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FPS Project Review Rule Advisory Committee July 17, 2024 1:00 PM - 4:00 PM via Zoom

RAC MEMBER ATTENDEES	
Aaron McGarry	GMA Architects
Barbara Hansen	Oregon Palliative Care & Hospice Association
Barbara Tauscher	Pacific Medical Practice Consultants, Inc.
Chris King	Fresenius Medical Care
Cindy Wagner	Salem Health
Danielle Meyer	Hospital Association of Oregon
Elaine La Rochelle	Grande Ronde Hospital
Janice Sanada	LRS Architects
Jeff Taylor	Providence Health & Services
Jeremy Stremme	Legacy Health
Jon Anderson	AD Architects
Jon Mehlschau	SRG+CannonDesign
Kelly Chanopas	ZGF Architects
Kristin Videto	Davita
Marcy Pierce	Asante
Matt Ottinger	JRJ Architects
Naomi Mathaba	OHSU
Sarah Kershner	PKA Architects
Scott Carroll	Good Samaritan Corvallis
Tim Clem	Oregon Society for Healthcare Engineering

Oregon Health Authority (OHA)/Department of Human Services (ODHS)		
Jerimiah Adams	ODHS – Nursing Facility Licensing	
Barbara Atkins	OHA-PHD-Facility Planning and Safety Program	
Lisa Humphries	OHA-PHD-Facility Planning and Safety Program	
Matt Gilman	OHA-PHD-Facility Planning and Safety Program	
Mellony Bernal	OHA-PHD-Health Care Regulation & Quality Improvement	
Patrick Young	OHA-PHD-Facility Planning and Safety Program	
Shane Jenkins	OHA-PHD-Facility Planning and Safety Program	

Welcome and Housekeeping

Mellony Bernal introduced self and welcomed attendees to this third rule advisory committee meeting to begin reviewing changes to OAR 333-071, 076 and 535 and recommended changes to FGI requirements.

- Given consideration of time, rather than roll call and introductions, attendees
 were asked to enter their name, title and organization into the Chat. Participants
 not considered a RAC member were asked to identify themselves in the Chat as
 a public participant.
- Attendees were asked to keep devices muted until called upon.
- RAC members were asked to type the word "Comment" to indicate they wanted
 to speak to a particular issue or ask questions. RAC members who did not want
 to talk but who wanted to share information were asked to type into the Chat
 "For the Record" and include the information they wished to share.
- It was noted that pursuant to the OHA policy, members of the public may attend
 but may not participate or offer public comment during the meeting. Members of
 the public who wished to provide comments or information were asked to email
 those comments to mellony.c.bernal@oha.oregon.gov or
 barbara.s.atkins@oha.oregon.gov at the conclusion of the meeting.
- It was noted that the RAC meeting would be recorded, and the recording and information shared in the Chat is public record and therefore subject to disclosure.
- Meeting notes will be drafted and shared with the RAC and posted on HCRQI's rulemaking activity webpage: http://www.healthoregon.org/hcrqirules.

Barbara Atkins noted that the RAC will begin discussing proposed amendments to the FGI standards which have been adopted for acute care facilities with the exception of freestanding birthing centers. The FGI standards have not been adopted for Oregon Department of Human Services (ODHS) regulated long-term care facilities, nursing facilities, residential care facilities, assisted living facilities and memory care endorsements. In a future meeting, the goal is to talk about hot topic issues previously identified to see if possible administrative rule language can be identified. B. Atkins indicated that any persons attending that represent DHS long-term care facilities or nursing facilities are welcome to stay for discussion or may choose to leave since the proposals being discussed will not impact them.

Administrative Rule Review

333-071 - Special Inpatient Care Facilities

The following rules are being amended as a result of legislation that has passed and to correct errors.

