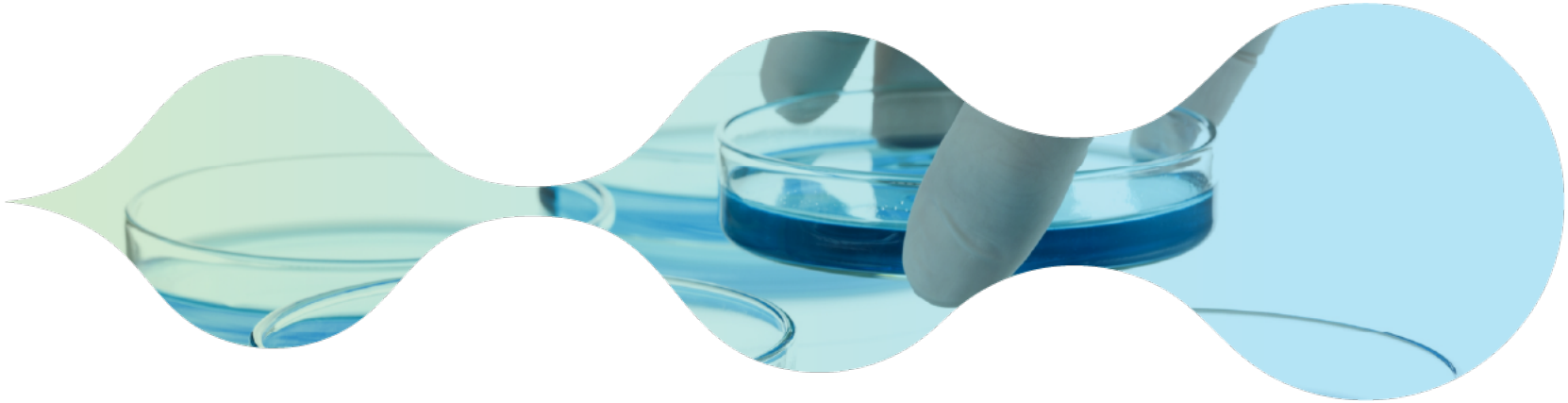
SfSAP
society for sterility assurance professionals

Pathways to develop expertise in different sterilization modalities by acquiring knowledge, skills, and experiences.

LEARNING FRAMEWORKS AND OUTCOMES

HEALTHCARE PRODUCTS EtO STERILIZATION



Version 1 26.3

Healthcare Products EtO Sterilization Learning Framework

DOCUMENT NUMBER: EtOLF001
Revision: 1

MODULE	KNOW What are the topics in this module that I need to know and understand?	APPLY How does an expert use (apply) this knowledge?	EXECUTE What experiences should I have where I can apply this knowledge? (Learn by doing; developing a repertoire of experiences)	DEMONSTRATE How can I demonstrate to an incumbent expert that I have the relevant knowledge and skills?	Competence	Acknowledge Competence
Process and equipment characterization ISO 11135:2014, Section 6.0, D6.0 / AAMI TIR 15:2016, Section 3.0 / AAMI TIR 16:2017, Section 3.0 / ISO TS 21387-2020, Section 6.3						
Product definition ISO 11135:2014, Section 7.0, D7.0 / ISO 11138-7:2019, Section 5.0, Annex B, D						
Process definition ISO 11135 Section 8 & Annex D.8.1 to D.8.6 / AAMI TIR16:2017 Section 4 / AAMI TIR 15:2016, Sections 5.0, 6.0, 7.0 / ISO 11138-7:2019, Section 7.0, 11.0, Annex A, C, F / ISO TS 21387-2020, Section 8.0						
Validation - IQ/OQ ISO 11135:2014, Section 9.2, 9.3, D9.2, D9.3 / AAMI TIR 15:2016, Section 3.0 / ISO TS 21387-2020, Section 9.2, 9.3 / ISO TS 21387-2020, Section 9.2, 9.3						
Validation - Microbiological performance qualification ISO 11135:2014, Section 9.4.1, 9.4.2, Annex A, Annex B, Annex C, Section D9.4.1, D9.4.2 / AAMI TIR 16:2017, Section 5 / ISO 11138-7:2019, Section 8.0, 11.0, Annex A, C, F / ISO TS 21387-2020, Sections 9.4.1, 9.4.2, 9.5.5						
Validation - Physical performance qualification ISO 11135:2014, Section 9.4.3, Annex C1, Annex C2, D.9.4.3, AAMI TIR 15:2016 Section 4 / ISO TS 21387-2020, Section 9.4.3						
Routine monitoring and control ISO 11135:2014, Section 4.4, 10, D10 / ISO 11138-7:2019, Sections 9.0, 12.0 / ISO 11138-8:2021, Section 7.0						
Product release from sterilization ISO 11135:2014, Sections 11, D11.1 / ISO 21387:2020, Section 11.1 / ISO 11138-7:2019, Section 10.2.3 / ISO 11138-8:2021, Section 4.0, 6.0, 7.0 / USP-NF 2022, Section 1222 Post-sterilization						
Maintaining process effectiveness ISO 11135:2014, Sections 12. 1, 12.2, 12.3, 12.4, 12.5 / AAMI TIR16:2017, Sections 4.8, 6.0 / ISO TS 21387-2020, Sections 12. 1, 12.2, 12.3, 12.4, 12.5						

