DCD COPY
DUPLICATE

THE CLEVELAND CLINIC FOUNDATION

A National Referral Center An International Health Resource

Radiation Safety / QQ10
216/444-6645

03002649

U.S. Nuclear Regulatory Commission
Document Control Desk
Washington DC 20555

September 26, 1996

To Whom It May Concern:

This correspondence is to report an incident which occurred at The Cleveland Clinic Foundation (CCF), NRC License #34-00466-01 on August 27, 1996 which resulted in removable contamination in an unrestricted area in excess of 2000 dpm/100 cm^2. This report is submitted as required per 10 CFR 20.2203(a)(3)(ii). License condition #39B of Amendment No. 63 for License #34-00466-01, commits the licensee to Appendix N, Regulatory Guide 10.8 Revision 2 for survey requirements for medical uses and indicates a removable contamination limit in an unrestricted area for Iodine-131 of 200 dpm/100 cm^2. The limit for removable contamination for surveys for non-medical uses is also 200 dpm/100 cm^2 for an unrestricted area. Following an Iodine-131 therapy dose administration on August 27, 1996, during which personnel contamination occurred which was not identified until August 28, 1996, a survey of the car of one of the involved individuals identified removable contamination on the driver's arm rest of 2744 dpm/100 cm^2. This area was successfully decontaminated on August 28, 1996, the date of discovery, prior to the individual leaving the workplace. No one other than the worker had been in the car since the August 27, 1996 dose administration. The homes and automobiles of all three individuals present during this dose administration were surveyed and no other removable contamination exceeding 2000 dpm/100 cm^2 was identified. All removable contamination exceeding 200 dpm/100 cm^2 was successfully decontaminated. One individual's pillow and the shirt worn during the incident were returned to CCF and placed in "storage-for-decay". All exposure readings in unrestricted areas indicated that no individual member of the public would have received greater than or equal to 0.002 rem in any one hour or greater than 0.1 rem in a year. All dose estimates for the workers involved did not exceed occupational dose limits.

Attached is a detailed report of the incident and the corrective steps implemented August 29, 1996, to ensure against a recurrence. If any additional information is required please contact me at (216) 444-6645.

Sincerely,

Judy A. McKenna

Judy A. McKenna, M.S., DABR
Director, Radiation Safety

010046

CC: NRC Region III

IE-22

SEP 27 1996

9610020060 XA 11/1/96

The Cleveland Clinic Foundation
30 Day Notification Report
Iodine-131 Contamination Event of August 27, 1996
September 26, 1996

On the morning of Wednesday, August 28, 1996, when Radiation Safety Technologist (RST) #1 turned on a GM survey meter in a research laboratory to perform a survey, he discovered that he was contaminated. At this time he returned to the Radiation Safety (RS) laboratory and initiated identification of the radionuclide and a survey of the RS lab by RST #2 and #3. At this time, RS Medical Health Physicist (MHP) #1 arrived at the RS lab who then contacted RS MHP #2 who in turn informed the RSO that RST #1 was contaminated with Iodine -131 (I-131) and that he had been present for the I-131 therapy dose administration on August 27, 1996. Upon arriving at the RS lab, MHP#2 started a thorough meter survey of RST#1, while MHP#1 went to survey RST#1's car. Nuclear Medicine (NM) was contacted to follow-up with the Nuclear Medicine Technologist (NMT) who administered the 196 mCi dose. RST #3 then went to NM to escort NMT#1 to the RS lab as contamination of her arm was identified. The RSO arrived at the RS lab and began interviewing RST #1 and NMT#1 as to the events associated with the dose administration the previous day. As some contamination was identified in RST #1's car, RST #3 was sent to RST #1's residence to survey the premises and bring a change of clothes for RST #1 as his pants and shoes were found to be contaminated.
During the interview process, it was discovered an additional NMT had been present observing the dose administration, NM was contacted for NMT#2 to monitor himself. Once thorough meter surveys were conducted on RST #1 and NMT #1 by MHP#2, checks for removable contamination were conducted. Once levels were found to be minimal, RST# 1 was escorted to NM to perform a thyroid bioassay to estimate the amount of activity involved. MHP#2 also performed a thorough meter survey of NMT #2 and decontamination as appropriate.

Summary of Survey RST#1: With a GM pancake probe - 1.4 mR/hr on right forehead/hair (read 0.0 mR/hr with an ion chamber); 0.7 mR/hr on right forearm; 0.2-0.4 mR/hr on hands; 0.6-0.8 mR/hr on pants (0.04 on skin of shin). Initial removable contamination <700 dpm/100 cm^2, post decon values <440 dpm/100 cm^2.

