RI - DNMS Licensee Event Report
Disposition

Licensee: Yale University

Event Description: Potential Overexposure

License No: 06-00183-03, 06-00183-06 | Docket No: 03000582, 03038332 | MLER-RI: 2016-011

Event Date: 06/30/16 | Report Date: 07/01/16 | HQ Ops Event #: 52060

1. REPORTING REQUIREMENT

- [ ] 10 CFR 20.1906 Package Contamination
- [ ] 10 CFR 20.2201 Theft or Loss
- [ ] 10 CFR 20.2203 30 Day Report
- [X] Other 10 CFR 20.2202(a)(1)
- [ ] 10 CFR 30.50 Report
- [ ] 10 CFR 35.3045 Medical Event
- [ ] License Condition

2. REGION I RESPONSE

- [ ] Immediate Site Inspection — Inspector/Date
- [ ] Special Inspection — Inspector/Date
- [ ] Telephone Inquiry — Inspector/Date
- [ ] Preliminary Notification/Report
- [X] Information Entered in RI Log
- [ ] Report Referred To:
- [ ] Daily Report
- [ ] Review at Next Inspection

3. REPORT EVALUATION

- [X] Description of Event
- [X] Levels of RAM Involved
- [X] Cause of Event
- [X] Corrective Actions
- [X] Calculations Adequate
- [ ] Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

- [ ] Release w/Exposure > Limits
- [ ] Repeated Inadequate Control
- [ ] Exposure 5x Limits
- [ ] Potential Fatality
- [X] Deliberate Misuse w/Exposure > Limits
- [ ] Pkging Failure>10 rads/hr or Contamination>1000x Limits
- [ ] Large# Indivs w/Exp>Limits or Medical Deterministic Effects
- [ ] Unique Circumstances or Safeguards Concerns

If any of the above are involved:

- [ ] Considered Need for IIT
- [ ] Considered Need for AIT

Decision/Made By/Date:

5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only) N/A

- [ ] Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
- [ ] Medical Consultant Used-Name of Consultant/Date of Report:
- [ ] Medical Consultant Determined Event Directly Contributed to Fatality
- [ ] Device Failure with Possible Adverse Generic Implications
- [ ] HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

REACTIVE INSPECTION

~~Non-Public~~

Public-SUNSI REVIEW COMPLETE

Inspector Signature: [signature] Date: 8/12/16

Branch Chief Initials: [initials] Date: 8/12/16

Location of File: G:\REFERENCE\BLANK FORMS\LER FORM.DOCX

Rev. 08/03/16

Public as per CRC TMD

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July 29, 2016

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Re: Report of Potential Overexposure, Event #52060
Yale University
License Nos. 06-00183-03, 06-00183-07

To whom it may concern:

Pursuant to 10 CFR 20.2203, Yale University submits the following report as a follow-up to the phone notification made on July 1st, 2016 and assigned event #52060. The phone notification was made at the start of the work day on July 1st immediately pursuant to receipt of written notification from Yale University's dosimetry provider, Mirion Dosimetry.

As discussed below, although the University has not yet determined definitively the exact cause of the elevated badge reading, significant doubt exists as to whether the badge exposure represents a true occupational dose to the individual involved. In fact, review of all information to date indicates that the badge result does not accurately represent the exposure received by the individual assigned the dosimeter in question. Accordingly, the University is actively continuing the investigation into the cause of the badge exposure and will supplement this report upon the discovery of additional relevant information.

For ease in following, this document is organized as follows:

Background Information

Yale University has contracted with Mirion Dosimetry for more than a dozen years to provide personnel monitoring services to identified individuals. Mirion Dosimetry officially notified Yale University of three unusually high dosimetry readings for badges worn by three individuals during the month of May, 2016, in a report sent via email late in the evening on June 30th. All three readings were for badges assigned to individuals working at the Yale University Positron Emission Tomography (PET) Center. Only one reading was for a whole body badge and only this one reading was above a Nuclear Regulatory Commission (NRC) occupational exposure limit.

The whole body badges used at Yale University are Mirion Dosimetry Type 36 and Type 35 Thermo Luminescent Dosimeters (TLD). The whole body badge reading in question was reported as 31 rem and was for a badge assigned to a Nuclear Medicine Technologist (NMT). The other two readings were for extremity dosimeters (TLD finger rings), which were reported at 35 rem and 37 rem. These extremity dosimeter readings are mentioned here even though they are not reportable doses, as they add to the pertinent information from which we ultimately draw conclusions. All three unusually high readings were immediately suspect for several reasons:

- Each individual for whom a high reading was received wears three pieces of dosimetry - a TLD finger ring on each hand and a TLD whole body (WB) badge. For the time period in question, May, 2016, only one piece of each set of dosimetry for each of the three individuals recorded a significant and unusual dose. For each of the three people involved, their other two pieces of dosimetry showed normal results. *Please see Appendix A for a chart depicting a summary of all suspect dosimetry results discussed in this document.*
- The sheer magnitude of the readings is in stark contrast to the typical readings measured at the PET Center since the facility's commissioning 10 years ago. Typical monthly dosimeter readings for the most exposed population at the PET Center average about 25 mrem for WB exposures and 500 mrem for extremity exposures.
- The individuals' known employment roles and their typical work with byproduct material would not result in readings of this magnitude, as supported by their previously measured exposures.
- Prior to the May WB badge reading, the NMT's total recorded whole body occupational dose for the entire time the NMT has worked at Yale (> nine years in the same role as her current role) was noted as 437 mrem. Further it was quickly learned that the NMT in question was only present at work for six days during the month of May and handled radioactive materials only four of those six days. Receiving a WB dose of 31 rem for four days of work while performing typical duties again immediately raised serious doubt about the results.
- Almost 200 badges are in circulation at the PET Center at any particular point in time. To only have three badges with extreme results and not others raised significant questions.

Subsequent to learning the results of these three high and unusual dosimeter readings, dosimeters worn by PET Center staff assigned badges exchanged on a monthly basis, were quickly collected and sent to Mirion

Dosimetry (Yale University's dosimetry provider) for emergency processing (approx. 25 badges). (It should be noted here that many other actions were also taken to ensure an unsafe situation did not exist. These and other actions are described further in the section of this report entitled *Immediate Actions*.)

All results for dosimetry worn by PET staff for the wear period of June, 2016 were typical, except for one individual. A second PET Center Nuclear Medicine Technologist (NMT) whose results showed higher than usual readings, particularly for this NMT's whole body dosimeter which was reported at 2.6 rem. The summary for the employee is found in line four of Appendix A. This NMT has worked and been monitored for radiation exposure at the Yale University PET Center since early 2010. Prior to this June badge reading, her reported total whole body occupational dose for the entire time the NMT has worked at Yale (> 6 years) in the same role as her current role was 1.4 rem. Receiving a dose of 2.6 rem in one month while performing typical duties as usual, again raised questions about the validity of these results.

The Yale University PET Center employs many people who don't frequently handle byproduct material, but who may frequent areas where licensed material is located or being actively used. This population is issued dosimetry, which is exchanged on a quarterly basis, rather than monthly. On Friday, July 1st, 2016, the start of the third quarter monitoring period, dosimeters exchanged on a quarterly frequency were exchanged, collected and sent to Mirion Dosimetry for emergency processing. This batch included six area monitors (dosimeters hung in spaces at the PET Center to document area readings).

Again, all dosimeter readings (approx. 145 badges) from this quarterly monitoring period (April-June) including the area monitors were typical, except for one individual. Results for the Director of the PET Center showed higher than usual readings on both the Director's whole body badge (2.2 rem) and extremity dosimeter (3.2 rem). These readings are summarized in line five of Appendix A. When these results were communicated to the Director, it was learned that he had been issued a spare WB badge for this quarter and never wore either of these dosimeters. Learning that dosimeters which had not been worn at all and yet were showing exposures in the rem range further corroborated what was suspected, that potential tampering with dosimeters had occurred. Thus, in addition to the immediate actions and safety investigation which were already underway, an Investigative Team was formed to look into the possibility of tampering. This team was commissioned by Yale's Office of General Counsel and includes the following individuals:

Mike Pearson, Associate Director - University Auditing
Tammy Stemen, CHP, Radiation Safety Officer- EHS
Alexandra D'Amico, Assistant Director-Employee Relations

Details of the investigation thus far can be found in Appendix C to this report. Appendix D contains the credentials of the team members.

