

Medical Center

5000 West National Avenue
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Milwaukee, WI. 53295



**Veterans
Administration**

June 29, 1987

In Reply Refer To: 695/115
Confirming Action Letter (31 December 1986)
License No. 48-02130-02

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

Att: Pat Vacherlon

Subject: Request to Amend our NRC License

In accordance with item number 3 of the above Letter of Understanding, please find attached the final draft of "Radiation Safety Procedures for Safe Handling of Isotopes During Therapeutic Implants".

It is therefore requested that this be incorporated into our license.

Sincerely,

A handwritten signature in dark ink, appearing to read 'R. E. Struble'.

R. E. STRUBLE

Medical Center Director

8803080347 880229
REG3 LIC30
48-02130-02 PDR

CONTROL NO 83831

"America is #1—Thanks to our Veterans"

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Radiation Safety Procedures for the Safe Handling of Isotopes during Therapeutic Implants VAMC, Milwaukee, Wisconsin

In general, the regulations of the United States Nuclear Regulatory Commission (NRC), as published in Title 10 CFR, and the specific conditions of our NRC by-product materials license apply in the handling and use of the radioactive sources used in radiation therapy. The recommendations given in NCRP Reports No. 37 and 40 should also be consulted and followed.

1 Definitions and Terms

For the purposes of this document, the following terms and abbreviations are introduced and defined:

Authorized User	a Radiation Oncologist who has been approved by the Radiation Safety Committee to use radioactive isotopes for specific therapeutic implant procedures.
ARSO	Assistant to the Radiation Safety Officer
Brachytherapy	The use of multiple implanted sources to provide a continuous level of irradiation to a volume of tissue to deliver a therapeutic dose.
Implant	A set of sources of radioactivity which can be used to perform brachytherapy.
RO	Radiation Oncologist
RP	Radiation Physicist
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer

2 Outline of Tasks and Responsibilities

Table 1 sets out, in abbreviated form, the duties and responsibilities encountered in the normal course of a brachytherapy procedure. The table lists the specific tasks and the individuals who have the primary and secondary responsibility of carrying them out. In addition, the table indicates the section of this document that describes details of the individual task.

TASK/FUNCTION	1 st DESIGNEE	2 nd DESIGNEE	SECTION
User Authorization	RSC	None	3
Order Sources	RP	RO	4
Source Check-In			
General	RSO	ARSO	5
Match	RP	RO	
Storage	RP	RO	6
Source Count (Pre)	RO	RP	11
Source Transport	RP	RO	8
Patient Transport	RP	RO	9
Source Handling	RP	RO	10
Nursing Training			11
General	RSO	ARSO	
Specific	RO	RP	
Nursing Monitoring	RSO	ARSO	12
Source Count (Post)	RO	RP	13
Room Survey (Post)	RSO	ARSO	13
Source Return	RSO	ARSO	14

Table 1: Outline of Functions and Designees for Implants

3 Participants

Only physicians designated by the RSC as authorized users for the specific procedures of brachytherapy and radioactive source implantation (or resident physicians in Radiation Oncology under the direct supervision of such an authorized user) shall be allowed to perform implant procedures. Secondary responsibilities (both medical and physics) for any implant procedure will be assigned by the Section Chief of the Radiation Therapy Section at the VA Medical Center. In addition, the RSO is responsible for certain activities listed below. In the absence of the RSO, the ARSO (or acting RSO, if the ARSO is not available), as appointed by the Chairman of the RSC, shall act in his place.

It shall be a prerequisite for any person requesting to become an authorized user for brachytherapy and implant procedures that they be familiar with the specific policies and procedures for this facility (as specified in this document and its appendices), and that they certify this in such manner as the RSC shall specify.

Furthermore, additional technical personnel (including, but not limited to, radiation physicists and radiation safety personnel), prior to being involved in such procedures, shall also be familiar with this document and also certify this in a manner specified by the RSC. Other involved personnel (such as radiation therapy technologists, and certain nursing and operating room personnel) shall, as a minimum, be familiar with the general principles of radiation safety and protection and, in addition, shall become familiar with the portions of this document relevant to their participation in the brachytherapy procedure. Only individuals who have met the above requirements, as determined by the RSC, shall act as authorized users or as "other involved personnel" during brachytherapy and implant procedures. On a regular basis (at least annually), all such individuals, in order to maintain their approved status, shall be required to review this document (with any modifications or revisions) and document this review in a manner specified by the RSC.

