Department of Health Care Access and Information

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

Office of Statewide Hospital Planning and Development

June 2026

Version 3.0

Department of Health Care Access and Information
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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taking three years each, the written code language will be at least 6 years old when it is first published and 9 years out of date before it is revised under the next code cycle.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)

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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 7, California Wildland Urban Interface 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 [1, 2]

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.*				

ROOM	USE		ROOM TYPE	LOCATION	SURFACES
Procedure room	*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*		*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. 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 2 imaging room	*Diagnostic and therapeutic procedures such as coronary, neurological, or peripheral angiography Electrophysiology procedures*				

ROOM	USE		ROOM TYPE	LOCATION	SURFACES
Operating room	*Invasive procedures[3] 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[3] 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.*

PATIENT CARE SPACE DESIGNATIONS FROM CALIFORNIA ELECTRICAL CODE (CEC)

Electrical requirements for patient care spaces are applied per Category as required by the California Electrical Code (CEC). This is also true for Imaging Rooms, but the Categories are ranked in reverse order of severity compared to Imaging Room Classifications. For example, a Category 1 space in the CEC is the most restrictive patient care space, whereas a Class 3 imaging room is the most restrictive imaging room classification. This can result in a complex overlay of requirements. Definitions and applications of patient care spaces and Category Requirements from the CEC are provided here as a reference when designing imaging rooms. An additional resource, the industry document, "ANSI/IES-RP-29 Recommended Practice: Lighting Hospital and Healthcare Facilities," is also referenced.

Patient Care Space. Any space of healthcare facility wherein patients are intended to be examined or treated. Information Note: The healthcare facility's governing body designates patient care space in accordance with the type of patient care anticipated.

Category 1 (Critical Care) Space. Space in which failure of equipment or a system is likely to cause major injury or death of patients, staff, or visitors. *Includes special care units, intensive care units, coronary care units, sub-acute units, angiography laboratories, cardiac catheterization laboratories, delivery rooms, operating rooms, portions of emergency departments, electroconvulsive therapy procedure rooms, post-operative recovery rooms and similar areas in which patients are intended to be subjected to invasive procedures and are connected to line-operated electromedical devices.* Informational note: These spaces, formerly known as critical care rooms, are typically where patients are intended to be subjected to invasive procedures and connected to line-operated, patient care-related appliances. Examples include, but are not limited to, special care patient rooms used for critical care, intensive care, and special care treatment rooms such as angiography laboratories, cardiac catheterization laboratories, delivery rooms, operating rooms, post-anesthesia care units, trauma rooms, and other similar rooms.

Category 2 (General Care) Space. Space in which failure of equipment or a system is likely to cause minor injury to patients, staff, or visitors. *Includes areas such as patient bedrooms, examining rooms, treatment rooms, clinics, and similar areas where the patient may come into contact with electromedical devices or ordinary appliances such as a nurse call system, electric beds, examining lamps, telephones, and entertainment devices.* Informational Note: Category 2 spaces were formerly known as general care rooms. Examples include, but are not limited to, inpatient bedrooms, dialysis rooms, invitro fertilization rooms, procedural rooms, and similar rooms.

Category 3 (Basic Care) Space. Space in which failure of equipment or a system is not likely to cause injury to the patients, staff, or visitors, but can cause patient discomfort.

Informational Note: Category 3 spaces, formerly known as basic care rooms, are typically where basic medical or dental care, treatment, or examinations are performed. Examples include, but are not limited to, examination or treatment rooms in clinics, medical and dental offices, nursing homes, and limited care facilities.

Category 4 (Support) Space. Space in which failure of equipment or a system is not likely to have a physical impact on patient care. Informational Note: Category 4 spaces were formerly known as support rooms. Examples of support spaces include, but are not limited to, anesthesia work rooms, sterile supply, laboratories, morgues, waiting rooms, utility rooms, and lounges.

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.

