U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION III

Report No. 03000287/80-02

Docket No. 03000287 License No. 22-00519-03

Licensee: Mayo Clinic
Rochester, MN 55901

Date of Investigation: December 19, 1980

Investigation At: Rochester, MN

Investigator: R. M. Burton — 5/6/81 Date

Inspector: Dr. W. J. Adam — 5/5/81 Date

Reviewed By: J. F. Streeter, Acting Director
Enforcement and Investigation Staff — 5/6/81 Date

D. G. Wiedeman, Acting Chief,
Materials Radiation Protection
Section I — 5-5-81 Date

Investigation Summary: Investigation on December 19, 1980 (Report No. 03000287/80-02)
Areas Investigated: An investigation was conducted to determine the circumstances surrounding a misadministration of P-32 sodium phosphate, a therapeutic radiopharmaceutical.
Results: Findings of the investigation indicate the failure to properly identify and assay the radiopharmaceutical used in the therapeutic dose resulted in the misadministration. One item of noncompliance was identified: License Condition 24, failure to count (assay) a radioiodide therapy dose in a sodium iodide scintillation detector. The investigation involved five manhours utilizing one inspector and one investigator.

REASON FOR INVESTIGATION

On December 18, 1980, the Region III NRC office was telephonically notified by the licensee of a misadministration of 11 millicuries of phosphorus 32 (P-32) labeled sodium phosphate. (The actual dose was subsequently determined to be 9.85 millicuries of P-32.) The correct administration was intended to be 11 millicuries of iodine 131 (I-131).

SUMMARY OF FACTS

An on site investigation was conducted at the licensee's facility on December 19, 1980. During the initial discussion with licensee management, a physician advised that he was responsible for the patient being administered P-32 rather than I-131.

The physician advised that on December 18, 1980 the personnel who normally administer the I-131 therapeutic doses were not present at the clinic. He stated in their absence he proceeded to administer an I-131 dose to a 72-year-old female patient. The physician indicated he had not administered I-131 therapeutic doses in several years and did not have the familiarity with Therapeutic Radiology Department's laboratory and its equipment that he had when he routinely administered I-131 years ago. In the process of preparing the therapeutic dose in the laboratory, the physician advised that he removed a vial from a lead box area where he was accustomed to the I-131 being located in the past. He related he was not aware P-32 was now located in that area. The physician stated he did not notice the vial was labeled P-32 because he apparently focused his attention only on the portion of the label which contained the assay information. He also related he did not assay the dose after it was prepared because he was unfamiliar with the operation of the sodium iodide scintillation counter. Subsequent to administering the dose and dismissing the patient, the physician stated he returned to the laboratory to clean up and discovered the vial was labeled P-32. He advised that a hematologist was immediately contacted for advice. The patient was contacted and returned to the hospital about an hour later. The patient's stomach was pumped and she was administered calcium carbonate and Amphogel in an effort to confine the P-32 and mitigate its effects.

On December 19, 1980, a reenactment of the physician's movements and actions was also conducted for purposes of observing the events which led to the misadministration.

A review of the clinic license and authorized user provisions confirmed that the physician is a current authorized user whose authorization includes I-131 and P-32 for therapeutic use.

One item of noncompliance was identified during the investigation.

DETAILS

1. Persons Contacted

Dr. J. Anderson, Radiation Physicist
Dr. D. S. Childs, Jr., Senior Consultant
Dr. J. D. Earle, Chief, Therapeutic Radiology
Dr. A. L. Orvis, Radiological Safety Officer
Dr. R. J. Vetter, Assistant Radiological Safety Officer

2. Introduction

On December 18, 1980 the Region III office was telephonically notified by the licensee of a misadministration of 11 millicuries of P-32 labeled sodium phosphate. (The actual dose was subsequently determined to be 9.85 millicuries of P-32.) The licensee advised that the patient was a 72-year-old female who was to receive 11 millicuries of I-131 for treatment of hyperthyroidism. The P-32 was erroneously administered (orally) at approximately 12:30 p.m. (CST) on December 18, 1980. At approximately 1:30 p.m. that same afternoon, the patient's stomach was pumped and six doses of Amphogel (an ion absorbtion agent) was administered.

