



DIVISION OF PUBLIC HEALTH

Jim Doyle
Governor

1 WEST WILSON STREET
P O BOX 2659
MADISON WI 53701-2659

Helene Nelson
Secretary

State of Wisconsin
Department of Health and Family Services

608-266-1251
FAX: 608-267-2832
dhfs.wisconsin.gov

September 17, 2004

U.S. NRC Region III
Attn: Jim Lynch
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-3025

Dear Mr. Lynch:

Please find attached a copy of the following documents for an event that occurred at the University of Wisconsin Madison on Friday, September 3, 2004:

- Reactive Narrative Inspection Report
- University of Wisconsin's Thirty-day report
- Non-compliance letter issued by DHFS to the licensee
- Initial NRC Operations Report and the
- NMED report (WI040017) for this incident

If I can answer any questions please feel free to contact me at (608) 266-9443 or huntjh@dhfs.state.wi.us.

Sincerely,

A handwritten signature in black ink that reads "Jason H Hunt".

Jason H Hunt
Nuclear Engineer – Senior
Radioactive Materials Program

Enc.

**Wisconsin Department of Health and Family Services
Radiation Protection Section
Inspection Report**



Reactive Narrative Inspection Report

| | |
|---|--|
| License Number: 25-1323-01 | Inspection Date: 09/03/04 |
| Licensee (name and address): University of Wisconsin - Madison 30 North Murray Street Madison, WI 53715 | Inspection Site Address (authorized use or storage): University of Wisconsin Calibration Lab |
| Licensee Contact: Ron Bresell | Contact Telephone No.: (608) 262-9178 |
| Date of Last Inspection: <i>OKR</i> 7/23/04 Next Insp. Date: <i>OKR</i> 7/01/2005 | Type of Inspection: <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Unannounced <input type="checkbox"/> Initial <input type="checkbox"/> Routine <input checked="" type="checkbox"/> Other: Reactive |
| Lead Inspector: (Sign Name) <u><i>Jason H Hunt</i></u> (Print Name) <u>Jason H Hunt</u> | Date <u>SEPT. 15, 2004</u> |
| Inspector: (Sign Name) <u><i>Leola DeKock</i></u> (Print Name) <u>Leola DeKock</u> | Date <u>9-15-04</u> |
| Reviewed By: (Sign Name) <u><i>Cheryl K Rogers</i></u> (Print Name) <u>Cheryl K Rogers</u> | Date <u>9-15-04</u> |

Description of Incident

On Friday, September 3, 2004, ~1:30 p.m., Paul Schmidt was notified by Ron Bresell, UW-Madison RSO, that the University of Wisconsin – Madison had inadvertently left an Ir-192 brachytherapy seed in a reentrant well chamber that was shipped to the University of Arizona Medical Center, Tucson, AZ, upon calibration. The University of Arizona Medical Center had notified the University of Wisconsin Calibration Lab on Friday, September 3, 2004 at ~ 1:00 p.m that they had found the Ir-192 seed.

Mr. Bresell had initially calculated an estimated dose from unshielded 0.4 mCi Ir-192 source at about 0.192 mR/hr @ 1 meter. Dan Silvain, RSO for the University of Arizona – Medical Center calculated the maximum dose rate from the package at 1.9 mR/hr. However the source was shielded inside the carrying case for the well chamber.

Scope of Inspection

On Friday, September 3, 2004, ~ 1:40 p.m. Leola DeKock and Jason Hunt of the Department of Health and Family Services Radiation Protection Section were dispatched to the University of Wisconsin – Madison.

Mr. Cleven had performed the calibration of the well chamber in question and was interviewed concerning the incident.

The two inspectors visited the calibration room, where the well chamber was calibrated. Sealed sources used for calibrations are stored in a locked lead lined safe.

Individuals Contacted During the Investigation

Paul Cleven, Physicist
John Micka, Associate Director of the Radiation Calibration Lab
Dr. Larry DeWerd, Director of the Calibration Lab
Ron Bresell, Radiation Safety Officer

Inspection Findings

Mr. Cleven stated that when sources are used, one source at a time is removed from the safe.

Mr. Cleven explained how this type of well chamber is calibrated. Part of the calibration includes loading calibration sources into different type of source holders. The Well Counter calibrated in this incident was a Standard Imaging 1000+ Well Counter, that utilizes 3 source holders: (1) Loop Holder; (2) High Dose Ir-192 Holder; and (3) Low Dose Single Seed Holder. The Loop Holder is the only one calibrated with the Ir-192 sealed source shipped to Arizona.

