

Isolation and Surge Capacity Q&A HRSA Critical Benchmark #2-2

Anteroom, Airlock and Isolation Rooms

Q: How is “isolation” defined?

A: The CDC defines isolation as “separation of a person or group of persons from other persons to prevent the spread of infection.”

Q: How do anteroom products work?

A: Anterooms are like air-locks. They are used to transition people in and out of airborne contaminated areas when the contaminated area is not under negative pressure. An anteroom is used as a transitional space between the hallway and the airborne infection isolation area. This transition area is where the HCW puts on their PPE when entering the Airborne infection isolation (All) room and takes it off when leaving the All. The HCW also will store all contaminated PPE in this area in proper contaminated storage containers.

Q: What are the specific limitations of an anteroom or airlock solution?

A: The anteroom functions as a transition area from the clean hallway to the airborne contaminated All room. This transition area allows a HCW to don/doff their PPE and control the potential spread of contamination. The anteroom is not an All area, nor should it function as one.

Q: How do anterooms compare to isolation rooms?

A: An Anteroom is not an Airborne Infection isolation room. An anteroom is only used to transition from the clean corridor into the All room .

Standards and Guidelines for Air Flow

Q: Does an anteroom satisfy the requirement of HRSA Critical Benchmark #2-2 for isolation capacity?

A: An anteroom does not meet the HRSA Critical Benchmark #2-2. The CDC guidelines for Airborne Infection Isolation (All) refer to the isolation of patients infected with organisms spread via airborne droplet nuclei <5 µm in diameter. CDC requirements for All include:

1. the direction of airflow must move from clean air, to dirty air, to outdoor release after HEPA filtration;
2. negative pressure must be sustained within the All;
3. at least 12 ACH (air changes per hour) must be achieved within the isolation room.

Q: What are the CDC guidelines for air flow?

A: CDC guidelines for airflow for Airborne Infection Isolation (All) require that clean air flows into a hallway or corridor of a healthcare facility, through the room door into the All room, then move towards the patient (the source of airborne contamination) and then to a HEPA filter to be exhausted to the outdoors as clean filtered air.

Q: Is the direction of airflow in a negative or positive environment important?

Ref: CDC Guidelines for Environmental Infection Control in Health-Care Facilities, 6 June 2003 [www.cdc.gov/mmwr/prevoew/mmwrjtml/rr5210a1.htm]

A: YES. The direction of airflow should move from clean air to dirty air to minimize the possibility of spreading contamination. In a negative environment, the airflow should move from the hallway flows across the patient’s bed and exit from the opposite side of the room to a HEPA filtration unit before being exhausted to the outdoors. In the protective environment, the airflow is the opposite direction where the filtered air enters from one side of the room flows across the patient’s bed and exits from the opposite side of the room.

FailSafe Air Safety Systems
Supporting the Standards for Safe Air

Q: Are there specifications that should be included in the planning and construction or renovation of All rooms?

Ref: CDC Guidelines for Environmental Infection Control in Health-Care Facilities, 6 June 2003 [www.cdc.gov/mmwr/prevoew/mmwrjtml/rr5210a1.htm]

A: YES, The CDC guidelines state that the following specifications should be included in the construction and renovation of All units:

1. Maintain continuous negative pressure (2.5Pa [0.01 inch water gauge]) in relation to the air pressure in the corridor, monitor air pressure periodically, preferably daily, with audible manometers or smoke tubes at the door or with a permanently installed visual monitoring mechanism
2. Ensure that rooms are well-sealed by properly constructing windows, doors, and air-intakes and exhaust ports.
3. Install self-closing devices on all All room exit doors
4. Provide ventilation to ensure >12 ACH for renovated rooms and new rooms, and >6 ACH for existing All rooms
5. Direct exhaust air to the outside, away from air-intake or populated areas. If this is not practical, air from the room can be recirculated (within the room) after passing through a HEPA filter.

Q: Does it make a difference where the HEPA filter is located within an isolation room?

A: Yes. It is important that the HEPA unit be placed with the advice of facility engineers to ensure that all isolation room air is properly mixed and filtered to remove contamination efficiently.