- OAR 333-071-0205 Special Inpatient Care Facilities (SICF) Definitions
 - o HB 4010 (2024) Physician Assistant to Physician Associate
- OAR 333-071-0215 SICF Application Review
 - o SB 556 (2023) On-site to in-person

- OAR 333-071-0360 Governing Body Responsibility
 - o HB 4010 (2024) Physician Assistant to Physician Associate
 - HB 3036 (2024) Physician Assistant and nurse practitioner privileges cleanup
- OAR 333-071-0400 Organizational Policies
 - o Reference error Change ASC to SICF
- OAR 333-071-0470 Patient Admission and Treatment Orders
 - o HB 4010 (2024) Physician Assistant to Physician Associate

OAR 333-071-0580 - SICF Physical Environment Requirements

For section (4), (6) and (7), it was noted that no changes are being proposed for SICF's classified as a freestanding hospice facility, substance use disorder treatment facility or religious institution.

For section (5), B. Atkins noted that FGI requirements for SICFs (and Extended Stay Centers (ESCs)) were finalized and filed before the FGI RAC had fully completed its work. As such, amendments that were made to FGI standards for an SICF classified as a rehabilitation hospital do not align with amendments made to changes specific to hospitals under OAR 333-535. The goal is to have alignment so that in the future only one rule needs to be amended that will apply to all hospital types. The proposed change points to the 333-535 rule for compliance. It was further noted that changes to rule that may result in a fiscal impact for an SICF classified as a rehabilitation hospital will be discussed under OAR 333-535 including handwash station requirements, worksurface areas and 96 hours of fuel in an emergency.

RAC members had no comments.

OAR 333-076 – Ambulatory Surgery Centers and Extended Stay Centers

OAR 333-076-1050 - Physical Environment: Appendix 1

It was noted that while CMS does not reimburse for services provided by an Extended Stay Center (ESC), Oregon law required the development of administrative rules for licensing of ESCs. There is currently one licensed ESC in Oregon.

B. Atkins remarked that the ESC rules include standards from both the Guidelines for the Design and Construction of Hospitals as well as the Design and Construction of Outpatient Facilities. It was noted that this amendment will require acoustic standards be met for patient rooms following the hospital standards. RAC member asked if <u>all</u> of the hospital acoustic requirements applied, or just for the patient room. B. Atkins responded only the patient room.

RAC members had no other comments.

OAR 333-535 – New Construction and Alterations of Existing Hospitals

OAR 333-535-0015 - Physical Environment

Section (1) removes dates that are no longer applicable.

Section (4) refers to standards from the FGI that are deleted. The following request was received from OSHE to add the following standards for deletion from the FGI:

2.1-5.1.2.2 (2)(b)(vi), 2.1-5.1.2.2 (3)(b)(v); and 2.2-3.11.8.3 – Documentation areas for decontamination room, clean workroom and scope processing Discussion:

- RAC member noted that there is no documentation occurring in these rooms.
- B. Atkins shared that typically they do not see complex sterile processing departments in smaller ASCs with one or two operating rooms; but will see large ASCs with multiple operating rooms with wall mounted computers which raises questions about use.
- RAC member commented that there is a difference between a work area (4 square feet) versus a wall mounted computer.
- Staff noted that it depends on the facility and perhaps language should be added that the facility needs to provide information on how the process works to ensure the correct standards are there to support the process. RAC member responded from a regulatory standpoint there should be no requirement.
- RAC member via Chat shared that typically a workstation is provided in the sterilization side only, not in decontamination or scope clean rooms.
- Staff provided scenarios including case carts, scopes, etc. If case carts used, then provide documentation area.
- Example of an ASC GI process shared. Documentation is not conducted in scope processing rooms.
- Several RAC members via Chat agreed that it should be at the discretion of the facility.

Section (5) - Amendments to FGI standards for hospitals:

1.1-3- Renovation

- Application of FGI to adjacent or related areas that are being renovated (similar to discussion that occurred under OAR 333-675). RAC members had requested more clarity, with specific and objective language. No language has been proposed at this time. B. Atkins asked if there were any additional comments.
 - Possible language such as "affected by project" or "only portion being altered or renovated" was shared and it was noted that FPS is not consistent or predictable. Subjective topic makes rule language difficult.
 - RAC member suggested allowing the facility to define what is affected by the project as part of the written narrative. Example: equipment replacement. B. Atkins noted that MEP may find insufficient air flow due to equipment replacement such as Xray or Cath lab.
 - Consider possible interpretive guidance versus rule language to allow for flexibility.