The Ir-192 brachytherapy calibration seed is ~.3 mm in diameter and ~3 mm long. The Ir-192 brachytherapy calibration seed is mounted on a ~2 inch plastic tube/stick that has a ribbon attached to the opposite end.

Mr. Cleven stated that after well chambers are calibrated they are placed in wooden carrying cases. The carrying case has room for the well chamber with a source holder inside and two additional storage ports for two remaining source holders.

The Calibration Lab did not know if the well chamber had been shipped with the Loop Holder (Ir-192 source inside) inside or if the holder was in one of the two storage ports. This is in violation of HFS 157.28(1), which requires a licensee to secure licensed radioactive material from unauthorized removal or access.

Mr. Cleven physically took the well chamber to the shipping and receiving department (which is located inside the Calibration Lab Department) and he prepared the well chamber for shipment back to Arizona. The shipment of the well counter took place on Monday, August 30, 2004 as a non-radioactive shipment. This is in violation of HFS 157.92(3), which requires a licensee to ship radioactive material in accordance with 49 CFR.

Mr. Cleven believed that he may have been interrupted while performing the calibration (specifically the Loop Holder part of the calibration) which made him forget about the Ir-192 seed inside the holder.

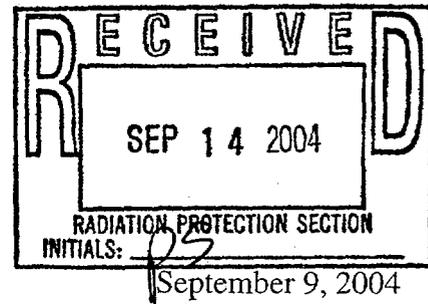
Mr. Bresell stated that the University of Wisconsin – Madison would comply their 30 day report required by Chapter HFS 157 ‘Radiation Protection’ and it would be submitted with-in the 30 day time limit.

Items of Non-Compliance

1. Contrary to HFS 157.28(1) the licensee failed to maintain security and control of licensed radioactive material.
2. Contrary to HFS 157.92(3) the licensee failed to comply with 49 CFR when shipping radioactive material.

Attachments

1. University of Wisconsin- Madison 30 thirty-day report dated Sept. 9, 2004 and signed by Ron Bresell.
2. NRC Operations Center Notification.



Radiation Protection Section
Attn: Radioactive Materials Program
P.O. Box 2659
Madison, WI 53701-2659

Re: Report of Loss-of-Control Incident (Ir-192 seed) for License # 25-1323-01

Attached is the Calibration Lab's report of the Iridium-seed incident and proposed corrective action. We discussed the incident with Calibration Lab personnel on Tuesday (7 Sept) afternoon and their proposed corrective action.

When we looked at this incident we asked, "Are there things which could have been done to have prevented this incident?" To our mind there were two areas where the error could have been caught: (1) in the room where calibrations are performed and (2) in the (non-radioactive) shipping and receiving area.

- 1. Calibration room** -- All calibration sources used are kept in shielded containers in a specially designed safe. Normally, there is only a single seed per shielded holder / drawer. There is only a few sources of various energies (e.g., Pd-103; I-125; Ir-192) used in calibrating well chambers. Sources used in well chamber calibration are removed from the safe, used to calibrate the instrument, and placed back in the safe. Only 1 source is used at a time because additional radiation from another source would invalidate the calibration. Another use of these seeds is by graduate students in research projects. In this instance, students "sign-out" the seed and remove it to a different location for their project and return the seed to the Calibration Lab personnel on completion. Because of these usage procedures, we suggested to the calibration lab that they have a visible, easy to use device to inform them (1) whether a source was "in" or "out" of the safe and (2) if out of the room, who and where the source was located.

Thus, we envisioned an "in / out" comment board, perhaps using magnetic markers (preferred) or a white board using erasable marking pens. A source is removed, the button moved from "in" to "out" and vice versa when the source is replaced. If the source is semi-permanently removed, the location and point-of-contact would also be written. When a source was permanently removed from the safe for further decay and ultimate disposal, the computer inventory would be annotated and the "in / out" board entry for that source would be erased. By having a visible source location device, when checking the room at the close of day, the person would only need view the board to assess source status.

