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Irish Standard
I.S. EN 17141:2020

Cleanrooms and associated controlled environments - Biocontamination control

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National Foreword

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 17141

August 2020

ICS 13.040.35

English Version

Cleanrooms and associated controlled environments - Biocontamination control

Salles propres et environnements maîtrisés apparentés - Maîtrise de la biocontamination

Reinräume und zugehörige Reinraumbereiche - Biokontaminationskontrolle

This European Standard was approved by CEN on 4 November 2019.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European foreword

This document (EN 17141:2020) has been prepared by Technical Committee CEN/TC 243 “Cleanroom technology”, the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2021, and conflicting national standards shall be withdrawn at the latest by February 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 14698-1:2003, EN ISO 14698-2:2003 and EN ISO 14698-2:2003/AC:2006.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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Introduction

Clean controlled environments are used to control and limit microbiological contamination where there is a risk to product quality, patient or consumer.

In this document the term “clean controlled environments” is used to cover cleanrooms, clean zones, controlled zones, clean areas and clean spaces.

This document gives guidance on best practice for establishing and demonstrating control of airborne and surface microbiological contamination in clean controlled environments. This document describes the requirements for microbiological contamination control and provides guidance on the qualification and verification of clean controlled environments.

In order to establish microbiological control, it is important to understand the risks of microbiological contamination. This is achieved by considering the sources of microbiological contamination, the associated microbiological concentrations and the likelihood of transfer and the impact on product quality, the patient or the consumer.

A formal system of microbiological control identifies, controls and monitors microbiological contamination on an ongoing basis. This is a process of continuous improvement and the principles of Plan – Do – Check – Act (PDCA) apply, as shown in Figure 1.

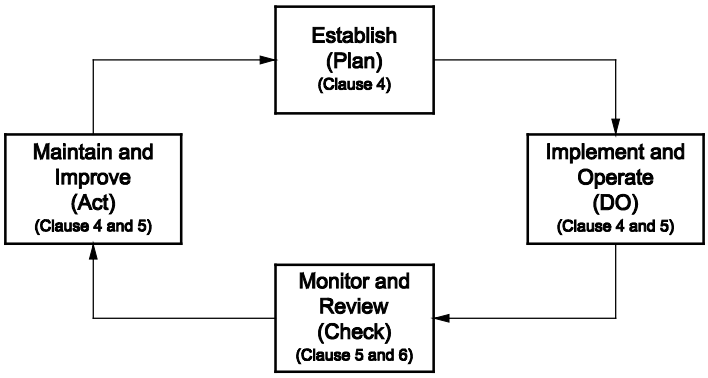

Figure 1 — Application of PDCA as the system for microbiological control

This document provides general guidance and considerations for a number of different applications. It is expected to have particular use in the Pharmaceutical, Biopharmaceutical, Medical Devices and other Life Science industries, as well as in Healthcare and Hospitals, Food, and related applications which use clean controlled environments.

In the regulated Pharmaceutical and Biopharmaceutical manufacturing sector there are already many applicable standards and regulatory guidelines. These include the EU Annex 1 GMP [31] guidance on the manufacture of Sterile Medicinal products and the FDA Aseptic Processing guidance [32]. The European and United States Pharmacopoeias also provide some guidance on certain related topics. There are numerous other documents and technical papers available from industry associations including the Parenteral Drugs Association (PDA), International Society of Pharmaceutical Engineering (ISPE) and Pharmaceutical Healthcare Sciences Society (PHSS). While there are regulations and standards on risk management of medical devices, for example EN ISO 14971 [2], there is less guidance on the microbiological control of clean controlled environments.

In the Healthcare and Hospital sector there are EU Directives, including the Tissue and Blood Directives for specialist and similar clean controlled environments. There are national standards and guidelines for specialised Operating Theatres, Isolation units, Immuno-compromised wards as part of infection

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control. In addition, Hospital Pharmacy aseptic compounding units, Radiopharmacies and specialist laboratories such as Stem Cell typically refer to Life Science industry guidance documents.

In the Food and consumer related industries, while there are regulations and standards on food, beverages and cosmetics for example there is insufficient guidance regarding microbiological control in clean controlled environments.

This document includes a number of informative annexes that provide further guidance on biocontamination control in specific applications, and includes, for example:

— tables of microbiological cleanliness levels for monitoring of microbiological contamination in certain types of clean controlled environments;

— guidance in specific areas of microbiological control relating to the choice of environmental monitoring (EM) sampling methods, the management and trending of collected data and the role of alternative and real time microbiological detection systems;

— appropriate methods for establishing control, selecting appropriate alert and action levels and target levels as necessary;

— establishing a microbiological environmental monitoring plan as part of demonstrating control of the clean controlled environment.

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1 Scope

This document establishes the requirements, recommendations and methodology for microbiological contamination control in clean controlled environments. It also sets out the requirements for establishing and demonstrating microbiological control in clean controlled environments.

This document is limited to viable microbiological contamination and excludes any considerations of endotoxin, prion and viral contamination.

There is specific guidance given on common applications, including Pharmaceutical and BioPharmaceutical, Medical Devices, Hospitals and Food.

2 Normative references

The following document is referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 14644-1:2015, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)*

3 Terms and definitions

For the purposes of this document, biocontamination control and microbiological control are synonymous, and the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia. available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
action level
level set by the user in the context of controlled environments, which, when exceeded, requires immediate intervention, including investigation of cause, and corrective action

3.2
alert level
level set by the user in the context of controlled environments, giving early warning of a drift from normal conditions, which, when exceeded, should result in increased attention to the process

3.3
clean controlled environment
defined zone in which microbiological contamination is controlled by specified means

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