

**Advisory  
Guide  
Series**

# A10

**FOR  
HOSPITAL FACILITIES  
[OSHPD 1] and CLINICS  
and OUTPATIENT  
FACILITIES [OSHPD 3]**

**IMAGING ROOM  
CLASSIFICATION  
Class 1, Class 2, and  
Class 3 Imaging Rooms  
and Related Exam/  
Treatment Rooms  
Procedure Rooms and  
Operating Rooms**

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## INTRODUCTION

The use of imaging equipment in the delivery of health care has evolved considerably over the past 15 to 20 years and is continuing to evolve at a very rapid pace. Building standards and code development rely on sufficient vetting, industry participation, and public comment period which requires a fair amount of time during a code adoption and amendment cycle. Since California adopts and amends nationally promulgated codes and standards, that process is compounded when adding those code cycles. With code adoption cycles taking three years each, the written code language will be at least 6 years old when it is first published and 9 years out of date before it is revised under the next code cycle. Since imaging equipment in particular, is highly influenced by rapid advances in technology, some allowance for adaptation of code language to respond to associated advances in the capabilities of the equipment and the procedures they support is critical.

This adaptation is anticipated in California Building Code (CBC) Section 1224.2, Exception 3 which allows: *“The provisions of this section do not prohibit the use of alternate space utilization, new concepts of design, treatment techniques, equipment, and alternate finish materials, provided the intent of this section is accommodated and written approval for such alternative is granted by the enforcing agency...”* This *Advisory Guide* is intended to provide interpretation and clarification of the intent of the CBC sections related to imaging equipment and some structure to providing supporting documentation of *“new concepts of design, treatment techniques, and equipment.”*

The *Guidelines for Design and Construction of Hospitals*, promulgated by the Facility Guidelines Institute (FGI), is the national standard for hospital construction in the United States and is revised on a 4-year cycle, with the 2022 version being the current edition. The California Building Code incorporates much of the FGI language as it becomes available and attempts to maintain consistency with the Centers for Medicare and Medicaid Services (CMS) requirements associated with the *Health Care Facilities Code* (NFPA 99) and *Ventilation of Health Care Facilities* (ASHRAE 170).

Various imaging modality equipment can be used in a variety of settings and used for diagnostic, therapeutic and even invasive procedures. The rooms in which they are installed need to provide the appropriate environment in response to the clinical risk associated with a particular procedure. Procedures requiring a Class 2 Imaging Room environment should not be performed in a Class 1 Imaging Room. Similarly, procedures requiring a Class 3 Imaging Room environment should not be performed in a Class 2 Imaging Room even though the imaging equipment is the same. Hospital facilities not currently meeting the subject regulations covered in these guidelines for procedures proposed in existing imaging procedure rooms could require physical construction or alteration to a hospital building when altering an imaging space or responding to the functional requirements of a different imaging room classification.

**Department of Health Care Access and Information (HCAI)**  
**Office of Statewide Hospital Planning and Development (OSHPD)**  
*has drafted this Advisory Guide in consultation with the*  
*California Department of Public Health (CDPH)*

## TABLE OF CONTENTS

<b>INTRODUCTION.....</b>	<b>i</b>
<b>TABLE OF CONTENTS.....</b>	<b>ii</b>
<b>SECTION 1 Code References .....</b>	<b>1</b>
<b>SECTION 2 Acronyms and Definitions .....</b>	<b>2</b>
<b>SECTION 3 Overview.....</b>	<b>5</b>
<b>SECTION 4 Imaging Procedure Room Classification Types.....</b>	<b>7</b>
<b>SECTION 5 Exam/Treatment, Imaging, Procedure &amp; Operating Room Classification .....</b>	<b>9</b>
<b>SECTION 6 Class 1 Imaging Room (Exam/ Treatment Room) .....</b>	<b>12</b>
<b>SECTION 7 Class 2 Imaging Room (Procedure Room) .....</b>	<b>17</b>
<b>SECTION 8 Class 3 Imaging Room (Operating Room) .....</b>	<b>21</b>
<b>SECTION 9 – Clinical Risk Assessment .....</b>	<b>26</b>
<b>SECTION 10 – HCAI/OSHPD Submittal Instructions .....</b>	<b>27</b>
<b>APPENDIX A – Proposed Procedure Clinical Risk Assessment.....</b>	<b>A-1</b>
<b>APPENDIX B – Class 1 Imaging Room Summary Checklist.....</b>	<b>B-1</b>
<b>APPENDIX C – Class 2 Imaging Room Summary Checklist.....</b>	<b>C-1</b>
<b>APPENDIX D – Class 3 Imaging Room Summary Checklist.....</b>	<b>D-1</b>
<b>Revision History .....</b>	<b>RH-1</b>

## SECTION 1 CODE REFERENCES

Access is provided to the Title 24 regulations promulgated by HCAI through the California Building Standards Commission website (<https://www.dgs.ca.gov/en/BSC/Codes>) with active links to each publisher's website for read-only public access versions of Title 24.

Part 1, California Administrative Code

Part 2, California Building Code, Volumes 1 and 2

Part 3, California Electrical Code (Note: Accessed through the National Fire Protection Association (NFPA), however, requires the creation of a user account to view the [Free Access - NFPA 70: 2022 California Electrical Code - NFPA 70 \(2020 NEC®\)](#))

Part 4, California Mechanical Code

Part 5, California Plumbing Code

Part 6, California Energy Code

Part 9, California Fire Code

Part 10, California Existing Building Code

Other referenced standards:

Facility Guidelines Institute (FGI), Guidelines for Design and Construction of Hospitals

American Society of Heating Refrigerating, and Air-Conditioning Engineers (ASHRAE)  
Standard 170 Ventilation of Health Care Facilities

## SECTION 2 ACRONYMS AND DEFINITIONS

Acronyms and Definitions assist the user in recognizing and identifying various acronyms and terms generally used in HCAI documents. Please refer to the Master Glossary of Acronyms and Definitions on the HCAI website at <https://hcai.ca.gov/document/master-glossary-of-acronyms-and-definitions/>.

Other definitions may also be found in the California Building Standards Code, Title 24, of the California Code of Regulations (Title 24).

**AMBULATORY SURGICAL FACILITY.** A surgical facility organized for the purpose of providing procedural, invasive surgical care to patients with the expectation that they will be recovered sufficiently to be discharged in less than a 24-hour period. **Note:** These may also include Class 2 and/or Class 3 Imaging Rooms.

**ANGIOGRAPHY.** The radiographic visualization of blood vessels following introduction of contrast material for purposes of diagnosis. **Note:** Angiography normally refers to diagnostic imaging unless specifically referenced as interventional angiography.

**BASIC SERVICES.** Those essential services required for licensure as a hospital, including medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, dietary services, and support services.

**Note:** this list is taken from the definition under Title-22 requirements for licensure as a hospital. “Radiology” as a Basic Service is intended to include all diagnostic imaging services independent of the imaging modality used. CBC Section 1224.18 had been renamed earlier as “Radiological/Diagnostic Imaging Service Space” to reflect this inclusion and is generally associated with Class 1 Imaging Rooms. “Surgery” as a Basic Service can also include procedure rooms where less invasive procedures are performed that do not require the sterile environment of an Operating Room. CBC Section 1224.15 “Surgical Service Space” includes reference to procedure rooms.

