

**Standard
Nuclear
Consultants, Ltd.**

Nuclear Medicine • Radiology • Industrial Specialists

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December 10, 1990

A. Bert Davis, Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Re: Standard Nuclear Consultants, Ltd. audit of Milwaukee County Medical
Complex license # 48-04193-01, Docket #030-03444

Dear Mr. Davis:

Following is the summary of our November 1, 2, & 29, 1990 audit of the radiation safety program at Milwaukee County Medical Complex (MCMC). This was conducted in follow up to recommendations made by the NRC after its September 26 - 28, 1990 inspection. The audit consisted of a two day review of the program by Robin Bauer, Stan Buhr and Jim Mikowski on 11/1/90 & 11/2/90, followed by preliminary recommendations and another visit on 11/29/90 to review progress on those recommendations.

This summary consists of both a broad overview of the program as well as specific items which should be addressed.

GENERAL:

In general, we feel there is a good attitude toward radiation safety among the Radiation Safety Office staff and a willingness on the part of the Radiation Safety Office, Radiation Safety Committee members and Administration to take whatever steps needed to improve the program.

We did note there are several areas in which there was not adequate attention to the details of the program to ensure that specific records and practices follow "verbatim" the license application and applicable regulations. In no instances did we observe any cases where this has caused an increased radiation exposure to the public or employees. The potential for errors or incidents, however, may be greater when the details of the program are overlooked.

RECEIVED

DEC 17 1990

REGION III

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REG3 LIC30
48-04193-01 PDR

A contributing factor has been the lack of time among Radiation Safety Office staff members to adequately monitor all phases of the program on a regular basis. It has apparently been necessary to spend a large share of the available time to the routine maintenance duties of the program and to the very important task of answering the radiation safety questions and concerns of employees working under the MCMC license.

STAFFING:

A decision has been reached by the Medical Complex to increase the size of the staff by hiring a full time Radiation Safety Officer and to add one additional support person at this time, with possibly another employee at a later date. Specific job descriptions have been prepared for the RSO, health physicist and health physics technicians.

We recommend that the support personnel should be cross trained to the extent that the program can continue to operate effectively during vacations, sabbaticals and temporarily vacant positions.

RADIATION SAFETY COMMITTEE:

The recent quarterly Radiation Safety Committee minutes were reviewed and found to be adequate. We recommended the discussions be documented in more detail. The Committee has now begun taping the discussions to aid in transcribing of minutes and to provide a backup for reference in the event questions arise later.

After our initial visit, we recommended following a more formal method of reviewing training records and granting authorization to users of radioactive materials. The committee has since significantly revised the approval categories and the applications to ensure that approvals are given only for those amounts, radionuclides and uses requested by the user and for which adequate training has been shown on the training records. We also recommended that in cases where committee members vouch for the training and experience of a user, this should be done in writing.

Training and Experience

We reviewed in detail the training records of twenty one (21) of the users chosen at random. There is evidence that prior to the NRC inspection the committee has not immediately approved all users. In several instances applications were denied until further training and experience could be shown and in other cases authorizations were granted conditionally, based on the training records.

There appears to have been confusion about the requirement for 40 hours training and experience stated in 10 CFR 33.15 (b). I telephoned an NRC license reviewer for an opinion on this and was informed the regulation does not specify how much of the forty (40) hour must be classroom and how much can

be obtained from on the job experience. In all cases reviewed, greater than 40 hours of experience was documented, with the range of 1.5 to 43 years. The majority of users have documented at least 6 years experience.

In many cases, applicants had not completed the section concerning the five categories of training (safe handling of radioactive materials, characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazards exposure to radiation) but have referenced college and graduate level courses which most likely included these topics. The applications have therefore been revised to include a worksheet to more accurately estimate the hours spent on each of these topics. Hour values can then be assigned to the portions of those courses which covered the above topics. Copies of the revised applications are attached. (See attachment A)

Approval Categories

The Radiation Safety Committee has now also revised the approval categories to replace the B1, B2, B3, B4 and B5 categories with a system specifically approving only the types, quantities and uses of radioactive materials needed.