Immediate Actions

1. Regulatory reports were made to the US Nuclear Regulatory Commission and State of CT Department of Energy and Environmental Protection as required by each of the agency's regulations.
2. The NMT with the 31 rem WB badge reading was suspended from further work with radioactive materials and any other sources of radiation exposure. It should be noted that at the time of receipt of her high dosimetry reading, she was already on an unrelated medical leave and has not been back to work at Yale University since May 10th.
3. EHS Health Physics staff was immediately dispatched to perform radiation monitoring throughout the entire PET Center facility.
4. The Radiation Safety Officer (RSO) and additional Environmental Health and Safety (EHS) Health Physics staff met with the senior leadership of the PET Center to inform them of dosimetry results, brainstorm ideas and discuss action items.
5. Yale University senior leadership and the Radiation Safety Committee were informed. A special RSC meeting was held within a week of notification of the high badge results.
6. The individuals whose dosimetry results were reported as high were immediately informed and ALARA investigations were initiated.
7. The RSO communicated with Mirion Dosimetry and asked for validation, and written detailed evaluation of the badge results. These communications and support are ongoing. Three technical dosimetry experts were assigned by Mirion to assist with this effort.
8. All personnel monitoring devices for staff working at the PET Center for the 2nd quarter of 2016 were exchanged and processed in a very timely manner.
9. Dosimeters hung in spaces at the PET Center facility, which are used as area monitors, were exchanged and processed rapidly.
10. All PET Center radioactive sealed sources were inventoried and accounted for. Leak tests of sources meeting leak test requirements were performed to ensure no evidence of leaking sources.
11. A radiation survey of the self-shielded PET Center cyclotron was performed while in operation.
12. Records regarding contamination incidents and other unusual events were reviewed for the time period in question. No unusual exposure situations which could have caused the readings in question were identified.
13. Additional monitoring devices were provided to two employees who had higher than usual dosimeter readings and who continue to routinely handle radioactive materials/sources at the PET Center.
14. In consultation with Mirion Dosimetry experts, EHS Health Physics staff, with assistance from identified PET Center staff, began purposeful exposures of Mirion TLD dosimeters to learn information about expected dose rates and patterns observed on WB dosimeters.
15. Calculations and measurements were performed to quantify how dosimeters may have been exposed to such high doses.
16. ALARA investigations were initiated immediately and are currently being finalized. No explanations for any of the unusually high readings were found to be readily apparent.

Additional Actions

1. A literature search was conducted and several radiobiologists were contacted in order to evaluate whether doses to individuals could be determined/validated biologically. Cytogenetic biodosimetry was decided to be used in the case of the 31 rem WB badge reading.
2. Improvements were made to the control and distribution process of dosimeters at the Yale University PET Center.
3. A retraining session was conducted with PET Center staff on the proper use and storage of personal monitoring devices.
4. General information and training materials provided to new users of dosimeters were updated for clarity and completeness.
5. Confirmation was made that no industrial radiography sources were on campus and in the vicinity of the PET Center during the time period in question.
6. Updates have been provided to involved staff and all PET Center employees on status of situation.
7. Retraining information has been prepared and will be distributed to all monitored Yale University individuals.

Results of Safety Investigation

As a result of all the actions taken to assess the potential cause of the elevated dosimetry readings, no atypical safety concerns were noted at the PET Center. No high or unusual dose rates were identified; no previously identified dose rates or contamination events that may have contributed to unusual dosimetry readings were identified.

Information Specific to the Whole Body Badge Reading 31 rem

- Monitoring period: month of May, 2016. WB badge worn on lab coat lapel.
- Assigned to a lead Nuclear Medicine Technologist who has worked at the Yale University PET Center for [redacted] years. No whole body exposures greater than 41 mrem in one month have ever been recorded as received by this individual while employed at the PET Center. Total whole body deep dose equivalent measured and assigned to this individual from August, 2007 thru April, 2016 equals 449 mrem.
- This NMT worked for only six days in May, 2016. Radioactive material was only handled by this NMT on four of those six days; May 3rd,5th,6th,10th. Detailed records are maintained by the PET Center for research projects. These records detail which NMT's performed which research protocol injections. Due to these records, it is known that this NMT performed the dose drawing work and associated subject injections for five separate research protocols on the four dates mentioned previously. A total of 157 mCi of Carbon-11 (Half life=20 minutes) was handled by this NMT over the four days.

- The work with radioactive material that was performed by this individual in May was standard, routine NMT work, which is performed almost daily by several different NMT's at the Yale University PET Center. Monthly exposures measured for NMT's employed at the Yale University PET Center average around 500 mrem per extremity and 25 mrem whole body.
- Whole body exposures for NMT's at the PET Center are typically 16 times lower than extremity badge readings. This is primarily because the vast majority of the exposure a NMT receives is received during their drawing of byproduct material doses (typically 5-20 mCi of C-11 or F-18 at the Yale PET Center) from a vial into a syringe (in preparation for injection into a research subject). This dose drawing is performed in a lead shielded dose drawing station like the one pictured here:

- No x-ray generating equipment was used by this person in May, 2016.
- No radioactive sealed sources were used by this person in May, 2016.
- The pattern on the badge has been characterized as suspect by Mirion Dosimetry due to a non-uniform exposure of the four TLD elements in the whole body badge. A badge exposed to high energy photon radiation from a distance of greater than six inches would be expected to show a uniform pattern. Please see Appendix B for a critical review of this badge and the other badges performed by the dosimetry experts at Mirion Dosimetry.
- The extremity dosimeters worn by this NMT for the month of May showed 52 mrem and 83 mrem on the left and right extremity monitors, respectively. These readings are considered expected for the activity handled by the NMT in May.
- Analyzing the [redacted] years of personal monitoring information on this NMT, and taking into account this NMT's finger ring results for the month in question, her WB exposure for the month of May would have been expected to be no more than 10 mrem.

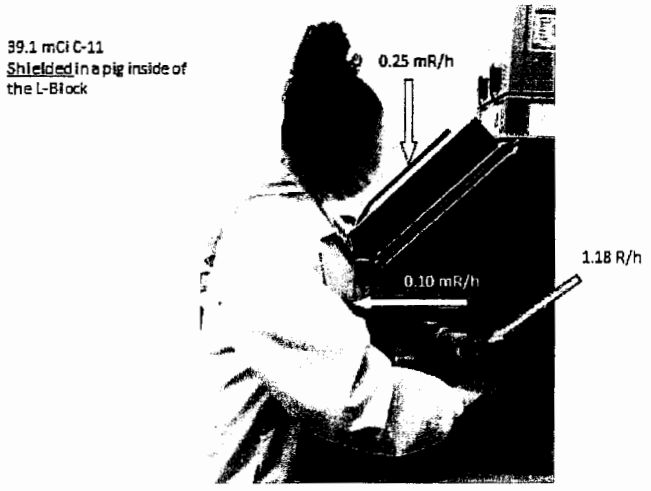
- A cytogenetic dosimetry assay is currently being performed on a blood sample provided by this individual. The assay is being conducted by the Biodosimetry lab in Oak Ridge, Tennessee, which is part of REAC/TS – the Radiation Emergency Assistance Center and Training Site https://orise.orau.gov/reacts/. The number of dicentric chromosomes in the blood sample is being analyzed and an estimation of radiation dose (if any) will be reported. Results from this assay are expected to be received on or about August 2nd .
- The NMT has been on a previously approved leave of absence since May 10th and is not expected to return to work at Yale University.

Technical Supportive Information

The most common byproduct materials typically handled at the Yale University PET Center include the positron emitting radionuclides Carbon-11 and Fluorine-18. These radionuclides are produced in the onsite GE PETtrace cyclotron, synthesized into radiopharmaceuticals in lead shielded, enclosed hot cells and after passing quality control checks moved in a lead shielded container to an imaging suite for injection into research subjects. C-11 and F-18 in mCi quantities is handled at the PET Center on an almost daily basis, Monday thru Friday. The cyclotron is not typically operated on the weekends. In addition to the C-11 and F-18 produced on site, F-18 is also procured from outside vendors.

Due to the high energy nature of the radiation emitted by C-11 and F-18, lead shielding of significant thickness is incorporated throughout PET Center facilities. This shielding along with reduced time and increased distance is an extremely effective way to limit radiation dose to handlers. In Diagram 1, the typical dose rates measured around a vial of 39 mCi of C-11 are depicted. These measurements were made using an ion chamber calibrated with high energy photons.