**INVASIVE PROCEDURE.** A procedure that is performed in an aseptic or sterile surgical field and penetrates the protective surfaces of a patient’s body (e.g. subcutaneous tissue, mucous membranes, cornea). Invasive procedures fall into one or more of the following categories:

1. Requires entry into or opening of a sterile body cavity (i.e. cranium, chest, abdomen, pelvis, joint spaces).
2. Involves insertion of an indwelling foreign body into a normally sterile site that results in a high risk of infection.
3. Includes excision and grafting of burns that cover more than 20 percent of total body area.

4. Does not begin as an open procedure but has a greater than 5 percent probability of requiring conversion to an open procedure.

**FGI Glossary 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 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.

**EXAM ROOM.** A room with a bed, stretcher or examination table and capability for periodic monitoring (e.g., measurement of blood pressure or pulse oximetry) in which procedures that do not require a specialized suite can be performed (e.g., pelvic examination, blood transfusion).

**TREATMENT ROOM.** A room designated for the performance of patient care activities that may require high-level disinfected or sterile instruments but do not require the environment of a procedure room. A treatment room may be used for a variety of functions, patient examination and various treatments or procedures, including wound packing, suture placement, or casting. This room may contain specialized equipment as identified in the functional program.

**PROCEDURE ROOM.** A room designated for the performance of patient care that requires high-level disinfection or sterile instruments and some environmental controls but is not required to be performed with the environmental controls of an Operating Room.

**OPERATING ROOM.** A room specifically designed for the performance of surgical procedures. (In common understanding, this means most types of surgical procedures, especially those involving the administration of anesthesia, multiple personnel, recovery room access and a fully controlled environment).

**HYBRID OPERATING ROOM.** A room that meets the definition of an Operating Room and is also equipped to enable diagnostic imaging before, during, and after surgical procedures. Imaging equipment is permanently installed in the room and may include MRI, fixed single-plane and bi-plane tomographic imaging systems and computed tomographic equipment. **Note:** Use of portable imaging technology does not make an Operating Room a hybrid Operating Room.

**Note:** Hybrid Operating Room and Class 3 Imaging Room are used interchangeably. They both refer to the same room type.

**UNRESTRICTED AREA.** Applies to any area of the surgery or medical department that is not defined as semi-restricted or restricted. These areas may include a central control point for designated personnel to monitor the entrance of patients, personnel, and materials into the semi-restricted areas; staff changing areas; a staff lounge; offices; waiting rooms or area; pre- and post-operative patient care areas; or access to procedure rooms. Public access may be limited.

**SEMI-RESTRICTED AREA.** Applies to peripheral areas that support surgical services or intermediate level procedures or imaging. These areas may include storage for equipment and clean and sterile supplies; work area for processing instruments; sterile processing facilities; hand scrub stations; corridors leading from the unrestricted area to the restricted area of the surgical suite; entrances to staff changing areas; pre- and post-operative patient care areas; and sterile processing facilities. The semi-restricted area of the surgical suite is entered directly from the unrestricted area past a nurse station or from other areas. Public access is controlled.

**RESTRICTED AREA.** Applies to a designated space contained within the semi-restricted area. The restricted area includes operating and other rooms in which operative or other invasive procedures are performed. Such space has one or more of the following attributes: specific signage, physical barriers, security controls and protocols that delineate requirements for monitoring, maintenance, attire, and use.



## SECTION 3 OVERVIEW

*2022 FGI Guidelines for Design & Construction of Hospitals – Section 2.2-3.5 Imaging Services – Appendix: Imaging services commonly include radiography, fluoroscopy, mammography, tomography, computed tomography (CT), ultrasound, magnetic resonance imaging (MRI), hybrid imaging technologies (e.g., PET/CT), hybrid imaging/therapy technologies (e.g., MRI/linear accelerators), and other imaging technologies. Of the various imaging modalities used, many are performed for diagnostic purposes by projecting energy through a mass (the patient) and recording the resulting energy characteristics. Some procedures involve various forms of therapeutic interventional imaging or image guidance in conjunction with invasive procedures. Others, such as nuclear imaging, place radioactive substances inside the patient and record metabolic energy emissions. For guidelines on radiosurgery and proton therapy facilities, see Section 2.2-3.6 (Radiation Therapy).*

Generally, Imaging Rooms will be located in the Radiological/Diagnostic Imaging Service Space (common for Class 1 Imaging Rooms), Surgical Service Space (common for Class 3 Imaging Rooms), or separately as a specialized suite (frequently for Class 2 Imaging Rooms). These locations have been a practical response to the evolution of new technologies that utilize imaging equipment for certain procedures.

A century ago, still X-ray and fluoroscopy (real-time X-ray) were the primary modalities of imaging equipment and were used to capture images for examination diagnoses and for follow-up examination after treatment. As such, the California Department of Public Health required “Radiology” as a Basic Service for hospital licensure and included the requirement for “one fluoroscopy room which can also provide X-ray examination services.” This Service Space was to be supported with: “a file processing room; a toilet room adjoining each fluoroscopy room, in addition to other toilet facilities located adjacent to or in the immediate vicinity; an office or other suitable area for viewing and reporting radiographic examination; storage spaces for all necessary X-ray equipment, supplies and exposed X-ray film, and for copies of reports; handwashing fixtures located within the unit; and dressing room facilities.” Consequently, that was all that was required in the California Building Code through the 2001 edition. The Radiological Service Space was generally used in support of the Emergency Service Space and located in close proximity.

Although other imaging modalities began to be used, they were not referenced in Title-22 or Title-24. Most of those other modalities were also diagnostic/examination in nature and often available to outpatients. The “Radiological/Diagnostic Imaging Service Space” has since captured many of the common diagnostic imaging procedures, including special room requirements and support spaces, in CBC Section 1224.18. Most of these procedures are now classed as Class 1 Imaging procedures.

Use of imaging equipment during therapeutic procedures has also evolved quite a bit. These procedures have been simplified to some degree with the use of image guidance resulting in safer and less invasive (and less clinical risk) procedures than what would

need to have occurred without image guidance. Many of these procedures still need to occur in an Operating Room (OR) and require the OR to have imaging equipment. CBC Section 1224.28 originally responded to “Supplemental Surgery” as a Supplemental Service to accommodate cardiovascular/open-heart surgery and other special procedures. This section grew to encompass cardiac catheterization, interventional imaging or interventional radiology (IR), and finally hybrid Operating Rooms.

The language in these CBC sections often duplicate some of the language in 1224.15 “Surgical Service Space” rather than reference it. Some of the requirements are a little different due to the use of sedation instead of anesthesia. Some sections focused on specific modalities of imaging equipment used. With the vast spectrum of possible image guided procedures, and continuing development of new capabilities and techniques, the simple division of “invasive” vs “non-invasive” and use of diagnostic procedures going to Section 1224.18 (Radiological/Diagnostic Imaging) and interventional procedures going to Section 1224.28 (Supplemental Surgery and Special Procedures) is imprecise. Once the procedure exceeds a diagnosis provided under 1224.18, the one-size-fits-all alternative offered by a hybrid Operating Room (1224.28.5) allows the management of worst-case scenarios but does not allow flexibility to tailor for procedures that are in between 1224.18, 1224.28, and 1224.28.5 (as provided under 1224.2 Exception 3).

