

Failure to Set Ventilator Arms at Issue in Lawsuit
Page...101

Excess Lubricant May Occlude PEEP Valve Output Hole
Page...99

Defibrillator-Monitor Problems: Switches and Connectors
Page...100

Programming Procedure May Cause Pacemaker Anomalies
Page...99

Biomedical Safety & Standards®

July 15, 1991

Volume 21, Number 13

FEATURE

FDA "Warning Letters" Policy Revised

The FDA has revised its regulatory practices involving "Warning Letters" sent to notify manufacturers of compliance deficiencies and possible enforcement actions. The revised procedures have eliminated the differences between "Notice of Adverse Findings Letters" and "Regulatory Letters." The procedural revisions decentralize somewhat the FDA's method of communicating its intent to proceed with enforcement actions. In many cases, the FDA's district directors will have the authority to directly issue "Warning Letters."

A spokesperson for the FDA's *Division of Compliance Policy* explained that the new procedures replace previous enforcement practices, which provided for communications documents that implied graduated levels of urgency. "We used to send a Notice of Adverse Findings Letter first...and if there were continued violations, then we sent a Regulatory Letter." The agency's intent to enforce any regulatory violations will now be communicated to companies, using one category of document.

FDA POLICY REVISED
continued on next page

CLINICAL SAFETY & PRODUCT HAZARDS

Patient Receives Air Instead of Oxygen: Canadian Safety Alert

An incident in which a patient was administered medical air instead of oxygen has prompted Canada's **Health Protection Branch (HPB)** to issue a medical device alert. The incident involved a medical air flowmeter that was apparently constructed with a threaded gas-specific outlet connector for oxygen and an inlet connector specific for air. This allowed the patient's oxygen tubing to be "inadvertently attached to the air flowmeter."

The HPB acknowledges that "some manufacturers supply air flowmeters with an oxygen outlet connector," but cautions that such flowmeters do not comply with the accepted Canadian standard for medical gas equipment. The **Canadian Standards Association** document, *CSA Z305.3-M87 Pressure Regulators, Gauges and Flowmetering Devices for Medical Gases* requires "the inlet and outlet connectors on a medical gas flowmeter to be gas-specific for the intended gas." Although Canada's medical device regulations do not mandate conformity with the standard, the HPB recommends that healthcare facilities ensure that flowmeters comply with the standard to prevent delivery of the wrong gas to the patient. "Defeating the gas-specific nature of such connections eliminates these important safety mechanisms, with potentially hazardous results," the agency warns.

The barbed fitting between the gas tubing and the connector poses another safety concern, the HPB continues. The agency is concerned that procedures at healthcare facilities could allow personnel to leave the gas-specific threaded connector attached to flowmeters with the push-on hose fitting exposed. Because many diameters of gas tubing can be easily connected to such fittings, the HPB advises users to "establish operating guidelines that will help prevent errors in attaching the wrong tubing at this site." The agency's *Bureau of Radiation and Medical Devices* is inviting comments on the standards, particularly those that address the issue of a gas-specific fitting between the oxygen hose and the connector. (Contact: Director, Bureau of Radiation and Medical Devices, Health Protection Branch, 775 Brookfield Road, Ottawa, ON K1A 1C1.) Index: Oxygen, air flowmeter safety alert; Gas-specific connectors, air flowmeter, safety alert; Air flowmeter, safety alert.

155

An independent, concise news source written exclusively for the fields of medical safety and standards. Includes timely, factual reports on safety hazards, product recalls, standards, legal actions, legislation & regulations, hospital safety, BMET & CE activities, education, and meetings.