NEWSLETTER ISSUE: APRIL 2026

the pure observer

Stay current on compounding, contamination control, and compliance best practices with pure microbiology

The BMBL and Sterile Compounding Pharmacies: What It Means When You Incubate Microbiological Samples

Sterile compounding pharmacies that incubate microbiological samples—whether viable air, surface, gloved fingertip, or media-fill tests—often find themselves in a gray area. Pharmacies are not traditional microbiology laboratories, yet once microbial growth is intentionally cultivated, the risks and responsibilities change. This is where the Biosafety in Microbiological and Biomedical Laboratories (BMBL) becomes relevant. If you've never heard of the BMBL before, you want to keep reading.

The BMBL, published jointly by the **CDC and NIH**, has served as the cornerstone of biosafety practice in the United States since 1984. The 6th edition reiterates an important point that is often misunderstood: BMBL is an advisory document, not a regulation. It is designed to provide best practice guidance using a risk-based framework for work conducted in biomedical and clinical laboratories. Despite its non-regulatory status, BMBL is frequently referenced by accrediting bodies, safety professionals, and inspectors because it represents the nationally recognized consensus on laboratory biosafety.

For 503A pharmacies that incubate samples, BMBL does not turn the pharmacy into a full blown microbiology lab, but it does inform how biosafety risks should be identified, assessed, and mitigated.

Why BMBL Applies to Pharmacies That Incubate Samples

When a pharmacy incubates microbiological samples, it is no longer handling "unknown cleanliness" but is intentionally

growing microorganisms. At that point, the activity overlaps with the type of work BMBL was written to address, which is controlled laboratory handling of biological material.

The BMBL emphasizes that biosafety decisions must be driven by risk assessment. The document makes clear that it is not possible to define every scenario or mitigation in advance; instead, organizations must evaluate the:

- organisms that may be present
- procedures being performed
- potential routes of exposure
- people and spaces involved

For pharmacies, this means that incubating any microbiological samples—even those expected to yield low-risk organisms like those commonly associated with humans—still requires intentional consideration of biosafety risks.

Biosafety Levels: Context Matters

BMBL defines four Biosafety Levels (BSL-1 through BSL-4), which establish graduated controls for laboratory work based on risk to personnel, the environment, and public health. The microbiological work performed in support of sterile compounding that would be performed in the pharmacy aligns with BSL-1 principles, provided the organisms are not known pathogens and the work is limited in scope.

At BSL-1, the BMBL emphasizes:

- standard microbiological practices
- no eating or drinking in the laboratory area
- proper waste handling and decontamination
- proper facility design
  - controlled access
  - sink for handwashing
  - eyewash station
  - cleanability (no carpet or porous surfaces)
  - adequate light

For pharmacies, the key takeaway is not that a formal “BSL-1 lab” must be built, but that BSL-1 behaviors and controls should be incorporated into the incubation process. Ask yourself:

- Do we have a dedicated “lab” space with controlled access?

- Are the appropriate safety measures in place, such as PPE and a sink for hand washing and the eye wash?
- Is the "lab" space able to be easily cleaned and disinfected?

Incubation: The Overlooked Biosafety Step

Incubators are often treated as passive equipment, just like the Ronco Showtime Rotisserie ads "set it and forget it." From a biosafety perspective, BMBL views incubation differently. Incubators are active growth systems that intentionally amplify microorganisms. As such, they represent a point of potential exposure if not managed correctly.

BMBL guidance relevant to incubation activities includes:

- Containment: Samples should remain closed and intact during incubation.
- Access control: Only trained personnel should handle incubated samples.
- Decontamination: Incubators and surrounding areas must be cleaned and disinfected.
- Waste handling: Contaminated plates and materials must be discarded in a biohazard waste stream.

For a pharmacy incubating samples internally, this translates into practical expectations:

- Incubators should be located in a controlled, low-traffic room, not a break room or shared office space.
- Staff handling incubated plates should be trained not only on reading results, but also on biosafety fundamentals. Think contaminated media-fill unit spill.
- Procedures should clearly define how samples are removed, read, stored, and discarded.

Risk Assessment Is the Core Requirement

Perhaps the most important contribution of the BMBL to sterile compounding pharmacies is its emphasis on documented risk assessment. The 6th edition reinforces that biosafety is not static. It is an ongoing process that must be revisited as conditions change.

For pharmacies, a defensible biosafety risk assessment for incubation activities should consider:

- types of samples incubated (air, surface, personnel)
- expected organisms (environmental flora versus known pathogens)
- volume and frequency of incubation
- who handles the samples
- where incubation and reading occur
- what happens during spills

BMBL vs. USP <797>

USP <797> defines the microbiological monitoring and testing requirements for sterile compounding; BMBL defines the biosafety framework for handling biological materials. These documents address different questions:

- USP <797>: *What samples must be collected, incubated, and evaluated?*
- BMBL: *How do we protect people and spaces while that microbiological work is being performed?*

BMBL does not override USP <797>, nor does USP <797> replace BMBL. For pharmacies incubating samples, BMBL fills an important gap by addressing worker safety, exposure prevention, and containment—areas that USP <797> does not explicitly detail.

What Inspectors and Surveyors Expect to See

While BMBL is not a regulation, it is widely viewed as the authoritative reference for biosafety practice. When pharmacies incubate samples, inspectors or surveyors may reasonably expect:

- a written risk assessment addressing incubation activities
- SOPs that describe safe handling, reading, and disposal of plates
- evidence that staff are trained on biosafety principles
- facilities and equipment that are appropriate for the level of risk

None of these require a pharmacy to become a microbiology laboratory. They do require intentionality.

Final Takeaway

Incubating microbiological samples is a necessary and valuable part of maintaining a state of control in sterile compounding. When pharmacies take on this activity, the BMBL provides the missing biosafety lens—helping organizations protect staff, prevent unintended exposure, and demonstrate that microbiological work is being managed responsibly.

The key is not compliance for compliance's sake. It is risk awareness, proportionate controls, and clear documentation. When applied thoughtfully, BMBL principles strengthen a pharmacy's microbiology program.

best practice makes perfect

Verify that you have the most current version of USP <797>. Some locations are working off public-comment versions because they haven't paid for access to USP. Our patients deserve more!

QUESTION of the MONTH

We have a 3-room cleanroom suite. How many surface samples should be collected for the monthly surface sampling?

Unfortunately, there is no standard that tells us how many. This is all based on risk. You'll want to watch work practices and do a risk assessment to determine the RIGHT locations for YOUR facility. Be sure that each ISO-classified space and each pass-through is sampled.

Pure Primer: Sterile Compounding and Handling Hazardous Drugs Live Training

May 12 - 15, 2026
August 31 - September 3, 2026

Join us for a 3.5-day in-person training, including lectures and skill-building activities. Two and a half days are spent focusing on USP General Chapter <797> requirements, best practices, and implementation strategies, while one day emphasizes the importance of USP General Chapter <800>, exploring requirements and real-life solutions.

REGISTER NOW

Use the discount code **20LiveTrain2026** for 20% off the list price.

puremicrobiology.com
E: abby.roth@premierinc.com | P: 610.417.4795

Abby Roth, founder of Pure Microbiology, has been supporting the testing and consulting needs of the pharmaceutical, medical device, and compounding industries since 2004. Her background in pharmaceutical microbiology includes extensive knowledge of environmental monitoring. Abby also has participated in multiple microbial excursion investigations, providing guidance on contamination sources and remediation options.