Lindsey B. Amerine, PharmD, MS, BCPS, FASHP

Director of Pharmacy
UNC Health

Preparing for Cleanroom Inspections

As guidelines for cleanrooms continue to evolve, enforcement of these safety guidelines has also increased. Within health systems and hospitals, sterile cleanrooms are a primary focus of regulators' reviews. During a 2019 Joint Commission visit, one of the four primary areas of focus throughout the hospital was sterile cleanrooms. This means that pharmacy represented 25% of the overall survey concentration. In order to ensure the standards are being met, it is important for pharmacy leaders to conduct internal mock surveys, maintain appropriate documentation, and address the importance of compliance standards in their cleanrooms.

Determine Baseline Compliance

Prior to performing a mock survey, area managers or leaders must understand the regulations and determine baseline compliance. Some state boards of pharmacy, such as North Carolina, provide their inspection checklists online; using these checklists is beneficial, as they comprise the same forms that the state inspectors will use.[1] Facilities can also build their own gap analysis if their state does not provide a checklist, or in the event that new standards have been published but are awaiting adoption by the state board (see the **TABLE**).[2] These forms can be completed by the area manager and saved to a central

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repository. If it is unclear whether compliance has been fully or partially achieved for a given item, err on the side of caution by logging the lesser compliance attained. Full compliance should only be documented if the item is known to be compliant and this can be supported with documentation.

Conduct a Mock Survey

A primary goal of mock surveys is to ensure compliance by identifying areas that need improvement, and resolving any issues prior to an outside inspection. Further, mock surveys are a useful internal control to validate the area manager's assessment of compliance. Establishing a routine timeline of mock inspections ingrains into the culture the expectation of continual survey readiness. The survey should include a thorough walkthrough of the area, a review of certification reports with the area leader, and observation of staff as they compound.

The mock survey should be completed by an individual who is knowledgeable about the standards but works in a separate area. Consider utilizing an operations manager from a different pharmacy area, a medication safety officer, or one of the institution's accreditation leaders who report outside of pharmacy. It is important that the surveys be conducted with the understanding that no leader will be punished or receive a poor evaluation if there are areas of partial or noncompliance. In addition, a constructive approach needs to be taken to ensure that results are reported accurately. For example, if operations managers are not able to provide constructive criticism to their peer for fear they may receive the same or worse criticism when their respective area is reviewed, it is recommended to have an outside party conduct the survey.

Document Results

The mock surveyor is tasked with documenting all items witnessed and discussed. A summary of those items with partial or noncompliance is created and shared with the area leader and senior pharmacy leaders. The area leader can then use this information to build an action plan with timelines in order to improve any deficiencies. A follow-up report can be embedded into regular pharmacy leadership meetings; further, consider incorporating these reports into the institutional accreditation meetings to help gain buy-in from the institution's senior leadership. This is especially helpful if capital investments or other institutional funding is required to resolve an issue identified in the mock survey.

A common trait among pharmacy leaders is the desire to preserve pharmacy's positive reputation and handle issues without notifying external departments, such as accreditation. However, refraining from sharing mock survey findings could lead to poor results from a surprise external survey. Collaboration and transparency are crucial to achieving full compliance with compounding standards. Establishing a nonpunitive, solution-oriented culture is key to ensure that staff are comfortable in reporting problems as they arise.

Preparing Staff for Surveys

With an increased focus on sterile preparations, staff members must be prepared for a surveyor to observe and evaluate their aseptic technique while compounding. Incorporating this step into the mock surveys will help staff become more comfortable during the live survey. Staff members should be familiar with the facility's sterile compounding Policies & Procedures and know where to locate them. During the inspection, the work in the cleanroom should continue as normal, as halting production due to a surveyor's presence would be counterproductive to patient care. Those staff members that surveyors ask to observe should take the time to answer the surveyors' questions and explain their usual compounding practices. However, as with any survey, if an answer is unknown, staff should be comfortable referring to their manager for assistance, rather than guessing in response to the surveyor's question.

Preparing for External Surveys

Surveys of sterile cleanrooms may be conducted by the state board of pharmacy, hospital accreditation body (eg, Joint Commission or DNV), and the US Food and Drug Administration (FDA). While most organizations have not had the FDA survey their site, the FDA reserves the right to do so; however, this article's focus is on the more common surveys by state boards of pharmacy and hospital accreditation organizations.

As mentioned, state boards of pharmacy may make their compliance document available online; using this as a tool to support compliance efforts is often the best way to ensure a successful visit. In the case of newly published standards, such as USP Chapter <800>: *Hazardous Drugs—Handling in Healthcare Settings*, institutions will need to build their own compliance documents to ensure

compliance prior to enforcement of the new standards. In addition, pharmacy must understand the remediation plan the board of pharmacy will expect if compliance is not achieved. For example, a state board of pharmacy may shut down a compounding location if any contamination is found; that site may not be allowed to re-open until retesting is conducted that confirms the absence of contamination.[3]

Like the state boards of pharmacy, the accreditation bodies are increasingly focused on cleanroom compliance. Surveyors are typically highly experienced pharmacists, and even non-pharmacist surveyors are appreciably more knowledgeable of the standards. In one recent accreditation visit, the institution had both a physician and a pharmacist surveyor. They conducted walkthroughs of each sterile compounding facility, including off-site locations, and they completed gowning and garbing to enter each sterile cleanroom. The surveyors watched staff prepare products in real time and assessed their compliance with the facility structure inside the cleanroom suite. After the physical review, the surveyor reviewed the biannual certification reports with the pharmacy director and each area manager. For any contamination event, the surveyor requested documentation of the remedial cleaning and retesting conducted to show the issue was fully resolved. In cases where surface contamination was noted on two consecutive visits, the surveyor requested the past 4 reports (2 years' worth) to identify how long the issue had persisted. This request occurred even though the problem area had been cleaned and subsequently retested, showing no contamination.

