INTERNATIONAL STANDARD

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Cleanrooms and associated controlled environments —

Part 4: Design, construction and start-up

Salles propres et environnements maîtrisés apparentés —

Partie 4: Conception, construction et mise en service

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Introduction

Cleanrooms and associated controlled environments provide for the control of airborne particulate contamination and, if relevant, other forms of contamination, to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of airborne contamination include those in such industries as aerospace, microelectronics, pharmaceuticals, medical devices, food and research and development laboratories and some applications in healthcare.

Cleanrooms and associated controlled environments are classified for air cleanliness by particle concentration (ISO 14644-1). Cleanliness attributes relating to chemicals, nanoscale particles and viable particles (microorganisms), as well as cleanliness of surfaces, can also be considered.

This document is one of the series of International Standards concerned with cleanrooms and associated controlled environments prepared by ISO/TC 209.

This document provides guidance for the design, construction and start-up of cleanrooms, both new and those undergoing modification or refurbishment. In this edition, a more structured approach is provided with separate normative sections on requirements, design, construction and start-up, supported by four corresponding informative annexes.

For this edition, key recommendations and considerations include:

a) A structured approach with a logical sequential flow through the design, construction and start-up stages. There will normally be reviews and iterations of the requirements, contamination control concepts, layouts and other considerations. The final design should be reviewed against the requirements before construction commences and when construction is complete. The operation and performance are verified against the requirements during start-up.

b) Inclusion of other cleanliness attributes. The ISO 14644 series has parts that deal with other cleanliness attributes, namely chemicals, nanoscale particles, macro-particles and, in ISO 14698, viable particles (microorganisms), as well as cleanliness of surfaces. These other attributes should be considered if relevant, bearing in mind that the primary requirement for a cleanroom or clean zone is that it meets a classification by airborne particle concentration according to ISO 14644-1.

c) Importance of a contamination risk assessment. Assessments should be carried out to better understand the contamination risk and its impact on the process and product and to identify the critical control points (locations) in the cleanroom or clean zone.

d) A clear statement of requirements, namely everything needed for input into the design, including the purpose of the cleanroom and the acceptance criteria for performance parameters. This is critical and should be documented prior to the start of the design process.

e) Ventilation effectiveness. This revision focuses on the importance of ventilation effectiveness through control of air-flow patterns and clean-up recovery rates. Two measures are identified: air change effectiveness (ACE) and contaminant removal effectiveness (CRE).

f) Using air supply rate for calculations of contaminant dilution and removal. This will make it possible to achieve energy-efficient cleanrooms while achieving the required level of air cleanliness.

g) Energy efficiency and life cycle considerations. Energy efficiency in cleanrooms is very important and is covered by ISO 14644-16.

h) A clean build protocol. This is included to minimize contamination during construction of the cleanroom.

Information directly relevant to cleanrooms and associated controlled environments is included in the informative annexes. Supporting information is given in the Bibliography.