[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR IONIZING RADIATION STERILIZATION

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [AES2]: The document coding system should be in line with the organization's existing system for document coding; in case such a system is not in place, this line may be deleted.

Distribution list

Commented [AES3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy no.	Distributed to	Date	Signature	Returned	
				Date	Signature

Change history

Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. PURPOSE, SCOPE, AND USERS 3

2. REFERENCE DOCUMENTS 3

3. IONIZING RADIATION STERILIZATION PROCESS 3

3.1. DOSE ESTABLISHMENT 3

3.2. DOSE MAPPING 4

3.3. ESTABLISHING ROUTINE PROCESSING SPECIFICATIONS 4

3.4. ALARA PRINCIPLE 5

3.5. IONIZATION STERILIZATION PROCESSING CYCLE 5

3.6. DOSE AUDITING 6

3.7. VALIDATION OF THE STERILIZATION PROCESS 6

3.7.1. Bioburden determination 6

3.7.2. Verification and material testing dose determination 6

3.7.3. Verification and material testing experiments 6

3.7.4. Sterility testing 7

4. MANAGING RECORDS KEPT ON THE BASIS OF THIS DOCUMENT 7

5. APPENDICES 7

1. Purpose, scope, and users

The purpose of this Procedure is to define the sterilization process for medical devices in the production and service provision process.

This procedure applies to all processes where requirements for sterile medical devices are applied.

Users of this document are all employees of [organization name] inside the scope of the Quality Management System (QMS).

2. Reference documents

- ISO 13485:2016 standard, clauses 6.4.2, 7.5.2, 7.5.5, and 7.5.7
- ISO 14971:2019
- AAMI TIR No. 17
- 21 CFR Part 820 Medical Devices: Current Good Manufacturing Practice (cGMP)
- ANSI/AAMI/ISO 11137-1: 2006
- ANSI/AAMI/ISO 11137-2: 2006
- ANSI/AAMI/ISO 11137-3: 2006
- MDR 2017/745 Annex IX – Chapter I
- Quality Manual
- Procedure for Production and Service Provision
- [other documents and regulations specifying document control]

3. Ionizing radiation sterilization process

Although physical or chemical processes cannot ensure absolute sterilization, an object is considered to be sterile when necessary conditions have been met during a sterilization process.

Application: Radiation is used to sterilize medical instruments by first sealing a clean (but not bacteria-free) [illegible]

3.1. Dose establishment

To establish a dose means to determine the minimal amount of radiation that will achieve the required Sterility Assurance Level (SAL). [illegible]

When determining the dose, [job title] must perform the following activities:

- Determine initial microbiological load of the components.

Commented [AES4]: Adapt to the organization's needs.

Commented [AES5]: Include the name of your organization.

Commented [AES6]: Delete if not applicable to the organization; ANSI/AAMI are used in the U.S. market, ISO and EN ISO in the EU market.

Commented [AES7]: Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

Commented [AES8]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

Commented [AES9]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "12_Production_and_Service_Provision".

Commented [AES10]: Typically, 10-6 or 10-3

Commented [AES11]: E.g., Sterilization Manager

Commented [AES12]: Insert here relevant regulations and [illegible]

- Calculate or extrapolate the dose according to the resistance of the microbiological population identified.
- [illegible]

Commented [AES13]: Adapt to needs of the organization and [illegible]

3.2. Dose mapping

After the component is qualified as to dose and materials, [job title] must approve facilities to process the product. [Job title] must profile the product and its final packaging to define high and low zones of absorbed dose in the product related to the energy field it travels through. [illegible]

Commented [AES14]: E.g., Sterilization Manager, Production Manager

Commented [AES15]: Time spent in the energy field absorbing the dose.

The volume of the product and its density will increase during the routine irradiation, because it is processed in a large carrier or tote; therefore, [job title] should place the dose in a larger irradiator to ensure an efficient process. [illegible]

Once the product is received by the processing facility, [job title] performs measurements of the product carton and density, defines when density and volume of product are processed, and performs dose mapping on the product if necessary. [illegible]

3.3. Establishing routine processing specifications

Once dose establishment and mapping have been performed, [job title] must define specifications that include necessary information for routine processing of the product at a facility. The specifications must contain, at a minimum, the following information:

- A description of the product and the packaging
- loading configuration of a carrier
- minimum acceptable dose for sterilization and material compatibility
- [illegible]
- [illegible]

Once the processing specifications are defined, [job title] will establish a routine process of irradiation according to the product code, [illegible]

If any changes occur in the size or density of the treated product, or a request is made to change the priority turn time, [job title] will contact the customer to discuss requirements.

