Applying the FGI *Guidelines* to Spaces Where Invasive vs. Noninvasive Patient Care is Delivered

The Facility Guidelines Institute (FGI) regularly receives inquiries from designers, infection preventionists, and clinical staff looking for guidance on where patient procedures can and cannot be performed in hospitals and outpatient facilities. During each *Guidelines* revision cycle, the Health Guidelines Revision Committee (the body responsible for updating *Guidelines for Design and Construction* content) strives to strengthen the *Guidelines* standards for new construction and renovation of areas where patient care is provided. However, the question of where patient procedures can be performed is not one the *Guidelines* can precisely answer, nor is the *Guidelines* language written with this intent.

The *Guidelines* requires health care organizations to develop a functional program and perform a safety risk assessment during the planning and design phases of every project. One of the primary objectives of using these owner-driven tools is to actively engage clinicians, infection preventionists, and other care providers in the planning and design processes. Development of the functional program is the opportunity to identify the types of patient care to be provided as well as the spaces needed to support that care. Performance of the safety risk assessment (SRA), particularly the infection control risk assessment (ICRA), will help the project team (including clinical and infection prevention staff as well as designers) determine how to allocate space for invasive and non-invasive procedures. In particular, the ICRA is essential to assure the new or renovated space will support the organization's infection prevention practices.

The types of procedures to be performed will dictate which floor/wall/ceiling surfaces, air exchange rates, and clearances are required for each room type as well as the locations for handwashing or hand scrub stations and the required number of medical gas outlets and vacuum inlets. To help decision-makers identify the physical environment features each treatment space will need to support planned clinical care, the *Guidelines* documents include a limited glossary definition of "invasive procedure" (see the sidebar at the end of this article) and—in the 2018 and the 2022 Hospital and Outpatient Guidelines—a table with examples of basic procedures appropriately performed in exam/treatment, procedure, and operating rooms (see the next page). (These tables do not present an exhaustive list of the requirements for these room types, but are meant to help distinguish their uses to support project planning.)

On one end of the spectrum is the operating room (OR) environment, which is classified as a "restricted area" and needs the maximum environmental control requirements. At the other end is the exam room or emergency department treatment room, where diagnostic procedures and simple treatments are provided. Between these two room types is the procedure room, which is the space type most likely to present a conundrum to design teams and health care organization leaders looking to classify and design these rooms. The tricky part is identifying when an OR may be required for procedures that otherwise could be safely performed in a procedure room. The table shows that an OR is the appropriate location for any procedure during which the patient will require physiological

Table 2.2-1

Exam/Treatment, Procedure, and Operating Room Classification¹

Room	Use	Design Requirements ²			
		Room Type	Location	Surfaces	
Exam or treatment	Patient care that may require high-level	Unrestricted area	Accessed from an	Flooring: cleanable and wear-resistant for the location; stable, firm, and slip-resistant	
room	disinfected or sterile instruments but does not require the environmental controls of a procedure room		unrestricted area	Wall finishes: washable	
				Ceiling: cleanable with routine housekeeping equipment; lay-in ceiling permitted	
Procedure room	Patient care that requires high-level	Semi- restricted	Accessed from an	Flooring: cleanable and wear-resistant for the location; stable, firm, and slip-resistant	
	disinfected or sterile instruments, and some environmental controls but does not require	area	unrestricted or a semi- restricted area	Floor and wall base assemblies in cystoscopy, urology, and endoscopy procedure rooms and endoscope processing room monolithic floor with integral coved wall base carried up the wall a minimum of 6 inches (15.24 centimeters)	
	the environmental controls of an			Wall finishes: washable	
	operating room Endoscopic procedures			Wall finishes in endoscopy procedure room and endoscope processing room: washable; free of fissures, open joints, or crevices	
				Ceiling: smooth and without crevices, scrubbable, non- absorptive, non-perforated; capable of withstanding cleaning chemicals; lay-in ceiling permitted if gasketed or each ceiling tile weighs at least one pound per square foot and no perforated, tegular, serrated, or highly textured tile	
Operating room		Restricted area	Accessed from a semi- restricted area	Flooring: cleanable and wear-resistant for the location; stable, firm, and slip-resistant	
				Floor and wall base assemblies: monolithic floor with integral coved wall base carried up the wall a minimum of 6 inches (15.24 centimeters)	
				Wall finishes: washable; free of fissures, open joints, or crevices	
				Ceiling: monolithic, scrubbable, capable of withstanding cleaning and/or disinfecting chemicals, gasketed access openings ⁴	

¹This table includes a brief description of what clinical services are performed in these room types and a summary of some applicable requirements that appear elsewhere in the 2022 *Guidelines for Design and Construction of Hospitals*. The table has been provided to help users determine when an exam/treatment, procedure, or operating room is required for a project. "Exam room," "treatment room," "procedure room," and "operating room" are defined in the glossary.

