MILWAUKEE COUNTY
medical complex

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-5936

M. Julie Hanser
Hospital Administrator

December 18, 1990

U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Control Number 90311

Gentlemen:

The following are our responses to each specific violation contained in your "Notice of Violations" dated November 23, 1990:

A. Reference: 10 CFR 20.105(b)

An amendment pursuant to 10 CFR 20.105(a) has been submitted to the materials licensing section to permit levels of radiation in unrestricted areas in excess of levels permitted in 10 CFR 20.105(b). This request is part of an amendment request (Control No. 90311) for authorization for use of the Selectron Afterloading Unit. This amendment request is still in process.

B. Reference: 10 CFR 10.201(b)

1. In the future, radiation surveys will be recorded on the attached form. (Attachment 1) All areas where measurements are to be made are identified on the form.

2. In the future, a radiation survey will be performed at the time of implant.

C. Reference: License Condition No. 28 Item application dated May 29, 1985.

Inventory control forms have been revised to elicit all required information. To insure that these records are completed and in compliance with our license condition, these inventory records will be reviewed quarterly. (Attachment 2)

D. Reference: License Condition No. 28 Item 7-Application dated May 29, 1985.

Inventories of all non-sealed radioactive materials will be documented weekly showing the amount of material possessed by each authorized user. Also shown will be the user's total possession limit, and the individual approving the order will use this information to verify that the amount ordered is within the authorized user's possession limit. A rubber stamp (Attachment 3 shows the information included on this stamp) has been prepared which will be used on purchase order requisitions to identify the individual's total possession limit and activity on hand. The allowable activity and activity ordered will then be compared. The individual approving the order will enter the date and initials.

E. Reference: License Condition No. 28 Item 2-Letter dated January 15, 1987.

The Radiation Safety Committee's procedures for reviewing the training and experience of individuals requesting authorized user status have been revised. The training and experience form individuals fill out when requesting authorization has been revised to elicit more detailed information. Attachment 4 is the revised application form and contains the revised training and experience form. In addition, a work sheet has been prepared to help individuals without formal training identify all previous training that they may have received. (Attachment 5)

F. Reference: License: 10 CFR 33.13(c)

All authorized users have been directed to provide instructions and training to new employees or others working in their laboratories. In order to facilitate this, a checklist of topics to be covered has been developed. A short quiz has been developed which will be used to document that this training has been given. (Attachment 6)

The graduate student identified as having received no training with regard to proper survey and monitoring requirements was interviewed by Standard Nuclear Consultants. They state, "during our visit to the research labs, I interviewed (on November 2, 1990) the graduate student who had been questioned by the NRC inspector. The graduate student seemed to be very timid and he told me that he had indeed been instructed by the user in the laboratory concerning radiation safety requirements".

G. Reference: License Condition No. 28 Item 17-Application dated May 29, 1985.

In the future, surveys as required will be performed at the specified frequencies. A schedule has been established for the Radiation Safety Office to verify compliance.

H. Reference: 10 CFR 30.34(c)

A license amendment requesting authorization to use this device has been filed (Control No. 90311) and is in process at this time.

Nuclear Corporation Model 4000 Remote Afterloader Branchytherapy device has never been used with iridium-192 for intracavitary treatments of cancer. See letter dated December 5, 1990 from Michael T. Gillin, Ph.D., Associate Professor of Radiation Oncology. (Attachment 7)

I. Reference: License Condition No. 28 Item 23-Application dated May 29, 1985.

To insure that required bioassays will be performed in the future, I-125 to be used for radioiodination will be kept by the Radiation Safety Office until the procedure is to be performed. The material will then be given to the authorized user and a prelabeling bioassay will be performed. An appointment for the postlabeling bioassay will be scheduled. If the user fails to keep his/her appointment, he/she will be contacted and instructed on the need for the policy. Corrective action will occur if users do not follow the appropriate procedure.

J. Reference: License Condition No. 28 Item 10-Application dated May 29, 1985.

Dose calibrator reference source checks will be performed on commonly used radionuclide settings at least weekly. The revised form for this test is attached. (Attachment 8)

K. Reference: License Condition No. 28 Item 15 dated May 29, 1985.

The requirement that eating, drinking or storage of food or beverages is prohibited in laboratories using radioactive materials has been emphasized to all authorized users. Compliance with the requirement is being monitored during the quarterly audits conducted by the Radiation Safety Office.

L. Reference: 10 CFR 20.401(b)

1. Any individual who fails to submit his/her assigned personnel dosimeter will be required to reply in writing concerning the reasons for the unreturned dosimeter. The attached form will be used to obtain this information. (Attachment 9) The employee will be asked for a statement of estimated exposure during the time period, and to identify any unusual circumstances, vacation, etc. An estimate will then be calculated based on past exposure history and this information will be submitted to the personnel dosimeter supplier.

2. Sink disposal logs are available in all laboratories and authorized users have been directed to record materials disposed into the sanitary sewage system.

M. Reference: License Condition No. 28 Item 17-Application dated May 29, 1985.

Quarterly audits of all active research laboratories are being performed by the Radiation Safety Office. The attached audit form is being used for the quarterly audits. (Attachment 10) A lab audit report will be made quarterly to the Radiation Safety Committee. This report will include the number of audits performed, the results of the audit and the identity of any individual who does not comply with the radiation safety requirements.

