

Call to Action

Time to Develop Requirements Appropriate to Food Safety in the Gas Industry

A Special Report from Bob Yeoman



I was recently invited to speak on the topic of ensuring the quality of food and beverage grade gases in the cylinder supply chain at the 2012 International Society of Beverage Technologists (ISBT) annual convention. From the ensuing discussions on evolving food safety regulations and the issues these regulations are beginning to create for the gas industry, I came away with a sense of déjà vu. It appears as if the gas industry may be approaching the evolving requirements for food and beverage gases in a manner similar to how they dealt with evolving Federal Drug Administration (FDA) (Agency) medical gas requirements in the early 90s. Many people may no longer remember a time before the great epiphany regarding medical gases and industry's subsequent 180 degree change of direction in its approach to FDA regulations, which was spurred on by the nearly unbearable enforcement pressure applied by the Agency. Today, we are seeing the introduction of new and evolving regulations for the food and beverage industry, many of which are a poor fit to the gas industry. This means it's time for the gas industry

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to step up and provide the leadership needed to develop a sound and logical set of compliance requirements that satisfy the intent of the food safety requirements and are still compatible with the unique attributes of the gas industry. This article is a call to industry executives for action.

Some History

In the late 80s, the FDA signaled the medical gas industry that changes in their enforcement practices were coming with a flurry of inspections that either introduced a new requirement or rescinded a previously held discretionary exempt status of a regulatory requirement. The net result was a rapid paced evolution of new regulatory requirements for medical gases.

At that time the gas industry failed to recognize that the FDA was using their traditional technique of high profile enforcement

to signal their change in thinking regarding medical gases. The FDA expected medical gas companies to see what they were doing, get the message, and fall into line. That kind of informal communication, however, did not work. Instead, the gas industry did what almost any industry would do when faced with a government agency's rapidly evolving regulatory requirements—they pushed back. In hindsight, there might have been a less divisive approach, but at the time the industry consensus was to argue against new policies; so it began to contend nearly every regulatory change broached by the FDA. For a time this strategy worked despite the often contentious meetings between the FDA and the gas industry. What the industry failed to see, however, was that a wall was being built between them and the FDA. Our reputation of being a contentious group was sealed, and this would hinder productive discussions for years to come.



Photo by Arden Tashjian

In the mid to late 90s, the FDA upped the ante and initiated an enforcement blitz on the gas industry that was without precedent. Unbeknownst to the medical gas industry at this time, FDA executives already had decreed the need to change the level of regulatory compliance. Given the power of the FDA, this made change in the gas industry inevitable. The gas industry took some time to finally recognize this inevitability. However, when faced with the FDA's actions—thousands of site inspections at medical gas facilities, numerous initiated seizures, and forced consent decrees on many of the major producers—the industry ultimately moved in the direction of improving the tone of their dialogue with the Agency. Unfortunately the two groups were so polarized that the FDA was unresponsive. It took the intervention of the US Congress before the gas industry got their second chance with the FDA. Since that time, the gas industry has modified their approach to regulatory change, and opened and maintained a direct line of productive communication with the FDA.

From this bit of history we have learned that when confronted with powerful forces for change it is often preferable to lead the

changes rather than resist them. Facilitating changes provides opportunities to shape their content and scope, and helps to avoid having onerous or unnecessary requirements forced upon you as a result of contentious dialogue.

Global Food Safety Initiative

Today the gas industry is again facing significant forces for change in the form of the evolving certification process tied to the Global Food Safety Initiative (GFSI). We need to fully appreciate the power that is driving these changes. In the US, GFSI certification is taking the route of the FSSC 22000 standard, which is an amalgam, the first element of which is the ISO 22000 quality standard. The second component of the ISO 22000 amalgam is the PAS 220 specification. (Note: PAS 220 is in the process of being replaced by the ISO/TS 22002 standard. These two documents contain essentially the same requirements and for clarity will be referred to in this article as PAS 220). The ISO 22000 standard is a quality management standard for dealing with food safety, and is a general derivative of the ISO 9000 standard. The PAS 220 specification defines the specific (prerequisite) programs and require-

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ments that firms must meet in order to achieve certification. The certification process assesses a firm's ability to comply with both elements. (For more information see: "The Food and Beverage Industry: Food Safety Initiatives Usher in New Requirements," *CryoGas*, August/September, 2011, p. 60.)

The ISO 22000 standard is broad, as ISO quality management standards typically are,

and outlines the basic management programs firms need to implement. Many are the same programs contained in ISO 9000, with a few new ones added to adapt to the food industries. Issues for the gas industry arise with the PAS 220 specification, whose requirements are much more focused and proscriptive. PAS stands for Publically Available Standards and the PAS 220 specification is part of a family of standards that cover everything from man-

aging shoplifting, to furniture removal activities, to managing biodiversity. PAS specifications require less consensus building than ISO standards, and can be used as a benchmark for assessment.

PAS 220 was written specifically for the traditional food industry and many of that industry's largest companies had a direct hand in its creation, such as Kraft, Unilever, McDonalds, and Nestle. If you visit a consumer food manufacturing site, you see facilities with specialized coatings on the walls and floors, workers in special clothing, employees not wearing any metal on their body and with hair nets on. These facilities follow very detailed cleaning and sanitization programs, insect and rodent control programs, and all finished products usually pass through metal detectors. You will find none of this at your typical food and beverage gas plant.