3.4. ALARA principle

ALARA (As Low as Reasonably Achievable) is a safety principle for reducing radiation doses and [illegible]

The three main principles of ALARA are:

- time
- [illegible]
- [illegible]

[Job title] must ensure that the following methods for minimizing time of exposure are established:

- Plan and discuss the task before entering the area.
- Use only the required number of workers to do the job.
- [illegible]
- [illegible]

[Job title] must ensure that the following methods for maintaining distance from sources of radiation are enforced:

- Stay as far away as possible from the source of radiation.
- Use remote handling tools whenever possible.
- [illegible]

Some methods of using shielding are:

- Barriers of lead, concrete, or water provide protection from penetrating radiation, such as gamma rays and neutrons.
- Special plastic shields stop beta particles, and air stops alpha particles.
- [illegible]
- [illegible]
- [illegible]

3.5. Ionization sterilization processing cycle

The product to be sterilized arrives on a truck and is unloaded by [job title] into the processing facility. [Job title] loads the product into a carrier/tote per established configuration, places the dosimeters, and the product is exposed to the radiation field. [Job title] monitors the dosimeters and analyzes them while the product is quarantined.

[illegible]

Commented [AES16]: If the organization uses separate SOP for [illegible]

Commented [AES17]: ALARA is often a regulatory obligation [illegible]

Commented [AES18]: Minimizing time in a field of radiation.

Commented [AES19]: Maximizing the distance from a source of radiation.

Commented [AES20]: Using shielding whenever possible.

Commented [AES21]: E.g., Sterilization Manager

Commented [AES22]: Radiation rate lowers at a further [illegible]

Commented [AES23]: Adapt to the organization's needs., or [illegible]

Commented [AES24]: If it's too close, or it takes a long time to set it up.

Commented [AES25]: Note: Once temporary shielding is [illegible]

Commented [AES26]: For example: specially designed [illegible]

Continuous units function with an automated conveyance system, moving the product through a "maze" (to prevent photons from exiting the shield), besides a gamma source, and back out on a permanent basis. [Job title] loads a set number of totes or carriers into a batch and positions the totes in the irradiation chamber. [illegible]

Commented [AES27]: Normally underwater.

3.6. Dose auditing

For medical devices labeled as sterile, [job title] ensures that the efficacy of the minimum dose is substantiated and that it conforms to legal and regulatory requirements. [illegible]

Commented [AES28]: E.g., Production Manager, Sterilization [illegible]

[Job title] must test samples at sub-lethal doses (as in the original sterilization dose experiment) according to the industry guidelines to check for continued dose efficacy. [illegible]

3.7. Validation of the sterilization process

Before starting routine gamma irradiation, the product labeled as sterile must undergo a process of validation [illegible]

3.7.1. Bioburden determination

In order to determine the processing parameters, [job title] uses the natural microbiological load present on the product and sealed packaging. [illegible]

3.7.2. Verification and material testing dose determination

[Job title] determines the appropriate radiation dose to apply to the product according to tables given in ANSI/AAMI/ISO 11137 to reach a specified Sterility Assurance Level. [illegible]

Commented [AES29]: E.g., Sterilization Manager

The appropriate method for determining sterility is selected by [job title] based on ANSI/AAMI/ISO 11137, level of sterility assurance, selected processing dose, and number of samples used in testing.

[illegible]

3.7.3. Verification and material testing experiments

The ANSI/AAMI/ISO 11137 Verification Dose is generally very low, and falls within a range of +/- 10% of the reference values for the Verification Dose.

[illegible]

Commented [AES30]: E.g., Sterilization Manager, employee in [illegible]

3.7.4. Sterility testing

Once the Verification Dose has been applied, the product samples are routed back by [job title] to the microbiology laboratory to perform a sterility test. [illegible]

Commented [AES31]: E.g., Sterilization Manager, Production Manager

4. Managing records kept on the basis of this document

Record name	Code	Storage			[illegible]
		[illegible]	[illegible]	[illegible]	
Record for Sterilization	PR14.6	[illegible]	[illegible]	[illegible]	[illegible]

Commented [AES33]: Adapt the information in this column to [illegible]

Commented [AES32]: Adapt the information in this column to [illegible]

Commented [AES34]: If the record is in electronic form, write [illegible]

5. Appendices

- Appendix 1 – Record for Sterilization

[job title]
[name]

_____
[signature]

Commented [AES35]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.