MATERIALS LICENSE

Amendment No. 56

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

396604

Licensee	
1. St. Elizabeth Hospital	In accordance with letter dated February 24, 1994 3. License Number 48-10219-01 is renewed in its entirety as follows:
2. 1506 South Oneida Street Appleton, WI 54915	4. Expiration Date February 28, 2002
	5. Docket or Reference No. 030-03466

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed (not to exceed 10 curies of I-131)
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy sources identified in 10 CFR 35.400	D. As needed
E. Iridium-192	E. Sealed sources (Byk Mallinckrodt Model CI L BV)	E. 2 sources, 1 source not to exceed 444 gigabecquerels (Gbq) (12 curies (Ci)), and 1 source not to exceed 370 Gbq (10 Ci).

9/

070041

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-10219-01
Docket or Reference Number
030-03466
Amendment No. 56

9 Authorized Use:

A. Medical use descr.bed in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

C. Medical use described in 10 CFR 35.300.

D. Medical use described in 10 CFR 35.400 and for instrument calibrations.

E. One source to be used in a Nucletron-Oldelft Corporation MicroSelecton HDR remote afterloading brachytherapy device for interstitial and intracavitary radiotherapy in humans and for instrument calibration. The source activity may not exceed 370 Gbq (10 Ci) at the time of installation. One source in its shipping container for source replacement.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1506 South Oneida Street, Appleton, Wisconsin and at 1611 Madison Street, Appleton, Wisconsin.

11. Radiation Safety Officer: Stanley Reed, M.S.

12. Brachytherapy Physicist: Stanley Reed, M.S.

13. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
A. John I. Halloran, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
B. Gregory J. Knudson, M.D.	10 CFR 35.100, 35.200 and 35.300.
C. Patrick O'Brien, M.D.	10 CFR 35.100 and 35.200, limited to cardiovascular clinical procedures.
D. Henry Chessin, M.D.	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit and 35.300 limited to strontium-89.
E. Stanley A. Reed, M.S.	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit for survey meter calibration.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-10219-01
Docket or Reference Number
030-03466
Amendment No. 56

F.	Robert G. Brucker, M.D.	10 CFR 35.100 and 35.200.
G.	T. O. Reinke, M.D.	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit and 35.300 limited to strontium-89.
H.	Robert R. Kinde, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.400 and iridium-192 in remote afterloading brachytherapy unit.
I.	James E. Murphy, M.D.	10 CFR 35.100 and 35.200.
J.	Timothy H. Seline, M.D.	10 CFR 35.100 and 35.200.
K.	Michael W. Milde	10 CFR 35.100 and 35.200.
L.	Stephanus J. Macrander, M.D.	10 CFR 35.100 and 35.200.
M.	Fred D. Panzer, M.D.	10 CFR 35.100 and 35.200.
N.	Peter Podlusky, M.D.	10 CFR 35.100.
O.	Kent W. Powley, M.D.	10 CFR 35.100 and 35.200.
P.	Sue A. Hausserman-Dugan, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
Q.	Uri Vaisman, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
R.	Rosita Sio Go, M.D.	10 CFR 35.300, 34.400, 35.500 and iridium-192 in remote afterloading brachytherapy unit.
S.	William O. Fletcher, M.D.	35.100 and 35.200 limited to cardiovascular clinical procedures.
T.	M. David Yoseloff, M.D.	35.100, 35.200 and 35.500.
U.	John R. Iglar, M.D.	10 CFR 35.100 and 35.200.
V.	Robert A. Belgam, M.D.	10 CFR 35.300, 35.400 and iridium-192 in remote afterloading brachytherapy unit.
W.	Kevin Dul, M.D.	10 CFR 35.100 and 35.200.
X.	Marion H. Scholz, M.D.	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-10219-01
Docket or Reference Number
030-03466
Amendment No. 56

Y. Brian Hebl, M.D. 10 CFR 35.100, 35.200, 35.300 and 35.500.

Z. Stephen M. Brink, M.D. 10 CFR 35.500.

14. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to conform that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

15. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:

A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each remote afterloading brachytherapy procedure.

B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr (μSieverts/hr), time, date and name of the individual making the survey.

D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

16. A. Access to the rooms housing the Nucletron-Oldelft, Micro-Selectron HDR afterloading brachytherapy device shall be controlled by a door at each entrance.

B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.

C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once each day of use.

D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-10219-01
Docket or Reference Number
030-03466
Amendment No. 56

17. Prior to initiation of a treatment program, and subsequent to each source exchange using the Nucletron-Oldelft, Micro-Selectron HDR remote afterloading brachytherapy devices, radiation surveys and tests shall be performed in accordance with the following:

    A. A radiation survey shall be made of:

        (1) The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 milliroentgen per hour.

        (2) All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:

            (a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.101 (10 CFR 20.1201).

            (b) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b) (10 CFR 20.1301).

18. The following shall be performed only by manufacturer's representatives or persons specifically authorized by the Commission or an Agreement State to perform such services:

    A. Installation and replacement of the sealed sources contained in the afterloading brachytherapy device(s).

    B. Any maintenance or repair operations on the Nucletron-Oldelft, Micro-Selectron HDR afterloading brachytherapy unit(s) listed in Item 9., Subitem(s) 9.E. involving work on the source safe, the source drive unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

19. The licensee shall perform the following safety checks as a minimal on a monthly basis on the Nucletron-Oldelft, Micro-Selectron HDR afterloading brachytherapy unit(s) listed in Item 9., Subitem(s) 9.E. The safety checks shall be performed in accordance with the manufacturer's instructions:

    A. Source position accuracy within the catheter guide tube to within ± 1 millimeter of the programmed position;

    B. Timer accuracy and linearity;

    C. Measurement of source guide tubes to confirm length to 1 mm accuracy; and

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 48-10219-01

Docket or Reference Number 030-03466

Amendment No. 56

D. Backup battery test to verify emergency source retraction capability upon power failure.

20. Notwithstanding the requirements of 10 CFR 35.404(a), the licensee may release from confinement for medical care patients with temporary eye plaque implants in place, provided that the survey requirements for permanent implant patients specified in 10 CFR 35.75(b) are met. Upon removal of the eye plaque, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The license shall retain a record of the patient survey in accordance with 10 CFR 35.404(b).

21. Notwithstanding the requirements of 10 CFR 35.406(a), after removal of each eye plaque, the patient may be released from the medical treatment facility after an inventory of the sources in each eye plaque is performed to confirm recovery of all sources. This must include disassembling the plaque to conduct a physical inventory of the seeds.

22. Notwithstanding the temporary nature of each eye plaque implant, the licensee must meet the requirements of 10 CFR 35.415(a)(5).

23. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

24. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Letters dated February 24, 1994 (with attachments), February 7, 1995, March 31, 1995, July 27, 1995 (with attachments), September 24, 1996, November 19, 1996, and December 30, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date January 30, 1997

By _____
Nuclear Materials Licensing Branch, Region III

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02230
STATUS CODE: 2
FEE CATEGORY: 7C 2B
EXP. DATE: 19940630
FEE COMMENTS: CODE 21
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: ST. ELIZABETH HOSPITAL
RECEIVED DATE: 940309
DOCKET NO: 3003466
CONTROL NO.: 396604
LICENSE NO.: 48-10219-01
ACTION TYPE: RENEWAL

2. FEE ATTACHED
AMOUNT: 1400.00
CHECK NO.: 283016

3. COMMENTS

SIGNED Deborah Hersey
DATE 3-11-94

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED / ✓)

1. FEE CATEGORY AND AMOUNT: 7C 2B $1400.00

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT
RENEWAL ✓
LICENSE

3. OTHER

SIGNED
DATE 4/5/94

RECEIVED
APR 11 1994
REGION III

ST. ELIZABETH HOSPITAL • A Member of the Wheaton Franciscan System
1506 SOUTH ONEIDA STREET • APPLETON, WISCONSIN 54915-1397

February 24, 1994

Log Mar 14 III
Remitter
Check No. 288016
Amount $1400
Fee Category 7C 2B
Type of Fee Renewal
Date Check Rec'd 3/5/94
Date Completed 4/5/94
By: SC

United States Nuclear Regulatory Commission
Region III
Material Licensing Section-Medical
801 Warrenville Road
Lisle, Illinois 60532-4351

NRC License No. 48-10219-01

Dear Medical License Reviewer:

St. Elizabeth Hospital's current byproduct material license expires on June 30, 1994, and enclosed is our renewal application and fee for processing. The application has had policies and procedures revised to be in a standard format with little content change and consistent with 10 CFR Part 20 revisions which went into effect January 1, 1994.

We desire having H. Anthony Tran, MD, amended as an authorized user of 35.300, limited to strontium-89 in addition to his prior approvals, and his American Board of Radiology Certificate is enclosed.

In addition, we also are requesting a change in our existing license condition (see 16A(2)) which requires all areas adjacent to the treatment room be surveyed after a source is exchanged (Ir-192)in an afterloading brachytherapy unit. This requirement is of little value since our unit is used in a room which was used for prior Cobalt-60 teletherapy treatments and is more than adequately shielded. Unless the shielding for the room is modified or regulations changed, the use of Ir-192 at maximum activity allowed will not create exposure levels exceeding non-occupational exposure levels. This can be (and was) clearly established before the initial treatments started. We request deleting the requirement of surveying adjacent areas after each source exchange (4 per year) unless regulation or activity limits, occupancy, or structural modifications occur.

Please contact Stanley A. Reed (414-738-2190) for questions concerning this renewal application.

Respectfully submitted,

RECEIVED
MAR 07 1994
REGION III

Otto L. Cox
Otto L. Cox
President/CEO

Stanley A. Reed
Stanley A. Reed, MS
Certified Medical Physicist

1506 SOUTH ONEIDA STREET • APPLETON, WISCONSIN 54915-1397
PHONE (414) 738-2000 • FAX (414) 738-

CONTROL NO. 396604

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine
Hereby certifies that

Hai Anthony Tran

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology

On this tenth day of June, 1993

Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Radiation Oncology

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

AMERICAN BOARD OF MEDICAL SPECIALTIES

Lee F. Rogers M.D. — President
Lester J. Peters — Secretary-Treasurer
Kenneth L. Freedlander M.D. — Executive Director

CONTROL NO. 396604

SUMMARY OF ITEMS 5-11 ATTACHMENTS

Item 5-6: Radioactive Material/Purpose

Reference Item 5, page 1

Item 7: Individuals Responsible for Radiation Safety Program and Their Training and Experience

Reference Attachment 7.1.1 and Attachment 7.1.2

Item 8: Training for Individuals Working In or Frequenting Restricted Areas

8.1 Training Program
We have developed a training program for your review that is appended as Attachments 8.1.1-8.1.3.

8.2 Other Training Program
NA

Item 9: Facilities and Equipment

9.1 Annotated Drawing
See Attachments 9.1, 9.1.a3 for labelled drawings.

9.2 Survey Instrument Calibration
We have developed a survey instrument calibration procedure for your review that is appended as Attachments 9.2.1a-9.2.6.

9.3 Dose Calibrator Calibration
We have developed a dose calibrator calibration procedure for your review that is appended as 9.3.1-9.3.5.

9.4 Personnel Monitor Program
Attached is a description of our personnel monitoring program appended as 9.4.1-9.4.2.

9.5 Imaging Equipment
NA

9.6 Other Equipment and Facilities
NA

10.1 Radiation Safety Committee/Radiation Safety Officer
See Attachments 10.1.1-10.1.3 for description of the Radiation Safety Committee and the delegation of authority for the RSO.

10.2 ALARA Program
We have developed an ALARA program for your review that is appended as Attachments 10.2.1-10.2.6.

10.3 Leak Test
We have developed a leak test procedure for your review that is appended as Attachments 10.3.1-10.3.4.

10.4 Safe Use of Radiopharmaceuticals
We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as Attachments 10.4.1-10.4.4.

10.5 Radioactive Spill Procedures
We have developed spill procedures for your review that are appended as Attachments 10.5.1-10.5.2.

10.6 Ordering and Receiving
We have developed a procedure for ordering and receiving radioactive material for your review that is appended as Attachments 10.6.1-10.6.5.

10.7 Opening Packages
We have developed a package opening procedure for your review that is appended as Attachments 10.7.1-10.7.3.

10.8 Unit Dosage Records 10.9 Multidose Vial Records 10.10 Molybdenum Concentration Records
See Attachments 10.4.2a-10.4.2b which contains all items listed in the model procedures in Appendix M.1-M.3 of Regulatory Guide 10.8, Revision 2, 1987.

10.11 Implant Source Use Records
We will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix M.4 to Regulatory Guide 10.8, Revision 2.

10.12 Area Survey Procedures
We have developed survey procedures for your review that are appended as Attachments 10.12.1-10.12.5.

10.13 Air Concentration Control
1. We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix 0.1 to Regulatory Guide 10.8, Revision 2.
2. We have developed a calculation method for determining worker doses from aerosols which is appended as Attachments 10.13.1-10.13.2.
3. Airborne effluent dose to the public was calculated for aerosols (only isotope of significance which is currently used that becomes airborne) and this description is appended as Attachment 10.13.2.
4. We will calculate spilled gas clearance items according to the procedure that was published in Appendix 0.4 to Regulatory Guide 10.8, Revision 2.

10.14 Radiopharmaceutical Therapy
We have developed equivalent procedures which are appended as Attachments 10.14.0-10.14.26.

10.15 Implant Therapy
We have developed a procedure for radiation safety during implant therapy for your review that is appended as Attachments 10.15.1-10.15.15.

10.16 Other Safety Procedures
Our policy addressing our Quality Management Program is submitted as Attachments 10.16.1-10.16.4, 10.14.25, 10.14.26.

10.17 High Dose Rate Afterloading Program
The program is appended as Attachments 10.17.1-10.17.9.

11.1 Waste Disposal
We have attached our waste disposal guidelines appended as Attachments 11.1.1-11.1.2.

11.2 Other Waste Disposal
NA

BYPRODUCT RADIOACTIVE MATERIAL AND PURPOSE

Byproduct, Source, and Special Nuclear Material 10 CFR	Chemical and/or Physical Form	Maximum Possession Amount	Purpose/ Authorized Use
5.a Material in §35.100	Any radiopharmaceutical identified in §35.100	As needed	6.a Medical use
5.b Material in §35.200	Any radiopharmaceutical identified in §35.200	As needed	6.b Medical use
5.c Material in §35.300	Any radiopharmaceutical identified in §35.300	(less than 10 Ci of I-131) As needed	6.c Medical use
5.d Material in §35.400	Any brachytherapy sources identified in §35.400	As needed	6.d Medical use and instrument calibrations
5.e Eye applicator (Sr-90) §35.400(e)	Sealed source	90 mCi	6.e Medical use
5.f Sr-90	Sealed source	1 mCi	6.f Instrument calibration
5.g Ir-192	Sealed source (BYK Mallinckrodt)	Two sources not to exceed 10 Ci each	6.g Medical use and instrument calibration in a remote afterloading brachytherapy unit

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License numb[illegible]
48-10219-01

Docket or Reference number
030-03466

Amendment No. 51

D. Medical use described in 10 CFR 35.400 and for instrument calibrations.

E. One source to be used in a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial and intracavitary radiotherapy and for instrument calibration. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1506 South Oneida Street, Appleton, Wisconsin.