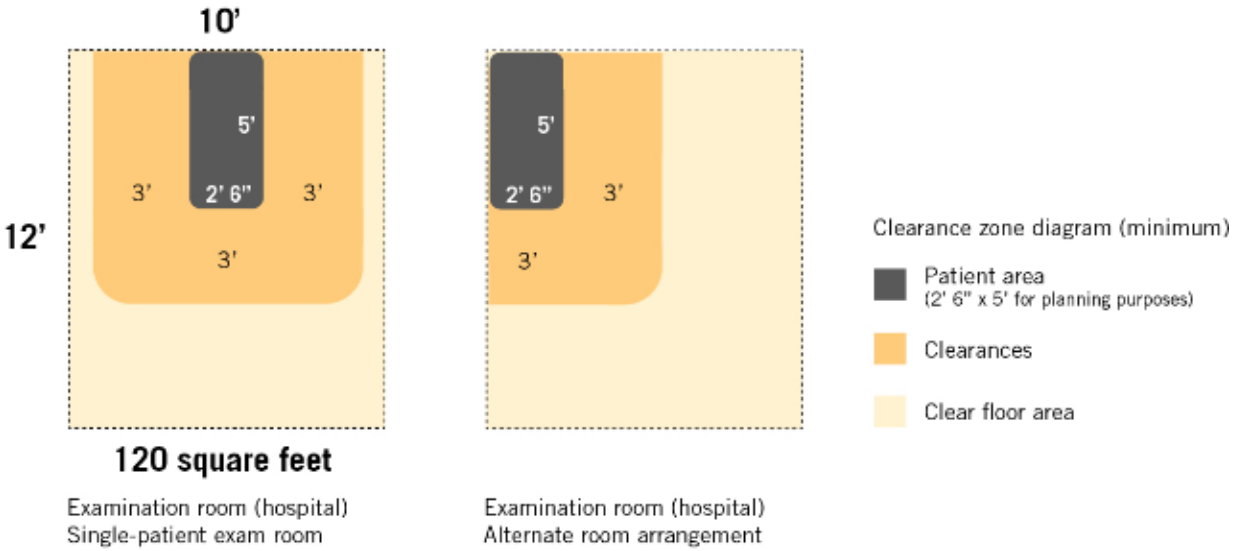


Figure 1

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 & 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 3 (Basic Care) space – There are no minimum receptacle quantities required for Class 1 imaging rooms unless it's an [OSHPD 1] imaging room containing imaging equipment approved by Licensing Agency for diagnostic services of emergency/trauma patients as found in California Building Code Section 1705A.13.3.1 7. If the imaging equipment is designated to support the Emergency Department (ED), task illumination and select receptacles in the imaging room shall be connected to the critical branch per CEC Article 517.34(A)(7).

Imaging equipment may be connected to normal, critical branch or equipment branch unless it's an [OSHPD 1] imaging room containing imaging equipment approved by Licensing Agency for diagnostic services of emergency/trauma patients found in California Building Code Section 1705A.13.3.1 7. If the imaging equipment is designated to support the Emergency Department (ED), it shall be connected to the critical or equipment branch per CEC 517.34(A)(7).

Lighting: See RP-29 for illumination level requirements. Note: Class 1 spaces should be considered non-invasive procedure spaces.

Nurse Call: Provide Staff Emergency station and Code Call station in all Imaging exam/procedure rooms.

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 & soiled holding may be shared with another department; patient waiting & 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

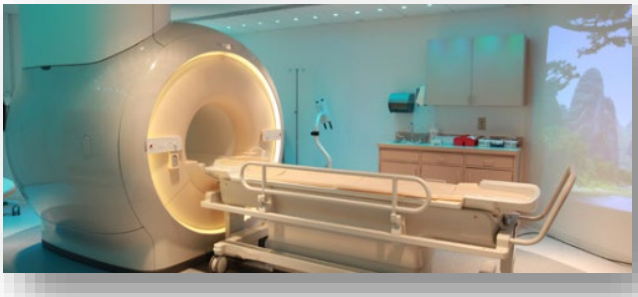
view windows are required, a minimum of 1’-6” shall be provided between the view window and outside edge of the partition. A control room, when provided, shall be physically separated from the Imaging Room with walls and a door.

Specific Imaging Modalities:

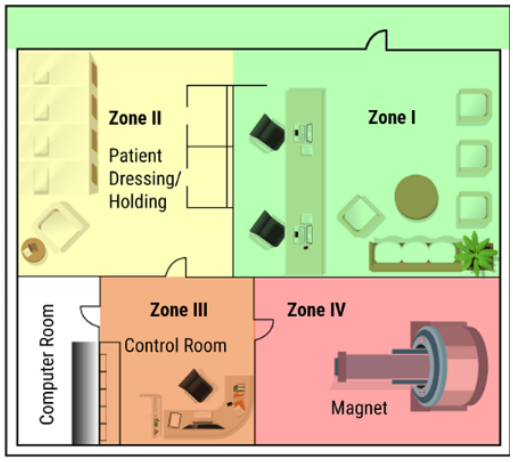
Fluoroscopy – A toilet room shall adjoin and be directly accessible to each fluoroscopy room.

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.

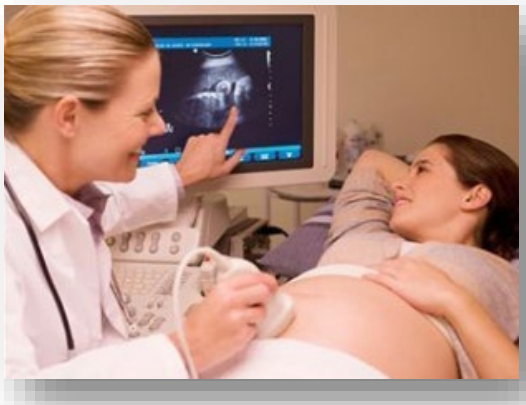
Computed Tomography (CT) Scanning – A control room, or alcove, shall be provided that is designed to accommodate the computer and other controls for the equipment. A view window shall be provided to permit view of the patient. A patient toilet room shall be readily accessible to the procedure room. **Note** 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/stretcher. 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 & 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, ommission 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.

