New requirements for use and storage of liquid nitrogen, dry ice

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October 2018—Laboratory personnel safety is at the center of two new requirements and a revised requirement in the latest edition of the CAP accreditation program checklists, released in August.

The requirements address the risks and hazards associated with the use and storage of liquid nitrogen (LN2) and dry ice, and they apply to all laboratories in the Laboratory, Biorepository, and Reproductive Laboratory accreditation programs.

Another new safety-related requirement is about restricting access to the laboratory.

An employee of a non-CAP-accredited laboratory in Georgia was critically injured in 2017 when an LN2 leak occurred. LN2 converts to colorless, odorless gas and replaces environmental oxygen. The unsuspecting laboratory worker was burned and then fell unconscious. One of the first responders who arrived on the scene to rescue her died of asphyxiation. The employee survived.


Dr. Geaghan

CAP accreditation program leaders viewed that accident as an opportunity "for greater occupational safety and protection of lab workers," says Sharon Geaghan, MD, emerita chief of pathology at Lucile Packard Children's Hospital at Stanford, emerita co-director of Stanford Clinical Laboratories, and a member of the CAP Checklists Committee. "It is representative of the best work that the Checklists Committee can do—to act as a mechanism for the College to respond to current-day, real-life challenges."

A group composed of members of the Checklists, Biorepository, and Reproductive Medicine committees came together to gather and share safe handling, storage, and usage practices from those areas of medicine most familiar with LN2 and dry ice use.

"We quickly realized there are many medical applications of liquid nitrogen in the health care environment that often are not appreciated," Dr. Geaghan says. "There was a heightened recognition that this involves all types of labs, and safety training and measures are paramount."

Philip A. Branton, MD, consulting pathologist in the Biorepositories and Biospecimen Research Branch at the National Institutes of Health and chair of the CAP Biorepository Committee, says while biorepositories were familiar with the hazards of LN2 even before the CAP's Biorepository Accreditation Program got underway in 2012, "other labs may have lagged behind." Now, however, "there is a new imperative to be familiar with the risks of liquid nitrogen and dry ice in day-to-day clinical medicine due to the rise of molecular medicine." Tissue that once was fixed in formalin and examined under a microscope may now be snap-frozen and put into a repository at -80°F for later molecular testing for gene and marker identification, he notes. "More and more tissues are being frozen even in hospitals, not just research institutions, going down to the community hospital level. So safety pertaining to LN2 and dry ice must be addressed across all lab types."


Dr. Branton

Revised requirement GEN.77500 "Liquid Nitrogen and Dry Ice" (which is in the biorepository checklist as GEN.85960) directs labs to have "adequate policies, procedures, and practices" for not only the use of LN2 but also now dry ice. Notes define what is required for safely handling LN2 and dry ice.

"The revised requirement has changed the notion of appropriate equipment being determined at the discretion of lab directors," says Jacob Frank Mayer Jr., PhD, a professor of obstetrics and gynecology at Eastern Virginia Medical School, Norfolk, and former director of the Jones Institute for Reproductive Medicine embryology laboratory. Dr. Mayer, who is a member of the CAP Reproductive Medicine Committee and deputy regional commissioner for the Reproductive Laboratory Accreditation Program, says, "We wanted to take some of the leeway out of it and stipulate that specific protective equipment must be used."

Laboratories are warned not to store LN2 or dry ice "in confined areas, walk-in refrigerators, environmental chambers, or rooms without ventilation." The note says, "An LN2 or CO_2 leak in such an area could cause an oxygen-deficient atmosphere."


Dr. West

A couple of asphyxiation deaths due to nitrogen have occurred every year for the past 10 years, says William West, MD, staff pathologist at CHI/Creighton University Medical Center and chair of the Checklists Committee, citing OSHA data. Dr. Geaghan referenced a 2003 report from the U.S. Chemical Safety and Hazard Investigation Board, which she says revealed that in the prior decade there were 85 nitrogen asphyxiation incidents in a variety of settings, some of them medical laboratories and facilities.

Too often, Dr. West says, people don't comprehend the rapidity with which asphyxiation from nitrogen occurs. "A person need only take a breath or two to become unconscious."

Laboratories using LN2 minimally may have one or two tanks stored in a closet space with little ventilation, Dr. Branton says. "But that is a tragedy waiting to happen, because even a small leak will displace a large amount of oxygen quickly."

