
Cleanrooms and associated controlled environments —

Part 7:

**Separative devices (clean air hoods,
gloveboxes, isolators and mini-
environments)**

Salles propres et environnements maîtrisés apparentés —

*Partie 7: Dispositifs séparatifs (postes à air propre, boîtes à gants,
isolateurs et mini-environnements)*

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Published in Switzerland

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Introduction

In the spirit of the generic requirements of an International Standard, the term “separative devices” was developed by Technical Committee ISO/TC 209 to encompass the wide continuum of configurations from open unrestricted air overspill to wholly contained systems. Common terms-of-trade, such as clean air hoods, gloveboxes, isolators and mini-environments, have different meanings depending on the specific industry.

Difficulties experienced in the manufacture and handling of certain products or materials have driven the development of separative devices. These difficulties include product sensitivity to particles, chemicals, gases or microorganisms; operator sensitivity to the process materials or byproducts; and both product and operator sensitivity.

Separative devices provide assured protection in varying levels by utilising physical or dynamic barriers, or both, to create separation between operation and operator. Certain processes may require special atmospheres to prevent degradation or explosions. Some systems may be capable of providing 100 % recirculation of the contained atmosphere to allow inert gas operation or biodecontamination with reactive gases.

Usually people do not work directly inside the separative-device environment during production. These separative devices may be movable or fixed, and used for transport, transfer and process. The product or process, or both, are manipulated remotely with access devices either manually, with protection by barrier technology such as wall-integrated personal interface systems (e.g. gloves, gauntlets, half-suits), or mechanically with robotic handling systems.

Air cleanliness definitions and test methods covered in ISO 14644-1, 14644-2 and 14644-3 generally apply within separative devices. In applications with biological contamination requirements, ISO 14698-1 and 14698-2 will apply. However, some applications can have special requirements for monitoring because of extreme conditions that may be encountered. These unique conditions are covered in this part of ISO 14644.

Transfer devices to move material in and out of separative devices form an important portion of this part of ISO 14644. In addition, material can be moved from one fixed separative device to another in transport containers.

Design and construction of cleanrooms, including generic aspects of clean zones, are covered in ISO 14644-4. ISO 14644-4:2001, Figure A.4, illustrates aerodynamic measures or air overspill often used in industry-specific separative devices called clean air hoods and mini-environments. Mini-environments are often used in the electronics industry with transport containers, called boxes or pods, to provide very clean process conditions. The application of barrier technology used in industry-specific separative devices called isolators is shown in ISO 14644-4:2001, Figure A.5. Separative devices, often called gloveboxes, containment enclosures or isolators, are used in the medical products and nuclear industries to provide protection to the operator as well as the process. Isolators may be rigid- or soft-walled depending on the application. The Bibliography contains industry-specific references. However, from a unifying conceptual standpoint, a continuum of separation exists between the operation and the operator, ranging from totally open to totally enclosed systems depending on the application. Similarly, a continuum exists for containment.

The concept of separative devices is not limited to one specific industry, as many industries use these technologies for different requirements. In that light, this part of ISO 14644 provides a generic overview of the requirements involved.