MEDICAL DEVICE REPORTING
User Facility Reporting

Issue No. 35 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Summer 2001

EXTENSIONS GRANTED TO ENFORCEMENT PRIORITIES FOR REPROCESSED SINGLE-USE DEVICES

The Department of Health and Human Services has granted 6-month extensions to four reprocessors that had submitted premarket applications (PMAs) for class III single-use devices (SUD) to the Food and Drug Administration on February 14, 2001. This extension to February 14, 2002, was granted to allow the reprocessors time to obtain additional clinical information necessary for PMA approval. The extension is limited to the cardiac ablation catheter PMAs that are under current review. **All other reprocessed class III SUDs may be available only under the Investigational Device Exemption (IDE) regulation**. For additional information about SUDs reprocessing, see issue 34 of the UFR Bulletin (http://www.fda.gov/cdrh/fusenews/ufb34.pdf).

As stated in the SUD Enforcement guidance (http://www.fda.gov/cdrh/comp/guidance/1168.pdf), after August 14, 2001, FDA would actively enforce the non-premarket requirements (i.e., establishment registration, device listing, medical device reporting as a manufacturer, corrections and removals, quality system requirements, labeling, and tracking). **Now, FDA will actively enforce only the non-premarket requirements for hospital reprocessors to register their establishments and to list their devices with the Agency**. FDA will use the additional year (until August 14, 2002) to focus on education rather than enforcement of the other non-premarket requirements for hospital reprocessors. **This revised policy does not apply to the premarket requirements or to third-party (commercial) reprocessors**. (See the FDA Talk Paper of August 16, 2001, entitled *FDA Actions on Reprocessed Single Use Devices* on the Internet at http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01098.html.)

Revised Enforcement Priorities Timetable

Dates for Premarket Submissions and Approvals

	Filing Date	Clearance or Approval Dates:
Class III	2/14/2001	2/14/2002*
Class II non-exempt	8/14/2001	2/14/2002
Class I non-exempt	2/14/2002	8/14/2002

**This new date applies only to the four class III PMAs already submitted to FDA.*

Dates for Enforcement of the Non-Premarket Requirements

Establishment Registration	8/14/01
Device Listing	8/14/01
Quality System Regulation	8/14/02
Medical Device Reporting as a manufacturer**	8/14/02
Medical Device Tracking	8/14/02
Labeling	8/14/02
Corrections and Removals	8/14/02

***There is **no change** in a hospital's MDR reporting responsibilities as a user facility.*

In This Issue:

MEDICATION ERRORS ASSOCIATED WITH MEDICAL GAS MIX-UPS*

By Duane S. Sylvia, B.S.

Problem

The Food and Drug Administration (FDA) is concerned about continuing deaths and injuries resulting from medical gas mix-ups. Following are three examples of mix-ups.

On December 7, 2000, a nursing home in Bellbrook, Ohio, reported two patients dead and eight patients injured following a mix-up in the oxygen supply system. Several days later, two more patients died from exposure to industrial nitrogen, bringing the death total from this one incident to four. The nursing home had supposedly received a shipment of four cryogenic vessels containing medical grade oxygen. Included in the delivery, however, was a cryogenic vessel of industrial grade nitrogen. The nursing home was running low on oxygen and sent a maintenance employee to connect a new oxygen vessel to the oxygen supply system.

The employee mistakenly selected a nitrogen vessel and discovered that he was unable to connect the vessel to the oxygen system. (As a safeguard, the connectors for oxygen vessels are specially fitted so they are compatible only with oxygen delivery systems.) The employee removed a fitting from an empty oxygen vessel and installed it on the nitrogen vessel. He then connected the deadly nitrogen to the oxygen system.