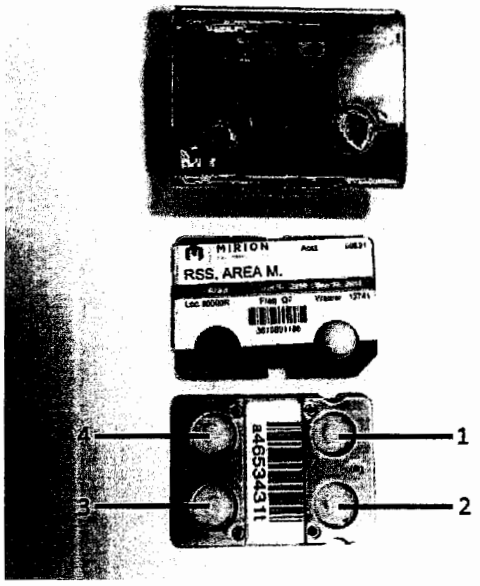
Diagram 1



The 1.18 R/hr reading is taken on the top of the open lead pig housing the vial of C-11. Maximum dose rates external to the lead shielded dose drawing station are also depicted and clearly show the significant protection factor afforded by both distance and lead shielding when using PET radionuclides.

The Mirion Dosimetry WB badges used by Yale for personnel monitoring contain four TLD elements as depicted in Diagram 2.

Diagram 2



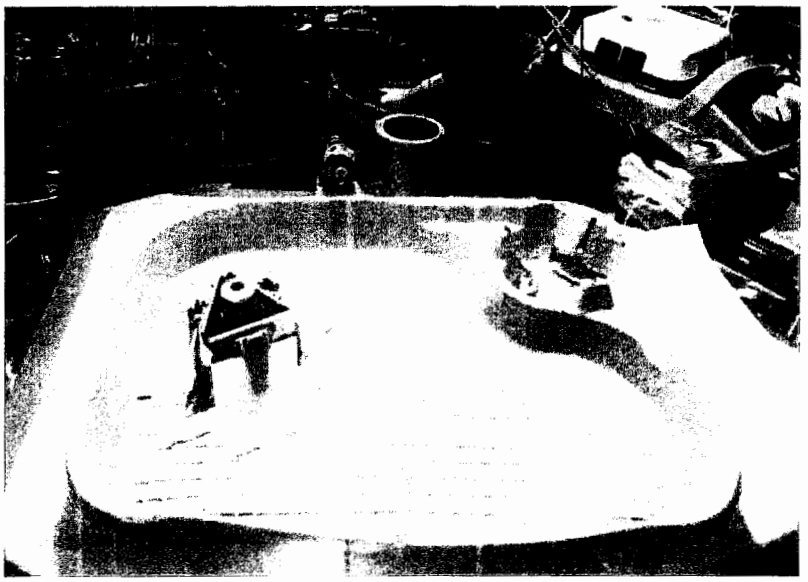
Mirion Dosimetry has advised us that when a TLD WB badge is exposed to high energy photons (such as those emitted by C-11 and F-18) they would expect a uniform exposure pattern (1,1,1,1) on the four TLD elements enclosed in the WB badge if the badge were exposed at arms distance. Arms distance for the purposes of this report is conservatively assumed be a distance of greater than six inches.

Mirion's analysis of the three WB badges involved in this case with unusual readings indicates that none of the three WB badges exhibit this expected uniform pattern. In fact, the WB badge assigned to the Director of the PET Center (Wearer # 15636), which was never worn, exhibits a pattern (1,1,3,3), which quite clearly to Mirion indicates that it was exposed up close to a high-energy source. They draw this conclusion in part because TLD elements in the same badge which are only about one centimeter apart were exposed to three times the radiation as the other two elements in the badge. Please refer to the spreadsheet in Appendix B, Wearer ID # 15636 to see the highlighted raw data reported by Mirion on the individual TLD elements in this badge.

A similar pattern (1,1,3,3) has been observed in WB badges that Yale University has very recently and purposely exposed on contact with unshielded vials of PET radiopharmaceuticals (C-11 and F-18). Perhaps more importantly, when WB badges were exposed to the same vials of C-11 and F-18 at various distances (contact, three inches, six inches, nine inches, 12 inches, etc...) the badges located six inches and further from the vial exhibited the expected pattern (1,1,1,1) of a WB badge worn on a person's torso measuring a whole body exposure while handling radioactive material at arms distance. The pattern observed on the WB badge with the 31 rem reading does not indicate the expected pattern (1,1,1,1) for an individual who only handled C-11 and wore their badge on their torso during this work.

The experimentation with badges purposely exposed to vials of C-11 and F-18 have not concluded, however, these experiments are also helping to determine the dose rates expected to be found at various distances from C-11 and F-18 vials. Preliminary results indicate that contact dose rates from a vial containing 71 mCi of F-18 would be expected to be 44 to 60 R/hr. This along with other data currently being analyzed allows us to conclude that it would only take on the order of 30 minutes for a badge placed in contact with a 71 mCi vial of F-18 to be exposed to 31 rem (the reading measured on the badge which caused the notification and is the subject of this report).

Diagram 3



Status of Tampering Investigation

Over a dozen interviews have already been conducted by the Investigative Team and hundreds of data points regarding access records have been scrutinized. The details of the investigation thus far can be found in Appendix C to this report.

Concluding Remarks

The University believes that the 31 rem WB badge reading does not represent an actual dose to a person. The exact cause of the reading is still undetermined. Numerous possibilities and theories are being explored. Accordingly, the University is actively continuing the investigation into the cause of the reading and will supplement this report upon the conclusion of the investigation.

Sincerely,

Stephanie S. Spangler, M.D.
Deputy Provost for Health Affairs and Academic Integrity

Tammy Stemen, CHP
Radiation Safety Officer

cc: Blake Welling, Chief, Materials Security & Industrial Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I

Michael Firsick
Supervising Radiation Control Physicist
Connecticut Department of Energy and Environmental Protection

Appendix A: Elevated Dosimetry Results Summary-PET Center

Position	Work Location at PET Center	Dosimeter	Result	Time Period	Comments
NMT #1	Imaging	WB	31 rem	May	Reading over 5 rem WB limit. Only on site 6 days in May. Only handled radioactive materials on 4 of those days. Rings normal.
Nurse	Imaging	Left Extremity	35 rem	May	Only on site 3 days in May. Other dosimeters normal.
Radiochemist	Radiochemistry	Left Extremity	37 rem	May	Other dosimeters normal.
NMT #2	Imaging	WB Right Extremity Left Extremity	2.6 rem 1.8 rem 1.4 rem	June	Typical work load for June. Atypical badge results – particularly WB badge
Director	Office Walk throughs in Imaging	WB Extremity	2.2 rem 3.2 rem	2nd quarter	Director did not wear this dosimetry at any time during the quarter.

Privacy Act Information: Not for Public Disclosure

Pursuant to 10 CFR 20.2203(b)(2), Yale University hereby provides the name, social security number and date of birth of the individual who was potentially exposed in excess of the occupational dose limit for adults, as notified by Yale University's dosimetry provider, Mirion Dosimetry in a written communication dated 7:27 pm on 6/30/2016.

Name: [redacted]
Social Security No.: [redacted]
Date of Birth: [redacted]

Appendix B: Mirion Review of High Dose Readings

MIRION TECHNOLOGIES

Dosimetry Services Division
2652 McGaw Ave
Irvine, CA 92614
www.mirion.com

Toll Free: (800) 251-3331
Tel: (949) 419-1000
Fax: (949) 296-1144

Radiation Safety Officer
Yale University
Environmental Health & Safety
135 College Street, Suite 100
New Haven, CT 06510

[redacted]

Account Number: 00631
Location: 00000PTQ/00000F13
Pr[redacted]mber: 0230658/0230634/0230650
Client Request No.: 10232

July 20, 2016

Dear Tammy,

In response to your request, the high dose readings in Processes 230568, 230650, and 230634 have been reviewed by the technical staff, Manager of Laboratory Operations, and Manager, Technical Services.

[redacted]alysis included:

- Incoming mail receipt contamination inspection which showed no contamination as evaluated in a Tool and Object Monitor (TOM), and confirmation that nothing contrary to standard operating processes upon receipt was performed
- A review of Controls and Element Reads, adjusting any as necessary, or noting any Controls not to be used
- A detailed review of glow curves, and individual historical performance of the dosimeters

In addition, the Technical Services Manager performed a detailed review of the past 4 years of Yale dosimetry results to assess if any trends in exposure existed.

The results for the WB dosimeter for [redacted] (Wearer 15683) for May 2016 wear period indicates higher readings for Elements 3 and 4 than for Elements 1 and 2, indicating the source was closer to the left side of the dosimeter (as you face the dosimeter).

