

718736

AEC INVESTIGATION OF IODINE-131 MISADMINISTRATION
AT THE
MEDICAL DIVISION, OAK RIDGE ASSOCIATED UNIVERSITIES

(Report of Investigating Committee)

September 4, 1973

REPOSITORY _____

COLLECTION _____

BOX No. _____

FOLDER _____

10944

Box 1

Contents

Introduction and Summary 1
General Description 1
Discussion of the Incident 2
 Chronology of Events 2
Findings of Fact 5
Signatures of the Investigating Committee 6

Introduction and Summary

On September 4, 1973, two female patients inadvertently received 284 microcuries of iodine-131 for thyroid uptake and scan studies at the Medical Division, Oak Ridge Associated Universities. This dose of iodine-131 is approximately ten times the currently used dose (30 microcuries) given for thyroid studies at ORAU. The misadministration was discovered on September 5, and the patients and their private physicians were informed of the occurrence on September 6. The ORAU physician advised the patients that the radiation received from this dose does not pose any risk of demonstrable injury or illness. The misadministration resulted from an arithmetic error made by a technician in calculating the volumes of the liquid doses. The patients were referred to the Medical Division, ORAU, by the Oak Ridge Hospital of the Methodist Church, with which the ORAU has cooperative arrangements to provide nuclear medicine services.

Following a preliminary investigation of the facts, the Assistant Manager for Operations, Oak Ridge Operations Office, appointed a committee to conduct a formal investigation of the incident. The members of the committee are:

R. E. Benson, Chairman

W. T. Thornton

This document presents the formal report of the committee.

General Description

The Medical Division, Oak Ridge Associated Universities (MD-ORAU), occupies AEC-owned facilities in Oak Ridge, Tennessee, under Contract No. AT-(40-1)-Gen-33 with the AEC, to perform basic and clinical research in nuclear medicine. Under cooperative arrangements with the Oak Ridge Hospital of the Methodist Church (ORHMC), approved by the AEC, the MD-ORAU performs various nuclear medicine services on a full cost recovery basis when so requested by the ORHMC.

The ORHMC referred two patients to the MD-ORAU on September 4, 1973, and requested that thyroid uptake and scan studies be performed. The administration of iodine-131 for thyroid uptake and scanning is a long standing fully established procedure in clinical nuclear medicine. Such studies have been performed at the MD-ORAU since the early 1950's.

In brief, routine iodine-131 thyroid uptake and scan studies conducted at the MD-ORAU consist of the following procedures:

1. Oral administration of iodine-131 in liquid or capsule form.
2. Radioactivity counts over the thyroid gland at 4, 24, and 48 hours following administration of the iodine-131 to determine the percent of administered dose of iodine-131 taken up by the thyroid.
3. Radioactivity scanning over the thyroid gland at 24 hours following administration of the iodine-131. This provides a visual printout (picture) of the radioactivity contained in the thyroid.
4. Following completion of these procedures, the results are compiled and given to a qualified physician for interpretation. The physician interviews and examines the patient and provides a written report of the test results and his interpretation to the referring physician and/or hospital.

Discussion of the Incident

Chronology of Events

1. Events Preceding September 4, 1973

Telephone communications between the Radiology Department of the ORHMC and the Clinical Research and Nuclear Medicine Section of the MD-ORAU were made to request the thyroid uptake and scan studies on the two patients and to set up mutually acceptable appointments. These actions were followed up with a written request, a "Nuclear Medicine Consultation Request", prepared by the ORHMC and forwarded to MD-ORAU. Upon receipt of this request, an MD-ORAU physician reviews the request and prescribes the radioisotopes, activity, and related procedures indicated, via a "Dose Information Form", which is sent to the radiopharmaceutical section. This section prepares the radioisotopes as prescribed and coordinates with the nursing staff and other support staff to accomplish the requested tests.

In this case, the MD-ORAU physician prescribed the standard dose of iodine-131 (30 microcuries) for a routine thyroid uptake and scan study for each of the two female patients given appointments on September 4, 1973.

2. Events on September 4, 1973

Patients One and Two arrived at the MD-ORAU around 8:00 a.m. for the scheduled thyroid tests.

Employee A prepared the iodine-131 solutions for the two patients. The iodine-131 doses are usually administered to the patients in the form of precalibrated capsules. On this occasion there were no ^{131}I capsules available in the MD-ORAU, so Employee A proceeded to prepare the two doses and a third dose for use as a standard from a stock solution of iodine-131.

Employee A intended to prepare iodine-131 doses containing 28.4 microcuries each (approximately 30 microcuries as prescribed). However, the employee made an arithmetic error during calculation of the volumes of ^{131}I stock solution required for the preparations, misplacing a decimal. Consequently, each dose contained 284 microcuries instead of 28.4 microcuries of iodine-131.

Employee A called the Radiation and Chemical Safety Office for a representative to verify the amount of radioactivity in the prepared doses on the dose calibrator. In accord with current ORAU procedures, in the absence of a representative of the Radiation and Chemical Safety Office, the person who prepared the dose is authorized to check the accuracy of the dose. After unsuccessful attempts to contact someone in the Radiation and Chemical Safety Office, the employee proceeded to verify the radioactivity in each dose using the dose calibrator equipment.

