

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Wisconsin
Madison, Wisconsin

Docket No. 30-03465
License No. 48-09843-18
EA 86-179

During an NRC special inspection conducted during the period September 2 through 19, 1986, violations of NRC requirements were identified. The violations resulted in a significant failure to control licensed material. As a result, 7 iridium-192 seeds used in animal experiments were lost. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1986), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to section 234 of the Atomic Energy Act of 1954, as amended, ("Act"), 42 U.S.C. 2282, PL 96-295, and 10 CFR 2.205. The violations and associated civil penalty are set forth below:

10 CFR 20.201(b) requires each licensee to make or cause to be made such surveys as (1) may be necessary for the licensee to comply with the regulations in this part and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

10 CFR 20.105(b) requires in part that no licensee possess, use, or transfer licensed material in such a manner as to create in any unrestricted area radiation levels that, if an individual were continuously present in the area, could result in that individual receiving a dose in excess of two millirems in any 1 hour, or 100 millirems in any 7 consecutive days.

1. Contrary to the above, on June 26 and 27, 1986, the licensee failed to perform a survey of unrestricted areas to assure compliance with 10 CFR 20.105(b) following the implant of 557 iridium-192 seeds in animals at the Charmany Instructional Facility.
2. Contrary to the above, from June 26 until August 21, 1986, the licensee failed to perform reasonable surveys under the circumstances to determine the extent of radiation hazards that may have been present. Specifically, surveys of the floor, rubber mats, and animal feces were not conducted to detect loose radioactive sources immediately prior to having the feces washed down the drain. This resulted in the loss of seven iridium-192 sealed sources.

Collectively, these violations have been categorized as a Severity Level III problem (Supplement IV).

Civil Penalty - \$1,250 - assessed equally among the violations.

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Pursuant to the provisions of 10 CFR 2.201, the University of Wisconsin is hereby required to submit to the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, within 30 days of the date of this Notice a written statement or explanation, including for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps which will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, the Director, Office of Inspection and Enforcement, may issue an order to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Considerations may be given to extending the response time for good cause shown. Under the authority of section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the University of Wisconsin may pay the civil penalty by letter addressed to the Director, Office of Inspection and Enforcement, with a check, draft, or money order payable to the Treasurer of the United States in the cumulative amount of One Thousand Two Hundred Fifty Dollars (\$1,250) or may protest imposition of the civil penalty in whole or in part by a written answer addressed to the Director, Office of Inspection and Enforcement. Should the University of Wisconsin fail to answer within the time specified, the Director, Office of Inspection and Enforcement, will issue an order imposing the civil penalty in the amount proposed above. Should the University of Wisconsin elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, such answer may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the five factors addressed in Section V.B of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201 but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The University of Wisconsin's attention is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

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Upon failure to pay any civil penalty due which has been subsequently determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to section 234c of the Act, 42 U.S.C. 2282.

FOR THE NUCLEAR REGULATORY COMMISSION


James G. Keppler
Regional Administrator

Dated at Glen Ellyn, Illinois,
this 11th day of December 1986.

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-03465/86001(DRSS)

Docket No. 030-03465

License No. 48-09843-18

Category G1

Priority II

Licensee: University of Wisconsin - Madison
Safety Department
317 N. Randall Avenue
Madison, WI 53715

Special Safety Inspection Conducted: Onsite September 2, 3 and 12, 1986,
Telephone on September 16, 17 and 19, 1986

Enforcement Conference Conducted: September 24, 1986

Inspector: *James R. Mullauer*
James R. Mullauer
Radiation Specialist

10/3/86
Date

Reviewed By: *D. J. Sreniawski*
D. J. Sreniawski, Chief
Nuclear Materials Safety
Section 2

10/3/86
Date

Approved By: *W. L. Axelson*
W. L. Axelson, Chief
Nuclear Materials Safety
and Safeguards Branch

10/6/86
Date

Inspection Summary

Inspection on September 2 through 19, 1986 (Report No. 030-03465/86001(DRSS))

Areas Inspected: Announced, special safety inspection to review the circumstances surrounding the reported loss of seven iridium-192 sources which were used in five animals (pigs) during a brachytherapy implant experiment. At the time of the reported loss on August 25, 1986, the sources had a calculated activity of 0.51 millicuries per seed. This inspection also included a review of the licensee's organization, authorization permit to conduct the experiment, Radiation Safety Committee approval, training of individuals involved, dosimetry (External), and independent measurements.

Results: Three violations of NRC requirements were identified during the course of the inspection; (1) 10 CFR 20.201(b)(1) - failure to perform surveys to insure compliance with 10 CFR 20.105(b) which limits levels of radiation in unrestricted areas (Section 6); (2) 10 CFR 20.201(b)(2) - Failure to perform reasonable surveys under the circumstances to evaluate the extent of radiation hazards that may be present (Section 6); and (3) 10 CFR 20.203(a) - Discharging Licensed Material into the sanitary sewerage system which was not soluble or dispersible in water (Section 6).

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DETAILS

1. Persons Contacted

- ^{1,2}Kathy Irwin, Attorney, University of Wisconsin
- ²Herb Attix, Vice-Chairman, Radiation Safety Committee
- ²Robert Radtke, Director, Safety
- ^{1,2}Sue Engelhardt, Radiation Safety Officer
- Lee Ann Kaiser, Health Physicist - II
- John Lorenz, Health Physicist - II
- Abdul Ben-Zikri, Health Physicist - II
- William Adams, Ph.D., Primary Investigator
- Cynthia Thomason, Medical Physicist
- Jim Linsley, Manager, Charmany Farms
- Claudia Hirsch, Supervisor, Charmany Farms
- Pat Warpinski, Animal Caretaker
- Andy Wolk, Animal Caretaker
- Leah Penza, Animal Caretaker
- Fay Hillery, Animal Caretaker

¹Attended telephone exit conference on September 19, 1986.

²Attended enforcement conference on September 24, 1986.

2. Purpose of Inspection

The licensee notified Region III on August 25, 1986, of the loss of seven iridium-192 brachytherapy sources sometime between from June 26 and August 21, 1986, during an animal experiment. The licensee conducted an extensive search by their health physics staff, however, the sources were not found.

3. Inspection History (Between 1979 and 1983)

- a. Routine Safety Inspection: July 13-15, 20-22, 25 and 26, 1983

Results: Four violations

Comments: Failure to wear required extremity dosimeter while handling >/mCi of P-32.

- b. Routine Safety Inspection: January 21-24, 1980

Results: Two violations

Comments: Extremity overexposure and failure to report the overexposure within 30 days (no enforcement action taken).

Area of concern was expressed by the NRC over the practice of the University allowing individual user applications to be approved by a single member of the Isotope Committee after review by the University Health Physicist.

c. Routine Safety Inspection: February 26 through March 2, 1979

Results: Six Violations with Civil Penalty

- Comments:
1. Failed to adequately train individuals (Civil Penalty \$200).
 2. Failure to determine air concentrations of radioactive material in restricted areas (Civil Penalty \$500).
 3. Failure to determine air concentrations of radioactive material in unrestricted areas (Civil Penalty \$400).
 4. Unauthorized user (Civil Penalty \$400).
 5. Bioassays not timely (Civil Penalty \$300).
 6. Incineration limits exceeded (Civil Penalty remitted).

4. Organization

Irving Shain, Ph.D., Chancellor
James Tracy, Chairman, Radiation Safety Committee
F. Herb Attix, Vice-Chairman, Radiation Safety Committee
Robert Radtke, Director, Safety
Sue Engelhardt, Radiation Safety Officer

5. Licensed Program

University of Wisconsin is holder of NRC Byproduct Material License No. 48-09843-18, Type A Broad Scope. The license currently authorizes the possession and use of any byproduct material with Atomic Nos. 3 through 83 with a total possession limit of 30 curies. In addition, the license authorizes certain other nuclides for calibration purposes, research, etc. Authorized use includes research and development, medical research, diagnosis and therapy including the internal and external administration of byproduct material to human beings, and tracer studies in laboratory animals.

No violations were identified.

6. Review of Incident

On August 25, 1986, at approximately 11:00 a.m. (CDT), the licensee's Radiation Safety Officer (RSO) notified NRC Region III that seven brachytherapy iridium-192 sources with a calculated activity of 0.51 millicuries per source were not accounted for. The seeds were used in five animals (pigs) in an experiment which began on June 26, 1986 and lasted until August 21, 1986. The following information was obtained during this special inspection. The Primary Investigator submitted an application to conduct a brachytherapy experiment using 560 iridium-192 seeds with an initial activity of 0.985 millicuries per seed. The procedure was as follows:

- a. Five pigs were to receive implants
- b. Four implant sites per pig
- c. Fourteen ribbons per site
- d. Two Iridium-192 seeds per ribbon

Totals

- e. 28 seeds per site
- f. 112 seeds per pig
- g. 560 seeds total in five pigs

(For details on protocol, see Attachment A.) Authorization to conduct the experiment was granted by the Chairman of the Radiation Safety Committee on June 24, 1986 and approved by the Vice-Chairman on June 27, 1986. (For details on Committee Approval, see Attachment C.) The experiment began on June 26, 1986, with two pigs receiving implants as follows:

Pig No. 26 received 112 seeds
 Pig No. 31 received 112 seeds
 Total seeds, 224 on June 26, 1986.