One Extremity ring for both [redacted] r the May 2016 wear period also indicate a high exposure , while the other ring for each were in the normal range. This might indicate either contamination or being next to a source for an extended period of time.

The WB dosimeter for [redacted] r the June 2016 wear period also indicates higher than expected readings for Elements 2 and 3, which again indicate the two elements at the bottom of the dosimeter (as you face the dosimeter) were possibly closer to a source than

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Elements 1 and 4. The dose readings in this case were an order of magnitude less than for the dosimeters of [redacted]

The WB dosimeter for [redacted] for the April wear period again indicated much higher readings on Elements 3 and 4 than on Elements 1 and 2. Also in this case the ring dosimeter for [redacted] also indicated a dose similar to what is found on Elements 3 and 4 of the WB dosimeter.

These results are shown in detail on the accompanying spreadsheet, along with the calculated doses assuming the algorithm paths selected. In the case of the [redacted] WB dosimeter, we determined the dose from the average of the four elements, rather than through the dosimeter algorithm. The exposure patterns to these specific whole body badges do not indicate the normal expected pattern from F-18 or C-11 at a distance of greater than 3 inches. A more standard pattern would have all four elements being more uniform across the dosimeter, as indicative of high energy photons (which are associated with your particular sources).

We have recommended performing exposures at contact, near contact, and further away to provide review of the exposure patterns to emulate the hypothesis of up close irradiation to the elements. This may also indicate if the exposures might have any angular components. The element response pattern of approximately 1000, 1000, 3000, and 3000 ([redacted] 4/1/2016) suggest a source being less than 3 inches from the E3 and E4.

We have verified the readings and have no reason to believe the readings were not assigned to the proper wearer.

If you should have any additional questions, please do not hesitate to contact us.

Sincerely,

Joel H. White
Manager, Laboratory Operations

949 419-2058

[redacted]

[redacted]

[redacted]

					Original Dose Equivalent (mrem)								Alg. Path	Inspection	GC	
Process	*Location*	*Unique ID*	*TLD No*	*Wearer No*	*E1*	*E2*	*E3*	*E4*	*Deep*	*Eye*	*Shallow*	*Neut*	*Chosen*	*Results*	*Review*	*Comments*
230568	00000PTQ	10398860	5098578	15683	23854	23516	38344	29209	31120	31120	31120	0	ACC LO	Good	Good	1
230568	00000PTQ	11044889	11044889	15683	83				-1	-1	83	-1	CS137			
230568	00000PTQ	11044888	11044888	15683	52				-1	-1	52	-1	CS137			
230568	00000PTQ	10398870	4682314	18044	4	4	3	3	0	0	0	0	WS300	Good	Good	
230568	00000PTQ	11044925	11044925	18044	34729				-1	-1	34729	-1	CS137		Good	1
230568	00000PTQ	11044926	11044926	18044	-38				-1	-1	0	-1				
230568	00000PTQ	2216167	5095667	18671	1	1	1	2	0	0	0	0	NODOSE	Good	Good	
230568	00000PTQ	11044933	11044933	18671	37295				-1	-1	37295	-1	CS137		Good	1
230568	00000PTQ	11044934	11044934	18671	-32				-1	-1	0	-1				
230634	00000PTQ	10524217	4677239	17100	2338	2836	3094	2431	2597	2597	2597	0	MIXMH	Good	Good	1
230634	00000PTQ	11052238	11052238	17100	1432				-1	-1	1432	-1	CS137		Good	1
230634	00000PTQ	11052239	11052239	17100	1819				-1	-1	1819	-1	CS137		Good	1
230650	00000F13	2214320	4125233	15636	1090	1065	3282	3229	2166	2166	2166	0	MIXMH	Good	Good	1
230650	00000F13	11034382	11034382	15636	3179				-1	-1	3179	-1	CS137		Good	1

Note 1: The reader quality assurance data, controls, and algorithm are satisfactory. The dosimeter results were reviewed and the Glow Curves evaluated.

There are unusual exposure patterns for the whole body dosimeters.

For the sources used by this client in the normal work loads, the only pattern seen historically is that all the elements are close to equal or on occasion hint of E3 increase due to betas.

Test irradiations of whole body dosimeters at 3 inches or further have demonstrated that radiation environment.

These unusual patterns, especially within dosimeter 4125233 combined with client discussions, suggest that near contact exposures with sources may have occurred.

Awaiting results of further tests by client for any possible revisions for recommended dose equivalents.

Appendix C: Investigational Summary as of July 25, 2016

Prepared by: Mike Pearson, Associate Director - University Auditing
Tammy Stemen, CHP- Radiation Safety Officer - EHS
Alexandra D'Amico, Assistant Director, Employee Relations

After the results of an initial safety investigation indicated that the exposure results reported on six dosimeters (assigned to five individuals) were highly unusual and extremely unlikely to represent actual doses of radiation to a person or persons, our investigative approach shifted towards exploring the scenario that the dosimetry badges in question were purposely exposed to radiation sources due to tampering by one or more individuals. Our approach to investigating the potential tampering has been multi-faceted, with steps including, but not limited to the following:

- Interviews of current and former PET Center Staff.
- Review of building access records for ID Readers that would allow access to the PET Center and to certain restricted rooms within the PET Center.
- Review of University time and attendance records to determine when individuals were present at the PET Center and when they were not.
- PET Center records of work performed at the facility during the period under review (March 1, 2016 – June 30, 2016).
- Records of deliveries of radioactive isotopes purchased from outside vendors.
- Dosimetry readings for PET Center staff from prior periods (used to establish apparent "norms" of exposure during the course of normal operational activities)
- Yale e-mail communications for PET Center employees (limited to information relevant to our investigation and only for a limited number of individuals for whom preliminary investigation results indicated information in e-mails may be useful to our investigation.) This review was also conducted to explore possible collusion amongst two or more PET Center employees in the apparent tampering.
- Radioactive material production and injection records.

We strongly believe, in order to achieve the levels of exposure measured on the dosimeters affected, the individual or individuals responsible would have needed 1) Access to a sufficient amount of radioactive material for the requisite amount of time to achieve the levels of exposure measured; 2) sufficient knowledge of radioactive materials to know not only how long badges would need to be exposed, but also how much material would be necessary and when in the relatively brief life cycle of the radioactive materials the badges could be effectively exposed, and 3) to be present at the facility and in possession of the badges at a time when materials were readily available.

We believe that all three of the above criteria would need to be met in order to successfully accomplish the alleged badge tampering to the extent that was noted during the 2nd quarter of 2016. Thus the employees most likely to have the access and knowledge required would be the Nuclear Medicine Technologists (working on the upper level of the PET Center with relevant work primarily taking place in the "hot lab" which is room 202 at the facility) and the employees working in Radiochemistry (located on the lower level of the PET Center). It is highly probably that the badges were exposed at one of these two locations within the PET Center. This narrows our population of individuals capable of carrying out the tampering, since others (i.e. nurses, custodial workers and administrative staff) would probably not have the requisite knowledge of and access to the amount of radioactive materials needed.

Experimentation with badges being purposely exposed to vials of C-11 and F-18 is being performed in an attempt to replicate readings and patterns measured and observed on suspect badges. The experiments are also helping to determine the dose rates expected to be found at various distances from C-11 and F-18 vials. Preliminary results indicate that contact dose rates from a vial containing 71 mCi of F-18 would be expected to be 44 to 60 R/hr. This along with other data currently being analyzed allows us to conclude that it would only take on the order of 30 minutes for a badge placed in contact with a 71 mCi vial of F-18 to be exposed to 31 rem (the reading measured on the badge which exceeds occupational exposure limits).

Our investigative procedures are focused on utilizing all of the information available to identify possible "windows of opportunity" where the dosimetry badges in question could have been acquired, and when it would have been possible to expose the badges to enough radioactive materials to achieve the readings on each of the badges in question. The windows of opportunity for acquisition and exposure of the six badges in question, and relevant facts based on what we know at this point in our investigation, are as follows:

PET Director 2nd quarter 2016 whole body (WB) and extremity (ring) badges with readings of 2.2 rem and 3.2 rem, respectively)

Background Information

The PET Director did not wear the badges in question at any point during the 2nd quarter of 2016. The Director was issued a spare badge on 5/9/16 when he realized that he was still wearing his first quarter 2016 badge and he inquired with the PET Center employee responsible for distributing and collecting dosimetry badges. According to this PET Center employee, it was noted during the badge sorting and distribution process for the quarterly badges, that the Director's badges were missing, but due to an oversight, Yale Environmental Health and Safety was not immediately notified of the missing badges (A retraining session has been performed with PET Center staff to correct this issue). Yale Environmental Health and Safety was notified of the missing badges on 5/9/16 after the Director's inquiry, and advised the PET employee to issue the Director a spare badge for the remainder of the quarter. The spare badge was worn exclusively for the remainder of the quarter; however both the spare badge and the missing WB and extremity badges were collected and sent out to the third party vendor for reading at the end of the 2nd quarter 2016. Thus it appears that the Director's missing 2nd quarter WB and extremity badges were returned to and collected from a wall rack (See Picture 1_) used to store dosimetry badges (where the employee responsible for distribution sits) in the Imaging suite. The originally issued WB and extremity badges, which we are confident were never worn by the director, both came back with abnormally high readings. Confirmation was received from the dosimetry vendor that the dosimeters in question were present in the shipment sent to the PET Center.

