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What are the FDA issues around security?

The FDA does not have the same type of security regulations as the DOT. However, there are several security related issues.

Drug Storage

The 2003, Draft Guidance for Industry - Current Good Manufacturing Practice for Medical Gases summarizes the FDA thinking and regulations about medical gas security:

B. Security

Medical gas manufacturers are wholesale distributors who are subject to the requirements of § 205.50 - Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

All facilities used for medical gas distribution must be secure from unauthorized entry (§ 205.50(b)(1)).

Entry into areas where medical gases are held must be limited to authorized personnel (§ 205.50(b)(1)(iii)). We recommend areas where nitrous oxide is held be especially secure.

The security requirements of § 205.50(b) apply to all facilities used for medical gas distribution. FDA interprets this regulation to include all facilities where loaded medical gas delivery trucks are parked prior to making deliveries, including at an employee's home when a loaded medical gas delivery truck is driven there and parked overnight for early morning runs.

A manufacturer could use an alarm system to secure the building and keep loading docks secure, rather than open and easily accessible.

Keep in mind that the Draft Guidance does not carry the same authority as the underlying regulations. However, it does represent the last published agency thinking about security and medical gases.

Nitrous Oxide

The FDA does not define “especially secure” storage areas for nitrous oxide. The Compressed Gas Association has published excellent guidelines for storing and securing nitrous oxide. GAWDA members can sign up for free access to these CGA resources. For further details, see:

- CGA G-8.3, *Safe Practices for Storage and Handling of Nitrous Oxide*
- CGA P-50, *Site Security Standard*
- CGA P-51, *Transportation Security Standard for the Compressed Gas Industry*
- CGA P-52, *Security Standard for Qualifying Customers Purchasing Compressed Gases*

Though not all items will apply in all cases, consider the following:

- Inventory control systems to detect theft or loss
- Access controls
- Property fencing
- Secondary fencing for nitrous cylinders and bulk storage
- Lockout devices to secure valves on bulk storage
- Security systems, alarms, etc.
- Procedure to determine if a customer is legitimate

Disaster and Emergency Plans

GAWDA members should consider developing a disaster emergency plan to ensure the continued security of Medical Gas products during a natural disaster.

Review local and state requirements when developing this disaster emergency plan as requirements vary considerably between locales, however, your plans may include at a minimum:

- Provisions for ensuring that medical gases designated as controlled substances are kept secure during times of natural disasters.
- Provisions for ensuring that medical gases are not un-intentionally contaminated as a result of floods or other natural disaster events
- Provisions for ensuring the integrity and availability of production records that indicate which medical products have been approved and released for distribution.
- Provisions for ensuring the integrity and availability of production records that indicate which medical products are still in process and have not been approved and released for distribution.
- Provisions for ensuring the integrity and availability of distribution records of medical products that would facilitate any potential recall of medical gas products.
- Considerations for reviewing fill system integrity and cleanliness prior to production re-starting after a natural disaster.
- Considerations for reviewing and ensuring purity, strength, and identity of product used to fill medical gas containers on return to production.
- Considerations for reviewing and ensuring the suitability of containers and components used to manufacture medical gases prior to introducing product into them following a natural disaster

Contact Tom Badstubner (tom@asteriskllc.com) or Amy (amy@asteriskllc.com) for a sample disaster/emergency plan for medical gases.

Electronic Records

The security of electronic records is regulated by 21 CFR Part 11. We are not required to keep any electronic records. But, if we do use electronic records for any compliance activities (fill logs, analytical results, lot number distribution, etc.) we are required to maintain the integrity of those records and protect them from loss or tampering.

In addition, we must have written procedures for:

- Validation of systems to ensure consistency, reliability, consistent intended performance and the ability to discern invalid or altered records;
- The ability to generate accurate and complete copies of records in both human readable and electronic form;
- Protection of records including limiting access to authorized individuals;
- Use of secure, computer-generated time-stamped audit trails to record operator entries and actions modifying records;
- Operational system checks to enforce permitted sequencing of steps and events;
- Use of authority checks to ensure that only authorized persons can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand;
- Terminal checks to determine the validity of source data input;
- Training of persons who use, develop, and maintain the system;
- Written policies regarding use of the system; and documentation of system controls.

Thank you
Tom Badstubner
GAWDA Medical Gas Consultant