



by Bob Yeoman

Keeping up with New Regulations to Survive in the Gas Business

Gawda consultants play vital role in keeping gas distributors viable and safe.

The industrial, medical, and specialty gas businesses, all highly regulated, cover a wide array of products that include pharmaceuticals, medical devices, flammable and toxic materials, and business operations. All of these involve manufacture, warehousing, and distribution. Just about every compliance initiative that works its way through the Federal bureaucracy has an impact on every level of the gases industry. Companies that deal with gases in any form must keep abreast of new and changing regulations to maintain their businesses in compliance with requirements that change constantly.

For years, welding and gases distributors kept abreast of evolving requirements by relying on the advice and support of the *GAWDA, Gases and Welding Distributors Association* (formerly NWSA), consultants. It was cost effective and successful. In 2002, however, GAWDA leadership decided to expand its support services by making significant changes in the safety and compliance consultant resources. These changes enhance even further the compliance assistance provided to association members. Traditional safety services were augmented, and new areas of focus and consulting support added. GAWDA members now have access to a larger group

of experts for compliance consulting and advice that cover a wider array of compliance initiatives.

DOT and Security

Mike Dodd, formerly the NWSA traffic consultant, has assumed responsibility for member consulting services related to all DOT compliance issues. His area



Michael L. Dodd

of expertise now encompasses consultation on cylinder retesting requirements and procedures and cylinder labeling issues, as well as shipping and transportation requirements for industrial and specialty gases and related products. Mike is also the GAWDA liaison to the CGA committees that covers fleet safety and DOT requirements.

Following the events of 9-11-2001, security issues in the industrial gases industry have taken on a greater emphasis. There has been a general increase in security precautions industry wide, with a particular emphasis on securing flammable and toxic materials. New forthcoming government regulations will

mandate that industrial and specialty gases firms implement even more rigorous security procedures and plans.

Mike Dodd has assumed the added responsibility of keeping GAWDA members abreast of the latest security related developments and requirements in the industrial and specialty gases businesses. He will provide consulting and advice on on-site security and employee background and employment checks, as well as storage and transportation security issues. He will also be the GAWDA liaison to the newly formed CGA security committee. Mike coordinated a security update at the GAWDA Spring Management Conferences.

OSHA and EPA

GAWDA has retained the services of Tom Eynon as its new OSHA and EPA consultant. Tom is a Senior Associate with B&R Compliance Associates, and brings to GAWDA a background of more than 35 years in safety and compliance, with more than 15 of his years in the gas and gas-related industries.



Thomas W. Eynon

years in the gas and gas-related industries.

Tom will spearhead an increased focus on basic OSHA safety compliance. With the tightening of the insurance market over the last few years, many companies are attempting to slow the growth rate of rapidly increasing workers compensation insurance premiums by reducing or eliminating accidents that occur inside their businesses. GAWDA members will now have access to the guidance and additional services they need to improve their accident and injury prevention programs.

Companies that manufacture, store, or package flammable, toxic, or other hazardous materials may find they are required to comply with OSHA Process Safety Management standards, or the EPA Risk Management Program. Many states such as Delaware and California have similar standards that are more stringent than the Federal regulations. Knowing what regulations apply to your business and staying abreast of changes in requirements can be difficult for smaller distributors. GAWDA members can now turn to Tom Eynon for assistance in understanding these complex regulations and, if needed, call on Tom to provide assistance in achieving and maintaining compliance.

Tom will also be the GAWDA liaison to the CGA safety and health and process safety committees.

Compliance Training

This spring, the popular GAWDA Safety and Compliance Training Seminar will be reintroduced. These sessions cover a wide range of compliance subjects from DOT and Hazmat requirements to OSHA compliance, and provide vital training for operations and compliance managers alike. There has been a gradual evolution of requirements over the last few years and if you have not been to a compliance training session during that period, it may be time to go back to school. Both Tom Eynon and Mike Dodd will introduce new materials and new topics this year.

Medical Gases

Last year, GAWDA decided to increase

the support and assistance to members in the area of medical gas compliance by developing and offering a medical compliance program. GAWDA asked firms that specialize in medical gas compliance to submit proposals, and through a competitive bidding process, selected B&R Compliance Associates LLC, headed by Ron Ball and Bob Yeoman who will serve as the association's medical gases consultants. B&R will make available to GAWDA members regulatory and technical support, and maintain the existing FDA compliance manual. In addition, GAWDA and B&R will offer a slate of new medical gas programs and services to assist members in managing compliance. Highlights of these new programs include:

- A Medical Gas SOP program, which is currently available. Program subscribers will receive from GAWDA a SOP manual that contains the quality procedures, work instructions, technical data, and forms required to compliantly fill high-pressure cylinders, liquid cylinders, and medical vans with Oxygen USP. B&R will track the on-going evolution of medical gas requirements and FDA enforcement trends and provide automatic updates to program members.



Ron Ball

- Program subscribers with requirements beyond Oxygen USP will be able to access the additional materials they need directly from B&R. Supplemental SOP modules for Air USP, Nitrogen NF, Carbon Dioxide USP, Helium USP, and Nitrous Oxide USP, as well as medical and device mixtures will be available. B&R will also offer support for medical micro bulk delivery and storage systems.

A special module, designed specifically for firms that distribute medical products but do not fill their own cylinders, will be available in early spring.

- Optional training programs, which in-

clude GAWDA-sponsored regional training sessions that cover both basic and advanced training for medical gas operations will be offered. The first of these regional training seminars will begin in April 2003. B&R currently offers a training subscription program. This package of training materials includes all the training support materials a firm needs to conduct its own cGMP training for its work force.

- Once the new FDA medical gas guidelines are released, many companies will want to consider a detailed assessment of how adequate and effective their existing compliance program is, based on new requirements. Audits are an effective tool that uncovers and highlights issues and prioritizes actions that improve compliance. B&R will offer two options that will assist GAWDA members in evaluating their firm's compliance with Medical Gas requirements—through either an on-site mock FDA inspection conducted by an experienced B&R auditor, or by using B&R's cGMP self assessment software and audit guide.

- B&R also offers SOP program members the opportunity to enroll in its **Total Solution Program**. Total Solution members will have B&R Compliance Associates as their virtual compliance staff. Each Total Solution package includes annual on-site employee training, an annual on-site mock FDA inspection, the supplemental SOP modules they need for their business, and many other benefits. Each Total Solution package is custom tailored to meet the member's individual business and compliance requirements. It is a cost-effective solution that helps achieve and maintain medical gas compliance.

SGR

*To learn more about the GAWDA programs for DOT compliance, security, and OSHA and EPA compliance, as well as medical compliance, visit the association's website at www.gawda.org, or contact: **B&R Compliance Associates at: brcompliance@brcompliance.com***