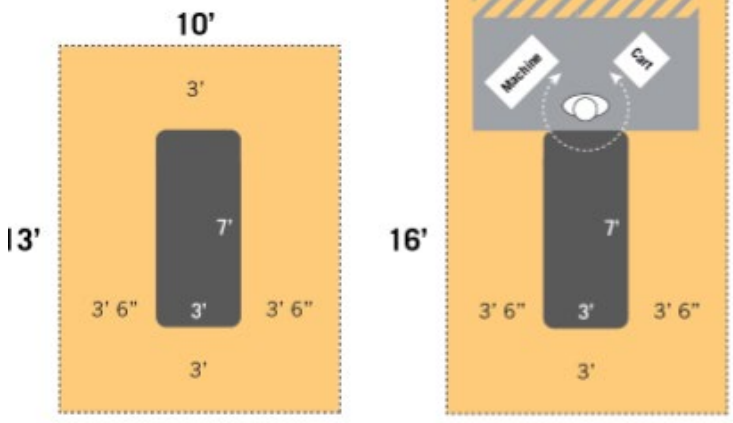


Figure 2a

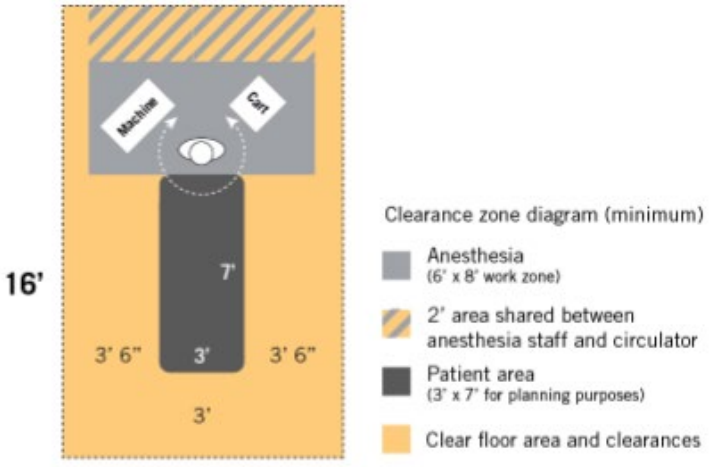


Figure 2b

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, & (1) Med Air. (WAGD inlets required where anesthetic gases are used)

Electrical: Class 2 imaging rooms are Category 1 (Critical Care) spaces. or Category 2 (General Care) spaces. Determination of the category of the space can be made based on what will happen to the patient if there is a failure of equipment or a system (ie power outage). See definitions of Patient Care Space Categories in Section 5.

For Category 1 (Critical Care) spaces - Provide 14 receptacles w/ critical & normal branch circuits, at least one receptacle on the normal branch or a critical branch circuit on a separate ATS. If the Category 1 space will use deep sedation or administer general anesthesia, then the imaging equipment will need to be circuited to the critical branch.

For Category 2 (General Care) spaces – There are no special requirements for branch circuits or receptacles. There is not a requirement to circuit the imaging equipment to the critical branch in Category 2 spaces. Imaging equipment can be circuited to either one of the following: normal power or the critical or equipment branch of the essential electrical system.

The critical branch shall supply power for task illumination, select receptacles, and select power circuits for the following areas:

(1) Category 1 or 2 spaces with at least one duplex receptacle per patient bed location, and task illumination as required by the governing body of the health care facility
(2) Angiographic labs
(3) Cardiac catheterization labs

Lighting: Class 2 imaging rooms can be designated as either non-invasive, minimally invasive or invasive spaces. See RP-29 for illumination level requirements. Note: For spaces identified as minimally invasive, it will be acceptable to meet the lighting illumination requirements for non-invasive spaces.

Task illumination and surgical lights shall be powered by critical branch (CEC 517.34(A)(1).

One or more battery-powered lighting units shall be provided in anesthetizing locations and shall be connected ahead of any local switches.

Nurse Call: Provide Staff Emergency station and Code Call station in all Imaging exam/procedure rooms and procedure rooms, including Endoscopy.

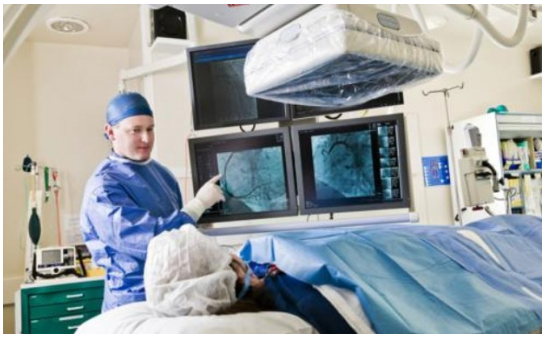
Handwashing: A handwashing station is required in the Class 2 Imaging Room (except where scrub stations are provided outside the procedure room in the semi-restricted corridor). Note that CPC Table 4-2 requires scrub sinks for some interventional imaging procedures.

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.

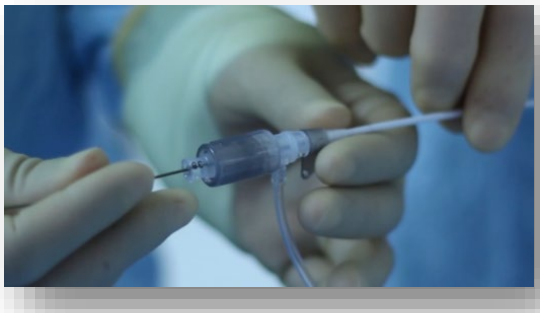
Support Areas: Pre/post-procedure patient care – a patient preparation holding and recovery area, or room, shall be provided and arranged to provide visual observation before and after the procedure with (1) Ox and (1) Vac, similar to FGI Phase-II recovery. Some procedures may require the support of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

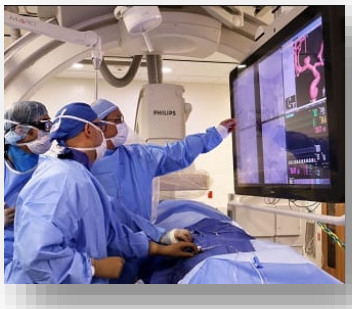
Specific Imaging Modalities

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.