– Examples:

- Equipment change resulting in looking at housekeeping closet that does not meet minimum sq. footage based on previous standards.
 But no changes are occurring to the closet so it should not need to meet the new standard.
- Insufficient water for cooling or airflow due to equipment replacement that results in more heat.
- RAC member suggested language that may identify existing functions. If you have the existing function that is not going to be modified, it would not need to comply with revised standards.
- New FGI requirements related to Patients of Size are not fully understood and results in required changes to an existing room with an existing function. M. Gilman acknowledged issues around equipment and Patients of Size. If a facility is going to see Patients of Size using new equipment, then shouldn't the facility need rooms that works for Patients of Size?
- RAC member indicated when scope leaves the confines of the job boundaries and goes into other spaces is when owners may disagree with FPS staff that other areas may be affected.
- RAC member comments via Chat:
 - Where does the "affected by the project" end?
 - Renovations are related to the specific room and any MEP system modifications only.
 - Exclude EVS rooms because we are not going back to Soiled or Clean rooms as well.
 - Scope adds being seen are less about MEP and more about adding construction to other rooms, like toilet rooms, etc.
 - Past experience replacing an X-Ray machine; requirement to increase an EVS closet and enclose a waiting room.
 - The room is required to meet FGI and ASHRAE 170 even for equipment replacement. New equipment requirements need to be met otherwise the warrantee on the equipment would be voided. If the equipment cannot support Patients of Size, then why does any of this matter?
 - Agree spaces for Patients of Size should be included in the scope.

1.2-6.1.1 - Acoustic Design

OSHE has requested an amendment allowing documentation by a licensed acoustic engineer as acceptable equivalency in meeting the requirements of Table 1.2-5 NRC and Table 1.2-6 STC. Discussion:

- Applies to both NRC (how loud a room is) and STC (how much sound transfers through a wall).
- Staff commented about multiple projects where numbers are checked, and size
 of room/material don't match, and overall calculation doesn't meet minimum
 requirement. Questioned how measurements were calculated (on-site physical
 measurement with speakers and recording devices of actual sound made and

- recorded to show it meets STC values or computer program where they know construction material and spit out number.)
- System perspective need flexibility to address in many ways noise cancellation, wall types, etc. Need to retain flexibility on how to remedy.
- Oregon recognizes acoustical engineers as a technical profession.
- Acoustic reports treated similarly to how MEP treats close-outs, where a TAB (Testing, Adjusting, and Balancing) report is not needed, just final documentation at the end (reviewed, held professionally liable because they stamped or signed that it meets compliance.)
- Noise reduction calculations, including calculations, methodology and coefficients used, have often been a point of disagreement between designers and FPS staff.
 Concerns noted about outdated standards.
- Several RAC members expressed agreement that if approved by someone who is a professional, it should be adequate.
- Comments by RAC member Chat:
 - Agree with the recommendation to accept acoustic engineer's documentation of compliance;
 - As long as it meets FGI requirements;
 - Hospitals need to know that this would be additional cost.

2.1-2.3.1.1 - Patients of Size

Per request from OSHE, the need for serving Patients of Size should be determined by the facility and documented in the functional program. PKA requested that a demographic threshold or similar metric be identified. The following amended language is proposed: "All patient care areas designated for care of Patients of Size shall meet the requirements in this section only when specifically cross-referenced from a FGI facility type requirement section. Built Environment compliance will otherwise not be reviewed by FPS." Discussion:

- B. Atkins noted for facilities making accommodations, they must still comply with requirements, but FPS will not review. It was further noted that FPS will only regulate and enforce Patient of Size requirements under emergency departments, bariatric care units and pediatric bariatric care units.
- Question posed by RAC member via Chat, "This would address in the functional program narrative or not?" B. Atkins responded that the proposal means it would not need to be addressed.
- RAC member via Chat asked what is that threshold 5%, 10%?
- In terms of putting responsibility back on facility, RAC member asked whether the design team would still need to determine there is an agreed upon threshold, will Patients of Size be defined? B. Atkins responded that if hospital group says Patients of Size will be served, it is expected that the design team and hospital will work together to find the appropriate accommodations for such persons.
- RAC member asked how the PHAMA should be completed? B. Atkins noted that the PHAMA can reflect that Patients of Size will be served, but FPS will not review unless it's an emergency department or bariatric care unit.
- RAC member via Chat indicated they are okay with the FPS amendment.