Response to areas of concern:

1. Reference: Radiation Safety Office staffing level.

A decision has been reached by the institutions to increase the number of staff and to hire a full-time Radiation Safety Officer and one additional technician. Recruitment for these positions is underway.

2. Reference: "Semi-Broadscope" Authorization

The Radiation Safety Committee has revised the approval categories and will only approve those types and quantities of use of radioactive material as requested by the authorized user. The revised application is included as Attachment 4.

3. Reference: Documentation of Survey Instrument Calibration

A standard operating procedure for calibration of survey instruments has been written. (Attachment 11)

4. Reference: Brachytherapy Storage Safe

   Access to the source storage area has been restricted. In addition, a storage container has been ordered for installation in the brachytherapy storage room which will allow immediate locking of sources upon return to the room.

5. Reference: Inadequate communication between the user physician and the Radiation Safety Office to insure accountability of brachytherapy sources.

   Efforts have been and will continue to be made to maintain and enhance this communication to insure accountability of all brachytherapy sources.

As you can see by the report of Standard Nuclear Consultants and the changes described above, the violations identified by the inspectors have been corrected. We are committed to providing the management control and detailed reports necessary to meet the Nuclear Regulatory Commission's requirements. Enclosed is a check in the amount of $3,750 for the penalty imposed on the Milwaukee County Medical Complex as a result of the violations. If you wish additional information or clarification of any statements in this report, please contact my office at 414-257-5936.

Sincerely,

Julie Hanser

Julie Hanser, FACHE
Hospital Administrator

JH/nh

Attachments

(Attachment 1)

Radiation Safety Office Survey Form

BRACHYTHERAPY ROOM SURVEY FORM

Date: _____ Patient Name: _____ Room 4179 SW

RAM: _____ mg.Ra.Eq. mCi : _____ Type of Implant: _____

Room implant performed: _____ Time of implant: _____ Time patient returned to room: _____

Estimated duration of implant: _____ Date of removal: _____ Time of removal: _____ Duration (hours): _____

Radiation Oncologist: _____ Resident: _____ Physicist: _____

Check List

_____ 1. Check out key for interstitial space from Plant Operations, room 1317 (1 East).
_____ 2. Sign on door.
_____ 3. Lead pig in room.
_____ 4. Survey meter in room.
_____ 5. Source Count form completed.
_____ 6. Lead shield in position.
_____ 7. Nursing Instructions in chart.

Room Survey

Survey the room with an ionization chamber. Unless otherwise indicated, measurements will be at waist level and 15 inches from walls. Prior to use verify the battery check and document check source.

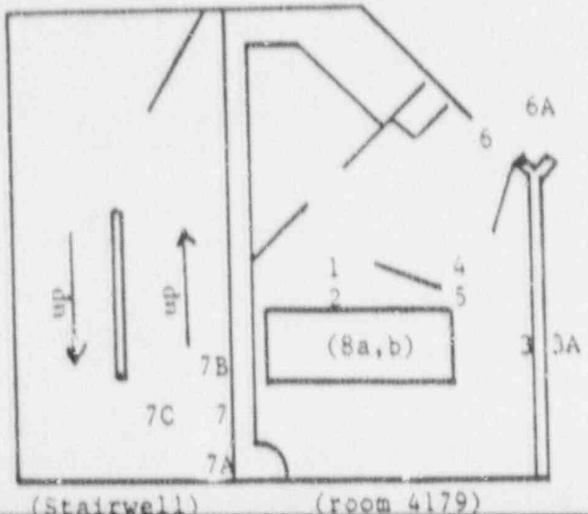
Survey instrument: _____ Check Source _____mR/hr.

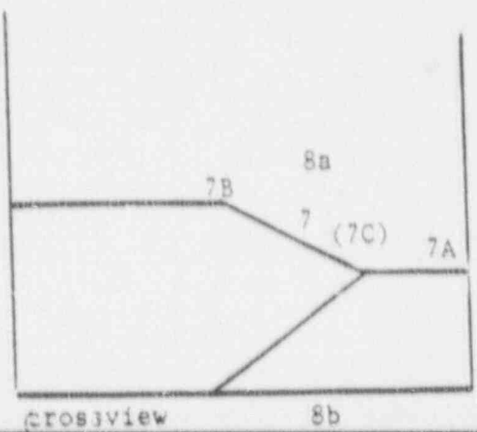
Location	Reading mR/hr	Location	Reading mR/hr
1. 1 meter from patient	_____	6. Doorway-door closed	_____
2. Bedside	_____	7. Stairwell	_____
3. At wall in room	_____	8. Interstitial space:	
4. Above bedside shield	_____	a. above room	_____
5. Behind bedside shield	_____	b. below room	_____

Measurements are to be taken at the following locations if adjacent areas are greater than 2.0 mR/hr (e.g. if station 3. is 3.4mR/hr then station 3A. would be monitored).

3A. Room 4181	_____	7B. Stairwell	_____
6A. Hallway	_____	7C. Stairwell	_____
7A. Stairwell	_____		

Each of the above unrestricted areas with a radiation measurement greater than 2 mR/hr the area shall be restricted. Radiation caution signs shall posted. If radiation levels are greater than 2 mR/hr in the adjacent room, no patient will be allowed to use the room.