On June 27, 1986, three pigs received implants as follows:

Pig No. 27 received 111 seeds
 Pig No. 28 received 110 seeds
 Pig No. 32 received 112 seeds
 Total seeds, 333 on June 27, 1986.

By the day's end on June 27, 1986, the licensee had implanted 557 Iridium-192 seeds between five pigs. At the end of each implant on June 26 and 27, 1986, the licensee performed the following surveys:

Survey date June 26, 1986 using a Victoreen 470 A.

Room 1238 housing Pigs No. 26 and 31.

Pig No. 26 - 500 millirem/hour at pig surface
 65 millirem/hour at one meter

Pig No. 31 - 480 millirem/hour at pig surface
 60 millirem/hour at one meter

The licensee performed a survey just inside room No. 1238 by the door entrance (restricted area) and measured 10 millirem per hour.

Survey dated June 27, 1986 using a Victoreen 470 A.

Room 1239 housing Pigs No. 27, 28 and 32.

Pig No. 27 - 510 millirem/hour at pig surface
 67 millirem/hour at one meter

Pig No. 28 - 480 millirem/hour at pig surface
 72 millirem/hour at one meter

Pig No. 32 - 500 millirem/hour at pig surface
 66 millirem/hour at one meter

The licensee performed a survey just inside room No. 1239 by the door entrance (restricted area) and measured 20 millirem per hour. When questioned about radiation levels in unrestricted areas, the licensee stated that no evaluation of radiation levels in these areas was made. These areas included adjacent rooms and a hallway. The licensee's failure to perform radiation measurements in unrestricted areas constitutes a violation of 10 CFR 20.201(b) to assure compliance with 10 CFR 20.105. 10 CFR 20.201(b) requires the licensee to make such surveys as may be necessary for the licensee to comply with 10 CFR Part 20. 10 CFR 20.105 limits radiation levels in unrestricted areas.

On Sunday, June 29, 1986, the student investigator checked all the pigs and found a problem with pig No. 26. The template at Site 1 was cracked and partially hanging from the skin. In addition, one ribbon containing two iridium-192 seeds was found on the floor of the pen. Pig No. 26 was then sedated in an attempt to explant all sources located at Sites 1 and 2. The sutures which were holding the templates to the skin were cut. The catheters which were glued to the templates were expected to come out of the tissue with the templates. When the student investigator removed the template at Site No. 1, it was found that two catheters had separated from the Template and worked their way in the animal tissue. The same problem was encountered at Site No. 2 where two catheters had separated from the template and were lodged under the tissue. On Tuesday, July 1, 1986, the student investigator attempted to explant all sources from Pig No. 26; however, 11 catheters could not be removed between Sites No. 3 and 4. A total of 15 catheters were still implanted in Pig No. 26. On July 4, 1986, Pig No. 26 was sacrificed and the remaining 15 catheters were surgically removed. At this point, all sources from Pig No. 26 were accounted for. Also, on July 4, 1986, explant from pigs No. 28 and 31 was attempted and the same problem was encountered where catheters separated from the template and were lodged under tissue. This problem prevailed until August 21, 1986, when the remaining four pigs were sacrificed. The following source retrieval was accomplished:

Pig No. 27 - All sources recovered
Pig No. 28 - "Four sources not recovered"
Pig No. 31 - "Four sources not recovered"
Pig No. 31 - All sources recovered

After the student investigator learned that eight seeds were unaccounted for, the Radiation Protection Officer was notified. On August 22, 1986, two Health Physicist from the Safety Department surveyed areas where the pigs were housed and found one seed embedded under a rubber floor mat. The remaining seven sources were not found. On August 25, 1986, when all surveys failed to locate the sources, the NRC Region III was notified, a press conference was held and a news release was made.

The licensee concluded that the sources were most likely washed down the drain located in the middle of the room where Pigs No. 28 and 31 were housed. This conclusion is based on the following; (1) The pens where the animals were housed required daily cleaning by scrubbing and hosing with water. The student investigator checked each room with a survey instrument to assure no sources separated from the animals. (Note: a plastic sheet was placed over the cup of the drain to trap any loose sources from washing down the drain). These surveys were performed daily between approximately 7:30 and 8:30 in the morning. On several occasions, hours passed before the caretakers cleaned the animal pens. For example, on July 1, 1986, the student investigator checked room No. 1235 at 8:10 in the morning, for loose sources; however, the room was not cleaned until 2:00 p.m., the same day. A source could have fallen out of an animal in the six hour span and washed down the drain. When the caretakers cleaned the room with a water hose, the plastic sheet covering the drain was removed to allow for drainage. (2) An interview with one of the caretakers revealed that periodically the caretaker turned the hose on the pigs themselves. The caretaker did this to keep the pigs away while the floor was being cleaned. The caretaker stated that no instruction was given to the contrary about hosing water on the animals. (3) It was learned during the inspection that starting on July 24, 1986, animal caretakers were given the responsibility of performing daily room surveys prior to cleaning the pens, since the student investigator was scheduled to be out of town from August 2 through 9, 1986. The student felt that with adequate training and procedures to follow, the animal caretakers could assume the survey responsibility in the student's absence. This proposal was not formally approved by the safety department or the radiation safety committee. The animal caretakers who performed surveys for loose sources were interviewed on September 12, 1986, and from these interviews the animal caretakers demonstrated that they were adequately trained in the operation of the survey instrument and survey technique. The caretakers were also given a written survey procedure to follow. (See Attachment B for Survey Procedure.)

The survey procedure required a visual inspection of the floor for loose catheters, a visual inspection of the implant sites for protruding catheters and a radiation survey of the drain. During interviews with the caretakers, they stated that it is likely if a ribbon was loose on the floor, the animal would probably consume the ribbon thus being eliminated later in the feces. Surveys of the floor, rubber mats and animal feces may have located loose sources prior to hosing the feces down the drain. However, the survey procedure did not specify these details. When the health physics staff performed their survey on August 22, 1986, one seed was immediately found embedded under a rubber floor mat in the animal pen. The licensee's failure to perform reasonable surveys under the circumstances is a violation of 10 CFR 20.201(b).

10 CFR 20.303(a) states no licensee shall discharge licensed material into a sanitary sewerage system unless: It is readily soluble or dispersible in water.

The licensee concluded that the seven iridium-192 sources were inadvertently washed down the drain. These sources are not soluble or dispersible, a violation of 10 CFR 20.303 (a).

Three violations were identified.

7. Committee Approval

License Condition No. 21 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in certain referenced applications and letters.

The referenced application dated September 30, 1980, Attachment No. 14(1)(iv) states the criteria for approving applications to use radioactive material.

The criteria covered the following situations:

- a. a new applicant (i.e., a person not previously authorized to use radionuclides on the University of Wisconsin Madison Campus);
- b. Non-routine uses, quantities, or types of radionuclides;
- c. An applicant with a history of significant noncompliance with University Radiation Safety regulations;

Approval will be granted only after consideration by a health physicist and the full (quorum) committee. At the discretion of the University Radiation Safety Committee chairman or Vice-Chairman and a health physicist, the committee will permit temporary authorization involving situations described in (a) through (c) to be granted, pending final review and approval by the committee as a body.

Application to perform this experiment was received by the radiation safety department on June 2, 1986. (See Attachment C for Application). A Health Physicist from the safety department reviewed the application with the Primary Investigator on June 10, 1986. After approval by the safety department, the application was submitted to the Chairman of the Radiation Safety Committee and was approved by the Chairman on June 24, 1986. After the experiment began on June 26, 1986, the Vice-Chairman of the Radiation Safety Committee granted approval on June 27, 1986. Although a full quorum committee had not approved this experiment between June 26, 1986 and August 21, 1986, after notification to the NRC of the lost sources, the Radiation Safety Officer (RSO) submitted the application and protocol to all committee members. According to the RSO the full committee would have approved this application.

No violations were identified.

8. Training

The Primary Investigator of this experiment is a Doctor of Veterinary Medicine and Professor at the University of Wisconsin - Madison. The Applicant's Training and experience with radioactive material shows, on application form-99, experience with radium sources used in therapy, experience with technetium-99m in imaging and experience with cesium-137 sealed sources.

The Student Investigator is a Medical Physicist and is certified by the American Board of Radiology in both diagnostic and therapeutic radiologic physics.