11. Radiation Safety Officer: Stanley Reed, M.S.

12. Authorized Users:

A. William B. Grubb, Jr. M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.400.

B. Gregory J. Knudson, M.D., for material in 10 CFR 35.100, 35.200 and 35.300.

C. Robert H. Spencer, M.D., for material in 10 CFR 35.100 and 35200, limited to cardiovascular clinical procedures.

D. Henry Chessin, M.D., for material in 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit and 35.300 limited to strontium-89.

E. Stanley A. Reed, M.S., for sources in 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit for survey meter calibration.

F. Robert G. Brucker, M.D., for material in 10 CFR 35.100 and 35.200.

G. T. O. Reinke, M.D., for material in 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit and 35.300 limited to strontium-89.

H. Robert R. Kinde, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.400 and iridium-192 in remote afterloading brachytherapy unit.

I. James E. Murphy, M.D., for material in 10 CFR 35.100 and 35.200.

J. John W. Fenlon, M.D., for material in 10 CFR 35.100 and 35.200.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
48-10219-01

Docket or Reference number
030-03466

Amendment No. 51

12. Authorized Users (Continued)

K. Michael W. Milde, for material in 10 CFR 35.100 and 35.200.

L. Stephanus J. Macrander, M.D., for material in 10 CFR 35.100 and 35.200.

M. Fred D. Panzer, M.D., for material in 10 CFR 35.100 and 35.200.

N. Peter Podlusky, M.D. for material in 10 CFR 35.100.

O. Kent W. Powley, M.D., for material in 10 CFR 35.100 and 35.200.

P. Sue A. Hausserman, M.D., for material in 10 CFR 35.100, 35.200 and 35.300.

Q. Uri Vaisman, M.D., for material in 10 CFR 35.100, 35.200 and 35.300.

R. Rosita Sio Go, M.D., for material in 10 CFR 35.300 and 34.400 and iridium-192 in remote afterloading brachytherapy unit.

S. Andrew K. Greenfield, M.D., for material in 10 CFR 35.100 and 35.200.

T. William O. Fletcher, M.D., for material in 35.100 and 35.200 limited to cardiovascular clinical procedures.

U. M. David Yoseloff, M.D., for material in 35.100, 35.200 and 35.300.

V. H. Anthony Tran, M.D., for material in 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit.

W. John R. Iglar, M.D., for material in 10 CFR 35.100 and 35.200.

13. Pursuant to 10 CFR Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material.

14. The licensee shall maintain records of information related to decommissioning at the location listed in item 2 as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		6/12/90	725-501-10	725-501-10A
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Kamrath		2-28-94
Division Head				
Management Staff				L.V.
Medical Advisor		Robert K Krude MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: IONIZING RADIATION SAFETY ORIENTATION AND TRAINING PROGRAM FOR EMPLOYEES				

POLICY:

All employees that utilize ionizing producing equipment or materials will have periodic in-services and an initial orientation based on their level of involvement. Ancillary personnel who may have indirect contact with ionizing producing equipment or materials will also be included in the radiation safety program.

PURPOSE:

To provide an adequate level of information necessary to safely work with and in the vicinity of ionizing radiation.

PROCEDURE:

Identification of employees who should receive training:

A. Employees working directly with ionizing radiation:

1) All employees who may be exposed to a significant quantity of ionizing radiation or may exceed a quarterly investigational limit as defined by our ALARA program (see policy #I-1(RI)) will have an initial orientation prior to unsupervised work in their department and an annual radiation safety in-service provided by the (Radiation Safety Officer) RSO or qualified designee. The determination of exposure risk will be made by the RSO. Personnel found in this area are most technologists in Diagnostic Radiology, Nuclear Medicine, and Radiation Therapy Departments.
2) Brachytherapy nursing personnel will have an annual in-service by the RSO and will be in-serviced by their supervisor or designee prior to participating in brachytherapy procedures. A video addressing radiation safety procedures is available for all new employees as well as a radiation protection handbook. The RSO is on site to specifically address questions that may occur.

3) All physicians and employees who participate in the use of remote afterloading brachytherapy procedures will have an annual training/retraining program and initial orientation. The training will be provided either by a qualified representative from the equipment manufacturer or trained/qualified medical physicist.

B. Employees working in areas where radioactive material or ionizing equipment is used or stored (not direct use):

1) Housekeeping in Radiology/Nuclear Medicine, Security and RIA laboratory personnel will be in-serviced by their supervisor or qualified designee prior to working unsupervised in areas that use ionizing radiation. An annual in-service will be provided by the RSO or qualified designee on an annual basis.
2) Ancillary personnel (surgery/urology, bronchoscopy, emergency, ICU, and areas where portable x-rays are taken) will be monitored in accordance with policy (I-1(RI)) and will be in-serviced by their supervisor or qualified designee. Due to the relatively low significant exposure risk the RSO will provide radiation safety information when requested. A radiation protection handbook is available for all employees.

C. Content of Radiation Safety In-Services:

Instruction will include but not limited to the following:

1) Applicable regulations and license conditions.
2) Proper handling of radioactive materials, if applicable.
3) Biological effects of radiation.
4) Radiation monitoring system and ALARA program.
5) Personnel's obligation to report suspected unsafe ionizing radiation conditions or the exceeding of designated action levels to the Radiation Safety Officer.
6) Procedures to be followed during radiation related emergencies or unsafe conditions.
7) Location of notices, policies, and the by-product material license in accordance with 10 CFR, Part 19, and HSS 157.
8) Radiation precautions and levels specific to the employee's work area.
9) Review of the Radiation Protection Handbook.

D. Content of Remote Afterloading Training:

1) General Radiation Safety (described in C. above)
2) Equipment Operation (treatment unit, console, applicators, treatment interruptions)
3) Emergency Procedures for HDR (tools necessary and available to perform procedure)
4) Radiation Safety Specific to HDR (survey meters and surveys, shields area, monitors, viewing system, interlocks)
5) Error Codes Potential Failure Items
6) Regulatory Requirements (personnel presence, written directives, misadministration)

Inservice Education Record

Date:_____ Speaker:_____

Time:_____

Topic:

Persons Attending:

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

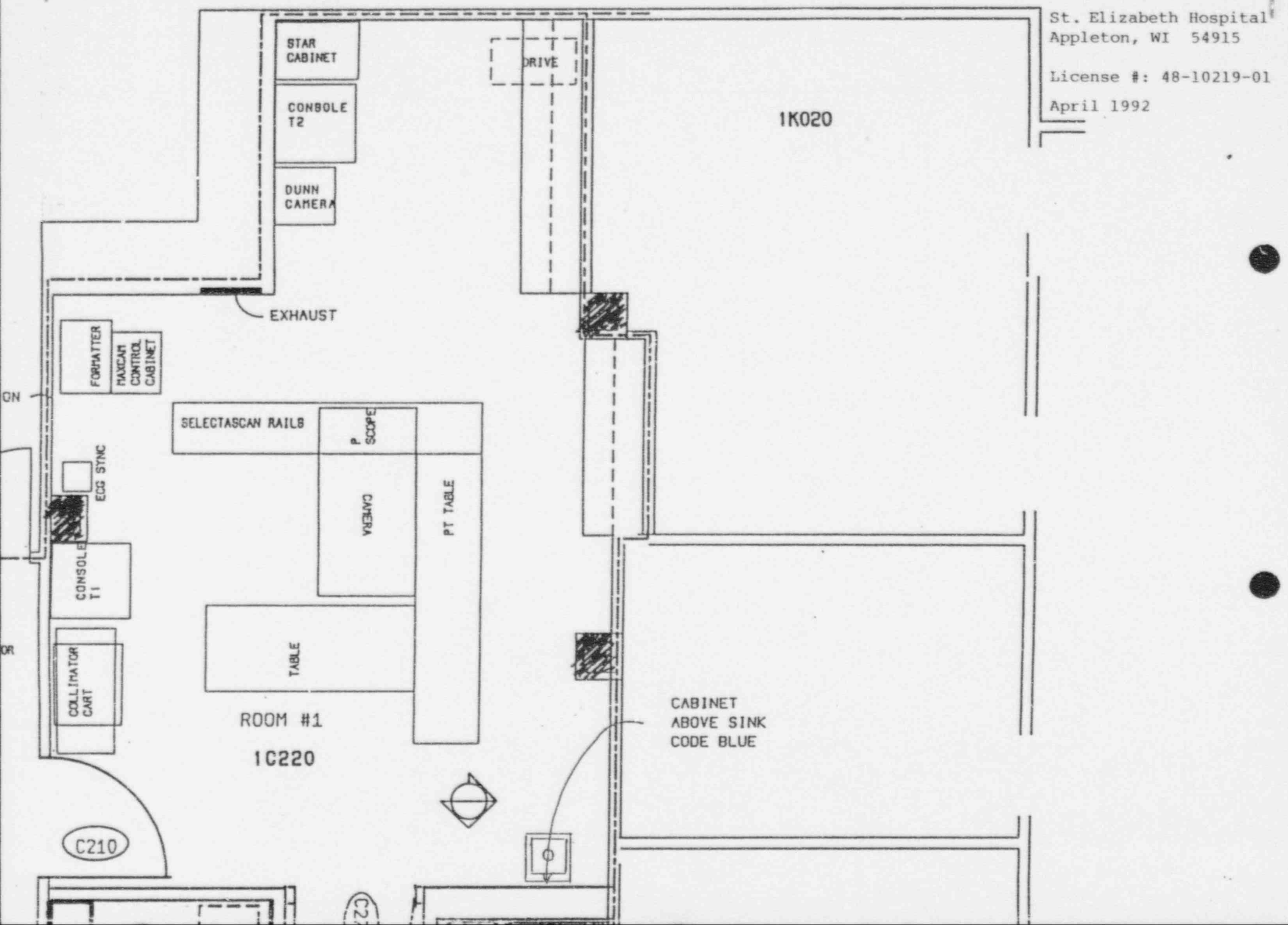
_____ _____

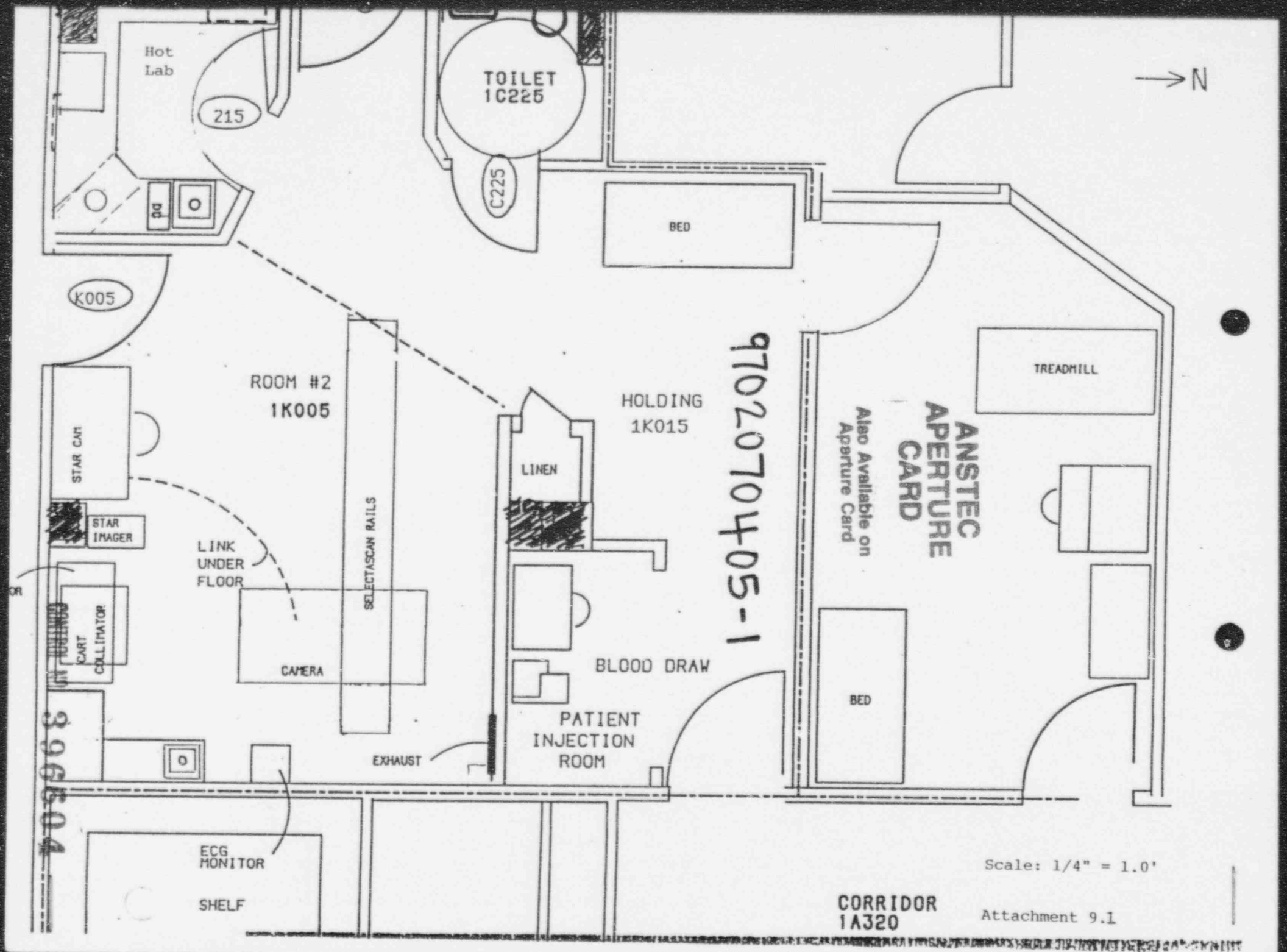
Summary of Material Covered:

