

Medical Consultant Report
(To be completed by medical consultant)

Medical Consultant Name: Ronald E. Goans, PhD, MD, MPH

Report Date: 12/6/2006

Signature

Ronald E. Goans MD 12/11/2006 - revised

Licensee Name: The University of Virginia

License No. 45-00034-26

Event No. 42716

Docket No. 03003296

Facility Name: Nuclear Medicine Department, the University of Virginia Medical Center

Incident Date: 7/11/06

Date of Notification: 7/31/06

Individuals' / Patient Physician Name and Address:

Richard Santen, MD
Department of Endocrinology, University of Virginia Medical Center
Charlottesville, VA 22904-4322

Individuals Contacted During Investigation:

Steve Sugarman, Health Physicist, REAC/TS
PO Box 117, MS 117, Oak Ridge, TN 37830
865-574-3131

Catherine S. Perham, Assistant RSO
University of Virginia Office of Environmental Health and Safety
434-982-4915
434-982-4921

Richard Santen, MD
Referring Endocrinologist, University of Virginia Medical Center
434-924-2961

Records Reviewed: (General Description)

1. NRC Enclosure - Description of the Medical Event
2. RI-DNMS Licensee Event Report
3. NRC Preliminary Notification of Event (Event # 42716)
4. NRC Medical Event Reporting and supporting literature
5. University of Virginia correspondence to the NRC
6. Detailed review of patient records and photographs
7. REAC/TS radiation dose calculations
8. Detailed University of Virginia Report to the NRC

Estimated Dose to Unintended Anatomic Region (see appendix A):

By assessment of clinical signs:

No more than a local skin dose of 6-10 Gy to the left thigh.

Probable Error Associated with Estimation: Clinical determination; $\pm 75\%$.

Prescribed Dose (Medical Misadministration Only):

Nominal 50 mCi activity I-131 to be administered for treatment of hyperthyroidism; calibrated I-131 activity 54.6 mCi.

Method Used to Calculate Dose: Time course of clinical symptoms, radiation medicine clinical dose profile and physical dosimetry.

Description of Incident:

The patient is a 86 year-old female with concurrent diagnoses of dementia and hyperthyroidism (toxic goiter). She was treated on July 11, 2006 at the University of Virginia Medical Center and was prescribed 50 mCi (calibrated 54.6 mCi) of I-131 orally by capsule for thyroid ablation. Instead of swallowing the pill as instructed, she initially said she hid the capsule in her mouth and later transferred it to her pocket and eventually to her shoe. Two adult children were present during the I-131 administration and the I-131 administration was also monitored by nuclear medicine staff. The patient was taken by her family in a three hour trip back to West Virginia and the I-131 capsule found its way under the cushions of the family couch. This is where the patient slept. After investigation by NRC staff and by me, her account of events now seems to be in considerable doubt.

On July 18, 2006, the patient's daughter found the capsule, consulted with staff at the University of Virginia, and took the capsule to Greenbrier Valley Medical Center in Ronceverte, WV. At Greenbrier, the capsule was assayed to be 25.1 mCi I-131, approximately one half-life decayed from the initial activity and also consistent with the intervening time period. It therefore seems likely that the I-131 capsule remained intact. After the University of Virginia was contacted, they sent a four person radiation safety team to West Virginia to investigate and to retrieve the capsule.

Clinical Details (See Appendix 1 for clinical pictures)

With respect to dose considerations, the main radiological issues are with the patient and her adult son and daughter. Both children had thyroid scans and there is no indication of internal uptake to the thyroid. So, the primary health issue currently is that of external dose. Regarding I-131, the gamma constant is 0.22 R/h at 1 m per Ci. For a 0.0546 Ci source and using the usual point source approximations, this gives an external dose rate of approximately 12 mR/h at 1 m. Given time and distance, I suspect that the external dose to the son and daughter are $< 1-2$ rad, and probably not that much.

External dose to the patient is another issue. Clinical pictures were obtained at the request of Dr. Santen and the radiation safety staff at the University of Virginia. These were done on July 28, 2006, approximately 2 1/2 weeks post accident. Figures 1 and 2 show a large area of erythema on the dorsum of the foot along with white patches consistent with dry desquamation. Initially, it

was thought that the foot lesion was consistent with the patient's statement that she placed the I-131 source in her shoe. Subsequent investigation by the NRC indicates that the lesion likely is a preexisting scar from a thermal burn and not related to this incident. In addition, Figures 3 and 4 show two lesions on the left thigh with possible dry desquamation in the center and erythema around the edges.