4See Section 2.1-7.2.3.3 (3)(b) [Ceilings: Restricted areas—Use of a modular or prefabricated laminar (or controlled) flow ceiling system...] for exceptions to monolithic ceilings in operating rooms.

(Excerpted from the 2022 FGI Guidelines for Design and Construction of Hospitals)

²Other design requirements that apply to these room types include, but are not limited to, ventilation, lighting, medical gas and vacuum systems, and sound transmission requirements. See Part 3 (ANSI/ASHRAE/ASHE Standard 170: *Ventilation of Health Care Facilities*) for ventilation requirements for these rooms. See Section 2.1-8.3.4.2 (Lighting for specific locations in the hospital) and facility chapters for lighting requirements, Table 2.1-3 (Oxygen, Vacuum, Medical Air, WAGD, and Instrument Air Systems) for medical gas and vacuum systems requirements, and Section 1.2-6.1 (Acoustic Design) for noise transmission requirements.

³"Invasive procedure" is defined in the glossary.

monitoring and is anticipated to require active life support. The HGRC intended "active life support" to mean a patient's basic respiratory or circulatory functions depend on a machine or will be made dependent on a machine during a procedure (i.e., the patient is unable to either breathe and/or circulate blood on their own or unable to do so sufficiently to preclude physiological damage).

In the 2018 Guidelines for Design and Construction of Hospitals and Guidelines for Design and Construction of Outpatient Facilities, an imaging room classification system was introduced to help designers and clinicians determine the room types needed when planning and designing imaging facilities. This framework is continued in the 2022 edition. The imaging classes correspond with the exam/treatment, procedure, and operating rooms: Class 1 imaging room for diagnostic procedures, Class 2 imaging room for diagnostic and therapeutic procedures, and Class 3 imaging rooms, which are ORs with mobile or built-in imaging equipment (the latter may be termed a hybrid OR), for invasive procedures (i.e., surgery). Like the conundrum of the procedure room described above, the distinction between when a Class 2 and a Class 3 imaging room is needed is the most difficult to determine. The Hospital and Outpatient documents in the 2018 and 2022 editions include a table (see the next page) to help users understand the differences between these imaging room types.

The *Guidelines* provides some guidance on uses for newly constructed procedure rooms and Class 2 imaging rooms; however, it is preferable to base final determinations on what type and how many of these rooms will be included in a project on (1) a clinical assessment of procedures to be performed in the rooms and (2) the environmental needs of the most stringent procedure to be performed in a given space. As noted above, these decisions are also supported by information developed during the functional program and SRA/ICRA processes.

Continuous advancements in non-invasive medical procedures, coupled with the lengthy duration of most capital projects, can cause a health care organization to revise its clinical plans for a new facility before the facility is occupied. To mitigate any need for changes to the physical environment that may result from such operational changes, the recommended goal is to design rooms that can flex to accommodate procedure types a health care organization may want to perform in the future. For example, an organization may plan to use newly designed rooms to address facility needs during a pandemic or other emergency condition that requires more stringent room controls. Building the cost of such rooms into a construction project is more cost-effective than retrofitting rooms for this purpose later.

How a space is used after occupancy is something the *Guidelines* cannot control. For example, a Class 2 imaging room may be built for cardiac catheterizations, in which a catheter is inserted into an artery or a vein in the groin, neck, or arm and threaded through blood vessels to the heart. Clinicians have indicated these procedures are safe to perform in a Class 2 imaging room; however, when a cardiac catheterization may result in surgery to close a hole in the heart or repair or replace a heart valve, balloon valvuloplasty, or another invasive procedure, clinicians recommend performing the surgical procedure in a Class 3 imaging room.

As the invasiveness of a procedure increases, so do the infection prevention requirements of the *Guidelines*. A room designed for one level of procedure but used for a more invasive procedure is not considered a safe environment for patients or staff. Thus, in the example above, a health care organization should assess how often their cardiac cath procedures turn into open heart surgery to determine how many Class 2 and Class 3 imaging rooms are needed.

