Choosing a Certification Professional to Evaluate Your Cleanroom Engineering Controls

By James T. Wagner

PERHAPS NOW MORE THAN EVER, CHOOSING A VENDOR FOR THE CERTIfication of your engineering controls is important to the practice of pharmacy. Today's choices in engineering controls have grown to include laminar airflow workstations (LAFWs), cleanrooms, biological safety cabinets (BSCs), barrier isolators, and ventilated balance safety enclosures (VBSEs).

Pharmacists and facilities engineers are faced with the daunting task of revamping their compounding facilities to meet the environmental requirements of USP and NIOSH. An experienced, well-trained, and knowledgeable certification professional can provide invaluable insight to assist you through this process. Most certification companies are independent firms familiar with the equipment choices the pharmacy community is struggling with. Provided your certification company does not sell those engineering controls, they can help you wade through the contradictory claims you are sure to encounter as you weigh your options to comply with today's standards.

Training and Experience

Experience alone is not an adequate gauge. An untrained certifier with 20 years' unsupervised experience will likely not do as good of a job as a well-trained and well-supervised technician with two years' experience. Consider both the experience and training of the individual who comes to your site. The qualifications of the company president don't mean as much to you as those of the actual individual working on your equipment.

Make sure the training programs for the company's technicians are adequate and well documented. If the company cannot provide you with training records for all of their technicians, consider it a warning sign. Most certification companies participate in industry training programs offered by the Eagleson Institute, CETA, NEBB (National Environmental Balancing Bureau), and many of the equipment manufacturers'. For example, NuAire, LabConco, Thermo Electron Corp, and other engineering-control manufacturers provide comprehensive and on-going training on their equipment. Some of the larger certification companies have begun to establish in-house training capabilities, often augmented by training centers with hands-on training opportunities. These programs should be run by qualified individuals and be well documented.

Training is perhaps the most important aspect to consider when choosing a certification company. Insist on a detailed set of training records as part of your due diligence. Certifiers should be quite used to this request and are generally well prepared to respond to it. Remember, when looking at training records, evaluate both initial training and on-going training. Engineering controls change constantly; therefore, what was good basic knowledge five years ago may be out of date today.

Make sure that your certification provider's experience is relevant to your existing or proposed facility. The new facilities requirements in USP Chapter <797> include equipment that may or may not be familiar to your existing contractor. For example, it is not unusual for a certifier that has been testing only pharmacy equipment his entire career to have little or no cleanroom certification experience. If you are installing a new cleanroom, have your certifier explain his or her experience certifying cleanrooms before assuming he or she is qualified. Barrier isolators are relatively new to the U.S. market, so do not expect to see a lot of experience with this equipment. However, look for some explanation of what the certifier has done to familiarize himself with the equipment.

Accreditation

There are currently two accreditation programs that apply to certifiers. NSF International has an accreditation program for individuals that certify Class II BSCs. While not every pharmacy has a BSC, the principles used here apply to most of the engineering controls employed in pharmacy. Individuals accredited by NSF International have proven themselves competent to certify BSCs. Cleanroom certification is an important factor for pharmacy since the adoption of USP Chapter <797>. NEBB's cleanroom certification accreditation program is more directed to the certification of microelectronics cleanrooms and has not yet been tailored to pharmacy cleanrooms. As such, its relevance must still be established. Participation in any industry accreditation is not considered mandatory, but is a good sign that the certifier takes their trade seriously.

Testing

Your certification provider's qualifications are best analyzed by looking at what he has done in the past. Review his or her certification reports, which should be complete and accurate. Are current certificates of calibration provided for test equipment used in the certification process? Ask about the report QA process: Are the certification reports reviewed, or is validated software employed that assures computational accuracy?

The certification report should include acceptance criteria for each test. A test that is not based on actual acceptance criteria is of no regulatory value. The acceptance criteria for certifying an NSF-listed BSC is published, and a professional certification provider will have access to that data. A pass-fail criterion for cleanroom certification, on the other hand, is not as obvious. It is often up to the end-user to assign appropriate performance criteria. This is where the value of an experienced and knowledgeable professional certifier becomes indispensable. A cleanroom certification should be based on pre-established acceptance criteria. It is not unusual for the pharmacist to look to the certifier to assist in assigning the criteria. The certification report should have unambiguous statements of pass or fail for every test, as well as for the overall cleanroom.

USP Chapter <797> has changed the accepted methods of pharmacy certification. While it is impossible to certify an area to an ISO cleanliness classification without a particle counter, some certifiers used to certify a laminar flow device without taking particle counts. This is simply not an acceptable practice any longer. USP now gives us specific guidance that ISO classified spaces need to be documented. Make sure your certifier is properly equipped for today's certification requirements. An optical particle counter in addition to the standard set of equipment required for NSF accreditation should be the minimum accepted. Your certifier should provide a comprehensive equipment list to match the list of tests in Figure 1.

Figure 1: Certification Tests

TEST	BSC	LAFW	BARRIER ISOLATOR	VBSE	CLEANROOMS
Airflow	Yes	Yes	Yes	Yes	Yes
HEPA filter leak test	Yes	Yes	Yes	Yes	Yes
Particle count survey	Yes	Yes	Yes	No	Yes
Induction leak test/ Backstreaming test	No	Yes	No	No	No
Airflow smoke pattern test	Yes	Yes	Yes	Yes	Yes
Pressure test	Yes for Type A1	No	Yes	No	No
Lighting intensity test	O	O	O	O	O
Sound level test	O	O	O	O	O
Vibration test	O	O	O	O	O
Site installation assessment test	Yes	Yes	Yes	Yes	Yes
Material ingress and egress test	No	No	Yes	No	No

O=Optional

The certification company should have a written QA program to assure the quality of their work. At a minimum, this should include a review of the test reports, maintenance of training programs, and calibration of the test equipment. It is considered minimum acceptable practice to calibrate certification test equipment at the equipment manufacturer's recommended interval. Due to the amount of abuse certification equipment receives because of the travel involved moving from site to site, reduced intervals are recommended. This should be an important differentiator when looking at competing firms.

Service

Certification firms are usually called on to service the equipment they certify. As such, verify that they have adequate staff to send someone to your facility within 48 hours of notification, or that they have a network of colleagues they can call on to help you in an emergency. Make sure you have an upfront written agreement on response time, including parts availability.

Summary

The price difference between the cheapest and most expensive certifier is often marginal, but the difference in professionalism may be dramatic. Remember that, often, "you get what you pay for." In summary, your certifier should:

- Have written training programs
- Provide written documentation of participation in industry training and continuing education programs specific to your equipment
- Provide written estimates and schedule of work before work begins
- Have an adequate capacity to service their geographical territory
- Provide complete, accurate, and professional documentation of their testing
- Provide documentation of all stated accreditations (preferably at least NSF)
- Have access to spare parts and supplies, as needed, to keep your equipment operating
- Provide a written QA program
- Calibrate their test equipment to the manufacturer's recommended intervals, but preferably more often
- Have adequate liability insurance to protect your facility in the event of an accident

Disclosure: *James T. Wagner spent 26 years in the employ of Micro-Clean, Inc., serving as a certification technician and eventually president of the company. He has served on the steering committee for the NSF International certifier accreditation program and is one of the instructors for the Eagleson Institute in Sanford, Maine. He is currently the president of CETA and a member of the USP Expert Committee on Sterile Compounding, as well as an independent engineering control consultant.*