SfSAP
society for sterility assurance professionals

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

LEARNING FRAMEWORKS AND OUTCOMES

USER GUIDE

Version 1 26.3.23

Table of Contents

What is SfSAP?

The Society for Sterility Assurance Professionals has been established as a collaborative not-for-profit initiative and supported by the iia, AAMI, ASTM, and PDA. It aims to enable the medical device and pharmaceutical industries to formulate a standard approach to meeting the requirements of Medical Device Regulations (MDR), ISO 13485:2016, and other relevant regulations such as Good Manufacturing Practices (GMPs). The Society has a formal constitution and has been created as a legal entity in the United Kingdom. A board of directors provides oversight of strategic matters while a steering committee co-ordinates all collaborative initiatives and the formation of working groups. Members of the working groups work together developing the required output (e.g., learning frameworks) and guidance in their area of expertise.

FOUNDING PRINCIPLES OF SfSAP

The Society for Sterility Assurance Professionals (SfSAP) is a professional association dedicated to the advancement of sterility assurance for medical and pharmaceutical products.

The founding principles of the SfSAP are:

VISION

The SfSAP will focus on defining the competency of sterility assurance professionals. It aims to highlight engaged education delivery organisations (EDOs) via an accreditation process and is working to ensure that sterility assurance professionals have access to a record keeping system.

COMPETENCY

To establish the required level of knowledge, skills, and experiences that a person needs to demonstrate based on the individual's role in the lifecycle of the sterilization modality.

COLLABORATION

To encourage better coordination in the training, testing, and development of Sterility Assurance professionals through a competency framework.

COMMUNITY

To support individuals in achieving their development goals and the needs of the healthcare community in the field of Sterility Assurance.

CONNECTION

To enable members of the community to build networks in order to achieve their career development goals and the needs of the wider healthcare community.

CAREER

To create a pathway for those involved in Sterility Assurance and the sterilization of medical and pharmaceutical products as individuals move from novice to competent to proficient to experts.

Developing competency through collaboration

SfSAP sees four key groups or stakeholders that can benefit from SfSAP's efforts. In some cases, an organization may fit into more than one group. For example, a contract sterilizer may also be an educational development organization (EDO) as it provides hands-on experiences to manufacturers. A manufacturer or regulator may also be an EDO for its personnel.

Modalities of sterilization

Sterilization is any process that removes, kills, or deactivates microbes like bacteria, molds, fungi, and viruses. This is critical for medical supplies, medical devices, and injectable (or low bioburden) pharmaceutical products in order to protect the safety and health of those that use such products. For something to be sterile, it must be free of micro-organisms.

Modalities of sterilization refers to the different methods available, including:

- Moist heat
- Radiation
- Aseptic processing
- Ethylene oxide gas

Supporting sterilization requires other sterility assurance professionals such as microbiologists who test products and identify organisms found during environmental monitoring, packaging experts who test and assure that packages and containers do not allow the ingress of microbial contaminants, and auditors and health authority inspectors who evaluate the effectiveness and performance of such operations.

SfSAP working groups

Several working groups with the SfSAP organization have been formed to create the learning frameworks and outcomes as well as to provide other support for these efforts. These working groups, comprised of volunteers, are:

- SfSAP steering committee
- Microbiology
- Aseptic processing
- Moist Heat
- Radiation
- Ethylene oxide gas
- Packaging / sterile barrier systems
- Bio-compatibility
- Regulatory / health authorities

Why these learning frameworks were created

The SfSAP learning frameworks were developed by an international set of experts in the different sterility modalities and support functions in order to:

- Present a "roadmap" of the knowledge, skills, and experiences that should be acquired by an individual wanting a career as a sterility assurance professional.
- Guide organizations in the knowledge, skills, and experience they should look for when hiring a sterility assurance professional.
- Identify the goals, learning objectives, topics, and reference sources that should be included in training / educational modules offered by educational or training organizations that offer learning opportunities in the field of sterility assurance.
- Provide a set of expectations that can assist auditors and health authority inspectors.
- Contribute to knowledge management by communicating explicit knowledge through education and training and the sharing of tacit knowledge through hands-on work and experiences.