(Attachment 2)

Iridium-192 Inventory

Radiation Oncology faculty, residents, physics staff and certain members of the Radiaiton Safety Office are permitted to handle Iridium-192 sources. A current list of Radiation Oncology users is kept in the Radiation Safety Office.

Today's Date:_____ MCMC Release #:_____

& Color of Ribbons:_____

of Seeds/Ribbon:_____

Manufacturer's Calibration and Date:_____

2nd and 3rd Cal and Colors (if needed):_____

Implant

Date and Time of Removal from Storeroom:_____

Patient Name and Room #:_____

Procedure:_____

# of Ribbons Removed from Storage:_____

# of Seeds and Activity Removed from Storage:_____

and Activity of Seeds left in Container:_____

Signature:_____

Return to Storage

Date and Time:_____

Patient Name and Room #:_____

# of Ribbons Returned:_____

# of Seeds and Activity Returned:_____

Total # of Seeds and Activity after Return:_____

Signature:_____

(Attachment 3)

POSSESSION LIMIT :_____
ACTIVITY ON HAND :_____
MAX ORDER ALLOWED :_____
ACTIVITY ORDERED :_____
RS OFFICE APPROVAL :_____ : / /

(Attachment 4)

APPLICATION FOR USE OF RADIOACTIVE MATERIALS

Date: _____

Applicant: _____

Title: _____ Application Type (check appropriate)

Department: _____ New___ Renewal___ Amendment___

Office

Room no.: _____

Phone no.: _____

Laboratory

Manager: _____

Room no(s): _____

Phone no(s): _____

Please complete the application in its entirety. Please submit only typed supporting paperwork. Attach supporting paperwork to the application. Send the completed application to the Radiation Safety Office, MCMC, Box 193. If you have any questions concerning the application, please contact the Radiation Safety Office at 257-5381.

Part 1: Categories of Use

Check all categories that pertain to this application and specify the radionuclides to be used.

Category of Use	Radionuclides to be Used
___ R1. ***Radioimmunoassay:*** procedures using prepackaged units of radioactive materials in accordance with 10CFR31.11.	_____
___ B1. ***Low Energy Beta:*** involves procedures using beta emitters of E_{max} of less than 500 keV.	_____
___ B2. ***High energy beta emitters:*** involves procedures using beta emitters of E_{max} of greater than 500 keV and positron emitters.	_____
___ G1. ***Low energy gamma emitters:*** involves procedures using gamma emitters of energies less than 50 keV *NOTE: This does not include unbound I-12.*	_____
___ G2. ***High energy gamma emitters:*** involves procedures using gamma emitters of energies greater than 50 keV. *NOTE: This does not include unbound I-123 or I-131*	_____
___ G3. ***Radioiodination:*** radioiodination labeling with unbound I-123, I-125 or I-131.	_____
___ S1. ***Sealed Sources:*** involves use of Cs-137 and Co-60 irradiators.	_____
___ S2. ***X-ray Generating Equipment:*** includes radiographic, fluoroscopic, x-ray diffraction units and electron microscopes	_____

Part 2: Education and Experience

The Nuclear Regulatory Commission regulations (Title 10, Chapter 1, part 33.15) stipulate that "material will be used only by, or under the direct supervision of, individuals who have received: (1) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and (2) at least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and the biological hazards of exposure to radiation appropriate to the type and forms of material to be used...".

Check one: ____I have required training and experience.
____I do not have required training and experience.

Submit a completed *Training and Experience form*(attached) for requesting applicant and each radiolabeler, in category G3.

Part 3: Use of Ionizing Radiation

For each radionuclide which will be used describe (1) the proposed use, (2) the laboratory methods to be employed, (3) the maximum activity in process at one time (i.e. the activity to be ordered, the activity drawn from stock solution per use), and (4) the total possession limit desired for each radionuclide.

Part 4: Facilities

Attach a drawing of your laboratory floor plans identifying work and storage areas, shielding materials and equipment. If your laboratory is shared with another faculty member(s), please submit a letter from each acknowledging their awareness of your proposal to use ionizing radiation in the shared facility.

Part 5: Waste Disposal

Describe the type and volume of radioactive waste generated from your use. State your proposed methods of disposal.

Part 6: Contamination Control

Describe the type(s) of surveys performed, frequency and areas.

Part 7: Certification

I certify that the information in this application is complete and correct to the best of my knowledge. I agree to abide by all the regulations and guidelines regarding the use of radiation as set forth by the Nuclear Regulatory Commission, State of Wisconsin and the institutional Radiation Safety Committee.

_____ _____
Applicant's Signature Date

RSC Comments/Action

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIOLABELER.

Name: _____ *Check appropriate*
Date: _____ Authorized User____
Radiolabeler____

EDUCATION

School	Major	Degree	Year Graduate
Undergraduate			
Graduate/Medical			

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING

Location	Course Title	Dates From - To	Lecture/ Laboratory Courses *(Hours)*	Supervised Laboratory Experience *(Hours)*
	Safe Handling of Radioactive Materials			
	Characteristics of Ionizing Radiation			
	Units of Radiation Dose and Quantities			
	Radiation Detection Instrumentation			
	Biological Hazards of Exposure to Radiation			

EXPERIENCE WITH RADIOACTIVE MATERIALS

Radio-nuclide	Maximum Activity	Location of Use	Dates From	To	Type of Use

RADIOACTIVE MATERIAL USE IN ANIMALS

RSO USE
Metabolic cages _____
Incineration _____

Date_____
Authorized User of
Radioactive Material:_____

New Application_____ Amendment to previously approved protocol_____

This form is to be submitted for *each separate* animal use or if there is a change in previously authorized procedures.