4 Ordering of Radioactive Sources

Sources will be ordered through a purchasing agent of the VA Medical Center. Specific source information, based on a dose prescription as ordered by the RO, will be approved by the RP. Delivery shall be to the RSO. A copy of the purchase order shall be delivered to the RSO.

5 Arrival of Radioactive Sources

Upon arrival of therapeutic sources, the RSO or his designee shall be responsible for the routine check-in procedures for radioactive materials. In addition, the RSO will notify the RP of the arrival of the sources. After notification, the RP will perform a check of the isotope form and perform an assay of the isotope activity in the Radiation Oncology dose calibrator. The isotope calibrator located in the Prep Room (C-1013) in Nuclear Medicine shall be used as a backup when necessary. The results of the assay shall be recorded and kept as part of the physics record in the Radiation Therapy Section. If either the form or the activity of the isotope do not meet the specifications as ordered, the RP shall notify the RSO immediately. The RP shall be responsible for reordering sources, if necessary.

6 Storage of Sources

Primary storage of all isotopes shall be in Room C-1008 of the Nuclear Medicine Service. Immediately prior to, during and after the implant procedure, the sources may be stored in Room B-25 in the Radiation Therapy Section. Within 24 hours of the completion of the implant, the RP shall be responsible for the return of the sources to Room C-1008 in Nuclear Medicine. Whenever there are sources stored in the Radiation Therapy Section, signs bearing the words "CAUTION - RADIOACTIVE MATERIALS" should be fastened to the outside of the safe and to the room door.

7 Source Log

The two card inventory system established by the RSO for this facility will be used for radioactive sources. The RP will keep one file card and update it as the sources are implanted and removed from the patient. Upon return of the isotope to the RSO, the file card will be returned to the RSO to become a part of the facility's permanent records. In addition to the file card log, the Radiation Therapy Section will maintain a separate source inventory sheet. This sheet is discussed in Section 13 and included as Appendix A.

8 Transport of Sources

The RP shall have primary responsibility of transportation of sources to and from the OR, the patient ward or the Radiation Therapy Section. Transportation of radioactive sources shall always be done in a shielded container and in conformance with the ALARA policy of this facility.

9 Transport of a Patient Containing Therapeutic Amounts of Isotopes

To limit unnecessary exposure to the general public, transportation of such a patient shall be done in a specially secured elevator. One of the B-wing service elevators with key control shall be used. The elevator shall be run as an "Express Car". Keys to control this bank of elevators have been issued to all Head Nurses and to the Operating Room Nursing Supervisor. Arrangements to obtain such an elevator for use in transporting a patient containing radioactive sources shall be the responsibility of RO personnel, who will coordinate with one of the above. In case of any difficulties with the elevators, Engineering Service shall be notified and shall provide assistance; information necessary for obtaining such assistance is included as Appendix B and shall be updated as needed.

10 Source Handling

Before and during the implant procedure, those personnel directly involved in the handling of unshielded sources, such as the RO or RP preparing the sources for use, should wear a finger dosimeter, if practical, as well as whole body dosimeters. Any other personnel classified as radiation workers (occupationally exposed persons) should wear their regular whole body monitoring device.

Included within the room to which the patient will be assigned will be remote handling devices, consisting of a long-handled tongs and a pig or other shield sufficient to contain the sources and provide adequate shielding. This equipment will be placed in the room prior to the arrival of the patient and removed only after the source removal and proper accounting has occurred.

11 Personnel Safety Instructions

The RO shall be responsible for reviewing with the nurse who has primary responsibility for the implant patient any special orders relative to nursing care for that patient. The RSO shall be responsible for insuring that radiation safety instructions have been reviewed with the charge nurse and other appropriate individuals. The RSO shall be responsible for insuring that appropriate Radiations Safety signs and notices have been posted. This shall include, when applicable, the posting of signs in the Recovery Room for a patient implanted in the Operating Room. Examples of suitable signs and notices are included as Appendix C.