Just as there are non-image-guided procedures that require more environmental controls than an Exam/Treatment Room, but less than those required for an Operating Room, there are image-guided procedures that require more environmental controls than a Class 1 Imaging Room, but not those required for a Class 3 Imaging Room (Hybrid OR). The Facility Guidelines Institute (FGI) introduced “Exam/Treatment, Procedure, and Operating Room Classification” and “Classification of Room Types for Imaging Rooms” in 2018. These, combined with ASHRAE 170 development, further defined the middle ground of “Procedure Room” and “Class 2 Imaging Room” with the same requirements for each. The California Building Code (CBC) followed suit in the 2022 Edition. As FGI continues to develop this approach, so will the CBC. The question becomes: what approach can be used to determine at what point do the procedures proposed require a Class 1 versus a Class 2 Imaging Room or a Class 2 versus a Class 3 Imaging Room?

This *Advisory Guide* is intended to facilitate that analysis of these important nuances and clarify the minimal environmental controls associated with each Class of Imaging Room. Some of the analysis will be incumbent upon the facility to assemble a multi-discipline Clinical Risk Analysis Team with appropriate staff expertise and experience to make such recommendations. The analysis will still be subject to concurrence by CDPH.

Radiology services are also used therapeutically, especially in oncology treatment. These are not considered under the Imaging Classification System and not discussed in this *Advisory Guide*. Requirements can be found in CBC Section 1224.34.

## SECTION 4

### IMAGING PROCEDURE ROOM CLASSIFICATION TYPES

An imaging room is a room in which imaging services are provided. Depending on what takes place within the imaging room, the room may be used for diagnostic, therapeutic, or invasive procedures, and as such should be designed to the same standards as required for those same procedures in non-imaging settings. The diagrams and checklists in this *Advisory Guide* will present information for the three types of Imaging Room Classification (and related procedure room type) environments as used under the national standards promulgated by FGI and listed in CBC Table 1224.4.11.4a, each of which having unique requirements:

**Class 1 Imaging Room (Exam or Treatment Room)** – An unrestricted area that is accessed from an unrestricted area. It is used for patient consultation, examination, and various noninvasive treatment and procedures. A Class 1 Imaging Room is *“an imaging room designated for the performance of patient care activities that may require high-level disinfected or sterile instruments but do not require the environmental controls of a Class 2 Imaging Room.”*

**Class 2 Imaging Room (Procedure Room)** – A Class 2 Imaging Room/Procedure Room is more restrictive than a Class 1 Imaging Room/Exam Room and less restrictive than a Class 3 Imaging Room/Operating Room. It is a semi-restricted area accessed from either an unrestricted or semi-restricted area. This access is one of the operational and planning decisions that must be discussed by a multi-disciplinary clinical risk assessment team as it has operational implications (e.g., staff attire, cleaning, and infection prevention). The room is intended for *procedures performed through orifices normally colonized with bacteria and percutaneous procedures that do not involve an incision deeper than skin*. A Class 2 Imaging Room is *“an imaging room designated for the performance of patient care activities that may require high-level disinfected or sterile instruments and some environmental controls but do not require the environmental controls of a Class 3 Imaging Room.”*

**Class 3 Imaging Room (Operating Room)** – A Class 3 Imaging Room/Operating Room has the most restrictive and robust minimum infrastructure of the basic room types. It is a restricted area that can only be accessed from a semi-restricted area. The room is designated and equipped for performing surgical and other invasive procedures. Procedures in this room typically meet the definition of “invasive procedure” and need to be performed in the cleanest environment. A Class 3 Imaging Room is *“an imaging room that meets the definition of an Operating Room and has equipment to enable diagnostic imaging before, during and after surgical procedures.”*

**Note:** An “Imaging Room” includes imaging equipment that is permanently installed in the room and may include MRI, fixed single-plane and bi-plane tomographic imaging systems and computed tomographic equipment. Use of portable imaging technology would not generally make an exam room, procedure room, or Operating Room, an

“Imaging Room.” In these cases, the underlying exam/treatment room, procedure room, or Operating Room requirements should be followed instead of the Imaging Room Classifications.

## SECTION 5 EXAM/TREATMENT, IMAGING, PROCEDURE & OPERATING ROOM CLASSIFICATION

Table 1224.4.11.4a was introduced into the California Building Code in the 2022 edition. It is based on both Table 2.2-1 “Exam/Treatment, Procedure, and Operating Room Classification” and Table 2.2-2 “Classification of Room Types for Imaging Services” as included in the 2018 and 2022 editions of FGI *Guidelines for Design and Construction of Hospitals*. Since the last three columns of both FGI tables are identical, the CBC version has combined the tables into a single table reinforcing the linkage between procedure room type and imaging room class.

CBC Section 1224.18 requires that “*to differentiate the design and construction requirements needed to achieve the environmental controls and other requirements that support the amount of intervention to be provided, imaging rooms shall be classified as described in Table 1224.4.11.4a.*” The table presents three basic procedure room types including: Class 1 Imaging Room (Exam/Treatment Room) which is primarily diagnostic in nature and where non-invasive procedures may be performed; Class 2 Imaging Room (Procedure Room) where diagnostic and minimally invasive procedures may be performed; and Class 3 Imaging Room (Operating Room) where invasive procedures are generally performed.

**TABLE 1224.4.11.4a**  
**EXAMINATION/TREATMENT, IMAGING, PROCEDURE, AND OPERATING ROOM CLASSIFICATION <sup>1, 2</sup>**

ROOM	USE		ROOM TYPE	LOCATION	SURFACES
Exam or treatment room	Patient care that may require high-level disinfected or sterile instruments but does not require the environmental controls of a procedure room		Unrestricted area	Accessed from an unrestricted area	Flooring: cleanable and wear-resistant for the location; stable, firm, and slip-resistant Wall finishes: washable Ceiling: cleanable with routine housekeeping equipment; lay-in ceiling permitted
Class 1 imaging room	Diagnostic radiology, fluoroscopy, mammography, computed tomography (CT), ultrasound, magnetic resonance imaging (MRI), and other imaging modalities. Services that either a) use natural orifice entry and do not penetrate natural protective membranes, or b) are low-risk needle-based procedures that do not require a sterile field.				

<b>ROOM</b>	<b>USE</b>		<b>ROOM TYPE</b>	<b>LOCATION</b>	<b>SURFACES</b>
<i>Procedure room</i>	<i>Patient care that requires high-level disinfection of the room, sterile instruments, and some environmental controls but does not require the environmental controls of an operating room. Endoscopic procedures</i>		<i>Semi-restricted area</i>	<i>Accessed from an unrestricted or a semi-restricted area</i>	<i>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. 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.</i>
<i>Class 2 imaging room</i>	<i>Diagnostic and therapeutic procedures such as coronary, neurological, or peripheral angiography Electrophysiology procedures</i>				

<b>ROOM</b>	<b>USE</b>		<b>ROOM TYPE</b>	<b>LOCATION</b>	<b>SURFACES</b>
Operating room	Invasive procedures <sup>3</sup> or any 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 assemblies: monolithic floor with integral coved wall base carried up the wall a minimum of 6 inches Wall finishes: washable; free of fissures, open joints, or crevices Ceiling: monolithic, scrubbable, capable of withstanding cleaning and/or disinfecting chemical, gasketed access openings
Class 3 imaging room	Invasive procedures <sup>3</sup> or any Class 2 procedure during which the patient will require physiological monitoring and is anticipated to require active life support				

1. This table includes a brief description of the services performed in these room types and a summary of some applicable requirements that appear elsewhere in the California Building Code.
2. Other requirements that apply to these room types include, but are not limited to, ventilation, lighting, and sound transmission requirements. See California Mechanical Code Table 4-A and ASHRAE 170 for ventilation requirements. See California Electrical Code, Article 517 for lighting and power requirements. See California Building Code Table 1224.4.19 for noise transmission requirements.
3. “Invasive procedure” is defined in Section 1224.3 definitions.



