

This event is closed for the purpose of this report.

AS 99-8 Therapeutic

Radiopharmaceutical
Misadministration of Samarium-153
at Merle West Medical Center in
Klamath Falls, Oregon

Date and Place—March 10, 1999;
Merle West Medical Center; Klamath
Falls, Oregon.

Nature and Probable Consequences—A patient with metastatic prostate cancer was prescribed a dosage of 2,294 megabecquerel (MBq) (62 millicurie [mCi]) of samarium-153 (Sm-153) to palliate bone pain. However, because of an error, the patient was administered a dosage of 3,589 MBq (97 mCi) of Sm-153. The recommended dosage for the Sm-153 procedure is “1 mCi per kg of body weight” (37 MBq per kilogram [kg]) (1 mCi per 2.2 pounds [lb]).

The misadministration resulted in an additional dose of 200 centigray (cGy) (200 rad) to the bone marrow. The patient's other organs received additional doses that were below 1,000 cGy (1,000 rad). The hospital checked with the manufacturer, DuPont Merck Pharmaceutical Company, concerning possible side effects of the misadministration. The pharmaceutical company indicated that other studies have been done using 74 to 92.5 MBq per kg (2.0 to 2.5 mCi per 2.2 lb) of Sm-153 with no significant side effects.

Both the attending physician and the patient's family were notified of the misadministration.

Cause or Causes—This event was caused by a human error. The licensee indicated that the dosage was calculated using the patient's weight in pounds instead of kilograms.

Actions Taken To Prevent Recurrence

Licensee—The incident was discussed with the Radiation Safety Committee (RSC). The licensee revised its Quality Management Program (QMP) for the use of Sm-153 and strontium-89 therapy to require the prescribing physician to calculate and personally order the dosage. The RSC approved the changes to the QMP. The technologist involved in the procedure was counseled concerning therapy procedures, dosage administrations, and the importance of rechecking calculations.

State Agency—The State cited the licensee for failure to report the misadministration within the required time.

This event is closed for the purpose of this report.

AS 99-9 Sodium Iodide

Radiopharmaceutical
Misadministration at St. Edward

Mercy Medical Center in Fort
Smith, Arkansas

Date and Place—December 7, 1998;
St. Edward Mercy Medical Center; Fort
Smith, Arkansas.

Nature and Probable Consequences—A patient was prescribed a thyroid scan using 222 megabecquerel (MBq) (6 millicurie [mCi]) dosage of technetium-99m (Tc-99m) pertechnetate. However, the patient was administered about a 148 MBq (4 mCi) dosage of iodine-131 (I-131).

The medical center routinely received unit dosages from a nuclear pharmacy packaged in appropriately sized syringes ready for injection to patients. However, in this case, instead of being in a syringe, the dosage was in a glass vial within a large lead container. The shipping package also contained two dispensing straws. The shipping container, the lead “pig,” and the vial were labeled by the nuclear pharmacy as 222 MBq (6 mCi) of Tc-99m. The licensee's staff surveyed the incoming package but saw nothing unusual. The licensee's staff attributed the change in the appearance of the package (a glass vial instead of a syringe and the presence of the dispensing straws) to a mistake made by the nuclear pharmacy. Therefore, the oral solution of the I-131 dosage, mislabeled as Tc-99m, was drawn into a syringe and was injected into the patient.

The licensee's medical physicist determined that the dose to the patient's thyroid based on the radiopharmaceutical manufacturer's package insert was about 48 gray (4,800 rad). The patient was notified of the misadministration by the licensee's radiation safety officer (RSO). The patient's attending physician was also notified of the circumstances and possible complications. The RSO advised the patient to continue long-term follow-up with the primary care physician.

Cause or Causes—This event was caused by the nuclear pharmacy mislabeling a radiopharmaceutical dosage. Also, it appears that the medical center's nuclear medicine staff did not question or address the unusual package upon receipt.

Actions Taken To Prevent Recurrence

Licensee—The licensee reported this event to the Arkansas Department of Health on December 7, 1998, and submitted a written report on December 8, 1998. The center's management revised the policy and procedure for the receipt of radiopharmaceuticals from the nuclear pharmacy. The revision states that only I-131 radioactive dosages will be accepted in glass vials.

Any suspect or other labeled isotope received in glass vials will be questioned or returned to the pharmacy for isotope verification. The nuclear pharmacy indicated that policies and procedures for dispensing radiopharmaceutical therapy products have been revised to prevent recurrence of similar incidents.

State Agency—The State staff performed an on-site investigation at the medical center and the nuclear pharmacy on December 8, 1998.

The investigation discovered violations associated with license conditions and regulations for activities conducted at the nuclear pharmacy.

This event is closed for the purpose of this report.

Dated at Rockville, Maryland, this 1st day of March, 2000.

For the Nuclear Regulatory Commission.

Andrew L. Bates,

Secretary of the Commission.