- RAC member asked and staff reiterated, if Patients of Size are being served, design teams/hospitals must review and comply with the FGI requirements and make accommodations. FPS will only review emergency departments and bariatric care units. If a complaint is received, it is incumbent on the facility to have complied and could be cited for failure to comply.
- RAC member asked whether there is a need to align how facilities are defining Patients of Size? Patients of Size are not just bariatric patients, but patients below that range. It is trying to create better access and safer environments for an underserved population. B. Atkins noted that the 2022 FGI changed language to "Persons of Size" which includes family members and caregivers and thus affects waiting rooms, lobbies, toilet rooms, etc. Staff will research whether the 2026 FGI is proposing a definition.
- P. Young asked RAC member whether consultants have been used to consider Persons of Size versus typical ADA accessibility. RAC member responded that consultants have not been used for this demographic at this time.
- RAC member asked whether it's up to the hospital to determine definition of Persons of Size? M. Gilman responded Yes. RAC member expressed support that the hospitals have the flexibility to define.
- RAC member shared concerns about critical access hospitals where there may be
 a restroom that is ADA compliance but conflicts with standards related to
 Patients of Size. There is often push back from small hospital systems and
 getting physicians on same page with design teams is difficult. RAC member via
 Chat agreed.

2.1-2.8.8.1 - Lighting

PKA proposed having the lighting level requirements be measured specifically at the work surface rather than the entire room. Current requirements make spaces overly bright in order to achieve 100 FC at every location in the room. Discussion:

- FPS staff commented on task lighting in medication safety zones where lighting levels are specified by the U.S. Pharmacopeia. The USP notes that task lighting is required at the medication safety zone cart. If using a cart and there is not enough lighting from room, the task light must live with that cart. The task cart is basically the work surface so it would be logical to assume the work surface in a room. It was further noted that because liquid medications can be measured over the sink, lighting level is measured at the sink as well.
- Medication safety zone usually includes the work surface, cart, hand washing station and Omnicell and where lighting is required. It was questioned whether any change in wording was needed based on interpretation.
- RAC members were asked whether to include reference to the sink in the
 proposed language. RAC member asked does that mean over the sink, directly
 over the Omnicell which is not where someone stands to use it, is a defined area
 needed? To what extent does the 100FC need to be measured in order not to
 introduce eye strain because it's overly lit at numerous locations?
- RAC member via Chat commented, "Are they preparing in the sink? It is just for handwashing." "We need a pharmacist to determine if any mixing is occurring in

- the sink." It was further noted that information from a professional should be considered.
- RAC member via Chat indicated, "Work counter lighting is easier to achieve as task lighting can be provided. Casework can often shade the work surface if we rely entirely on standard lighting in the room, not to mention increasing lighting to excessive levels."
- RAC member indicated that lighting requirements should be applied to the worksurfaces that are identified by the facilities where only medication preparation is occurring by pharmacy personnel. (Not the Omnicell, not the handwashing station.)
- FPS staff noted that the standard does not apply to just pharmacies but anywhere where there is a Pyxis or Omnicell or Med Prep room where people will work. We need to think about how people do things and where to determine what counts or not.
- RAC member via Chat indicated that a Pyxis or Omnicell are dispensing only.
- RAC member expressed concern that the discussion is trying to break down to
 defined areas and doesn't apply to nurse who gets injectable medication from
 Omnicell, takes medication into patient room and draws from syringe to get
 proper dosage. Becomes another situation that is hard to review; irrelevant.
 Staff noted that medication safety zones are defined by the hospital. If hospital
 staff are drawing up medication in the room, there should be a cart with
 appropriate lighting. If no carts, then there needs to be a defined space in the
 room as medication safety zone. RAC member disagreed.
- B. Atkins stated that the USP defines a medication safety zone as "any critical area where medications are prescribed, transcribed, prepared and administered."
 RAC member stated via Chat that the term critical would need to be defined.