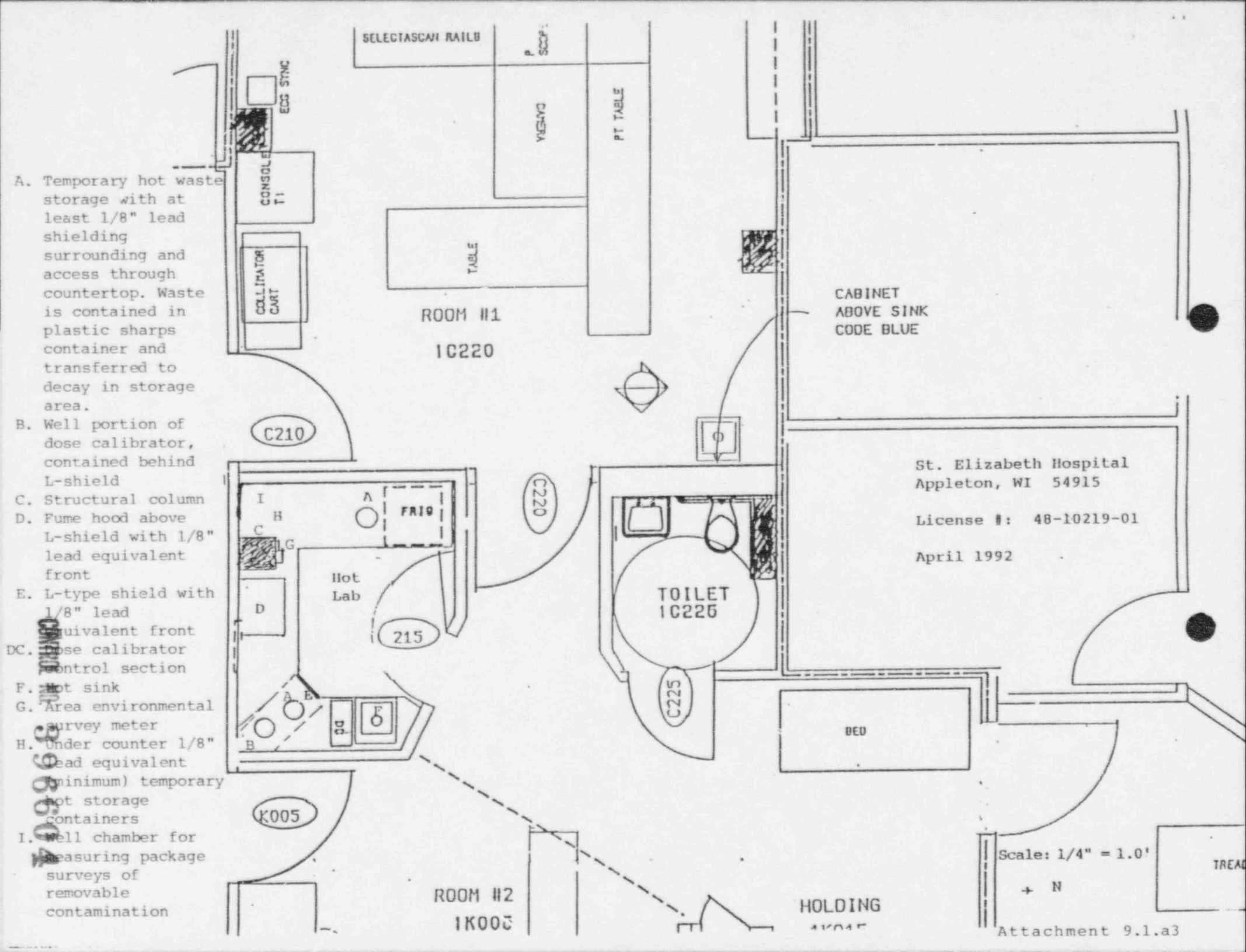
St. Elizabeth Hospital
Appleton, WI 54915

License #: 48-10219-01

April 1992




Hot Lab
215
TOILET 1C225
C225
BED
N
K005
ROOM #2
1K005
HOLDING
1K015
LINEN
STAR CAM
STAR IMAGER
LINK UNDER FLOOR
SELECTASCAN RAILS
CAMERA
CART COLLIMATOR
BLOOD DRAW
PATIENT INJECTION ROOM
EXHAUST
ECG MONITOR
SHELF
CORRIDOR 1A320
TREADMILL
BED
ANSTEC APERTURE CARD
Also Available on Aperture Card
9702704-1
3966504
Scale: 1/4" = 1.0'
Attachment 9.1


A. Temporary hot waste storage with at least 1/8" lead shielding surrounding and access through countertop. Waste is contained in plastic sharps container and transferred to decay in storage area.
B. Well portion of dose calibrator, contained behind L-shield
C. Structural column
D. Fume hood above L-shield with 1/8" lead equivalent front
E. L-type shield with 1/8" lead equivalent front
DC. Dose calibrator control section
F. Hot sink
G. Area environmental survey meter
H. Under counter 1/8" lead equivalent (minimum) temporary hot storage containers
I. Well chamber for measuring package surveys of removable contamination
SELECTASCAN RAILS
ECG SYNC
CONSOLE T1
COLLIMATOR CART
TABLE
PT TABLE
ROOM #1
1C220
C210
C220
C225
FRIG
Hot Lab
215
TOILET
1C226
CABINET
ABOVE SINK
CODE BLUE
BED
K005
ROOM #2
1K005
HOLDING
St. Elizabeth Hospital
Appleton, WI 54915
License #: 48-10219-01
April 1992
Scale: 1/4" = 1.0'
N
Attachment 9.1.a3

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		725-501-13
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Ramsett		2-28-94
Division Head				
Management Staff				U.V.
Medical Advisor		Robert R Kuick MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: CALIBRATION OF SURVEY INSTRUMENTS				

POLICY:

All survey instruments in use at St. Elizabeth Hospital will be calibrated after repair or at least annually at St. Elizabeth Hospital (License #48-10219-01). The calibration will include at least two points at approximately 1/3 and 2/3 full scale for each scale that reads below 1R/hr. Those scales reading above 1R/hr will not be used for an accuracy measurement. If exposure rates are exceeding 1R/hr, then a NBS traceable ionization chamber and electrometer will be used. Survey meters that have an automatic ranging digital display device will be calibrated in accordance with Appendix B of Regulatory Guide 10.8, Revision 2.

PROCEDURE:

1) A survey meter may be considered properly calibrated when the instrument readings are within ±10% of the calculated values for each point checked. Readings with ±20% will be considered acceptable if a calibration chart or graph is attached to the instrument. An energy response curve will be available for those instruments requiring one.

2) The sources used for survey meter calibrations will be Cesium-137 sealed sources or Ir-192 for high rate scales. One 25 mg. Ra. equivalent Cesium-137 was calibrated at NBS and this source was used to intercompare all of our Cesium-137 sealed sources. The comparison between our NBS calibrated source was performed on our CRC-22NB dose calibrator utilizing a constant and fixed geometry. Ir-192 sources will be checked for calibration in a NIST traceable well chamber (standard imaging HDR 1000 ion chamber). All Ir-192 high dose rate sources will be positioned remotely from outside of the shielded treatment room.

3) A calibration report (see Attachment 9.2.4) will identify the instrument and its normal location. Expected and measured exposure values and check source readings will be identified along with correction values, if required. The probe

orientation and its angle with respect to the primary radiation field will be recorded in addition to a description of the configuration or design used (e.g. energy discrimination sleeve). The person calibrating the instrument will be listed on the report. Each instrument will be labelled which identifies correction factors, if necessary, probe orientation during calibration, apparent exposure rate from check source and person calibrating the instrument. Scales not calibrated will also be identified on the label.

A. Cs-137 Test Set-Up Procedure: (See Figure #1 - Attachment 9.2.3a)

1) Survey meters are calibrated in the HDR brachytherapy room (prior Co-60 teletherapy room) in the Radiation Therapy Department. The source is placed in a prepositioned calibration block (see Figure #2 - Attachment 9.2.3a) with additional lead blocks surrounding to protect the person performing the calibration and one additional block which acts as a door for the window of the calibration block. The center of the detection probe is placed a specified distance from the center of the sealed source maintaining a central axis for both. The block is removed from in front of the window and the meter is allowed to stabilize for approximately one minute before a range of values are recorded over the next one minute interval. An initial optimization value is selected prior to calibration if the meter has only one adjustment potentiometer. This optimization point is usually selected on the basis of either midrange meter scale or the most likely in field usage depending on the circumstances. The exact calibration procedure will be performed as stated in Attachment 9.2.1a. A window block is slid in front of the window whenever probe positioning is done, and the person performing the calibration does not enter into the unshielded cone of radiation.

2) Attached is a typical survey meter calibration sheet (Attachment 9.2.4) along with a form (Attachment 9.2.5a) used to predetermine expected exposure rate values for sources used.

3) Pocket dosimeters are used for monitoring nursing personnel providing occasional care for brachytherapy patients. These dosimeters are calibrated using the calibration jig and set-up depicted in Attachment 9.2.3a, utilizing three points to determine an exposure response curve for each device over its useful integrating range. These devices are checked annually and upon replacement. An exposure response curve is used for each device (Attachment 9.2.6).

4) Radiation Safety Precautions: (Cs-137)

A single Cesium-137 sealed source is removed from our storage safe located in our Cesium-137 storage room in the Radiation Therapy Department. This source is placed into a long plastic tube with spacers to center its location in our calibration block. All work is performed behind L-block shields designed for use with brachytherapy sources, and all source manipulation is done with long forceps. The source is transported to the HDR brachytherapy room in a shielded container used for transportation of sealed Cesium sources for brachytherapy patients.

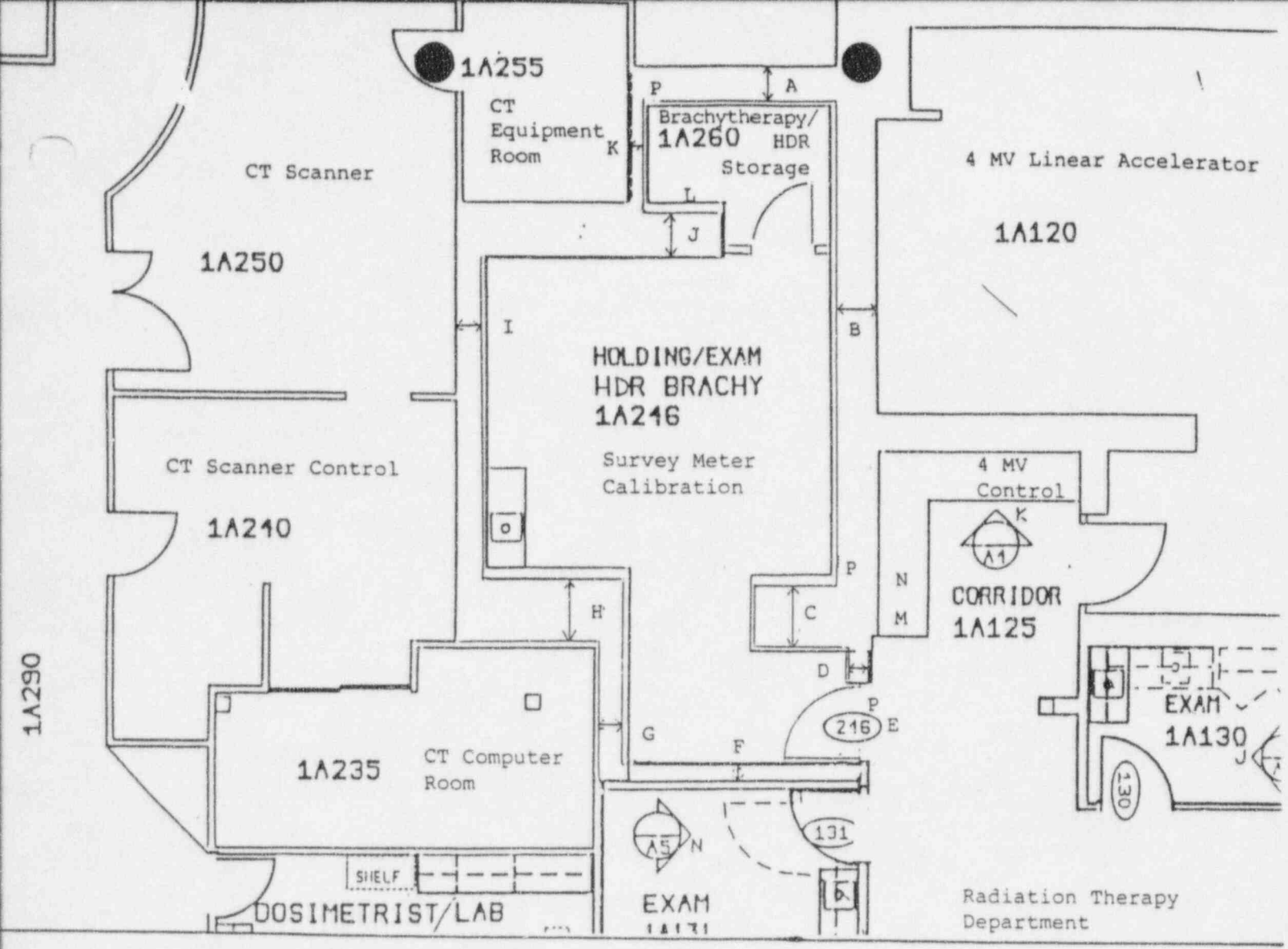
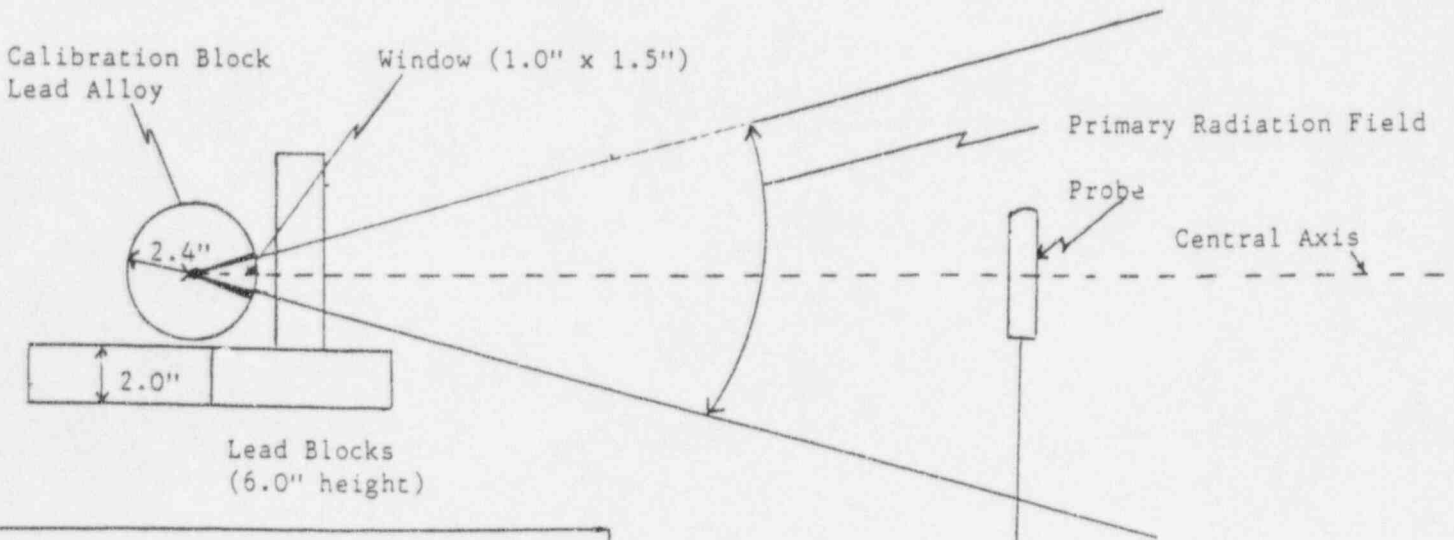
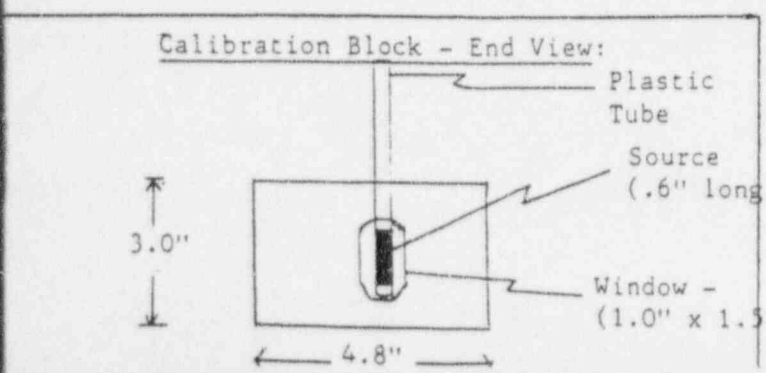
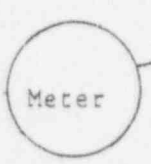


Figure #2 (Top View - Calibration Set-up)







Operator

Attachment 9.2.3a

SURVEY METER CALIBRATION

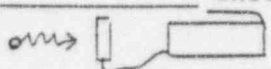
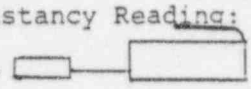
Date: _____ Location: _____

Manufacturer: _____ Meter Model #: _____ Meter S/N: _____ Probe Model #: _____ Probe S/N: _____

Reason for Calibration: ☐ Annual Check ☐ Repair

Calibration Procedure: Distances are measured from the center of the Cs-137 source to the center of the detection probe with the probe's axis as indicated. The source is in a shielded calibration jig with a window 5cm^2 at a distance of 5cm from the source. Readings are taken over a one minute time interval and a range (approximately 90% of the time) of values recorded. A calibration set point (*) is initially set for the instrument's most likely used scale.