Safety Department

a unit of Facilities Planning and Management

University of Wisconsin—Madison
608-262-8769

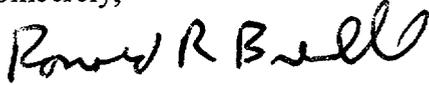
30 North Murray Street
<http://www.fpm.wisc.edu/safety>

Madison Wisconsin 53715—1227
FAX 608/262-6767

2. **Shipping room** -- This room is not used for shipping / receiving of radioactive material. Thus, we proposed a passive, sensitive monitor be emplaced near the door. Sources in containers would trigger the monitor's alarm. We use similar systems at our hospital's loading dock and laundry area to catch sources and other wastes containing radioactive material. While shipping room personnel are not radiation workers, the goal of this device would be to assure them that radioactive material is not entering their area and that their exposures are being maintained ALARA.

If you have any questions about this letter, please call (262-9178) or eMail me.

Sincerely,



Ronald R. Bresell
Associate Director
UW Safety Department
rbresell@fpm.wisc.edu



UNIVERSITY OF WISCONSIN



ACCREDITED DOSIMETRY CALIBRATION LABORATORY

1300 University Avenue, Room 1530, Madison, Wisconsin 53706-1532

Phone: (608) 262-6320 Fax: (608) 262-5012

Ronald Bresell
Radiation Safety Officer
University of Wisconsin
30 North Murray St.
Madison, WI 53717

Mr. Bresell,

Per our telephone conversation of September 3, 2004, I have provided the following information. On August 30, 2004 a reentrant well chamber that was at the University of Wisconsin Radiation Calibration Lab for calibration, report number LDR2519, was returned to the University of Arizona Medical Center, to the attention of Thomas C. Cetas, PhD. In this shipment an Iridium-192 sealed source was inadvertently left in one of the source holders and put in the case with the chamber. This source had a decayed activity of 0.369 mCi on the shipment date of August 30, 2004 12:00 noon CST. On September 3, 2004 Dr. Cetas contacted John Micka, Associate Director of the Radiation Calibration Lab, noting the erroneous shipment. Dr. Cetas also contacted Dan Silvian, Manager of Medical Health Physics for the University of Arizona, Tucson and reported the incident. John Micka reported the incident to Dr. Larry DeWerd, Director of the Calibration Lab who then along with John Micka informed me of the error. I then contacted you who then contacted the State of Wisconsin Department of Health and Family Services (DHFS). The State of Wisconsin radiation protection division immediately sent Jason Hunt, senior nuclear engineer, to our lab. Mr. Hunt compiled a history and practice initial report.

My memory of the events leading to the loss of control is not crystal clear. Apparently I removed the Ir-192 source from the source drawer and inserted it into the loop holder. The loop holder was placed into the well chamber and data was taken to ascertain a calibration factor. I then removed the holder from the chamber and placed the holder with the source still in it into the well chamber case. This source is normally stored in a lead drawer in a locked safe in the ADCL brachytherapy room B486A. It is my normal practice to leave the drawer open when I have removed a source. This is a reminder that

the source is in service. I must have then closed the drawer without checking to be sure the Ir-192 source was replaced in the drawer. Also a new source was received from the manufacturer on August 27, 2004. This new source was calibrated by me and placed in the drawer/safe on August 30, 2004. I do not remember noting that there wasn't a source in the drawer that was to be replaced (the source in question). If I had followed procedure I would have noted that the source wasn't in the drawer and made every attempt to locate the source. This could have prevented the shipment to Arizona as I could have intercepted the shipment and removed the radioactive material before the chamber left the Calibration Lab.

This source was originally sent to the Calibration lab on March 8, 2004. The manufacturer performed a wipe test on the stated date. I also wipe tested the source upon our calibration on March 10, 2004. Our Calibration report number is EQS0408.

Dan Silvain contacted me with preliminary results of dose level calculations at the shipping package surface. The maximum dose rate was 1.9mR/hr. The package should have been labeled as a white I radioactive material.

To eliminate this type of problem in the future the calibration lab will implement the following procedures.

1. An appropriate area monitor will be installed in the shipping and handling area to monitor radiation levels in the room.
2. The inventory system will be modified to note source location within the calibration laboratory area
3. All use of radioactive material will have a real time physical, visual process (In/Out board), to allow monitoring of source use when sources are not in their documented control storage area.
4. Time will be mandated to check and update radioactive material inventory on a monthly basis.
5. Procedures will be implemented that if a source is not found in its designated location the physics staff of the calibration lab will cease all other functions till the source is found and returned to its designated location.