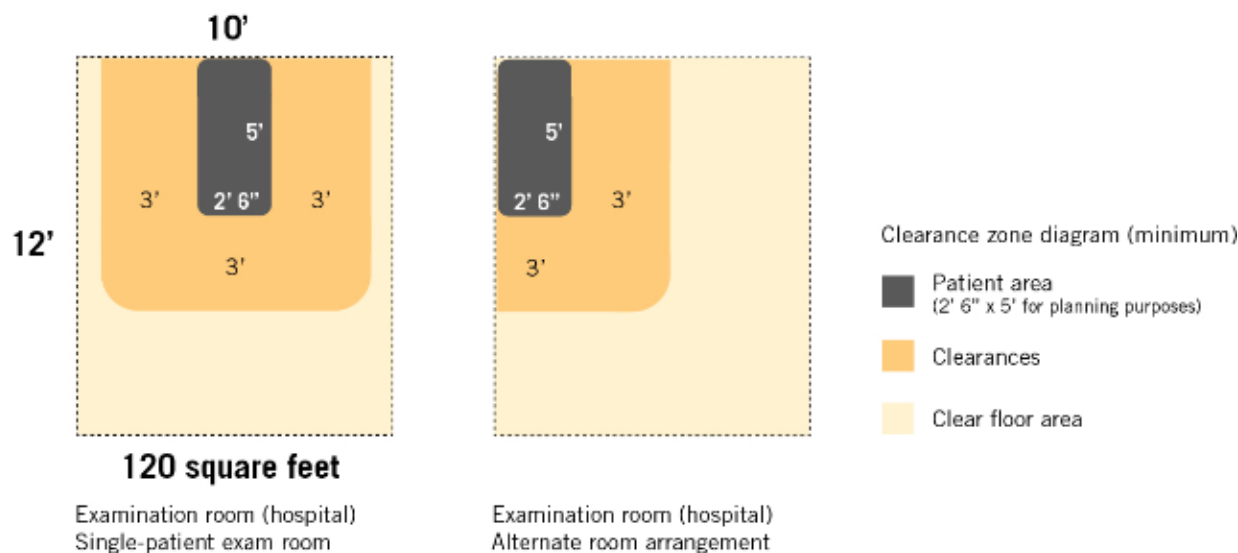
## SECTION 6

### CLASS 1 IMAGING ROOM (EXAM/TREATMENT ROOM)

Class 1 Imaging Rooms are Examination/Treatment Rooms with permanent imaging equipment used in diagnostic examination and/or minor treatment procedures. Exam Rooms are regulated under CBC Section 1224.4.4.1.1 and Treatment rooms under Section 1224.4.4.1.2. While a simple exam room could be as small as 80 square feet, the smallest Class 1 Imaging room listed under Section 1224.18 requires 100 square feet due to the imaging equipment. If any minor (non-invasive) procedures are performed, it is a treatment room and requires a minimum area of 120 square feet unless the procedure and/or imaging equipment requires more space. Most Class 1 Imaging Rooms would be located in the Radiological/Diagnostic Imaging Service Space, although some satellite imaging rooms might be provided in other Service Spaces (e.g., Emergency Service Space).

**Procedures:** Procedures may include: diagnostic radiological imaging; blood draw; injections; minor cuts and sprains (including wound packing); stitches and casting; minor dermatological procedures (including removing skin tags); use of natural orifice entry and not penetrating natural protective membranes; and low-risk needle-based procedures (e.g., biopsies) that do not require a sterile field. Procedures must meet criteria set by the Clinical Risk Assessment as discussed in Section 9 and qualify to be performed in a Class 1 Imaging Room.

**Room Size:** 100 square feet diagnostic exam only, 120 square feet for treatment room (minor non-invasive procedures), unless more space is required for the specific procedure modality.



*Figure 1*



**Room Type:** Unrestricted Area – Basic interior finishes under Section 1224.4.11 and Tables 1224.4.11 and 1224.4.11.4a.

**Access:** Accessed from an unrestricted area (e.g., Radiological/Diagnostic Imaging Service Space internal circulation corridor).

**Ventilation:** Standard diffuser and return air grilles with 2 Outside Air Changes (OSA) / 6 total air changes per hour.

**Pressure Differential:** No requirement.

**Medical Gas:** No requirement (1 Ox, 1 Vac and/or 1 Med Air may be required for some imaging procedures).

**Electrical:** Category 2 (General Care) space – 8 receptacles w/ critical branch and normal branch circuits with at least one receptacle on each.

**Handwashing:** Handwashing station required in the Class 1 Imaging Room (except MRI).

**Anesthesia/Sedation:** Generally, none is necessary (MRI Pediatrics may have mild sedative). The Functional Program should include identification of the level and type used.

**Support Areas:** Pre/post-procedure patient care - point-of-care in procedure room; clean supply and soiled holding may be shared with another department; patient waiting and dressing facilities.

**Radiation Protection:** Many imaging room classes require radiation protection as specified by a certified physicist or other qualified expert. Where approved alcoves with view windows are required, a minimum of 1'-6" shall be provided between the view window and outside edge of the partition. A control room, when provided, shall be physically separated from the Imaging Room with walls and a door.



### **Specific Imaging Modalities:**

**Fluoroscopy** – A toilet room shall adjoin and be directly accessible to each fluoroscopy room.

Some procedures may require a Class 2 or Class 3 Imaging Room. Procedures must meet the criteria established by the multi-disciplinary Clinical Risk Assessment Team as described in Section 9.

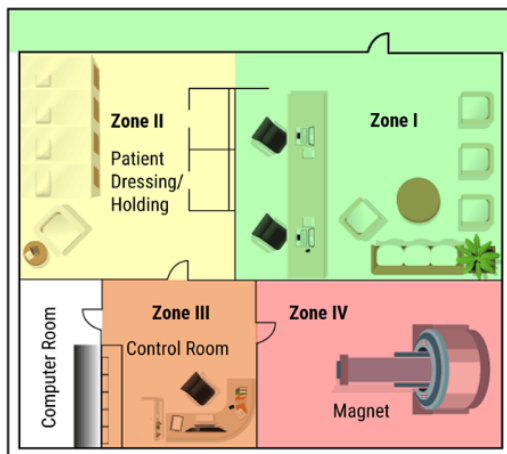


**Computed Tomography (CT) Scanning** – A control room, or alcove, shall be provided that is designed to accommodate the computer and other controls for the equipment. A view window shall be provided to permit view of the patient. A patient toilet room shall be readily accessible to the procedure room. **Note** that intraoperative CT scanning shall comply with Class 3 Imaging.



**Magnetic Resonance Imaging (MRI)** – A control room shall be provided with a full view of the patient in the MRI scanner. The control console shall be positioned so the operator has a full view of the approach and entrance to the MRI scanner room. Patient toilet room convenient to the procedure room. An anteroom or area 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 [see 4-zone safety zones for magnetic resonance imaging defined by the American College of Radiology]. The room or area shall be outside the restricted areas of the MRI's magnetic field. A computer room shall be provided.