Healthcare Products EtO Sterilization Learning Framework

MODULE	KNOW What are the topics in this module that I need to know and understand?	APPLY How does an expert use (apply) this knowledge?	EXECUTE What experiences should I have where I can apply this knowledge? (Learn by doing; developing a repertoire of experiences)	DEMONSTRATE How can I demonstrate to an incumbent expert that I have the relevant knowledge and skills?	Competence	Acknowledge Competence
Process equivalence ISO 11135:2014, Section 12.5.1 and Section D12.5.1 to D12.5.10 / AAMI TIR 28:2016, Section 4 / AAMI TIR 15:2016, Section 8						
Non-conformity ISO 11135:2014, Sections 11.2, 11.3, D11.3 / ISO 21387:2020, Section 11.2 / ISO 11138-7:2019, Sections 10.2.2, 10.2.4 / USP-NF 2022, Section 1222 Post-sterilization						
Product adoption AAMI TIR28 / ISO 11135:2014, Sections 12.4, 12.5.2, D.12.5.11						

Healthcare Products EtO Sterilization Learning Outcomes

DOCUMENT NUMBER: EtOLO001
Revision: 1

This document is to use in conjunction the **Medical Device Ethylyen Oxide (EtO) Sterilization Learning Framework** above to define expected learning outcomes from each of the modules within the curriculum.

For continual development in each of the modules **Further Continual Development learning outcomes** have been suggested.

Healthcare Products EtO Sterilization Learning Outcomes

Module
Process and equipment characterization ISO 11135:2014, Section 6.0, D6.0 / AAMI TIR 15:2016, Section 3.0 / AAMI TIR 16:2017, Section 3.0 / ISO TS 21387-2020, Section 6.3

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment

• Define and characterize sterilization equipment to be used, including pre-conditioning area (if used), sterilization chambers and ancillary equipment, and the aeration area (if used)
• Understand the purpose of pre-conditioning and aeration and the use of "all-in-one" cycles
• Design sterilization process that is sustainable, addressing the following:
  ○ EO concentration
  ○ Relative humidity
  ○ Temperature
  ○ EO exposure time
  ○ EO removal system
  ○ Fugitive emissions
  ○ Parametric release (if used)		

Healthcare Products EtO Sterilization Learning Outcomes

Module
Product definition ISO 11135:2014, Section 7.0, D7.0 / ISO 11138-7:2019, Section 5.0, Annex B, D

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Review product design for sterilizability (including resterilization feasibility), safety (including EO residuals), and product/packaging performance (including material compatibility) • Define how product will be packaged • Define the manufacturing process for the product • Determine product density • Understand product configuration and challenge it represents to the sterilization process • Select potential challenge locations for testing sterilizability (most difficult-to-sterilize locations) • Determine biological indicator type needed • Define and design internal process challenge device to represent products(s) • Define if the product will be a new product family or adopted into an existing product family • Rationalize product adoption into an existing product family, if applicable		

Healthcare Products EtO Sterilization Learning Outcomes

Module
Process definition ISO 11135 Section 8 & Annex D.8.1 to D.8.6 / AAMI TIR16:2017 Section 4 / AAMI TIR 15:2016, Sections 5.0, 6.0, 7.0 / ISO 11138-7:2019, Section 7.0, 11.0, Annex A, C, F / ISO TS 21387-2020, Section 8.0

