Formal Interpretations
Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014 edition

Decisions published here were rendered after a multi-person panel of Health Guidelines Revision Committee (HGRC) members reviewed the request and consensus was achieved. These decisions are considered formal interpretations of the HGRC, but they are not binding for states that reference the *Guidelines*. Rather, they are advisory in nature and are intended to help users and adopting authorities having jurisdiction (AHJ) maximize the value of the *Guidelines*.

Further comments from members of the Interpretations Committee have been added to some interpretations. These comments are intended as explanatory information for users of the *Guidelines* and are not to be considered part of the formal interpretation.

Formal interpretations are rendered on the text of the requested edition of the *Guidelines*. However, any interpretation issued shall apply to all editions in which the text is identical, except when deemed inappropriate by the HGRC.

In all cases, it is important to remember that the ultimate interpretation of information contained in the *Guidelines* is the responsibility of the authority having jurisdiction.

The Facility Guidelines Institute administers the procedure for developing formal interpretations. Please visit the FGI website at www.fgiguidelines.org/interpretations to read "Rules for Requesting a Formal Interpretation" before submitting a request. Also on the FGI website is an electronic form for requesting a formal interpretation.

This document has been downloaded from the FGI website at the address just above. Interpretations are compiled continuously, and this summary document is periodically updated.

REQUEST

Guidelines edition: **2014 HOP** *Paragraph reference:* **Glossary**

Question: Please confirm that the intent of the definition of an invasive procedure in the 2014 edition requires that all four bulleted conditions be met in order for a procedure to be considered invasive. If only some of the bulleted items apply, but not all, then it is not an invasive procedure and thus may be performed in a procedure room in accordance with the requirements of Section 3.7-3.2 (Procedure Room).

Response: For a procedure to be "invasive," as defined in the 2014 edition, all four of the bulleted items must apply.

REQUEST

Guidelines edition: **2014 HOP** *Paragraph reference:* **2.1-2.4.2.4 (1)(c)**

Question: We recently added two airborne infection isolation (AII) rooms to our hospital as part of a renovation project. The AHJ ruled that Section 2.1-2.4.2.4 (1)(c) requires that all edges of an AII room door (i.e., top, sides, *and* bottom) must be sealed. It was our understanding that a half-inch gap is allowed

at the bottom of a negative pressure isolation room door to allow for airflow into the room to create the negative pressure. Is it the intent of Section 2.1-2.4.2.4 (1)(c) that there be no gap at the bottom of the door?

> **2.1-2.4.2.4 Special design elements**
>
> (1) Architectural details. These requirements are in addition to those in Section 2.1-7.2.2 (Architectural Details) that apply to AII rooms.
>
> (a) AII room perimeter walls, ceiling, and floor, including penetrations, shall be sealed tightly so that air does not infiltrate the environment from the outside or from other spaces.
>
> (b) AII rooms shall have self-closing devices on all room exit doors.
>
> (c) Doors shall have edge seals.

Response: It is not necessary to seal the bottom of an AII room door if the negative pressure of the room can be maintained at a negative 0.01 inches of water column (negative 2.5 pascals) without a door sweep.

Please note: This interpretation also applies to Section 2.1-2.4.2.4 (1)(c) in the 2010 *Guidelines for Design and Construction of Health Care Facilities*.

Further Comments

Health care environment specialist: Sealing an AII room is extremely important and, of course, the three edges around the door and the bottom are weak links. However, if the room is sufficiently sealed, any leakage into the room from the use of a door undercut should not be an issue. The room perimeter walls, floor, and ceiling (above and below the dropped ceiling) need to be sealed to minimize infiltration. If there is too much leakage and minimum pressure is not attainable, a door sweep can be added to assist in obtaining the required negative pressure. Sealing the room and providing a proper ventilation offset will assure pressure management. If the door with an undercut can maintain the minimum negative pressure differential (.01"WC) that is acceptable.

Facility manager (mechanical engineer): I have seen two different design paths for providing airflow to an AII room. The first is to utilize the undercut of the door to allow transfer air into the room, while providing a ducted exhaust system for the room that carries air out of the building. The second is to provide a traditional HVAC system where the supply diffuser is located near the entrance door and the exhaust grille is located near the head of the patient.

So, the bottom door sweep may be omitted if the designer thinks the undercut of the door allows sufficient clean makeup air into the room to maintain required airflow, temperature, and pressurization.

