

**Edward B. Silberstein, M.D.**

TELEPHONE: (513) 558-9032  
FAX: (513) 558-7690  
E-MAIL: silbereb@UH.UC.edu

**University Hospital**

Room G 026  
Mont Reid Pavilion  
P.O. Box 670577  
Cincinnati, Ohio 45267-0577

June 25, 1997

To: Roy J. Caniano, Acting Director  
Division of Nuclear Materials Safety  
United States Nuclear Regulatory Commission, Region 3  
801 Warrenville Road  
Lisle, IL 60532-4351

From: Edward B. Silberstein, M.D.

The Incident:

This communication concerns an incident May 14, 1997 at the Mallinckrodt Nuclear Medicine facility, Maryland Heights, Missouri where an individual doing research involving perrhenate (rhenium-186) in solution noted that, following his experiments, and before he left home, a radiation survey instrument indicated some elevated counts. He thought this was due to background radiation from the material with which he was working. He failed to perform a hand-survey before he left, indicating later that he had worked for 12-hours that day and was simply fatigued and forgot to take this step. The details of this incident have been supplied by the licensee and will not be repeated.

The next morning, on coming to work, the licensee's radiation survey equipment found a small amount of contamination on the palmar side of the left thumb after the appropriate radiation safety authority had told him he had radioactivity in his urine (which proved to be iodine-131). The licensee notified the NRC promptly.

Dosimetry/ Medical Data:

I have assumed that the thumb was contaminated by rhenium-186 (perrhenate) with an area of 1 square centimeter on the skin surface, reaching one millimeter deep. The mean range of the rhenium-186 beta particle is 1.1 mm. Using a spherical shell model in MIRDose 3, and the self dose S-value of 5.9 rads/uCi.hour exposure for 12 hours, I obtain a dose to the thumb area of approximately 350 rads.

**Edward B. Silberstein, M.D.**

TELEPHONE: (513) 558-9032  
FAX: (513) 558-7690  
E-MAIL: silbereb@UH.UC.edu

**University Hospital**

Room G 026  
Mont Reid Pavilion  
P.O. Box 670577  
Cincinnati, Ohio 45267-0577

Biological dosimetry is also possible since the erythema threshold for acute radiation injury to the skin is 300 rads and the threshold for bulla formation is approximately 1100-1200 rads. The thumb was photographed daily and then every other day for up to four weeks, and no cutaneous abnormalities were visualized. Thus, the skin dose was unequivocally less than 1100 rads and, in the absence of erythema, probably close to the calculated dose provided above.

#### Licensee Response:

As soon as Mallinckrodt Corporation was notified of the contamination, the employee, his home and transportation (car) environments (and even a soccer ball he touched) were surveyed promptly. Decontamination in the employee's vehicle and home was prompt, and no removable contamination remained. The contaminated household items found were placed in storage for decay.

The skin was decontaminated so that, by report of the licensee, only 4% of activity remained on the skin.

Urinalysis has been performed to search for internal Re-186 contamination but none was found, although the iodine-131 in the urine is of interest. I should like to know if the thyroid was surveyed. Perrhenate can localize in the thyroid so an appropriate energy window would have to be employed.

It is clear that the licensee responded quickly to address all issues raised by this contamination, with prompt survey of all potentially contaminated people and sites, and intelligent decontamination. The licensee is looking at ways to reduce direct handling, since we must assume a hole in a protective glove led to this contamination. Their list of corrective actions is excellent and need not be repeated.

While the licensee plans to move the activity transfer box and reevaluate site wide portal monitors, the systems were in place to detect this contamination, but human error led to the individual ignoring the information warning him of contamination.

I believe we need more information on the iodine-131 contamination found in the urine however. How much was found? How much was in the thyroid? Why?

**Edward B. Silberstein, M.D.**

TELEPHONE: (513) 558-9032  
FAX: (513) 558-7690  
E-MAIL: silbereb@UH.UC.edu

**University Hospital**

Room G 026  
Mont Reid Pavilion  
P.O. Box 670577  
Cincinnati, Ohio 45267-0577

Deterministic and Stochastic Effects:

I expect no deterministic effects on the thumb of the exposed individual. Four weeks have passed with no skin changes whatsoever, consistent with dosimetry estimates ranging from 240-470 rads (mine is 350 rads).

There may be an increased lifetime risk of skin cancer on the contaminated thumb however, for which simple surveillance will be quite adequate.

Further Suggestions:

Follow up on the iodine-131 in the urine. Is this a widespread problem? How did this occur?

# MEDICAL CONSULTANT REPORT

(To Be Completed By Medical Consultant)

Medical Consultant Name: Edward B. Silberstein Report Date: 7/11/97

Signature: Edward B. Silberstein, M.D.

Licensee Name: Mallinckrodt Corp. License No. \_\_\_\_\_  
Nuclear Medicine

Facility Name: \_\_\_\_\_

Individual's/Patient's Identification No.: \_\_\_\_\_

Incident Date: 5/14/97

Individual's/Patient's Physician Name and address: unknown

Referring Physician Name and address: N/A  
(Medical Misadministration Only) \_\_\_\_\_

Individuals Contacted During Investigation: Ray Brown  
(Name and Title) Pres., Mallinckrodt Nuclear

Records Reviewed: (General Description)

Licensee's report to NRC  
NRC preliminary description

Estimated Dose to Individual or Target Organ: 350 rads (skin of thumb)  
Probable Error Associated with Estimation: Failure to self decontaminate Prescribed Dose (Medical Misadministration Only): \_\_\_\_\_ Method Used to Calculate Dose: MIRDose 3

Description of Incident:

See attached

Assessment of probable deterministic effects of the radiation exposure on the individual:

See attached

Briefly describe the current medical condition of the exposed individual:

See attached

Was individual or individual's physician informed of DOE Long-Term Medical Study Program?

(Y) N (but does not meet criteria of > 6 Gy to skin)

If yes, would the individual like to be included in the Program? Y N

unknown

### COMPLETE FOR MEDICAL MISADMINISTRATION

(To Be Completed by Medical Consultant)

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to NRC pursuant to 10 CFR 35.33 in the following areas:

- |  |       |
|--|-------|
| a. Why the event occurred                      | (Y) N |
| b. Effect on the patient                       | (N) N |
| c. Licensee's immediate actions upon discovery | (Y) N |
| d. Improvements needed to prevent recurrence   | (Y) N |

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 35.33), provide the basis for your opinion:

The patient's urine showed I-131 contamination, but no further information was provided on how this occurred, patient dosimetry, preventive measures.

3. Did the licensee notify the referring physician of the misadministration? Y N *unknown*

Did the licensee notify the patient's or the patient's responsible relative or guardian? ☒ Y ☐ N

If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with 10 CFR 35.33? Y N *N/A*

Explain rationale for response.

4. Provide an opinion of the licensee's plan for patient follow-up, if available.

*Responsible, close follow-up to be provided.*