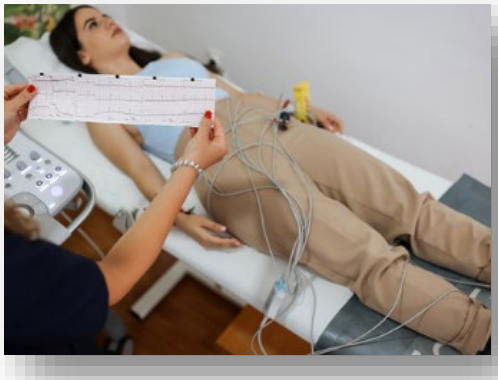


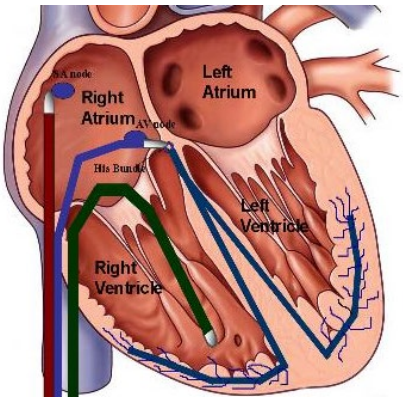
Interventional Imaging – Image-guided interventional procedures (also known as Interventional Radiology IR) shall be performed in suites in compliance with 1224.28.4 with a minimum clear dimension of 18 feet and allow a minimum clearance of 4 feet on all sides of the procedure table. Pre-procedure and 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 & 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.

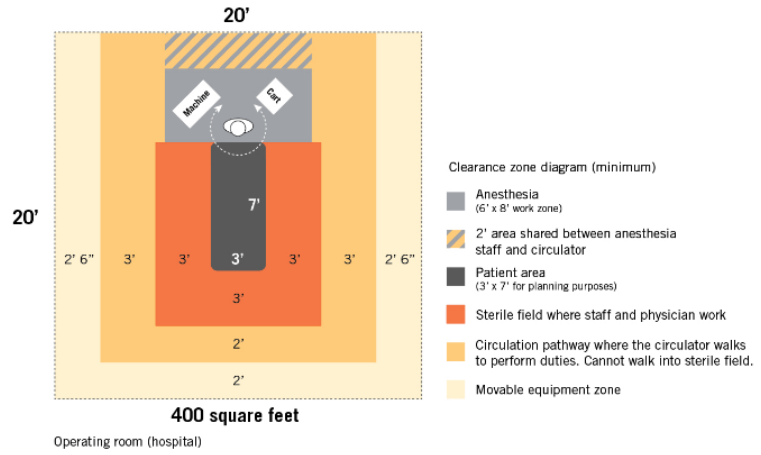
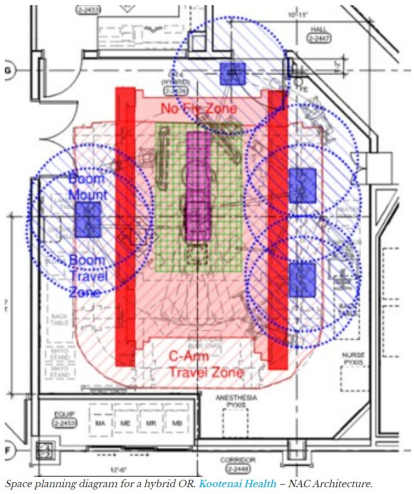


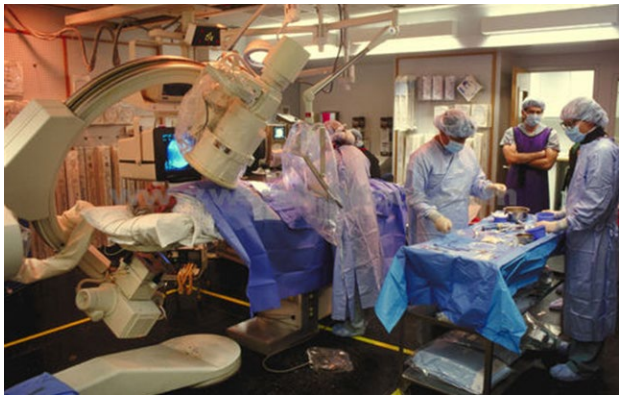
Figure 4



Space planning diagram for a hybrid OR. Kootenai Health – NAC Architecture.