Estimates of local skin dose (primarily beta) by REACTS health physics staff were 1300 Gy/h at contact using a first principles approach. A Varskin 3 calculation gives an initial contact dose rate of 288 Gy/h and a decay-corrected skin dose of 1140 Gy. It therefore is not unreasonable to see clinical signs consistent with local skin dose of 10-15 Gy, given that the source likely moves over a period of time.

The thigh lesions are consistent with a point source that moved, giving two distinct lesions. I have spoken with Jonathan Pierson, PA, at the Dermatology Centers, Inc., Ronceverte, WV, (304-645-7546). There seems not to be progression of the lesions and possibly healing. So, it is likely that any local skin dose is less than 6-10 Gy, probably more toward the lower end of the estimate. Consideration has been given that the thigh lesions are from insect bites, but it is my medical opinion that areas of central necrosis do not generally occur in most insect bites.

It is not possible to estimate a reliable number for whole-body external dose, but I suspect that it is less than 20-30 rad. This case would have been a good candidate for chromosome cytogenetic dosimetry since the time and motion study of the patient with respect to the source is unreliable.

In my medical opinion, there has not been adequate follow-up of the progression of the thigh lesions. I have requested Mr. Pierson at the Dermatology Center to schedule the patient for a follow-up examination and he has agreed to do so. In any event, this appears to be a relatively minor radiological incident, given the initial potential for personal dose.

Assessment of Probable Deterministic Effects of the Radiation Exposure on the Individual:

Acute local irradiation events to the skin occur with deterministic thresholds as follows for certain clinical signs:

- (1) 300 cGy threshold for epilation, beginning 14-21 days post-accident.
- (2) 600 cGy for erythema, soon post-accident, and possibly again 14-21 days thereafter. The pathophysiology for erythema includes arteriolar constriction with capillary dilation and local edema. Erythema may occur in a few hours post-accident (primary erythema) or come and go in waves. Secondary erythema occurs 14-21 days post-accident.
- (3) 1000-1500 cGy for dry desquamation of the skin secondary to radiation to the germinal layer. Dry desquamation results from response of the germinal epidermal layer to radiation. There is diminished mitotic activity in cells of the basal and parabasal layers with thinning of the epidermis and desquamation of large macroscopic flakes of skin.
- (4) 2000-5000 cGy for wet desquamation (partial thickness injury) at least 2-3 weeks post-exposure, depending upon dose. In moist desquamation, microscopically, one finds intracellular edema, coalescence of vesicles to form macroscopic bullae, and a wet dermal surface, coated by fibrin.

- (5) For dose >> 5000 cGy, overt radionecrosis and ulceration secondary to endothelial cell damage and fibronoid necrosis of the arterioles and venules in the affected area.

Briefly describe the current medical condition of the exposed individual:

I have interviewed Dr. Santen and he believes that the patient is in satisfactory medical condition, but there has not been adequate follow-up due to difficulties of distance and the fact that the patient is now managed by another physician. Since the dose estimates are from clinical considerations only, it is always possible to have an underestimate of local radiation dose.

Examination of the patient now would be highly desirable and the Dermatology Center has agreed to bring her back to ensure that the lesions are healing. All clinical signs and symptoms now lead us to believe that this is a relatively minor radiological event, at least from a medical viewpoint.

References

LF Fajardo L-G, M Berthrong, and RE Anderson. *Radiation Pathology*. Oxford Press. 2001.

GH Fletcher. *Textbook of Radiotherapy*. 3rd edition. Lippincott, Williams & Wilkins. 1980.

RE Goans. Clinical Care of the Radiation Accident Patient: Patient Presentation, Assessment, and Initial Diagnosis. In *The Medical Basis for Radiation-Accident Preparedness. The Clinical Care of Victims*. Eds. Robert C. Ricks, Mary Ellen Berger, and Frederick M. O'Hara, Jr. Proceedings of the Fourth International REAC/TS Conference on the Medical Basis for Radiation-Accident Preparedness, March 2001, Orlando, FL. The Parthenon Publishing Group, 2002.

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

Yes

If yes, would the individual like to be included in the program?