Potential Acquisition of Badges

- We confirmed that the badges were sent to Yale EHS from the dosimetry vendor, including the badges for four other Yale employees who had badges shipped in the same bag as the PET Director. Those other individuals received their 2nd quarter dosimetry, wore them throughout the quarter, and received normal readings.
- The badges were sent over to PET by Yale Environmental Health and Safety on either 3/30/16 or 3/31/16 and left on the desk of the PET employee responsible for distributing and collecting dosimetry at the facility. The desk is in a room that is accessible to anyone with access to the Imaging (upper) floor of the PET center. Access to Imaging is restricted to authorized

individuals and is only attainable through three access points (an elevator, a stairwell, and a door between the Imaging floor and an adjacent Yale building).

- The PET employee responsible for distributing dosimetry badges was out sick the afternoon of Wednesday 3/30/16 and all day on both Thursday 3/31/16 and Friday 4/1/16. The employee returned to work on Monday 4/4/16 and distributed badges via her normal process (monthly badges first and then quarterly) that morning. According to the employee, the distribution process takes about four hours.
- According to the PET employee responsible for distributing dosimetry badges, the PET Director's badges were not in the bag of badges received at PET from Yale Environmental Health and Safety when the employee distributed the badges the morning of 4/4/16. We can conclude with relative certainty that the badges were delivered to the PET Center with all of the other 2nd quarter 2016 and April 2016 monthly badges. Thus, the window of opportunity for someone to acquire these badges appears to be between the time they were delivered to the facility by Environmental Health and Safety (3/30/16 or 3/31/16) and when the PET employee responsible for distribution of dosimetry performed the quarterly badge distribution (likely mid-late morning on Monday 4/4/16).
- According to building access records, the PET employee responsible for distributing dosimetry badges arrived at the facility at 7:52 a.m. Based on the employee's description of the process, distribution would have begun with monthly badge distribution shortly after she arrived and would have continued until approximately noon, when quarterly badge distribution would have been completed. During this time, access records indicate that she was moving about the building on both the Imaging floor and Radiochemistry (lower) floors. Thus, there was likely a period of time on the morning of Monday 4/4/16 during distribution of monthly badges where quarterly badges may have been left unattended on the employee's desk.
- Based on the above, we are intensely scrutinizing building access records during the period between when the badges were delivered to PET by Yale Environmental Health and Safety (beginning with 3/30/16) and the likely completion of quarterly badge distribution at approximately noon on Monday 4/4/16. We will identify individuals who accessed the area during that time and review for anomalies (i.e. swipes in locations not typical for a given employee or outside of normal work hours). We will use this information in compiling a detailed timeline of events, and will discuss anomalies with employees as necessary.

Potential Exposure of Badges

- The window of opportunity to purposely expose the Director's 2nd quarter 2016 badges is significantly larger than the opportunity to acquire the badges. The time between when the badges were missing and the time they were collected was approximately three months. Based on the volume of research activity at the PET Center during that time and the frequent use of radioactive materials during this period, there were numerous opportunities for an individual meeting all the required criteria described above to successfully carry out a purposeful badge exposure on the Director's 2nd quarter 2016 badges. As such, our focus with respect to these badges to this point has been heavily weighted towards examining who had an opportunity to acquire the badges.

Nuclear Medicine Technologist with May 2016 WB badge reading of 31 rem

Background Information

The WB badge reading of 31 rem was highly unusual and suspect for several reasons:

- The employee was only at work for six days during the month of May and only handled radioactive materials on four of those days.

- The employee's left and right extremity badge readings were normal (50-90 mrem) for the same month.
- For the work performed by a Nuclear Medicine Technologist at the Yale PET Center, it would be virtually impossible to receive a WB exposure of 31 rem without any significant exposure to extremities. See typical work set up for a NMT at the Yale PET Center in Picture 2.
- The NMT has been employed at the Yale PET Center for [redacted] and has a total Yale occupational whole body exposure history of 437 mrem for those combined [redacted] prior to the month of May.
- ALARA Investigation looking at a detailed account of the NMT's work failed to find any reason for the elevated WB badge reading.

This employee is currently out on a previously approved leave of absence and has not been at the PET facility since 5/10/16. We have held several conversations with this employee as part of this investigation, and the employee has reported nothing out of the ordinary with respect to work related activities that required handling of radioactive materials during the month of May. She has communicated that she does not believe the WB badge reading to be a true measure of her dose.

Potential Acquisition of Badges

- The window of opportunity for acquisition of this employee's May 2016 WB badge would have been relatively wide because she spent a significant portion of the month away from the PET facility.
- The employee said the May 2016 WB badge that was exposed would have been left in her office, either on her desk or on her lab coat. The employee's desk is located on the Imaging floor of the PET Center, in an office shared with nurses that work at the facility. The office is not locked and is accessible to anyone with access to the Imaging floor (as described above).
- Additionally, the PET employee responsible for distributing and collecting dosimetry badges collected the May badges and distributed June badges on 6/1/16, but then left for vacation one day later. Therefore, the May dosimetry badges were not returned to Yale Environmental Health and Safety (to be sent out for processing) until the employee returned from vacation on Monday 6/13/16. As a result, it is our understanding that the May badges remained at the employee's desk, unattended, from Friday 6/3/16 until the employee returned on Monday 6/13/16.
- Based on the above, we believe the most likely window of opportunity to acquire this employee's badge would have been between Wednesday 5/11/16 and Monday 6/13/16 (more specifically from the employee's office between 5/11/16 and 6/1/16; and from the bag on the desk of the PET employee responsible for distributing and collecting badges between 6/3/16 and 6/13/16). Acquisition of this badge would have been relatively easy to accomplish undetected, since it was known that the employee was out of work for an extended period.

Potential Exposure of Badges

- We believe that the window of opportunity for exposure of this employee's badge is roughly the same as the window of opportunity for acquiring the badge.
- The window of opportunity to expose the badge is relatively large. Based on the volume of research activity at the PET Center during that time and the frequent use of radioactive materials during this period, there were numerous opportunities for an individual meeting all the required criteria described above to successfully carry out a purposeful badge exposure on this employee's WB badge. We will however focus on days during this window of time where conditions related to access and availability appear most favorable for badge exposure. We will focus heavily on building access reports for those days to determine which days and times offer the highest likelihood for exposure and will question employees as necessary.

Nurse (Imaging) with May 2016 Left Extremity Reading of 35 rem

Background Information

The left extremity badge reading of 35 rem was highly unusual and suspect for several reasons:

- The Nurse is a contract Nurse who only worked at the PET Center three days during May 2016 and did not directly handle radioactive materials during that time. Nurses at the Yale PET Center typically work with research subjects who have been injected with radioactive materials, but not the actual materials themselves. During May 2016, the Nurse may have handled blood samples in transit to their blood counting lab, but these samples contain miniscule amounts of radioactive material and are inconsequential from a dose perspective.
- The Nurse's WB and right extremity badges readings were normal for the same month.
- It would be extremely unlikely to receive a left extremity exposure of 35 rem without any significant exposure to the WB or right extremity badges.
- The Nurse has been employed at the Yale PET Center for [redacted] and has a total Yale occupational exposure history for her left extremity of 160 mrem for those combined [redacted]
- ALARA Investigation looking at a detailed account of the NMT's work failed to find any reason for the elevated WB badge reading.

Potential Acquisition of Badges

[redacted] May 2016, the Nurse with the 35 rem left extremity reading only worked 5/6, 5/26, and 5/27/16. Thus, the window of opportunity for acquisition of this employee's May 2016 left extremity badge would have been relatively wide because she spent a significant portion of the month away from the PET facility.