Battery Check: _____ Check Source Constancy Reading: _____ mR/hr

Calibration Geometry: ☐  (perpendicular ⊥) ☐  (parallel - //) ☐ other

Detection Window: ☐ open ☐ closed ☐ fixed

Source	Meter Scale	Distance	Expected Reading	Instrument Reading	Range of Acceptable Readings	Correction Factor	Observations

Name: _____
Medical Physicist

Attachment 9.2.4

CALIBRATION EXPOSURE RATES - SURVEY METERS

Source	Identification	Exposure Rate as of Date		Calibration
Cs-137	S/N #0575	20.4 mR/hr-m	10-6-80	NIST
Cs-137	S/N #0494	4.20 mR/hr-m	10-6-80	Intercomparison with NIST Source #0575
Ir-192				Well ionization chamber calibrated with NIST traceability

Cs-137 Exposure Rate Constant: _____

Ir-192 Exposure Rate Constant: _____

Date: _____

Distance	#0575 Exposure Rate (mR/hr)	#0494 Exposure Rate (mR/hr)	Ir-192 Exposure Rate (mR/hr)	Exposure Rate (mR/hr)

Attachment 9.2.5a

Pocket Dosimeter Calibration:

All pocket dosimeters used for personnel monitoring of brachytherapy patients will be calibrated annually with a NBS traceable Cesium-137 sealed source. Three points on the useful part of the dosimeter scale will be measured and a corresponding exposure response curve will be used if the actual readings vary more than 10% of the expected readings.

Dosimeter Identification	Distance	Time	Expected Exposure	Measured Exposure	Variance	Leakage/72 hrs

Date: _____

Reference Source: _____

Accuracy (uncertainty): _____

Expected Exposure Rate: _____
(as of date above)

Signature of Individual Performing Test: _____

SARmmm

Index: 725-501-13	SUBJECT: CALIBRATION OF SURVEY INSTRUMENTS

B. Survey Meter Calibration Using Ir-192 in a Remote Afterloading Device:

1) Survey meters calibrated with Ir-192 will use the existing shielded HDR treatment room (prior Cobalt-60 teletherapy room). The calibration geometry will be set-up with the source in the retracted shielded position and a portable television camera will be used to read the meter scale. All source positioning will be done remotely outside the treatment room. The source would only be used for those scales which exceed 10 mR/hr.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		722-501-28
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Kamrath		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kirchner MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: CALIBRATION OF DOSE CALIBRATOR				

POLICY:

Dose calibrators shall be checked in accordance with Nuclear Regulatory Commission regulations to verify proper operation.

PROCEDURE:

Methods for Calibration of Dose Calibrator:

St. Elizabeth Hospital uses an ionization chamber type dose calibrator. This instrument will be checked for accurate operation at the time of installation and periodically according to the following description: (action level tolerance not to exceed)

A. 1. Instrument linearity at installation and quarterly, (±5%)

2. Geometrical variation at installation, (±5%)

3. Instrument accuracy at installation and annually, (±5%)

B. After repair, adjustment, or event which may affect the performance of dose calibrator, then the tests in A will be repeated as appropriate.

C. Daily Constancy Check: (see Attachment 9.3.3a)

The net activity of a Cesium-137 source greater than 50 microcuries will be checked and recorded on a daily basis at two common instrument settings. If the instrument reading exceeds the expected reading by more than ±5% then this will indicate a need for evaluation and possible instrument repair, adjustment or recalibration. Higher than normal background activity levels will be investigated and corrected, if possible. Instrument readings significantly different than anticipated values during the working day will be investigated.

Index: 722-501-28	SUBJECT: CALIBRATION OF DOSE CALIBRATOR

The medical physics department or the biomedical engineer responsible for the equipment should be timely contacted for technical assistance or evaluation of possible equipment malfunction.

D. Inspection of the dose calibrator will be made when the linearity test is performed to assure that the measurement chamber liner is intact, and that the zero is properly set and functioning according to the manufacturer's instructions.

E. Test of Instrument Linearity:

1. Linearity of our dose calibrator is checked over our clinical range. If we change procedures which would use patient doses exceeding 40 mCi then we would change our linearity procedures to be above the largest clinical activity for a single dose. All nuclear medicine patient doses are checked on our dose calibrator prior to patient administration and adjusted as appropriate.

2. The linearity of the dose calibrator will be performed quarterly according to one of the following procedures (I or II):

I. a. A sample of approximately 40.0 mCi Tc-99m will be contained in a syringe. The syringe will be of a typical size and volume.

b. An assay of the Tc-99m syringe will be made in the dose calibrator, subtracting out the background level. The reading, background, and net activity will be recorded.

c. Step 2 will be repeated at approximate time intervals of 6, 24, 30 and 48 hours after the initial assay.

d. The 30 hour activity will be compared to the recorded instrument value and the percent deviation indicated.

e. An instrument deviation of greater than ±5% of the expected value will indicate an instrument deficiency and the cause will be corrected.

II. a. Instrument linearity may also be demonstrated utilizing a commercially available attenuation system which shields a radioactive source (Tc-99m) with various lead thicknesses. The lead thickness will provide a range of attenuation values which demonstrate linearity over clinical values. This system will be initially compared to the linearity test performed in (I) above to determine that the system is linear. The same source will be used for both procedures to determine a set of calibration factors to be used with the commercial system. Please see Attachment 9.3.4 for the form used with I and II.

b. A dose calibrator with a deviation greater than ±5% of the initial calibration will indicate an instrument deficiency and the cause will be corrected.

Index: 722-501-28	SUBJECT: CALIBRATION OF DOSE CALIBRATOR

F. Tested for Geometrical Variation:

The procedure used will follow that listed in Regulatory Guide 10.8, Revision 2, Appendix C6, 1987.

G. Test for Instrument Accuracy: (Attachment 9.3.5)

The accuracy of the dose calibrator will be checked annually and following repair which may change the instrument's response. At least two NBS traceable reference standards with activities greater than 50 microcuries will be used with the appropriate range of energies consistent with our diagnostic procedures and established regulations. The following procedure will be used:

1. Each reference standard will be assayed in the dose calibrator at the appropriate setting and a background level will be subtracted to obtain a net activity.

2. The average activity determined in Step 1 should agree with the certified activity of each reference source within ±5% after decay corrections.

3. A record of this accuracy test will be kept.

4. Accuracy checks which do not agree within ±5% indicate that the instrument should be repaired or adjusted.

5. A qualified individual (medical physicist or radiation safety officer) will review and sign the records of geometry, linearity, and accuracy tests.

6. The dose calibrator will have a label indicating the date of the last accuracy test.

7. A relative response using at least one of our reference standards will be measured for each radioisotope setting used on the dose calibrator on an annual basis.

DEPARTMENT OF NUCLEAR MEDICINE

Model #: CRC-22NB
S/N: 33585

DOSE CALIBRATOR AND SURVEY METER CONSTANCY CHECK

DATE	INITIALS	VOLTAGE	Cs-137 #77325		DATE	INITIALS	VOLTAGE	Cs-137 #77325	
			Other: 220	Tc-99m				Other: 220	Tc-99m

Date	Survey Meter Jig Reading-Cs 137	Date	Survey Meter Jig Reading-Cs 137	Date	Survey Meter Jig Reading-Cs 137

Action: If the dose calibrator or survey meter constancy check is outside of e listed below notify the RSO and immediately discontinue clinical use of the . nt.

Expected Readings:	Year	Dose Calibrator Cs-137 (± 5%)	Dose Calibrator Tc-99m	Survey Meter Cs-137 #77325 (± 10%)
	1994:	289 ± 15	532 ± 27	2.4 mR/hr ± .2
	1995:	282 ± 14	520 ± 26	2.3 mR/hr ± .2
	1996:	276 ± 14	508 ± 25	2.3 mR/hr ± .2
	1997:	270 ± 14	497 ± 25	2.2 mR/hr ± .2

Survey Meter Constancy Check: The GM probe should have the sleeve covering the chamber and the slot should be directed away from the source while in the Ostalloy 158 test jig.

Attachment 9.3.3a

DOSE CALIBRATOR LINEARITY CHECK

Date: _____

Instrument: _____ S/N _____

Voltage: _____

Linearity Procedure:

The unit is rezeroed and the background is set as close to zero as possible prior to taking measurements. A 10 ml. glass vial with approximately 5 ml. volume is used initially with 2 mCi Tc-99m added then additional Tc-99m is added to provide an approximate 40 mCi source. Both sources have a test performed to test the entire clinical range of the dose calibrat . The lead attenuator sequence goes from black to purple in the order shown below.

Color Code Lead Attenuator	Calibration Factor (CF)	Reading (mCi)	Reading x CF	Deviation	Reading (mCi)	Reading x CF	Deviation
Background							
Black							
Black & Red							
Black & Orange							
Black & Yellow							
Black & Green							
Black & Blue							
Black & Purple							
		Sum:			Sum:		
		Mean:			Mean:		
		mean x 1.05:					
		mean x .95:					

Summary/Comments:

_____
Medical Physicist

Attachment 9.3.4

[redacted]OSE CALIBRATOR - ACCURACY CHEC[redacted]

Date: _____ Model #: _____

Instrument Voltage: _____ Serial #: _____

Setup: Use the vial E size source and place at the bottom level of the syringe holder/T-bar. Rotate the source 360° in 90° increments and take an average reading (record) of the four positions.

Source Identification	Source	Original Calibration	Elapsed Time	Instrument Setting	Instrument Reading	Bkgd	Expected Reading	Measured Variance ± %
Model: ICN S/N: 77325 ($t\frac{1}{2}$ = 30.0 yr)	Cs-137	418 uCi 5/31/78		Cs-137				
Model: NES-358 S/N: 3580185A-04 ($t\frac{1}{2}$ = 10.74 yr)	Ba-133	271 uCi 1/18/85		Ba-133				
Model: NES-358 S/N: 3580185A-04 ($t\frac{1}{2}$ = 10.74 yr)	Ba-133			I-131				
Model: S/N: ($t\frac{1}{2}$ = 270.9d	Co-57			Co-57				
Model: S/N: ($t\frac{1}{2}$ = 270.9d	Co-57 / Cs-137			Tc-99m	_____			
	Co-57 / Cs-137			Tl-201	_____			
	Co-57 / Cs-137			Ga-67	_____			
	Co-57 / Cs-137			In-111	_____			
	Co-57 / Cs-137			I-123	_____			
Model: ICN S/N: 77323 ($t\frac{1}{2}$ = 5.26yr	Co-60	.515 mCi 8/78						

Action Level: The measured activity should agree with the certified activity (decayed) within ± 5%.

Summary:

_____
Medical Physicist

Attachment 9.3.5

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Radiation Safety Committee		7/25/90		
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Zoya E. Kamuar		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kunde MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: PERSONNEL MONITORING PROGRAM OF EXTERNAL AND INTERNAL OCCUPATIONAL DOSE DUE TO IONIZING RADIATION				

PURPOSE:

To identify who is responsible for the personnel monitoring program and who receives radiation monitoring devices at St. Elizabeth Hospital.

POLICY:

This policy is based on 10 CFR §20.1502 and §20.1201 from the federal regulations and HSS 157.12 from the State of Wisconsin code on radiation protection. All personnel will have an appropriate radiation monitoring device assigned and required to be used properly according to the procedure listed below:

PROCEDURE:

1. The Radiation Safety Officer, or designee, is responsible for assigning appropriate monitoring devices for all individuals working in ionizing radiation areas at St. Elizabeth Hospital.

2. The determination of whether an individual is assigned a radiation monitor will be made by the Radiation Safety Officer in accordance with state and federal regulations stated in #3 below. Generally, all employees working with ionizing radiation or ionizing radiation producing equipment should be given a radiation monitor (excluding exempt quantity isotope workers). In addition, individuals handling radioisotopes or persons using their hands near a primary radiation source will be assigned an additional radiation monitor for their hands. If, after a minimum of 6 months, an individual does not receive a significant reading, then the monitoring may be terminated by the Radiation Safety Officer, or designee. Reassignment of a radiation monitor will occur if an individual changes working conditions that might increase ionizing radiation exposures. Occasionally, exposed personnel such as security, secretarial workers and nurses who work with patients receiving diagnostic dosages will not normally be issued radiation monitors.

Index:	SUBJECT: PERSONNEL MONITORING PROGRAM OF EXTERNAL AND INTERNAL OCCUPATIONAL DOSE DUE TO IONIZING RADIATION

3. An appropriate radiation monitor is required to be properly used for the following individuals:

   1) Adult employees who are likely to receive an annual external exposure in excess of 500 mrem (5 mSv).
   2) Minors and declared pregnant women likely to receive an annual external exposure in excess of 50 mrem (.5 mSv).
   3) Individuals entering a high or very high radiation area.

4. The radiation monitoring program will comply with the conditions stated in 10 CFR Part 20 (effective implementation date January 1994).

5. Individuals on a temporary assignment, new employees, physicians or visitors will be given radiation monitors when necessary. The department manager is responsible for timely notifying the Radiation Safety Officer, or designee, whenever a new employee is added, whenever an existing monitored employee terminates employment, or if an individual will possibly be present during an ionizing radiation procedure.

6. The Radiation Safety Officer, or designee, is responsible for obtaining prior exposure history for new employees and amending the radiation dosimetry report to reflect prior exposure history.

7. Each individual assigned a radiation monitor must use the device appropriately and intentionally. Aberrant exposure of the radiation monitor will result in disciplinary procedures. Suspected, accidental exposures, damage to the monitor, or lost monitors shall be reported to the Radiation Safety Office, or designee, as soon as reasonably possible.

8. Each individual assigned a radiation monitor will be responsible for assuring that the monitor is intact, and is exchanged, if required, on a monthly basis (new monitors are generally available for exchange from the 23rd of the month until the end of the month). A convenient system for exchange will be formulated on an individual department basis.

9. A dosimetry report will be posted on a timely basis in several areas and any individuals exceeding investigational levels will be identified on the monthly report and will receive at least on a quarterly basis written notification that investigational levels were exceeded and what action should be taken. The Radiation Safety Officer, or designee, will investigate exposure levels as necessary.

RADIATION SAFETY COMMITTEE

Responsibility:

The committee is responsible for:

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

3. Ensuring that the use of licensed material is consistent with the ALARA philosophy and program (see ALARA policy).

Duties:

The committee shall:

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.