Protocol

a. Title:_____ _____
_____
_____

b. ARC Project #_____

c. Principal Investigator:_____

Procedure

a. Type(s) of animals to be used:

b. Radioactive materials and chemical forms to be administered:

c. Proposed dosage schedule:
Include activity per administration, number of administrations per study and method of administration.

d. Duration of program:
Number of animals and time period.

e. Location(s) where project will be performed:

f. Animal Disposition:
check all appropriate conditions
___ Animal returned to ARC after administration of Radioactive material
___ Sacrificed during experiment
___ Sacrificed immediately after experimant
___ Sacrifice delayed after experiment
___ animal returned to ARC after the experiment

Project Description

Provide a brief description of the proposed project. If more space is needed, attach pages to the application.

Training and Experience Work Sheet and Instruction

A MCW faculty member can be authorized to use radioactivity if he/she received:

1. A college degree at the bachelor level or equivalent training and experience in the physical or biological science or in engineering, and
2. At least 40 hours of training and experience in:

   i) the safe handling of radioactive materials
   ii) the characteristics of ionizing radiation
   iii) units of radiation dose and quantities
   iv) radiation detection instrumentation
   v) biological hazards of exposure to radiation appropriate to the type and forms of byproduct (radioactive) materials to be used.

Training

For those individuals who have had a course(s) or portion of a course which dealt with the above subject material, please indicate the course title(s), institution(s) or organization(s) where this training was received on the Training and Experience Form. Also indicate the total number of hours of lecture, lab and study you may have devoted to this training.

For those individuals who have not had a formal course(s), please review the following outline. In all likelihood at some time in your academic career you have had a formal lecture(s) which touched on some of the topics listed under the five subheadings. Estimate the total hours of lecture, lab and study you devoted to these topics in the blanks on the worksheet. Enter the total hours on the Training and Experience Form and attach the worksheet to your application.

Experience

Enter the length of time you have worked with radioactive material, the institution, the activity handled and type of materials. If you received on-the-job instruction, indicate which institution, the date and the name(s) of the individual(s) who provided the training. On the job training and work experience can be used in lieu of formal classroom training but the length and type of experience hours should be clearly stated.

I. Safe Handling of Radioactive Material — Hours

A. Remote Handling Devices and Their Application ____
   1. Tongs, cap removers
   2. Bulb pipettes

B. Shielding and Its Uses ____
   1. Lead - Gamma and X-Rays
      a. Aprons, bricks, L-blocks, head foils
      b. Relationship between energy and shield thickness
   2. Plastic - Beta Ray
   3. Other shielding materials

C. Inverse Square Law ____

D. Protective Clothing and Proper Use ____

E. Contamination Control ____
   1. Monitoring procedures and instrumentation
   2. Decontamination of laboratory surfaces
   3. Decontamination of skin

F. Emergency Procedure for Major and Minor Spills ____
   1. Restriction
   2. Call lists of individuals to contact
   3. Decontamination procedures

G. Recommended Laboratory Facilities ____
   1. Ventilation, air flows through hoods
   2. Storage cabinets
   3. Laboratory surfaces
   4. Glass vs. plastic containers

H. Common Sense Laboratory Rule ____
   1. Cleanliness
   2. No Smoking
   3. No Eating
   4. Signage; Caution in Radioactive Material, Radiation Area

II. Characteristics of Ionizing Radiation — Hours

A. Structure of the Atom ____
   1. Bohr's Model
   2. Atomic Component (proton, neutron, electron)
   3. Terminology (nuclides, isobars, isotopes, etc.)
   4. Periodic Table

B. Ionizing Radiation (Directly vs. Indirectly Ionizing) ____
   1. Alpha rays
   2. Beta rays
   3. Gamma rays
   4. X-rays
   5. Neutrons
   6. Protons

C. Interaction of Ionizing Radiation with Matter ____
   1. Heavy Charged Particle, Alpha's Protons
      a. Range, straggling
      b. Linear Energy Transfer (LET)
   2. Beta Rays
      a. Range vs. energy
      b. Generation of x-ray
      c. Difference between high and low energy betas
   3. X and Gamma Rays
      a. Photoelectric
      b. Compton (Incoherent) Scattering
      c. Pair production
      d. Attenuation - half value layer
   4. Neutrons
      a. Scattering
      b. Capture

D. Radioactive Decay Moles, Transitions and Emissions ____
   1. Alpha
   2. Beta and Positron
   3. Gamma Emission and Isometric Transition
   4. Electron Capture
   5. Internal Conversion
   6. K Fluorescent X-ray
   7. Auger Electron

E. Mathematics of Radioactive Decay ____
   1. Exponential Equation
   2. Linear vs. Semilog Plots of Activity vs. Time
   3. Activity
   4. Decay Constant
   5. Half-life

F. Sources of Radioactive Materials ____
   1. Natural
   2. Reactor
      a. Neutron Activation
      b. Nuclear Fission
   3. Accelerators

