A clean bill of health

Ron Ball leads us through the shifting regulatory landscape for bulk medical gas systems.

The industry consensus standards and regulatory requirements regarding hospital bulk medical gas system installation and maintenance have been continuously evolving over the last few years. Over the same period we have seen state and local regulatory officials become more interested in the training and certification of personnel performing work on these systems. This article will look at how this regulatory landscape is changing and the tools available to firms to stay abreast of those changes.
Until recently the full set of requirements for designing, installing, servicing, and maintaining a healthcare facility bulk medical gas system was contained within the National Fire Protection Association standard, NFPA 99, and included specifications governing where the bulk medical oxygen tanks could be placed, and clearances to things ranging from doors and windows to fuel oil tanks and non-ambulatory patients. However, NFPA 99 only pertained to medical installations. Industrial installations of the same gas were governed under a different set of NFPA standards, namely NFPA 50 (oxygen). Other standards, such as NFPA 50A & NFPA 50B covered hydrogen installations.

To minimize potential duplication and conflicting requirements, NFPA in 2002 proposed to consolidate all gas requirements in a new document - NFPA 55. This single document would then house the regulatory requirements for all gas system installations. When NFPA 55 - 2005 was released it also contained a significant paradigm shift in the thinking about the role the document would play. All previous versions were written as standards, to then be adopted by states, either fully or in part, depending on the state. Often states would adopt sections of NFPA standards into their existing codes, and in other locales the state code would cite the NFPA standard, in effect making the standard a code. In contrast, the new NFPA 55 publication entitled Compressed Gases and Cryogenic Fluids issued in 2005 has been written as a model code. This document is intended to be adopted in full by state and local authorities. In theory this should hopefully start to rectify the patchwork approach to code implementation across the 50 states that exist today, at least for gases.

In NFPA 55 some of the gases such as oxygen and hydrogen have chapters that cover the hazard properties and issues specific to those gases. Common hazards for cryogenic and / or compressed gases are lumped into sections of the code all together. This grouping process has caused some unintended problems. For example, NFPA 55 can be interpreted as requiring no smoking signs and spill aprons for inert gases like Nitrogen and Argon, even though this was not the intent of the code writers. The NFPA 55 committee is expected to make some corrections to the document in the 2013 edition to correct these unintended issues.

Once NFPA 55 was issued the old 50 series of standards was then withdrawn. At the same time the NFPA 99 standard went under the editing knife to remove the requirements transferred to NFPA 55 and to add the appropriate references to the new standard. All of this code creating, withdrawing, and editing has been completed in the 2012 edition of the NFPA 99 document, to be issued early next year. Like NFPA 55 the new NFPA 99 - 2012 publication will be issued as a model code. NFPA 99 still contains the design, installation, testing, and commissioning requirements for medical systems, but system installers and designers now need to consult

NFPA 55 for specifics on clearances and system layout and placement considerations, along with code requirements related to the gas hazards, such as spill aprons for Oxygen systems.

Here too there is the potential for confusion among local code enforcement personnel, and as with any major evolution in regulatory requirements this change ushered in its own set of issues. State regulations and inspectors, and third party verifiers who referenced, relied on, and were comfortable with the old NFPA 50 series of standards now find them withdrawn. Some local installers may experience confusion over which standard or specific requirement to comply with, as the new NFPA 55 contains similar, but not identical requirements to the 2005 edition of NFPA 99.

All this highlights that individuals working with bulk medical gases systems should be planning to head back to the class room to update their training on these new codes, and learn how to deal effectively with state and local code officers and third party verifiers as to what specific requirements apply to their area. B&R Compliance is offering a series of refresher training seminars covering the changes to NFPA 99 (2012 edition), where the old 99 requirements can be found in the new NFPA 55 code, together with other topics that bulk medical gas healthcare technicians need to stay current with concerning changing regulatory requirements. Give us a call to schedule your refresher training.

There is a second evolution spreading through the states regarding training, qualification, and certification of bulk system installation and maintenance technicians. In some locales it is no longer acceptable for a technician to simply have X years of experience to be considered adequately qualified. Code officials, third party verifiers, and the healthcare facilities themselves are beginning to expect technicians to possess documented evidence of training and qualification, and that typically involves certification, typically to the ASSE 6015 standard.