- The Nurse left all three of her assigned badges in a bin in the Nurse's office when she was not at the PET Center. As described above, the office is shared with the Nuclear Medicine Technologist with the 31 rem WB badge reading for the same month. The office is not locked and is accessible to anyone with access to the Imaging floor (as described above).
- Additionally, the PET employee responsible for distributing and collecting dosimetry badges collected the May badges and distributed June badges on 6/1/16, but then left for vacation one day later. Therefore, the May dosimetry badges were not returned to Yale Environmental Health and Safety (to be sent out for processing) until the employee returned from vacation on Monday 6/13/16. As a result, it is our understanding that the May badges remained at the employee's desk, unattended, from Friday 6/3/16 until the employee returned on Monday 6/13/16.
- Based on the above, we believe the most likely window of opportunity to acquire the Nurse's badge would have been any day in May 2016 EXCEPT 5/6, 5/26, and 5/27/16 (from the employee's office) or from the bag on the desk of the PET employee responsible for distributing and collecting badges between 6/3/16 and 6/13/16). Acquisition of this badge would have been relatively easy to accomplish undetected, since the nurse was only at the PET Center three days during the month of May 2016.

Potential Exposure of Badges

- We believe that the window of opportunity for exposure of the Nurse's extremity badge is roughly the same as the window of opportunity for acquiring the badge.
- The window of opportunity to expose the badge is relatively large. Based the volume of research activity at the PET Center during that time and the

frequent use of radioactive materials during this period, there were numerous opportunities for an individual meeting all the required criteria described above to successfully carry out a purposeful badge exposure on the Nurse's left extremity badge. We will however focus on days during this window of time where conditions related to access and availability appear most favorable for badge exposure. We will focus heavily on building access reports for those days to determine which days and times offer the highest likelihood for exposure and will questions employees as necessary.

Radiochemist with May Left Extremity Badge Reading of 37 rem

Background Information

The left extremity badge reading of 37 rem was highly unusual and suspect for several reasons:

- The Radiochemist's WB and right extremity badges were normal for the same month
- It would be extremely unlikely to receive a left extremity exposure of 35 rem without any significant exposure to the WB or right extremity badges
- While the Radiochemist [redacted]he PET Center working most days during May 2016, historical dosimetr[redacted]gs for months with a similar workload have always been normal. According to the Radiochemist, he did not do anything out of the ordinary during May 2016.
- The Radiochemist is unique in that he is the only one of the five PET Center employees that experienced abnormal readings that works outside of Imaging. No other PET employees working in Radiochemistry (lower level of the facility) had unusual readings.
- The Radiochemist has been employed at the Yale PET Center for [redacted]nd has a total Yale occupational exposure history of 0 mrem for his left extremity for those combined [redacted]
- The individual who the Radiochemist worked closely with for the month of May received no exposure for the same time period.
- An ALARA Investigation looking at a detailed account of the Radiochemist's work is underway, but thus far fails to find any reason for the extremely elevated extremity badge reading.

Potential Acquisition of Badges

- The Radiochemist was working at the PET Center on all regularly scheduled work days during the month of May 2016 EXCEPT Monday, 5/23/16. Thus the window of opportunity to acquire the Radiochemist's badge during the month without risking detection and maintain possession of the badge until a sufficient amount of radioactive materials were available was relatively limited.
- The Radiochemist kept his extremity badges in the pocket of his lab coat when they were not being worn. Badges were typically worn only when entering the Radiochemistry lab to work with radioactive materials. The lab coat is typically left in his locker, which is in the main hallway outside the Radiochemistry lab and is accessible to anyone with access to the lower level of the PET Center. Access to the lower level of the PET Center is restricted by ID card reader access at several different entry points, including an elevator, a stairwell, and a door from the MRI patient waiting room.
- Many PET Center employees that typically work upstairs in the Imaging suite do have access to Radiochemistry and need to go to the lower level of the facility when performing injections on animal research subjects. As such, Imaging employees would have routinely walked through the area where the Radiochemist's locker is holding his badges when not in use.
- Additionally, the PET employee responsible for distributing and collecting dosimetry badges collected the May badges and distributed June badges on 6/1/16, but then left for vacation one day later. Therefore, the May dosimetry badges were not returned to Yale Environmental Health and Safety (to be sent out for processing) until the employee returned from vacation on Monday 6/13/16. As a result, it is our understanding that the May badges

remained at the employee's desk, unattended, from Friday 6/3/16 until the employee returned on Monday 6/13/16.

- Based on the above, we believe the most likely window of opportunity to acquire the Radiochemist's badge would have been either on Monday 5/23/16 or from the bag on the desk of the PET employee responsible for distributing and collecting badges between 6/3/16 and 6/13/16). Thus, the Radiochemists left extremity badge would have been in Imaging on the upper floor of the PET Center for an extended period of time and accessible to anyone with access to that floor during that period.

Potential Exposure of Badges

- We feel that the window of time for exposure of the Radiochemist's badge is roughly the same as the window of opportunity for acquiring the badge.
- The window of opportunity for exposure of the Radiochemist's badge is significantly smaller than for the three employees described above. That said, it still spans almost two weeks and likely leaves a significant number of opportunities for exposure. We will however focus on days during this window of time where conditions related to access and availability appear most favorable for badge exposure. We will focus heavily on building access reports for those days to determine which days and times offer the highest likelihood for exposure and will question employees as necessary.

Nuclear Medicine Technologist #2 with June 2016 WB exposure of 2.6 rem

Background Information

The WB badge reading of 2.6 rem was highly unusual and suspect for several reasons:

- Left and right extremity readings, while higher than normal, were not found to be completely implausible considering what this employee normally receives on extremity badges and the work performed for the month. If the WB badge reading of 2.6 rem were a true exposure to this person, we would expect extremity readings far greater than what were observed (since NMT's work with radioactive materials using their hands while their body remains behind a shield. See picture 2)
- The NMT with the 2.6 rem WB badge reading in June 2016 was at work all work days with the exception of two and reported nothing out of the ordinary with respect to work performed. This WB badge reading is far outside the norm of historical readings for this employee.
- The NMT 2 has been employed at the Yale PET Center for [redacted] and has a total Yale occupational whole body exposure history of 1,392 mrem for those combined [redacted] through May, 2016.
- An ALARA Investigation looking at a detailed account of the NMT's work failed to find any reason for the elevated WB badge reading.

Potential Acquisition of Badges

- The NMT was working at the PET Center on all regularly scheduled work days during the month of June 2016 EXCEPT Thursday 6/9/16 and Friday 6/10/16.
- The NMT reported that she always puts on her dosimetry badges when she arrives at the PET Center to start the day. When she leaves for the day, badges are left in a paperclip holder on a desk in room 206 on the Imaging floor (the same room where the PET employee who is responsible for distributing badges sits).
- The NMT does not recall the badges being out of place after returning to work on Monday 6/13/16. Badges were worn for the rest of the month with nothing unusual noted.

- Based on the above, we feel strongly that the window of opportunity to acquire this NMT's badges for an extended period of time was likely limited to Thursday 6/9/16 and Friday 6/10/16. Acquisition of this badge would have been relatively easy to accomplish since it was maintained in a common area and other PET employees would have been aware that the NMT was scheduled off on both days.

Potential Exposure of Badges

- We believe that the window of opportunity for exposure of the NMT's badge is roughly the same as the window of opportunity for acquiring the badge, specifically 6/9 – 6/10/16.
- We believe that the window of time for the NMT's June 2016 badge to be exposed is significantly smaller than that for any of the other four individuals with unusually high readings. It appears that opportunities to expose the badge during this period were limited, but the results of our analysis described above support that this exposure could have easily been accomplished in a short period of time with materials that were readily available during these limited opportunities. We are focusing intently on events during these two days where conditions related to access and availability appear most favorable for badge exposure. We are focusing heavily on building access reports for those days to determine which days and times offer the highest likelihood for exposure and will questions employees as necessary.

While we cannot conclusively determine exactly how and when the badges were exposed and by whom at this point in our ongoing investigation, we feel we have made significant progress and our results to date support our assertion that the abnormal readings were the result of tampering rather than a real dose of radiation to a person or persons. At this point, based on evidence examined, it seems most likely that the badges were exposed in Imaging on the upper level of the PET Center. However, we are not discounting the possibility that one or more exposures could have happened downstairs in Radiochemistry and will thus continue to review evidence of activities in Radiochemistry on the dates of interest. We are closely examining access records to determine who was available on all dates of interest during the windows of possibility described above. We believe at this point that, while we are not ruling out the possibility of collusion amongst two or more employees, the unusually high badge readings noted could have been the result of the actions of one person purposefully exposing badges.