Summary of Survey NMT#1: With a GM pancake probe - 0.15-0.3 mR/hr on hair/forehead; 0.2 mR/hr on hands; 1.2 mR/hr on right forearm. Removable contamination initially 1115 dpm/100 cm^2 on forearm all others < 230 dpm/100 cm^2, post decon all areas < 450 dpm/100 cm^2.

Summary of Survey NMT#2: With a GM pancake probe - 0.1-0.2 mR/hr on forehead/hair; 0.04-0.07 mR/hr on right forearm/hand. Removable contamination <230 dpm/100 cm^2.

Both NMT's were instructed to perform thyroid bioassay on August 28, 1996 and all three involved individuals were instructed to collect the first void the morning of August 29, 1996 and August 30, 1996 and deliver to RS. All three individuals were instructed to restrict contact with Iodine-131 for the remainder of the week and to repeat thyroid bioassay on Thursday the 29th, Friday the 30th and Tuesday the 3rd (Monday the 2nd was Labor Day - holiday).

Dose estimates for RST#1: The thyroid uptake from 8/28/96 thyroid bioassay results was estimated at 150 nCi. Urinalysis results from 8/29/96 indicated a 117 nCi predicted uptake for 8/29/96 with thyroid bioassay results on the 29th yielding an uptake of 132 nCi. Using the 150 nCi uptake as a worst case estimate, an intake of 1071 nCi is calculated with a thyroid CDE of 1150 mrem and CEDE of 36 mrem. (Calculations based on information in ICRP Publication 54.)

Dose estimates for NMT#1: The thyroid uptake from 8/28/96 thyroid bioassay results was estimated at 44 nCi. Urinalysis results from 8/29/96 indicated <27 nCi (urinalysis results were less than MDA) predicted uptake for 8/29/96 with thyroid bioassay results on the 29th yielding an uptake of 38 nCi. Using the 44 nCi uptake as a worst case estimate, an intake of 314 nCi is calculated with a thyroid CDE of 337 mrem and CEDE of 11 mrem.

Dose estimates for NMT#2: The thyroid uptake from 8/28/96 thyroid bioassay results was estimated at 68 nCi. Urinalysis results from 8/29/96 indicated a 46 nCi predicted uptake for 8/29/96 with thyroid bioassay results on the 29th yielding an uptake of 61.5 nCi. Using the 68 nCi uptake as a worst case estimate, an intake of 486 nCi is calculated with a thyroid CDE of 522 mrem and CEDE of 16 mrem.

A survey of NMT#1's car was performed the afternoon of 8/28/96. As NMT#2 had driven a different car 8/28/96 then on 8/27/96, he was asked to survey both cars and his home and report the results to RS the next day. No readings above background were reported from these surveys. On 8/30/96, it was realized NMT#1's home had not been surveyed, MHP #1 was sent to the residence that afternoon to conduct a meter and wipe survey.

Summary of Survey RST#1 car: All mR/hr readings with GM pancake probe. PREDECON: driver's door inside handle 0.1 mR/hr(333 dpm/100 cm^2); stick shift 0.5 mR/hr (758 dpm/100 cm^2); steering wheel 0.3 mR/hr (812 dpm/100 cm^2); drivers seat 0.1 mR/hr (178 dpm/100 cm^2); emergency brake lever 0.1 mR/hr (325 dpm/100 cm^2). POSTDECON all wipes < 140 dpm/100 cm^2 and all readings <0.3 mR/hr.

Summary of Survey NMT#1 car: All mR/hr readings with GM pancake probe. PREDECON: Middle armrest 0.5 mR/hr (2744 dpm/100 cm^2); drivers seat 0.5 mR/hr (344 dpm/100 cm^2). POSTDECON: all removable contamination <70 dpm/100 cm^2.

Summary of Survey RST#1 home: Meter readings with GM pancake probe revealed a pillow with 0.15 mR/hr and the shirt from the previous day above background. These items were returned to CCF for decay-in-storage. Removable contamination was < 55 dpm/100 cm^2.

Summary of Survey NMT#1 home: Meter readings with a GM pancake probe were all comparable to background. Removable contamination was < 20 dpm/100 cm^2.