2. Reviewing the training and experience of any individual who uses radioactive material (including physicians, technologists, physicists and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g. nursing, security and housekeeping personnel) are properly instructed as required by Section 19.12 of 10 CFR Part 19.

4. Review and approve all requests for authorization to use radioactive material within the institution.

5. Prescribed special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users and special monitoring procedures.

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records and reports made by the radiation safety officer or designee, results of NRC inspections, written safety procedures, and the adequacy of the management control system.

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

8. Maintain written minutes of all committee meetings, actions, recommendations, decisions and attendance.

9. Ensure that the byproduct material license is amended, when necessary, due to any changes in facilities, equipment, policies, procedures and personnel.

10. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to those whose occupational exposure appears excessive.

Administrative Information:

1. The medical isotopes committee shall meet as often as necessary to conduct its business, but not less than once in each calendar quarter.

2. Membership will include at a minimum one authorized user for each type of use authorized by the license, the RSO, a representative performing nursing care in an ionizing radiation area, and a representative of management who is not an authorized user or a RSO.

3. To establish a quorum, one-half of the committee membership, including the RSO and management representative or designee, must be present.

4. All other ionizing radiation concerns will be addressed at the committee meeting in addition to NRC requirements.

Memorandum

1506 South Oneida Street
Appleton, Wisconsin 54915-1397

414/738-2000

St. Elizabeth Hospital

TO: All Employees

FROM: Jeff Jenkins, Executive Vice-President, Chief Operations Officer

SUBJECT: Delegation of Authority

Stanley A. Reed, MS, Medical Physicist, has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

The Radiation Safety Officer is also responsible for assisting the Radiation Safety Committee in the performance of its duties.

Attachment 10.1.3

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed September 1980		December 1988	720-501-96	725-501-6
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Ramsath		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kindrad		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: ALARA				

I. Management Commitment

a. We, the management of St. Elizabeth Hospital are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

b. We will perform an annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgement, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will be also maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of the radiation doses received by all involved individuals.

II. Radiation Safety Committee (RSC)

a. Review of Proposed Users and Uses

1. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

2. Wher considering a new use of by-product material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

3. The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

1. The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

2. The RSC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the committee will record the basis for its action in the minutes of the committee's quarterly meeting.

c. Review of ALARA Program

1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

2. The RSC will perform a quarterly review of occupational radiation exposures with particular attention to instances where Investigational Levels in Table I below are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see paragraph VI).

3. The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. The review will include the efforts of the RSO, authorized users, and workers as well as those of management.

III. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

2. Quarterly review of Occupational Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VI of this program.

3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels recorded for unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for an ALARA Program

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

2. The RSO will assure that authorized users, workers and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

1. The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

2. The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices; and, if possible, determine the causes. When the cause is known, the RSO will implement changes in the program to maintain exposures ALARA, if a reasonable solution exists as determined by the RSC and RSO.

IV. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

2. The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of the Authorized User to Those He Supervises

1. The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure are trained and educated in good health physics and practices and in maintaining exposures ALARA.

V. Persons Who Receive Occupational Radiation Exposure

a. The worker will be instructed in ALARA concept and its relationship to his working procedures and work conditions.

b. The worker will know what recourses are available if he feels that ALARA is not being promoted on the job.

VI. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Exposures

St. Elizabeth Hospital hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigational by the Radiation Safety Committee and/or the Radiation Safety Officer. The Investigational Levels that we have adopted are listed in Table 1 below. These levels apply to the exposure of individual workers.

The NRC has emphasized that the following "Investigational Levels" are not new dose limits but serve as check points above which the results are considered sufficiently important to justify further investigations.

	Investigational Levels - (mrem per calendar quarter - deep dose equivalent)	
	LEVEL I	LEVEL II
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

*Not normally applicable to nuclear medicine operations except those using significant quantities of beta emitting isotopes.

The Radiation Safety Officer will review the dosimeter processor's personnel monitoring report (equivalent to form NRC-5) not less than once in any calendar quarter. Personnel ionization radiation exposure records will be maintained in accordance with 10 CFR §20.2106. The following actions will be taken at the Investigational Levels as stated in Table 1:

a. Quarterly exposure of individuals to less than Investigational Level I.

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table I values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

   The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. He will report the results of his reviews at the first RSC meeting following the quarter when the exposure was recorded. A written copy of the individual's quarterly exposure record will be furnished to the individual if it exceeds Level I values. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the committee or RSO. The committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the committee minutes.

c. Exposure equal to or greater than Investigational Level II.

   The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II, and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the committee minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection. A written copy of the individual's quarterly exposure record will be furnished to the individual if it exceeds Level I values.

d. Re-establishment of an individual occupational worker's Investigational Level II above that listed in Table I.

   In cases where a worker's or a group of worker's exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

Index: 725-501-6	SUBJECT: ALARA

The Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph C above will be followed.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		725-501-14
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Ramsett		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kinder MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: SEALED SOURCE LEAKAGE/CONTAMINATION TESTING				

POLICY:

Except as noted below each sealed radioactive source in clinical use containing byproduct licensed material, other than Hydrogen-3, with a half-life greater than thirty days, with an activity exceeding 100 uCi, and in any form other than gas shall be tested for leakage/contamination at six month intervals (the testing interval will be within ±15 days of the scheduled testing month). Sources primarily emitting alpha particles shall be tested at three month intervals. Cs-137 sealed sources will be wipe tested at three year intervals.

PROCEDURE:

1) Test each source for leakage/contamination before first use unless the licensee has a certificate from the supplier indicating proper leak testing. The source shall be tested at six month intervals.

2) Wipe samples should be taken from the sealed source directly or from surfaces where leakage/contamination would be expected to occur. A solvent (alcohol) should be used on the wipe. Use protective shields and long handle forceps when possible.

3) Measure samples in an instrument capable of easily detecting the presence of 0.005 microcuries. (Instrumentation: Series 30 Canberra multichannel analyzer with 2 inch well scintillation crystal and low background shield.)

4) Maintain records of leak tests for five years. Records shall keep the results listed in microcuries, the model and serial number (if available) of the source, the identity and activity of each source radionuclide, a description of the testing method, the date of the test, and the signature of the Radiation Safety Officer or qualified designee. (See attachment 10.3.4 for test recording form.)

5) If the leakage/contamination test reveals the presence of more than 0.005 uCi from the wipe sample then the source shall be withdrawn from use and handled/stored in accordance with Parts 20 and 30 of 10 CFR. A report detailing the equipment, tests results and action taken will be filed with the Region III Nuclear Regulatory Commission Office within five days of the known tests results which indicate unacceptable leakage/contamination. A copy of the report will be sent to the Director at the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission in Washington, DC.

SEALED SOURCE WIPE TEST

Date: _____ Surveyor: _____

Method: An alcohol moistened cotton swab is used to wipe the readily accessible surface of the source. The swab is placed in a labelled plastic test tube and counted in a well scintillation crystal selecting an energy window completely containing the main photopeaks. A reference source will be used to determine the proper instrument settings and detection efficiency for this energy window setting.

Amplifier Gain: _____ MCA: Canberra: Model 3100

Voltage: _____

Source	Identification	Original Activity	Date	Decayed Activity	Energy Window Lower Level	Energy Window Upper Level	Measured cts/60sec	Bkgd cts/60sec	Removable Activity (uCi)

Information: 1) Wipe tests are required every six months on beta and gamma emitting sealed sources which exceed 100 uCi (unless not in use).
2) This record shall be kept for five years.

Summary: All wipes are below .005 uCi and no action is necessary: Y / N

The following action should be taken:

_____
Stanley A. Reed, M. S., Medical Physicist

Attachment 10.3.4

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		722-501-15
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Ramsatt		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kinder MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL				

POLICY:

To provide guidelines for the safe use of radioactive material in accordance with current regulations.

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves while handling radioactive materials unless the use of gloves would significantly hinder the efficacy of the test and cause increased handling times.

3. Monitor hands and clothing periodically for contamination during the work day and record readings before leaving the area (see Attachment 10.4.3) for the day.

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve) if possible.

5. a. Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.

   b. Do not store food, drink or personal effects with radioactive material.

6. a. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10% (see Form 268A, Attachment 10.4.2a), except for prescribed dosages of less than 10 microcuries.

   Before administering doses, check the patient's name and identification number, the radionuclide, the chemical form and the activity/dosage vs. the exam ordered.

Index: 722-501-15	SUBJECT: GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at collar or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.

8. Wear TLD finger badges during elution of generator and preparation, assay and injection of radiopharmaceuticals, and when holding patients during procedures.

9. Dispose of radioactive waste only in specially designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Survey generator kit preparation, and injection areas for contamination at the end of the day (see Attachment 10.12.3) or if contamination is suspected. Decontaminate as required.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity and radiation level, if applicable. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study or the patient's name.

13. Transport and store radioactive material in appropriately shielded containers. Flood sources and hot waste should be transported in shielded containers.

14. Form 268A - 3/87 (Attachment 10.4.2a) will be used to document patient doses and generator elution record.

15. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. Survey daily, preparation and injection areas with an instrument sufficiently sensitive to detect 0.1 mR/hr. If necessary, decontaminate area or secure the area for decay. (See Attachments 10.12.1 - 10.12.4)

ST. ELIZABETH HOSPITAL - A Member of the Wheaton Franciscan System
1506 SOUTH ONEIDA STREET - APPLETON, WISCONSIN 54915-1397

RADIOISOTOPE PATIENT RECORD

Form RAD 268a rev. 2/94

RADIONUCLIDE LABEL

PRESCRIBED DOSE RANGES

Tc-99m		range mCi
Cardiolite	1st	7 - 9
	2nd	20 - 23
Disofenin (hepatobiliary)		3.5 - 5.5
DTPA (lung vent)		45 - 65
DTPA (renal)		15 - 20.5
MAG3 (renal)		5 - 10
MAA (vent after perf)		1.5 - 3.0
MAA (perf only)		4 - 5.5
MDP (bone)		22.5 - 27.5
PYP (MI)		15 - 20
Sulfur Colloid (liver)		3.5 - 5.5
(gastric emptying)		.6 - .9
TcO_4 (brain flow)		15 - 20.5
TcO_4 (GI bleed)		15 - 20.5

Tc-99m	range mCi
TcO_4 (Meckel's)	15 - 20.5
TcO_4 (RBC hemangioma)	15 - 20.5
TcO_4 (testicular)	15 - 20.5
TcO_4 (thyroid)	3 - 5.5
TcO_4 (MUGA)	22.5 - 27.5

Other Isotopes	range mCi
Gallium	5.5 - 6.5
I^{123} (thyroid)	.2 - .3
I^{131} (body)	3 - 5
I^{131} (thyroid therapy)	as prescribed
I^{131} (thyroid)	as prescribed
In^{111} (DTPA)	.45 - .55
In^{111} (Oncoscint)	4.5 - 6.5
In^{111} (WBC)	.4 - .6

Other Isotopes		range mCi
P-32		as prescribed
Sr89		as prescribed
Tl-201 (heart)		3 - 4
Tl-201 (reinjection heart)		0.8 - 1.5
Tl-201 (parathyroid)	1st	2.4 - 3.6
TcO_4	2nd	8 - 12

Children: calculated on an individual basis

Radioactive waste is stored for 0IS (decay) unless indicated

DATE	KIT	EXPIRATION DATE	LOT NO.	MEASUREMENT TIME	ACTIVITY/VOL.	PATIENT	MEASURED DOSE	PROCEDURE	TECH	COMMENTS

Attachment 10.4.2a

ST. ELIZABETH HOSPITAL - A Member of the Wheaton Franciscan System
1506 SOUTH ONEIDA STREET - APPLETON, WISCONSIN 54915-1397

RADIOISOTOPE PATIENT RECORD

Form RAD 268b rev. 2/94

RADIONUCLIDE LABEL

DATE	KIT	EXPIRATION DATE	LOT NO.	MEASUREMENT TIME	ACTIVITY/VOL.	PATIENT	MEASURED DOSE	PROCEDURE	TECH	COMMENTS

NUCLEAR MEDICINE DEPARTMENT

PERSONNEL MONITORING

DATE	TIME	TECHNICIAN	BKGD	HANDS		CLOTHING	
			cts/sec	cts/sec	mR/hr	cts/sec	mR/hr

St. Elizabeth Hospital
Appleton, Wisconsin

Survey Instrument (cts/sec): Berthold LB 1210B x10 scale
(mR/hr): Victoreen 493 (used only in accordance with action levels)

Form 279

Attachment 10.4.3

PERSONNEL MONITORING ACTION LEVELS

1. If an area on an employee measures more than five times background then a survey meter shall be used to determine a mR/hr value (approximately 1 cm from the contaminated location and recorded on the personnel monitoring sheet).

2. Exposure rates exceeding 2.0 mR/hr:

   a) Skin: Scrub all contaminated areas (with a brush) in a sink located in Nuclear Medicine. The isotope involved and the resulting exposure rate (mR/hr and cts/sec) shall also be recorded. Notify the Radiation Safety Officer as soon as reasonably possible. Prevent the spread of further contamination.

   b) Clothing: Remove all contaminated clothing and isolate with a protective covering (i.e. plastic bag) and store in a shielded location. Surgical scrubs are available, if necessary. If shoes, eyeglasses, and other essential items are contaminated which are necessary for continued job performance they shall be removed and isolated, and provisions shall be made by the supervisor to obtain temporary replacements. Notify the Radiation Safety Officer as soon as reasonably possible. Use standard prevention and isolation techniques to avoid spreading contamination.

3. Exposure rates less than 2.0 mR/hr and greater than 5 times background:

   Skin areas shall be vigorously cleaned and clothing isolated whenever possible. Record initial and final skin exposure rates (mR/hr and cts/sec) and the action taken. Prevent the spread of contamination. Record the isotope(s) likely involved. If Iodine isotopes are involved then notify the Radiation Safety Officer as soon as reasonably possible.

4. Exposure rates between background and five times background:

   Clean skin and isolated clothing whenever possible.

5. Personnel shall monitor and record exposure rates for hands and likely areas that clothing can become contaminated (i.e. shoes) before leaving the area for the day and if contamination is suspected or found during the workday.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		722-501-16
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E Kamrath		2-28-94
Division Head				
Management Staff				V.V.
Medical Advisor		Robert R Kinde MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: RADIOACTIVE SPILL PROCEDURES				

POLICY:

To determine appropriate action in the event of radioactive material spills or loss of radioactive material.

PROCEDURE:

Minor Spills: (Liquids and Solids)

MINOR SPILL	ISOTOPES
Less than 100 mCi	Tc-99m
Less than 10 mCi	Co-57, Ga-67, Tl-201, In-111, I-123
Less than 1.0 mCi	I-125, I-131

1. NOTIFY: Notify persons in the area that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Include all other contaminated materials such as disposable gloves.

4. SURVEY: With a G.M. Survey Meter, check the area around the spill, your hands and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer (RSO).

6. The RSO will follow-up on the incident and will document the situation if the cleaned area exceeds 2 mR/hr or if it occurs outside of the designated Nuclear Medicine controlled areas.

Index: 722-501-16	SUBJECT: RADIOACTIVE SPILL PROCEDURES

Major Spills: (For liquid or solid quantities greater than listed above)

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

6. PERSONNEL DISCONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water. If contamination remains, induce perspiration by covering the area with plastic, if possible, then wash again.