Picture 1

Picture 2

Appendix D: Investigatory Team Credentials

Michael Pearson Bio

Mike joined the Yale University Internal Audit department in January of 1998 and has held various roles within the department for the past 18 years. He currently holds the position of Associate Director, and has a team of four employees reporting directly to him. Mike is responsible for oversight of all special projects and investigations that require Audit involvement. In this capacity, Mike works closely with Yale's Department of Human Resources, Office of the General Counsel, Office of Research Administration, and other central University departments to ensure compliance with policies, procedures, laws, and regulations. During the past 18 years, Mike has conducted and led more than 100 internal investigations, conducted hundreds of investigatory interviews, and has been successful in resolving many complex cases. Many investigations have required extensive data analysis and other forensic accounting techniques in order to develop fact based conclusions. When investigations reveal significant control weaknesses, Mike and his team will identify potential improvements aimed at addressing the root cause of the issue that allowed the fraudulent activity to take place, with the goal of preventing future recurrence. In addition to delivering results to senior management at Yale, Mike has presented cases for consideration by both local and federal law enforcement. Mike also has a great deal of experience in advising University officials on many different types of regulatory compliance issues as part of his special projects work in University Auditing. Mike holds professional certifications as a Certified Fraud Examiner, Certified Internal Auditor, and Certified Information Systems Auditor.

Alexandra (Ali) D'Amico Bio

Ali joined Yale University in October 2012 as a Human Resources Generalist supporting a number of client groups including Police, Security, Graduate Housing, Yale Printing & Publishing, Campus Mail, Traffic, Receiving & Storage and Human Resources. Since June 2015, Ali has held the position of Assistant Director of Employee Relations for Yale School of Medicine where she manages five HR Generalists covering various Medical School departments. Ali's role in HR is multi-faceted and covers a wide range of HR related functions, including Employee Relations, Labor Relations, Compensation, Recruiting and Organizational Effectiveness. A key responsibility within Employee Relations is to conduct investigations regarding various issues, including employee misconduct, attendance and performance. As appropriate, Ali will collaborate with internal partners including the Office of General Counsel, Internal Auditing, the Office for Equal Opportunity Programs and other University departments. Prior to joining Yale, Ali spent 6 years at J.P. Morgan's Investment Bank in New York City. Her prior role as Human Resource Business Partner included extensive experience conducting internal investigations concerning employee misconduct. A number of investigations while at J.P. Morgan were complex in nature involving senior level employees and spanning multiple countries. Ali has attended training on conducting investigations over her career and most recently attended an all-day session at Yale in early 2016.

Tammy Stemen Bio

Tammy is a Certified Health Physicist and has worked in the Yale University Health Physics program in various capacities for over 25 years. Her resume follows.

Tammy J. Stemen, CHP

CERTIFICATIONS

American Board of Health Physics
Comprehensive Certification in Health Physics — Awarded November 1998, Recertified thru January 2020

RADIATION SAFETY WORK EXPERIENCE

Yale University - Environmental Health and Safety (EHS) — New Haven, Connecticut
Radiation Safety Officer — September, 2008 to Present

As the Radiation Safety Officer for a large and complex university with a robust research program including a world renowned medical school, I am responsible for the management of an extensive and varied health physics program. Yale has over 600 labs in which over 2,000 trained users handle approximately 5 Curies of radioactive material each year. Over 4,500 Curies of short lived isotopes are also generated and used in Yale's Positron Emission Tomography (PET) center where state of the art animal and human subject research is conducted. In an effort to maintain 3 Nuclear Regulatory Commission (NRC) licenses (Type A Broadscope, specific Medical Use, and Cyclotron Production), multiple State of Connecticut Department of Energy and Environmental Protection (DEEP) registrations for over 50 x-ray units and 50 sealed sources requiring leak tests, and the GE PETtrace cyclotron at the PET center, I:

- Provide direct management of Yale University's radiation safety program and maintain university wide compliance with all NRC licenses and State registrations.
- Ensure adequate staffing of radiation safety programs, sufficient facilities and resources, and provide for appropriate training of EHS radiation safety staff.
- Lead a comprehensive radiation safety program through planning and supervision of radiological surveys, leak testing of sealed sources, surveys of x-ray machines and other radiation producing devices, consultation with authorized users and pregnant workers, training, meter calibration, emissions monitoring, facility security and the implementation of security procedures.
- Work directly with the State of Connecticut DEEP and NRC staff in maintaining licenses, reporting of incidents and events, license submissions, renewals, amendments and registrations.
- Serve as the University's technical expert on radiation related issues.
- Document compliance and ensure maintenance of required records associated with licenses and radiation safety programs.
- Worked closely with the Yale PET Research Center Director and staff and our PET Health Physicist, to develop, implement and oversee NRC compliant radiation safety policies and procedures at this facility following the NRC's expansion of the definition of byproduct material.
- Serve on the Yale University Radiation Safety Committee (RSC) and coordinate meetings, including development of agendas, drafting of minutes and coordination of all follow-up needs.
- Serve on the Yale University Radioactive Drug Research Committee (RDRC).
- Maintain strong programs to ensure the security of radioactive materials. Serve as a Reviewing Official for Yale's Cesium irradiator increased controls program.
- Provide oversight to internal and external dosimetry programs and implementation and maintenance of Yale University's ALARA program. Calculate, review and sign off on dosimetry results. Conduct hazard evaluations and ALARA investigations aimed at effectively reducing and/or preventing whole body, skin and extremity doses.
- Conduct audits of the radiation safety program and provide annual reports to the RSC. Institute improvements and corrective actions as necessary.
- Serve on the Yale-New Haven Hospital Radiation Safety Committee and act as a liaison between the separate university and hospital radiation safety programs.
- Serve on Yale's Human Research Protection Program Steering Committee.
- Ensure all radiation safety training programs are of high quality, are conducted by knowledgeable staff, are effective and reach all intended audiences.

- Oversee the management of the radioactive waste disposal program including decay-in-storage.
- Evaluate federal, state, and local regulations. Plan and implement radiation safety compliance programs to meet University needs and expectations of the NRC and other regulatory agencies.
- Coordinate new x-ray unit installations and registrations, determine structural shielding requirements, confirm adequate shielding installations and develop safe use protocols for equipment.
- Directly supervise five professional staff members including the Laser Safety Officer, and oversee the radiation safety work products of an additional twenty EHS staff members.
- Serve as a primary member of the EHS 24-Hour Emergency Response team. I have responded too and resolved numerous emergency/incident type situations involving radioactive materials.

Yale University - Office of Environmental Health and Safety (OEHS) — New Haven, Connecticut
Assistant Radiation Safety Officer — November 1998 to September 2008

- Reporting directly to the Radiation Safety Officer, provided direct program management of Yale's radiation safety Training, Radioisotope Use Authorization, Hazard Evaluation and Radioisotope Purchasing programs.
- Worked closely with the RSO, Yale PET Research Center Director and staff and our PET Health Physicist, to develop, implement and manage the University's PET Research Center's radiation safety program, policies and procedures in preparation for the NRC's new regulatory requirements regarding its expanded definition of byproduct material.
- Conducted numerous and varied radiation safety seminars to all levels of administrative, scientific, technical, professional, ancillary and non-technical personnel within the university.
- Calculated and reviewed dosimetry results and conducted hazard evaluations/ALARA investigations aimed at effectively reducing/preventing whole body, skin and extremity doses.
- Served on the Yale-New Haven Hospital Radiation Safety Committee and acted as a liaison between the university and hospital radiation safety programs.
- Worked directly with Connecticut DEP and federal NRC inspectors during visits, audits, inspections, reports of incidents, license submissions and registrations.
- Participated in Radiation Safety Committee meetings and coordinated all follow-up responsibilities.
- Worked closely with the Environmental Affairs Section of OEHS to improve communications between OEHS and laboratory staff on radioactive waste handling protocols and minimization of radioactive wastes.
- Provided operational oversight of the daily radioactive package receipt and delivery program.
- Coordinated new x-ray unit installations and registrations, and developed associated safe use protocols.
- Acted as a primary liaison with the Yale Animal Resources Center (YARC) for all issues pertaining to use of radioactive materials in animals
- Served as a primary member of the OEHS 24-Hour Emergency Response team. Responded to and resolved numerous emergency situations involving incidents with radioactive materials.
- Provided training and guidance to EHS Safety Advisors with respect to instrument selection and calibration, laboratory contamination surveys, bioassays, emergency response, decontamination techniques, authorization renewals, and various other radiation safety issues.
- Assisted with the development of the Guilford Nuclear Cardiology Clinic and Yale PET Research Center radiation safety programs. Served as a primary health physics contact for these specialized groups.