**Note** that an intraoperative magnetic resonance imaging (iMRI) suite shall comply with Section 1224.28.5 as Class 3 Imaging.



**Ultrasound** – Rooms used for ultrasound examination/treatment shall have a minimum clear floor area of 120 square feet, with a minimum clear dimension of 3 feet provided on three sides of the table/stretchers. A patient toilet shall be directly accessible to the ultrasound procedure room. The patient toilet may be permitted to serve more than one ultrasound procedure room. A processing room with distinct areas for cleaning and decontaminating instruments shall be provided with a handwashing station, work counter and storage room/cabinets for HLD (high-level disinfection) probes. If self-contained disinfection units are used, the soiled utility room may be used in lieu of the processing room.



**Mammography** – Mammography rooms shall be a minimum of 100 square feet. Each x-ray room shall include a shielded control alcove. For mammography machines with built-in shielding for the operator, omission of the alcove shall be permitted when approved by the certified physicist. A handwashing station shall be provided within the procedure room.





## SECTION 7

### CLASS 2 IMAGING ROOM (PROCEDURE ROOM)

Class 2 Imaging Rooms are Procedure Rooms with permanent imaging equipment used in diagnostic examination and/or minimally invasive procedures. Procedure Rooms are regulated under CBC Section 1224.4.4.1.4. While a simple procedure room could be as small as 130 square feet, the Class 2 Imaging room procedure and/or imaging equipment may require more space. Some procedures in Class 2 Imaging Rooms may involve local anesthesia, and minimal or moderate sedation, and will require additional space for the anesthesiologist resulting in a minimum room size of 160 square feet. Class 2 Imaging Rooms could be located in the Radiological/Diagnostic Imaging Service Space, in the Surgical Service Space, or in a separate specialized suite.

**Procedures:** Procedures could include placement of temporary pacing wires; endoscopy; bronchoscopy; and electrophysiology procedures. Procedures must meet criteria established by the multi-disciplinary Clinical Risk Assessment Team as described in Section 9.

**Room Size:** 130 square feet minimum, 160 square feet for procedures using anesthesia, unless more space is required for the specific procedure modality. 3'-6" minimum clearance at each side and 3'-0" at the foot of the gantry table and maintenance clearance to the back of the gantry if there is one. Where an anesthesia machine and associated supply cart is used, the clearance at the head shall be 6 feet. Fixed mono-plane tomography will likely take more space, and bi-plane (two "C" arms) will take even more. The size of the room will need to respond to the procedures, people and equipment needed.

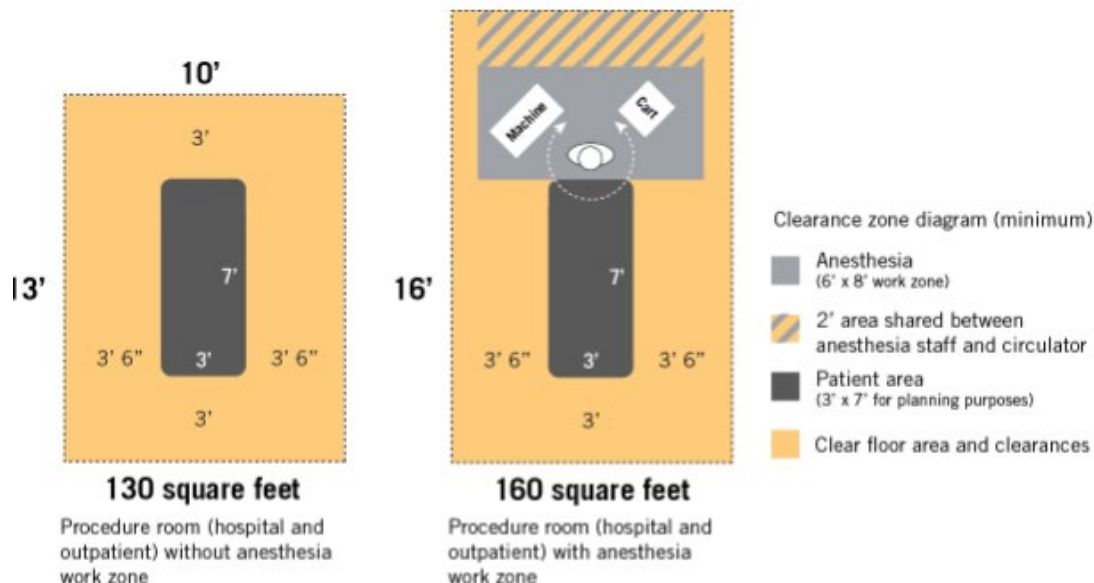


Figure 2a

Figure 2b

**Room Type:** Semi-restricted Area – semi-restricted interior finishes under Section 1224.4.11 and Tables 1224.4.11 and 1224.4.11.4a.

**Access:** Accessed from a semi-restricted area (e.g., surgical suite corridor) or an unrestricted area (e.g., Radiological/Diagnostic Imaging Service Space internal circulation corridor). See anesthesia/sedation below.

**Ventilation:** Standard Group E diffuser and return air grilles with (3) OSA / (15) total air changes per hour. The Clinical Risk Assessment may determine that a non-aspirating diffuser is more appropriate for specific procedures.

**Pressure Differential:** Positive relative to surrounding spaces unless specially noted otherwise for the procedure (e.g., bronchoscopy procedure rooms will be negative, and endoscopy procedure rooms have no pressure differential requirement).

**Medical Gas:** (2) Ox, (2) Vac, and (1) Med Air. (WAGD inlets required where anesthetic gases are used)

**Electrical:** Category 1 (Critical Care) space - 14 receptacles w/ critical and normal branch circuits, at least one receptacle on the normal branch or a critical branch circuit on a separate ATS.

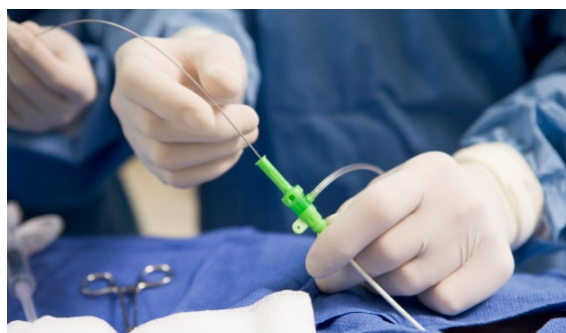
**Handwashing:** A handwashing station is required in the Class 2 Imaging Room (except where scrub stations are provided outside the procedure room in the semi-restricted corridor). Note that CPC Table 4-2 requires scrub sinks for some interventional imaging procedures.

**Anesthesia/Sedation:** Local anesthesia and minimal and moderate sedation may be administered in the Class 2 Imaging Room. Moderate sedation and/or anxiolytic medications administered under monitored anesthesia care where conversion to general anesthesia is likely to become necessary must be in a Class 3 Imaging Room. The type and level of sedation should be included in the Functional Program.

**Support Areas:** Pre/post-procedure patient care – a patient preparation holding and recovery area, or room, shall be provided and arranged to provide visual observation before and after the procedure with (1) Ox and (1) Vac, similar to FGI Phase-II recovery. Some procedures may require the support of a Post-Anesthesia Care Unit (PACU) in compliance with Section 1224.16.