We noted that the approval letters in use prior to the inspection did indicate that the authorization is being made "in accordance with statements in your application dated ..." (Attachment B) Because the letters also included a statement that approval is for one or more of the above categories, the authorization letters have been revised to be more specific to the radionuclides and amounts requested.

During our review of the user training records, we also reviewed the user applications and approval documentation. Because of the categories used, there had been several cases where users were granted authorization to use radionuclides or quantities for which there was not documentation of experience on file. Since the inspection, the Radiation Safety Officer has asked all users to resubmit training records and has then sent letters to all of the users more closely restricting them to the radionuclides and quantities shown on those records. In nearly all cases, this will not affect the users as they have been using materials as described in their applications rather than as described in the approval categories.

The authorizations will now be based on a more specific radionuclide/possession system. In cases where the previous experience does not specifically cover the intended use, an individual will work under the supervision of another user until sufficient experience has been obtained. This experience will be documented and maintained on file in the users' record.

INVENTORY:

Daily inventories of radioactive materials possessed by each individual user and by the licensee are now printed. Actual quantities of radioactive materials on hand have remained well below the license possession limit.

There have been no further cases since the time of the NRC inspection of individual users receiving more activity than their individual possession limits allow. To avoid any further incidents of exceeding a possession limit, a stamp containing the information shown on attachment C has been prepared to record on the order form which accompanies each incoming shipment of radioactive materials the possession limit and the current possession (the daily inventory reading plus the activity of the package).

There have apparently been problems in the past with availability of radionuclide activities in the concentrations or amounts desired (for example, a user requiring 5 mCi may only be able to purchase that radionuclide in 20 mCi portions). In those cases, the user will either reapply to the RSC for authorization for the larger amounts or the larger quantity will be maintained in possession of the Radiation Safety Office and given out as needed to the user. If user experience cannot be documented for the larger quantity, the use could remain under the authority of another user until the proper experience has been obtained.

PERSONNEL MONITORING:

Personnel exposure results are reviewed and reported quarterly to the RSC. Results for radioactive materials workers are evaluated according to the ALARA program action levels. There have been a few cases of exposures above Action Level I (10% of MPD) but no recent cases of exposures above action level II (30% of MPD).

There have been cases in which employees have lost whole body or extremity badges, resulting in incomplete cumulative exposure totals. These will now be evaluated on a monthly basis, estimates calculated and the badge supplier notified to add these estimates to the lifetime totals. At the time of badge collection, if there are any missing badges, the employee will be contacted to determine if it has been lost. If so, the employee is asked for a statement of estimated use during that time period (i.e., average use, unusual circumstances, vacation, etc.). An estimate will then be calculated based on past exposure history and the information submitted to the badge supplier. See attachment D.

Since the time of the inspection, the procedure for bioassays has been modified to require that users of iodines must have a baseline thyroid check and schedule the post-labeling check prior to receiving the material. Because the receipt of material is contingent upon the bioassay check, it is unlikely that this requirement will be overlooked.

In the case of two absent bioassay results on one researcher noted by the NRC inspector, one of those results, dated 12/29/89, was located. It cannot be shown that the other one was actually performed, but the Radiation Office staff indicated that he has always been very diligent about having the tests performed. The reason for the lost results may have been due to the practice of researchers occasionally leaving the results on a scrap of paper if the RSO or another member of the RSO staff was not available at the time of the

thyroid count. This has been corrected by requiring that the bioassay counts be scheduled at a time when a staff member is present to record the results directly in the log.

RESEARCH LAB AUDITS:

Audits of all active research labs were completed by the Radiation Safety Office between the time of the NRC inspection and October 29, 1990. In most cases full compliance was noted to be in effect. In some cases, surveys had not been completed at the specified frequency and in some cases "cold zones" had not been posted. During our 11/29/90 visit, we visited approximately 1 dozen of those labs which were not in full compliance at the time of the October 1990 Radiation Safety Office visits, and in all cases found that full compliance had now been reached.