2.1-2.8.8.2 (1) and (2) – Medication Preparation Room and Medication Dispensing Units

PKA has proposed having more clear definitions for medication preparation rooms and medication dispensing units, stations and carts. They propose one is a room where preparation is occurring, and the other is a stand-alone dispensing unit where pre-mixed; dosed; etc. drugs are dispensed to patients. Existing language makes this distinction, but enforcement is inconsistent. FPS proposed definitions were noted. Discussion:

- RAC member stated that FGI doesn't make it clear that the option is (1) versus

 (2) and comes to play in imaging rooms where there is no preparation and
 refrigerator is not needed. Facilities need to more clearly state in their narratives
 which option is being used and why.
- RAC member via Chat indicated that section (1) only addresses medication prep, not administration. Administration is only listed in the section header.
- RAC member asked, for medication dispensing whether it is just to provide more lighting to be able to read the label, otherwise it is unclear why this requirement is needed at the dispensing location. FPS staff noted that the USP refers to light being both at preparation and dispensing areas. Studies indicate that even a few foot candles of extra lighting reduce medication errors.

- RAC member asked whether a specific size for the area needs to be defined? B. Atkins noted that existing FGI standards require worksurfaces to be a minimum of four-square feet. In terms of dispensing units, medication safety zone language indicated that were a cart or unit is provided, there shall be adequate space for such equipment.
- RAC member agreed with clarity on option (1) or (2) and gave example of medical refrigerators having to be added to rooms that don't need them. Need to allow facilities to be the vehicle of determining when a medical refrigerator is needed, not FGI.
- Staff noted that in some projects, it is disclosed that there will be a medication preparation room that also has a Omnicell or Pyxis which results in reviewing both (1) and (2) requirements. If was further noted that medication preparation rooms clearly fall under section (1) and if an Omnicell is used, it falls under (1)(b)(iv). If the requirement of section (1) is met, then the requirements of section (2) are also met. RAC member concurred via Chat.
- RAC member indicated that they have Medication Prep rooms that have both
 work surfaces and Omnicells or Pyxis. There are some areas where there may be
 just an Omnicell (Cath lab, clinic) and want the option of just meeting section
 (2). FPS staff noted that this has been seen and the question that needs to be
 answered is it preparation or just dispensing?
- Example of exam room shared that is NOT considered a medication safety zone
 just because a flu vaccine is being administered that was pulled from an
 Omnicell in a clinic. It is not a 'critical area.' FPS staff noted that FGI has defined
 medication safety zone which is very similar to USP. It was suggested that the
 FGI definition be retained. Question was raised whether "critical area" refers the
 medication safety zone being a critical area or medication safety zones only
 happen in critical areas such as a critical care area.
- RAC stated the desire is to get clear actionable direction from FPS. If medication
 is traveling to different areas and it becomes a medication safety zone, than
 clear language must be added to describe. If the code is not being defined in a
 way that allows for anticipating the variables of a care team, making an entire
 room 100FC, is not balancing wellness of patients.
- RAC member via Chat indicated we need to think about the intent which is adequate lighting where needed. The facility narrative determines where the zone is to be located. RAC members agreed via Chat.
- It was recommended that the definition of medication administration be removed and focus on dispensing and preparation which will focus on sections (1) and (2) of the room. RAC members concurred via Chat. RAC member stated that besides being mentioned in the header, there is no further mention about medication administration anywhere. It should be removed or clarified.
- Aligning intent and having specific language that defines the rules and requirements is very difficult. The only vehicle to provide adequate lighting is 100FC at the worksurface. A rule stating must provide adequate lighting is very different than adequate lighting defined as 100FC. RAC member concurred via Chat.