On December 18, 1980, the Region III office contacted NRC medical consultant Dr. E. L. Saenger, M.D., who had conferred with the licensee and the patient's physician. Dr. Saenger indicated the licensee's response to the misadministration, to date, had been appropriate.

An on site investigation was initiated on December 19, 1980.

3. Initial Discussion with Licensee Management

Upon arrival at the licensee's facility in Rochester, Minnesota, on December 19, 1980, NRC investigators met with Doctors Anderson, Childs, Earle, Orvis and Vetter of the licensee's staff. During the meeting Dr. Childs advised that he was responsible for the patient being administered P-32 rather than I-131.

4. Interview with Dr. D. S. Childs, Jr., Senior Consultant

On December 19, 1980, Dr. Childs was interviewed and related the following information regarding the misadministration. On December 18, 1980 the two technicians and one physicist who normally administer the I-131 therapeutic doses were not present at the clinic. In their absence, Dr. Childs decided to administer without assistance an 11.0 millicurie therapeutic dose of I-131 to a 72-year-old female patient for treatment of hyperthyroidism. Dr. Childs interviewed the patient, informed her of the treatment procedure, and proceeded to the Therapeutic Radiology Department's laboratory at between 12:00 and 12:15 p.m., to prepare the dose.

Upon examination of the I-131 log book, he found it was necessary to withdraw the material from more than one I-131 vial. Dr. Childs went into the laboratory to locate the vials and determine how many milliliters from each vial were to be withdrawn. He had not administered I-131 therapeutic doses in several years and was not aware that the lead shielded box-type area (shown in Exhibit A), where he was accustomed to I-131 being kept years ago, was now the location where the P-32 was kept. Dr. Childs removed from the lead shielded area a full vial which he found contained enough material for the dose. He said he apparently focused his attention only on that portion of the vial's label which contained the assay information. He then calculated the number of milliliters necessary for the dose, correcting for decay; withdrew the proper number of milliliters; placed the material in a lead shielded cup, and administered it to the patient. Dr. Childs related he did not assay the dose in the "cup counter" (sodium iodide scintillation counter) to verify its activity because he was unfamiliar with the device's operation. This action is in noncompliance with License Condition 24 which states, in part, the licensee will possess and use licensed material in accordance with procedures listed in the letter dated March 15, 1979. Item 4.a. of that letter requires each radioiodide therapy dose to be counted in a sodium iodide scintillation detector.

When the patient departed, Dr. Childs returned to the laboratory to "clean up" and noticed the vial from which he withdrew the material was labeled P-32 sodium phosphate. He immediately set in operation measures to recall the patient, which included contacting the Clinic's security force and Minnesota State Police. The patient returned to the Clinic and her stomach was pumped at approximately 1:45 p.m. In the meantime, Dr. Childs had contacted a hematologist well versed in the physiology of sodium phosphate who informed him that such materials as calcium carbonate and Amphogel could "fix" sodium phosphate in the bowel. Following the completion of the stomach pumping and lavage, Dr. Childs administered six doses of one tablespoon each of Amphogel at 15 minute intervals and discussed with the patient what had happened.

At the conclusion of the interview, Dr. Childs provided a written statement attesting to the information related, a typewritten copy of which is attached as Exhibit B.

After the initial interview, Dr. Childs remembered that normally there was an erratic and loud audio reaction from the radiation monitor (positioned at the entrance/exit of the laboratory) whenever a patient, subsequent to receiving I-131 therapy, exited the laboratory. He recalled there was not any such reaction when the patient, subsequent to receiving the P-32, exited the laboratory. He indicated that, although he did not recognize it at the time, the "lack of reaction" from the monitor was an indication that the patient had not received the intended I-131 therapy.