VS

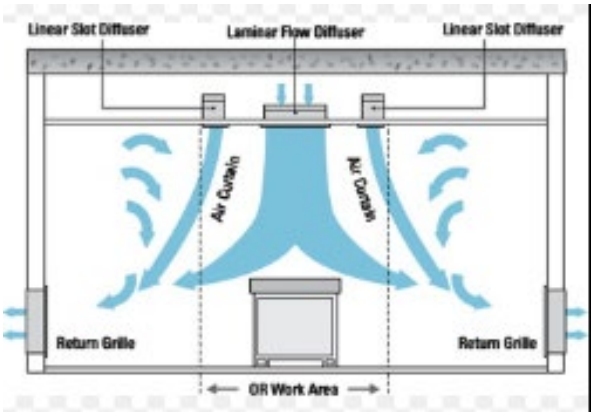
Surgical Team – Cardiothoracic surgeon(s) and Fellow(s)	**Perfusion Team** – Perfusionist (1 or 2)	**Echo Team** – Echocardiographer – Echo tech
Anesthesiology Team – Anesthesiologist – Nurse Anesthetist	**Interventional Team** – Interventional cardiologist(s) and Fellow(s)	**Nursing/Support Staff** – Scrub nurse(s) – Circulating nurse(s) – OR nurse(s) – Radiology tech(s)

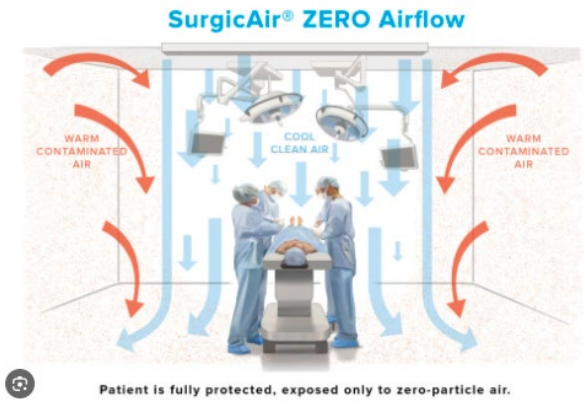


Room Type: Restricted Area – restricted interior finishes under Section 1224.4.11 and Tables 1224.4.11 and 1224.4.11.4a.

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.*

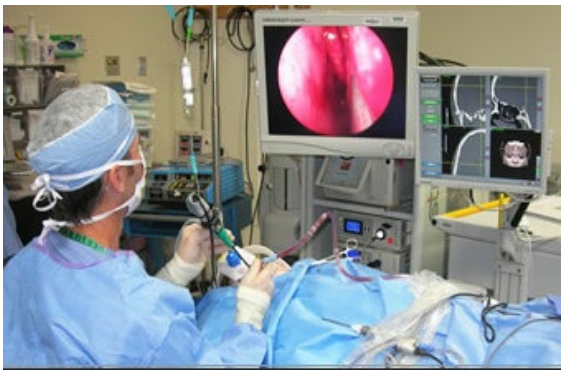
Ventilation: Non-aspirating laminar flow unidirectional primary supply diffuser array above the sterile field (12” beyond the width and length of the table) & low-level sidewall return air grilles with 4 OSA/20 total air changes per hour.





Pressure Differential: Positive relative to surrounding spaces.

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



Electrical: Operating Rooms and Hybrid Operating Rooms are Category 1 (Critical Care) Spaces. Each Operating Room and Hybrid 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. Fixed equipment will need to be circuited to the critical branch in Hybrid OR's. Equipment grounding and bonding will follow the requirements in CEC Article 517.19.

Operating Rooms and Hybrid Operating Rooms shall be considered to be a wet procedure locations unless a risk assessment conducted by the health care govering body determines otherwise. For wet procedure locations, provide isolated power systems or ground-fault protection for equipment within the patient care area. (CEC 517.19(F), 517.20 & 517.160).

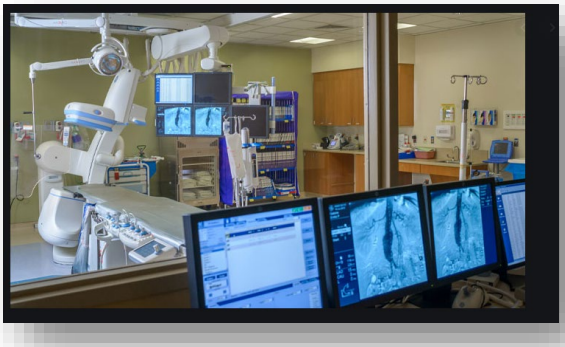
Lighting: See RP-29 for illumination level requirements. Note: Class 3 spaces should be considered as Invasive Procedure Spaces.

Task illumination and surgical lights shall be powered by critical branch (CEC 517.34(A)(1).

One or more battery-powered lighting units shall be provided in anesthetizing locations and shall be connected ahead of any local switches.

Nurse Call: Provide Staff Emergency Station and Code Call station.

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 phyiscally 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.