III. Radiation Quantities and Units Hours

A. Exposure ____
   1. Roentgen - Definition
   2. Air Ionization Chambers
   3. Pocket Chambers

B. Absorbed Dose ____
   1. Rad and Gray - Definition
   2. Calorimetry
   3. Relationship between exposure and dose
      a. 'F' Factors
      b. Bragg-Gray Theory

C. Dose Equivalent ____
   1. Rem and Sievert
   2. Relative Biological Effect
   3. Quality Factors and LET

D. Activity ____
   1. Curie and Becquerel
   2. Disintegration rate vs. count rate

E. Maximum Permissible Doses (MPD) ____
   1. Occupational vs. General Public
   2. Whole Body, Eyes, Gonads
   3. Skin
   4. Extremities

F. ALARA in Medical Institutions ____

G. Sources of Population Exposure ____
   1. Cosmic, Terrestrial, Internal
   2. Radon
   3. Consumer Products
   4. Medical Sources
   5. Occupational Exposure
   6. Nuclear Power

IV. Radiation Detection Instrumentation — Hours

A. Gas Detectors ____
   1. Ionization Chamber
      a. Survey Instrument
      b. Pocket Chambers
      c. Dosimeters
   2. Proportionate Counter
   3. Geiger-Mueller Counter

B. Scintillation Detectors ____
   1. Organic, Plastic
   2. Inorganic - NaI (TL)
      a. Photomultiplier tube operation
      b. Pulse Shaping
      c. Pulse Counting
   3. Liquid
      a. Solvents Solutes
      b. Light Collection
      c. Coincidence Counting
      d. Quenching and Correction
      e. Double Label Counting

C. Gamma Ray Spectrometry - Multichannel Analyzer ____

D. Film Badge ____

E. Thermoluminescent Dosimeters ____
   1. Lithium Fluoride
   2. Calcium Fluoride
   3. Lithium Borate

V. Biological Hazards of Exposure to Radiation Hours

A. Mammalian Cell Radiobiology
   1. Radiation Chemistry
   2. Effect of Radiation
      a. DNA
      b. Macromolecules
      c. Chromosomes
   3. Mechanism of Radiation Cell Killing
   4. Cell Survival Curve

B. Physical and Biological modifiers of Radiosensitivity
   1. Oxygen Effect
   2. LET and RBE
   3. Cell Cycle Effect
   4. Dose Rate Effects
   5. Repair Mechanisms
   6. Radiation Sensitizers and Protectors

C. Normal Tissue Radiobiology
   1. Acute and Late Effects of Radiation
      a. Normal Tissue
      b. Whole Body
      c. Specific Organs (eye, blood, gonads, etc.)
   2. Radiation Accident Management
      a. Blood Counts
      b. Antibiotic therapy
      c. Bone Marrow Replacement

D. Effects of Fetal Irradiation
   1. Carcinogensis
   2. Physical Defects
   3. Mental Retardation

E. Radiation Mutagenesis and Carcinogenesis

F. Radiation Protection
   1. Radiation Risk Estimate
   2. Occupational Exposure Standards
   3. Population Exposure Standards
   4. Source of Background Radiation Exposure

(Attachment 6)

RADIATION SAFETY
INSTRUCTION AND TRAINING CHECKLIST

All individuals working with radioactive materials are to be instructed in the safe handling, use, storage and disposal of such materials. Additionally, individuals frequenting areas where the radioactive materials are used or stored are to be instructed in the type of use and locations of storage. It is the responsibility of every Authorized User of radioactive materials to ensure that all personnel working under his/her supervision or working in areas user his/her authority where radioactive materials are used of stored have been instructed and trained as appropriate. Please refer to the checklist provided below for a list of subjects to be covered.

Individual's Name: _____ *Please Print*

Position Type *(check one)*

Department: _____ Permanent____

Authorized User: _____ Temporary____

Position: _____ If temp, how long?_____

Date of Training: _____

Start Date: _____

Supervisor's Name: _____

Trainer's Name:

____ Individual frequents area where radioactive materials are used or stored.
____ Individual works with radioactive materials.

TOPICS

List of topics for all individuals

____ Type of radioactive materials used.
____ Location where the radioactive materials are used and stored.
____ NRC Regulations - read NRC Form 3, *Notice to Employees.*
____ The general contents of the Radiation Safety Manual.
____ The identity and phone number of the Radiation Safety Officer.
____ Emergency procedures.

List of topics for all individuals working with radioactive materials.

____ List of authorized radionuclides.
____ Authorized possession limits for the radioactive materials.
____ Laboratory/work areas to be surveyed.
____ Frequency and type of surveys to be conducted.
____ Use of survey meters.
____ Corrective action for contamination.
____ Personnel monitoring requirements.
____ Authorized waste disposal procedures.
____ Authorized animal use (if any).
____ Bioassay requirements (if any).
____ Personnel monitoring requirements.
____ Prenatal Radiation Exposure Instructions *(NRC Regulatory Guide 8.13).*

This is to confirm that I have received training in and understand the above described areas of radiation safety.

_____ _____

Trainee's signature Date Supervisor's signature Date

The original is to be retained by authorized user for review by the RSO. A copy of this is to be sent to the Radiation Safety Office as soon as instructions are completed.