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Understand the goal and essence of process definition activities • Know and understand the critical parameters for sterilization (including parametric release if used) and their importance for the process effectiveness • Understand the different parameters limitations linked to the product and the equipment • Understand the limitations, advantages, and inconveniences of selecting a pilot vessel or a production chamber to conduct process definition. • Understand the different methods to calculate the rate of microbiological inactivation to reach the expected SAL (Annex A and/or Annex B of ISO 11135) • Interpret data supporting the pertinence of the biological indicators in relation to the naturally occurring bioburden. • Understand how to determine the appropriateness of a process challenge device used for process definition, validation and in future routine monitoring. • Perform calculations (D-value, sterility assurance level, EO gas concentration, flammability analysis, % RH) Continued on next page		

Healthcare Products EtO Sterilization Learning Outcomes

Module - CONTINUED

Process definition
ISO 11135 Section 8 & Annex D.8.1 to D.8.6 / AAMI TIR16:2017 Section 4 / AAMI TIR 15:2016, Sections 5.0, 6.0, 7.0 / ISO 11138-7:2019, Section 7.0, 11.0, Annex A, C, F / ISO TS 21387-2020, Section 8.0

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
Further Continual Development learning • Determine most appropriate location to place biological indicators in relation to the naturally occurring bioburden and product configuration • Interpret process definition data in order to identify the most appropriate method selection for PQ study • Evaluate the appropriate position for Bi's in the product and for spored unit within the load		

Healthcare Products EtO Sterilization Learning Outcomes

Module
Validation – IQ/OQ ISO 11135:2014, Section 9.2, 9.3, D9.2, D9.3 / AAMI TIR 15:2016, Section 3.0 / ISO TS 21387-2020, Section 9.2, 9.3 / ISO TS 21387-2020, Section 9.2, 9.3

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment

• Understand and determine requirements for IQ
  ○ Descriptions of the physical and operational characteristics of the equipment (including ancillary equipment)
  ○ Design specifications
  ○ Drawings, process and instrumentation diagrams (P&ID), and schematics
  ○ User requirements specifications
  ○ Functional design specifications
  ○ Equipment has been properly installed
• Understand and determine requirements for OQ
  ○ Calibration procedures and schedule for sterilization chamber and ancillary equipment
  ○ Preventative maintenance procedures and schedule for sterilization chamber and ancillary equipment
  ○ Unplanned maintenance
  ○ Software validation
  ○ Test cycles to define and demonstrate the capability of the equipment to deliver the range of operating parameters and operating limits contained in the process specification(s)		

Healthcare Products EtO Sterilization Learning Outcomes

Module
Validation – Microbiological performance qualification ISO 11135:2014, Section 9.4.1, 9.4.2, Annex A, Annex B, Annex C, Section D9.4.1, D9.4.2 / AAMI TIR 16:2017, Section 5 / ISO 11138-7:2019, Section 8.0, 11.0, Annex A, C, F / ISO TS 21387-2020, Sections 9.4.1, 9.4.2, 9.5.5

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Define processing category with product families included in validation • Understand challenge of product families to the validation • Ensure process definition has been completed and appropriateness of biological indicator has been established • Understand load configuration and impact to validation • Determine load configuration(s) for MPQ and define/test worst case configurations • Define/determine impact of re-use of sterilization loads • Understand and select approach to demonstrate lethality • Define sterilization process parameters for MPQ • Depending on approach, calculate equivalent exposure time, D-value, spore log reduction and sterility assurance level (SAL) • Understand requirements for validating parametric release and establishing parametric release parameters, if parametric release is to be used • Determine number and locations for placing iPCDs and temperature/RH sensors • Understand requirements for storage, handling, and shipping iPCDs to testing laboratories		

Healthcare Products EtO Sterilization Learning Outcomes

Module
Validation - Physical performance qualification ISO 11135:2014, Section 9.4.3, Annex C1, Annex C2, D.9.4.3, AAMI TIR 15:2016 Section 4 / ISO TS 21387-2020, Section 9.4.3

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Understand requirements for minimum numbers of Temperature and Rh sensors to be used in each stage of the sterilization process • Understand sensor calibration accuracy and precision • Define distribution of Temperature and Rh Sensors in the Validation Load • Evaluate Temperature and Rh Profile of the load achieved at the end of Preconditioning (if used) • Evaluate Temperature and Rh Profile of the load achieved at the end of Conditioning • Evaluate Temperature Profile of the load achieved during EO exposure dwell • Evaluate Temperature Profile of the load achieved during Post-conditioning/ Primary Aeration/ Secondary Aeration (if used) • Determine Process Reproducibility • Establish tolerances in process specification • Develop strategies for Qualification of a Minimum Temperature of the Load at the start of the process to ensure validated minimum conditions are met throughout the load by the end of the minimum specified Preconditioning/Conditioning phases • Determine the effect of product, packaging, and load presentation on load conditioning. • Understand requirements for establishing parametric release parameters (if parametric release is to be used) • Determine resterilization qualification requirements		