A report on lab audits will be made quarterly to the Radiation Safety Committee. This report will include the number of audits performed, the results of the audits and the identity of any individual who does not comply with the radiation safety requirements.

During our visits to the research labs, I interviewed (on 11/2/90) the graduate student who had been questioned by the NRC inspector. The graduate student seems to be very timid and he told me that he had, indeed, been instructed by the user in the laboratory concerning radiation safety requirements. He indicated he was at the time confused by the terminology used by the inspector. When asked if he was aware of requirements to complete surveys, the graduate student said he pictured the use of an instrument (such as a survey meter). The student had always referred to these tests as wipe tests rather than surveys. He also indicated he had been told by the user of the requirement for performing wipe tests for removable contamination. He did not remember at the time of the inspection that they were required after each use of 1 mCi or more of P-32.

During our detailed audits of six (6) randomly selected laboratories on November 1 and 2, 1990 we found no cases in which lab employees had not been instructed by the user. In most cases, however, there were not records of the training to prove this.

To avoid further cases in which the training of specific employees is in doubt, all users will be required to document future training of employees using a form similar to attachment E and a quiz similar to attachment F used to document understanding of the material presented.

During our 11/29/90 visits to the laboratories all workers questioned were well aware of the contamination limits for the radionuclides in use.

We recommended that operational checks be performed on all survey instrumentation on a day of use frequency. The Radiation Safety Office has agreed that operational check sources, such as lantern mantles, will be available to all labs for this purpose.

Entrance doors to labs or areas where radioactive materials are used or stored are posted with "caution, radioactive materials" signs in accord with 10 CFR 20.203 (e).

We recommended after our initial visit that emergency decontamination procedures be posted in each of the labs. This had been completed by the time of our 11/29/90 visit.

IMPLANT THERAPY PROCEDURES:

We reviewed in detail the five (5) implant therapy cases completed since the time of the NRC inspection. Each included proper documentation of patient name, treatment dates, dates and number of sources removed from storage, surveys of patient rooms and unrestricted areas upon implant and surveys of patients to confirm removal of sources upon explant. Times of implant and explant were also properly recorded.

To improve the inventory and tracking of the implant sources, the inventory forms have been revised to include the identity of the person who removed the sources from the storage and the date, time and number of sources returned to storage as well as the identity of the person returning the sources. See attachment G. We recommended that this additional information be maintained in preparation for the possible NRC mandated quality assurance program that has been proposed and additional license conditions when the license is renewed.

During this visit, we were present during the initial surveys of a brachytherapy patient room immediately after implant. Radiation levels to unrestricted areas surrounding the room were found to be within the NRC limits. There have been no further cases of exposures in the adjacent stairwell exceeding 2 mr/hr. Until this situation has been resolved, calculations have been made of maximum source activities to be used to avoid exceeding the 2 mr/hr limit and treatments have been limited to those quantities.

Access to the source storage room is restricted with the exception that maintenance may need to gain access to the elevator controls in an emergency. The entrance door has now been posted with a sign to contact the RSO or other authorized personnel in this case.

Additionally, a shielded, secured storage module has been ordered for installation in the brachytherapy source storage room to allow for immediately locking sources upon return to the room.

An amendment is currently pending for licensing the Selectron instrument. It was noted during our 11/29/90 visit, that this instrument had never been used for intracavitary treatments as stated in Item H of the 11/23/90 Notice of Violation from the NRC. This will be addressed further in the response from MCMC to that letter.

DISPOSAL RECORDS:

A calculation of radioactive material release to the sanitary sewage system had been made in the past and was on file in the Radiation Safety Office. The calculation shows that because of the quantity of sewage release, there is no problem in complying with the release limits. To aid in recording individual lab disposals of liquid radioactive materials, forms have been posted near the "hot sink" in each lab where sink disposals may take place and each user has been requested to record quantities and dates as closely as can be estimated on an ongoing basis. During our 11/29/90 lab visits, we noted these are being recorded in all cases.