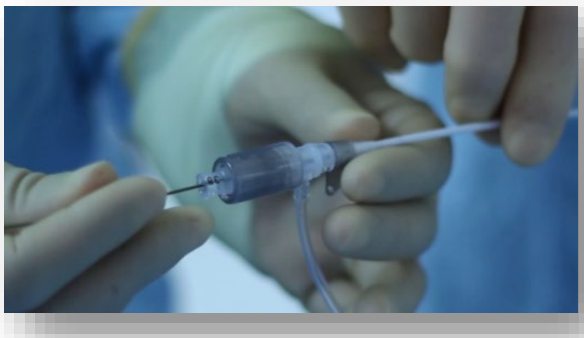
Anesthesia: Although specific procedures might not require deep sedation or general anesthesia, or even moderate sedation/anxiolytic medication administered under monitored anesthesia care that could result in administration of general anesthesia; all Class 3 Imaging Rooms must provide for possible administration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

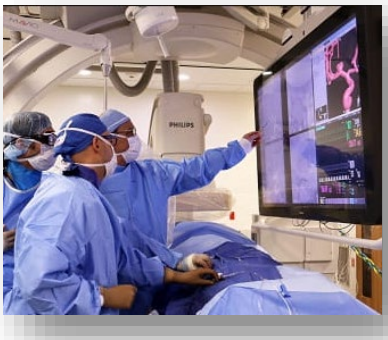
Pre- and Post-Operative Patient Care: The surgical service space shall be located and arranged to provide direct support from the anesthesia/recovery service space to the semi-restricted corridor with a common door to prevent nonrelated traffic through the surgical service space. The pre-procedure and 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 & 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.

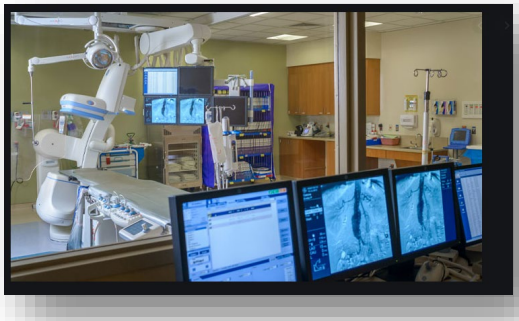
Specific Imaging Modalities

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. For 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 (CRA) as support for the use & 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.

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. A 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.

SECTION 10
RESPONDING TO A CONTINUUM OF IMAGING PROCEDURES

The introduction of “Procedure rooms,” and “Class 2 Imaging Rooms,” was intended to provide a middle ground between Class I Imaging Rooms (Exam/Treatment Rooms) and Class-3 Imaging Rooms (Hybrid Operating Rooms). However, three levels of environments is insufficient to respond to the variety of procedures performed. Additional flexibility needs to be provided in the imaging classification system. This flexibility can be provided by right-sizing the square footage requirements of an imaging modality and the environmental controls required by a class of procedures.

The Class 1 designation currently provides for different sizes based on modality. Diagnostic exams require a 100 square foot room, but treatment rooms require a minimum of 120 square feet. The caveat for providing adequate space per specific imaging modality remains in place, such as fluoroscopy, MRI, and CT scanning requiring more square footage. In all cases, the environmental controls remain minimal (exam/treatment level) and the space is considered unrestricted.

Similarly, the minimum space for Class-2 is equivalent to “procedure room” at 130 square feet, and additional flexibility is provided per imaging modality and procedure. If anesthesia is used, an additional 30 square feet is required at the head of the table, for a room total of 160 square feet. Cardiac Cath Labs (400 square feet) and Interventional Imaging (4’ clear on all sides of the procedure table with a minimum room dimension of 18’) also accommodate specific procedures needing larger spaces. Additional provisions are made for Cath Lab and IR suites which require specific staff traffic patterns and patient recovery spaces. Again, in all cases, the environmental controls are at the intermediate level (procedure room) and spaces are considered semi-restricted.

The Class 3 designation is intended to accommodate an open surgical procedure in a Hybrid Operating Room. Procedures that start as catheter-based procedures may convert to an open surgical procedure. For example, a trans-aortic valve replacement (TAVR) might be attempted using catheters in a nominal Class 2 environment but could require conversion to open-heart surgery. In this case the procedure should begin in the Class 3 environment if the likelihood of conversion to an open surgery, based on all contributing factors (facility’s experience, patient condition/screening, contraindications, etc.), exceeds a 5% threshold. The life-support staff and equipment (anesthesia/intubation and profusion) are already in the room and supporting the patient. The hospital needs to have cardiovascular surgery as a supplemental service on their license, and the procedure can continue in what is essentially a cardiovascular room under CBC Section 1224.28.1 *Cardiovascular and other special procedures*.

Likewise, the Class 2 and Class 3 Imaging Rooms must provide flexibility to respond to the continuum related to actual medical practice. Note that a Class-3 Hybrid OR currently requires a minimum size of 650 square feet. As mentioned above, this grew out of conversion of a catheter-based cardiac procedure to an open-heart procedure. There may be non-cardiac image-guided procedures that warrant an OR setting, but not

the size of a cardiovascular surgery. This can be addressed using the OSHPD submission requirements listed in Section 11. The room layout diagram (item 5) should be used to delineate the actual size requirement for the worst-case procedure proposed. The room layout diagram shall clearly show all the fixed and mobile equipment, casework, medical staff, and appropriate circulation space while maintaining the sterility of the environment.