From the interview process, no unusual occurrences were noted with the patient during the dose administration i.e., no coughing or sneezing, etc. It was discovered that rather than delivering the liquid dose through the "straw method", as the straw had been left in NM, NMT #1 removed the metal rim and rubber septum from the vial, poured the dose into a cup and rinsed the vial several times with the washings placed in the same cup as the dose which was then given to the patient to drink. From examining contamination patterns on the three individuals and of items present in the area during the dose administration, it is presumed that when the vial was opened a "puff" or "cloud" of the I-131 was released which then settled down on items present in the patient's room. Monitoring equipment located outside the room at the doorway was not found to be contaminated. Although NMT #1 and #2 had used the foot (monitors the bottom of the shoe) and hand (mounted GM pancake probe) monitors in NM upon return to the department 8/27/96, they had not monitored their clothing/labcoats. As gloves had been worn during the administration and only the tops of shoes were found to be contaminated, the monitoring performed was not adequate to detect the contamination present on shoe tops, clothes, face and hair. RST#1 had not performed any personal monitoring prior to departing from CCF on 8/27/96.

On the afternoon of 8/28/96, the RSO reviewed the information and data collected to estimate the initial dose commitments and to evaluate any NRC notification requirements. This included the following:

1. Skin dose evaluations - using the Skin Dose Estimate procedure, for Iodine-131 a 25 rem dose estimate for a plane source correlated to a trigger level of 38 kcpm/2 cm^2 or a meter reading of 12 mR/hr for the equipment in use. The highest reading recorded had been 1.4 mR/hr, therefore there were no reporting requirements for skin dose estimates.
2. Air concentration evaluation - during the dose administration a concentration of 1.12×10^{-6} µ/ml was measured for a sampling time of 5 minutes. This yields 4.7 DAC-hrs or if one assumes this concentration was present for a worst case estimate of 1 hour, 56 DAC-hrs. No reporting requirements exist due to air concentrations.
3. Thyroid bioassay results - from initial measurements and calculations for RST#1, an estimate of 174 nCi uptake was calculated. The Derived Recording Level for uptakes at Day 1 after intake is 215 nCi which corresponds to a 1536 nCi uptake and a thyroid CDE of 1650 mrem or 1/30 of the CDE annual limit and 51 mrem CEDE or 1/100 of the CEDE annual limit. As the worst case estimate of thyroid uptake at this time was 174 nCi, no reporting requirements existed due to dose commitments from bioassay results.

As CCF is committed to Regulatory Guide 8.20 for thyroid bioassay, the first action level identified for Iodine-131 is 0.04 µCi. This requires an investigation, evaluation of removing from further work in the area, determination of corrective actions, repeat bioassay within 2 weeks, and reports of notification as required in the regulations. An investigation was already underway as to the cause and the individuals had been removed from further I-131 work for at least the remainder of the week of the 26th. Corrective actions identified at this time were modifying the survey sheets used for therapy dose administrations to incorporate monitoring of personnel present for

procedures prior to their leaving the immediate area and restricting the use of "open" liquid doses. Repeat bioassays were scheduled for the following day and from evaluations performed as indicated above, no reporting requirements existed. The second action level in Regulatory Guide 8.20 for I-131 was 0.14 μCi, as this level was exceeded by the initial estimate the actions required were reviewed. The second action under this level indicated to refer to an appropriate medical consultant for recommendations regarding therapeutic procedures to accelerate removal of the I-131 from the body. The Regulatory Guide went on to indicate this should be conducted within 2-3 hours after exposure. As approximately 24 hours had already elapsed, and until further clarification of the true thyroid burden was determined from bioassay on the 29th and evaluation of urinalysis on the 29th, medical consultation was deferred at this time. The last requirement under this action level was for bioassay to be repeated at weekly intervals. As stated previously bioassay was to be conducted the 29th, 30th and the 3rd with further evaluations to be determined from these results.

4. Review of 10 CFR 20.2202 and 20.2203 - reviews of these sections of the regulations did not identify any immediate or 24 hour notifications as required under 20.2202. Review of survey results for notifications under 20.2203 (a) (2) (iv) and (a) (3) (ii) did not identify any results yielding 0.002 rem in one hour or 10 times 200 dpm/100 cm^2. Please note at this point a math error had been made in determining dpm values for the results of NMT#1's car yielding results less than 2000 dpm/100 cm^2.