Employee A's initial error was perpetuated by his failure to pay close attention to the location of the decimal point on the readout register of the dose calibrator. The dose calibrator correctly read out 284 microcuries, as confirmed later by recounting the identical dose standard prepared by Employee A. However, with the patients waiting and with the prior knowledge of the amount of radioactivity he thought was contained in each dose, he incorrectly read the register as 28.4 microcuries.

Each of the patients inadvertently received a dose of iodine-131 that was approximately ten times the prescribed dose, i.e., 284 microcuries instead of 30 microcuries.

The patients remained at the MD-ORAU for an additional 4 hours to receive the 4-hour uptake count. Employee B who usually conducts the uptake counts was absent on leave; therefore, Employee A

conducted the 4-hour uptake count. Employee A was familiar with correct procedures for conducting the uptake counts but was unfamiliar with the expected counts or results for normal uptakes and did not analyze the results following the test. The 4-hour uptake counts were not analyzed until the next morning.

3. Events of September 5, 1973

Patients One and Two returned for their 24-hour thyroid tests.

Employee B conducted the 24-hour uptake counts on patients One and Two. Employee C conducted the 24-hour thyroid scans and during the process observed that the count rates were higher than expected. Employee C consulted with Employee B who had just completed preliminary analysis of the uptake counts and they agreed that the counts were higher than expected.

Employees B and C reported their results to their supervisors, who checked and verified their results that indicated a greater amount of radioactivity was present than was normal for routine thyroid uptake and scan studies.

The patients were released following completion of the thyroid uptake counts and scans, and were asked to return again the next morning for their 48-hour (final) tests.

The Radiation and Chemical Safety Officer and the appropriate physician were informed of the misadministration around 9-10:00 a.m. The Radiation and Chemical Safety Officer telephoned the Health Protection Branch, ORO, about 3:30 p.m. to report the occurrence but was unable to contact the individual called. A request to return his call was left with the secretary.

4. Events of September 6, 1973

The Radiation and Chemical Safety Officer called AEC about 8:30 a.m. and this time was successful in reporting the misadministration to a staff member of the Health Protection Branch, ORO.

Patients One and Two returned for their 48-hour thyroid tests. Following completion of the tests, the MD-ORAU physician reviewed the thyroid uptake and scan results then interviewed and examined the patients. He then informed the patients and the patients' private physicians of the misadministration. The MD-ORAU physician

advised the patients that the radiation received as a result of the misadministration posed no significant risk of demonstrable injury or illness.

The MD-ORAU physician gave Patient One Lugol's solution to suppress further uptake of iodine-131 by the thyroid. Similar prophylactic treatment for Patient Two was not given because of her very low uptake of iodine-131 by the thyroid, i.e., two percent. The patients were then discharged.

The MD-ORAU physician reported the misadministration of iodine-131 and his interpretation of the thyroid uptake and scan results to the ORHMC via usual procedure, i.e., the "Nuclear Medicine Consultation Report". He also reported the incident internally to the Chairman of the MD-ORAU.

Findings of Fact

The following facts were determined as a result of this investigation:

1. Two female out-patients were referred to MD-ORAU by the ORHMC on September 4, 1973, for thyroid uptake and scan studies in accord with established agreements between the two institutions.
2. The MD-ORAU physician in charge prescribed the standard dose of iodine-131 (30 microcuries) for a routine thyroid uptake and scan study for each of the two patients.
3. An experienced technician prepared the iodine-131 solutions for each patient and followed standard preparation procedures. The technician acknowledged committing an arithmetic error in calculating the correct volumes of iodine-131 stock solution required for preparation of the prescribed doses. The technician subsequently acknowledged that he perpetuated his initial error by failure to correctly read the readout register on the dose calibrator when he attempted to verify the amount of iodine-131 in each dose.
4. Calibration of the dose calibrator using certified standards is not routinely practiced. However, in this case the accuracy of the dose calibrator is not in doubt since post-incident checks confirmed its accuracy.

5. Each of the two patients inadvertently received a dose of iodine-131 on September 4, 1973, approximately ten times greater than the prescribed dose.
6. Uptake counts conducted on the patients at 4 hours following administration of the iodine-131 were not promptly analyzed, and therefore the overdoses were not detected at that time.
7. The overdoses were first detected during the process of performing the 24-hour thyroid scans, at which time the count rates were observed to be about ten times greater than expected for routine thyroid scans. Analyses of the 4-hour and 24-hour uptake counts and rechecks of the dose standard on the dose calibrator verified the overdoses of iodine-131.
8. Procedures for preparation of the iodine-131 doses, the verification of the radioactivity in each dose, and administration, as documented, were followed by MD-ORAU technicians.
9. The misadministration of iodine-131 was reported to the patients and their private physicians following the 48-hour uptake counts on September 6, 1973.

SIGNATURES OF THE INVESTIGATING COMMITTEE


R. E. Benson, Chairman


W. T. Thornton