- Additional RAC member comments via Chat:
 - Does a Lab have the same lighting requirements for lighting for blood draw? Staff responded that labs do not require 100FC.
 - We get too hung up on the 100FC number.
- Areas of concern for medication administration Imaging with PET (direct injection in vein); ability for certain patients to have their multidose vials in room with them (diabetics).
- RAC member indicated it would seem that the overall intent is to reduce medical errors, which the FGI has a whitepaper. The 1066 USP, Table 1, the 100FC is 'recommended.' RAC member indicated via Chat, it is a recommendation not a requirement. FPS staff further clarified that FGI made it a requirement by stating USP recommended levels shall be used.

2.1-2.8.8.2 (1) - Medication Preparation Room

PKA has asked whether indirect observation could be considered. The proposed language change indicates, Medication preparation room (a) This room shall be under direct or indirect (i.e. camera) visual control of the nursing staff. Discussion:

- RAC member asked, "who monitors the camera?" RAC member asked about other stations besides a nurse station. Possible language offered included adding (i.e. camera, monitored from a nurse or staff station).
- RAC member remarked that the pharmacist should be consulted since this is about medication preparation.
- RAC member suggested, "monitored camera" instead.

2.1-2.8.8.2 (1)(b)(iii) - Lockable Refrigerator

PKA provided comments on the locking refrigerator requirement and noted that imaging rooms are often enforced under section (1) which requires a refrigerator; however, many times these rooms do not store refrigerated drugs. FPS suggested amending as follows: "Lockable refrigerator where refrigerated medications are used." Discussion:

• RAC members agreed via Chat.

2.1-2.8.8.2 (2)(c) - Handwashing station

PKA suggested allowing for handwashing station OR hand sanitizer. B. Atkins noted that the 2018 FGI Inpatient Hospital standard requires a handwashing station whereas the Outpatient standard allows either a handwashing station or hand sanitizer. This is how the standards were published and is not an Oregon specific amendment. Discussion:

- Some medication safety zones are in the sterile core of a surgical suite and open plumbing shouldn't be in sterile core. Proposed language states that a handwashing station shall be located next to stationary medication-dispensing units or stations unless the medication-dispensing unit, station or cart is located within the restricted or semi-restricted areas of a surgical suite then a hand sanitation dispenser is acceptable.
- FPS staff noted that semi-restricted areas allow for handwash stations as that is
 where scrub stations are also located. If a medication safety zone is semirestricted than it should be required to have a handwashing station. It was noted
 that 'semi-restricted' by definition is how someone accesses an operating room
 so the sterile core must be semi-restricted.
- Several RAC members via Chat agreed with recommendation to allow hand sanitizer at dispensing machines.
- RAC member asked RAC thoughts on how to balance infection prevention risks where there are other concerns pushing back.
- RAC member noted that language is pulled from FGI 2022 where this change was made but is not currently allowed by OAR. Grande Ronde project was shared as an example working with infection prevention staff. Scrub sinks are in a semi-restricted corridor on patient entry to operating room, but on the sterile core side between the operating room and central sterile processing, is the type of area where, if a medication zone, where hand sanitizers can be used. Infection prevention staff and nurses are adamant that a sink should not be in this area. There is currently a sink, but staff want it gone due to infection prevention.
 - Staff noted they will verify 2022 FGI language to ensure alignment if change is made if there is discussion about the areas that qualify for the omission, that should also be referenced.
- RAC member via Chat indicated agreement with scrub sinks at the entry into the restricted area and asked can we consider a minimum distance to a hand washing sink or use the scrub sinks?
- B. Atkins shared example of an ASC project that had decentralized nurse stations and wanted to use the scrub station as their handwash station. CMS ASC surveyor reported back 'bad idea' in order not to distract staff that are scrubbing in for a surgery.
- Clean core in a surgical facility is not on the scrub side.
- RAC member questioned via Chat remove semi-restricted and change to sterile core?
- RAC member via Chat asked do we need to restrict this to "of a surgical suite?"
- RAC member stated via Chat that it would be nice to keep it less restrictive we will have Omnicell machines in an operating room or Cath lab and do not want to put handwashing sinks in them.
- RAC member asked whether the sterile core is considered a semi-restricted or restricted space? If it is restricted, no sink can be in there. B. Atkins responded that terms are defined in surgical rules, and one definition for restricted, such as an operating room, indicates 'you shall enter the operating room from a semirestricted area.' That definition forces the clean core to be semi-restricted,

unless the clean core only serves one operating room, then it can be restricted since it is part of the operating room function.