The asphyxiation risk extends to dry ice, which can displace oxygen with CO_2. Says Dr. Mayer: "There have been cases where lab workers bend over into chest freezers used to store dry ice. They put their heads into the freezer chambers to find something, and if the oxygen has been replaced by CO_2, they quickly pass out. They don't even realize anything is happening to them; it is like going to sleep. They are found later—dead, hanging over the freezer."

All laboratories must know that proper ventilation and high turnover of air in storage and usage areas are imperative, he adds.
Other additions to the requirement call for "training on the safe handling of LN2 and dry ice" and signs marking areas where LN2 and dry ice are used and stored. "The training referenced in the note alerts labs to provide training specific to LN2 and dry ice," Dr. West says. "We wanted to bring attention to the need to understand certain things about safe use of LN2, including storage tanks," for example.

Dr. Branton says he has seen LN2 stored in tanks "the size of soda bottles" as well as in large tanks weighing 200 pounds. "Left unrestrained, they can tip over and result in serious crush injuries. It's one of the odd little things people don't usually stop to think about."

GEN.77550 "Liquid Nitrogen Environmental Monitoring" is a new requirement calling for oxygen sensors with a low-oxygen alarm mounted in an appropriate location and sufficient airflow to prevent asphyxiation in areas where liquid nitrogen is used. Appropriate placement of sensors is at typical breathing height, it says. This requirement is in the biorepository checklist as GEN.84800.

"I have inspected storage areas in some labs that are a closet in the basement," Dr. Branton says, "with a monitor up at the ceiling. First, there should be several monitors installed, in the event there is a pocket of gas caused by air currents in one part of the room. And they must be installed at human levels."

Because LN2 is a heavy gas, it falls to the floor first and fills the room from floor to ceiling. "If an alarm is six to eight feet above the floor, the entire room would have to fill with nitrogen before the alarm goes off," he says. "If a lab worker were seated on the floor or on a low stool, the alarm would be too late for them. They could be passed out or dead by the time it sounded. Sensors must be at the height you are working, more likely waist
level than eye level."

[dropcap]A[/dropcap]lso for the safety of personnel, there is a new requirement calling for a written policy for restricting access to the laboratory to authorized individuals.
"There are many compelling reasons to require controlled access," Dr. West says of GEN.59980 "Restricted Laboratory Access."

"We deal with patients all the time in our facilities, and that creates patient privacy issues when they are giving specimens or having blood drawn. There are patient specimens in our facilities. There is a lot of private data in various locations and various forms within the lab that need to be protected from a HIPAA perspective." And there are visitors—people coming from different parts of the hospital to drop things off, for example. "You wouldn't want nurses from the floor walking into the wrong section of the microbiology laboratory while lab workers are dealing with culture and specimens," Dr. West says.

Some transfusion medicine laboratories use cesium irradiators, which require restricted access.

"Lastly, unfortunately there is a need for protection against malicious events," Dr. West says. "Whether someone intends physical harm to employees and/or patients, or just destruction to lab equipment, supplies, and/or records, we must take steps to safeguard against such possibilities."

Until now, there was no requirement for laboratories to have a specific policy for access. "When the Checklists Committee tackled this, we took into account the variety of labs we serve, from highly complex, large labs with hundreds to a thousand employees, all the way to rural settings where a small group of individuals provide laboratory services," Dr. West explains. "There is a huge spectrum, so we did not believe there was a way for us as a committee to prescribe to them exactly how to do this in a universal way. We decided to say, 'You need to sit down in your own laboratory environment and contemplate these issues and come up with a policy and procedure to decide what kind of control to access is needed in your lab and which authorized individuals will be allowed.'"

Inspectors will ask to see the policy and procedures. "They will want to see what the lab thought about, what they decided, and how they will carry it out. While we do not prescribe what labs can and cannot do," Dr. West says, "we want them to think about systems for handling different situations."

In the discussions of safety now covered in the 2018 checklists, other important issues were raised. Drs. Branton and Mayer pointed to a need to safeguard specimens that are stored frozen by way of LN2 and dry ice and in electrical freezers. The imperatives to ensure specimen safety, to maintain adequate backup tanks and freezers in the event a freezing unit becomes inactivated, and to consider these specimens in times of disaster have all been brought to the table. "We are looking at these things for 2019," Dr. West says.

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The CAP Council on Accreditation leads the work to reexamine and revise the checklists. For some of the other revisions found in the 2018 edition, see the August and September 2018 issues of CAP TODAY.

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