No

**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 the NRC pursuant to 10 CFR 35.33 in the following areas:

- a. Why the event occurred – Yes. Circumstances of this event were largely beyond control at the University of Virginia.
- b. Effect on the patient – Yes.

My independent dose estimates generally agree with those provided by the hospital.

- c. Licensee's immediate actions upon discovery – There was immediate reporting of the event to the NRC.

d. Improvements needed to prevent recurrence - Yes.

This is a human factors issue, correctable by education and improved procedures. The issue was also addressed through the hospital Radiation Safety Committee. Currently, I-131 administration is monitored by the chief nuclear medicine technician and the formulation of I-131 has been changed from capsule to liquid. The department also now monitors transit of the medication from the oral cavity to the stomach.

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: N/A

3.

Did the licensee notify the referring physician of the misadministration? Yes

Did the licensee notify the patient's or the patient's responsible relative or guardian?

Yes

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?

N/A

Explain rationale for response.

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

The patients will be followed clinically by private physicians as indicated. I believe that the hospital system and specifically, the nuclear medicine department, will institute an effective program to prevent a recurrence of this event. The information in the preliminary notification has also been reviewed with licensee management.

Appendix 1 (Clinical Pictures)

Figure 1 - Likely Thermal burn



Figure 2 - Likely thermal burn



Figure 3 - Thigh lesions of undetermined etiology

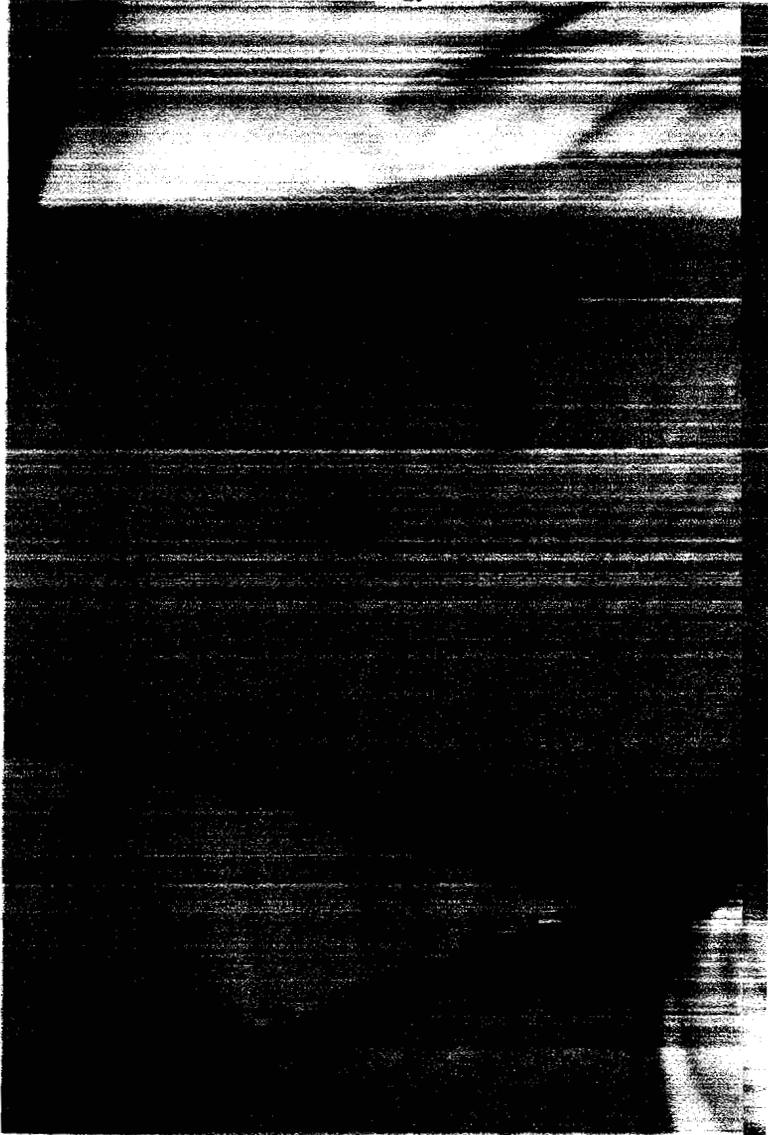


Figure 4- Thigh lesions of undetermined etiology