[FR Doc. 00-5473 Filed 3-6-00; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

Submission for Office and Management Budget Review; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549

Extension:

Rule 15g-4, SEC File No. 270-347, OMB Control No. 3235-0393; Rule 15g-5, SEC File No. 270-348, OMB Control No. 3235-0394; Rule 17a-8, SEC File No. 270-53, OMB Control No. 3235-0092; Rule 17Ac2-1 and Form TA-1, SEC File No. 270-95, OMB Control No. 3235-0084; Rule 19d-2, SEC File No. 270-204, OMB Control No. 3235-0205.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) has submitted to the Office of Management and Budget requests for extension of the previously approved collections of information discussed below.

Rule 15g-4 requires brokers and dealers effecting transactions in penny stocks for or with customers to disclose the amount of compensation received by the broker-dealer in connection with the transaction. It is estimated that approximately 270 respondents incur an average of 100 hours annually to comply with the rule.

Rule 15g-5 requires brokers and dealers to disclose to customers the amount of compensation to be received by their sales agents in connection penny stock transactions. It is estimated that approximately 270 respondents incur an average of 100 hours annually to comply with the rule.

Rule 17a-8 requires brokers and dealers to make and keep certain reports and records concerning their currency and monetary instrument transactions. The requirements allow the Commission to ensure that brokers and dealers are in compliance with the Currency and Foreign Transactions Reporting Act of 1970 ("Bank Secrecy Act") and with the Department of the Treasury regulations under that Act. The reports and records required under this rule initially are required under Department of the Treasury regulations. Additional burden hours and costs are not imposed by this rule.

Rule 17Ac2-1 requires transfer agents to register with the Commission, the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, or the Federal Deposit Insurance Corporation, and to amend their registration. It is estimated that on an annual basis, the Commission will receive approximately 250 applications for registration on Form TA-1 from transfer agents required to register as such with the Commission. Included in this figure are amendments made to Form TA-1 as required by Rule 17Ac2-1(c). Based upon past submissions, the staff estimates that the average number of hours necessary to comply with the requirements of Rule 17Ac2-1 is one and one-half hours, with a total burden of 375 hours.

Rule 19d-2 prescribes the form and content of applications to the Commission by persons desiring stays of final disciplinary sanctions and summary action of self-regulatory organizations ("SRO") for which the Commission is the appropriate regulatory agency. It is estimated that approximately 30 respondents will utilize this application procedure annually, with a total burden of 90 hours, based upon past submissions. The staff estimates that the average number of hours necessary to comply with the requirements of Rule 19d-2 is 3 hours.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Written comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange

Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, D.C. 20503; and (ii) Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Comments must be submitted to OMB within 30 days of this notice.

Dated: February 2, 2000.

Margaret H. McFarland,

Deputy Secretary.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

[USCG-2000-6974]

National Preparedness for Response Exercise Program (PREP)

AGENCY: Coast Guard, DOT.

ACTION: Request for comments on PREP triennial exercise schedule for 2000, 2001 and 2002.

SUMMARY: The Coast Guard, the Environmental Protection Agency (EPA), the Research and Special Programs Administration (RSPA) and the Minerals Management Service (MMS), in concert with the states, the oil industry and concerned citizens, developed the Preparedness for Response Exercise Program (PREP). This notice announces the PREP triennial cycle, 2000-2002, requests comments from the public, and requests industry participants to volunteer for scheduled PREP Area exercises.

DATES: Comments and related material must reach the Docket Management Facility on or before May 8, 2000.

ADDRESSES: To make sure your comments and related material are not entered more than once in the docket, please submit them by only one of the following methods:

(1) By mail to the Docket Management Facility, (USCG-2000-6974), U.S. Department of Transportation, room PL-401, 400 Seventh Street SW., Washington, DC 20590-0001.

(2) By hand to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) Electronically through the Web Site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this notice. Comments and documents, as indicated in this notice, will become part of this docket and will be available for inspection or copying at room PL-401 on the Plaza Level of the Nassif Building at the same address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may electronically access the public docket for this notice on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: For questions on this notice and general information regarding the PREP program and the schedule, contact Mr. Robert Pond, Office of Response, Plans and Preparedness Division (G-MOR-2), U.S. Coast Guard Headquarters, 2100 2nd St. SW., Washington, DC 20593-0001, telephone 202-267-6603, fax 202-267-4065 or e-mail rpond@comdt.uscg.mil. For questions on viewing, or submitting material to, the docket, contact Ms. Dorothy Walker, Chief, Dockets, Department of Transportation, telephone 202-366-9329.

SUPPLEMENTARY INFORMATION: The PREP Area exercise schedule and exercise design manuals are available on the Internet at <http://www.uscg.mil/hq/g-m/gmhome.htm> (see index, then oil response). To obtain a hard copy of the exercise design manual, contact Ms. Melanie Barber at the Research and Special Programs Administration, Office of Pipeline Safety, at 202-366-4560. The 1994 PREP Guidelines booklet is available at no cost by writing or faxing the TASC Dept Warehouse, 3341 Q 75th Avenue, Landover, MD 20785, fax: 301-386-5394. The stock number of the manual is USCG-X0191. Please indicate the quantity when ordering. Quantities are limited to 10 per order.

Request for Comments

We encourage you to participate by submitting comments and related material. If you do so, please include your name and address, identify the docket number [USCG-2000-6974], indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by mail, hand delivery, fax, or electronic means to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or hand delivery, submit them in an unbound format, no larger than 8½