

# ISO 14644-5 Offers a One-stop Guide to Cleanroom Operations

Anne Marie Dixon, Cleanroom Management Associates, Inc.

After a cleanroom has been built, validated, and certified, the daily operation of that facility is an ongoing task to ensure that the products manufactured or tested in the cleanroom meet quality standards and customer expectations. Cleanroom managers can turn to *ISO 14644-5: Cleanrooms and associated controlled environments—Part 5: Operations* for information on requirements and protocols for minimizing contamination risks that would compromise quality.

## Keywords

ISO, 14644, cleanroom, standard, operations

There are hundreds of standards covering the various aspects of cleanroom operations that users could research for guidance. However, *ISO 14644-5: Cleanrooms and associated controlled environments—Part 5: Operations* provides a single source addressing the following six key areas of cleanroom operations:

- Operational systems
- Cleanroom clothing
- Personnel
- Stationary equipment
- Materials and portable and mobile equipment
- Cleanroom cleaning

The normative (mandatory) portion of the ISO Standard lists the required systems and procedures for maintaining cleanliness levels and consistent quality. A corresponding annex for each category provides informative guidance on policies and methods cleanroom managers can implement to meet the requirements.

## Operational systems

The operational systems section defines the basic organizational components that provide a framework for producing quality products while observing proper cleanroom practices. These components include standard operational procedures, risk assessments, training, documentation, maintenance records, safety, and methods for modifying and upgrading the cleanroom.

Annex A lists examples of accepted risk assessment and management methods and discusses the contamination risk factors that may affect clothing, personnel, equipment, and environmental quality. Other topics covered in this informative annex include:

- Subjects that should be incorporated into a training curriculum
- Procedures for maintaining and monitoring mechanical support systems
- Considerations for upgrading or modifying a cleanroom
- Elements of a safety program

### **Cleanroom clothing**

Cleanroom garment systems protect the product from the contamination generated by personnel and can, if required, also protect personnel from products. People are the primary source of contamination in any cleanroom; therefore, the selection of clothing and garment systems is critical to the quality of the products manufactured in the cleanrooms and the overall operation of the cleanroom.

The choice of clothing is based on three key factors: product sensitivity, classification of the cleanroom, and safety. Annex B assists in the selection process with discussions of clothing design and construction; clothing properties such as barrier, electrostatic, particulate control, and thermal comfort; and storage considerations.

### **Personnel**

Training, protocols, and rules and regulations are required for personnel working in any class of cleanroom. Annex C highlights the policies critical to operations involving personnel. This section includes a sample gowning procedure and a guide to cleanroom conduct to help users establish internal standards. Hygiene and safety protocols also are covered.

### **Stationary equipment**

ISO 14644-5 focuses on the entry of permanent equipment into the cleanroom, including the following considerations:

- Where and how the equipment should be cleaned and prepared for admittance
- How the equipment should be unpacked and transported to the final sitting location
- Installation procedures
- Equipment removal from the cleanroom

Annex D elaborates on these steps and also contains a section on maintenance and repair with a two-fold emphasis: 1) scheduling maintenance to occur before the equipment becomes a source of contamination, and 2) contamination control during the maintenance and repair process.

### **Materials and portable and mobile equipment**

After personnel, the second largest risk to cleanroom operations is the transfer of materials and mobile equipment. Procedures are required to prevent contamination of these items, to manage materials stored in the cleanroom, and to dispose of waste.

Annex E covers a wide range of items, from chemicals conveyed through pipes to notebooks carried by personnel. Selection criteria are provided for materials and mobile equipment, such as a list of specific characteristics that allow exterior surfaces to be properly decontaminated and

cleaned. The annex also outlines procedures for entry and exit that can be used as the basis for site operational procedures, and provides specifications for cleaning tools and equipment.

### **Cleanroom cleaning**

The requirements for cleanroom cleaning encompass methods, personnel assignments and training, cleaning schedules, and contamination checks. Annex F describes procedures for routine cleaning and special situations such as construction, maintenance, and emergency conditions. Details are provided on basic cleaning methods, scheduling, surface classification, cleaning specific surfaces, and monitoring of cleaning effectiveness. Table F-1 describes the 10 stages of a construction-related cleaning program, including definition, purpose, responsible party, method, and standard for each stage.

The requirements and procedures ISO 14644-5 outlines for these six critical areas of cleanroom operations are designed to assist the user in maintaining a facility at its defined cleanliness level. This document is indispensable for anyone building, managing, maintaining, or planning a cleanroom.

*Anne Marie Dixon chairs the ANSI-accredited US Technical Advisory Group to ISO TC 209 and is head of the US delegation to ISO Technical Committee 209, Cleanroom and associated controlled environments. Dixon is managing partner of Cleanroom Management Associates, Inc., Carson City, Nevada, which specializes in competitive benchmarking, training, and auditing of clean and aseptic operations and management. She holds a BS in finance from the University of Illinois, a BS in engineering from the University of Nevada, and an MBA from the University of Chicago. Dixon is an IEST Fellow and Past President.*