The progression from novice to expert

Becoming an expert in any field does not happen in a year or two. It takes a combination of foundational knowledge, specific training in field, and then a series of experiences such as writing or reviewing standards, providing training, and solving a variety of problems. The learning frameworks include all of these ways of acquiring knowledge, skills, and experiences.

Frameworks available

The list below shows the learning frameworks that the teams of international experts have been developing. Those in **bold** will be published soon on the SfSAP website; the others will follow.

Microbiology, bio-compatibility, and packaging/sterile barrier systems are important as they support the different sterilization modalities and need to be assessed before products can be commercialized and put on the market.

- Microbiology
- **Aseptic processing**
- Moist Heat
- **Radiation**
- Ethylene oxide gas
- Packaging / sterile barrier systems
- Bio-compatibility

A work in progress

As the expert teams have been developing the frameworks, the information that they include and how that information is presented have been changing. Additionally, the SfSAP learning model is also evolving, for example, identifying different roles (job positions) and using a step-wise progression in moving through the topics. This means that the learning frameworks are being improved as we get more experience with them through comments from experts and learners alike. We also envision that a future version of the learning frameworks will distinguish between "core" topics – those that apply to all people involved in a sterilization modality and "supplemental" topics – those that would be applicable to persons wanting to focus on a particular facet of the modality, for instance, operations, quality, validation, facility design, etc.

Keeping up-to-date

In addition to this document, as SfSAP makes organizational and structural changes and the working teams revise and complete progress in their frameworks, "addendums" with updated information will be prepared and will be included in revisions to this published document. All published SfSAP documents are available on the SfSAP website along with an addendum that will identify any updates and/or corrections to published material. Users should ensure that they check the addendum regularly.

What the typical framework includes:

The table below is an example of a page taken from the Learning Framework for Radiation. See corresponding annotated numbers with details on the right.

Healthcare Products Radiation Sterilization Learning Outcomes

DOCUMENT NUMBER: RHL0001
Revision 1

1 Framework Category / Module	2 Reference Documents
Core Foundational *Dose Establishment*	VDMAX / Method 1/ Method 2 ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI ST 67

3 Knowledge and skills required	4 Learning Outcome *(what person should be able to do with the knowledge and skills)*	5 Outcome met? Y/N	6 Comment
• The rationale behind each method • The limitations, advantages and disadvantages of each method • Determining the method selection for your product • Performing each method including calculating verification and sterilization doses • Interpretating data • Translating results to routine processing parameters	• Describe the scientific rational that supports each method for establishing dose *(100 level)* • Identifying the limitations, advantages, and disadvantages of each method *(100 level)* • Given a specific product, select the appropriate dose-establishment method *(200 level)* • Describe how to perform each method by calculating the verification and sterilization doses *(200 level)* • Provide a correct interpretation to a given a set (what kind) of data *(200 level)* • Describe how the results (of what?) translate into routine process parameters *(200 level)* • Diagnose root causes and recommend corrections and corrective actions for problems related to dose establishment *(300 level / Exp)*		

1 **The framework category** Core foundational
Facilities, operations, processing, sterility assurance

Module is a set of related topics

2 **Reference documents** are the primary source materials that are the basis for this module. This information may be supplemented with other relevant examples and articles selected by the instructor.

3 **Knowledge and skills** required is a list of the topics that have been identified by the expert teams that a sterility assurance professional should know or be able to perform. These can help guide learners as they read through the reference documents.

4 **Learning outcomes** are behavioral statements of how someone would use the knowledge and skills. They can be considered learning objectives. As the frameworks evolve, the learning outcomes number-coded as shown here:

100 level – foundational outcomes, best associated with a person transitioning from a new hire/novice to competent

200 level – advanced outcomes best associated with a person transitioning from competent to proficient

300 level / EXP – outcomes derived primarily from experiences, best associated with a person transitioning from proficient to expert

5 **Outcome met** is where you can simply document if the learning outcome has been achieved. Additional confirmation (e.g. completion certificate is important to have as well.

6 **Comment** is useful for identifying who provided the training or a description of the experience that contributed to the learning outcome.