7. The RSO will supervise the cleanup of the spill and will complete a spill report equivalent to Exhibit 10 and 11 of Regulatory Guide 10.8, Revision 2.

Loss of Byproduct Material:

If byproduct material (e.g. check sources, unit doses, generator, hot waste container, etc.) is lost or stolen immediately notify the Radiation Safety Officer. Take appropriate security measures dependent on the type of incident. Appropriate notifications of regulatory agencies will occur dependent on the type and quantity of material.

RADIATION SAFETY OFFICER: Stanley A. Reed
OFFICE PHONE: Ext. 2190
Home Phone: 733-3442

On Call Nuclear Medicine Technologist: As designated
On Call Rad Office Phone: Ext. 2160
Dept. Phone: Ext. 2192

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		722-501-17
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Ramsett		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kinde MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL				

POLICY:

All radioactive labelled packages shall be handled and received in accordance with 10 CFR Parts 19, 20 and 35, and the Department of Transportation 49 CFR regulations.

PROCEDURE:

I. Ordering Radioactive Material:

1) The acting Chief Nuclear Medicine Technologist or designees will place all orders for radioactive materials, will ensure that the requested materials and quantities are authorized by the license, and will verify that possession limits are not exceeded. Ordering individuals (designees) for radioactive material include qualified nuclear medicine technologists, qualified medical physicists for calibration and testing radioactive materials, and authorized users.

2) All radioactive material orders not ordered from a Nuclear Pharmacy are written on a purchase order form indicating the isotope, chemical form, activity level, quantity and supplier. A copy of this form is retained in the Nuclear Medicine Department for at least one year to verify radioactive shipments.

3) Radioactive material ordered from a Nuclear Pharmacy will occur verbally by qualified individuals described in (1) above. The patient schedule will indicate what is the proper quantity of radioactive material to order and generally the material is packaged in unit dose form which is labelled with the patient's name, activity, chemical form and isotope.

4) Therapeutic radioisotopes (I-131, P-32, Sr-89) and any orders of I-131 or I-125 which exceed 30 microcuries will have a written directive which will be referenced to order the proper material and also used to confirm that the proper material (activity, isotope, chemical form) is received. The written directive will indicate the date, patient, activity, isotope and authorized user's signature and is defined in our Quality Management Policy.

Index: 722-501-17	SUBJECT: PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

II. Receiving Radioactive Material:

1) Normal Working Hours:

During normal working hours carriers may deliver packages to our Shipping and Receiving Department or if radioactive material is transported from a regional Nuclear Pharmacy then the packages are delivered directly to the Nuclear Medicine Department's hot lab. Radioactive packages delivered to Shipping and Receiving will be handled in accordance with the procedure described in Attachment 10.6.4. Radioactive material packages delivered during normal working hours will be monitored for external radiation levels and surface contamination within three hours after receipt. If removable contamination exceeds 22 dpm/cm^2 or if the external radiation levels exceed the limits of 10 CFR 71.47 (see action levels on Attachment 10.7.2) then the NRC Regional Office and final delivery carrier will be notified immediately.

2) Outside Normal Working Hours:

When radioactive material is received outside of normal working hours the carrier enters the Emergency Department and the Emergency Department personnel notify the Security Officer on duty. Security personnel accept delivery of the package following the procedure outlined in Attachment 10.6.3. Radioactive packages received outside normal working hours will be monitored for external radiation levels and surface contamination within three hours from the beginning of the next working day.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		722-501-18
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Kamrath		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert K Knick MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: SECURITY PERSONNEL: PROCEDURE FOR RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL				

All Radioactive Packages:

1) Any packages containing radioactive material that arrive between 5:00 p.m. and 7:00 a.m. on weekdays, or that arrive on Saturday, Sunday, or holidays shall be signed for by the security guard on duty after visually verifying that the package is not significantly damaged (crushed, internally caused wetness, or punctures). Damaged packages will not be accepted until proven safe from radioactive contamination (see below).

Damaged Radioactive Packages:

2) If the package appears to be damaged, then the security guard shall instruct the carrier to remain at the hospital until it can be determined that contamination of the driver, vehicle or transportation route has not occurred. Suspected damaged packages shall be handled with gloves and should be located away from traffic areas and personnel until the contamination assessment occurs by the RSO or Nuclear Medicine technologist.

3) Immediately notify the Nuclear Medicine technologist on call or the Radiation Safety Officer by contacting the Radiology Department in person or at Ext. 2160. The Radiology Department will have the on call list and will contact the correct person. Security personnel should instruct the Radiology Department to have the on call Nuclear Medicine technologist or RSO contact them as soon as possible to assess the situation, provide instructions, and verify if radioactive contamination has occurred. Area surveys and decontamination procedures will be instigated by the RSO or Nuclear Medicine personnel, as necessary.

Acceptable Radioactive Packages:

4) All appropriately radioactive labelled and structurally sound packages shall be immediately delivered to tne Nuclear Medicine Department.

Index: 722-501-18	SUBJECT: SECURITY PERSONNEL: PROCEDURE FOR RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

5) Radioactive packages should not be hand carried but transported by cart or wheelchair.

6) Radioactive labelled packages shall be placed on the floor or right side counter in the Nuclear Medicine hot lab unless refrigeration is necessary.

7) Packages requiring refrigeration shall be placed in the hot lab refrigerator.

8) If radioactive material is being delivered by a Nuclear Pharmacy the carrier may also be picking up containers with unit dose shields or expired radioactive material. Proper labelling will accompany these packages.

9) Lock all department doors after delivery of the package.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		722-501-19
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Kamrath		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kriderni		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: SHIPPING/RECEIVING PERSONNEL: PROCEDURE FOR RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL				

All Radioactive Marked Packages:

1) All packages that are marked radioactive on the exterior surface shall be inspected visually for damage (crushed, internal wetness, or punctures) before the package carrier leaves the hospital.

Damaged Radioactive Packages:

2) If the radioactive labelled package appears to be damaged, then the carrier shall be instructed to remain on site and the package should not be moved or handled any further.

3) Immediately notify the Nuclear Medicine Department (Ext. 2192), or the Radiation Safety Officer (Ext. 2190) and a qualified individual will respond to assess if radioactive contamination has occurred and what procedures will be necessary to rectify the situation.

Acceptable Radioactive Packages:

4) All appropriately labelled and structurally sound radioactive packages shall be delivered in a timely manner (within one hour of receipt) to the Nuclear Medicine Department.

5) Transportation of radioactive packages should be on a hand cart and not hand carried.

6) If a packing slip is not on the exterior surface then the Nuclear Medicine technologists will open the package in the Nuclear Medicine hot lab and provide the slip to shipping/receiving personnel, as necessary.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		722-501-20
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Ramaker		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kinder MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: PROCEDURE FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL				

Action:

The NRC Regional Office will be notified by the Radiation Safety Officer or qualified designee if the actual removable contamination exceeds 2200 dpm/100 cm^2 or if external radiation levels exceed the action levels (If the wipe exceeds 2200 dpm/100 cm^2 (sensitivity and background corrected) then timely notify the RSO or designee before proceeding with further unpacking.) listed on Attachment 10.7.3 (10 CFR 71.47).

Opening Packages:

1) Put on disposable gloves to prevent hand contamination.

2) Visually inspect package for any sign of damage (e.g. punctures, wetness, crushed). If any damage is noted, stop procedure and notify the Radiation Safety Officer.

3) Measure the exposure rate at 1 meter from package surface and at the package surface. Record the readings on Form 286. If a reading is greater than the maximum levels listed at the bottom of the form then stop the procedure and notify the Radiation Safety Officer or qualified designee.

4) Check for exterior radioactive contamination on all labelled (White I, Yellow II, Yellow III) packages by taking a wipe of 100 cm^2 area and counting the removable contamination with an instrument capable of detecting 22 dpm/cm^2 above background. If the external surface wipe exceeds a sensitivity corrected value of 2200 dpm/100 cm^2 then notify the Radiation Safety Officer or designee.

5) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents (compare requisition, packing slips and label on source container). Check integrity of final source container (inspect for breakage of seals, loss of liquid,

discoloration of packing material). Check also that shipment does not exceed possession limits. If anything is unexpected in the package, stop and notify the RSO or designee.

6) If there is any reason to suspect contamination, wipe the external surface of final source container with moistened cotton swab and measure the amount of removable radioactivity using an instrument capable of detecting 22 dpm/cm^2 above background. If the wipe exceeds 2200 dpm/100 cm^2 (sensitivity and background corrected) then timely notify the RSO or designee before proceeding with further unpacking. Precautions shall be observed to prevent the spread of suspected contamination. Radioactive gases will not have a wipe test.

7) Monitor the packing material and packages for contamination before discarding:

   a) If contaminated, treat as radioactive waste and notify the necessary individuals, as appropriate.

   b) If not contaminated, obliterate radiation labels before discarding in regular trash.

   c) Form 286 (Attachment 10.7.3) will be used to document package delivery, monitoring, and method of disposal.

8) For unlabelled radioactive packages received under the general license in §31.11, the following procedure for opening each package will be followed:

   a) Visually inspect the package for any sign of damage (e.g. wet or crushed). If damage is noted, stop procedure and notify the RSO or Nuclear Medicine Department.

   b) Check to ensure that the material received is the material that was ordered.

ST. ELIZABETH HOSPITAL
Appleton, Wisconsin
Nuclear Medicine - Radiology

Form RAD 286 rev. 1/94

RADIOACTIVE SHIPMENT RECEIPT RECORD

DATE	TIME	P.O. NUMBER	RADIONUCLIDE AND ACTIVITY ON LABEL	CONDITION OF PACKAGE *1	MEASURED RADIATION LEVELS (mR/hr) *2		SWIPE RESULTS (CPM/100 cm²) OUTER *3		SOURCE CONTAINER *4		SURVEY OF PACKING MATERIAL (mR/hr) *5	DISPOSAL METHOD *6	TECH.
					PACKAGE SURFACE	3' FROM SURFACE (TI)	bkgd	reading	bkgd	reading			
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O.	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	
				I:D							B:O	S:O	

Action Levels:

*1 - Condition of Package: Circle if the package is intact or has visible damage/possible contamination. Describe damage if present. I = intact; D = damaged

*2 - Notify the RSO immediately if the following radiation levels occur:

Measurement Location	White I	Yellow II	Yellow III
Package Surface	≥ .5 mR/hr	≥ 50 mR/hr	≥ 200 mR/hr
Transport Index (TI) (3' from package surface)	> twice background	≥ 1 mR/hr	≥ 10 mR/hr

*3 - Swipe 100 cm^2 area on external surface of all packages labeled with White I, Yellow II or III within 3 hours. If the net reading from the wipe counter exceeds 1500 cts/60 sec per 100 cm^2, then notify the RSO immediately and treat the package as contaminated. The NRC Regional Office and final delivery carrier shall be notified if these radioactive contamination limits are exceeded.

*4 - If the internal source container appears to have damage or leakage then wipe and measure. Notify the RSO if the 100 cm^2 wipe exceeds 1500 cts/60 sec (net counts above background)

*5 - Packing material may be discarded (obliterate radioactive labels) if at background level. B = at background (< .1 mR/hr); O = other, list level

*6 - S = stored, held for decay; O = other, list method

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		722-501-21
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Komsat		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kindrat MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: AREA SURVEY PROCEDURE				

POLICY:

To outline the appropriate methods for performing area surveys in locations where radioactive material is used.

PROCEDURE:

Ambient Dose Rate Surveys (see Attachment 10.12.3)

1) Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter sufficiently sensitive to detect 0.1 mR/hr. Diagnostic administrations made occasionally in patients' rooms need not be surveyed unless contamination is suspected.

   b. In laboratory areas, except those operating under a general license (§31.11, of CFR 10), where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), a monthly survey will be made with a survey meter sensitive enough to detect 0.1 mR/hr.

   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with an appropriate radiation detection survey meter. (see Attachment 10.12.4a)

   d. In sealed source and brachytherapy storage areas, survey quarterly with an appropriate radiation survey meter. (see Attachment 10.12.10)

2) Immediately notify the RSO if unexpected levels are measured and/or if action levels are exceeded.

Index: 722-501-21	SUBJECT: AREA SURVEY PROCEDURE

Removable Contamination Surveys (see Attachment 10.12.4)

1) Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. Diagnostic administrations made occasionally in patients' rooms need not be tested unless contamination is suspected.

   b. In laboratory areas, except those operating under a general license (§31.11, of 10 CFR), where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2) The wipe sample assay procedure uses a sodium iodide well counter with a multichannel analyzer and has a detection efficiency exceeding 80% for the commonly used isotopes. Therefore, we establish an action level of 1600 detected counts/60 sec for a 100 cm^2 wipe for most non-iodine isotopes. This action level more than compensates any reduction in efficiency due to the measuring device sensitivity. Iodine isotopes are only used in solid form (capsules) in the department therefore unless a liquid is used the action levels will reflect the 1600 dpm type level. If iodine is used in liquid form then our action levels will be 200 dpm/100 cm^2 times the efficiency of the detection device.

3) Notify the RSO or designee in accordance with action levels established on Attachments 10.12.3 and 10.12.5.

Records

1) See Attachment 10.12.3 for information recorded for weekly contamination surveys and action levels established.

2) See Attachment 10.12.4a for information recorded for daily surveys and established action levels.

3) The RSO or designee will review and initial in a timely manner those cases in which action levels were exceeded. A review by the RSO or designee of area surveys will occur on a quarterly basis.