On April 22, 1998, a hospital in Idaho discovered that a large cryogenic vessel of industrial nitrogen had been connected to the oxygen system supplying the operating rooms, labor and delivery rooms, and emergency room. The hospital discovered that the medical gas delivery person initially had been unable to connect the incompatible nitrogen vessel outlet fitting to the oxygen system. So, he used a wrench to disconnect the nitrogen fitting and replace it with an oxygen fitting. Two patients died as a result of this medical gas mix-up.

In October 1997, a hospital in Nebraska received a shipment of medical grade oxygen in large cryogenic vessels. The shipment included one cryogenic vessel of industrial grade argon that was properly labeled. The hospital was running low on oxygen and sent a maintenance employee to connect an oxygen vessel to the oxygen supply system. Without examining the label, the employee selected an argon vessel. Discovering that he was unable to connect the vessel to the oxygen supply system, he removed a fitting from an empty oxygen vessel, installed it on the argon vessel, and connected the deadly product to the oxygen system. Argon was administered to a patient undergoing minor surgery. The patient died.

These three cases reveal striking similarities:

- The person connecting the vessel to the oxygen system (e.g., the delivery person or the facility employee) was not properly trained and did not understand that connection incompatibility is a built-in safeguard.
- Before installing the cryogenic vessel to the oxygen supply system, the person making the connection did not examine the drug label applied to the cryogenic vessel to ensure that the product was medical oxygen.

Safe Practice Recommendations

To minimize the risk of medical gas mix-ups, the FDA makes the following recommendations to hospitals, nursing homes, and other health care facilities:

- ***Never*** change the fittings or use adapters on medical gas containers. If a connection does not fit, contact the supplier immediately.
- Store ***medical grade*** products and ***industrial grade*** products separately and in well-defined areas.
- Train personnel handling medical gas to recognize medical gas labels and to examine all labels carefully before hooking containers to the system.
- Always have a knowledgeable person check the container and connection **before** introducing the gas into the system.
- Because medical gases are prescription drugs, manufacturers that receive reports of death or serious injury associated with the use of medical gases are required by law to report those incidents to the FDA (see *Title 21 of the Code of Federal Regulations* at sections 310.305 and/or 314.80).
- Hospitals, nursing homes, and other healthcare facilities should submit reports of such mix-ups (whether or not they resulted in a serious injury) to FDA's voluntary reporting program, ***MedWatch***. You can report by calling 1-800- FDA-1088, by FAX at 1-800- FDA-0178, or by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland, MD, 20857-978.

Duane S. Sylvia, B.S., is a Compliance Officer in the Center for Drug Evaluation and Research (CDER).

*Adapted from *Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities* by the Food and Drug Administration, March 2001. This guidance is available on the Internet at http://www.fda.gov/cder/guidance/4341fnl.htm.

FDA Public Health Advisory: Potential for Injury from Medical Gas Misconnections of Cryogenic Vessels

(You are encouraged to copy and distribute this Advisory)

July 20, 2001

To: Hospital Administrators
Risk Managers
Directors, Biomedical Engineering
Directors, Respiratory Therapy
Nursing Home Administrators
Home Health Care Agencies

This advisory is to alert you to the potential for patient injury when cryogenic vessels containing medical gas are misconnected to oxygen delivery systems. Misconnections cause patients who should receive medical oxygen to receive another gas, such as nitrogen, instead. Over the past four years, FDA has received reports of seven deaths and fifteen injuries associated with medical gas misconnections that occurred in acute care and nursing home settings.

Nature of the Problem

Oxygen supply systems in medical facilities are equipped with gas-specific connectors that fit only the corresponding connectors on the cryogenic vessels in which oxygen is delivered. In the cases we have reviewed, deaths and injuries occurred when two errors were made in sequence. First, a cryogenic vessel containing another gas was mistakenly identified as containing oxygen. Then, the gas-specific connector on this cryogenic vessel was changed or misadapted so that it could deliver the wrong gas to an oxygen-delivery system. In many of the reported incidents, the person connecting the vessel to the oxygen delivery system (either the delivery person or the facility employee) did not understand that the gas-specific connector was a safeguard designed to prevent such mishaps from occurring.