License Condition NO. 21 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The referenced application dated September 30, 1980, states in Attachment No. 14(c)(iv)(a) under "minimum training," that before beginning work in a radionuclide facility, individuals must have read the handbook "Radiation Safety for Laboratory Technicians" and submitted the associated exam to the health physics staff.

A record review covering training of all individuals involved in this experiment showed all individuals were at least minimally trained, i.e., animal caretakers.

No violations were identified.

9. Personnel Dosimetry (External)

License Condition No. 21 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The referenced application dated September 30, 1980, stated in Attachment No. 14(c)(i) that the authorized user shall insure that the use of radionuclides are performed in a safe manner and in accordance with the conditions of the authorization. Condition No. 2 of authorization dated June 25, 1986, states extremity and body dosimeters must be worn when handling sources.

When animal caretakers were given the responsibility of surveying the animal pens for loose radioactive sources prior to cleaning the pens, they were instructed to use long forceps to remove any catheters (containing sources) seen protruding from the animals. (See Attachment B for Survey Procedure and source handling.) Records show that animal caretakers removed catheters from animals on August 2, 3 and 16, 1986. Interviews with these caretakers confirmed that they handled catheters using 12 inch long forceps on these dates and other dates which were not documented. Personnel required to care for these animals were all issued whole body dosimeters; however, were not issued extremity dosimeters based on the licensee's determination through calculation that caretakers would not receive 25% of the quarterly limit specified in 10 CFR 20.101.

The Primary and student investigators were issued whole body and extremity dosimeters. For the period June 15 through September 14, 1986, the maximum whole body film badge reading for the animal care staff was 80 millirem. The student investigator received 370 millirem to the whole body badge and 1850 millirem to the extremity badge for the same period. The student investigator exclusively performed implants and explants during this experiment except for those sources handled with forceps by the caretaker staff. (See Attachment D for dosimetry report.)

No violations were identified.

10. Licensee Surveys and NRC Confirmatory Measurements

Between August 22, 1986 and August 25, 1986, the licensee conducted surveys of the entire Charmany Farms area. On August 22nd, initial radiation surveys located one source in room 1235 embedded under a rubber floor mat. The seven remaining sources were never found. On August 27, 1986, two University Health Physicists surveyed Badfish Creek with negative results. Badfish Creek receives treated effluent water which is discharged by the Madison Sewerage District. (See Attachment E for Search Effort.)

The Madison sewerage district receives 300,000 to 600,000 gallons of liquid waste per day of which approximately 5% is solid sludge. The sludge is treated in pits for approximately 21 days before being used as fertilizer. The sludge is then transported by truck to area farms where it is pressure injected into the soil as fertilizer.

On September 3, 1986, the NRC inspector performed confirmatory measurements on the animal carcasses using a Ludlum Model No. 19, Micro R Meter (NRC 014809) calibrated on July 31, 1986. The instrument was checked against a known source of radiation and functioned properly. Background readings at Charmany farms varied between 4-8 micro R per hour. The animal carcasses used in the experiment were carefully monitored with negative results. On September 3, 1986, the NRC authorized disposal of the animal remains. No readings above background were detected at the farm facility.

No violations were identified.

11. Areas of Concern

License Condition No. 21 which references application dated September 30, 1980, stated in Attachment No. 14(a)(iv) that at the discretion of the University Radiation Safety Committee Chairman or Vice-Chairman and a Health Physicist, the committee will permit temporary authorization pending final review and approval by the committee as a body. This inspection revealed that the Chairman of the committee approved this project on June 24, 1986, the project began on June 26, 1986, and the Vice-Chairman approved the project on June 27, 1986. The project was scheduled to last only 5 to 10 days. The inspector expressed concern over the fact that the Radiation Safety Committee was not scheduled to meet until late August or early September, well after the animal project would be concluded. Therefore, a full committee review could not be achieved until well after this unusual experiment.

The inspector also expressed concern over the lack of involvement of the Health Physics staff during this project. Problems with the experiment as early as two days after implant when a ribbon containing two iridium-192 seeds were found on the floor of the animal room were reported to the University Safety Department. As other problems occurred the safety department was kept informed; however, the Health Physics staff did not perform an onsite evaluation of the problems until the seeds were reported missing. These concerns were addressed during the enforcement conference on September 24, 1986, and the licensee agreed to establish new criteria requiring greater involvement between the Radiation Safety Committee and Health Physics Staff on problem experiments.

The University Radiation Safety Committee met on September 25, 1986, to discuss these matters. (See Attachment F for the minutes of the September 25, 1986, meeting.)

12. Exit Meeting

At the conclusion of this inspection on September 19, 1986, a telephone discussion was held between the inspector and Kathy Irwin, the University Attorney. The apparent violations, areas of concern and possible enforcement actions were reviewed and discussed.

13. Enforcement Conference

An enforcement conference was held in the Region III office on September 24, 1986 as a result of the special inspection which identified three apparent violations of NRC requirements. The purpose of the conference was to (1) discuss the apparent violations, their significance and causes, and the licensee's corrective actions, (2) determine whether there were any aggravating or mitigating circumstances, (3) discuss specific areas of concern which were expressed during this special inspection.

Mr. A. B. Davis, Deputy Director of NRC Region III, opened the meeting by describing the purpose and scope of the meeting as well as the NRC enforcement policy and concerns raised as a result of the September 2 through 19, 1986 inspection.

In addressing the violations the licensee acknowledged the facts as presented by the Region III staff and discussed corrective actions to prevent recurrence. The licensee was informed that escalated enforcement action was being considered.

Attachments:

- A. Experiment Protocol
- B. Survey Procedures Followed by
Animal Caretakers
- C. Application to Conduct Experiment
- D. Dosimetry Report
- E. Licensee's Search for Missing
Sources
- F. Minutes of the September 25, 1986,
Committee Meeting

Attachment A

Effect of Treatment Volume on Radiation Tolerance of Normal Pig Muscle

Part I

Goal: To determine the influence of treatment volume on the tolerance of normal muscle tissue to the radiation dose delivered by removable interstitial implants of Ir-192. Results obtained here will be compared with predictions of cumulative radiation effect as determined by existing models. The results will also be compared with the effects of hyperthermia on normal pig muscle.

Animals: Five Landrace-White pigs, 40-50 kg.

Procedure: This will determine the baseline response of a fixed volume of muscle tissue for a range of total radiation doses. The fixed volume arbitrarily has been chosen to be 20 cm³ (The choice was primarily determined by the cost of radioactive seeds). The volume is defined as that enclosed by the 50 rad/hr dose line and is consistent with the definition used for human clinical treatments. The strength of the Ir-192 seeds used will be 0.5 mg Ra eq which is, again, consistent with clinical treatments. The source configuration will follow that obtained using a prostate template with 14 needles (See Figure 1). Two Ir-192 seeds will be used in each needle with a center-to-center spacing of 1 cm. This gives a total of 28 seeds/implant with a total activity of 14 mg Ra eq. The total doses used will range from 6,000 to 12,000 rads in four equal measurements (i.e. 6,000, 7,500, 9,000, 10,500, and 12,000 rads). These dose levels correspond to treatment times of 120, 150, 180, 210 and 240 hours (5, 6.25, 7.5, 8.75 and 10 days). Five pigs will be given four implants each to obtain four data points at each dose level. Specifics of the procedure are given below.

Insertion of the implant: The animals will be housed, each in separate pens at Charmony Farms. The animal will be anesthetized in its pen. The areas of the pig to be implanted will be shaved. Four sites will be implanted on each

animal and the approximate sites are shown in Figure 2. The exact sites are dependent on the weight and length of the actual animals and will be chosen to maximize the distance between sites. (Calculations show that if two implants are 20 cm apart, the dose delivered to one implant from the other is approximately 0.3% of the dose delivered from the implant itself. Therefore, implants 20 cm or more apart should have little effect on one another).

A diagnostic ultrasound scanner will be used to determine the amount of fat over each implant site. This is necessary to assure the implant is inserted to the correct depth.

After determining site and depth of the implant, the template will be sutured to the animal. The template, shown in Figure 1, is used to guide the implant needles into place and to secure the radioactive sources during treatment. Also at this time, the implant site will either be tattooed or several sutures will be placed to allow identification of the site at the time of necropsy.

After the template is sutured in place, a guide template will be taped over the sutured template. The guide template has an identical placement of needle holes, but is much thicker than the sutured template. It is used only while inserting the implant to insure all needles are inserted parallel to one another. The needles used will consist of a 16 ga hyperthermia type catheter inside a 14 ga breakaway needle. The needle will be inserted through the template to the proper depth and then removed leaving the catheter inserted in the pig muscle. The guide template is removed after all 14 catheters are in place. The catheters will then be cut flush with the top surface of the template and glued to the template.