There may be cases where a catheter-based procedure performed in a Cath Lab or IR suite may need the support of additional environmental controls, but not to the level of a Hybrid OR. In these cases, a Class 2 Imaging Room could accommodate those procedures, if the appropriate environmental controls and/or interior finish requirements are augmented to what would be considered a code-minimum Class 2 Imaging Room. Class 2 Imaging Room requirements are minimum requirements; providing environmental controls beyond the minimum is not prohibited. Certain procedures may warrant environmental controls beyond the minimum, yet not to the extent of a Class 3 room. For example, the use of General Anesthesia providing life-support in response to impaired ventilatory function might warrant a cleaner, more sterile, environment in a room sized to a particular procedure.

Any proposed augmentations would need to respond to the actual Clinical Risk Assessment of the procedures and mitigate the identified risks to an appropriate level. Proposed mitigation may need to include special protocols to offset cases where the built environment is not able to accommodate all augmentations. For example, a Class 2 Imaging Room could be enhanced with a laminar flow diffuser providing 20 air changes per hour, and monolithic interior finishes that are scrubbable and able to withstand disinfecting chemicals associated with terminal cleaning. However, the procedure room would remain a semi-restricted space.

Proposals of Imaging Room Classes, and the inclusion of any augmentations, must include careful consideration of the anticipated anesthesia services and life support measures required for the proposed procedures. Anesthesia services are addressed in both the 2024 NFPA 99 Health Care Facilities Code and the CMS Conditions of Participation. They are included here for reference.

Anesthesia Services

The use of, and variety of, anesthesia administration has evolved over the past few decades. Ether (very flammable) has all but been replaced by Nitrous Oxide as inhaled anesthesia. Additionally, anesthesia can now be administered via inhalation or IV through Monitored Anesthesia Care (MAC). Levels of sedation under either modality can vary.

2024 NFPA 99 Chapter 3 Definitions:

> **3.3.70.1 General Anesthesia**. A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive-pressure

ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

3.3.70.2 Deep Sedation/Analgesia. A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

3.3.70.3 Moderate Sedation/Analgesia (Conscious Sedation). A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

3.3.70.4 Minimal Sedation (Anxiolysis). A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

CMS Conditions of Participation

§482.52 Condition of Participation: Anesthesia Services

"If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital."

Interpretative Guidelines:

- The provision of anesthesia services is an optional hospital service
- If a hospital provides any degree of anesthesia services to its patients, the hospital must comply with all the requirements of this Condition of Participation (CoP)
- "Anesthesia services throughout the hospital (including all departments in all campuses and offsite locations where anesthesia services are provided) must be organized into one anesthesia service, under the direction of a qualified doctor of medicine (MD) or doctor of osteopathy (DO). Areas where anesthesia services are furnished may include (but are not limited to):
    - Operating room suite(s), both inpatient and outpatient;
    - Obstetrical suite(s);
    - Radiology department;
    - Clinics;
    - Emergency department;
    - Psychiatry department;

• Outpatient surgery areas; and
• Special procedures area (e.g., endoscopy suite, pain management clinic, etc.)."

Resource: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R59SOMA.pdf

Application

"General Anesthesia" (inhaled or IV) will often result in impaired ventilatory function and possible cardiovascular function, resulting in intubation and possible cardio/pulmonary bi-pass life support. This level of anesthesia will often be restricted to administration in an OR or Hybrid OR setting, depending upon the Clinical Risk Assessment of the procedure(s) anticipated.

"Deep Sedation" (inhaled or MAC) might require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. This administration would normally be administered in a Procedure Room or Class-2 Imaging Room, however some procedures may be more appropriate in a sterile environment, or even an OR or Hybrid OR setting, depending upon the Clinical Risk Assessment.

"Moderate Sedation" (inhaled or MAC), where patients do not require any intervention to maintain a patent airway and spontaneous ventilation is adequate, will normally be administered in a Procedure Room or Class-2 Imaging Room setting, depending upon the Clinical Risk Assessment.

"Minimal Sedation" (inhaled or MAC), where patients are normally able to respond to verbal commands, can easily be administered in an Exam/Treatment Room or Class-1 Imaging Room.

In all cases, it is the **Clinical Risk Assessment** that will address and document the procedure selection process and the proposed Imaging Room Classes. It will drive the assignment of the appropriate environmental setting (i.e. Exam/Treatment, Class-1 Imaging Room, Procedure Room, Class-2 Imaging Room, Operating Room, Class-3 Imaging Room). The level of sedation and modality of anesthesia administration will vary as appropriate. For example, Inhaled Nitrous Oxide might be minimal as in a dental operatory, or result in a total loss of consciousness, ability to maintain ventilatory function, and impairment of cardiovascular function, as in open-heart surgery. (Note that presence of piped Nitrous Oxide and Waste Anesthesia Gas Disposal (WAGD) is not a governing indicator of a procedure room type.)