On 8/29/96 a meeting was arranged with representation from NM and RS to review the incident and any recommendations for procedure changes. Present were Dr. S. Cook (NM physician, acting as department chair during chair's absence), Dr. D. Neumann (NM physician, chair of the Radioisotope & Radiation Safety Committee), Dr. G. Saha (nuclear chemist for NM), Ms. S. Khandekar (lead technologist for NM), Ms. X. Zhu (RS medical health physicist) and Ms. J. McKenna (RSO). The initiation of monitoring to be performed by RS immediately following dose administrations was reviewed in addition to discontinuation of "open" vial administrations unless required by a physician (RS would investigate the procurement of a "glovebox" type device for these cases), a refresher inservice to be scheduled by Ms. Zhu and Ms. Khandekar for all NMT's to review the proper personnel monitoring procedures, and Ms. Khandekar would review procedures for administering therapeutic doses and personnel monitoring for any required modifications. A review of the actions required based on the bioassay results was also presented with the concurrence of the deferring of the medical consultation for RST#1 based on an estimated uptake exceeding the 0.14 μCi trigger level. Notification of NRC was discussed, both mandatory and as this was not mandatory reporting as informational only. This became irrelevant once the error in calculation for the dpm on NMT#1's car was identified later on the afternoon of the 29th to exceed the 2000 dpm/100 cm^2 limit and 30 day notification was now required. The RSO then informed management of the need to report the incident within 30 days.

The requirement for surveys following dose administration was identified to RS staff prior to the next patient treatment scheduled for 9/3/96. The need to perform routine personnel monitoring was also discussed with RS staff. Inservices for the NMT's were scheduled and performed on 9/5/96, 9/9/96 and 9/11/96. All but three technologists attended, a make-up session will be scheduled. Attached is a copy of Nuclear Medicine's evaluation of the continued use of liquid doses for therapeutic I-131 treatments.

Compiled and submitted by:

Judy A. McKenna, M.S., DABR
Director, Radiation Safety
Radiation Safety Officer
September 26, 1996

The Cleveland Clinic Foundation
30d Notification Report
September 26, 1996
Addendum

Identification of Individuals

RST#1 - [redacted]

NMT#1 - [redacted]

NMT#2 - [redacted]

THE CLEVELAND CLINIC FOUNDATION
Nuclear Medicine Department

MEMORANDUM

TO: Judy McKenna
Director, Radiation Safety

FROM: Shashi Khandekar SK
Chief Technologist

DATE: September 26, 1996

SUBJECT: Follow up on memo regarding I131 Dose Administration

On September 11, 1996 during the departmental staff meeting, Dr. Go, discussed the I131 dose administration with all other Staff Physicians and Dr. Saha who is in charge of the Nuclear Pharmacy.

1. Dr. Saha has already informed Mallinckrodt Medical Inc., the main supplier of I131 doses, to deliver the I131 solution in closed cap vials only. I have enclosed the copy of his letter to Mallinckrodt Medical Inc. with this memo.

2. The patients who experience difficulty in swallowing, have excessive cough or cannot use a straw to drink I131 solution, will be given I131 capsules.

3. We have instructed technologists to use distilled water in place of tap water.

4. All the technologists have been reinstructed to use the special straw provided by the vendors, in the administration of I131 oral solution. No one is to pour the dose in the cup for administration.

5. We have also made a revision in our Treatment Protocol to include the whole body survey of individuals giving the treatment after each treatment is given.

There were no I131 treatments on June 15, 17, 28, 1994 and January 3, 1996, where the vial was opened for administration. Also, Winnie Zhu gave several in-service conferences to our technologists on the topic of I131 treatment during the first two weeks of September.

We always appreciate your help.

SK:amk

THE CLEVELAND CLINIC FOUNDATION
One Clinic Center 9500 Euclid Avenue Cleveland, Ohio 44195-5074
A National Referral Center An International Health Resource

Gopal B. Saha, Ph.D.
Nuclear Medicine / Gb3
216/444-2777

September 10, 1996

Mr. Steven Schulte
Facility Manager
Mallinckrodt Medical Inc.
9455 Midwest Ave.,
Garfield Hts OH 44125

Dear Steve:

As I discussed with you on the phone, we have encountered several radiation safety problems in using ^{131}I-NaI oral solutions supplied in screw-cap vials by your pharmacy. For this reason, and under the edict of the Radiation Safety Office, I request that effective immediately your pharmacy supply the ^{131}I solution in a closed-cap vial using the rubber septum.

Please notify each of your pharmacists about this change in policy. If at any time you send in screw-cap vials, you will be asked to pick them up and send them back in closed-cap vials.

As always, I appreciate your cooperation on the matter.

Sincerely,

Gopal Saha

Gopal B. Saha, Ph.D.
Director of Nuclear Chemistry
and Pharmacy

GBS/rmb