Table 2.2-2

Classification of Room Types for Imaging Services¹

Room	Use	Design Requirements ²			
	ose	Room Type	Location	Surfaces	
Class 1 imaging room	Diagnostic radiography, fluoroscopy, mammography, computed tomography (CT), ultrasound, magnetic resonance imaging (MRI), and other imaging services Services that use natural orifice entry and do not pierce or penetrate natural protective membranes Imaging services for which an anesthesia machine is used only to immobilize the patient (for the benefit of the imaging exam) ³	Unrestricted area	Accessed from an unrestricted area	Flooring: cleanable and wear-resistant for th location; stable, firm, and slip-resistant Wall finishes: washable Ceiling: cleanable with routine housekeeping equipment; lay-in ceiling permitted	
Class 2 imaging room	Diagnostic and therapeutic procedures such as coronary, neurological, or peripheral angiography Electrophysiology procedures	Semi- restricted area	Accessed from an unrestricted or a semi- restricted area	Flooring: cleanable and wear-resistant for the location; stable, firm, and slip-resistant Floor and wall base assemblies: monolithic floor with integral coved wall base carried up the wall a minimum of 6 inches (15.24 centimeters) Wall finishes: washable; free of fissures, open joints, or crevices Ceiling: smooth and without crevices, scrubbable, non-absorptive, non-perforated capable of withstanding cleaning chemicals, lay-in ceiling permitted if gasketed or each ceiling tile weighs at least one pound per square foot and no perforated, tegular, serrated, or highly textured tiles	
Class 3 imaging room	Invasive procedures ⁴ Class 2 procedure during which the patient will require physiological monitoring and is anticipated to require active life support	Restricted area	Accessed from a semi- restricted area	Flooring: cleanable and wear-resistant for the location; stable, firm, and slip-resistant Floor and wall base assemblies: monolithic floor with integral coved wall base carried up the wall a minimum of 6 inches (15.24 centimeters) Wall finishes: washable; free of fissures, oper joints, or crevices Ceiling: monolithic, scrubbable, capable of withstanding cleaning and/or disinfecting chemicals, gasketed access openings ⁵	

¹This table includes a brief description of the imaging services performed in these room types and a summary of some applicable requirements that appear elsewhere in the 2022 *Guidelines for Design and Construction of Hospitals*. The table has been provided to help users determine when a Class 1, Class 2, or Class 3 imaging room is required for a project.

(Excerpted from the 2022 FGI Guidelines for Design and Construction of Hospitals)

²Other design requirements that apply to these imaging room types include, but are not limited to, ventilation, lighting, electrical receptacle, call system, medical gas and vacuum systems, and sound transmission requirements. See Part 3 (ANSI/ASHRAE/ASHE Standard 170: Ventilation of Health Care Facilities) for ventilation requirements for these rooms. See Section 2.1-8.3.4.2 (Lighting for specific locations in the hospital) and facility chapters for lighting requirements. See Table 2.1-1 (Electrical Receptacles for Patient Care Areas in Hospitals) for electrical receptacle requirements, Table 2.1-2 (Locations for Nurse Call Devices in Hospitals) for call system requirements, Table 2.1-3 (Oxygen, Vacuum,

A reminder: The FGI *Guidelines* requirements are developed and adopted for use on new construction or major renovation projects for hospitals, outpatient facilities, and residential health, care, and support facilities. They are not intended to be applied retroactively or used to evaluate whether an existing space is appropriate for the procedures being performed in it. These decisions are the responsibility of the health care organization and the enforcing authorities. FGI will continue to work with national associations, authorities having jurisdiction, health care organizations, and the design community to provide the best guidance we can for specifying elements of the built environment for safe patient care.

2018 and 2022 FGI *Guidelines* Glossary Definition of Invasive Procedure

A procedure that is performed in an aseptic surgical field and penetrates the protective surfaces of a patient's body (e.g., subcutaneous tissue, mucous membranes, cornea). An invasive procedure may fall into one or more of the following categories:

- Requires entry into or opening of a sterile body cavity (i.e., cranium, chest, abdomen, pelvis, joint spaces)
- Involves insertion of an indwelling foreign body
- Includes excision and grafting of burns that cover more than 20 percent of total body area
- Does not begin as an open procedure but has a recognized measurable risk of requiring conversion to an open procedure

Note: Invasive procedures are performed in locations suitable to the technical requirements of the procedure with consideration of infection control and anesthetic risks and goals. Accepted standards of patient care are used to determine where an invasive procedure is performed. "Invasive procedure" is a broad term commonly used to describe procedures ranging from a simple injection to a major surgical procedure. For the purposes of this document, the term is limited to the above description. The intent is to differentiate those procedures that carry a high risk of infection, either by exposure of a usually sterile body cavity to the external environment or by implantation of a foreign object(s) into a normally sterile site. Procedures performed through orifices normally colonized with bacteria and percutaneous procedures that do not involve an incision deeper than skin would not be included in this definition.

Source Information

This article has been updated to reflect the content of the 2022 edition of the *Guidelines*. The tables included here have been excerpted from the 2022 FGI *Guidelines for Design and Construction of Hospitals*. The same tables also appear in the 2022 FGI *Guidelines for Design and Construction of Outpatient Facilities* as Table 2.1-5 (Exam/Treatment, Procedure, and Operating Room Classification) and Table 2.1-6 (Classification of Room Types for Imaging Services).

The tables also appear in the 2018 edition of the *Guidelines*. However, if you are using the first printing of the 2018 Hospital or Outpatient document, please note that an error in the procedure room "use" description in Table 2.2-1 (Hospital) and Table 2.1-5 (Outpatient) was corrected on the errata sheets for these documents on September 13, 2019.