

Health Canada Offers Certification Guidelines

Detailed Process Required for Containment Facilities

Containment laboratories in Canada are accustomed to using a team approach in order to obtain the necessary certification for startup and continued operation. Health Canada, the federal body that develops policy and enforces biosafety guidelines, knows how important it is for laboratories to have a third party involved from the beginning of the process to ensure successful certification.

“There has to be some kind of third-party involvement whether it’s a biosafety expert, a regulatory agent, or a colleague from a neighboring facility,” says Maureen Best, director of the Office of Laboratory Security at Health Canada in Ottawa. “We work with our clients, including a variety of biosafety and biocontainment facilities, from the very beginning. They call us because they don’t want any surprises at the end of the day and we are all trying to work together to get these labs up and running as quickly as possible.”

Biosafety and inspections personnel from Health Canada thoroughly review all documentation pertaining to the design and construction of biocontainment facilities. The architectural design is reviewed to pinpoint features such as entrance and exit sites, location of biosafety cabinets and HEPA filters, and placement of ductwork. Architectural and mechanical drawings are studied to help the Health Canada team members become familiar with each facility before they make their final inspection.

“This helps us become knowledgeable with the facility before we ever show up and start working with the team,” says Best. “We will get drawings at all stages from conceptual design all the way through to the end. We are not going to come in at the end of the day and take a look at the drawings because that means changes which cause delays and that, in turn, means more money.”

Critical Testing

Conducting the proper tests to ensure the facility will meet specific guidelines, which vary depending on what country the lab is located in, is essential. Health Canada provides a detailed list of the tests that should be performed and the criteria that must be met in order to achieve certification. While these are procedures specifically used in Canada, they can be applied to almost any containment lab in the world.

The first test targets the integrity of the room, focusing on all of the penetrations and seals. A visual check is made and a smoke pencil can be used to see if air is breaking any of the penetrations. Other items that must be examined for structural integrity are the interior windows, the ductwork, piping, electrical conduits, and finishes on the walls and floors. The joints where the floor meets the walls and where the walls meet the ceiling should also be closely checked.

Inward directional airflow must be checked by using a smoke pencil to verify the flow through every door of the facility. Regulators want to be sure that air from the dirty areas of the lab is not going into the clean areas.

Communications devices, including everything from telephones to access and security equipment, are an important part of the pre-inspection testing. All telephone equipment should be in proper working order and all relevant phone numbers should be posted in a convenient location. Key cards and other access equipment should be checked not only to guarantee the system is accepting all personnel access numbers, but also to ensure that incorrect numbers cannot be used to gain entry.

Efficient door interlocks are vital to a good containment system and should be part of the inspection review process, as well. The proper doors should interlock with each other in the correct sequence to allow for maximum lab containment. Making sure the emergency egress overrides are in top working order is equally important.

Load testing must be done before the autoclaves can be certified. This can be done by looking at different types of loads, including dry, liquid, lab clothing, and wastes that lab operators have actually tested.

“For example, in our own Level 3 facility, we have a research lab and we were wearing suits which are coated a little bit more than some of the other laboratory clothing,” says Best. “When we ran those suits through, it was really hard to get a good decontamination through the autoclave. Always remember to include positive controls on biological indicators.”

The interlocks on the doors of the autoclaves, especially if they are the barrier-type, and the alarm system that prevents both doors from opening at the same time, should be examined to see if the seal is intact.

The effluent treatment system should be designed in such a manner that it can be microbiologically evaluated. The design needs to be incorporated into the system at the beginning of the project planning in order to avoid problems.

Inspectors also check the biological safety cabinets and the equipment they hold. Calibration reports for the equipment are often requested.

Health Canada recommends that clients list all of the HEPA filters in their facility and the results of recent leak tests on each of them. The type of test, whether it was a scan or probe, should also be specified and the ductwork around all filters should be put through an integrity test.

Control systems represent one of the most important areas of inspection and

many labs often find the required testing to be a challenge. Failures should be simulated for the exhaust fans, supply fans, and power units. The audible and visual alarms should activate correctly to signify each failure.

“The control systems testing has to be done for containment purposes and done again and again so you can tweak the system to get it to work right,” notes Best. “We do exhaust fan testing, supply fan testing, and power failure testing. You need to do control systems failure testing to see what happens to the air in the lab. This is really important.”

