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On the Need for a Separate Standard for Performance Testing of Negative-Pressure Isolation Rooms

TO THE EDITOR—All patient rooms in hospitals should provide an acceptable environment for patients to recover and a good working environment for the healthcare professionals who attend to them. The special purpose of a negative-pressure isolation room is to protect healthcare workers, other patients, and visitors in a hospital from exposure to an airborne infectious agent in the event that an infectious patient is staying in the room. A principal design goal for a negative-pressure isolation room, then, should be to achieve and maintain an adequate level of airborne infection protection in the environment surrounding an infectious patient—in other words, to *contain* the airborne infectious material in such a way that the threat of exposure to healthcare personnel in the isolation room and others outside the room is minimized. Isolation rooms are designed and constructed with this in mind, and their performance should be adequately tested to ensure that they function properly.

Performance testing can consist of a combination of measuring with permanent monitors and monitoring with transient testing methods—that is to say, monitoring with equipment that is used for a certain test or check and then removed. Performance testing can occur either before or as part of the commissioning of a new isolation room or as part of periodic maintenance. Performance testing of isolation suites can include monitoring of various parameters and events: pressure differentials between rooms, any pressure drops for high efficiency particulate air (HEPA) filters (particularly for extract registers, which can become clogged over time), the direction of airflow between rooms, within-room airflow patterns, the air exchange rate, the supply and exhaust air volumes and ventilation differential volume, envelope tightness (ie, the amount of leakage the isolation room has), containment, thermal comfort, and any leakage of installed HEPA filters.

In existing national guidelines that deal with control of airborne infection, discussions of elements of negative-pressure isolation room ventilation strategy and design tend to be sprinkled with advice, recommendations, and/or requirements regarding performance testing. For example, in the Centers for Disease Control and Prevention guidelines from 1994,[1] there are paragraphs describing smoke testing for observation of airflows within and between rooms and use of pressure-measuring devices in the section "Achieving Negative Pressure in a Room" (on p. 56), whereas recommendations for pressure-drop and leakage testing of HEPA filters are given in the "HEPA Filtration" section of "Supplement 3: Engineering Controls" (on p. 60). A fragmented picture emerges of what really needs to be done to determine whether the performance of a negative-pressure isolation room is good enough.

It is informative in this regard to look at performance testing of cleanrooms. Cleanrooms employ a form of protective isolation that is vital to the manufacture of pharmaceuticals. Ventilation engineers with a specialization in cleanrooms often also work on isolation room design. The published international standard for cleanrooms includes separate and specific parts dealing with design,[2] performance testing methods and metrology,[3] and specification of which tests and monitors are necessary to demonstrate continued satisfactory performance over time.[4] Obviously, for relatively straightforward tests, such as those used to measure pressure differentials and the direction of airflow between rooms, there isn't a lot of uncertainty about the right way to do things (though there is a great disparity in national infection control standards regarding how much pressure difference is enough). For more-complicated and specialized tests, however, there is a lack of guidance and consensus about how the tests should be done in isolation rooms and what the results should be. How to deal with more complicated testing would not be a serious issue if room pressure differentials and visualization of airflow patterns alone could adequately characterize isolation room containment and if ventilation system parameters never deviated from design values. Performance testing could then be limited to measurement of the pressure differentials at the time the room is commissioned and performance of some smoke tests to make sure flow is inward through door openings and mixing is good throughout the isolation room. Then the pressure differential could be monitored over time to verify that the differentials and airflow don't change, in conjunction with replacement of filters at recommended intervals. This is, in fact, the extent of performance testing of isolation rooms in many hospitals.

Unfortunately, system parameters always deviate from design values—if not at the start, then at some point during the service life of the system. And there is much evidence that there is more to containment than just maintenance of pressure differentials and visualization of smoke patterns. If

we look back again at the cleanroom analogy, the international standard for cleanrooms details test methods and equipment for airflow volumes, installed filter leakage, air exchange rate (ie, recovery time) and containment, in addition to pressure differentials and airflow visualization.[3] The recent design manual for hospitals published by the American Society of Heating, Refrigerating and Air-Conditioning Engineers points out that "maintaining a negative air pressure between the AII (airborne infectious isolation room) and the corridor may not be enough to provide isolation" and "the truly significant factor in determining the amount of air volume migration from the room to the corridor is the airflow volume differential" and that it is necessary to "maintain a specific differential airflow rate" in an isolation room.[5(p134)] How can one be certain of maintaining a specific differential airflow rate if it is not periodically measured? Airflow volume differential is dependent on envelope tightness and pressure differential. Without a sufficiently tight envelope for the isolation room, pressure differentials cannot be maintained and airflow direction cannot be controlled. The isolation room guideline from Norway[6] recognizes this and explicitly calls for envelope tightness testing as part of isolation room commissioning. Unfortunately, the guideline doesn't say how to do the test nor does it give any indication as to what value is acceptable for an envelope tightness test result for an isolation room.

Because isolation room ventilation system parameters do change over time and do deviate from design values, the natural question arises as to what impact a particular deviation—for example, a pressure differential that is deemed to be too low—has on containment performance. In the international standard for cleanrooms,[4] intervals for performance testing are specified, and documentation requirements are given. If specified commissioning or maintenance test results fall outside of prescribed limits, then the cleanroom is considered to be in a state of noncompliance, and a remedial action plan is implemented to correct the out-of-compliance condition. Requalification is necessary to bring the cleanroom back into compliance.

The time is ripe for a similar standardization of performance testing for isolation rooms. A separate and distinct guideline that deals exclusively with testing and test methods is desirable. At present, considerable resources are dedicated to the design and construction stages of a project, with little thought (or budget) allocated to follow up on testing of the finished product. A consensus international standard detailing what needs to be tested and documented and how often, as well as what to do and when to do it, in the event that test results deviate from design values, will be an important step forward in minimizing the risk of exposure in hospitals and healthcare facilities. An international committee of ventilation and infection control experts needs to be established to get the ball rolling. The first step is to get governments and funding agencies interested in this development. It cannot happen, however, without the interest and support of healthcare professionals working at the forefront of infection protection.

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Infect Control Hosp Epidemiol 2006; 27:531-532

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Colonization of a Water System by *Legionella* Organisms and Nosocomial Legionellosis: A 5-Year Report From a Large Italian Hospital

TO THE EDITOR—*Legionella* infections in the region of Piedmont, Italy, have been reported since 1980.[1,2] In a 1-year period alone (March 1984 to April 1985), 58 cases of pneumonia, 13 of which were ascribed to *Legionella pneumophila* serotype 1, were diagnosed at a major regional hospital on the basis of direct clinical observation and culture of lung specimens obtained at autopsy. Inspection of the hospital's water system, specifically the pipes delivering hot water to the wards where the patients had been hospitalized, revealed extensive contamination with *L. pneumophila* serotype 1. This raised considerable alarm and led to the implementation of corrective measures.