Disposal of other wastes by transfer by transfer to the Radiation Safety Office storeroom are well documented. Records of disposal from this room are also in compliance with applicable license conditions and regulations.

NUCLEAR MEDICINE:

We audited both nuclear medicine departments and found the records to be largely up to date and in compliance with applicable license conditions and regulations. We made recommendations after our 11/2/90 visit, to more closely comply with applicable license conditions and regulations.

1. Xe-133 gas trap efficiency checks are to be performed on a monthly frequency.
2. Records of the semi-annual measurements of the nuclear medicine exhausts where Xe-133 gas is used are to be maintained. (See attachment H)
3. Weekly surveys of waste storage areas are to also include wipe tests for removable contamination.
4. One portion of the license application indicates that dose calibrator accuracy checks are to be completed on a quarterly frequency. This is currently the frequency used for the MCMC nuclear medicine dose calibrator and will also be used at the Froedtert facility until a license amendment for an annual frequency is obtained.
5. Weekly constancy on all commonly used radionuclide settings are now being performed at both departments (since the time of the NRC inspection).
6. We recommended that the daily g.m. surveys of elution, preparation and injection areas always be completed on a day-of-use frequency, including those times when personnel are called in for emergency procedures on weekends. (See attachment I memo concerning this.)
7. We recommended improving the recording of Mo-99 assays on generator eluate to include the ratio, expressed as μCi of Mo-99 / mCi of Tc-99m in addition to the individual entries of Mo-99 activity and the Tc-99m eluate activity.

8. We recommended revising the waste disposal forms to include the date the disposal container was initiated, date ended, date disposed, survey reading, background reading, instrument used and initials. This will more clearly document that the materials are held a minimum of 10 half-lives prior to disposal.

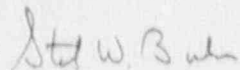
The nuclear medicine laboratories have followed each of the above recommendations as of the date of this letter.

MANAGEMENT SCHEDULES:

To aid in avoiding incidents of missed surveillances in the future, the Radiation Office staff has developed management schedules to ensure that the many requirements are completed at the required frequencies. These will also be used to apprise the Radiation Safety Committee and administration of the compliance with radiation safety requirements. A sample is attached as Attachment J.

If there are additional questions concerning this letter or our audit of the MCMC facilities, please contact us at the letterhead telephone number. Thank you.

Sincerely,



Stan Buhr

SB/jo

cc: Julie Hanser, FACHE, Hospital Administrator, MCMC
Charles R. Wilson, Ph.D., Radiation Safety Officer, MCMC
Janice Lato, Assistant Administrator, MCMC



MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue

Milwaukee, WI 53226

414-257-7900, TTY 257-5774

October 17, 1990

Dear Dr. Ryan:

The Radiation Safety Committee has authorized you to use ionizing radiation in categories B2 and B3 in accordance with the statements made in your application dated November 17, 1986 and letter dated October 2, 1990. This authorization expires December 31, 1990. If any conditions of your use change, it is your obligation to contact the Radiation Safety Committee.

CONDITIONS

Possession Limits

Under this authorization you are allowed to possess radioactive materials up to the following activities:

<u>Categories</u>	<u>Possession Limits</u>
B1: RIA kits	Less than 10 uCi/kit Total Possession less than 200 uCi
B2: Low <u>energy</u> beta emitters Low <u>activity</u> gamma emitters (< 250 uCi in process at one time)	5 mCi each beta emitter 2 mCi each gamma emitter Total Possession less than 20 mCi
B3: High <u>energy</u> beta emitters High <u>activity</u> gamma emitters	5 mCi each beta emitter 10 mCi each gamma emitter Total Possession less than 50 mCi
B4: Radiolabeling H-3, I-125 or I-131	H-3 150 mCi each use I-125 10 mCi each use I-131 10 mCi each use Total Possession H-3 less than 200 mCi Total Possession Iodine less than 20 mCi

Attachment A.