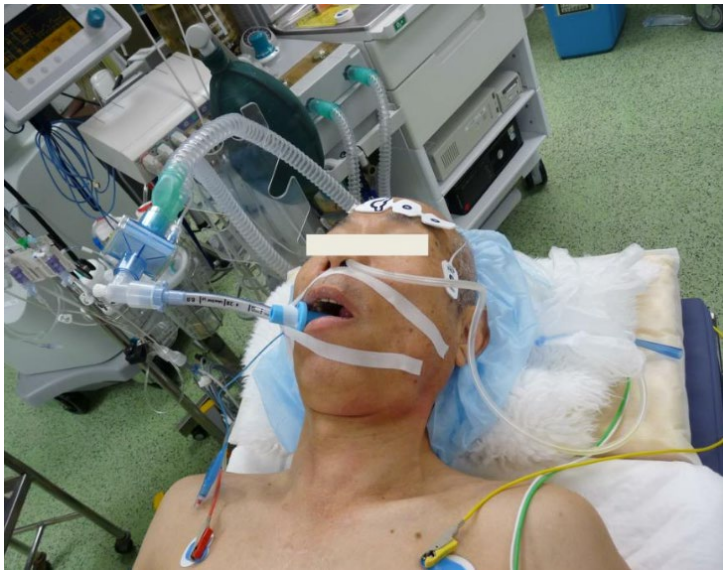
2025 CBC Table 1224.4.11-4a provides a simplified criterion for Operating Rooms & Class-3 Imaging Rooms to include "*any procedure during which the patient will require physiological monitoring and is anticipated to require active life support*." "Active life support" in this case is meant as advanced airway management such as endotracheal intubation and possible cardiovascular support. The criterion is supported by the definition of "Invasive Procedure" which includes those that do not begin as an open procedure but have a greater than 5% probability of requiring conversion to an open

procedure. The essential difference between Procedure/Class-2 and OR/Class-3 is the sterility of the surgical site to limit infection. While there is some correlation between an open surgical wound and the need for the patient to be in a deep sleep, pain free, and most importantly, immobile during the procedure, intubated patients do not necessarily need a sterile field.

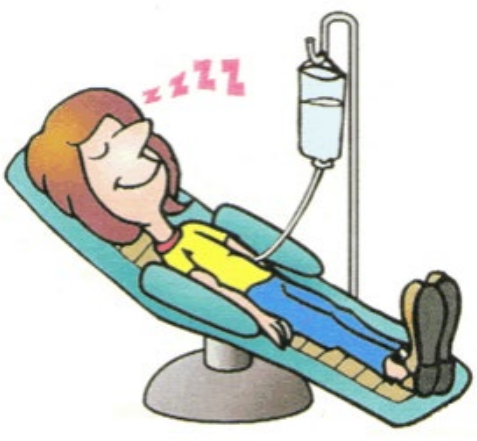
General anesthesia is now recognized as an imprecise metric for procedure room selection. For example, an ICU room housing an intubated patient has an equivalent sterility to a Procedure Room, not an OR. Rather than a prescriptive approach, the Clinical Risk Assessment can help determine the room classification. The Clinical Risk Assessment Team must include representation from the anesthesia team, but also the surgical/proceduralist team and the Infection Prevention Team to properly assess the relative risks of infection and mitigation/protocols necessary to justify the venue selection.

FGI is no longer using the definition of “Invasive Procedure” nor their simplified Tables 2.2-1 (exam/treatment, procedure and operating room classification) and 2.2-2 (classification of room types for imaging services). Appropriate assessment of the various procedures proposed, relative to the environmental controls required in support of those procedures, is far more complex than what can be covered comprehensively in a tabular format. The use of a Clinical Risk Assessment conducted by a Clinical Risk Assessment Team including representation from surgical, radiological, nursing, anesthesia services, and qualified infection preventionists(s) has now been introduced into the 2026 FGI Code for Planning and Design of Hospitals.

OSHPD is following this path as well. The Clinical Risk Assessment is intended to be shared with CDPH for confirmation/agreement for the procedure room/imaging room selection. The Clinical Risk Assessment will also communicate to OSHPD the considerations behind the base Imaging Room Class selection, as well as any necessary features required, to provide the most appropriate built environment for licensing. General Anesthesia usually requires intubation (active life support), but not always.



Monitored Anesthesia Care (MAC) usually does not include intubation, but might for deep sedation



SECTION 11
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. 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 & 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), there is no need to provide a list of procedures or a Clinical Risk Assessment. The project already is proposing the highest standard of environmental controls. For projects associated with Class 1, Class 2 or Class 3 Imaging Rooms, the Clinical Risk Assessment will help confirm the classification.

Provide a Clinical Risk Assessment (CRA) of all the proposed procedures considering the requirements for surveillance, prevention, and control of hospital acquired infection (HAIs) 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, & qualified infection preventionist(s) appointed by the governing body, and include facility management and the design team. 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.

The CRA Team should also verify that the CRA for the imaging project conforms with the various operational plans required to be continuously maintained by healthcare facilities' by CMS Conditions of Participation. The content of these plans will inform the CRAs themselves. Incorporating portions of these plans will assist in successfully communicating the intricacies of more complex and specialized CRAs.

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 3.0	June 2026	Third revision. A new Section 10 was added to the Guide to provide a path to “respond to a continuum of imaging procedures”. It is a clarification in nature and addresses how certain environmental controls can be added beyond the basic requirements for Class 2 Imaging Rooms that could address and respond to increased clinical risks associated with selected procedures without going to a Class 3 Imaging Room. It also clarifies the use of specific room layout diagrams to defend room sizes other than that required under CBC Section 1224.28.5.1.Electrical requirements shown in the Imaging Room Classifications under Section 6 through 8 have also been clarified.
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 clarifies 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.