Recommendations

We urge you to take every opportunity to promote proper handling of medical gases. Inform all personnel handling and using cryogenic vessels of these recommendations. To avoid possible injuries from misconnected medical gases, we recommend the following:

- When connecting a cryogenic vessel, check the label carefully to ensure that it contains the appropriate gas for the intended application.
- Never use adapters or change the connectors or fittings on cryogenic vessels. **If a connector will not connect to the oxygen supply system, the contained gas is likely not oxygen and should not be used**. Contact the gas supplier for further information and guidance.
- Make sure that all personnel who will be handling medical gases are properly trained to understand the operations and connections of the medical gas system. Make sure that personnel are trained to examine and recognize medical gas labels.
- If your facility receives both medical and industrial grade gases, store them separately.

Reporting Adverse Events to FDA

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices, including devices used to deliver medical gases. We request that you follow the procedures established by your facility for such mandatory reporting.

We also encourage you to report other adverse events associated with the use of a medical gas. You can report these directly to the device or medical gas manufacturer. You can also report to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by one of four ways: online at http://www.accessdata.fda.gov/scripts/medwatch/ by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(Continued on Page 4)

PUBLIC HEALTH ADVISORY - *From Page 3*

Getting More Information

Further information regarding medical gas misconnections may be found at http://www.fda.gov/cder/guidance/4341fnl.htm. Should you have questions regarding this letter, please contact Paula Simenauer, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by FAX at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. Additionally, a voice-mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

All of the FDA medical device postmarket safety notifications can be found on the World Wide Web at http://www.fda.gov/cdrh/safety.html. Postmarket safety notifications can also be obtained through e-mail on the day they are released by subscribing to our list server. You may subscribe at http://list.nih.gov/archives/dev-alert.html.

Sincerely yours,

David W. Feigal, Jr., MD, MPH
Director
Center for Devices and Radiological Health
Food and Drug Administration

Janet Woodcock, MD
Director
Center for Drug Evaluation and Research
Food and Drug Administration

REPORTING PROBLEMS WITH MEDICAL DEVICES: OVERVIEW

User facilities, importers, and manufacturers must submit reports of device-related adverse events to the Food and Drug Administration (FDA) as specified by the Medical Device Reporting (MDR) regulation. The reports provide FDA with significant information that allows problems to be identified and corrected quickly. User facilities (e.g., hospitals and nursing homes) are required to report suspected device-related deaths to both FDA and the manufacturers. User facilities also must report device-related serious injuries to the manufacturer. If the medical device manufacturer is not known, the facility should report the device-related serious injury to FDA. Health professionals within a user facility should become familiar with their institution's procedures for mandatory reporting of device-related adverse events to the FDA.

Consumers and health professionals may report device problems and adverse events to the MedWatch program (http://www.fda.gov/medwatch/), FDA's voluntary problem reporting program for medical products.

For questions about Medical Device Reporting, contact FDA at:

Reporting Systems Monitoring Branch (HFZ-533)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive
Rockville, MD 20850

The following telephone numbers are for specific questions (please use FAX numbers except for emergencies):

Interpretation of MDR reporting policy:

- 301-827-0038 (FAX)
- 301-594-2735 (voice)

Emergencies (after normal East Coast business hours):

- 301-443-3757 (FAX)
- 301-443-1240 (voice 24 hours/day)

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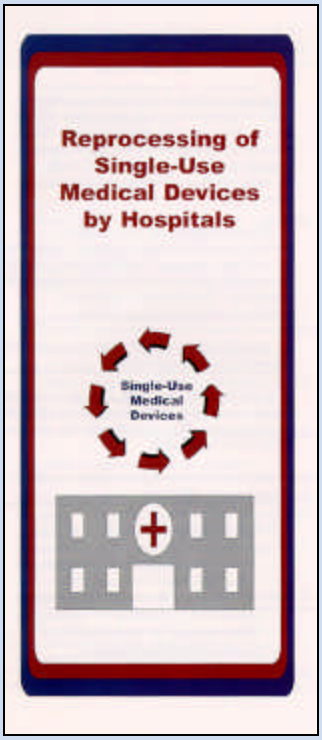