Q: Do anterooms or airlocks satisfy CDC guidelines for All?

A: NO, an anteroom alone does not satisfy CDC guidelines for airborne infection isolation:

1. An anteroom alone does not allow the airflow to go from the hallway into the All area, then to the patient and then exit through a HEPA filter to be exhausted to the outdoors.
2. An anteroom alone does not generate a minimum of 12 ACH (Air Changes per Hour)
3. An anteroom alone does not generate a negative air pressure within the room of >0.01 in wc.

Q: Does an airlock or anteroom emit contaminated air into the hallway or corridor?

A: The airflow that moves from the hallway into the anteroom mixes with any escaped contaminated air from the All room and dilutes any potential airborne contamination before it has a chance to escape into the hallway by entry/egress procedures. Therefore, the risks are high that contaminated air can be emitted into a hallway, corridor, or other parts of a healthcare facility.

Q1: Do I need to exhaust 100% air to the outside to meet CDC smallpox response guidelines?

Ref: CDC Guide C, Part 1: Infection Control Measures for Healthcare and Community Setting

A. YES, The isolation measures as part of the response to a smallpox emergency refer to three types of containment facilities:

- 'C' for people with confirmed illness
- 'X' for people who high fever and are placed under observation
- 'R' for people who were exposed but no signs of illness

The type C facility requires that there are no shared HVAC systems and that 100% of the air is exhausted to the outside through a HEPA filter or located at least 100 yards from any other occupied building or area.

The medical isolation area that is used for observations of patients that have a fever but either not confirmed with smallpox or with rash also require the same air handling as the type 'C' facility. Thus, 100% of the air should be exhausted outside through a HEPA filter

The medical isolation room that is used to treat a single patient with smallpox or other infectious disease should be treated as a type X facility where the patient is under observation until diagnostic confirmation is obtained.

Q: The airflow characteristics required to support CDC guidelines state that 100% of the air should be exhausted outside through a HEPA filter. If an anteroom doesn't comply with these guidelines, are there other acceptable solutions that allow for that?

A: Products such as FailSafe's Mobile Containment Systems support CDC guidelines for All and meet the HRSA Critical Benchmark #2-2. This includes:

1. the direction of airflow moves from clean air, to dirty air, to outdoor release after HEPA filtration;
2. negative pressure can be sustained within the All room [note that these products also allow for the setup of positive pressure environments];
3. at least 12 ACH (air changes per hour) can be achieved within the isolation room.

For individual, transportable isolation, FailSafe also sells the **only FDA cleared portable isolation units on the market today.**

Portable Isolation Solutions

Q: Our hospital is looking for a solution that's portable for isolation of large groups of people. What are my options?

A: You can either retrofit an existing structure to provide a negative pressure environment (using products such as FailSafe's Mobile Containment Systems) or you can use a separate structure that provides negative pressure capabilities (such as FailSafe's Portable Isolation Containment System).

Q: How do anterooms compare to true isolation rooms?

A: An anteroom is not an Airborne Infection Isolation room. **Anteroom solutions are merely used to transition a HCW from a clean hallway or corridor into the All room.**

Q: Can you transport anteroom products?

A: Yes, many anteroom products are portable, although by themselves they do not satisfy the CDC guidelines for All.

Q: Why would this type of solution be attractive to a hospital?

A: This type of product appears to be easy to use and setup – a “quick fix” to a complex problem, although they do not meet the CDC guidelines for All.

Q: How long does a HCW need to stay in the anteroom once they have been in the contaminated area?

A: A HCW needs to stay in an anteroom a sufficient amount of time to allow any airborne contamination that has absorbed on them to outgas. The time spent in the anteroom is based on the number of air changes within the anteroom that one desires to insure that any contaminated air from the All room is sufficiently diluted. Only then can the door from the anteroom to the hallway be opened to prevent any contamination from escaping.

Q: Are air lock systems safe?

A: The probability is high that contaminated air will be blasted into the airlock itself, which presents a safety hazard to all healthcare workers who come in contact with the anteroom before or after they don their PPE.

