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How Long Should Cleanroom Certification Really Take?

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Every test performed during a routine certification visit can be measured in time—whether it's scan and flow rates, testing durations, setup, or breakdown. Certification providers use these time factors to create accurate service quotes and build efficient schedules for on-site work. Depending on the scope, certifiers may be dedicated to a single location or have multiple stops in a day. Travel time is also considered in the planning process.

Let's identify the key components of routine certification testing and explore how long your vendor should realistically be in your pharmacy performing these services. Several factors can influence the timeline. No two pharmacies are the same, and each may present unique challenges or delays. It's important to know that the timelines provided do not account for equipment failures, repairs, or specific customer preferences, which may extend the duration.

Arrival, Entry, and Equipment Setup: What to Expect

Let's start with what happens before testing even begins—arrival, entry, and equipment setup.

Once the certifier arrives on-site, the first step is typically unloading equipment—often in a parking area not conveniently located near the pharmacy. However, the biggest delays often occur at the facility entrance. Can the certifier just walk in like they own the place? Maybe… but often not.

Many facilities require vendor registration, which can cause delays. It might be a simple two-minute sign-in and a short walk, or it could involve multiple layers of verification, phone calls to the pharmacy contact, and a walk across a large hospital campus.

Once the certifier reaches the pharmacy, it's essential to align expectations. This includes confirming the scope of work (usually by reviewing the work order) and understanding what the pharmacy may require before granting entry to the compounding area. This typically involves hand hygiene, proper garbing, and reviewing cleanroom conduct expectations.

Don't Forget: Staff Presence for Dynamic Testing

A critical aspect of certification is dynamic testing, which requires active pharmacy staff participation. Certain tests, like smoke pattern studies, require surrogate or simulated activities to evaluate airflow under normal operating conditions. If no staff are available, these tests may be delayed or skipped. Be sure to plan accordingly and have trained personnel on hand.

Equipment Cleaning and Testing Sequence

Before any equipment enters the compounding area, it must be cleaned and disinfected. Certifiers follow a "cleanest to dirtiest" workflow to minimize contamination. Some tests, like particle counts or viable sampling, are minimally invasive. Others, like airflow or HEPA filter testing, can stir up particles and should be performed after more sensitive procedures.

Remember, certification testing evaluates sterile environments, but it is not a sterile process itself. That's okay—as long as it's performed with proper cleaning, sequence, and containment.

Segregated Compounding Areas (SCAs)

Since there is typically no cleanroom application, traditional SCAs require little to no certification testing. The ISO 5 devices are the star of the show. Laminar airflow workbenches (LAFWs), restricted access barrier systems (RABSs), and biological safety cabinets (BSCs) require certification, but each has common certification tests and other testing that is specific to the individual device to ensure compliance. This also means that these devices take various timeframes to test.

LAFW Testing in SCAs (Timeframe: 1.5–2 hours)

Test	Estimated Duration
Viable air & surface sampling	30 min.
Total particle count testing	10-15 min.
Airflow velocity testing	10-15 min.
LAFW-specific tests (CAG-003)	10 min.
HEPA filter integrity testing	7-10 min.
Smoke pattern testing (USP <797>)	15-20 min.

RABS and BSC testing is typically more involved, especially when used for hazardous drug compounding. These devices require additional testing due to their connection with facility exhaust systems. For RABS, especially in hazardous settings, testing follows CETA's CAG-002 Compounding Isolator Testing Guide, which includes device-specific requirements.

Containment segregated compounding areas (C-SCAs) should also be verified for proper negative airflow. Testing confirms the space maintains at least 12 air changes per hour (ACH) and a pressure between -0.010" and -0.030" inches of water column.

BSC & RABS Testing (Timeframe: 1.5–3 hours)

Test	BSC Time	RABS Time
Viable sampling	30 min.	30 min.
Total particle count testing	10–15 min.	10–15 min.
Airflow velocity	10–15 min.	10–15 min.
NSF-specific tests	20 min.	60 min. (CAG-002)
HEPA filter integrity	7–10 min.	7–10 min.
Smoke pattern testing	20–30 min.	20–30 min.
C-SCA room testing	N/A	15-20 min.

- Total time for BSC: 1.5–2 hours
- Total time for RABS in SCA: 2–3 hours
- Standard BSCs in non-pharmacy settings often take 45 minutes

Certification Workflow and Efficiency

With experience, certifiers can gain efficiency—especially when multiple devices are located within the same room. For example, simultaneous viable sampling or airflow testing across several ISO 5 units is often possible, provided compounding activity allows for it.

A two-person team can further streamline workflow: one performs in-room testing, while the other processes data or prepares reports outside the cleanroom. Still, there's no universal method for cleanroom certification beyond the standardized procedures outlined in CETA guidance and other industry standards. Workflow and test order can depend on both certifier preference and customer needs.

Beware of "Sticker Lickers"

Let's address a real concern: cut corners. While most certifiers are thorough and professional, there's an unfortunate reputation in the field for a few "sticker lickers"—those who rush through or skip tests just to get it done quickly. But this isn't always about the certifier. Sometimes customers push for speed without understanding the scope or time needed for proper testing.

For instance, I've had clients ask to start testing at 6 a.m. so they can begin compounding by 9 a.m. That's fine—but they may not realize that full certification of a large cleanroom suite with multiple ISO 5 devices can take well beyond three hours, especially if staff need to participate in dynamic smoke pattern studies. When testing is rushed, something is likely to be missed.

SCA	2-Room Cleanroom Suite	3-Room Cleanroom Suite
Non-HD & HD	Anteroom	Anteroom
1 LAFW or 1 RABS/BSC	Non-HD buffer room	Non-HD buffer room
1 certification tech	3 LAFWs	HD buffer room
Total time: 2 to 3 hours	Two certification techs	3 LAFWs
	Total time: ~5 hours	2 BSCs
		Two certification techs
		Total time: 8 to 9 hours

Final Thoughts

Routine cleanroom and device certification is a structured, methodical process that takes time to do correctly. While there are efficiencies to be gained through experience and planning, cutting corners is never worth the risk—especially when patient safety and compliance are on the line.

Plan ahead, communicate with your certifier, and allow the time it takes to do it right.

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