The American Society of Sanitary Engineers (ASSE) introduced 6015 as a training and qualification standard for bulk medical gas system installers in response to the gases industry request to create a requirement that adequately reflects the true training and qualification elements bulk system installers need to meet. As you might expect ASSE 6015 covers the relevant requirements in NFPA 99. Once this document is revised it will also reference sections of NFPA 55. In addition, 6015 certified individuals must also demonstrate proficiency in brazing to an acknowledged standard. The final piece to achieving ASSE 6015 certification is qualification under an appropriate FDA compliance program that covers installation and maintenance of bulk medical gas systems, and meets FDA's good manufacturing practices (GMP) requirements applicable to those systems. This last requirement is what sets ASSE 6015 apart from all other ASSE standards.
Technicians who install, commission, test, and maintain bulk medical gas systems are working on field-erected drug delivery systems. This single issue creates a world of difference between bulk system technicians and those technicians who only work on the pipeline systems inside healthcare facilities. While FDA does not regulate what goes on inside the healthcare facility, they do have full regulatory authority over the bulk gas systems which supply those facilities. This means bulk system technicians must conduct their activities in accordance with FDA regulations found in the Code of Federal Regulations (CFR) Part 21, sections 210 & 211. Those requirements cover a laundry list of topics too long to include in this article, but a few of the key requirements are:

- Employee training
- The use of written procedures
- Documentation for all activities
- Establish and Train a QC Unit
- Record review and approval by the QC Unit

Firms also need to adhere to one of the most basic FDA requirements, and that is to have the QC Unit approve and release the installation prior to permitting the healthcare facility to use the product from the system. This review and

approval step for bulk medical gas systems is just like what occurs with drug products, which must be released from quarantine by the QC Unit before those drugs can be shipped to consumers.

To assist independent firms to comply with FDA requirements B&R has been offering our Health Care Installers (HCI) Standard Operating Procedures program since 2003. This total solution program combines all the operating procedures, forms, and tools together with access to expert consulting firms need to install and maintain bulk medical gas systems in compliance with NFPA codes and FDA regulations.

The shift taking place in the market place is that state and local regulatory officials are beginning to require bulk medical gas technicians possess formal credentials attesting to their training and qualifications. In some states documentation of training in a program such as B&R's HCI program is acceptable. In other states officials are looking for evidence of certification to the ASSE 6015 standard itself. For example, the state of California has initiated a move towards requiring some form of certification such as ASSE 6015, or equivalent for all bulk medical gas system technicians operating within the state. Here again B&R can provide the tools firms need to comply. Since 2007 we have trained and certified over 125 technicians to the ASSE 6015 standard.

We forecast this trend will gain even more momentum and spread to other states in the next couple of years. Consider that 10-12 years ago ASSE certification for plumbers working inside healthcare facilities was not even close to being a uniform requirement in the US. Today virtually every state in the nation requires that technicians installing, maintaining, testing, or verifying medical gas systems have documentation of certification to the appropriate standard applicable to their job. There is every reason to believe that 3-5 years from now ASSE certification will be as ubiquitous for bulk system installers as it is today for everyone else who works on the inside parts of healthcare medical gas systems.

When selecting a company to provide your technicians with 6015 training there are a few key points to consider. ASSE 6015 involves both NFPA and the FDA. Does the company providing your 6015 training understand FDA regulations? Firms that are used to providing ASSE training to plumbers and inside technicians are generally not familiar with FDA regulations. Most of them are unfamiliar with FDA as the agency does not directly regulate what goes on inside healthcare facilities. Therefore, we recommend you utilize a company that understands FDA compliance. Another consideration is that bulk systems are very different from the typical equipment inside a healthcare facility. We recommend that any individual or company offering ASSE 6015 training be able to demonstrate an in-depth knowledge and experience with bulk medical gas systems and their components. And finally you need to remember that any individual or firm offering ASSE 6015 training falls under the FDA requirement in 21 CFR δ 211.34 covering consultants and their qualifications. Any consultant must be able to demonstrate sufficient education, training, and experience to advise on the subject for which they are utilized, and that records of their qualifications must be kept on file.

If you have any questions on the topics in this article, such as ASSE 6015, NFPA 99, bulk medical gas systems, or have a question about medical gases or FDA compliance in general, please feel free to give us a call or drop us a line to discuss how we can help your business.


By Ron Ball