ST. ELIZABETH HOSPITAL
NUCLEAR MEDICINE DEPARTMENT

HOT LAB/DAILY AREA MONITORING

Survey Instrument: |_| GM Model 493 |_| Other _____

All readings below are in mR/hr:

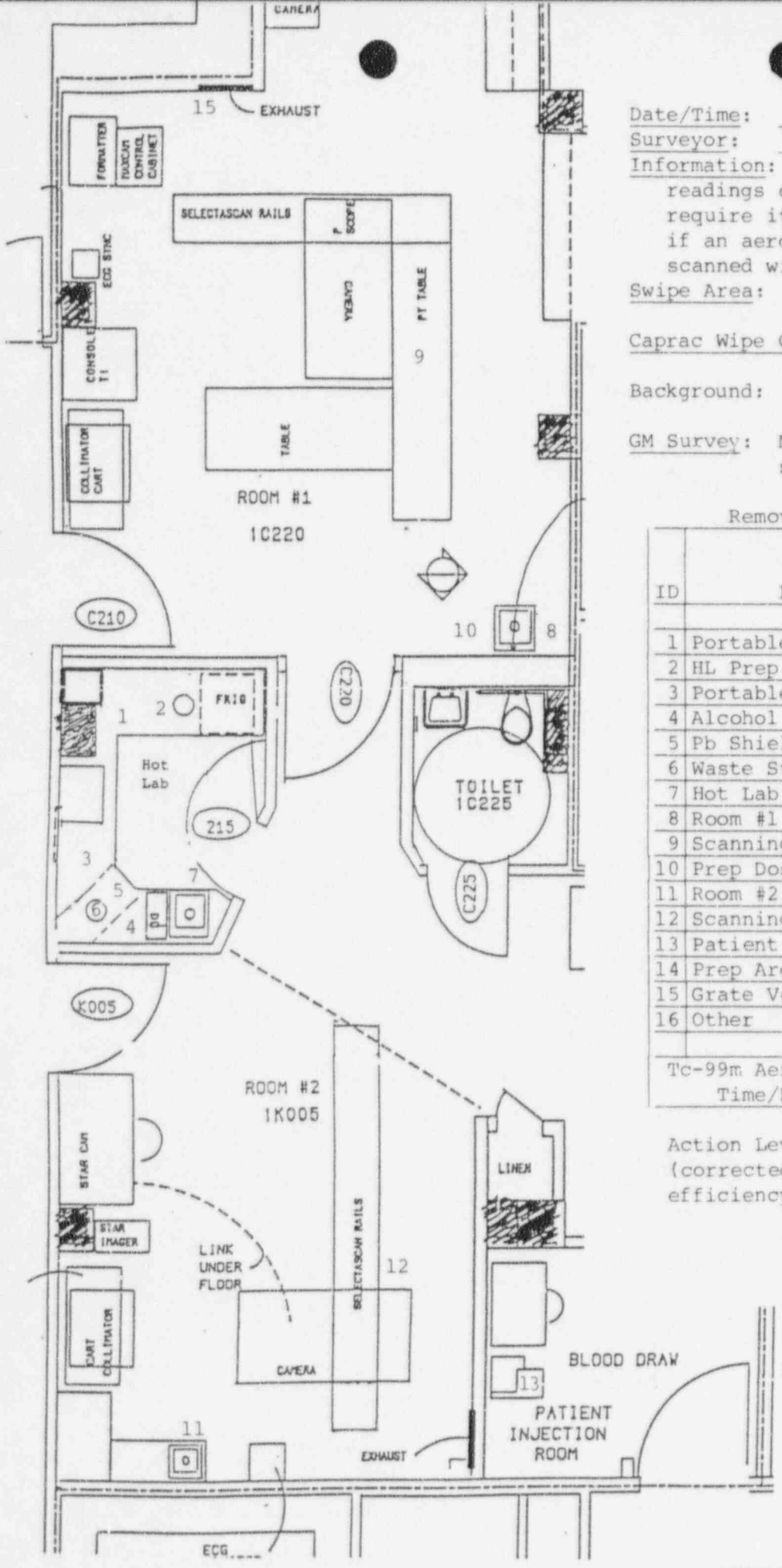
DATE/ INITIALS	SURVEY METER CHECK	AREA I	AREA II	AREA III	AREA IV	AREA V	AREA VI	AREA VII	AREA VIII	AREA IX	AREA X	AREA XI

Action Level: If readings in the hot lab exceed twice normal/expected values or if readings outside of the hot lab exceed 1.0 mR/hr then promptly notify the RSO (Ext. 2190).

CODE: (All locations refer to attachment 10.12.4a)

Area I = Prep Area I (Location 6)
Area II = Floor at Prep Area I (Location 6)
Area III = Prep Area II (Location 4)
Area IV = Prep/Disposal Area III (Location 2)
Area V = General Trash Disposal Can (Hot lab)
Area VI = Prepared Doses (Location 11)
Area VII = Scan Table (Room #1) (Location 10)
Area VIII = Prepared Doses (Location 12)
Area IX = Scan Table (Location 14)
Area X = Prep Area CPS
Area XI = Prep Area LaSalle

Attachment 10.12.3



St. Elizabeth Hospital
Weekly Swipe Survey

Date/Time: _____

Surveyor: _____

Information: Notify RSO if unexpected readings occur or if action levels require it. Only swipe exhaust areas if an aerosol patient has been scanned within the last 24 hours.

Swipe Area: 100cm^2, if possible

Caprac Wipe Counter: Unrestricted Window

Background: _____ cpm

GM Survey: Maximum in waste storage room: _____ mR/hr

Removable Contamination Survey

ID	Location	dpm, net	final dpm, net
1	Portable Tray		
2	HL Prep Area		
3	Portable Syringe Holder		
4	Alcohol Prep		
5	Pb Shield Prep		
6	Waste Storage Handle		
7	Hot Lab Sink		
8	Room #1 Sink		
9	Scanning Table Rm #1		
10	Prep Doses Rm #1		
11	Room #2 Sink		
12	Scanning Table Rm #2		
13	Patient Injection Area		
14	Prep Area Treadmill NM		
15	Grate Vent Rm #1		
16	Other		
	Tc-99m Aerosol Time/Date:		

Action Level (circle): I II III
(corrected for background and instrument efficiency)

I. All net swipes <2200 dist/60sec

II. All net swipes >2200 dist/60sec were cleaned to give a final dist/60sec <2200

III. The Radiation Safety Officer was notified that either an area could not be cleaned to a net level below 2200 dist/60sec or an area outside of the hot lab (9-20) exceeded a net level of 2200 dist/60sec.

MULTICHANNEL ANALYZER SETTINGS

Instrument: CANBERRA Series 30 Multichannel Analyzer
Model 3100 : (S/N 2841740)

Settings: N=1 : M=2 : switch in T_L
Vertical = variable (X1): memory 1/1
ACQ = PHA(add) : I/O = out (TTY)
ADC Gain = 1024
ADC Offset = 0
DISC = 0.0
Amp Gain = as specified below
Input Level: Low

Crystal Designation	keV/channel	Amplifier Gain Setting	Date
Probe	1 keV/channel		
Well	1 keV/channel		
Well	2 keV/channel		

Isotope	Integral ROI-Channels	Center Peak Energy (keV)	Action Level (includes efficiencies) dpm/100 cm^2	Detection Efficiency (with ROI listed)
Tc-99m	110 - 170	140.5	1440	72% well
I-123	129 - 189	159	-	.0075% probe
Cr-51	280 - 360	320	600	est. 30%
Cs-137	612 - 712	661.6	-	14.4% well
General Wipe Tests/Surveys-Well	1 - 712	-	1600	Tc-99m (80.6%)
I-131	292 - 436	364 (83%) 284 (5%) 637 (7%)	60 -	30% - well .064% - probe using thyroid phantom

Note: If x-rays are being taken in room 1 adjacent to the MCA then it is possible to detect additional background on the well counter when doing wipe test-surveys. Most of the time the effect is not significant but avoid swipe measurements if possible, or use >1 mm of lead over the well when counting. Probe measurements will not be affected due to the low energy (<80 keV) x-rays being outside of clinical windows. If the net counts/min exceed the Action Level, decontaminate or isolate and notify the RSO or designee.

Surveyor: _____

CALCULATION OF WORKER DOSE FROM AEROSOLS IN WORK AREAS:

At our facility Tc-99m is used in a single use delivery device specifically designed to provide an aerosol to the patient. The delivery device and procedure were experimental analyzed several years ago and we determined that Tc-99m aerosols do not behave like a gas and only stay airborne a relatively short time. An air sampling device was internally calibrated and used for air sampling during procedures. A surrounding area wipe survey was also performed for many patients to analyze the surface contamination clinically occurring. If we use a properly designed aerosol single use delivery device and have cooperative patients no activity was detected in the air samples. Due to the dynamics of aerosols, we designed our imaging rooms to have the vents near floor level and located near the procedure. In addition, the direction of air flow is away from the nuclear medicine technologist assisting the patient during the procedure. Our personnel also evaluate patients on their ability to successfully perform the study and poor candidates generally do not have aerosols done. If a patient may have difficulty maintaining a good system seal then we have a jump suit and surgical masks available to significantly reduce personnel contamination. Part 20, Appendix B to §§20.1001-20.2401, lists the ALI for Tc-99m at 80 milliCuries (oral) and 200 mCi (inhalation). One-tenth of the values would be 8 milliCuries and 20 mCi respectively and our personnel would not approach these levels (see description below).

Number of procedures: 3/week = 156/year

20% may have some procedure difficulty = 31/year

12 x 700 ml/breath per minute - average patient breathing

% of activity breathed in 5 minute study - 10%

Total activity (average) per study = 60 mCi

Activity at mouthpiece/5 min $\cong$ 6 mCi

Expected activity loss with patients having difficulty = 5% (300 uCi)

Assume local air volume environment of $(3.05m)^3 = 28.4m^3$ (2.84×10^7 cm^3)

300 uCi/2.84×10^7 ml = 1.06×10^{-5} uCi/ml

1.06×10^{-5} uCi/ml x 700 ml x 12 breaths/min = .09 uCi/min

(minimum local air clearance) 800 cfm = (2.83×10^4 ml/cf) x 800 = 2.27×10^7 ml/min

In ten minutes the local air environment would be cleared about 8 times and most activity should be cleared or settled.

.09 uCi/min x 10 min = .9 uCi (maximum) inhaled per patient having difficulty

.9 uCi x 31 patients = 27.9 uCi/year

This calculation does not account for the fact that there are three technologists of which only one will be present for the exam and our vent and personnel location would keep activities lower than calculated.

The total annual effluent which vents at an unoccupied area on the roof (300 uCi x 31 = 9300 uCi) would be dispersed in the large volume of air and most would be adhering to the sides of the vent before releasing to outside air. Our single use delivery device traps most of the activity on a filter and we expect very little additional activity to add to the annual effluent beyond the loss occurring from patients having difficulty maintaining a consistent and effective seal at the mouthpiece.

Maximum permissible air concentrations: (Tc-99m)

restricted (weekly): 1×10^{-4} uCi/ml

unrestricted (weekly): 3×10^{-7} uCi/ml

$$\frac{(300 \text{ uCi/pat})\,(3 \text{ patients/week})}{(2.83 \times 10^{4} \text{ ml/cf})\,(800 \text{ cfm})\,(60 \text{ min/hr})\,(x \text{ hours})} \leq 3 \times 10^{-7} \text{ uCi/ml}$$

This implies if all activity stayed airborne that our exhaust would need to be on 2.2 hours or more per week using the method described in Regulatory Guide 10.8, Revision 2.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		722-501-24
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Kamrath		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert K Kinde MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: SUMMARY OF RADIATION SAFETY AND PROCEDURES TO FOLLOW DURING IODINE-131 THERAPY OVER 30 MILLICURIES				

POLICY:

All patients administered I-131 doses greater than 30 millicuries will be handled in accordance with the following policies, procedures, and attachments:

A. Physics/Radiation Safety:

1) Radiation Safety During I-131 Therapy Over 30 Millicuries (Attachments 10.14.1-10.14.3)
2) Radiation Exposure Rates (Attachment 10.14.4)
3) Nuclear Medicine Therapy Patient Instructions (Attachment 10.14.5)
4) Radioactive I-131 Thyroid Therapy Room Preparation (Attachments 10.14.6-10.14.7)
5) Nuclear Medicine I-131 Thyroid Burden Measurements (Attachment 10.14.8)
6) Nursing Instructions for Patients Treated with I-131 (Attachments 10.14.9, 10.14.10, 10.14.10a)
7) Nuclear Medicine Survey Report (Attachment 10.14.11)
8) Radiation Safety Checklist (Attachment 10.14.12)
9) Nursing Instructions for Patients Treated with P-32 or Sr-89 (Attachment 10.14.24)

B. Nursing:

1) I-131 Radioisotopes (Attachments 10.14.13-10.14.16)

C. Nuclear Medicine:

1) High Dose I-131 Therapy (Attachments 10.14.17-10.14.18)
2) Informed Consent for I-131 Therapy (Attachment 10.14.19)
3) Nuclear Medicine Patient Instructions (Attachment 10.14.20)
4) I-131 Record (Attachment 10.14.25)
5) Radiopharmaceutical Therapy Record (Attachment 10.14.26)

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		722-501-22
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Kamrath		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kridel MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: RADIATION SAFETY DURING IODINE 131 THERAPY OVER 30 MILLICURIES				

SAFETY STATEMENT:

Use the following policy and procedure for reducing the hospital personnel and general public's dose during high dose radiopharmaceutical therapy using I-131.

POLICY:

During the period of radioactive isolation:

1) Nursing personnel shall be inserviced annually by Medical Physics on radiation safety procedures as well as provided with written instruction and materials for dealing with accidental contamination. (Refer to Attachments 10.14.9, 10.14.10)

2) Housekeeping personnel shall be inserviced annually on radiation safety procedures as well as provided with written instructions for patient room preparation during radiopharmaceutical therapy. (See Attachments 10.14.6, 10.14.7)

3) All personnel attending therapy patients shall be assigned a personal radiation monitor.

4) The therapy patient will be briefed on radiation safety and personal care during isolation prior to administration of the radiopharmaceutical. (Refer to Attachment 10.14.5)

5) Personnel present during administration of radioactive iodine shall be measured for thyroid burden within three days after administration, as stated in Code of Federal Regulations (10 CFR 35.315(a)(8)). (See Attachment 10.14.8)

6) The patient's room shall be posted with a "Radioactive Materials" sign immediately following administration.

7) Radiation exposure rates (mR/hr) at 1 meter from the patient's umbilicus, at bedside, and at the doorway shall be recorded daily and posted in the patient's medical record. Unrestricted areas shall be limited in accordance with Code of Federal Regulations 10 CFR 20.1301.

8) Visitors should not be allowed to enter the room during radioactive isolation. If a visitor is related and necessary for the patient's well being (i.e. pediatric patient) then radiation precautions and procedures shall be reviewed and followed.

9) The patient shall be released from isolation in accordance with the Code of Federal Regulations 10 CFR 35.75(a) (dose rate less than 5 mrem/hr at 1 meter or the activity less than 30 mCi).

10) All radioactive waste shall be disposed of by decay-in-storage in a shielded storage area and monitored after at least 10 half lives before disposal in conventional trash.

11) The patient's room will be decontaminated prior to release to the admitting office. Contamination limits are described in Code of Federal Regulations 10 CFR 35.315 (200 dpm/100 cm^2). Refer to Attachment 10.14.11 for the survey report.

PROCEDURE:

1) The medical physics department staff shall provide annual radiation inservices to personnel attending patients with I-131 therapies (greater than 30 mCi). This shall include appropriate nursing, housekeeping, and Nuclear Medicine personnel. An appropriate personnel radiation monitoring system shall be available.

2) Each patient shall have a review of expected radiation safety procedures which will be discussed individually with a medical physics department staff member prior to administration of the radioisotope.

3) The medical physics department staff shall also be responsible for the following:

   a) Obtaining bioassay measurements on personnel present for the radioisotope administration.

   b) Verifying that all signs, and safety precautions are in effect.

   c) Measuring dose rates at bedside, 1 meter from the patient, doorway, and unrestricted areas.

   d) Determining that the patient is at less than 5 mrem/hr at 1 meter or contains less than 30 mCi of I-131.

   e) Contacting the referring physician to allow the patient to be discharged after determining that (d) criteria is met.

Index: 722-501-22	SUBJECT: RADIATION SAFETY DURING IODINE 131 THERAPY OVER 30 MILLICURIES

f) Verifying that there is no removable contamination in excess of 200 dpm/100 cm^2. If there are areas that exceed more than 200 dpm/100 cm^2 that can't be cleaned, then the room will be restricted from use until contamination limits are satisfied.

g) Releasing the room for general cleaning after removing all protective materials and storing them for decay in the appropriate locked storage room.

h) Assuring that materials released into regular trash have decayed more than 10 half lives, have been surveyed and measured at background prior to release.

RADIATION EXPOSURE RATES

Patient Name: ______________________________ Patient Room #: __________

Patient Number: ____________________

CAUTION: _______ mCi of Radioactive Iodine-131 administered at ______ am pm on __________.