Healthcare Products EtO Sterilization Learning Outcomes

Module
Routine monitoring and control ISO 11135:2014, Section 4.4, 10, D10 / ISO 11138-7:2019, Sections 9.0, 12.0 / ISO 11138-8:2021, Section 7.0

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Understand monitoring and data requirements for parametric release • Determine data to record and retain for each sterilization cycle including: • Data for the temperature of products entering the preconditioning area • Data for biological indicator product release, if applicable • Data for parametric release, if applicable • Data for chemical indicators, if applicable • Understand requirements for storage, handling, shipping BIs to testing laboratories, and testing BIs		

Healthcare Products EtO Sterilization Learning Outcomes

Module
Product release from sterilization ISO 11135:2014, Sections 11, D11.1 / ISO 21387:2020, Section 11.1 / ISO 11138-7:2019, Section 10.2.3 / ISO 11138-8:2021, Section 4.0, 6.0, 7.0 / USP-NF 2022, Section 1222 Post-sterilization

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Confirm acceptable process parameters (including parametric release if used) • Confirm acceptable biological indicator results (if used) • Confirm of acceptable EO residues (up front qualification or individual batch testing) • Confirm of acceptable physical testing (e.g., product functionality, package integrity, etc.) • Confirm any other requirements • Determine if all requirements have been met and the product can be released • Determine requirements for BI reduced incubation time, if it will be used		

Healthcare Products EtO Sterilization Learning Outcomes

Module
Maintaining process effectiveness ISO 11135:2014, Sections 12. 1, 12.2, 12.3, 12.4, 12.5 / AAMI TIR16:2017, Sections 4.8, 6.0 / ISO TS 21387-2020, Sections 12. 1, 12.2, 12.3, 12.4, 12.5

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Understand revalidation requirements (Annual Reviews) • Understand the requirements needed for continued effectiveness of the sterilization process (including parametric release, if used) • Understand impact of Process variables, Process Characterization, and Equipment Characterization • Understand impact of Preventive maintenance planning, performance, review and documentation. • Use the outcome of the annual review assessment to determine the extent of the requalification. (IQ. OQ. PPQ, MPQ) • Evaluate the impact a change may have on the validated sterilization process, PCD, BI's and SAL. • Understand the requirements needed to maintain process equivalence.		

Healthcare Products EtO Sterilization Learning Outcomes

Module
Process equivalence ISO 11135:2014, Section 12.5.1 and Section D12.5.1 to D12.5.10 / AAMI TIR 28:2016, Section 4 / AAMI TIR 15:2016, Section 8

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
Evaluation if process equivalence can be claimed and maintained, and execution of such study requires the following skills/knowledge: • Execution of basic validation activities (full validation of original equipment and IQ/OQ of candidate equipment). • Execution of a microbiological evaluation based on a reduced MPQ of the candidate chamber(s). • Evaluation of differences in bioburden levels or load properties due to different geographical locations. • Execution of process analysis and evaluation, based on a comparison of critical parameters inside the processed load (usually Temperature and RH determined during PPQ), equipment (usually the parameters defined in process specification). Application of valid statistical methods to evaluate differences of these parameters between the chambers. • Execution or definition of change control for maintenance of equivalence.		

Healthcare Products EtO Sterilization Learning Outcomes

Module
Non-conformity ISO 11135:2014, Sections 11.2, 11.3, D11.3 / ISO 21387:2020, Section 11.2 / ISO 11138-7:2019, Sections 10.2.2, 10.2.4 / USP-NF 2022, Section 1222 Post-sterilization

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment

• Evaluate the criticality of non-conformities during routine EO processing
• Investigate and report the results of a failure from the following parties
  ○ Sterilization process
  ○ BI testing
  ○ BI manufacturer
  ○ Product manufacturer
• Assess and determine the appropriate actions
  ○ If parameters/specifications are not achieved during sterilization
  ○ For BI failures or misplacement of BIs
  ○ Troubleshooting guide		

Healthcare Products EtO Sterilization Learning Outcomes

Ethylene Oxide Troubleshooting Guide: Non-Conformities & Recommended Actions
This guide may be used to address ISO1135:2014 Sections 11.1, 11.2, 11.3, D.4.4