(Attachment 6)

Radiation Safety

QUIZ FOR NEW EMPLOYEES

Individual's Name: _____ *Please Print*

Department: _____

Authorized User: _____

Position: _____

Date of Training: _____

Position Type *(check one)*

Permanent____

Temporary____

If temp, how long?_____

(check appropriate)

____ I frequent area where radioactive materials are used or stored.
____ I work with radioactive materials.

QUIZ

1. Who instructed you in the radiation safety procedures and requirements to be followed in the laboratory? _____

2. What radioisotopes will you be expected to use?_____

3. Radioactive materials should never be poured down the sink? T F

4. I must wear a personnel dosimeter each time I handle radioactive material? T F

5. If you anwsered F to question 4, please explain._____
_____
_____
_____

6. The only type of contamination surveys required to be recorded are wipe test results? T F

7. Who is the Authorized User in your laboratory? _____

8. Where are the emergency procedures posted in your laboratory?
_____

9. What is the date on the NRC form 3 posted in your laboratory? *(Date is located in the lower left hand corner of the form)*

10. What is the telephone number of the Radiation Safety Office?

(Attachment 7)

MEDICAL COLLEGE OF WISCONSIN

12/5/90

J. Frank Wilson, M.D., FACR
Chairman

Roger W. Byhardt, M.D.
Beth A. Erickson, M.D.
Maurice Greenberg, M.D., FACR
Nora A. Janjan, M.D.
Colleen A. Lawton, M.D.
Kevin J. Murray, M.D.
Laird E. Olson, M.D.
Christopher C. Schultz, M.D.

Medical Radiation Physics
Michael T. Gillin, Ph.D.
Daniel F. Grimm, M.S.
Darwin L. Zellmer, Ph.D.

Radiation Biology
John E. Moulder, Ph.D.

Department of Radiation Oncology

Radiation Safety Office
Milwaukee County Medical Complex
Attn: Charles Wilson, PhD

Dear Chuck,

In their correspondence of November 23, 1990, the U.S. Nuclear Regulatory Commission in section H of the Notice of Violation and Proposed Imposition of Civil Penalty states that "the licensee purchased and, on several occasions from 1987 through mid-1990, used Ir-192 as sealed sources in a Nucletron Corporation Model 4000 remote afterloader brachytherapy device for intravcavitaty treatment of cancer." The Department of Radiation Oncology denies that such actions ever took place. The Department has used this device for interstitial and intraluminal procedures, but never for intracavitary procedures.

Perhaps the most comprehensive definition of intracavitary brachytherapy can be found in Physical Aspects of Brachytherapy by T..J. Godden, which is published by Adam Hilger. Chapter 7 of this text states the following:

> Intracavitary brachytherapy, as the name implies, involves the insertion of radioactive sources into natural body cavities. Over the years various lesions in sites such as bladder, anus, rectum, antrum, oesophagus, nasopharynx and auditory tube have been treated in this way. The most widespread use of this form of therapy, however, has been in the treatment of gynaecological malignancies. In the treatment of carcinoma of the uterus and uterine cervix the sources, in suitable containers, are inserted directly into the vagina and the uterus....

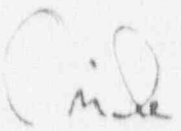
Milwaukee County Medical Complex
8700 West Wisconsin Avenue
Milwaukee, Wisconsin 53226
(414) 257-5636

ICRU Report 38, Dose and Volume Specification for Reporting Intracavitary Therapy in Gynecology, can also be cited to support the position that intracavitary refers primarily to gynecologic work.

In any case, the Department has not performed any intracavitary procedure, as defined above, with Ir-192 sources. The Department views any restriction that limits the use of Ir-192 sources to interstitial therapy only as unduely restrictive and not in the interest of good medical care or radiation safety. (Why use an isotope with limited physical lengths and more penetrating gamma rays, Cs-137, when other isotopes with adjustable lengths and less penetrating gamma rays, e.g. Ir-192, are available?) In a separate correspondence to you, the Department will request a license amendment to a more flexible position, which reflects comtemporary practice. Sealed source brachytherapy includes intracavitary, interstitial, intraluminal, and mold techniques. If it is necessary to explicitly state each isotope and each use, then the Department is anxious to work with Radiation Safety Personnel to create such a document.

Thank you for your consideration of this. Additional information will be supplied, if requested.

Sincerely,



Michael T. Gillin, PhD
Associate Professor
Radiation Oncology

cc: J. Frank Wilson, MD

(Attachment 8)

MULTI-ISOTOPE CONSTANCY VERIFICATION FOR MCMC RADIONUCLIDE DOSE CALIBRATOR

DIRECTIONS: PLACE THE CO-57 REFERENCE SOURCE IN THE DOSE CALIBRATOR
AND RECORD THE READING FOR EACH OF THE PREASSIGNED RADIONUCLIDE KEYS

TUESDAY	Tc99m	Xe133	I-131	I-123	Ga-67	Tl201	In111	Mo-99	Initials
10/09/90	4.85	2.91	3.20	2.06	4.35	2.79	1.91	24.62	K O
10/16/90	4.73	2.85	3.12	2.02	4.24	2.73	1.87	24.01	K O
10/23/90	4.64	2.79	3.07	1.99	4.17	2.67	1.83	23.64	K.O
10/30/90	4.54	2.73	3.00	1.94	4.06	2.62	1.79	23.11	K.O
11/06/90	4.45	2.69	2.94	1.90	3.99	2.57	1.76	22.64	K.O/E.G
11/13/90	4.394	2.646	2.912	1.877	3.950	2.541	1.758	22.39	KS/AP
11/20/90	4.31	2.59	2.85	1.84	3.86	2.48	1.70	21.89	K O
11/27/90	4.23	2.55	2.79	1.80	3.79	2.44	1.67	21.75	E.G
12/04/90									
12/11/90									
12/18/90									
12/25/90									
1/01/91									
1/08/91									
1/15/91									
1/22/91									
1/29/91									
2/05/91									
2/12/91									
2/19/91									
2/26/91									
3/05/91									
3/12/91									
3/19/91									
3/26/91									

