

Table 23-2 Functional Specifications to Be Validated for Isolators

Function	Examples
Air supply specifications	Air change rate Air velocity Particulate air specification Recirculation rate Temperature and humidity Aeration of the decontaminating agent
Leak testing	Pressure decay test Tracer gas detection test
Ergonomics	Eventual and uneventful situations
Rapid transfer ports	Seal integrity
Facility requirements	Classification of isolator room Temperature and humidity control Process utilities
User requirements	Sterility assurance—sterilization and decontamination methods Cleaning Containment Environment control and monitoring Microbiological monitoring Process simulation

Source: From Ref. 10.

DESIGN

Isolator design includes materials of construction (rigid vs. flexible; compatible with cleaning agents and sterilants), size (especially considering length of human arms and ability to reach all parts of the isolator interior), ease of cleaning and sanitization and/or sterilization, ergonomics (e.g., height and length of gloves), lighting, ability to connect to other systems (e.g., sterilization tunnels), and other considerations that isolator manufacturing companies are well aware of now after years of experience overcoming many problems. An isolator needs to be equipped with filters capable of microbial retention. HEPA filters are required, but ultra low particulate air filters may be substituted. While the isolator is at rest, it must meet the particulate requirement for an ISO 5/Grade A area. There is no particulate requirement while the unit is in operation during a sterility test, and there is no requirement for air velocity or air exchange rate. The isolator should be leakproof, but it may exchange air with the surrounding environment. While direct openings to the surrounding environment should be avoided, air overpressure can be employed to maintain sterile conditions within the isolator. Air overpressure should also be employed to help avoid ingress of non-sterile air in the event of an unexpected leak.

Location

The isolator does not need to be installed in a classified clean room, but the surrounding room should be limited to essential staff. Environmental monitoring of the surrounding room is not required.

The surrounding room should have sufficient temperature and humidity control to maintain operator safety and comfort, to allow for proper operation of the associated sterilizer (the air should exhaust to an outside source for safety reasons) unit, and to allow for proper operation of the isolator. The temperature within the room should be as uniform as possible to avoid the formation of condensation within the isolator.

Installation Qualification

The installation qualification (IQ) should include a detailed description of all of the mechanical aspects of the system such as dimensions, internal configuration, serial numbers of the equipment, blueprints, purchase orders, electrical supply, specifications, exhaust, vacuum supply, and equipment manuals. All documentation should be reviewed for accuracy. The documentation that is recommended is discussed next (10).