Process Parameter	Below Specification Response	Above Specification Response
Preconditioning		
Duration	Add time to preconditioning if possible. If sterilization process complete, reprocess the load.	Remove from preconditioning, cool the product, replace Process Challenge Devices (PCDs) (if used). If product has been processed, then assess for product/package damage.
Temperature		
Humidity (%RH)		
Transfer Time	Not applicable.	Reprocess if there isn't qualification data to support the time.
Sterilization Cycle – To End of EO Dwell Phase		
Initial evacuation level	Abort the cycle (may allow a restart). Reprocess the load.	Evaluate product/package.
Evacuation time/rate	Abort the cycle. Reprocess the load.	Evaluate product/package.
Inert gas addition terminal pressure-Wash	Abort the cycle Reprocess the load.	Continue processing. No impact.
Inert gas addition terminal pressure	Evaluate ethylene oxide (EO) residues if additional EO is added.	Reprocess the load if insufficient EO added.

Healthcare Products EtO Sterilization Learning Outcomes

Process Parameter	Below Specification Response	Above Specification Response
Humidity inject pressure	Reprocess the load.	Reprocess the load if insufficient EO added. Evaluate product/package.
Direct humidity measurement (parametric release)		Evaluate product/package.
Conditioning time		Evaluate product/package.
EO gas addition pressure or weight (depends on specification requirement)		Evaluate EO residues.
EO concentration (parametric release)		Evaluate EO residues.
Exposure Time		Evaluate EO residues.
Chamber Temperature		Evaluate product/package.
Sterilization Cycle – After EO Dwell Phase		
Evacuation pressure	Evaluate EO residues. If post EO exposure is identified as part of the process to achieve the appropriate Sterility Assurance Level (SAL) then reprocessing would be necessary.	Evaluate product/package.
Inert gas or air pulse pressures	Evaluate EO residues.	Evaluate product/package.
Hold times at vacuum or pressure		
Flushing time/rate	No impact	Evaluate EO residues. Evaluate product/package.
Chamber Temperature	Evaluate EO residues.	Evaluate product/package.

Healthcare Products EtO Sterilization Learning Outcomes

Process Parameter	Below Specification Response	Above Specification Response
Aeration		
Time	Add time to aeration if possible. Evaluate EO residues.	Evaluate product/package.
Temperature	Add time to aeration if possible, to compensate for time below spec. Evaluate EO residues.	Evaluate product/package.
Biological Indicators (BIs)/PCDs		
Number	Reprocess if the number of BIs is below the International Organization for Standardization (ISO) guidance.	N/A.
Growth of the indicator organism	N/A.	Reprocess the load.

Notes

1. In situations where critical parameters were below specification, the BI results cannot be used to justify release of the load.
2. When a BI is positive with the indicator organism, acceptable parameters and test of sterility on product cannot be used to justify release of the load.

Healthcare Products EtO Sterilization Learning Outcomes

Module
Product adoption AAMI TIR28 / ISO 11135:2014, sections 12.4, 12.5.2, D.12.5.11

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment

• Understand / demonstrate how to perform technical assessment comparing candidate product to validated predicate product (TIR28, 3.3)
  ○ Understand how to identify differences (i.e. know what to look for, what are critical attributes for comparison – start with TRI28 Annex A)
  ○ Understand impact on adverse effects for candidate product (e.g. stability, biocompatibility / residuals, etc.) – reference AAMI TIR17
  ○ Understand impact of variability in EO cycle (i.e. worst-case conditions for product impact)
  ○ Understand impact of product design and product materials attributes on adoption
  ○ Understand impact of load configuration (temperature, humidity, EO penetration)
  ○ Understand impact of manufacturing changes (e.g. impact on bioburden)
 	
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Healthcare Products EtO Sterilization Learning Outcomes

Module - CONTINUED

Product adoption
AAMI TIR28 / ISO 11135:2014, sections 12.4, 12.5.2, D.12.5.11

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment

• Understand / demonstrate how to address results of technical assessment for adoption
  ○ Define what testing is required
  ○ Perform and interpret results of comparative resistance test (TIR28, 3.4.1)
  ○ Perform Temperature and humidity assessment (TIR28, 3.4.2)
  ○ Perform Residuals assessment (TIR28, 3.4.3)
• Understand how to establish and maintain EO processing category (TIR28, 3.2, 3.5)
  ○ Tracking design and manufacturing changes
  ○ Bioburden monitoring		