Applications

Q: Can I supplement air cleaning during intubation and extubation for TB patients who require surgery?

Ref: CDC Guidelines for Environmental Infection Control in Health-Care Facilities, 6 June 2003 V.Infection-Control and Ventilation Requirements for Operating Rooms C. [www.cdc.gov/mmwr/prevoew/mmwrjhtml/rr5210a1.htm]

A. YES, the FASS Mobile Containment Systems can be used to supplement air cleaning during these procedures. The units are positioned so that all room air passes through the filter. Unit placement should be based on consultation with plant engineers.

FailSafe Air Safety Systems
Supporting the Standards for Safe Air

Q: How can I use FASS Mobile Containment systems to remove smoke and odors from cafeteria, kitchens or other areas?

A. The FASS Mobile Containment System should be placed close to the airborne smoke and odor source. The HEPA filter capture and contain airborne smoke particulates and using the ozone timer can be used to generate ozone to chemically oxidize any odorous volatile organic compounds [VOC]. The removal of smoke and odors is also easily handled by the FASS units.

Q: Can the FASS Mobile Containment Systems be used to manage the aerosol hazards generated in laser surgery procedures?

Ref: CDC Guidelines for Environmental Infection Control in Health-Care Facilities, 6 June 2003 VI .Other Potential Infectious Aerosol Hazards in Health- Care Facilities
[www.cdc.gov/mmwr/preview/mmwrjhtml/rr5210a1.htm]

A. YES. The FASS Mobile Containment Systems can be used to manage the generation of large amounts of laser plume when abating tissue infected with human papilloma virus (HPV) or when performing procedures on a patient with extrapulmonary TB.

Q: Can an immunocompromised patient be placed in an All room?

Ref: CDC Guidelines for Environmental Infection Control in Health-Care Facilities, 6 June 2003
[www.cdc.gov/mmwr/preview/mmwrjhtml/rr5210a1.htm]

A. YES. However when an infectious immunocompromised patient is placed in isolation, special air handling requirements must be met: clean HEPA filtered air must flow into the All room. It is preferred to have the All room input airflow directly over the patient. This is to protect the immunocompromised patient from being infected from any residual airborne infectious materials that are insufficient to infect HCW but can easily infect immunocompromised patients. The All room air must then be HEPA filtered before it is exhausted to the outdoors

Q: There are many products on the market that claim to be “proven”, “clinically tested” solutions for isolation. How do they compare to FailSafe products?

A: FailSafe’s products are the only FDA cleared portable isolation products on the market today.

Q: We’ve been told that an environmental containment unit is a bona fide isolation room. Is that true?

A: Most environmental containment units are not adequate as isolation rooms:

- a) they are too small to be used as a personal decontamination area – contaminated clothing can compromise the interior if a HCW brushes against its walls. In addition, individuals entering the unit can get contaminated.
- b) they do not properly support CDC guidelines for Airborne infection isolation [All].

Q: Why is FDA clearance important?

A: The role of the FDA is to protect the public and the medical community from ineffective and/or fraudulent products. “Each person who wants to market Class I, II and some III devices intended for human use in the U.S. must submit a 510(k) to FDA at least 90 days before marketing ...” .To do this, the FDA states that a company must prove (with valid independent test data to support their claims) product efficacy in meeting or surpassing claims such as support for CDC guidelines for airborne infection isolation in a healthcare facility. The FDA states that “A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA).” This means that if a company wants to state that they meet CDC guidelines, they must submit valid independent test data to support that claim. The FDA approval of FailSafe’s 510(k) Premarket Notification Application means that FailSafe has submitted test data that demonstrates the efficacy of its patented technology and that its products meet or surpass the CDC recommended guidelines for airborne infection isolation for healthcare facilities. *The value of this FDA approval means that the healthcare worker and infection control practitioner can be assured that FailSafe products meet the CDC guidelines for Airborne infection isolation (All).*

Q: My state is reluctant to purchase specialized equipment that may never be used. Can I use the FailSafe products for anything other than surge capacity or isolation?

A: Yes, our customers often use FailSafe Mobile Containment Systems for mold remediation, odor abatement and environmental services.