Infection preventionist: Not sure I'd expect AII room perimeter barriers to be completely sealed, that is, that there would be no gap between the entry door and the floor. Most AII rooms I've seen have a narrow gap at the bottom of the door. This is permitted in the 2005 CDC TB guideline as well. The broader envelope of the room (i.e., ceiling, walls, and windows) or an improper HVAC pressure relationship to adjacent spaces is a more likely source of leakage from this space. I scanned the CDC requirements and do not see any language that specifies a complete seal between the door and the floor.

In my visits to numerous facilities, I can't recall seeing a sweep or other feature that provides a 100% seal. My sense is that release of particles carrying infectious agents would more likely come from a breach in

the room envelope or improper pressure relationship to adjacent spaces than from release of these particles underneath a narrow gap at the bottom of the entry door.

Designer (mechanical engineer): Even though the HVAC system serving the room may be able to maintain the required negative pressure, the greater the aggregate size of openings in the room construction (including under the door), the greater the energy spent to maintain that pressure. Thus, the opening under the door should be the minimum required for proper door operation.

REQUEST

Guidelines edition: **2014 HOP** *Paragraph reference:* **2.2-2.12.1.1**

Question: Section 2.2-2.12.1.1 (Nursery Unit—Location) states nurseries shall be "accessible" to the postpartum nursing unit and obstetrical facilities. There is no definition in the glossary for "accessible" as a stand-alone term. The question, then, is which term under "location terminology" in the glossary does apply to the nursery. (The 2010 *Guidelines* used the term "convenient" in Section 2.2-2.12.1.1.)

Response: The intent was to locate the nursery *in* the obstetrical unit, which includes postpartum rooms, antepartum rooms, LDRP rooms, and related areas.

Please note: This interpretation also applies to Section 2.2-2.12.1.1 in the 2010 *Guidelines for Design and Construction of Health Care Facilities*.

REQUEST

Guidelines edition: **2014 HOP** *Paragraph reference:* **2.2-3.4.4.3 (4)**

Please note: This question was originally asked about text in Section 2.2-3.4.4.2 (3) in the 2010 edition, but as the same text exists virtually unchanged in the 2014 edition, the response applies here as well.

Question: In the design of MRI suites, is it the intent of the *Guidelines* that the anteroom required by Section 2.2-3.4.4.3 (4) be located between the door to the MRI room and the control room so the tech must pass through a door and into the anteroom before reaching the MRI room door?

> **2.2-3.4.4.3 Design configuration of the MRI suite**
>
> (4) A control vestibule visible from the control room shall be located outside the MRI scanner room so that patients, health care personnel, and other employees must pass through it before entering the scanning area and control room. This room shall be outside the restricted areas of the MRI's magnetic field.

Response: The intention was to require a secured area (ACR Zone-III) between the MRI scanner room (Zone-IV) and areas where unscreened individuals (Zone-II) might be. (The zones indicated are from the ACR *Guidance Document on MR Practices*.) The description of an anteroom, with view from the operator's console, was not meant to compel the creation of another room (although that would be permitted if desired), but rather to designate an area that is:

- Located within the controlled access perimeter defining Zone-III
- Visible from the operator's console
- Located prior to the entry to the MRI scanner room (Zone-IV)

In most MRI suites, the control room serves as this intermediate space and the secured area is the region of the control room between the access points to Zone-II and Zone-IV.

Changes to Section 2.2-3.4.4.3 (4) in the 2014 *Guidelines* have been made in the 2018 edition to clarify this meaning. The 2018 text, shown below, can be considered an interpretation of the 2014 language.

2.2-3.4.5.5 Control vestibule

(1) The control vestibule shall be located outside the MRI scanner room so that patients, health care personnel, and other employees must pass through it before entering the MRI scanner room.

(2) The control vestibule shall be permitted to be either a part of the MRI control room or directly visible from the control room.

REQUEST

Guidelines edition: **2014 HOP** *Paragraph references:* **3.7-3.6.13 and 3.7-5.1**

Question 1: Is it the intent of Section 3.7-3.6.13.2 to allow gross decontamination and debridement of soiled instruments in the sterile processing room? Isn't there a cross-contamination potential between the dirty and clean sides of the room?

Response: Yes. The function of this room is intended for all instrument decontamination functions, including all major cleaning such as scrubbing, soaking, forced-air "blow-out," and similar functions. Flushing of soiled waste from the surgical suite occurs as indicated in Section 3.7-3.6.14 (Fluid Waste Disposal Facilities). Cross-contamination was considered when writing the requirements for the sterile processing room. Compliance with strict operational controls in the room will prevent contact contamination between the dirty and clean sides.