When the templates and catheters are thus secured at each of the four implant sites, the Ir-192 seeds will be afterloaded into the catheters. The seeds are enclosed in polyethylene tubing which will also be cut flush with the surface of the template and glued in place. When all sources are in place in a given

A

implant, the entire surface of the template will be covered with adhesive backed mylar to further secure the sources. The sites will also be covered with a dressing and/or tape.

This procedure should take a maximum of 30 minutes/site prior to source insertion. It should take approximately 5-10 minutes to load all sources so that the total time should be 2-2 1/2 hours (not including anesthesia), per animal.

Animals will have to be kept one animal/pen in a restricted area until the implants are removed.

Removal of the implant: Removal of the implants will take place 5-10 days after their insertion. Animals will be anesthetized and the sutures holding each template in place will be cut. The entire assembly (template, catheters and sources) will be removed together. It should take approximately 5 minutes to remove each implant so total time per animal outside of anesthesia should be less than 30 minutes. All implants on a given animal will be treated to the same dose level allowing all implants to be removed at the same time.

Sacrifice: Animals will be sacrificed 30-40 days after the start of treatment. At this time, tissue samples will be removed for histology and biochemical assay, (If possible, infusion of a barium solution would be done at this time, so microangiography could be done).

Endpoints: 1) Histology - done in a manner similar to that performed in the last hyperthermia study.

2) Hydroxyproline assay - biochemical assay used to quantify collagen formation. Two to three, three to four cm tissue samples from each site would be required.

3) Microangiography - (possibly?) This would assess vascular damage and is expected to be the most sensitive endpoint.

Technical support required:

Days 1 and 2: implantation, anesthetic for each animal.

Days 5-10: removal of implant, anesthetic for each animal.

Days 30-40: animal sacrifice and removal of tissue samples; possibly infusion for microangiography.

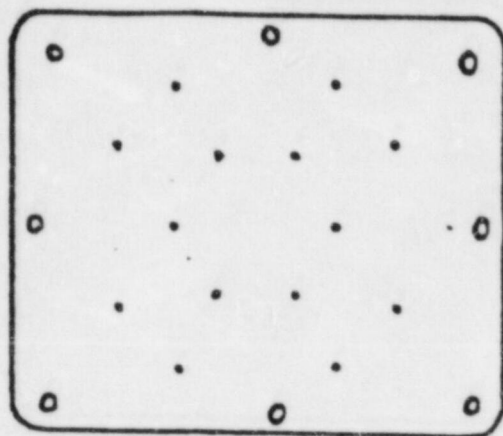


Figure 1 Prostate Template, top view (actual size)
3mm thick, acrylic

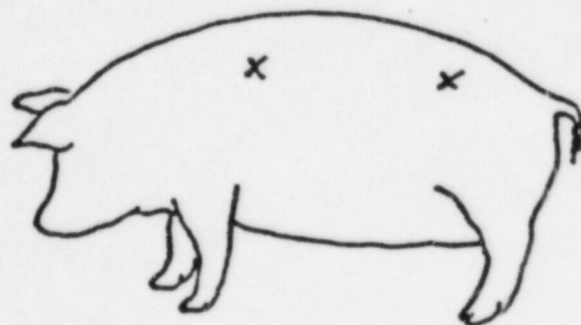


Figure 2

A

ATTACHMENT 2

Survey to be performed prior to
cleaning room containing
radioactive pigs

- 1) Visually inspect floor of room for loose catheter (Catheter is a thin piece of white plastic tubing 1 - 1 1/2 inches long.) If nothing is seen, proceed to 2). If a catheter is seen, see 4)A below.
- 2) Visually inspect each of 4 implant sites on each pig for protruding catheters. If none are seen, proceed to 3). If a catheter is seen protruding from pig, see 4)B below.
- 3) Lastly, use yellow Victoreen 450 survey meter to check drain of room for radioactive catheters.
To operate survey meter:
 - A. Depress ON-OFF button on front of meter. A display should be seen above button.
 - B. Wait outside room for about 2 - 3 minutes to allow meter to stabilize. Scale indicator should decrease and finally show value on left side of scale. Reading should be less than 1 mR/hr.
 - C. Move the round silver portion of the meter slowly, about 2 - 3 inches above the drain. Try to keep the pigs as far from the drain as possible since they will cause a reading on the meter if close enough.
 - D. A reading on the meter doesn't necessarily mean a radioactive catheter is present. The radioactivity inside the pigs can cause a reading. However, readings due to the pigs will vary only slightly or not at all when the meter is moved over a distance of several inches. A reading caused by a loose radioactive catheter will change dramatically when the meter is moved several inches. (Remember to move the meter slowly- it has a slow response.) Readings due to a catheter should be at least 50 mR/hr above the 'background' reading.

If nothing unusual is seen, the room can now be cleaned.

- 4)
- A) If a catheter is found on the floor: Using the long handled forceps, pick up the catheter and place it in the lead container. Then call me*
 - B) If a catheter is seen protruding from the pig. Call me*. If I cannot be reached within several hours, the catheter should be removed from the pig. This can be done by restraining the pig and pulling the catheter out using the long handled forceps. The catheter should pull out easily and then should be placed in the lead container.
 - C) If a catheter is detected in the drain: Do not proceed to clean the room. Lift the cover off the drain. Visually inspect the trash bag and basket for the catheter and, if seen, remove it using the long handled forceps and place in the lead container. Call me*

* Cindy Thomason

3-7265

231-2499

3-8500 (messages)

If I can't be reached within several hours, call radiation safety. (Dee Ann Kaiser would be the best one there to talk to.)

B

ATTACHMENT C

RECEIVED

JUN 02 1986

APPLICATION FOR POSSESSION AND USE OF RADIONUCLIDES SAFETY DEPT.

URSC (090982)
Form 99 (Rev. 2)

37265

Authorization Expires

JAN 1989

(For Safety Dept. Use Only)

(For details on application

1. Name of applicant(s):

(For joint authorizations, please underline name of the person to be the principal "authorized user" for purposes of mailings, ordering, etc. The information requested in item 16 must be completed for each applicant if not already on file with the URSC+.)

Mailing address: 2015 Linden Ave School of Vet MedPhone: 376-56Can your name be given to sales representatives requesting a list of radionuclide users? — YES ☒ NO

2. Check one:

Adams

☒ New application (applicant is not currently authorized to possess radionuclides)☐ Amendment to current authorization (Fill in only those blanks which represent a change from current authorization)☒ Renewal application

3. Room number(s) and building(s) where radioactive—

Charmany Research Facility / School of Vet Med (Kear)
1235, 1238, 1239 (holding rooms) & 1236 (work station) CR
materials will be used and/or storedBTC Clinical Sciences Center (Stored)wastes will be stored
pending disposal or
decaynot applicable

4. How will security of materials be maintained in rooms where total radionuclide activities are greater than those listed in the URSR, Appendix P?

☐ Materials will be stored in a locked cabinet, refrigerator or freezer.☒ Room will be locked when unattended.☐ Other (specify) _____

5. REQUESTED MATERIALS

(Add additional sheets if necessary)

Radionuclide	Chemical Form(s)	Physical Form*	Order Limit**	Possession Limit***
1. Ir-192	platinum-iridium metal alloy	encapsulated solid	300 mg/eq	600 mg/eq
2.			~ 5/16 mCi	~ 10±0 mCi
3.	$A = Ra \left(\frac{1}{T_{1/2}} \right)$			
4.				
5.	$= 300 (8.25)$			
6.	(4.8)			
7.				
8.				
9.				
10.				

* Physical Form: solid, liquid, gas or sealed (list sources separately)

** Order Limit: the maximum quantity in any single order or transfer (specify units)

*** Possession Limit: the maximum quantity on hand at any time (specify units)

6. Radionuclides procured from:

☒ CORD*☐ VA Radiopharmacy☐ U.W. Accelerator☐ Other NRC License (specify) _____☐ U.W. Reactor☒ Other sources (specify) RTC

* Central Ordering, Receiving and Distribution

(CORD obtains nuclides at your request from most commercial vendors.)

7. Will radionuclides be administered to or used on humans?
☒ No ☐ Yes - submit form 98.8. Will animals be used in your radionuclide program?
☐ No ☒ Yes - submit form 99a.9. Will use include student lab?
☒ No ☐ Yes - course # _____

10. Describe your intended use of radionuclides. If you have a written description of procedures, attach copies to this application. If not, give information as to the medium or organisms used, type of procedure (labelling, synthesis, RIA, uptake, etc.), and radionuclide involved. If iodinations are to be performed, please include a protocol describing your iodination procedure. (Add sheets as necessary.)

