[Organization logo]

[Organization name]

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

PROCEDURE FOR INFRASTRUCTURE AND WORK ENVIRONMENT

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

©2023 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License Agreement.

Change history

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

Table of contents

©2023 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License Agreement.

1. Purpose, scope and users

The purpose of this Procedure is to determine the requirements for infrastructure and work environment in order to ensure product and service conformance.

This Procedure applies to all processes within the QMS.

Responsibility for providing proper physical, social, and psychological conditions in the workplace is on HR department personnel and the manager of the department. Temperature, lighting, cleanliness, language, and relationships among employees are their responsibilities as well.

Product nonconformities could be the result of extreme environmental conditions influencing the quality of employee performance. The heads of the production and quality departments are responsible for the identification of such environmental conditions.

Users of this document are [all staff] of [organization name].

Commented [AES4]: Extreme environmental conditions include high or low temperature, high humidity, vibrations, etc.

Commented [AES5]: Adapt to organization's practice.

Commented [AES6]: Include the name of your organization.

2. Reference documents

- ISO 13485:2016 standard, clauses 6.3, 6.4.1, and 6.4.2
- Quality Manual
- MDR 2017/745 article 10(9); Annex IX – Chapter I

Commented [AES7]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

Commented [AES8]: 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/

3. Infrastructure and work environment

All staff in all processes are included in this Procedure.

The buildings and environment in which components, devices, and records are received, processed, built, or stored, and the personnel who perform these operations, should be controlled so that finished devices will consistently meet the specifications established by the manufacturer. [redacted]

Commented [AES9]: E.g. Production Manager, QA Manager, [redacted]

3.1. Requirements

[Organization department] determines the requirements for environmental conditions in all areas where materials, components, or medical devices could be contaminated, degraded, or damaged by inappropriate environmental conditions.

Commented [AES10]: E.g. R&D

[redacted]

Commented [AES11]: You can delete this if the medical device [redacted]

©2023 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License Agreement.

Production is responsible for ensuring that required environmental conditions are maintained in production, packaging, and storage areas.

Commented [AES12]: You can delete this if there is no classical

3.2. Control program

[Job title] organizes incoming control of product and materials.

Commented [AES13]: E.g. Quality Controller

General operational controls for maintaining a suitable environment in all relevant areas include, as appropriate:

- good housekeeping practices
- [illegible]

Commented [AES14]: You can delete this if there is no classical

Where microbiological and/or particulate limits are specified for the environment, [Production Manager] must define a program for meeting the environmental requirements, and maintaining the environment in compliance with those requirements. The program can include, but is not limited to:

Commented [AES15]: These limits can be defined either by

Commented [AES16]: Adapt to organization's practice.

- defining areas to be sealed or isolated (clean rooms)
- defining and maintaining the necessary air pressure and air filtration activities
- personnel requirements including procedures for entering clean rooms, garments to be worn, washing of hands, etc.
- [illegible]

Commented [AES17]: Adapt to organization's needs.

3.3. Cleaning of production areas and equipment

Production, packaging, and storage areas, as well as related equipment and furniture, are designed to allow proper cleaning and maintenance.

[illegible]

Commented [AES18]: E.g. Production Manager, Quality

[illegible]

Commented [AES19]: E.g. Production Manager, Quality

Where special cleaning techniques and methods are required, [job title] documents them in work instructions and the cleaning personnel are trained in their use.

3.4. Personnel requirements

©2023 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License Agreement.

[Job title] ensures that personnel requirements are specified to maintain the required level of environmental control. The requirements are specified in the following areas:

- restrictions on drinking, eating, smoking, and chewing gum in controlled areas
- garments and gowning requirements in controlled areas, and applicable gowning procedures
- rules for covering head and facial hair, wearing of watches and rings, and applying and removing cosmetics
- [illegible]
- [illegible]

These requirements, rules, and procedures are documented in written procedures, work instructions, signs, and posters. All relevant personnel are provided with demonstration and training in how to use the procedures.

[illegible]

External contractors, consultants, auditors, and other personnel who are required to enter clean rooms are either trained in relevant procedures, or are accompanied by a trained person.

3.5. Monitoring and measuring environmental conditions

Environmental conditions are monitored and measured to ensure that they comply with requirements, and that environmental control systems and methods are effective.

The environmental monitoring program is developed by [job title], and includes:

- Testing for particulate and other contaminants: air and surface sampling and analysis. Documented instructions defining the frequency of sampling; operating conditions; location, number, and volume of samples to be taken; methods for testing and interpretation of data; and requirements for records.
- [illegible]

Instruments and devices used to monitor and measure environmental conditions must be maintained according to the Procedure for Equipment Maintenance and Measuring Equipment.

The Procedure for Control of Nonconforming Product will be applied to all products that are under environmental conditions that are outside the specified limits. [illegible]

Commented [AES20]: E.g. Production Manager, Quality [illegible]

Commented [AES21]: Adapt to organization's needs.

Commented [AES22]: You can adapt this according to the [illegible]

Commented [AES23]: E.g. Production Manager, Quality [illegible]

Commented [AES24]: Testing for particulate and other contaminants is performed only in cases when a "clean room" is needed for the production of your medical device.

[illegible]

Commented [AES25]: You can adapt this according to the [illegible]

Commented [AES26]: You can find a template for this [illegible]

Commented [AES27]: You can find a template for this [illegible]

©2023 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License Agreement.

4. Managing records kept on the basis of this document

Record name	Code	Storage		
		[illegible]	[illegible]	[illegible]
Record of Infrastructure Maintenance	PR06.1	[illegible]	[illegible]	[illegible]

Commented [AES28]: Adapt the information in this column to [illegible]

Commented [AES29]: If the record is in electronic form, write [illegible]

5. Appendices

- Appendix 1 – Record of Infrastructure Maintenance

[job title]
[name]

_____
[signature]

Commented [AES30]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.

©2023 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License Agreement.