12 Personnel Dosimetry

Persons present during the actual implant procedure (including, when applicable, Operating Room and Recovery Room personnel) or during the treatment who would be likely to receive a whole body dose of more than 20 mRem shall wear a personal dosimeter. Personnel dosimetry shall be the responsibility of the RSO. Dosimeters will generally be in the form of pocket-pen ionization chambers. The RSO shall be responsible for instructing the nursing staff on the correct use of the dosimeters, as well as their distribution, retrieval, and evaluation of any reading they may show. Instructions for the use of these pocket dosimeters and of the exposure recording form are included as Appendix D.

13 Source Count and Room Survey

Patients who undergo implantation of radioactive sources will be assigned to private rooms identified and supplied by the Surgical Service. Implant procedures will be coordinated with the Surgical Service to ensure availability of such a room.

In compliance with NRC regulations, a source count, both before and after the implant, and a room survey shall be performed. Appendix A, entitled "Brachytherapy Patient Source Count and Survey Verification", shall be used to record this information. The responsibility for counting the sources as they are introduced into the patient and as they are removed belongs to the RO.

As a minimum, the room survey shall consist of a measurement of the exposure rate at one meter from the site of implant. It shall be the responsibility of RSO to perform this survey. This survey shall be done using an appropriate ionization survey instrument. The room survey to be performed at the completion of the implant is done to show that no sources remain in the room and should be done with a GM survey instrument. In addition, all adjacent rooms and areas shall be monitored, as required by 10 CFR 20.105; this data shall be recorded on the diagram and sheet provided with Appendix A. The proper performance and recording of this survey shall be the responsibility of the RSO.

All room and area surveys shall include the date and time of measurement.

In addition to the above measurements, which constitute a minimum acceptable survey, the RSO, at his discretion, may perform or request the RO to perform, additional measurements which he feels are necessary for radiation protection and safety.

14 Return of Sources

For sources that can be returned to the manufacturer, shipment will be performed within two weeks of final use of the isotope. Final use will be determined by the RO. Packaging and documentation of the source shipment shall be the responsibility of the RSO. The RP shall assist the RSO in the actual packaging of the isotopes and in the completion of appropriate shipping documents.

Appendix A

Source Count and Survey Verification Form

A.1 SOURCE INSERTION

PATIENT NAME _____ ROOM NO. _____
PATIENT HOSPITAL NUMBER _____
This patient contains _____ mg Ra eq.
mCi of _____ introduced
on _____, 19____, _____ A.M./P.M.

A.2 SOURCE COUNT

Number of sources introduced _____

By _____
(Signature) (Date)

A.3 ROOM SURVEY

Exposure rate at 1 m. from patient _____ mR/hr (using an appropriate survey
instrument). This data measured on _____, 19____, _____ A.M./P.M.

By _____
(Signature) (Date)

.....

A.4 SOURCE REMOVAL

A.4.1 Source count

Number of sources removed _____. This data measured on ___, 19___, ___ A.M./P.M.

By _____
(Signature) (Date)

A.4.2 Radiation Survey

The patient was surveyed with a G.M. Survey Instrument and the survey indicated that there were no sources remaining. The NRC license requirements for the release of this patient have been fulfilled.

By _____
(Signature) (Date)

NOTE: PATIENT MAY NOT BE DISCHARGED UNTIL FINAL RADIATION SURVEY HAS BEEN PERFORMED.

ROOM SURVEY

A Adjoining room= _____ mR

B Adjoining room= _____ mR

C One meter from implant= _____ mR

A

Room Number _____

Dates _____

Patient Name _____

Source I.D. and Activity

_____ mCi.

R.C.O. Signature

B

Appendix B

Procedures for Contacting Hospital Engineering

To report problems with securing an "express" elevator car during normal hours, call Engineering Service at extension 2758 and ask for Dick or Dan.

The hospital elevator engineer can be reached via beeper by calling extension 5-459 and stating the department phone number to be called (e.g. 2548).

Finally, for problems after hours, one must call Graphics Control at extension 2600. Graphics Control will dispatch an operator to Radiation Therapy.

Appendix C

Nursing Instructions for Patients with Temporary Implants

Patient's Name: _____ Ward: _____

Radioactive Material: _____ Amount: _____ mCi.