Per the request of Dan Silvain, Manager of Medical Health Physics, University of Arizona I am requesting that you contact the State of Wisconsin, DHFS, radiation protection division, and have them send report of this incident to the State of Arizona so as to complete the communication loop.

I apologize for any difficulties I have caused and thank you for your help. If you have any other questions or informational need please do not hesitate to contact me.

Sincerely,

Paul Cleven
Staff Physicist, RSO
University of Wisconsin ADCL
pdcleven@wisc.edu 608/265-9748

CC: Larry A. DeWerd Ph. D.
John A. Micka
Steve Bazan



DIVISION OF PUBLIC HEALTH

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MADISON WI 53701-2659

Helene Nelson
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State of Wisconsin
Department of Health and Family Services

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DATE: September 3, 2004
TO: NRC Operations Center FAX: (301) 816-5151
FROM: Wisconsin Radiation Protection Section
Contact Person: Jason Hunt (608) 266-9443

On Friday, September 3, 2004 at approximately 1:30 p.m., the Wisconsin Radiation Protection Section (RPS) received a telephone call from the University of Wisconsin - Madison (license number 25-1323-01) informing the section of a lost Ir-192 source that had been inadvertently shipped to the University of Arizona Medical Center, Tucson, AZ. [HFS 157.32 (1) (a)]

Preliminary Information From the Licensee

On Monday, August 30, 2004, the University of Wisconsin - Madison calibration lab had completed calibration of a Standard Imaging, Model 1000+ reentrant well chamber (ion chamber used to determine brachytherapy seed dose) and shipped it back to the chamber owner, the University of Arizona Medical Center. Shortly after arrival, the U.A. Medical Center discovered that the chamber contained a 0.4 mCi Iridium-192 brachytherapy seed that had been used during calibration. The U.A. Medical Center subsequently notified the U.W. Madison of the incident on Friday, September 3, 2004.

The licensee estimates that the dose rate from an unshielded 0.4 mCi Ir-192 seed source would be approximately 0.192 mR/hr at 1 meter. The licensee believes that the chamber shielded the source so the dose rate on the surface of the shipping container was negligible.

We are reporting this event under:

Loss of control of radioactive material

DHFS, RPS staff have been dispatched on Friday, September 3, 2004 to investigate.



DIVISION OF PUBLIC HEALTH

Jim Doyle
Governor

Helene Nelson
Secretary

State of Wisconsin

Department of Health and Family Services

1 WEST WILSON STREET
P O BOX 2659
MADISON WI 53701-2659

Phone 608-267-4797
FAX: 608-267-3695
www.dhfs.state.wi.us

September 15, 2004

University of Wisconsin - Madison
Attn: Ronald R. Bresell, RSO
30 North Murray Street
Madison, WI 53715

COPY

Dear Mr. Bresell:

This refers to the reactive inspection conducted by Leola DeKock and myself of this office on September 3, 2004 and to the discussion of our findings with Ron Bresell on September 15, 2004.

This inspection was an examination of the activities leading up to the loss of control of an Ir-192 seed used under your WI Radioactive Material License number 25-1323-01. In addition a selective examination of procedures and representative records, observations and interviews with personnel as they relate to radiation safety and to compliance with Wisconsin Administrative Code, Chapter HFS 157 'Radiation Protection' were made.

Based on the results of this reactive inspection, certain of your activities were not conducted in full compliance as set forth in the enclosed Notice of Noncompliance.

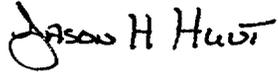
Submit a written statement or explanation in reply including:

- (1) Corrective actions that have been taken by you and the results achieved.
- (2) Corrective actions which will be taken to avoid further items of noncompliance.
- (3) The date when full compliance will be achieved. This report shall be received by this office before October 15, 2004.

This is to advise you that you are required to post the enclosed notice of non compliance of radiological working conditions and your response to DHFS [HFS 157.88(1)(c)].

If you have any questions or concerns regarding this inspection, please contact me at (608) 266-9443 or e-mail at huntjh@dhfs.state.wi.us.

Sincerely,

A handwritten signature in black ink that reads "Jason H Hunt". The signature is written in a cursive style with a large initial "J".

Jason H Hunt
Nuclear Engineer - Senior
Radioactive Materials Program

BPH/

Encl.