## **Specific Imaging Modalities**

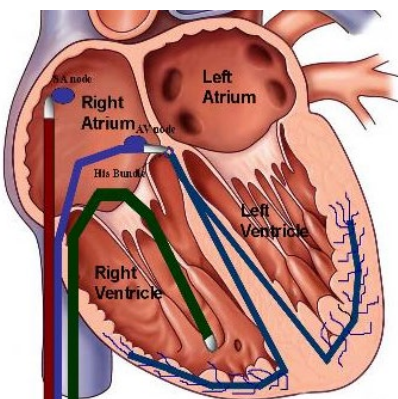
**Diagnostic Angiography** – Diagnostic angiography space shall accommodate a control room with a view window to permit full view of the patient, a scrub sink located outside the staff entry to the procedure room, a patient holding area shall accommodate at least one patient gurney with a minimum of 3-foot clearance on the long side, and storage for portable equipment and catheters shall be provided. Note that if interventional angiography procedures are to be performed, the suite shall comply with the requirements of Section 1224.28.4. If cardiac catheterization procedures are performed refer to Section 1224.28.2.



**Interventional Imaging** – Image-guided interventional procedures (also known as Interventional Radiology IR) shall be performed in suites in compliance with 1224.28.4 with a minimum clear dimension of 18 feet and allow a minimum clearance of 4 feet on all sides of the procedure table. Pre-procedure and recovery areas shall comply with 1224.16 (Anesthesia/recovery Service Space). Scrub facilities shall be located outside of sterile areas with one scrub sink for each interventional procedure room; medication station provided per 1224.4.4.4; clean and soiled utility rooms per 1224.4.4.6 and 1224.4.4.7; dedicated housekeeping per 1224.4.15 and staff changing area to ensure a traffic pattern so that personnel can enter from outside the suite, change their clothing, and move directly into the interventional imaging suite. Note that requirements for these rooms are greater than for generic Class 2 Imaging Rooms although less restrictive than Class 3 (Hybrid ORs). The Clinical Risk Assessment will determine whether the procedures are appropriate for a Class 2 Imaging Room in compliance with Section 1224.28.4 or if they need to be performed in a Class 3 Imaging Room in compliance with 1224.28.5.



**Cath Lab - Electrophysiology (EP) Studies** – If purely diagnostic procedures such as EP studies are performed in a Cath Lab, then the clinical risk could suggest a Class 2 Imaging Room would be appropriate. The patient may be awake or receive minimal or moderate sedation (as defined by the American Society of Anesthesiologists) during the test, and not under general anesthesia if performed in a Class 2 Imaging Room.



**Cardiac Catheterization** – The procedure room shall have a minimum clear floor area of 400 square feet in addition to control, monitoring, and recording equipment; one scrub sink for each cath lab; control room permitting full view of the patient; equipment space (x-ray transformers, etc.); staff change area entering from outside the service space and move directly into the cardiac catheterization service space; patient preparation, holding, and recovery area with visual observation before and after the procedure; clean and soiled utility rooms; and housekeeping dedicated to the surgical service or cardiac catheterization service space. Where electrophysiology (EP) studies are performed, dedicated space and equipment for emergency resuscitation and stabilization shall be immediately accessible to the procedure room.

The Clinical Risk Assessment will determine whether the procedures are appropriate for a Class 2 Imaging Room in compliance with Section 1224.28.2 or if they need to be performed in a Class 3 Imaging Room in compliance with 1224.28.5. CDPH should review the list of procedures and concur with the classification selection.



## SECTION 8 CLASS 3 IMAGING ROOM (OPERATING ROOM)

Class 3 Imaging Rooms (Hybrid Operating Rooms) are Operating Rooms with permanent imaging equipment used before, during and after invasive procedures. Hybrid Operating Rooms are regulated under CBC Section 1224.28.5 and must meet the requirements of Operating Rooms under Section 1224.15. While an Operating Room could be as small as 400 square feet, the Class 3 Imaging Room procedure and/or imaging equipment will require a minimum of 650 square feet, or more space depending upon the procedures/equipment involved. Class 3 Imaging Rooms would be located in the Surgical Service Space, or in a separate specialized suite.

**Room Size:** 650 square feet minimum unless different space is required for the specific procedure modality. 24'-0" minimum clear dimension to accommodate the sterile field and surgical team, sterile instrument table(s), circulating nurse access, imaging equipment, anesthesia equipment and team, perfusion equipment and team if there is one, and maintenance clearance to the back of the gantry if there is one dependent upon the imaging modality equipment used.

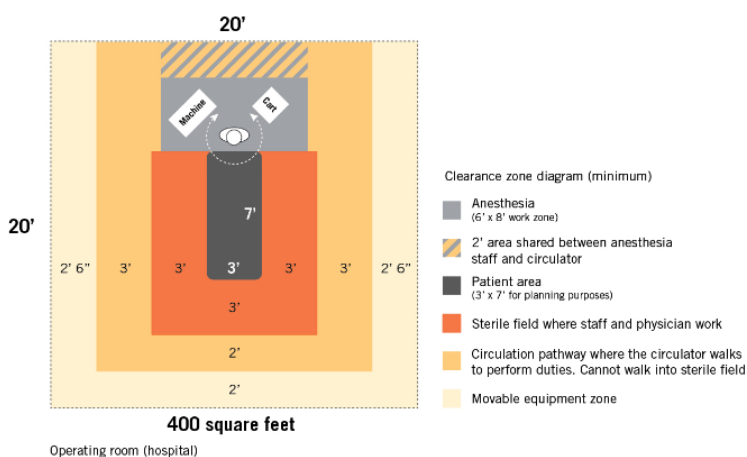
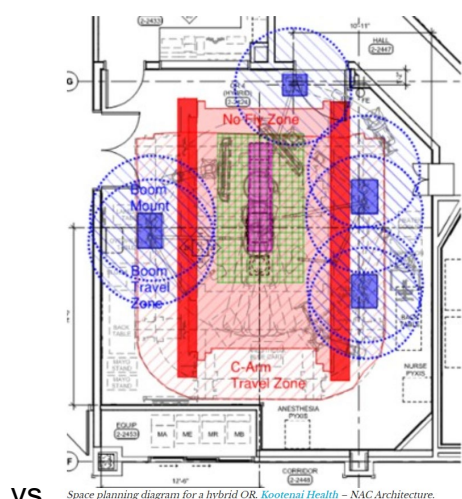
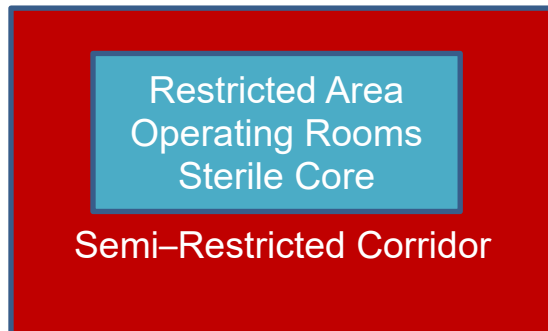


Figure 4

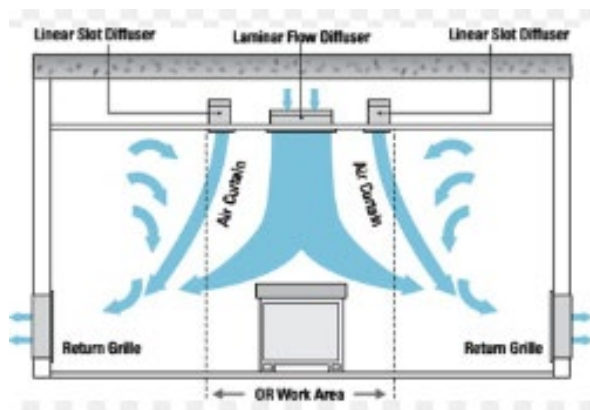


**Room Type:** Restricted Area – restricted interior finishes under Section 1224.4.11 and Tables 1224.4.11 and 1224.4.11.4a.