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UPCOMING REUSE EVENTS

September 11, 2001
Central New York Healthcare Central Service Professionals, Verona, New York, FDA Speaker: Sharon Kalokerinos

October 4-5, 2001
Texas Society of Infection Control Practitioners, Harlingen, Texas, FDA Speaker: Lily Ng.
For more information: LaurieD.Jonsson@vbmc.org.

November 4-7, 2001
RAPS 2001 Conference, Baltimore, Maryland, FDA Speaker: Lily Ng.
For more information: http://www.raps.org/educ/uprogs.cfm

November 9-10, 2001, Japanese Association for Operative Medicine, Tokyo, Japan, - FDA Speaker: Tim Ulatowski

For more information visit the Reuse website at:

http://www.fda.gov/cdrh/reuse/index.shtml

REPORTING PROBLEMS - *From Page 4*

Reporting Adverse Events and Device Problems:

- Voluntary reporting: 301-827-0361
- Mandatory MDR reporting: 301-827-0360 (Call this number to request permission to submit an MDR by FAX.)

Documents

- *Note Concerning the March 27, 2000 Amendments to the MDR Regulation to Implement FDAMA Changes* (http://www.fda.gov/cdrh/postsurv/note_932700.html)
- *Medical Device Reporting: An Overview* (http://www.fda.gov/cdrh/mdrovrvw.pdf)
- *Medical Device Reporting for User Facilities* (http://www.fda.gov/cdrh/mdruf.pdf)
- *Medical Device Reporting for Manufacturers* (http://www.fda.gov/cdrh/manual/mdrman.html or http://www.fda.gov/cdrh/manual/mdrman.pdf)
- *Medical Device Reporting by Consumers or Health Professionals* (http://www.fda.gov/medwatch/)
- *Medical Device Reporting Guidance, Exemptions and Variances* (http://www.fda.gov/cdrh/mdrgdocs.html)
- *Medical Device Reporting Forms and Instructions* (http://www.fda.gov/cdrh/mdrforms.html)

Other MDR Information and User Facility Reporting Documents

- General Information about the Medical Device Reporting Program (http://www.fda.gov/cdrh/mdrinfo.html)
- *User Facility Reporting Bulletins* (http://www.fda.gov/cdrh/fusenews.html)
- *Federal Register Notices* related to MDR (http://www.fda.gov/cdrh/frmdr.html)
- Medical Device Reporting (MDR) data (http://www.fda.gov/cdrh/mdrfile.html) are available for the years 1984 to 1996. Manufacturer reports after July1996 are part of the Manufacturer and User Facility Device Experience (MAUDE) (http://www.fda.gov/cdrh/maude.html) database.

HOSPITAL BED SAFETY WORK GROUP: HIGHLIGHTS OF MARCH MEETING

By Mary Lou Pijar, B.A., and Mary Ann Wollerton, M.P.A

The Hospital Bed Safety Work Group (HBSW) met on March 28-31, 2001, for a fourth time. (See Issues 29 and 30 of the *Bulletin* for previous reports of the HBSW.) Participants were representatives from national healthcare associations, the Federal government, the medical bed industry, and consumer advocacy groups. This work group has made strides toward its goal of reducing the problem of patient entrapment in hospital bed rails and has completed or nearly completed a number of educational products. These are discussed below.

Hospital Bed Safety Brochure

A brochure entitled "A Guide to Bed Safety" was completed in October 2000 and 50,000 copies were printed. Participating members distributed the brochures. Because of the success of the brochure, FDA funded the printing of an additional 50,000 copies. You can read and download the brochure at: http://www.fda.gov/cdrh/beds. You can also order a limited number of brochures by contacting:

Beryl Goldman
Kendal Corporation
P.O. Box 100
Kennett Square, PA 19348
Telephone: 610-388-5586.