How to use the learning framework: Individuals

If you are an individual on the pathway to becoming a sterility assurance professional, here is how you can use the learning framework.

Healthcare Products Radiation Sterilization Learning Outcomes

DOCUMENT NUMBER: RHL0001
Revision 1

Framework Category / Module	Reference Documents
Core Foundational *Dose Establishment*	VDMAX / Method 1/ Method 2 ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI ST 67

Knowledge and skills required	Learning Outcome *(what person should be able to do with the knowledge and skills)*	Outcome met? Y/N	Comment
• The rationale behind each method • The limitations, advantages and disadvantages of each method • Determining the method selection for your product • Performing each method including calculating verification and sterilization doses • Interpretating data • Translating results to routine processing parameters	• Describe the scientific rational that supports each method for establishing dose *(100 level)* • Identifying the limitations, advantages, and disadvantages of each method *(100 level)* • Given a specific product, select the appropriate dose-establishment method *(200 level)* • Describe how to perform each method by calculating the verification and sterilization doses *(200 level)* • Provide a correct interpretation to a given a set (what kind) of data *(200 level)* • Describe how the results (of what?) translate into routine process parameters *(200 level)* • Diagnose root causes and recommend corrections and corrective actions for problems related to dose establishment *(300 level / Exp)*		

1. **Module.** When looking for a training course or event, this title may be useful in your search.

2. **Reference documents** are the primary source materials that are the basis for this module. This information may be supplemented with other relevant examples and articles selected by the instructor.

3. **Knowledge and skills required** are the topics that are important for a sterility assurance professional to know or be able to perform in regards to this module. If you are searching for a training course, look to see if these topics are included in the course outline. These topics may not be found in one specific course; rather, they may be contained in different courses or modules.

4. **Learning outcomes** are the activities you would need to complete and be able to demonstrate to show that you have acquired the defined knowledge and skills. In some cases (e.g., describe or discuss) you would demonstrate your knowledge and skills by talking to an instructor, a more knowledgeable expert or sometimes demonstrating performance. Or, you could write a paragraph or two that is assessed by an instructor. In other cases, a learning outcome might be demonstrated by completing a task.

5. **Outcome met** is where you can keep track of your progress through the learning framework.

   NOTE – SfSAP is developing a more comprehensive solutions to documenting outcome.

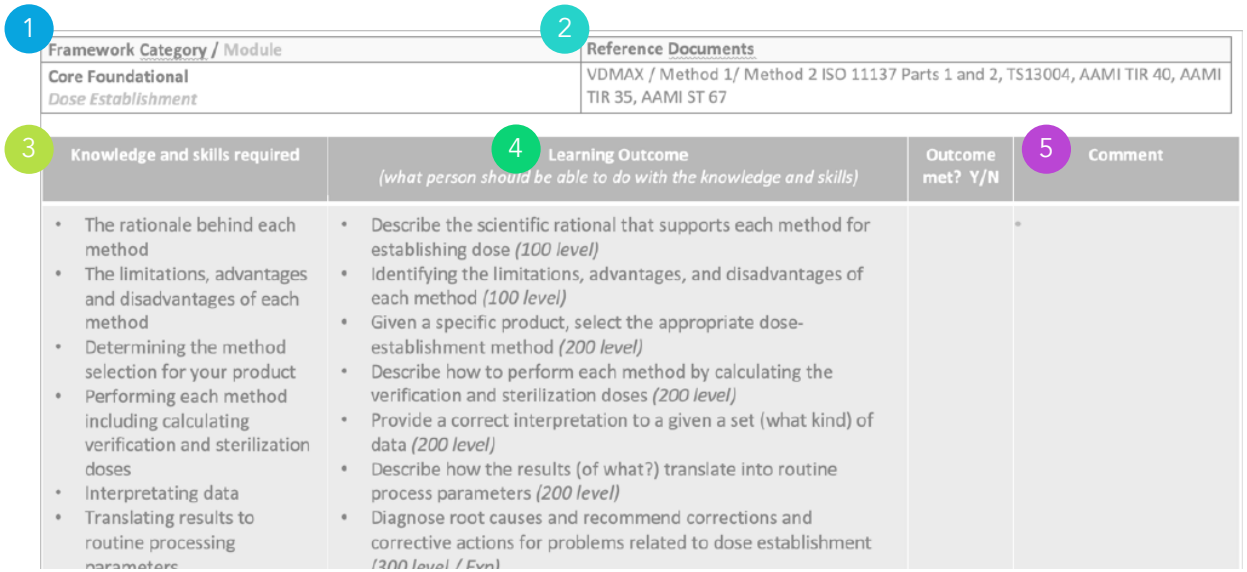
6. **Comment.** Include here a reference to support or confirm that the outcome has been achieved. This might include a certificate or a statement from a supervisor.