2.1-2.8.14.2 - Environmental Services Room

It was noted that when making amendments to the Outpatient Book to require the EVS room be 35 square feet, it was inadvertently left out of changes from the Hospital requirements. This change aligns Hospitals with Outpatient requirement. Discussion:

• RAC member concurred.

2.1-4.1.2.6(1)(a) - Terminal Sterilization

B. Atkins noted that the FPS program completed a high-level review of the 2026 FGI draft standards and staff are proposing an amendment now to avoid additional waiver requests for the current lab rule that requires terminal sterilization where biohazardous waste is generated. The 2026 edit allows a vendor to dispose of the waste without needing to sterilize first. Discussion:

- RAC member asked if a vendor can come in and pick up non-terminally sterilized samples than why can't hospital staff to do it. It was noted that they trust the hospital to care for the waste in such a manner that a vendor can pick up to incinerate.
- This is only in regard to labs. There are no other rules in place for other areas.

2.1-4.2.3.1 - Pharmacy Sterile Workroom

PKA requested change from current requirement that medication safety zones are required to have an NRC of .15 as within compounding pharmacy clean areas, communication primarily occurs within the electronic medical record system. It was noted that the 2026 FGI draft standards has proposed to amend stating "Pharmacy clean/sterile compounding rooms (meet the definition of medication safety zone) are not required to meet NRC compliance in this table." As such, the proposal is to align with the 2026 proposed FGI standard. Discussion:

- RAC member asked what the reason is for referencing the anteroom in the proposed language. B. Atkins responded that the anteroom overlaps with requirements where a handwash station is required.
- RAC member indicated that they would also like the NRC requirements for the anteroom not to be enforced.
- Staff will consider further what requirements apply to the anteroom.

2.1-7.2.2.8 - Marine-grade Substrates

The proposed change is to require only newly constructed or newly installed countertops to have a marine-grade substrate. It was noted that replacing the existing standard in good condition is a financial hardship and unreasonable.

• RAC member did indicate that at a minimum existing countertops needs to be fully sealed and caulked.

2.2-3.3.2.1 - Procedures Rooms

B. Atkins noted that FPS is proposing an amendment that specifies procedure rooms when accessed from a semi-restricted area or when used for endoscopies where a

monolithic ceiling is provided need not comply with Table 1.2-4: Minimum Design Room-Average Sound Absorption Coefficients. Discussion:

- B. Atkins asked should it be all procedure rooms or just endoscopy rooms? 2026
 FGI draft standards propose to amend Table 1.2-4 with a footnote 6 and 7: (6)
 Endoscopy procedure rooms are excluded from this requirement. (7) Special
 patient care rooms that require all solid surface finishes (e.g. airborne infection
 isolation room) are excluded from this requirement."
- RAC member asked whether it would just apply to procedure rooms or also Class 2 imaging rooms?
- M. Gilman responded that when infection control conflicts with noise reduction there is a waiver request. Perhaps change to any room that requires a hard lid because of infection control should be exempt.
- RAC member inquired whether the text should be changed from "where monolithic ceiling is provided" to "where monolithic ceiling is required."
- Staff member noted that monolithic is not required in endoscopy and Class 2 but is often provided. RAC member noted that if infection prevention states it is needed, then NRC should be waived.
- RAC member suggested stating, where required or provided.

Next Meeting

The FPS Project Review RAC is scheduled to meet again on August 28, 2024 from 9 a.m. until Noon. A reminder email with the Zoom link will be shared.

M. Gilman thanked RAC members for their participation and engagement in the process.

Meeting adjourned at Noon.