5. Reenactment

A reenactment of events leading up to the misadministration was also conducted on December 19, 1980. Dr. Childs retraced his movements

beginning at the receptionist's desk outside the entrance to the Therapeutic Radiology Department's laboratory. After indicating the location of the I-131 log book at the receptionist's desk, he entered the laboratory, walked a few steps toward the lead box-type area where the sodium phosphate was kept, stopped, and removed a vial in the same manner he had prior to the misadministration. Dr. Childs demonstrated how he held the vial (as shown in Exhibit C) with the assay information his only apparent point of focus. He then placed the vial on the laboratory counter top without focusing his attention on its label, and exited the laboratory in the same manner as he did on December 18, 1980. Dr. Childs indicated he noticed the vial was labeled sodium phosphate when he subsequently reentered the laboratory to "clean up".

6. Dose Calculations

Activity Administered (licensee's calculation)

Assayed for Noon, 12/19/80, used Noon, 12/18/80

$A = 14 \text{ ml} \times 0.67 \text{mCi/ml}$
$0.952 \text{ (decay)} = 9.85 \text{ mCi}$

Dose Estimates (based on values taken from ICRP-2)

	Dose/uCi(rem)	Dose(rem)
Whole Body	7.4×10^{-3}	73
Target Organ (bone)	3.8×10^{-2}	375
G. I. tract (insoluble form)	8.4×10^{-2}	828
G. I. tract (soluble form)	2.1×10^{-2}	207

6. Review of Mayo Clinic License Regarding Authorized Users

A review of the Clinic's byproduct materials license revealed that authorized users are not specifically named, but rather designated by the Radioisotope Committee. Approval as an authorized user is granted after submission of an acceptable application (which includes the prospective user's training and experience) to the Committee. Renewal is required at three or five year intervals and includes a review of the procedures employed by the applicant. There is no verification of applicant's current knowledge of established procedures.

Dr. Childs' authorization for therapeutic use of I-131 and P-32 was renewed by the Radioisotope Committee on October 13, 1978.

7. Management Discussion

At the conclusion of the investigation on December 19, 1980, the findings were discussed with Dr. A. L. Orvis and other members of his staff.

Attachments:

1. Exhibit A - Lead Shielded Box-Type Area where P-32 is kept
2. Exhibit B - Typewritten copy of statement provided by Dr. Donald S. Childs, Jr.
3. Exhibit C - Photograph of Dr. Childs holding vial from which P-32 was drawn

LEAD SHIELDED BOX-TYPE AREA WHERE P-32 IS KEPT

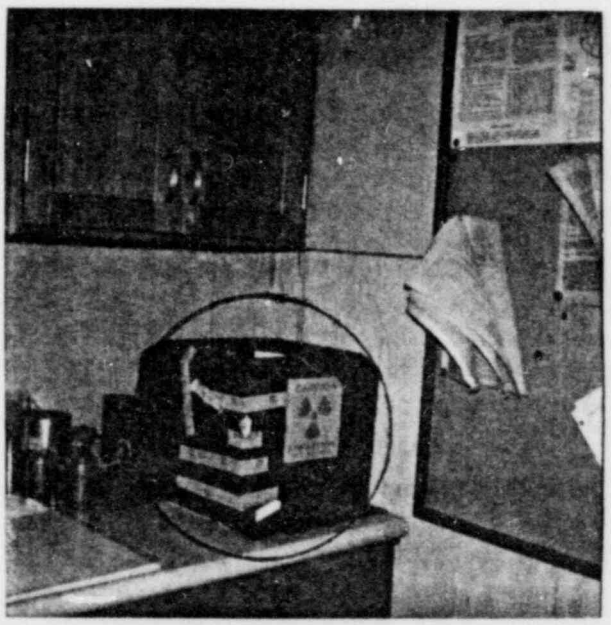


EXHIBIT A

Location: Mayo Clinic
Rochester, Minnesota
Date: December 19, 1980
Time: 11:45 a.m.

I, Donald S. Childs, Jr., hereby make the following voluntary statement to Robert M. Burton who had identified himself to me as an Investigator with the U. S. Nuclear Regulatory Commission. I make this statement freely under no threats, or promises of reward having been made to me. Investigator Burton is handwriting this statement for me at my request.