Encapsulated Ir-192 seed sources will be used in temporary brachytherapy implants on pigs

11. At what frequency will your radionuclide facilities be surveyed?

☐ Monthly

☐ Semiannually (permitted for rooms in which $< 200 \mu\text{Ci}$ is in use at any given time or if nuclides are in storage only)

☒ Other (specify) sources will be stored in tank in Radiotherapy CSC and survey + inventory will be according to their procedures

12. Which of the following will be used to perform surveys?

☐ Wipe tests and liquid scintillation counter.

☐ Wipe tests and gamma counter

☐ Survey meter model(s) _____, to be calibrated by:

☐ Safety Department

☐ Commercial calibration service (specify) _____

☐ Other (attach name and procedures) _____

Specify calibration frequency: _____ annually _____ other

☒ Other (specify) equipment and procedures as used in radiotherapy

13. Describe the training or instructions you will provide or require for all personnel who will work with or in the vicinity of radionuclides used under your authorization.

☒ Personnel will be required to read the handbook Radiation Safety for Laboratory Technicians and to submit the associated exam to Safety.

☐ Additional training (specify. Add additional sheets if necessary):

14. What precautions will be taken in storing stocks and wastes of gamma and/or high energy beta emitters to minimize doses to lab workers?

Stocks/wastes will be stored:

☐ in a separate room

☐ in an area of the laboratory not frequented by workers

☒ behind appropriate shielding material (describe) Pb

☒ Other animals (pigs) will "shield" implants

☐ Not applicable (low energy beta use only)

15. What methods do you intend to employ for disposing of your radioactive waste? Indicate whether your response pertains to solid (S), liquid (L) or gaseous (G) waste by writing the appropriate letter(s) beside each applicable method. not applicable

☐ Consolidation (by nuclide) and proper packaging, etc. for pickup and disposal by the Safety Department.

☐ For liquid waste only please estimate total volume generated in a specific time interval _____.

☐ Decay

☐ Dilution to acceptable concentration limits and disposal to the sewer/atmosphere. How will airborne releases be assessed and controlled? (specify)

☒ Other (specify) sources will be returned to manufacturer

☐ Waste generation not anticipated

for disposal

16. Applicant's training and experience*

reinstated
~~for Dr. Patrick, see attached CV~~

deleted from authorization - he (RTC) will provide sources

Type of Training	Where Trained	Duration of Training	On the Job or Formal Course
A. Principles and practices of radiation protection	Univ. of PA School of Medicine " of Vet. Med.	4 wks 3 yrs	formal both
B. Radioactivity measurement, standardization, and monitoring techniques and instruments	"	2 wks 3 yrs	formal on the job
C. Mathematics and calculations basic to the use and measurement of radioactivity	Mid school Vet school "	2 wks 2 wks 3 yrs	formal formal on the job
D. Biological effects of radiation	"	2 wks 2 wks	formal "

Experience (Actual use of radionuclides or equivalent experience)

Radionuclide	Maximum Quantity Used	Where Experience Was Gained	Duration of Experience	Type of Use
Radon				
Radon	10mcCi	U. of P. Vet School	3 yrs	Cancer therapy
^{99m} Tc PP	100mcCi	Univ of Ill.	4 yrs	Nuclear imaging
Cesium	40mcCi	Univ of Ill.		again: cancerous

*Photocopy and send duplicated sheets if more than one applicant.

Please read before signing:

The applicant agrees to abide by all applicable regulations regarding the use of radionuclides as set forth by the NRC, the State of Wisconsin, and the University Radiation Safety Committee (URSC)/the VA Radiation Safety Committee (VARSC). These regulations include, but are not limited to, the following:

- a. The authorized user has the responsibility to see that all personnel who work with or in the vicinity of radionuclides under this authorization, including animal caretakers and students, are trained in accordance with URSR V.A. and V.B. if the cumulative activities used are greater than those listed in Appendix V of URSR.
- b. All personnel must wear dosimeters when required by URSR VI.A. and VI.B. using tritium or radioiodine must have urine or thyroid monitoring as applicable, as required by URSR XIII.B. and XIII.C.
- c. All rooms containing radionuclides must be posted in accordance with URSR XVI and surveyed as required by URSR XI. Records of radionuclide receipt, use and disposal must be kept as specified by URSR XIV. Radioactive wastes must be handled as specified in URSR XIX.
- d. Any procedures which may result in the production of activities greater than 0.1 of those listed in Appendix V of URSR in the form of gases, aerosols, or airborne dust must be carried out under a fume hood, or other facility approved by the Safety Department. Radioiodine effluents from hoods must be monitored as specified in URSR XIII.B. If the release of airborne activities could exceed 10 times the limits listed in Appendix V in one year, contact the Safety Department.

William M. (Chess) Adams

RETURN TO:

Brandon R. Racine May 29/84

Applicant's Signature

Date

Health Physicist
Safety Department
317 North Randall Ave.
Phone #: 262:8769/0667

University Job Classification and Department

URSC/VARSC
Form No. 99

This application has been reviewed and approved for consideration by the URSC/VARSC subject to the conditions listed below:

Signed:

Dr. Ann Kaiser

Date: 6-17-86

UW Health Physicist/VA Radiation Safety Officer

Comments: Met with Dr. Adams on 6-10-86 and reviewed applicable URSC. Suggested he request an exception to transport Ir-192 (see attached)

Conditions: 1) Ir-192 must be transported in ^{PL in} properly labelled DOT packages 2) Dosimeters must be worn when handling sources & 3) Jim Linley (OF Animal Care Staff) must be informed of exposure rates from implants. A Approval recommended.

4) Sr-90 source may not be left unattended in treatment room. The URSC/VARSC grants permission to obtain and use the radionuclides in accordance with the statements contained in this application and any conditions listed below:

Duration of authorization: ☐ To expire with current authorization

☒ 3 years

☐ Other (specify) _____

Signed:

[Signature]
URSC Member/VARSC Chairman

Date: 24 June 1986

with approval of the VARSC (Meeting of _____)

Signed:

[Signature]
URSC Chairman

(for new applicants and exceptions)

24 June 1986

Comments:

J. H. Ottix - 6/27/86

Form 99a

Animal Use of Radionuclides

1. Complete the table below for each radionuclide-animal experiment you anticipate:

Radionuclide	Animal	Maximum Activity/ Animal	- Number of Animals/ Experiment	Time Interval Between Radionuclide Administration and Sacrifice
Ir-192	pig	56 mCi Ra (= 96.25 mCi)	5	5-10 days 30-40

2. Where will the animals be housed for the duration of the experiment(s)?

_____ In authorized user's laboratory; _____ room

_____ In animal care facility; _____ room

X Other (describe) 1235 1238 & 1239 CIF
(Charman Instructional Facility)

3. Who will provide care for the animals? (All personnel must have passed the Radiation Safety Exam.)

_____ Laboratory personnel

_____ Animal care personnel

X Other (specify) CIF Animal Care staff

4. How will radioactive animal carcasses and waste be stored pending Safety Department pickup?

_____ Stored in lab freezer

_____ Stored in freezer provided by Safety Department

X Other (specify) N/A - not radioactive, implants to be removed

5. Specify survey methods and frequency, including cage surveys:

Measure exposure rate at pig surface - inform Animal Care staff

Applicant Signature

Date

Health Physicist

Date

Comments:

H. N. Pitter
URSC Member

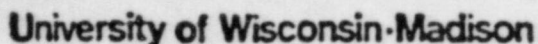
27 June '86
Date

[Signature]
Chairman, URSC

24 June 1986
Date

see form 99

(completed per discussion with Dr Adams.)



SAFETY DEPARTMENT
317 N. Randall Avenue
MADISON, WISCONSIN 53715
608 262-8769 - 262-0667

Form URSC
No. 130 (Rev. 3)

Date: June 25, 1986

TO: W.M. (Chess) Adams, DVM
2058 Veterinary Medicine

FROM: DeeAnn Kaiser
Health Physicist

Application Type:

184 New Authorization

☐ Renewal

/ Amendment (amended items are underlined or italicized)

/X/ Exception

URSC Member Representative: Jim Tracy

Your application for authorization to use radionuclides has been approved by the University Radiation Safety Committee (URSC). Your "per order" and "possession" limit for each radionuclide is specified below. In addition, please note any conditions to your authorization or applicable exception to the University Radiation Safety Regulations which may be given below.* This authorization and all exceptions will be valid until January 1, 1989, unless terminated at your request or by the URSC. Forms and information necessary for authorization renewal will be sent to you in advance of this date. Please notify the Safety Department if you plan to leave the University or discontinue your radionuclide program prior to this date. If you have any questions about your authorization, please feel free to contact me (or another health physicist).

[illegible]

You are authorized to use and/or store radionuclides only in room(s): Sr-90 in 1143, 1147 and Small and Large Animal Treatment Rooms at Veterinary Medicine, and Ir-192 in 1235, 1236, 1238 and 1239 Charman Instructional Facility.