APPLICATION FOR USE OF RADIOACTIVE MATERIALS

Date: _____
 Applicant: _____
 Title: _____
 Department: _____

Application Type (check appropriate)
 New ___ Renewal ___ Amendment ___

Office Laboratory

Room no.: _____ Manager: _____
 Phone no.: _____ 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 192. 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.

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

Application for use of radioactive materials in research
page 2

Name: _____

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 RADIOLABLER

Name: _____
Date: _____

Check appropriate
Authorized User _____
Radiolabeler _____

EDUCATION

School	Major	Degree	Year Graduated
<i>Undergraduate</i>			

Graduate/Medical

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING

Location	Course Title	Dates From - To	Lecture/Laboratory Courses (Hours)	Supervised Laboratory Experience (Hours)
	<i>Safe Handling of Radioactive Materials</i>			

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 ANIMAL

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 experiment
 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.

APPLICATION FOR USE OF RADIOACTIVE MATERIAL
IN HUMANS
FOR DIAGNOSTIC PURPOSES

Date: _____

Applicant Name: _____

Title: _____

Department: _____

Office: Building/Location _____ Number: _____ Phone: _____

_____ Procedures Authorized Under This Authorization _____

This is to request authorization for the use of radioactive material in humans for diagnostic purposes. Authorization is requested for the following procedures.

1. Uptake, dilution, and excretion studies.

This permits use of any radioactive material in a radiopharmaceutical and for diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). Use of such materials will comply with the package insert instructions regarding indications and method of administration.

2. Use of radiopharmaceuticals, generators and reagent kits for imaging and localization studies.

This permits use of any radioactive material in a radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing by-product material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The elution of the generators and preparation of the reagent kits is to be in accordance with the manufacturer's instruction.

_____ Regulatory Requirements _____

Minimum requirements for the human use of radioactive materials are licensure to practice medicine in the State of Wisconsin and board certification by appropriate speciality boards. Contact the Radiation Safety Office for details

APPLICATION FOR USE OF RADIOACTIVE MATERIAL
IN HUMANS
FOR DIAGNOSTIC AND THERAPEUTIC PURPOSES

Date: _____

Applicant Name: _____

Title: _____

Department: _____

Office: Building/Location _____ Number: _____ Phone: _____

This is to request authorization for the use of radioactive material in humans for diagnostic and therapeutic purposes. Authorization is requested for the following procedures.

1. Uptake, dilution, and excretion studies.

This permits use of any radioactive material in a radiopharmaceutical and for diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). Use of such materials will comply with the package insert instructions regarding indications and method of administration.

2. Use of radiopharmaceuticals, generators and reagent kits for imaging and localization studies.

This permits use of any radioactive material in a radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing by-product material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The elution of the generators and preparation of the reagent kits is to be in accordance with the manufacturer's instruction.

3. Use of radiopharmaceuticals for therapy.

This permits use of any radioactive material in a radiopharmaceutical and for therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). Use of such materials will comply with the package insert instructions regarding indications and method of administration.

Regulatory Requirements

Minimum requirements for the human use of radioactive materials are licensure to practice medicine in the State of Wisconsin and board certification by appropriate speciality boards. Contact the Radiation Safety Office for details

APPLICATION FOR USE OF RADIOACTIVE MATERIAL
IN HUMANS
FOR THERAPEUTIC PURPOSES

Date: _____

Applicant Name: _____

Title: _____

Department: _____

Office: Building/Location _____ Number: _____ Phone: _____

This is to request authorization for the use of radioactive material in humans for therapeutic purposes. Authorization is requested for the following procedures.

1. Use of radiopharmaceuticals for therapy.

This permits use of any radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). Use of such materials will comply with the package insert instructions regarding indications and method of administration.

2. Use of sources for brachytherapy.

This permits use of the following brachytherapy sources in accordance with the manufacturer's radiation safety and handling instructions.