DWP File: manyisot

(Attachment 9)

Radiation Safety Office
INTER-OFFICE COMMUNICATION

Date :

To : {1}

From : Robert Yoss, Radiation Safety Coordinator

Subject: Unreturned Personnel Dosimeters

Your personnel dosimeter; issued to you at {2}, in series {3}, of the {4} type, number {5}, dated {6} was not returned within the allotted time. If the badge is in your possession, please return it to the Radiation Safety Office at once. If your dosimeter has been lost or damaged, notify the Radiation Safety Office. An estimate of your occupational exposure will be made based on the information supplied below and previous occupational exposure. In order to assist us, please provide the following information:

You are an important person within this department. We are concerned with your safety; therefore it is vital that you understand the importance of returning in a timely manner and properly using assigned dosimeters. Repeated failure to comply with rules and guidelines for radiation dosimetry will result in a written reprimand placed in your file. Persistent noncompliance will be cause for further review and possible disciplinary action.

1. My dosimeter was lost_____damaged____.

2. Please briefly explain the details of answer 1.

3. Did you work with radioactive materials during the time period?
   Yes No

4. If you answered "yes" to the question above, please provide the following additional information:

   a. Was your use or exposure similar to that of the preceding month(s)? Yes No

   b. If use was different from the preceding month(s), identify the materials you used, the specific use, and the amount of material(s) used:

   c. Estimate your exposure in mrem; if you cannot make this estimation, call the Radiation Safety Officer (5381).
   _____ mrems

_____ _____
Signature of badge holder Date

COMPLETE AND RETURN THIS MEMO <u>WITHIN 5 DAYS</u> TO:
Radiation Safety Office
MCMC/Box 193

(Attachment 10)

Laboratory Audit 1991

Lab Room No.: _____

Auth. User: _____ Categories: _____

Lab Manager: _____ Authorization Expiration:

RESTRICTIONS: _____

CONDITION: _____

		Calendar Quarter 1	2	3	4
1. Date					
Surveyor					
2. Person(s) interviewed					
3. Active Use	Yes				
	No				

RECORD KEEPING

4. Lab Surveys Performed					
a. as required/on time	Wipe				
	G-M				
b. recorded properly	Wipe				
	G-M				
c. contaminated areas cleaned and retested					
d. floor plan current					
5. Quarterly inventory returned					
6. Dosimeters returned on time					
7. Sink disposal log current					
8. New worker training documented					

LABORATORY POSTINGS

Check to ensure postings are current, legible and in good shape

9. NRC Form 3 & Notice to Employees-current					
10. Caution Radiation Signs					
a. doors					
b. work areas					
c. sinks					
d. containers					
e. "cold zones"					
f. emergency procedures					
11. Laboratory Appearance					
a. food and drink in area					

RADIATION SAFETY SURVEY

12. Radiation Safety Survey	G-M				
vial number(s)					

COMMENTS ON REVERSE SIDE OF THIS FORM

(Attachment 11)

Policy and Procedure

CALIBRATION OF SURVEY METERS

Purpose

-To maintain consistent methodology is the calibration of equipment.
-To ensure accurate measurements in the detection of radiation.

Policy

NRC "Application for Materials License-Medical" *(NRC Form 313M)*, dated May 29,1985, item 10A states the method and procedure for the calibration of survey meters. The calibration shall be performed so that each scale is calibrated at 2 points (approximately one-third and two-thirds full scale) by placing the instrument in a known radiation field. The instrument's reading will be adjusted to within ± 10 percent of the expected dose rate. Instruments that cannot be adjusted to agree within ± 10 percent, but which do not deviate more than ± 20 percent, will not be provided a calibration certificate. Instruments which read only in cpm will be provided a graph or table to relate cpm readings to exposure rate. Scales greater than 500 mR/hr will not be calibrated but will be checked to verify operation. The frequency of the calibration shall be at least annually and after servicing. The sources to be used for the calibration are sealed cesium-137 sources in various activities that are available to produce radiation fields with known exposure rates. All sources used will be intercompared with a cesium-137 sealed source equivalent to approximately 14 milligrams of radium. The facilities the calibrations are performed in Room 363, located on the 3M wing in the Medical Physics Section and room 37-8 in the Radiation Oncology Department. While calibrations are being performed, sources are placed in a lead cylindrical container, approximately 12 inches high and 9 inches wide, for short-term storage, the source holder is slid into its bottom-most position and locked into place. In this position, a minimum of approximately 3 inches of lead surrounds the source in all directions with the exception of the vertical direction. For long-term storage, the sources are kept in Room 37-8.
A facsimile of the calibration certificate used is attached.