Additional testing required for a Level 4 biocontainment lab includes checking the integrity of the positive pressure suits, the backup systems for the breathing air, the chemical shower systems, and the alarms.

Full Speed Ahead

In addition to the design and testing of the facility’s physical plant, operational procedures must be included in the certification process.

“You can walk away from a facility that is the most beautiful thing you have ever seen, but how the operators use it is going to be the critical thing at the end of the day,” says Best. “There is a whole laundry list of items that need to be included, such as entry and exits for people and animals, supplies, materials, decontamination, disinfection, hazardous wastes, and cleaning.”

Training is a crucial part of getting the scientists to understand how the facility works, how the equipment was designed and how it operates, what happens in a failure scenario, and what containment components are available. Cross-training to let the operations personnel know what the scientists do on a daily basis is recommended.

The on-site visit by inspectors features a walkthrough of the facility with a thorough examination of the layout, construction, penetrations, all equipment that was previously tested, and all operational aspects.

“You need to ensure the facility is going to keep working day to day and year to year because you will have to go through a re-certification process,” says Best.

Standard operating procedures that must be reviewed include the roles and responsibilities of facility occupants, conditions of access, medical surveillance and employee health, entry/exit, personal protective equipment, decontamination and disinfection, hazardous waste management, housekeeping, animal care and safety, emergency response, and incident reporting.

“You can avoid surprises at the end by using teamwork. We call it cooperative regulation in Canada. We are part of the team with the operators, the designers,

the safety staff, and the users, so we work with the facilities from the beginning to ensure they are getting their labs done in a timely manner and they are going to be safe for everyone.”

A copy of the guidelines is available on the Health Canada Web site at <http://www.phac-aspc.gc.ca/ols-bsl/lbg-ldmbl/index.html>.

International Initiatives

Several initiatives are currently under way as part of an international approach to certification. The World Health Organization is developing an international certification regime that will be applied to facilities working on polio eradication efforts. The WHO and countries belonging to the World Health Assembly are conducting an inventory of all labs holding wild polioviruses.

The WHO is working on an enhanced definition that would outline the polio-specific requirements for a biosafety facility. The protocol for certification, which is currently being developed, will include a list of tests a lab must go through under the polio-specific requirements. All labs on a worldwide inventory must complete the certification process. Those not meeting the biosafety requirements must discontinue work and develop a plan to implement corrective action within six months.

WHO guidelines can be found at <http://www.polioeradication.org/content/publications/WHO-VB-03-729.pdf>.

The second initiative is being conducted by the Global Health Security Action Group (GHSAC), a subgroup of the G7, to form an international network of high-containment laboratories which could work together and respond to an outbreak of diseases on an international scale. The G7 is a group of health ministers from the United States, Canada, France, Germany, Italy, Japan, United Kingdom, plus Mexico who are aimed at improving global health security.

The GHSAC wants to achieve standardized international certification procedures that would facilitate easier operations on a global level with the import/export of agents, exchange of diagnostic procedures, and staff exchange. There are several challenges which must be overcome, including the presence or absence of a national biosafety regulatory authority in member countries, conflict with national regulatory requirements, differences in national classification of pathogens, and financial expenses if upgrades are necessary.

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Biography

Maureen Best is the director of the Office of Laboratory Security at Health Canada where she is responsible for the national certification program for high-containment laboratories. As a member of the World Health Organization's Biosafety Advisory Committee, she has been involved in the development of an international certification system for containment labs handling wild polioviruses under the WHO's polio eradication program. Best is a registered biosafety professional and past president of the American Biological Safety Association.

This report is based on a presentation given by Maureen Best at Tradeline's *International Conference on Biocontainment Facilities* in April 2004.

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The effluent treatment system at a biocontainment facility should be designed in such a manner that it can be microbiologically evaluated. This can be accomplished by incorporating the design into the system at the beginning of project planning. (Photo courtesy of Health Canada.)

The ductwork surrounding all HEPA filters should be put through regular integrity tests. A list should be kept on hand to show the location of all filters and the results of recent leak tests. (Photo courtesy of Health Canada.)



All audible and visual alarms should be inspected regularly to ensure they activate properly. (Photo courtesy of Health Canada.)