- a. Cesium - 137
- b. Cobalt - 60
- c. Gold - 198
- d. Iridium - 192
- e. Iridium - 90
- f. Iridium - 126

Regulatory Requirements

Minimum requirements for the human use of radioactive materials are licensure to practice medicine in the State of Wisconsin and board certification by appropriate speciality boards. Contact the Radiation Safety Office for details

EDUCATION AND EXPERIENCE

Education		Major	Degree	Date
<u>Undergraduate</u>	<u>Institution</u>			
<u>Medical</u>				

Training		Dates	
		From	To
<u>Residency Training</u>			

Licensure/Certification

State of Wisconsin Medical License Number _____

<u>Speciality Board</u>	<u>Category</u>	<u>Month and Year</u>

Experience

List other institutions where you have been approved to use radioactive materials in humans.

<u>Institution</u>	<u>City/State</u>	<u>Type of Use</u>	<u>Duration</u> From To

Certification

I certify that the information submitted in this application is complete and correct to the best of my knowledge. I agree to abide by all of 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.

Signature of Applicant: _____ Date: _____

_____ RSC Action _____

Date of RSC review: _____

Date of RSC approval: _____

Comments:

RADIONUCLIDE APPROVAL

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

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 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 from _____ to _____? 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).
_____ mrem

Signature of badge holder_____
Date

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

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 under his/her authority where radioactive materials are used or 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 *Please Print*
 Name: _____ 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.

Radiation Safety Office
NEW EM' LOYEE'S QUIZ

Individual's *Please Print* Position Type *(check one)*
 Name: _____ Permanent _____
 Department: _____ Temporary _____
 Position: _____
 Date of Training: _____ 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 answered 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?

Iridium-192 Inventory

Radiation Oncology faculty, residents, physics staff and certain members of the Radiation 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 #: _____