Further Comments

Epidemiologist, infection preventionists, perioperative nurses: There is low risk of aerosolization of biological contaminants in this room assuming those who design the space use information from an infection control risk assessment (ICRA) that maps out work practices and flows to mitigate risk of cross-contamination. This risk assessment should consider use of physical barriers/dividers plus spatial separation of soiled work areas (e.g., where soiled surgical instruments are cleaned) from clean work areas (e.g., where instruments are packaged for subsequent sterilization) to minimize risk of contamination by splash or splatter.

In developing the sterile processing room requirements, the 2014 Health Guidelines Revision Committee applied lessons learned from a study of the relationship between the design of hand-washing stations and a waterborne disease outbreak in a clinical area. This study* demonstrated that contaminated water droplets can travel a distance of about 1 meter, and findings from this investigation provide the basis for spatial separation as sufficient protection from cross-contamination. There is little if any evidence that contaminated water droplets from manual instrument cleaning activities would be dispersed farther than 1 meter; however, a physical barrier will offer additional protection against contamination of adjacent areas. As well, there is no evidence of dissemination of microorganisms via air over longer distances as most of these would be contained within water droplets, not suspended in air like classic airborne agents. For these reasons, work practices in the sterile processing room should be aimed at avoiding simultaneous use

*S. Hota et al. (2009), "Outbreak of Multidrug-Resistant Pseudomonas aeruginosa Colonization and Infection Secondary to Imperfect Intensive Care Unit Room Design," *Infection Control and Hospital Epidemiology* 30:25-33.

of the space for soiled (manual cleaning of instruments) and clean (instrument packaging) processes as another strategy to minimize the risk of cross-contamination.

Of note, instruments that are packaged or enclosed in sealed containers for sterilization are protected from contamination when removed from the sterilizer. However, the outside container/wrapping is not considered sterile, so handling a container or wrapped instrument in the clean area of the sterile processing room presents no more cross-contamination risk than carrying the container through the semi-restricted corridor to the operating room. As well, once the container or package is taken into the OR, the cover of the rigid container or the wrapping is removed and only the sterile contents are introduced into the sterile field.

Question 2: The requirements in Section 3.7-3.6.13 appear to be written around immediate use sterilization, not terminal sterilization for storage. Is it the intent of Section 3.7-5.1 that a single sterile processing room is the only space needed for all sterilization activities in outpatient surgical facilities, regardless of size and scope?

Response: No. The intent of this section was to set *minimum* standards for sterile processing in outpatient facilities and to have these standards be similar to those required in hospitals. Certain outpatient facilities, particularly large ambulatory surgery centers, may need to go beyond the minimum requirements to meet standards similar to those for hospitals.

Further Comments

Epidemiologist, infection preventionists, perioperative nurses: While this room is used for immediate use sterilization in the inpatient hospital, the layout also provides a minimum standard for terminal sterilization activities in smaller outpatient facilities. The sterile processing room design is the minimum required standard for facilities where simple procedures with smaller caseloads are performed. When planning a new facility, an infection preventionist and representatives from sterile processing and surgical services should be consulted during the functional programming phase to determine if separate decontamination and clean rooms should be considered to avoid the cumulative risks from many people processing high volumes in a small area.

Question 3: If the answer to question 2 is "no," what is an appropriate threshold for requiring a facility to have separate rooms?

Response: An infection control risk assessment (ICRA), which is performed as part of the project safety risk assessment, should be used to identify which facilities are better served by having a separate clean workroom and decontamination room than a single sterile processing room.

Further Comments

Epidemiologist, infection preventionists, perioperative nurses: The scope of functions to be performed in the sterile processing room should be described in the functional program, including:

- Volume of procedures to be performed in the facility,
- Types of procedures to be performed,
- Number of different teams who will use the space, and
- Types and volume of equipment to be used.

The ICRA should then consider this information to determine what sterilization facilities are appropriate for a project. A single sterile processing room may be sufficient to accommodate the needs of small

facilities where the procedures performed require a limited number of instruments. Facilities with high volumes, complex equipment sets, or time-sharing arrangements in which multiple teams share the same sterile processing room would benefit from provision of a wall and a door to physically separate the clean and decontamination areas instead of using distance or a partial wall. All of the risks must be considered in the ICRA, which should provide recommended strategies to reduce, mitigate, or eliminate identified hazards.

Question 4: Table 7.1 in ANSI/ASHRAE/ASHE 170-2013: *Ventilation of Health Care Facilities* (Part 4 of the 2014 Hospital and Outpatient *Guidelines*) does not list this type of room. What is the appropriate ventilation arrangement for the sterile processing room?

Response: This question has been handed off to ASHRAE SSPC (Standing Standard Project Committee) 170; keep an eye out for a response from them, which will be posted on both the ASHRAE and the FGI websites.