**Access:** Accessed from a semi-restricted area (e.g., surgical suite corridor). 1224.15: *The surgical service space shall be divided into two designated areas: 1) semi-restricted areas (e.g., storage areas for clean and sterile supplies, sterile processing rooms, scrub stations and corridors leading to restricted areas of the surgical suite, etc.); and 2) restricted areas (e.g., Operating Rooms, hybrid Operating Rooms, sterile procedure rooms, cardiac catheterization labs, sterile cores, etc.) that can be reached only through a semi-restricted area. The surgical service space shall be located and arranged to provide direct support from the anesthesia/recovery service space with a common door to prevent nonrelated traffic through the surgical service space.*

**Ventilation:** Non-aspirating laminar flow unidirectional primary supply diffuser array above the sterile field (12" beyond the width and length of the table) and low-level sidewall return air grilles with 4 OSA/20 total air changes per hour.



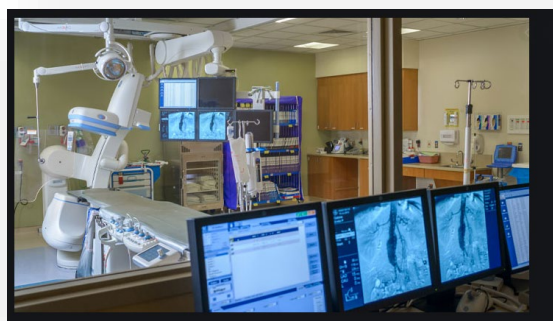
**Pressure Differential:** Positive relative to surrounding spaces.

**Medical Gas:** Boom-mounted medical gas per Table 1224.4.6.1: 2 Ox, 5 Vac, and 1 Med Air. WAGD required for anesthesia use.



**Electrical:** Hybrid Operating Rooms are Category 1 (Critical Care) Spaces and might be determined to be be wet procedure locations. Each Operating Room shall be provided with a minimum of 36 receptacles divided between at least two branch circuits. At least 12 receptacles, but no more than 24, shall be connected to either the normal branch system or a critical branch circuit supplied by a different transfer switch than the other receptacles at the same location. Equipment grounding and bonding will follow the requirements in CEC Article 517.19.

**Control Room:** The control room shall have a clear floor area of 120 square feet which may include fixed work surfaces. The room shall be physically separated from the hybrid Operating Room with walls and a door. The room shall have viewing windows that provide a full view of the patient and the surgical team.



**Scrub Facilities:** Scrub facilities with direct-wired or battery-operated clock shall be located outside of sterile areas. A minimum of two scrub sinks shall be provided in a surgical unit containing one Operating Room or hybrid Operating Room. Four scrub sinks shall be provided in surgical units containing two Operating Rooms and/or hybrid Operating Rooms. One additional scrub sink shall be provided for each additional Operating Room or hybrid Operating Room.



**Anesthesia:** Although specific procedures might not require deep sedation or general anesthesia, or even moderate sedation/anxiolytic medication administered under monitored anesthesia care that could result in administration of general anesthesia; all Class 3 Imaging Rooms must provide for possible administration of general anesthesia.

**Pre- and Post-Operative Patient Care:** The surgical service space shall be located and arranged to provide direct support from the anesthesia/recovery service space to the semi-restricted corridor with a common door to prevent nonrelated traffic through the surgical service space. The pre-procedure and recovery areas shall comply with the requirements of Section 1224.16 (Anesthesia/recovery Service Space) – PACU.

**Support Spaces:** Traffic through the staff changing area from unrestricted space to semi-restricted space; clean and soiled utility rooms off the semi-restricted corridor per Sections 1224.15.3.7 and 1224.15.3.8; a medication station shall be provided per Section 1224.4.4.4; anesthesia workroom; equipment storage; and housekeeping dedicated to the surgical service space.

### **Specific Imaging Modalities**

**Interventional Imaging** – Interventional Imaging Procedures that require environmental controls beyond a Class 2 Imaging Room in compliance with 1224.28.4 must be performed in a Class 3 Imaging Room (Hybrid OR) in compliance with 1224.28.5.



**CT** – Hybrid Operating Rooms with intraoperative computed (CT) systems shall have control rooms that comply with Section 1224.18.3.1



**iMRI** – Hybrid Operating Rooms with intraoperative magnetic resonance imaging (iMRI) systems shall provide the space and clearance requirements of Section 1224.18.4, except clearance shall meet the requirements of Section 1224.28.5.1; the control room shall comply with Section 1224.18.4-Item1; the anteroom shall comply with Section 1224.18.4.2; and entry doors to iMRI hybrid rooms shall swing outward from inside the room.



**Vascular Imaging** – Hybrid Operating Rooms with vascular imaging shall also comply with Section 1224.28.4 (Interventional Imaging).

**Cardiac Catheterization** – Cardiac Catheterization Procedures that require environmental controls beyond a Class 2 Imaging Room in compliance with 1224.28.2 must be performed in a Class 3 Imaging Room (Hybrid OR) in compliance with 1224.28.5.

## SECTION 9 CLINICAL RISK ASSESSMENT

The Classification of an Imaging Room depends on the procedures that are to be performed in that room. HCAI seeks to align its approval of imaging room classification with CDPH Licensing & Certification's approval of the facility's proposed procedures. HCAI collaborates with CDPH to ensure that HCAI's review of a proposed Imaging Room Classification will also meet CDPH licensure requirements.

To anticipate CDPH's expectation for an Imaging Room, HCAI requires facilities to submit a list of the proposed procedures to further define the use/function of the Imaging Room(s) and their related support spaces, to be shared with CDPH. It is essentially a narrow/focused Functional Program (as normally required under CAC Section 7-119) when defining a particular functional area, or a change in function leading to a different code section. More information on how to submit a successful Functional Program, see [Advisory Guide A16 – Functional Program](#).

FGI employs a similar approach in the 2026 Guidelines and will be requiring a specific Clinical Risk Assessment as support for the use and classification of procedure rooms and imaging rooms. This assessment is to be conducted by a multi-disciplined Clinical Risk Assessment Team, assembled by the facility, and tasked with identifying and classifying the specific procedures proposed in alignment with the procedure room and imaging room classifications. This assessment would be part of the Safety Risk Assessment (SRA) that is already a part of the required Functional Program.

The Clinical Risk Assessment Team is a robust multi-disciplinary team with the clinical backgrounds necessary to make such assessments and includes representatives from surgery, anesthesiology, infection prevention, facility management, and the design team. The approach is a quantifiable assessment of the procedures to be performed in the imaging room presented in a standardized format for the authority having jurisdiction consideration. The Clinical Risk Assessment is in addition to the Infection Control Risk Assessment (ICRA) and part of a comprehensive Safety Risk Assessment (SRA). A Clinical Risk Assessment (CRA) should score all the proposed procedures considering: patient demographic; the medical team and equipment involved; duration of the procedure; degree of invasiveness; and potential risks to the patient. The CRA will need to quantifiably substantiate the Imaging Room Classification(s) determined by the Clinical Risk Assessment Team.