Jim Doyle
Governor

Helene Nelson
Secretary

State of Wisconsin
Department of Health and Family Services

DIVISION OF PUBLIC HEALTH

1 WEST WILSON STREET
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NOTICE OF NON COMPLIANCE
University of Wisconsin - Madison
Radioactive Material License Number 25-1323-01

Based on the results of the Wisconsin Department of Health & Family Services, Radiation Protection Section inspection of the University of Wisconsin - Madison, 25-1323-01 conducted on September 3, 2004, certain of your activities are not in compliance with Wisconsin Administrative Code, Chapter HFS 157 'Radiation Protection' as indicated below:

1. Contrary to HFS 157.28(1) the licensee failed to maintain security and control of licensed radioactive material.

This is considered a Severity Level III violation.

2. Contrary to HFS 157.92(3) the licensee failed to comply with 49 CFR when shipping radioactive material.

This is considered a Severity Level III violation.

Full Report

09/17/2004

Item Number: WI040017

Last Updated: 09/17/2004

Event Type: TRS - TRANSPORTATION

Event Cause: IMPROPERLY LABELED PACKAGING

Event Date: 09/03/2004

Report Date: 09/03/2004

Licensee/Reporting Party Information:

Name: UW-MADISON

License Number: 25-1323-01

City: MADISON

State: WI

Zip Code: 53715-

Other Information:

| | | | |
|-----------------------------|---|--------------------------|------|
| Reportable Event: | N | Reciprocity: | NONE |
| Atomic Energy Act Material: | N | Abnormal Occurrence: | N |
| Investigation: | Y | Send this Report to NRC: | Y |
| Consultant Hired: | N | Event Closed by State: | Y |

Narrative:

On September 3, 2004 the University of Wisconsin - Madison notified the Wisconsin Department of Health and Family Services (DHFS) that the UW-Madison had inadvertently left an Ir-192 brachytherapy seed in well chamber that was shipped to the University of Arizona Medical Center, Tucson. The University of Arizona Medical Center notified the UW-Madison Calibration Lab on Friday, September 3, 2004. Two DHFS inspectors were dispatched to UW-Madison.

Upon arriving at the UW-Madison Calibration Lab the DHFS inspectors met with University officials and the physicist that performed the calibration of the well chamber. Well chambers are calibrated in a dedicated calibration room. The physicist stated with this particular type of calibration individual sources are loaded into different source holders that are included with the well chamber. In the Standard Imaging 1000+ Well Counter, there are three source holders: (1) Loop Holder; (2) High Dose Ir-192 Holder; and (3) Low Dose Single Seed Holder. The Ir-192 seed is only the source used in the Loop Holder calibration. The physicist stated his policy was to removed one source at a time from the source safe when performing calibrations. The physicist stated that sometime during the calibration he may have been interrupted while performing the calibration, which lead him to forget about the Ir-192 seed inside the holder.

After completing the calibration the physicist transported the well chamber and source holders inside a transport case to the shipping room where he shipped (Monday, August 30, 2004) the well chamber.

The UW-Madison Calibration Lab is currently in the process of installing an in/out board in the calibration room and passive monitors at the entrance to the shipping room.

Corrective Actions:

| | |
|----------------|--|
| Action Number: | Corrective Action: |
| 1 | NEW EQUIPMENT OBTAINED |
| 2 | PERSONNEL RECEIVED ADDITIONAL TRAINING |

Keywords:

IMPROPERLY PACKAGED MATERIAL
MATERIAL LOST AND FOUND

Source of Radiation:

Source Number: 1

Form of Radioactive Material: SEALED SOURCE

Radionuclide or Voltage (kVp/MeV): IR-192

Source Use: BRACHYTHERAPY

Activity: .000369 Ci 0.013653 GBq

Manufacturer:

Model Number:

Serial Number:

Device/Associated Equipment:

Device Number: 1

Device Name: N/A

Model Number: SINGLE SEED CAL.

Manufacturer: BEST MEDICAL

Serial Number:

References:

| Reference Number: | Entry Date: | Coder Initials: | Reference Type: |
|-------------------|-------------|-----------------|--------------------------------|
| 09/15/04 | 09/17/2004 | JHH | WISCONSIN INVESTIGATION REPORT |



STATE OF WISCONSIN

DEPARTMENT OF HEALTH & FAMILY SERVICES
DIVISION OF PUBLIC HEALTH
1 WEST WILSON STREET
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PRESORTED
FIRST CLASS



FIRST CLASS MAIL

US NRC Region III
Attn: Jim Lynch
2443 Warrenville Road, Suite 210
Lisle, IL 60532-3025