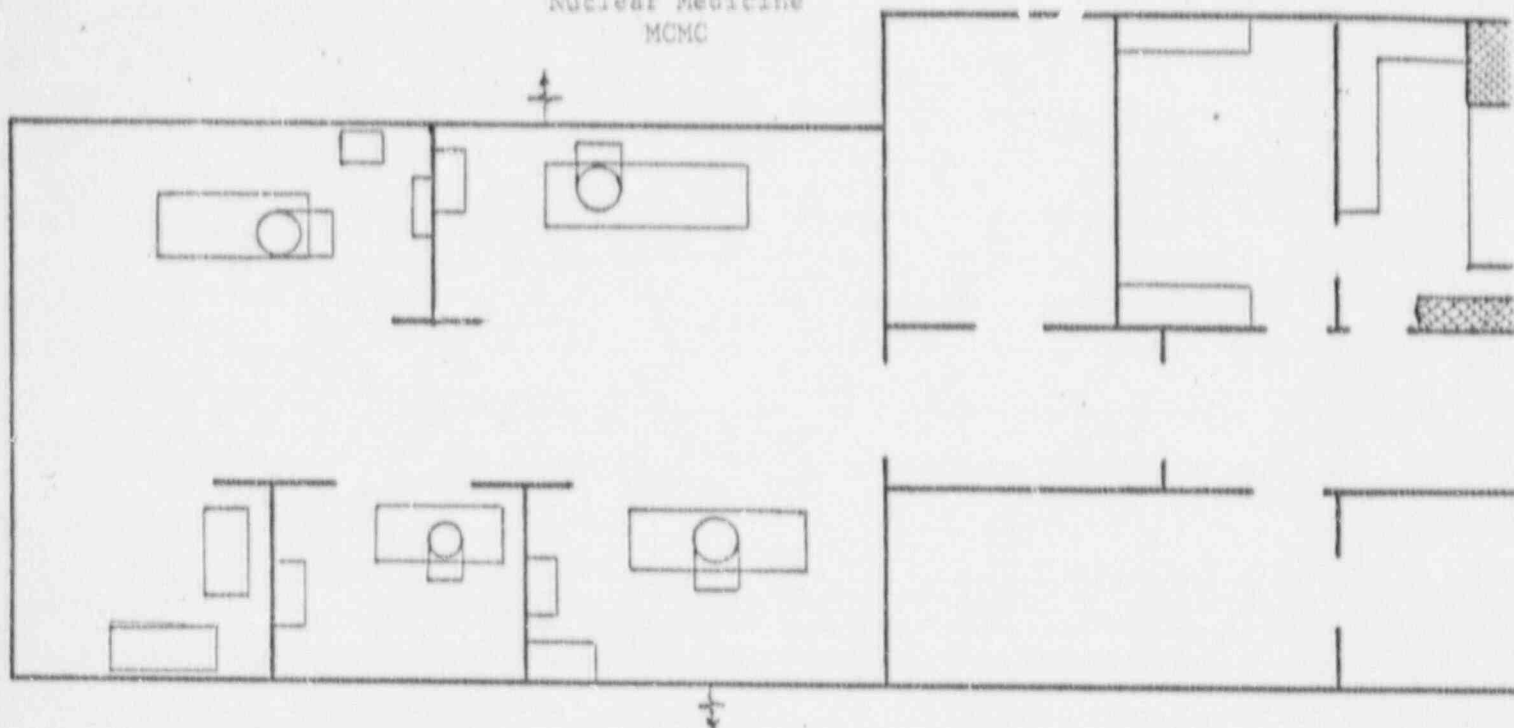
of Ribbons Returned: _____

of Seeds and Activity Returned: _____

Total # of Seeds and Activity after Return: _____

Signature: _____

Nuclear Medicine
MCMC



AIR FLOW SURVEY

DATE _____

CONDITIONS	MAIN DOOR (lfm/cfm)		XENON EXHAUST VENT (lfm/cfm)	
AIR CONDITIONERS OFF EXHAUST FAN OFF	_____	_____	_____	_____
EXHAUST FAN ON	_____	_____	_____	_____
AIR CONDITIONERS ON EXHAUST FAN OFF	_____	_____	_____	_____
EXHAUST FAN ON	_____	_____	_____	_____
HOT LAB HOOD hood open _____ inches hood is 64 inches long	_____	_____		
WET LAB HOOD hood open _____ inches hood is 64 inches long	_____	_____		

COMMENTS: _____



MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue

Milwaukee, WI 53226

414-257-5936

M. Julie Hanser
Hospital Administrator

DATE: December 5, 1990

TO: All Nuclear Medicine Technologists

FROM: Frank G. Steffel
Nuclear Medicine Manager

cc: Dr. Charles Wilson

It is **REQUIRED** by the NRC, that a g.m. survey of all working areas must be completed on a day-of-use frequency, including those times when personnel are called in for emergency procedures on weekends. Also, **YOU MUST** do a pre-and-post bioassay before handling one millicurie or more of I-131. Your assistance is critical to compliance with NRC rules and regulations.

THIS POLICY IS IN EFFECT IMMEDIATELY.

FGS/ab

RADIATION SAFETY OFFICE
MANAGEMENT SCHEDULE
1991

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
	TASK- INVENTORY-RAM											
	FREQUENCY- QUARTERLY											
SCHED	X			X			X			X		
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
	TASK- INVENTORY-SEALED SOURCE											
	FREQUENCY- QUARTERLY											
SCHED	X			X			X			X		
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
	TASK- RADIATION SAFETY COMMITTEE MEETING											
	FREQUENCY- QUARTERLY											
SCHED		X			X			X			X	
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
	TASK- RESEARCH LAB AUDIT											
	FREQUENCY- QUARTERLY											
SCHED			X			X						X
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
W			X			X						X
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
W			X			X			X			X
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
W		X			X			X			X	
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
W		X			X			X			X	
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
INST	X			X			X			X		
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
H	X			X			X			X		
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
IC	X			X			X			X		
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
H	X			X			X			X		
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
	TASK- XENON TRAP EFFICIENCY											
	FREQUENCY- MONTHLY											
SCHED	X	X	X	X	X	X	X	X	X	X	X	X
COMPL	---	---	---	---	---	---	---	---	---	---	---	---
IC	X	X	X	X	X	X	X	X	X	X	X	X
COMPL	---	---	---	---	---	---	---	---	---	---	---	---