How to use the learning framework: Education delivery organizations (EDOs)

If you provide education or training to support the development of sterility assurance professionals, here are some ways you can use the learning frameworks. (If a manufacturer provides training for its personnel it could also be considered an EDO.)

Healthcare Products Radiation Sterilization Learning Outcomes

DOCUMENT NUMBER: RHL0001
Revision 1



Framework Category / Module	Reference Documents
Core Foundational *Dose Establishment*	VDMAX / Method 1/ Method 2 ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI ST 67

Knowledge and skills required	Learning Outcome *(what person should be able to do with the knowledge and skills)*	Outcome met? Y/N	Comment
• The rationale behind each method • The limitations, advantages and disadvantages of each method • Determining the method selection for your product • Performing each method including calculating verification and sterilization doses • Interpretating data • Translating results to routine processing parameters	• Describe the scientific rational that supports each method for establishing dose *(100 level)* • Identifying the limitations, advantages, and disadvantages of each method *(100 level)* • Given a specific product, select the appropriate dose-establishment method *(200 level)* • Describe how to perform each method by calculating the verification and sterilization doses *(200 level)* • Provide a correct interpretation to a given a set (what kind) of data *(200 level)* • Describe how the results (of what?) translate into routine process parameters *(200 level)* • Diagnose root causes and recommend corrections and corrective actions for problems related to dose establishment *(300 level / Exp)*		

1. **Module.** Consider arranging your training courses or sessions using the module name.

2. **Reference documents** are the primary source materials that are the basis for this module. This information may be supplemented with other relevant examples and articles selected by the instructor.

3. **Knowledge and skills required.** Consider having these topics specifically included in the description of your courses and in the course outlines.

4. **Learning outcomes** are the behavioral objectives to cover as you design and implement the training. A variety of assessment approaches can be used including have learners work on case studies, do "on the job" projects, or discuss with a knowledgeable experts. Quizzes or tests can also be used but try to avoid simple multiple choice or fill-in type methods.

5. **Comment.** Include here any other details that may be useful like time required for completion or a course number.

How to use the learning framework: Manufacturer, service provider, contract sterilizer

If your organization uses a modality of sterilization or provides a related service (e.g., microbiology laboratory), here are some ways that you might use the learning frameworks.

Healthcare Products Radiation Sterilization Learning Outcomes

DOCUMENT NUMBER: RHL0001
Revision 1

1 Framework Category / Module	2 Reference Documents
Core Foundational *Dose Establishment*	VDMAX / Method 1/ Method 2 ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI ST 67

3 Knowledge and skills required	4 Learning Outcome *(what person should be able to do with the knowledge and skills)*	Outcome met? Y/N	Comment
• The rationale behind each method • The limitations, advantages and disadvantages of each method • Determining the method selection for your product • Performing each method including calculating verification and sterilization doses • Interpretating data • Translating results to routine processing parameters	• Describe the scientific rational that supports each method for establishing dose *(100 level)* • Identifying the limitations, advantages, and disadvantages of each method *(100 level)* • Given a specific product, select the appropriate dose-establishment method *(200 level)* • Describe how to perform each method by calculating the verification and sterilization doses *(200 level)* • Provide a correct interpretation to a given a set (what kind) of data *(200 level)* • Describe how the results (of what?) translate into routine process parameters *(200 level)* • Diagnose root causes and recommend corrections and corrective actions for problems related to dose establishment *(300 level / Exp)*		

1. **Module.** Consider arranging your training courses or sessions using the module name.