Yale University - Office of University Safety — New Haven, Connecticut
Senior Health Physicist — March 1990 to November 1998

- Supervised the Training, Hazard Evaluation, Radioisotope Use Authorization and Isotope Purchasing programs. Direct reports included one Health Physicist and two Administrative Assistants.
- Developed a variety of educational programs designed to instruct scientific personnel in the proper handling of radioactive materials.
- Conducted numerous and varied radiation safety seminars to all levels of administrative, scientific, technical, professional, ancillary and non-technical personnel within the university.
- Restructured and administered the Radioisotope Use Authorization Program. Included reviews, interviews, inspections and formal reports to the Radiation Safety Committee.

- Worked directly with principal research investigators to construct and maintain safe radioactive material use facilities within research laboratories.
- Supervised and monitored various experiments conducted by laboratory personnel involving the use of radioisotopes to evaluate, ensure and improve the safety of these experiments.
- Served as a member of the Radiation Safety Subcommittee to review and approve investigator use of radioisotopes.
- Presented status reports and made recommendations to the University Radiation Safety Committee on current health physics issues.
- Performed dose calculations to assist in properly evaluating and analyzing personnel exposures to radiation.
- Responded to and resolved numerous emergency situations involving accidents with radioactive materials.
- Developed and maintained a program to effectively deal with the special concerns of pregnant women working in radioactive material use laboratories.
- Provided training and guidance to department health physics technicians with respect to instrument selection and calibration, laboratory contamination surveys, bioassays, emergency response, decontamination techniques, and various other radiation safety issues.

Hybritech Incorporated — San Diego, California
Health Physicist/Assistant to Radiation Safety Officer — August 1987 to February 1990

As the principal Health Physicist for a multi-facility biotechnology company where curies of Yttrium-90 and Indium-111 were used on a weekly basis, I was responsible for the daily operation of an extensive and varied health physics program. In an effort to maintain a State of California Broadscope license, I:

- Administered the Hybritech dosimetry and ALARA programs and investigated and analyzed employee exposures which exceeded ALARA limits.
- Trained all employees in appropriate radiation safety practices and procedures. This instruction program included the training and testing of all new employees, authorized users of radioactive materials, annual retraining of all users, and specialized instruction to high level users.
- Performed audits of Radioactive Material Use Authorizations to ensure compliance with written procedures and license requirements.
- Served as a member of the Radiation Safety Committee. Presented status reports to the committee on current issues and provided health physics recommendations.
- Monitored the safe operation of a production iodination facility, including significant air sampling and thyroid bioassay programs.
- Directed work activities and approved completed assignments of health physics technicians and student health and safety interns.
- Reviewed laboratory contamination surveys and providing any necessary follow-up.
- Managed the radioactive waste decay and disposal program.
- Participated as a member of the Hybritech Emergency Response Team.

Purdue University - Radiological Control Office — West Lafayette, Indiana
Health Physics Intern — August 1986 to December 1986

Gained applied work experience as a health physics assistant by being involved in all areas of the university's radiation safety program.

- Conducted radiation safety surveys.
- Participated in collection and disposal of radioactive wastes.
- Performed instrument calibrations.
- Monitored incoming shipments of radioisotopes.
- Collected and analyzed bioassay data.
- Assisted in health physics oversight activities at the university's research reactor.

TMA Eberline Albuquerque, New Mexico
Health Physics Technician June 1986 to August 1986

- Prepared a radiological environmental assessment of an inactive uranium reprocessing mill.
- Performed numerous calculations pertaining to the assessment.
- Gained insight into government regulations and procedures.

EDUCATION

Purdue University — West Lafayette, Indiana
Bachelor of Science in Environmental Health — May 1987
Major: Health Physics

SPECIAL RADIATION SAFETY TRAINING

- **Radiation Shielding for Medical Facilities** — January 2012
  American Academy of Health Physics
- **Medical Radiation Safety Officer Training** — August 2009
  Oak Ridge Associated Universities
- **Cyclotron/PET Safety Training** — February 2006
  GE Medical Systems
- **Basics of Lasers and Optics** — October 2002
  Rockwell Laser Industries
- **Advanced Radiation Safety Officer** — March 2001
  CSI - Radiation Safety Academy
- **Applied Health Physics**, five week intensive HP course — April 1996
  Oak Ridge Associated Universities
- **Operation of Mark I-68A Shepherd Irradiator** — September 1991
  J.L. Shepherd and Associates
- **Safe Use of Radionuclides** — December 1990
  Oak Ridge Associated Universities

Non-Agreement State	Event Number: 52060
Rep Org: YALE UNIVERSITY Licensee: YALE UNIVERSITY Region: 1 City: NEW HAVEN State: CT County: License #: 06-00183-03 Agreement: N Docket: NRC Notified By: TAMMY STEMEM HQ OPS Officer: JEFF HERRERA	Notification Date: 07/01/2016 Notification Time: 09:36 [ET] Event Date: 06/30/2016 Event Time: 19:30 [EDT] Last Update Date: 07/01/2016
Emergency Class: NON EMERGENCY 10 CFR Section: 20.2202(a)(1) - PERS OVEREXPOSURE/TEDE >= 25 REM	Person (Organization): HAROLD GRAY (R1DO) NMSS_EVENTS_NOTIFIC (EMAI) PAMELA HENDERSON () NMSS INES COORDINATO ()

Event Text

WHOLE BODY BADGE EXPOSURE READING OF 31 REM

The following report is a summary of information provided via email:

"We [Yale University] received notification from our dosimetry vendor (Mirion Dosimetry) of the following unusually high results on three dosimeters for individuals who all work at our PET [Positron Emission Tomography] Research Center, for the month of May:

"Nuclear Medicine Technologist - Whole Body Badge - 31 Rem; Contract Nurse - L Extremity Dosimeter - 35 Rem; Radiochemist - L Extremity - 37 Rem

"The Nuclear Medicine Technologist (NMT) was only at work for six days in May. She only handled radioactive material 4 of those 6 days. She used routine NMT amounts (milliCuries) of C-11 on those 4 days and reports nothing unusual about her work those days. She wears extremity monitors as well and although I [Yale University Radiation Safety Officer (RSO)] don't have the official report from Mirion on these rings, the raw data I have indicates 50 to 85 mRem on her rings. These readings would be considered typical for her work. She is currently on medical leave and has not been at work since May 10th. She does not believe the reading to her whole body badge can be accurate. She does not recall anything unusual for the time period in question.

"The Contract Nurse only worked three days in May. Her other ring badge and her whole body badge recorded no exposures. She does not recall anything unusual for the time period in question and questions the validity of the result.

"The Radiochemist worked his typical schedule in May and handled radioactive materials as part of his work most days. He recalls nothing unusual. His other ring badge and his whole body badge recorded no exposures.

"We [Yale University] immediately collected all [the] PET Research Center staff June monthly badges and have sent in these three individual's badges (and several others) for emergency reads and the remaining for quick reads. [The RSO] expects to get the emergency results today and the remainder early next week. We [Yale University] also reviewed

dosimetry of others in the facility, reviewed surveys conducted in May in the facility and conducted a radiation survey at the facility yesterday and find nothing unusual or out of the ordinary.

"We [Yale University] are in contact with several dosimetry experts at Mirion Dosimetry and they are assisting in our investigation. [The RSO] has asked for several pieces of information in writing as related to their processing of the badges including:

"Verification that the results of the three high readings have been scrutinized and reanalyzed for validity and accuracy.
"A description of the type of radiation believed to have caused the exposure on the whole body badge and the energy range of this radiation.
"Can any information about the orientation of the whole body badge when exposed be determined? Was it exposed upside down or backwards, for instance? If you can make any judgments about this please indicate in report.
"Review and confirmation that the TLD chips from each of the dosimeters in question were tracked correctly and are indeed from the badge and rings from the individuals reported.
"Verification that nothing unusual happened with the badges once received by Mirion. Please include the dates the badges were received by Mirion and track them each through processing. I'd like to know when each of the TLD's were analyzed at your facility and if they were analyzed on the same readers and such.

"[The RSO doesn't] believe that any of the three readings reflect actual doses to people. Nonetheless, We [Yale University] are taking the situation very seriously and are expending significant time and effort to try to determine the cause in a timely manner. Our RSC [Radiation Safety Committee] is aware of the situation as is senior Yale leadership."