While preparation of a Clinical Risk Assessment is not a Title 24 requirement, proactive analysis of the procedures to be performed, the associated risks to the patient, and determination of the appropriate environment is strongly encouraged. The Clinical Risk Assessment should present a quantifiable assessment intended for clarification and discussion of the procedures, aided with the benefit of quantifiable scoring of the procedures proposed and the classification then warranted. Since the patient's condition will be a consideration in the classification of imaging spaces, patient admission/screening criteria/co-morbidity information for the proposed procedures should be included in the Clinical Risk Assessment.

## SECTION 10

### HCAI/OSHPD SUBMITTAL INSTRUCTIONS

1. In addition to Title 24 citations listed in this document, imaging room projects, as with all construction, remodeling, and alteration of hospital buildings, are required to be designed in conformance with applicable regulations as noted in Code Application Notice CAN 1-0 Enforceable Codes.
2. For those projects which are affected by local planning and zoning, evidence of approval is required as part of the submittal to HCAI.
3. A *Clinical Risk Assessment* (CRA) shall be made by the facility's Clinical Risk Assessment Team in the assessment of the various procedures proposed. The team must consist of medical representatives from surgery, anesthesiology, infection prevention, facility management and the design team (lead by the design professional in responsible charge [CAC 7-115]), in the preparation and submission of project documents. This assessment is a normal component of the Safety Risk Assessment (SRA) and is in addition to the Infection Control Risk Assessment (ICRA). Inclusion of the CRA for all HCAI submittals for imaging room projects is used to facilitate a more expeditious review.
4. Suite Layout – Provide a floor plan of the entire suite including: all the required support spaces and access including the semi-restricted corridor when required.
5. Room Layout – Provide a comprehensive floor plan including everything in the Imaging Room associated with the worst-case procedure. Clearly delineate: the room configuration; built-in cabinetry; mobile cabinetry; case carts; equipment needed for the procedure; space for the anesthesiologist(s) and anesthesia equipment; space for the perfusionist(s) and cardiopulmonary bypass equipment if used; appropriate clear space and maneuvering for surgeons, proceduralists, scrub nurses within the sterile field; instrument table(s); clear space and path of travel for circulating nurse(s); fluid waste collection system; robotic equipment, console and display equipment if used; power/med gas booms; surgical light booms; monitor booms; and demonstrate appropriate clearances and circulation required to perform the procedure.
6. *Appendix B – Imaging Room Summary Checklist for Class 1 Imaging Rooms* is required for all HCAI submittals for imaging room projects that include Class 1 Imaging Rooms. Provide as a separate document.
7. *Appendix C – Imaging Room Summary Checklist for Class 2 Imaging Rooms* is required for all HCAI submittals for imaging room projects that include Class 2 Imaging Rooms. Provide as a separate document.
8. *Appendix D – Imaging Room Summary Checklist for Class 3 Imaging Rooms* is required for all HCAI submittals for imaging room projects that include Class 3 Imaging Rooms. Provide as a separate document.
9. Projects that include more than one Imaging Room Class should submit an assessment and the appropriate *Imaging Room Checklist* for each class proposed.

## APPENDIX A PROPOSED PROCEDURE CLINICAL RISK ASSESSMENT

Title 24 provides for non-invasive diagnostic procedures performed in exam/treatment/Class 1 Imaging Rooms; a range of minimally invasive diagnostic and therapeutic procedures performed in a range of procedure/Class 2 Imaging rooms; and invasive procedures requiring ORs/Class 3 Imaging Rooms. The Clinical Risk Assessment is intended to assist in classifying which procedures may be performed in a Class 1 Imaging room, which may be performed in one of the Class 2 Imaging Rooms, and which need to be performed in a Class 3 Imaging Room. For projects that only involve Class 3 Imaging Rooms (Hybrid ORs), a list of procedures and Clinical Risk Assessment is still appropriate. Some procedures may require additional support facilities such as licensed Cardio-Vascular OR space. For projects associated with Class 1, Class 2, and/or Class 3 Imaging Rooms, the Clinical Risk Assessment will help confirm the classification and support spaces.

Provide a Clinical Risk Assessment (CRA) of all the proposed procedures considering requirements for surveillance, prevention, and control of hospital acquired infection (HAIs) as delineated in the Code of Federal Regulation, Title 42 §482.42 (required under CMS Conditions of Participation). The Clinical Risk Assessment Team shall include, at a minimum, representation from the surgical, radiological, nursing, anesthesia services, and qualified infection preventionist(s) appointed by the governing body and include facility management and the design team. Note that the Clinical Risk Assessment is only one component of the project Safety Risk Assessment (SRA) and is in addition to, and complementary with, the project Infection Control Risk Assessment (ICRA). The SRA should be included in response to Appendix A and include the CRA.

The Safety Risk Assessment Components of an Imaging Room project would normally include an Infection Control Risk Assessment (ICRA) addressing ventilation and humidity environmental controls and inclusion/prohibition of plumbing fixtures in response to risk from transmissible waterborne, opportunistic pathogens and establish strategies to mitigate risk; Patient Handling and Mobility Assessment (PHAMA) addressing patient flow related to pre- and post-procedure care areas; medication safety assessment; and the Clinical Risk Assessment. Note that Infection Preventionists (IPs) are an essential component of this ongoing process as IP duties include ongoing infection surveillance and monitoring of infection control practices. The Infection Preventionist is consequently an essential voice on the Clinical Risk Assessment Team for any Imaging Room project.

It is understood that there is no acceptable, one-size-fits-all risk assessment tool. Each facility must have a multi-disciplinary team of “clinicians, infection preventionist(s), and other care providers” who, under the direction of the facility’s governing body, perform ongoing “safety risk assessments” and “infection control risk assessments.” The Clinical Risk Assessment (CRA) must evaluate all the proposed procedures and quantifiably substantiate the Imaging Room Classification(s) determined by the Clinical Risk Assessment Team for consideration by CDPH.



Since the patient's condition is a consideration in the classification of imaging spaces, include patient admission/screening criteria, co-morbidity information for the proposed procedures in the Clinical Risk Assessment.

## APPENDIX B CLASS 1 IMAGING ROOM SUMMARY CHECKLIST

Please see the [Class 1 Imaging Room Summary Checklist](#) on our HCAI website.

## APPENDIX C CLASS 2 IMAGING ROOM SUMMARY CHECKLIST

Please see the [Class 2 Imaging Room Summary Checklist](#) on our HCAI website.

## APPENDIX D CLASS 3 IMAGING ROOM SUMMARY CHECKLIST

Please see the [Class 3 Imaging Room Summary Checklist](#) on our HCAI website.

## REVISION HISTORY

Version 2.0	September 17, 2025	Second revision. Revisions to Section 9 clarify that a patient's condition will be a consideration in the classification of imaging spaces. Appendix A clarify a list of procedures and Clinical Risk Assessment is still appropriate that involve Class 3 Imaging Rooms (Hybrid ORs).
Version 1.0	September 2025	First Issued