* See Attached

W.M. (Chess) Adams

Conditions of Radionuclide Authorization:

- 1.) Your exception request to transport Ir-192 has been temporarily approved provided you notify CORD (2-6511) prior to each transfer, transport the Ir-192 in a lead pig inside a properly labelled DOT package (RTC can provide this) and comply with the procedures specified in your request dated June 11, 1986. Assume final URSC approval unless otherwise notified.
- 2.) Extremity and body dosimeters must be worn when handling sources.
- 3.) Exposure rates from implanted sources must be measured and Jim Linsley, CIF animal care staff supervisor, informed of any special procedures or precautions that may be necessary.
- 4.) The Sr-90 source may not be left unattended in VMTH treatment rooms and must be returned to storage immediately after use.

Attachment D

Sir,

Readings for 8-15-86 to 9-14-86 badge for Chairman
Animal Care People.

10x rem

10 m rem

10 m rem

M

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10 m rem

10 m rem

M

PROCESSED ON	CLIP AT DATE	DATE RECEIVED	DATE RECEIVED BY
50026	02006	82060	2 1

Landauer®

317 N RANDALL AVE
MADISON WI 53715
RADIATION DOSIMETRY REPORT SEP 5 1986

Accredited by the
National Bureau of Standards
through NIST
DUPLICATE COPY

2 Science Fwd, Glenwood, Illinois 60425-1586
(312) 755-7000

DISKETTES TO FOLLOW THIS REPORT

2U - PH 3633 - 60

PARTICIPANT ID NUMBER	NAME	SOCIAL SECURITY NUMBER	DATE OF BIRTH (MM/DD/YY)	RADIO BADGE NUMBER	EXPOSURE TO BADGE (MILLIREMS) FOR PERIOD(S) INDICATED BELOW	CUMULATIVE TOTALS (MILLIREMS)										ADJUSTMENTS	EXPOSURE DATE TO MODALITY	TO DATE
						CALENDAR QUARTER		YEAR TO DATE		PERMANENT								
						DEEP	SHALLOW	DEEP	SHALLOW	DEEP	SHALLOW							
					07/14/86	SECOND	1986											
FOR EXPOSURE PERIOD 06/15/86						WITH THE FOLLOWING PERSONNEL DOSIMETERS:												
***** NO CONTROL DOSIMETER RETURNED					K1 P 80	80	80	80	80	80	80	1010	1070					
					K1 P 30	30	30	30	30	30	30	1370	1440					
					K1 P 60	60	60	60	60	60	60	1500	1500					
					K1 P 50	50	50	50	50	50	50	1300	1300					
					K1 P 20	20	20	20	20	20	20	5490	5490					
					K1 P 60	60	60	60	60	60	60	2660	2660					
					K1 P 30	30	30	30	30	30	30	2900	2900					
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33425 G99

UNIV OF WISCONSIN
ATTN ROBERT R RADTKE
SUE ENGELHARDT
317 M RANDALL AVE
MADISON WI 53715

RADIATION DOSIMETRY REPORT

SEP 5 1986

SEP 5 1986

E0826 82886 82680 2 1

Lardauer

R. S. Lardauer, Jr. & Co.
Division of TechOps, Inc.
2 Science Road, Glenwood, Illinois 60425-1588
(312) 755-7000

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DISKETTE TO FOLLOW THIS REPORT

2U - PH 3433 - 600

PATIENT NAME	NAME	SOCIAL SECURITY NUMBER	FOR EXPOSURE PERIOD 06/15/86	EXPOSURE TO RADIATION INDICATED BELOW				CALENDAR QUARTER				CUMULATIVE TOTALS (MILLIREMS)				BIRTH DATE	NUMBER OF DOSE REPORTS
				BADGE (MILLIREMS)		FOR PERIOD(S) INDICATED BELOW		SECOND		THIRD		YEAR TO DATE		PERMANENT			
				DEEP	SHALLOW	DEEP	SHALLOW	DEEP	SHALLOW	DEEP	SHALLOW	DEEP	SHALLOW				
XXXX NO CONTROL DOSIMETER RETURNED	FOR EXPOSURE PERIOD 06/15/86			07/14/86	80	80	80	80	80	80	80	80	80	80	1010	1070	
					30	30	30	30	30	30	30	30	30	30	1370	1440	
					60	60	60	60	60	60	60	60	60	60	1500	1500	
					50	50	50	50	50	50	50	50	50	50	1300	1300	
					20	20	20	20	20	20	20	20	20	20	5440	5490	
					60	60	60	60	60	60	60	60	60	60	2490	2660	
					30	30	30	30	30	30	30	30	30	30	2900	2900	

Badges worn

6-15-86 to 8-14-86

DISKETTE TO FOLLOW THIS REPORT

UNIV OF WISCONSIN
ATTN DEBBY ROETS
RADIOTHERAPY CNTR/CSC
K4-849/600 HIGHLAND AVE
MADISON WI 53792

RADIATION DOSIMETRY REPORT

ACCOUNT NO	DATE
33425	G10

SEP 5 1986 JCL

PACKAGE NO	DATE	QUANTITY	DATE	DATE
E0826	82080	82680	2	1

QUALITY CONTROL
JL

Landauer JAE
R. S. Landauer, Jr. & Co.
Division of TechOps, Inc.
2 Science Road, Glenwood, Illinois 60425-1508
(312) 755-7000

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DISKETTE TO FOLLOW THIS REPORT

20 - PR 3433 - 6

PARTICIPANT ID NUMBER	NAME	SOCIAL SECURITY NUMBER	NOTE (SEE REVERSE SIDE)	DOSEMETER TYPE	RADIATION QUALITY	EXPOSURE TO BADGE (MILLIREMS) FOR PERIOD(S) INDICATED BELOW		CUMULATIVE TOTALS (MILLIREMS)						ADJUSTMENTS	SERIES PART OF PERMANENT ACCUMULATED DOSE (MILLIREMS)	BIRTH DATE			NUM BAD REPO TO DATE
						DEEP	SHALLOW	CALENDAR QUARTER		YEAR TO DATE		PERMANENT				MO	DA	YR	
								DEEP	SHALLOW	DEEP	SHALLOW	DEEP	SHALLOW						
00610	TLD CONTROL	007/15/86	UD			08/14/86	THIRD	1986										223	
						M	M	M	M	370	370	390	120						
						M	M	M	M		1850		1930						

USE LOGS (SEE REVERSE SIDE)
THERMAL STABILITY
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DO NOT WRITE ON THIS REPORT
EXPOSURE IS POSSIBLE ONLY THROUGH THE FILM PACKET
AND APPEARED OUT OF THE FILM PACKET

IMPORTANT: SEE REVERSE SIDE FOR ADDITIONAL EXPLANATIONS

W 04-249

August 27, 1986

TO: Sue Enoelhardt

FROM: John Lorenz

On August 27, 1986, Abdul and I surveyed Badfish Creek from the sewage plant outlet to County Highway B searching for the lost Ir-192 seeds. Our survey showed no radiation levels above background.

We used the pulse rate meter with the low energy gamma probe and surveyed as close as possible to the shoreline on the emergent vegetation along the shore. In many places along the Creek, the shoreline was not accessible. In those areas we monitored as near to the shore as we were able to go. The only place it is likely that the seeds would stop in the creek is in the emergent vegetation along the shore. In all other areas of the stream, the flow of the water is fast enough that it would almost certainly carry the seeds downstream.

We were concerned about the possibility that one of the seeds might lodge in an area where people could fish. However, the shoreline is such that in only one small spot between the outflow and the highway would fishing be feasible. South of the highway, there is one more small area where fishing would be possible. Both the potential fishing spots were carefully surveyed and only background radiation levels were found.

The remainder of the creek south of the highway appeared to be inaccessible because of the vegetation along its banks.

There are raspberry (or related species) plants along the creek, and there was evidence of people having been present and picking the berries. Even if sources were present in the creek, however, doses to those people, would be minimal for the following reasons.

1. The water along the bank was a minimum of 12 inches deep in every location where we looked. This means the radiation would be attenuated significantly before it left the water.
2. The people who were picking the raspberries would be at least 1.5 - 2 meters from the bank.

Exposure rates for this situation can be calculated from Table 1.