Procedure

1. **Determine the activity of cesium-137 needed to perform the calibrations.** Consideration should be given to the *distance from the source for the required readings.* Too short of a distance allows for higher probability for error. Too long of a distance allows for the possibility of high radiation readings in unrestricted areas. Generally the geiger-mueller meters can be calibrated with a 1 (one) mg. Ra. eq. source (approximately 2.5 mCi). The ionization chambers require a larger source because of the higher scales. The highest reading is approximately 750 mR/hr. Use of the 3 25 mg. Ra. eq. sources allows great enough distance that measurements can be made quickly and accurately.

2. **Intercompare the sources to be used for the calibration with the NBS traceable standard.** The NBS traceable source is a nominal 15 mg. Ra. Eq. capsule, serial number 2021. The calibrator settings are: isotope-other, calibration (potentiometer)- 220 and range setting is dependent on activities. Record readings for all sources used. Note the activities are in millicuries. Calculate the activity of the NBS standard and compare with the measured activity. Correct the activities of the sources to be used in the calibration procedure.

3. **Transport sources to calibration facility.** Use a shielded container and hand truck to transport the sources. Measure the exposure rate surrounding the container prior to leaving the storage room. Radiation exposure rates shall not exceed 2mR/hr at any edge of the hand truck. *Transport only the sources to be used for the geiger counters.* The higher activity sources will create a high "background" reading for the lower scales on the geiger counters.

4. **Place the source(s) to be used in the shielded container used for calibrating instruments.** Lock the sources in the "down" position. Sources are to be secured from unauthorized removal.

5. **Determine the survey meter readings that will reflect approximately one-third and two-thirds of full scale.** Use the *Reflex* software to determine the distances required to achieve the anticipated readings. The file is *"EXPVSDIS"*. See attached for sample. For all existing survey equipment predetermined exposures have been established. Use the same exposures as previous calibrations. New survey equipment generally will be able to use the same exposures as the current meters.

6. **Set up work sheets to document exposures.** *Reflex 2* software, file *"SURVEY"*, report file *"CER"*. Replace the *"obs"* with an underline. Print the worksheets for the equipment to be calibrated.

7. **Calibrate survey meters.** Use the worksheets and printout of the distance vs exposure to calibrate survey instrument. First, check batteries to ensure they are within operating range. Second, measure the check source and record the geometry and reading on the worksheet. Third measure the exposures at the predetermined distance. Record the readings. If exposure is within 10 % of the expected, proceed to the next reading or scale. If reading is between 10 % and 20 % determine a correction factor and record. If reading is greater than 20 %, remove the meter from service and notify the RSO and the owner.

8. **Survey meter calibration adjustments.** Only qualified persons may make adjustments of survey meters do not measure at the expected readings.

9. **Print certificates and labels.** *Reflex* software, file *"SURVEY"*. Record the measured reading in the appropriate sections. Save the file. Go to *Reflex 2* software, file *"SURVEY"*, report file *"CER"*. Print the report. Go to *Reflex 2* software, file *"SURVEY"*, report file *"LABEL"*. Print the file.

10. **Submit certificates for review.** Verify the readings with worksheet and sign the certificate and submit the certificates to the RSO.

DISTANCE vs EXPOSURE FOR Cs-137 SOURCES FOR 1990
A=1, B=15, C=25, BC=40, D=75 (activity in mg. Ra.

EXPOSURE	DIST A	DIST B	DIST C	DIST BC	DIST D
0.05	358.35	1338.31	1681.66	2154.06	2933.81
0.15	201.82	767.60	965.83	1238.58	1688.77
0.35	127.98	498.37	628.14	806.69	1101.41
0.50	105.11	415.01	523.58	672.97	919.55
1.50	55.62	234.53	297.22	383.47	525.83
2.00	46.56	201.50	255.79	330.48	453.77
3.50	32.26	149.39	190.43	246.89	340.09
5.00	25.03	123.03	157.37	204.61	282.58
7.50	18.24	98.25	126.29	164.86	228.52
15.00	9.38	65.96	85.78	113.06	158.08
20.00	6.52	55.52	72.68	96.30	135.29
35.00	2.00	39.04	52.01	69.87	99.34
50.00	-0.29	30.70	41.56	56.50	81.15
75.00	-2.44	22.86	31.73	43.93	64.06
100.00	-3.72	18.19	25.87	36.43	53.87
150.00	-5.24	12.65	18.92	27.55	41.78
200.00	-6.14	9.35	14.78	22.25	34.58
750.00	-8.98	-0.97	1.83	5.69	12.05

DISTANCE vs EXPOSURE FOR Cs-137 SOURCES FOR 1990
formulas for determination of distances

EXPOSURE:

DIST A: 100 * @SQRT((0.332 * 2.0656) / EXPOSURE) - 12

DIST B: 100 * @SQRT((0.332 * 27.46) / EXPOSURE) - 12

DIST C: 100 * @SQRT((0.332 * 43.2) / EXPOSURE) - 12

DIST BC: 100 * @SQRT((0.332 * 70.66) / EXPOSURE) - 12

DIST D: 100 * @SQRT((0.332 * 130.69) / EXPOSURE) - 12
(1) (2) (3) (4) (5)

(1) correction factor
(2) specific gamma ray constant for Cs-137
(3) activity of source in millicuries
(4) same as the number in the EXPOSURE column
(5) corrects for the 12 cm between the sources in the calibration shielding and the start of the tape measure.