When the PAS 220 specification was developed, I am fairly confident there was no consideration given to how it would be implemented in the gas industry, which is a small but critical piece of the food industry. I also think little or no consideration was given to the problems that our industry would have in trying to meet a proscriptive specification




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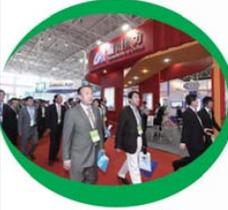
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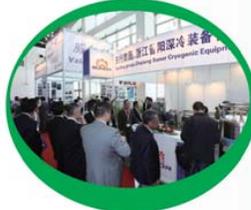
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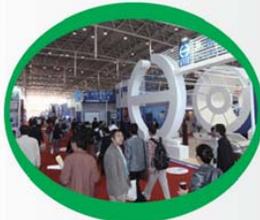
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New food safety initiatives are being driven by customer requirements, not a government agency, and in many ways supply chain pressures are even harder for gas companies to resist than evolving government regulations.

focused on a very different manufacturing and production environment. Today, auditors come to gas facilities expecting to see employees wearing uniforms that contain no buttons or zippers and they are looking for rodent and pest control programs. These are just a few examples of specifications that are not appropriate to the gas industry production model.

Some remarks on the new food safety standards from those in our industry are reminiscent of the reaction to the FDA requirements of the early 90s. Comments like, “We have been doing this for 45 years, so I don’t understand why we have to change now” or “The gas industry is different and these requirements should not apply to us” represent the push back approach to problem solving, which did not work 20 years ago and is unlikely to be taken seriously today.

Another proposed industry solution of how GFSI regulations relate to the gas industry is

to have cylinder gases removed from the scope of GFSI certification, using the logic that it should only apply to bulk gases. I see this as short sighted thinking, as it presumes that the gas industry has the ability to make that kind of decision stick in the marketplace. New food safety initiatives are being driven by customer requirements, not a government agency, and in many ways supply chain pressures are even harder for gas companies to resist than evolving government regulations. In the highly competitive 21st century gas industry, if a customer wants and expects a particular accommodation, including certification to a third party standard, someone is usually ready to step up and provide it. Once that occurs, everyone who wants to sell in that market will need to be able to meet the new customer standard. In my opinion, attempting to exclude specific segments of the supply chain from food safety requirements is doomed to failure.

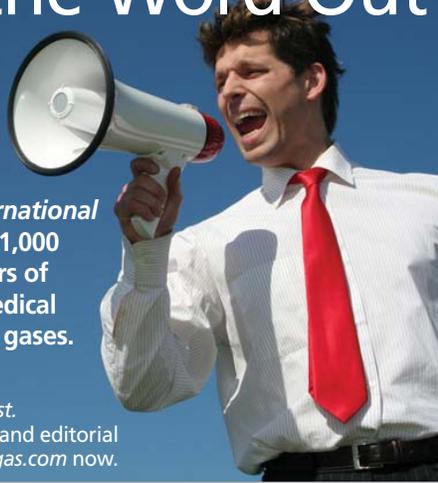
Window of Opportunity

There is a window of opportunity for the gas industry to step up and deal head on with these evolving food safety issues. Other industries that supply the food industry have already seen the light and promulgated their own PAS specification. For example, PAS 223—Managing Food Safety for Packaging was recently released. The packaging industry is now able to point their certification bodies to this specification, which presumably more appropriately fits the requirements and differences of food packaging.

This is a model the gas industry should emulate. To successfully develop a PAS specification for the gas industry our industry needs to provide leadership and facilitation. We also must be prepared to work with both customers and certification bodies to develop consensus requirements that can be accepted by all parties. While the effort required will be significant, the gas industry has shown in their work with pharmaceutical regulations they have the capability to be effective on these types of large scale, long term projects.

Success in this endeavor also means new working relationships between the Compressed Gas Association (CGA) and ISBT

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will need to be forged. The contributions and influence of the gas users, such as the major bottling firms, who are also members of ISBT will be instrumental in developing a new PAS specification for food and beverage grade gases and achieving its acceptance as a basis for GFSI certification.

I believe the gas industry senior executives need to set a mandate and undertake this initiative or their companies will continue to chaff

under the requirements of the PAS 220 specification for years to come. Trying to influence the GFSI certification bodies by issuing CGA publications is not the direction to take, as CGA publications do not generally incorporate input from the customer base those product serve, which is a basic tenet on which food safety standards are all based. The industry may attempt to push back with the certification bodies. However, FDA is already becoming

critical about certification firms relaxing standards during audits, so there is pressure on the certification firms to be tough. I also believe trying to exclude segments of the supply chain from the certification process will be ineffective, as ultimately the gas business is a customer focused industry. If a customer wants it, then someone in the gas industry will figure out a way to supply it. The FSSC 22000 standard is expected to achieve much wider acceptance and implementation than the ISO 9000 standard. This will likely translate to increasing pressure on more gas suppliers and distributors to become GFSI certified, or for firms already certified to add additional elements of their business over time.

Food safety initiatives are a relatively young and still evolving set of requirements. I believe now is the time for our industry to invest the time and effort needed to develop a set of requirements that appropriately reflect how food safety should be managed in the gas industry. Delay in action will only serve to increase the amount of time, effort, manpower, and resources the gas industry will have to invest, as ultimately the logic of developing an industry specific PAS specification is inescapable. ■

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