E

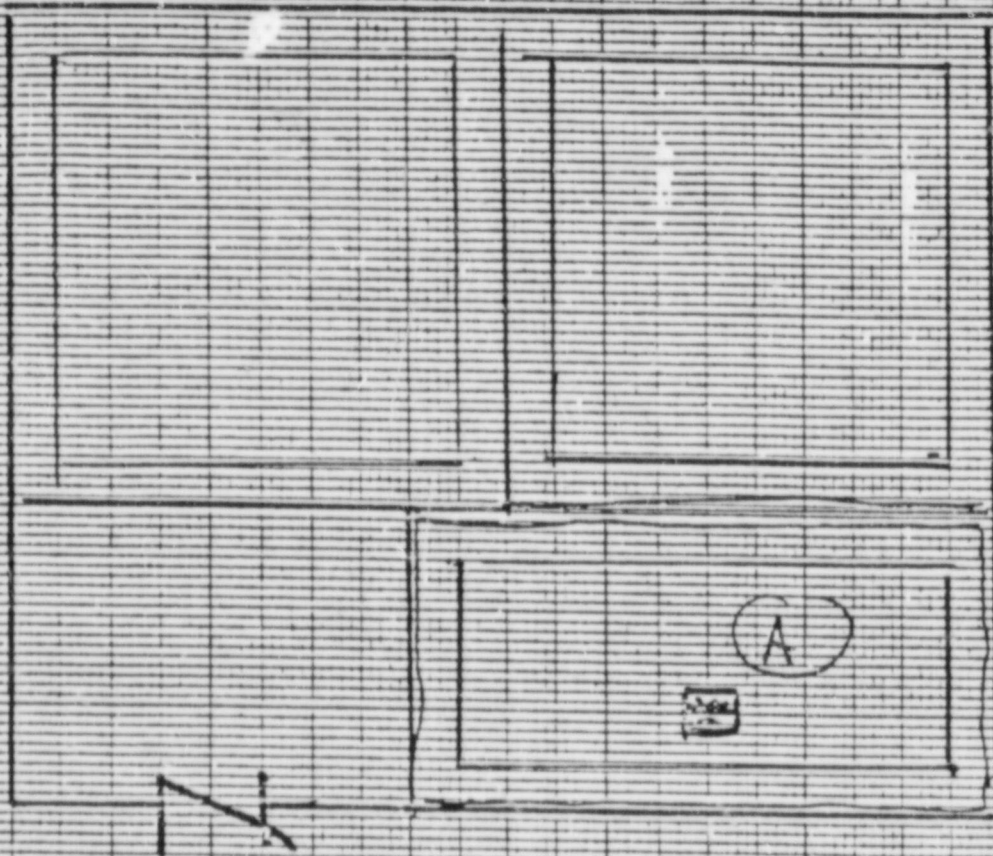
RADIONUCLIDE FACILITY SURVEY

DATE: 8-22-86
INITIALS: ARJ+LD

DETAILED SKETCH OF FACILITY

CODE: LB-Lab Bench; H-Hood; S-Sink; R-Refrigerator; F-Freezer; D-Desk; T-Table;
I-Incubator; C-Centrifuge; LSC-Scintillation Ctr.; *-Nuclide Storage

1235 CHAMBERLAIN EAVES



SURVEY METER RESULTS

☒ Eberline E-120 with HP-190/210 probe
Other _____
Background 04025 mR/hr
NA

WIPE TEST RESULTS

____ Packard LSC-L + =, LLD=0.2, 50% Gain
Other _____
Background = 44 cpm

(A) 25 mR/hr @ ~

10 cm above mat.

Room was remonitored after seed removal
and was Background.

Decontamination needed?

Yes

No

Monitoring was done using Eberline Meters E-120 and 6112 Teletector. All readings were background except in the pigpen in room 1235. One seed was recovered in that room under a mat about 5 inches away from the wall. This strongly suggests the seed was transported to that location by the water flow, when the pigs or the room are being washed.

On August 25, 1986 the Health Physics staff monitored the entire Charmany Farms facilities, this included two Hall way drain traps for rooms 1239, 1235, 1238, and four man holes located on LW at Charmany Farms, but no seeds were found.

Conclusion, the seeds are most likely washed down the drain and are in the Madison sewerage system.

August 26, 1986

TO: Sue Engelhardt

FROM: A. BenZikri

On August 22, 1986 at 9:00 AM Leola DeKock and I monitored the following rooms & areas for the missing Ir-192 seeds at Charmany Farms. Total of 8 seeds were missing, the activity of each seed on August 22, 1986 is 0.571 mci.

Restricted Areas:

1. Pig Housings- Room #'s 1239, 1235, and 1238
2. Surgery Rooms- Room #'s 1050, 1236, and the Necropsy room
3. Storage Room- Room # 1151
4. Drains- Drains and drain traps in rooms 1239, 1235, 1238, 1050
5. All Hall ways between the above rooms

Unrestricted Areas

1. All lockers.
2. Men's wash room, 1110.
3. Women's wash room, 1103.
4. TV room, 1125.
5. Break room, 1139.
6. Pig's walk path from room 1050 to Necropsy room.
7. Foot bath water room, 1136.
8. Men restroom, 1205.
9. Women restroom, 1203.

Estimates of worst case exposures to individuals due to lost Ir-192 pellets--

A. A person fishing in Badfish Creek catches a fish that has swallowed a ribbon containing two of the pellets, puts the fish in a creel hanging at his side, and carries the fish around for three hours, then takes it home and cleans it. The fish waste stays in the trash for one week.

The gonad dose (D) to the individual while carrying and cleaning the fish would be:-

$$D = \frac{.1 \text{ mR m}^2/\text{hr}}{(.15\text{m} \times .15\text{m})} = 4.44 \text{ mR/hr} \times 3.2 \text{ hr} = 14.21 \text{ mR}$$

The dose received for the time spent near the garbage can would be:-

$$D = \frac{.8986 \text{ mR-m}^2/\text{hr}}{3\text{m} \times 3\text{m}} \times 1 \text{ hr} = .05 \text{ mR}$$

Giving a total dose of 14.3 mrem.

This of course is a ridiculous scenario^{as} to the fate of the lost pellets. A much more realistic one is that all seven pellets will settle somewhere in the sewage treatment facility. Workers will be exposed for 40 hours per week at an average distance of approximately 3 meters. The sources will be shielded by a minimum of 12 inches water equivalent.

$$D = \frac{.0718 \text{ mR-m}^2/\text{hr}}{(3\text{m} \times 3\text{m})} \times 1.44 \times 72.04 \times \frac{40}{168} \times 24$$

$$= 4.726 \text{ mR}$$

TABLE 1

Exposure rate (mR/hr at one meter)
caused by:

	1 mCi	1 Pellet	7 Pellets
Shielded by			
Unshielded	.4453	.2536	1.7767
6 inches water	.0880	.0502	.3511
12 inches water	.0180	.0103	.0718
6 inches dry soil	.1444	.0623	.5762
12 inches dry soil	.0482	.0275	.1923
12 inches sludge	.0262	.0149	.1045

We did not find the seeds in Badfish Creek, and could not expect ever to find them in the watershed using the methods we used. The only way to find the seeds would be to place a very sensitive underwater detector somewhere in the watercourse and find them as they pass. This is assuming they haven't already passed. On the other hand there is no radiation hazard present in the area we surveyed and no reason to think the seeds would pose a hazard if they were present.



University of Wisconsin-Madison

SAFETY IS OUR CONCERN...

SAFETY DEPARTMENT
317 N. Randall Avenue
MADISON, WISCONSIN 53715
608 262-8769 - 262-0667

Attachment F

26 September, 1986

Mr. James Mullauer
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL, 60137

Dear Mr. Mullauer,

On 25 September, 1986 the University Radiation Safety Committee met to discuss the Ir-192 incident and our proposed corrective action. Please see the attached minutes of that meeting. You also requested a copy of the URSC members and their areas of expertise. The list I sent is that for the members on the URSC at the time of the problem. Since then a new committee has been appointed, so some of the members on this list are no longer members. Finally, you requested the date that the Ir-192 protocol for Dr. Adams project was sent to all of the URSC members. I have enclosed the cover letter to this mailing for your convenience.

Sincerely,

Sue Engelhardt

Sue Engelhardt
Radiation Safety Officer

SEP 29 1986

UNIVERSITY OF WISCONSIN - MADISON

University Radiation Safety Committee
September 25, 1966

Minutes

Members Present: J. Tracy, chair, H. Attix, vice-chair, S. Engelhardt, M. Gould, R. Inman, F. Larson, R. Nickles, R. Radtke, E. Thomadsen

Guests of the Committee: F. Rice, J. Lorenz
Consultant: K. Irwin

The URSC was convened to discuss the incident in which seven Ir-192 seeds were lost at Charmany Farms and recommend corrective action. Kathleen Irwin, the University's attorney, summarized the enforcement conference at the NRC - Region III office in Glen Ellyn, Illinois. The enforcement conference was attended by Sue Engelhardt and Robert Radtke of the Safety Department, Herb Attix of the URSC, and Ms. Irwin.