2. **Reference documents** are important to be able to access when developing processes, writing procedures, providing training, or perform audits/inspections. Be sure the most current versions are available.

3. **Knowledge and skills required.** If you are hiring a sterility assurance professional, look to see if they have the knowledge and skills listed here.

   Few people have all of these, so you look across your organization to see if collectively your organization has these.

4. **Learning outcomes** are ways that people should be able to demonstrate they have the knowledge and skills listed. This may come from training or, more practically, experiences that they have had.

   During an interview, you might find it valuable to discuss the topics or have someone describe how they have accomplished the outcome in a real-life situation.

How to use the learning framework: Health authorities / regulators

Regulations require that personnel are competent to do their jobs by having the relevant education, training, and experience. Health authorities can use the learning frameworks in two different ways:

(1) Seeing what industry experts consider being relevant as individuals develop their expertise and

(2) Ideas to include in the training of inspectors and auditors.

Healthcare Products Radiation Sterilization Learning Outcomes

DOCUMENT NUMBER: RHL0001

Revision 1

Framework Category / Module	Reference Documents
Core Foundational *Dose Establishment*	VDMAX / Method 1/ Method 2 ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI ST 67

Knowledge and skills required	Learning Outcome *(what person should be able to do with the knowledge and skills)*	Outcome met? Y/N	Comment
• The rationale behind each method • The limitations, advantages and disadvantages of each method • Determining the method selection for your product • Performing each method including calculating verification and sterilization	• Describe the scientific rational that supports each method for establishing dose *(100 level)* • Identifying the limitations, advantages, and disadvantages of each method *(100 level)* • Given a specific product, select the appropriate dose-establishment method *(200 level)* • Describe how to perform each method by calculating the verification and sterilization doses *(200 level)* • Provide a correct interpretation to a given a set (what kind) of data *(200 level)*		

1. **Module.** Consider arranging your training courses or sessions using the module name.

2. **Reference documents** are important to be able to access when developing processes, writing procedures, providing training, or perform audits/inspections. Be sure the most current versions are available.

3. **Knowledge and skills required.** If you are hiring a sterility assurance professional, look to see if they have the knowledge and skills listed here.

   Few people have all of these, so you look across your organization to see if collectively your organization has these.

4. **Learning outcomes** are ways that people should be able to demonstrate they have the knowledge and skills listed. This may come from training or, more practically, experiences that they have had.

   During an interview, you might find it valuable to discuss the topics or have someone describe how they have accomplished the outcome in a real-life situation.

SfSAP APPROACH

The diagram below shows the concept that underlies the learning frameworks shown above. It is meant to convey that there is considerable flexibility in how someone acquires and are able to demonstrate that they have the requisite knowledge, skills, and experience.

Acknowledged Competency

Global industry experts identify knowledge and skills needed by experts in the field.

Know

What are the topics in this module that an expert in this domain needs to know and understand?

- Build foundation of knowledge in the scientific area associated with the sterilization modality
- Network with experienced users of the science associated with the sterilization modality.

Knowledge and skill learning opportunities can come from a variety of sources.

Apply

How does an expert use (apply) this knowledge?

- Can vary based on the role of the person (QA, engineering, MSAT)
- Statements begin with a behaviour verb (e.g. "discuss, "assess") that can become a learning objective

Applying can depend on the role the individual has.

Demonstrate

How can someone demonstrate to an incumbent expert or authority that they have the relevant knowledge and skills?

- This is intended to provide confidence to an organization, regulatory authority, colleagues and the individual that they have the needed knowledge and skills to be successful in the specific field of interest.

Demonstration may be to a number of knowledgeable persons.

Execute

What are specific examples of experiences that could be listed whereby someone develops a "repertoire of experiences"?

- Could include short or long-term projects, work experience, product types
- For example, "Uses risk assessment to define an environmental monitoring (EM) program."

Execution emphasises the pratical nature of learning.

Revised 21 March 2022 – AD & JV

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

sfsap.org