I state that I am a Physician in the Therapeutic Radiology Department of the Mayo Clinic and have held this position for 31 years. On December 18, 1980, both our technicians and physicist who normally administer our I-131 therapy to patients here at the clinic were not available. In their absence I personally proceeded to administer a 11.0 millicurie therapeutic dose of I-131 to one of the patients. I interviewed the 72 year old female patient and told her what was going to happen; excused myself to prepare the dose for her at between 12:00 and 12:15 p.m. I went to our I-131 log book and found I was going to have to withdraw the material from more than one vial. I went into the hot lab to locate the vials and determine how many millilitres from each vial I could withdraw. Apparently my attention was focused on the portion of the label which contained the assay. I then went and calculated the number of millilitres correcting for decay; withdrew the proper number of millilitres; placed it in a shielded cup, and administered it to the patient. I did not assay the dose in the cup counter. When she had left I returned to the hot lab to "clean up" and noticed that the vial was labeled sodium phosphate. I immediately set in operation measures to retrieve the patient. The patient was retrieved and her stomach was pumped at 1:45 p.m. In the meantime I had contacted a hemotologist who is well versed in physiology of sodium phosphate, who told me that such materials as calcium carbonate and amphogel could fix sodium phosphate in the bowel. Accordingly, following the completion of the stomach pumping and lavage, I administered 6 doses of one tablespoon each of amphogel at 15 minute intervals, and discussed with the patient what had happened and what was to be done.

I have read the foregoing statement consisting of 2 handwritten pages. I have made any necessary corrections and have initialed them. I have signed my name in the margin of each page. This statement is the truth to the best of my knowledge and belief.

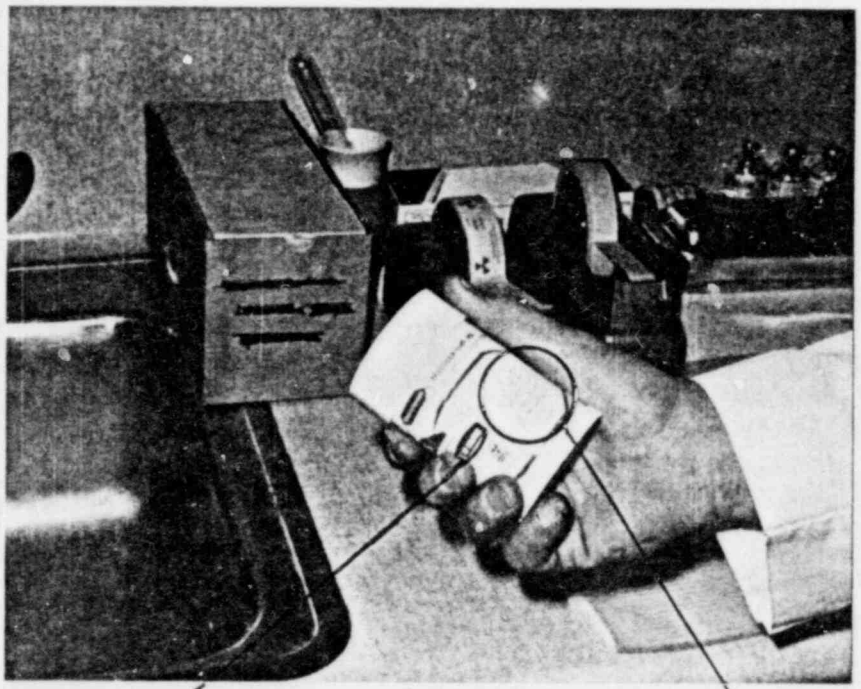
(Signed) Donald S. Childs, Jr.

Witnessed by: (Signed) Robert M. Burton
Investigator, U.S.NRC

(Signed) William J. Adam
Radiation Specialist, U.S. NRC

EXHIBIT B

PHOTOGRAPH OF DR. CHILDS HOLDING VIAL FROM WHICH P-32 WAS DRAWN



PORTION OF LABEL WHICH READS "P 32 SOLUTION" IS PARTIALLY VISIBLE

PORTION OF LABEL WHICH CONTAINS ASSAY INFORMATION; WHICH DR. CHILDS STATED WAS APPARENTLY THE FOCUS OF HIS ATTENTION

EXHIBIT C