Formal Interpretations

***Guidelines for Design and Construction of Outpatient Facilities* 2022 edition**

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

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

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

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

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

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

REQUEST

Guidelines edition: **2022 Outpatient** *Paragraph reference:* **2.1-3.5.8.19 (2)(b)**

2.1-3.5.8.19 Facilities for processing ultrasound probes. Where cleaning and high-level disinfection of ultrasound probes are performed in a dedicated room or area outside of a central sterile processing area, the following requirements shall be met:

...

(2) Where ultrasound probes are processed at the point of use or in a separate room or area using a self-contained, automated high-level disinfection unit specifically designed for ultrasound probes:

(a) Space for the device with access to an electrical receptacle shall be provided.

(b) Access to a soiled workroom with an instrument-washing sink shall be provided in the same clinical area to support probe decontamination when necessary.

Question: If a self-contained unit (Trophon) is used for probe decontamination, is a soiled *workroom* required or does the "when necessary" language in 2.1-3.5.8.19 (2)(b) mean it is up to the health care organization to decide whether or not a soiled workroom is provided? Specifically, can a soiled *holding room* be provided instead of a soiled *workroom*?

Response: Where ultrasound probes are processed in a separate room or area using a self-contained, automated high-level disinfection unit specifically designed for ultrasound probes (such as a Trophon), the requirements in (a) and (b) apply; space for the device with access to an electrical receptable shall be provided and access to a soiled workroom with an instrument-washing sink shall be provided in the same clinical area. *A soiled workroom is required.*

Further comments

Vice president, plant services/facilities: The soiled workroom includes a sink, which is necessary in the decontamination process for the probes, even if a Trophon is used. The sink is used to wash bulk material from the probe. "When necessary" refers to when high-level disinfection is necessary, not whether the health care organization decides to include a soiled workroom. High-level disinfection triggers the requirement for the soiled workroom.

Authority having jurisdiction, state plan reviewer: These self-contained, automated high-level disinfection units are not plumbed, so any biological material that is on the probe could not be disposed of in that unit; therefore, the probes should be cleaned, when necessary, prior to being placed in the unit.

Engineering program manager, state department of health: The term "when necessary" refers to occasions when probes must be cleaned in an instrument-washing sink before high-level disinfection. Therefore, the minimum requirement is an instrument-washing sink in the same clinical area as the Trophon. Instrument-washing sinks are generally found in a soiled workroom and not a soiled holding room.

Manager of infection prevention and control: IPC (infection prevention and control) guidelines recommend use of a probe cover with probes that will require high-level disinfection. The probe still needs to be cleaned, but generally the cover prevents gross contamination of the probe that would require a soiled workroom to remove remaining bioburden. As well, other guidelines describe means for transporting probes when and if a soiled workroom is needed. In other words, there are options when a soiled holding room would work as long as staff have access to a soiled workroom somewhere in the same clinical space. Which type of room is chosen needs input from frontline staff or clinicians who are using the space and performing the procedures. In the ultrasound area, they might have a soiled holding room; however, there needs to be a soiled workroom readily accessible (e.g., in the imaging department) to support probe decontamination when it's necessary.

Authority having jurisdiction, state plan reviewer: Probe decontamination requires provision of a soiled workroom with a sink suitable for instrument-washing (e.g., utility sink), not just a soiled holding room. The Trophon unit produces water as a byproduct "that can be disposed of in a sink" per the manufacturer's website. The appropriate fixture for such disposal is an instrument-washing sink, either in

an ultrasound probe processing room or in a soiled workroom. There should not be any temptation to use (and contaminate) a handwashing station. “When necessary” means probe disinfection is not necessary after every procedure, but it is required at times; therefore, the soiled workroom shall be provided.

Assistant director, design and construction: A soiled workroom with an instrument-washing sink is mandatory. It may not be necessary to use the instrument-washing sink for every case. Saying that, provision of a soiled workroom specifically for ultrasound is not necessarily required. It shall be provided, but it can be in the same clinical area. It may only be required if the probes are being processed at the point of use or in a specific room solely designated for ultrasound probes as stated in 2.1-3.5.8.19 (2). Even so, staff need access to a soiled workroom in the same clinical area. If the ultrasound room(s) in a facility are in the same clinical area as other modalities that require a soiled workroom and that room can be accessed by ultrasound staff, a soiled holding room may be provided, if necessary, operationally.