The sit-down review process comprised one and a half days of the accreditation survey. The depth of the survey highlights the importance of involving senior pharmacy leaders in the process to drive survey readiness.

TABLE

Sample Checklists for Mock Survey

Use these sample checklists to conduct a mock survey. Note: this list is not all-inclusive; a full survey will include additional areas of examination.

Courtesy of Elissa King, PharmD, MS, BCPS; Clinical Manager, UNC Medical Center.

	Compliant			
Requirement: Facility Design	**Yes**	**No**	**N/A**	**Comments**
PEC ISO 5 in non-controlled room (segregated) 12-hour BUD only (low-risk only).				
CAI and CACI placed in an ISO 7 buffer area, unless ISO class 5 is maintained during dynamic operations; transfer of ingredients during compounding preparations.				
PEC ISO 5 located in buffer with ante-room (solid walls); buffer maintains ISO 7.				
Pressure differential 0.02-0.05 between rooms; must have magnahelix or pressure gauge and document daily.				
PEC ISO 5 located in buffer without ante-room; must have 40 FPM or 0.2 meters/second airflow across line of demarcation (need meter). Only low- and medium-risk compounding allowed. Needs to be documented.				
No ledges.				
Buffer area is well lighted.				
Maintains a comfortable temperature.				
Pre-sterilization area with powder containment hood for high risk compounding (weighing and measuring) must be ISO 8 with 20 ACPH. **Note:** Must be fully garbed and gloved; garbing and gloving must be changed prior to entering ISO 7 cleanroom. Cannot be in buffer.				
Only the furniture, equipment, supplies, and other materials required for the compounding activities are brought into the area, and they are nonpermeable, non-shedding, cleanable, and resistant to disinfectants; before such items are brought into the area, they are cleaned and disinfected.				
Wall to floor coved or caulked to avoid cracks and crevices where dirt can accumulate.				
Buffer area has no sink or floor drain.				
Cleanroom-grade ceiling tiles are impervious.				
Ceiling tiles are caulked (**Note:** no gaskets).				
Carts are stainless steel wire or solid shelving with cleanroom casters.				

TABLE

Sample Checklists for Mock Survey (continued)

Requirement: Facility Design	Compliant: Yes	No	N/A	Comments
Storage shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, non-shedding, cleanable, and disinfectable; their number, design, and manner of installation promotes effective cleaning and disinfection.				
The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices and non-shedding; the surfaces are resistant to damage by disinfectant agents.				
No cardboard within the buffer or ante-room.				
Storage is kept to a minimum.				
Trash is removed on a regular basis with minimal agitation.				
Lights have flush-mounted, smooth surfaces.				
Penetrations through walls are sealed.				
Hazardous compounding is conducted in a separate ISO 7, negative pressure room with 0.01-0.03 inches wc, which is documented daily.				
Ante-room between positive pressure and negative pressure cleanrooms must be ISO 7.				
Low-use exemption (3 doses per week) BSC or CACI in non-negative pressure with the use of a CSTD.				

Requirement: Environmental Monitoring (Non-viable)	Compliant: Yes	No	N/A	Comments
Particle count of ISO 5 PEC (LAFW, BSC, CAI, CACI) is performed every 6 months or more frequently (note frequency).				
ISO 5 Action level: not more than 3520 particles 0.5 µm and larger size per cubic meter of air for any LAFW, BSC, CAI, and CACI.				
Particulate count of ISO 7 buffer performed every 6 months or more frequently (note frequency).				
ISO 7 Action level: not more than 352,000 particles of 0.5 µm size and larger per cubic meter of air for any buffer area.				
Particulate count of ISO 8 ante performed every 6 months or more frequently (note frequency and type of media used; best practice bacterial and fungal growth-supported media).				
ISO 8 Action level: not more than 3,520,000 particles or 0.5 µm size and larger per cubic meter of air for any ante-area.				

Conclusion

Preparing for cleanroom inspections is a continuous process that should be embedded into the pharmacy's culture. Because a survey can occur at any time, survey readiness must be an ongoing effort. Pharmacy's compliance strategy requires an ability to identify and resolve internal issues while also being open to partnering with departments outside pharmacy. By incorporating regular mock audits into survey preparation strategies, pharmacy can ensure that inspections are successful and surprise-free.

References

1. North Carolina Board of Pharmacy. Hospital Pharmacy Inspection Form. www.ncbop.org/phcyinspectionforms.html. Accessed June 27, 2021.
2. Mekoba BC, Turingan EM, Roberts PA, et al. A pharmacy-led United States Pharmacopeia (USP) chapter 800 compliance collaborative at an academic medical center. *Am J Health Syst Pharm.* 2018;75(10):627-32.
3. California Board of Pharmacy. 2021 *Lawbook for Pharmacy*. www.pharmacy.ca.gov/laws_regs/lawbook.pdf. Accessed June 29, 2021.