarding of a second validation coordinator in June of 2023, which can help in alleviating some of the workload burdens of the current validation coordinator and QAM. With fewer validation duties to take on, the QAM will have more available time to devote to the timely review of records. Evidence of the new hire was confirmed</p>	Accredited

Appendix 5: Reference Documents

Document Number	Title
ISO 13485	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
21 CFR Part 820	Code of Federal Regulations – Title 21 – Quality System Regulation
GHTF/SG3/N99-10:2004	Quality Management Systems - Process Validation Guidance
ISO 11135	Sterilization of health care products – Ethylene Oxide
ISO 11137-1	Sterilization of health care products – Radiation
ISO 11137-3	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine
ASTM 52303	Guide for absorbed-dose mapping in radiation processing facilities
ASTM 51649	Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV
ASTM 51702	Standard Practice for Dosimetry in a Gamma Facility for Radiation Processing
ASTM 51261	Practice for calibration of routine dosimetry systems for radiation processing
ASTM 52628	Standard practice for dosimetry in radiation processing
ASTM 52701	Guide for performance characterization of dosimeters and dosimetry systems for use in radiation processing
ASTM E3270	Standard Guide for Operational Qualification of Gamma Irradiators
AAMI TIR 14	Contract Sterilization Using Ethylene Oxide
AAMI TIR 28	Product adoption and process equivalence for ethylene oxide sterilization
AAMI TIR 15	Physical Aspects of Ethylene Oxide Sterilization

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