Many organizations are actively distributing the brochures, writing journal and newspaper articles, and placing the HBSW information on their websites.

Clinical Guidance

The Clinical Guidance provides a uniform set of recommendations for caregivers in hospitals, long term care facilities, and home care settings to use when assessing their patients' needs for and possible use of bed rails.

(Continued on Page 6)

HOSPITAL BED SAFETY WORK GROUP - *From Page 5*

The Guidance stresses assessment of an individual patient by an interdisciplinary team to determine the extent of his or her vulnerability to entrapment. Every patient, regardless of care setting, must be assured a safe, comfortable and dignified sleeping environment. When at-risk patients are identified, the health care team should consider the interventions that promote the highest level of independent functioning specific to the patient's health and safety needs. The HBSW group will launch a major outreach effort when the Clinical Guidance is ready for distribution.

Dimensional and Assessment Guidance

The HBSW developed measurement recommendations that define maximum and minimum dimensions for gaps or openings in the bed systems' component. Complying with these recommendations will reduce the risk of entrapment. The U.S. Food and Drug Administration received the dimensional recommendations of the HBSW and will incorporate them as a guidance document to be published in the Federal Register. Watch for this guidance in early November and send FDA any comments that you wish to have considered.

The dimensional recommendations were derived by extensive examination of anthropometric data and by reviewing previous incident data. Three key parts of the body were found to be of the greatest risk of entrapment. These are the neck, the head, and the chest. Entrapment involving any of these body areas could lead to a life-threatening situation.

The working group established seven zones in the bed system with the potential for entrapment. The bed system includes the bed frame, bed rails, mattress, and bed ends. The dimensional tests involve the use of assessment tools, a cone and a cylinder-shaped object, designed to simulate the size of the body part considered at risk of entrapment. This cone or cylinder is placed into or moved through the open space to determine if entrapment is likely to occur. For some of the tests, a load is applied to the cone to simulate body forces or gravity that can be generated as a portion of the body moves through an opening in the bed system.

In addition to defining the design limits on the bed systems and developing a tool to effectively measure the bed systems, the HBSW prepared instructions for evaluating the bed systems, an instructional videotape to demonstrate the assessment process, and a bed system corrective action plan.

To conduct an assessment, one individual is needed to physically measure the bed system with a second person to record the results. The assessment time is about 15 minutes per bed system. The bed should be unoccupied to allow for mattress movement and ease of measurement.

The Hospital Bed Safety Group plans to have the assessment kits available for hospitals, nursing homes, and home care use. Each kit will include the Bed System Entrapment Dimensional and Assessment Guidance, the measurement tools, an instructional video, Clinical Guidance, and the Bed System Corrective Assessment Plan. It will be available for purchase from ECRI by early 2002.

Get this brochure from the FDA Hospital Bed website at: http://www.fda.gov/cdrh/beds or by sending an e-mail to dsma@cdrh.fda.gov or a FAX to 301-443-8818.

Mary Lou Pijar, B.A., is a General Health Scientist and Mary Ann Wollerton, M.P.A., is a Public Health Advisor in CDRH's Office of Health and Industry Programs.

ELECTRONIC NOTIFICATION FOR THE *USER FACILITY REPORTING BULLETIN* IS NOW AVAILABLE

If you would like to be notified electronically (via e-mail) when a new issue of the *User Facility Reporting Bulletin* is released, you can sign-up for our new List Service at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCDRHNew/listman.cfm

USER FACILITY REPORTING BULLETIN

FDA produces the *User Facility Reporting Bulletin* quarterly to assist hospitals, nursing homes and other medical device user facilities in complying with their statutory reporting requirements under the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Administration Modernization Act of 1997. The *Bulletin's* contents may be freely reproduced. Comments should be sent to the Editor.

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