This patient contains a therapeutic dose of radioactive material as listed above. Precautions must be exercised to assure that no person receives radiation in excess of that permitted by federal radiation safety codes.

1. Patients shall be restricted to their assigned room.
2. A sign titled "Caution -- Radioactive Materials" shall be placed on the patient's door and this instruction sheet shall be attached to the patient's chart.
3. Visitors shall be permitted to visit for one hour per day and shall remain 3 feet from the patient. No pregnant women or persons under 18 years of age will be permitted.
4. Nursing personnel shall limit their time with the patient and shall wear a pocket dosimeter while with the patient. No pregnant personnel will be allowed to care for the patient; any personnel who believe they may be pregnant should notify their supervisor so that appropriate scheduling arrangements can be made.
5. In the event a source is dislodged or nursing personnel suspect a source (or other form of contamination) is no longer in the patient, nursing personnel shall use the forceps and lead pig (which shall be present in the patient's room) to pick up and store the suspected item. Following this, they shall immediately contact the Radiation Safety Officer, followed by either the Radiation Physicist or the Radiation Oncologist at the telephone numbers listed below.
6. No materials are to leave the room before being monitored by the Radiation Safety Officer.
7. In case of patient death, immediately notify both the Radiation Safety Officer and the Radiation Oncologist involved or on call. Do not remove the body from the room before the radioactive material has been removed.
8. Radiation Safety Officer Office: ext. 2139 Home:
Radiation Physicist Office: ext. 2548 Home:
Radiation Oncologist Office: ext. 2548 Home:

9. These restrictions apply:

Starting _____ and End _____
(DATE) (DATE)

Signature: _____

Patient's Name _____

Unit Number _____

CAUTION
RADIOACTIVE MATERIAL



TEMPORARY IMPLANT

Radionuclide _____

mCi _____

Insertion _____

(DATE) _____

Initial Exposure Rate at 1 Meter _____

(SIGNATURE) _____

To Be Removed _____

(DATE) _____

INSTRUCTIONS:

Patient must remain in hospital until implant is removed.

When implant is removed, "Radioactivity Precaution Tags" may also be removed.

For further information call Radiation Protection _____

(Ext. _____)

In case of emergency, the telephone operator _____

Has for use when the Radiation Protection _____

not open.

Date _____ Signature _____

RADIATION PROTECTION SUPERVISOR

ATOMIC PRODUCTS CORP.

Center Morristown, N. J. 07914

APPENDIX D
INSTRUCTIONS FOR USE OF POCKET DOSIMETERS

Pocket dosimeters will be furnished by the R.S.O. for use while caring for a patient that has a therapeutic amount of radiation.

These dosimeters are numbered and each person should choose a different numbered one for their use.

The dosimeters are charged before being issued and should show a 0 reading if held to the eye and viewed towards a light source. A hair wire on the scale will indicate the amount of radiation in millirems (mRem).

Always take a reading before you put yours on and record it on the dosimeter card next to your number and name. Before you put it away after use, also take a reading and record that as before on the card.

If a dosimeter must be reused, or you must use one used by someone else, note the reading before you use it and after you are done with it.

These dosimeters are shock sensitive, so if you drop it, take a reading and record it and the fact that it was dropped.

The dosimeter card is to remain in the nursing station and will be picked up by the R.S.O. upon completion of the implant, with the dosimeters.

The wearing of these dosimeters are part of our radiation safety program and must be used as stated.

<u>SN.</u>	<u>ASSIGNED</u>	<u>DATE</u>	<u>READING BEFORE</u>	<u>READING AFTER</u>
6045E(1)				
6049E(2)				
6050E(3)				
6056E(4)				
6057E(5)				
6044E(6)				
6042E(7)				
6040E(8)				
6038E(9)				
6037E(10)				
5975E(11)				
5974E(12)				

PATIENT _____ SSN _____ DATE _____

ROOM _____ ISOTOPE _____ ACTIVITY _____

DATE IN _____ DATE OUT _____

THESE DOSIMETERS HAVE A RANGE OF 0 TO 200 MILLIROENTGENS IN INCREMENTS OF 10.
PLEASE RECORD VALUE BEFORE AND AFTER USE.

CONTROL NO. 83831