H. Attix made and F. Larson seconded the following motion:

1. That the Health Physics staff start immediately categorizing Form 99 applications into those recognizable by the RSO as "routine renewals" or "other". The routine renewals would continue to be handled and approved as is now done. The "other", including all new applications and significant exceptions/amendments to current applications, be circulated with Health Physics staff recommendations to all URSC members, for consideration at the next URSC meeting.
2. That the URSC will meet often enough to handle the volume of paperwork and to avoid delaying important research.
3. That mail ballots be used, but sparingly, for cases judged to be urgent by the RSO or URSC chair.

4. That the URSC will "red-flag" cases that will require unusually intensive H.P staff participation.
5. That the URSC re-examine how this policy is working in January, 1987, and modify it if necessary.
6. That Ellis Seavey, Director of Animal Care for the Medical School and recently appointed as a URSC member, review all applications involving the use of radioactive material in animals. He will review and sign the animal use consent form (Form 99A).

The motion passed unanimously.

The Committee next considered William Adams' applications for authorization to possess and use radioactive material. Committee members agreed that had the applications been submitted to them before the loss of the sources, they would have approved the applications. However, in light of the incident, M. Gould moved that the URSC disapprove the applications and support the previous administrative revocation of Dr. Adams' authorization. F. Larson seconded the motion and it was approved unanimously.

UNIVERSITY RADIATION SAFETY COMMITTEE

James Tracy

Asst. Professor, Vet. Medicine, Rm. 3158 Vet. Medicine

F. Herb Attix

Professor, Medical Physics, Department Chairman, Rm. 1475
MSC

Bruce Thomadsen

Clinical Assoc. Professor, Radiophys & Medical Physics, Rm.
K4/B49 CSC

Myrwood Besozzi

Asst. Professor, Nuclear Medicine, Rm. H6/352 CSC

Robert Bremel

Professor, Dairy Science, Rm. 850 Animal Science

Paul DeLuca

Professor, Radiophys & Medical Physics-Health Physics, Rm.
1530 MSC

Michael Gould

Assoc. Professor, Rad Biology & Medical Physics, Rm. K4/332
CSC

Philip Helmke

Professor, Soil Science, Rm. 163A Soils

Frank Larson

Professor, Director of the Clinics, Rm. B4/251 CSC-
University Hospitals

Robert (Jerry) Nickles

Professor, Medical Physics & Radiology, Rm. 1530A MSC

William Vogelsang

Professor, Nuclear Engineering, Rm. 143 Mechanical Engr.

F

Robert Radtke
Director, Safety Dept., 317 N. Randall

Sue Engelhardt
Radiation Safety Officer, Safety Department, 317 N. Randall

September 10, 1986

TO: URSC Member

FROM: Sue Engelhardt

Re: Ir-192 Procedures

Attached is a complete description of Dr. W Adams' protocol of the Ir-192 seeds. This information is for you to review, and I will have an HP contact you about it after a few days. In addition, we will all have some background when this matter is brought up during the next URSC meeting. I will let you know the date of the meeting when it is announced.

thank you

INSPECTOR'S REPORT
Office of Inspection and Enforcement

Mullauer, James B.
REVIEWER
Sreniawski

INSPECTOR'S

LICENSEE/VENDOR	TRANSACTION TYPE	DOCKET NO. (8 digits) OR LICENSE NO. (10+7 digits)	REPORT NO.	SEQ.	MO	YR
<i>University of Wisconsin</i>	☒ I - INSERT ☐ M - MODIFY ☐ D - DELETE ☐ R - REPLACE	<i>03003465</i>	<i>816001</i>	<i>A</i>	<i>07</i>	<i>81</i>
<i>Madison, WI 53706</i>				<i>B</i>	<i>10</i>	<i>81</i>
				<i>C</i>		
				<i>D</i>		

PERIOD OF INVESTIGATION/INSPECTION	INSPECTION PERFORMED BY	ORGANIZATION CODE OF REGION/NO CONDUCTING ACTIVITY (SEE NRC 0530 "Mandowee" and "Woods" Mandowee Reporting - BY CODE)
FROM: MO <i>09</i> DAY <i>02</i> YR <i>86</i> TO: MO <i>09</i> DAY <i>19</i> YR <i>86</i>	☒ 1 - REGIONAL OFFICE STAFF ☐ 2 - RESIDENT INSPECTOR ☐ 3 - PERFORMANCE APPRAISAL TEAM OTHER	REGION <i>2</i> DIVISION <i>4</i> BRANCH <i>2</i>

REGIONAL ACTION (Check one box only)	TYPE OF ACTIVITY CONDUCTED (Check one box only)	14 - INQUIRY - NO A	15 - INVESTIGATION
☒ 1 - NRC FORM 581 ☐ 2 - REGIONAL OFFICE LETTER	☒ 02 - SAFETY - <i>fee</i> ☐ 03 - INCIDENT ☐ 04 - ENFORCEMENT ☐ 05 - MGMT. AUDIT ☒ 06 - MGMT. VISIT ☒ 07 - SPECIAL - <i>fee</i> ☐ 08 - VENDOR ☐ 09 - MAT. ACCT. ☐ 10 - PLANT SEC. ☐ 11 - INVENT. VER. ☐ 12 - SHIPMENT/EXPORT ☐ 13 - IMPORT		

INSPECTION INVESTIGATION FINDINGS (Check one box only)	TOTAL NUMBER OF VIOLATIONS AND DEVIATIONS	ENFORCEMENT CONFERENCE HELD	REPORT CONTAIN 2730 INFORMATION	LETTER OR REPORT TRANSMITTAL DATE
☒ 1 - CLEAR ☐ 2 - VIOLATION ☐ 3 - DEVIATION ☐ 4 - VIOLATION & DEVIATION	<i>03</i>	☒ 1 - YES	☐ 1 - YES	MO <i>10</i> DAY <i>06</i> YR <i>86</i>

MODULE INFORMATION													MODULE INFORMATION																								
REC ORD		MODULE NUMBER INSP					MODULE REQ. FOLLOWUP						REC ORD		MODULE NUMBER INSP					MODULE REQ. FOLLOWUP																	
TYPE	NUMBER	PHASE	MANUAL	CHAPTER	PROCEDURE	NUMBER	LEVEL	PRIORITY	DIRECT INSPECTION EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED	TO DATE	STATUS	TYPE	NUMBER	PHASE	MANUAL	CHAPTER	PROCEDURE	NUMBER	LEVEL	PRIORITY	DIRECT INSPECTION EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED	TO DATE	STATUS	PHASE	MANUAL	CHAPTER	PROCEDURE	NUMBER	LEVEL						
	5	3	0	7	0	3	B		0.02					5	9	2	7	0	3	B		0.0															
meeting														bulletin/IAL follow-up																							
	5	8	7	1	0	0			0.26	1	0	0	C		5	8	6	7	4	0	B		0														
materials inspection program														transportation																							
5 9 2 1 0 0 B														5 8 6 7 4 0 B																							
CANCELLED 4/1/85 independent inspection effort														10 CFR 61																							
5 9 2 1 0 0 B														5 8 4 8 5 0 B																							
follow-up Previous H/C														Rad. Protection																							

Office of Inspection and Enforcement

DOCKET NO 18-04-151 OR LICENSE
C 187 PRODUCT 1113-04-151

REPOB!

NO

MC

MODULE NUMBER	
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5, 8, 7, 2, 0, 0, 8

VIOLATION OF 18 USC 878

2414
25-03-00

VIOLATION OR DEVIATION is near up to 20 characters for each item. If the test records this number, it will be necessary to paraphrase. Limit lines to 30 characters each.

Nov, Item (1) 10C.F.R 20.201(b)(2)

INSPECTOR'S REPORT
(Continuation)

Office of Inspection and Enforcement

SOCKET NO. (8 digits) OR LICENSE NO. (8 digits) PRODUCT (12 digits)										REPORT NO.		MODULE NUMBER		DATE	
03403465										85001		587100B		10/10/71	
										A		VIOLATION OF SECURITY OR DEVIATION		DATE RELATED	
										B		1 2 3 4 5 6 7 8		10/10/71	
										C		X		10/10/71	
										D		X		10/10/71	

VIOLATION OR DELATION is near up to 2400 characters for each item. If the 11 exceeds this number, it will be necessary to purchase 1 and lines is 30 characters each.

Nov item 2 10CFR20.201(b)(1)

Office of Inspection and Enforcement

SOCKET NO. 00 (digital OR LICENSE) (00" PRODUCT) (13 digits)										REPAIR		MODULE NUMBER						DATE			
034034615										85001		B40		5871008						1971	
												A		INDICATION OF VOLTAGE ON OR OFF						DATE RELATED	
												B		1 2 3 4 5 6 0						A C	
												C		X K						X K	
												D									

VIOLATION OR DEVIATION of not up to 2400 characters key down them. If the total exceeds this number, it will be necessary to paraphrase. Limit line s to 30 characters each.

Ver Item 3: 10 CFR 20.203(a)