Nuclear Medicine Personnel Instructions

1. Measure exposure rate using Victoreen 450 ionization chamber.
2. Except for Day 0, have patient void prior to measurement.
3. Take measurements at 24 hour intervals.
4. Measure exposure rate at 1 meter above patient's trunk. Record highest reading. With patient centered in bed, measure exposure rate at bedside. Record highest reading. Record highest exposure rate at door.

Unrestricted Areas: door - _____mR/hr; rm # _____ _____mR/hr rm # _____ _____mR/hr

Restricted Zone:

Date	Time	@ Bedside	1 meter from	Doorway	__________
___-___-___	___:___ am pm	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr

	*Activity Remaining	**Permissible Time in Restricted Zone/Day
___-___-___	__________________	__________________
___-___-___	__________________	__________________
___-___-___	__________________	__________________
___-___-___	__________________	__________________

* Based on 0.17 mR/hr-mCi at 1 meter. Authorized for release below 5 mR/hr or 30 mCi.

** Based on limiting personnel exposure to 20 mR/day at bedside.

CONTROL NO. 396604

Attachment 10.14.4

NUCLEAR MEDICINE THERAPY PATIENT INSTRUCTIONS

1. You must remain in the room for the duration of the therapy. You should remain in bed until the morning following administration except when at toilet.

2. Visitors are not allowed inside restricted zone (tape on floor).

3. If you feel nauseous or if vomiting or incontinence occur, please notify the nurse.

4. Careful bathroom habits are important. Flush toilet 3 times after use and wash hands thoroughly. Do not use the shower until restrictions are lifted.

5. You have been given two containers for "Radioactive" waste disposal, one for trash and one for linen. Eating utensils, dishes, straws, kleenex, and other items having direct contact with saliva or other body secretions should be disposed of in the container marked "Radioactive"-Trash. All linen will have to be saved so please use provided hospital clothing and place used items in container marked "Radioactive"-Linen.

   Please follow these additional steps to minimize waste storage:

   a. Pour milk and other liquids down the sink.

   b. Flush uneaten (easily dissolvable) food items down the toilet whenever possible.

   c. Discard newspapers, disposable meal trays/lids and snack food wrappings in the wastebasket for non-radioactive items.

6. Upon release from the hospital:

   a. Avoid close contact with children and pregnant women; this results in unnecessary radiation exposure. An occasional hug is not harmful, but prolonged contact is discouraged.

   b. Use separate eating utensils.

   c. Flush the toilet 3 times after use and clean the bathroom area thoroughly when finished.

   d. Avoid mouth to mouth contact. Items that contact your mouth should be kept from use by other individuals (toothbrush, glass, etc.).

These precautions should be taken for _____ days following release from the hospital.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		722-501-23
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E Kamrath		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kinder (M)		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: RADIOACTIVE I-131 THYROID THERAPY (GREATER THAN 30 MILLICURIES) ROOM PREPARATION				

POLICY:

The I-131 therapy patient's private room shall be prepared to prevent radioactive contamination prior to the administration of the radioisotope.

Materials: (for each preparation)

2 rolls of "packing" tape
1 roll of "transpore" tape
3 rolls of "adhesive" cloth tape (2 or 3 inch wide)
plastic backed paper floor covering
2 packages of Chux (blue absorbent pads)
plastic wrap (Glad cling wrap)

PROCEDURE:

A. Floor Covering:

1) Cover entire floor of patient's room to a point about one foot past patient's bathroom door. "Restricted Area Line"
2) Cover entire bathroom floor including doorway.
3) Overlap each section by approximately one inch.
4) Use "packing" tape liberally to secure all seams in paper.
5) Use "packing" tape to patch any holes formed in paper.

B. Absorbent Covering:

1) Cover entire sink surface, except inside basin, securing with "adhesive" cloth tape.
2) Cover entire toilet surface, except inside bowl and base of pedestal, securing with cloth tape.
3) Cover entire toilet seat surface and use cloth tape to secure seat in the down position.

Index: 722-501-23	SUBJECT: RADIOACTIVE I-131 THYROID THERAPY (GREATER THAN 30 MILLICURIES) ROOM PREPARATION

4) Cover immediate floor area under and in front of toilet bowl with a Chux pad. Tape in position.
5) Cover top surface of patient's night stand and tray table with a Chux pad and secure with cloth tape.
6) Use "adhesive" cloth tape liberally to secure all loose edges.

C. Plastic Wrap Covering:

1) Cover entire phone.
2) Cover nurse call hand-set and bed controls.
3) Cover sink and toilet handles and soap disp. handles.
4) Cover hand rail in bathroom.
5) Cover door and closet handles.
6) Use "transpore" tape to secure loose ends.

NUCLEAR MEDICINE I-131 THYROID BURDEN MEASUREMENTS

Patient Name	Date of Administration	Personnel Name	Date of Bioassay	Bkgd Counts/Min	Thyroid Counts/Min	Net DPM	Thyroid Activity

Comments: _____

_____

_____

Thyroid Probe Efficiency: _____

Attachment 10.14.8

NUCLEAR MEDICINE

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH IODINE-131

Patient Name: _____ Patient Room: _____

Patient Number: _____ Radiologist: _____

CAUTION: _____ mCi of Radioactive Iodine-131 was administered at _____:_____ am pm

Physicist's Signature: _____ Date: _____

A. General Nursing Instructions:

1) Pregnant personnel shall not attend the patient.

2) Avoid unnecessary contact with the patient, but perform required nursing care. Wear your supplied film badge. Door to room need not be closed.

3) The patient is restricted to his room throughout the therapy and should remain in bed (except when at toilet) from time of administration until the following morning. A "restricted zone" is indicated on the floor of the patient's room.

4) No visitors are allowed throughout the therapy.

5) Disposable food trays and eating utensils must be used. There will be a container provided in the room for all items coming into direct contact with the patient's saliva and perspiration.

6) Soiled linen is to be placed in appropriate containers and saved in the patient's room.

7) Disposable shoe covers should be worn in the "restricted zone" and discarded in the appropriate container before leaving. Disposable gloves should be worn when handling items that may have become contaminated with perspiration, saliva, or urine and feces. Discard urine and feces in toilet. Flush three times.

8) The room is not to be cleaned by housekeeping during the therapy. No biological samples (urine, blood, etc.) are to be taken without approval of the medical physicist (radiology).

B. Nursing Instructions When Contamination is Suspected:

1) If there is any suspicion that accidental contamination has resulted from the patient's excreta or vomitus, from spillage, or from other causes, the medical physicist should be notified immediately. While awaiting his arrival, immediate steps should be taken to prevent the spread of the contamination and prevention of personnel from entering the area. An area containing the entire region of potential contamination should be marked off. No person should be

permitted to walk through this area. Any person who enters this area should not leave it without being monitored. Precautions shall be taken to prevent the spread of contamination to other areas.

If there is an appreciable amount of liquid, paper towels should be dropped upon it and left until the medical physicist arrives. If there is contamination of the patient or of other persons, clothing should be removed and stored within the marked area. Contaminated skin should be scrubbed, using a washroom in this area, or wash basins brought to the area for this purpose. Contamination shall not be removed from the area or further clean-up attempted before arrival of the medical physicist.

Personnel should remain at least 6 feet from the covered spill.

To contact medical physicist call:

Scott Moon	office:	738-2221
	home:	954-8076
Stan Reed	office:	738-2100
	home:	733-3442

ATTENTION NURSES AND OTHER STAFF ATTENDING PATIENT

Please read the "Nuclear Medicine Therapy Nursing Instructions" form posted on door or in patient chart before entering room. You must wear personal radiation film badge. Sign below to verify that you have read and understand the instructions. If you have any questions, please call medical physicist or the attending physician.

	PLEASE PRINT:	SIGNATURE:
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____
6.	_____	_____
7.	_____	_____

NUCLEAR MEDICINE SURVEY REPORT
OF CONTAMINATION IN THERAPY PATIENT ROOM

Background (DPM)

1) _____

2) _____

3) _____

Average = _____

Swipe (DPM)

1) _____ 7) _____

2) _____ 8) _____

3) _____ 9) _____

4) _____ 10) _____

5) _____ 11) _____

6) _____ 12) _____

Area Survey (mR/hr)

Toilet _____

Sink _____

Bed _____

Background (mR/hr) _____

Instrument _____

*Patient room must not be reassigned until removable contamination is less than 200 DPM/100 cm^2

Well counter I-131 efficiency _____

Instrument _____

Signature:

Medical Physicist _____

Technologist _____

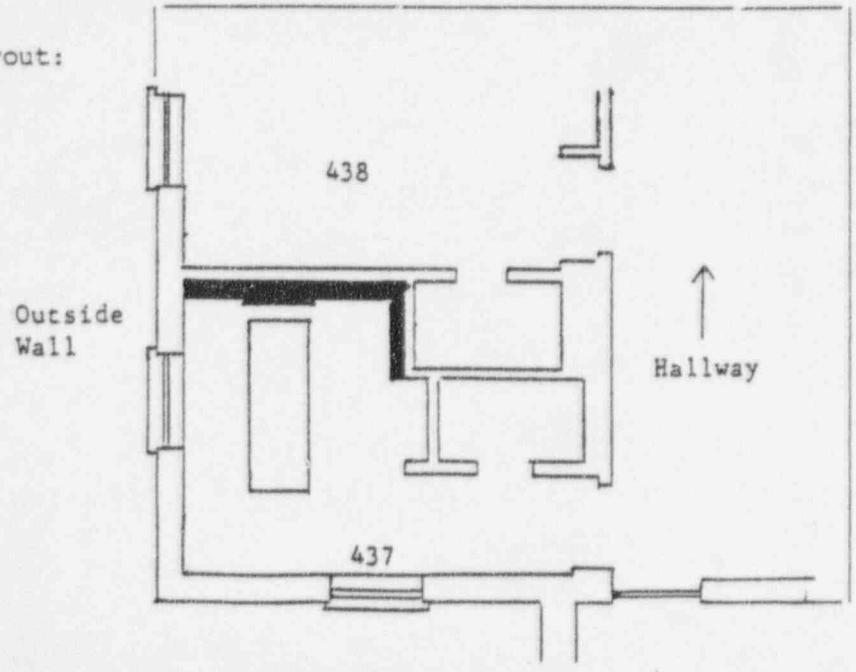
Patient Name _____

Room Number _____

Isotope Used _____

Date Patient Released _____

Room Layout:



Attachment 10.14.11

RADIATION SAFETY CHECKLIST FOR
IODINE THERAPY OVER 30 MILLICURIES

Patient: _____ Room: _____ Date: _____

PREPARATION

- [ ] Schedule a private room (436 or 437), with private sanitary facilities.
- [ ] Cover large room surfaces with absorbent paper and small surfaces with absorbent paper or plastic bags.
- [ ] Prepare labeled bags for used linen, disposable waste, and nondisposable contaminated items.
- [ ] Stock room with disposable gloves and shoe covers, absorbent paper, and "Radioactive Material" labels.
- [ ] Mark a "Restricted Area line" on the floor.
- [ ] Order disposable table service.
- [ ] Notify housekeeping to not clean the room until further notice.
- [ ] Brief the nursing staff on radiation safety measures.
- [ ] Supply the nursing staff with personnel radiation dosimeters.

ADMINISTRATION

- [ ] Clear the room of unneeded personnel.
- [ ] Brief the patient on the clinical procedure.
- [ ] Administer the dosage.
- [ ] Measure dose rates at bedside, 1 meter from bedside, "Restricted Area line", and surrounding hallways and rooms.
- [ ] Post the room with a "Radioactive Materials" sign.
- [ ] Post the patient chart with "Radioactive Patient" sticker, include instructions for personnel.

FOLLOW-UP

- [ ] Measure the thyroid burden of all personnel who were present for the administration.
- [ ] Pick up waste for decay-in-storage or decontamination.
- [ ] Release the patient.
- [ ] Decontaminate and survey the room. Remove the "Radioactive Materials" sign.
- [ ] Call the housekeeping office to clean the room.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Anne Doyle, OCN		10/93	None	616-026
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		L Bailey 11-24-93		
Division Head		Judy French 11-24-93		
Management Staff				
Medical Advisor				
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: HIGH DOSE I-131 RADIO-ISOTOPES				

SAFETY STATEMENT:

All personnel are to wear gloves for any contaminated material and shoe covers while in the room.

DEFINITION: R.S.O. - Radiation Safety Officer - Refer to guidelines on the chart in order to contact the RSO.

POLICY:

During the period of Radioactive Isolation:

1. Patients will be admitted to private room 437.

2. No visitors are allowed throughout the hospitalization. This will be noted on the door and in the Hospital Information System on the computer.

3. Pregnant personnel should not care for the patient.

4. The patient is restricted to his/her room throughout the therapy and should remain in bed (except when using the toilet from the time of the I-131 administration until the following morning).

5. The toilet is to be flushed three times post each use.

6. Disposable equipment (thermometer, utensils, and food tray) are used for the patient. (Thermometers are stored in Medication Room) Supply Room with one package of chux on admission.

7. Everything is collected in appropriately marked containers in the patient's room and not removed until cleared by the Radiation Safety Officer (RSO).
   - "Radioactive Waste" - linen
   - "Radioactive Waste" - trash

   All equipment must remain in the room until cleared by the RSO.

INDEX	SUBJECT I-131 RADIO-ISOTOPES

8. No other studies, labs, are to be done during the therapy unless cleared by the RSO.

9. The room is not be cleaned by housekeeping during therapy.

10. The RSO is to be notified if patient spills excreta so that the RSO can supervise or clean up the spill.

11. The patient is discharged by the unit clerk per normal routine, the screen will read N/R. Only the RSO may release the room. He/She will notify the unit clerk of clearance. The unit clerk will notify Housekeeping to clean the room.

12. In case of a code situation, staff should proceed with code. Notify the RSO immediately. Try to limit number of people in room without jeopardizing the code.

13. In case of a death, it must documented on the Record of Death that the patient received I-131, the date and time.

14. In other emergencies (i.e., tornado, fire), protocol for each code will be followed. The RSO must be notified. He/She will follow up by checking the area for contamination.

15. A Radiation monitor must be worn by all staff exposed to the patient.

16. Remove shoe covers, then gloves before leaving the room.

17. The nursing staff will deliver trays and document amount taken.

PROCEDURE:

A. Pre-admission

1. The patient will be pre-scheduled by Nuclear Medicine through Central Scheduling, who will notify Registration Department. Central Scheduling will notify 4 West by written message.

2. The unit clerk will put the information in the 4 West scheduling book and reserve room 437 twenty-four hours prior to admission.

3. The room will be prepared by housekeeping under the direction of the RSO. Housekeeping will need room available 24 hours prior to admission of the patient.

4. Women of child-bearing age (menses to menopause) will have a pregnancy test within 48 hours of procedure. The report will be on the chart. This will be coordinated by the admitting department.

B. Knowledge

1. Review and explain policy and rationale with patient and family.
   a. No visitor policy.
   b. Restriction of patient and all equipment and line to the room.
   c. Flush toilet three times after use and wash hands thoroughly.
   d. Instruct patient about use of containers. Encourage self care in this area as appropriate.
      Key Note: Minimize waste storage
      - pour liquids down the sink
      - flush uneaten foods down toilet whenever possible
   e. Set up room
      - 4 disposable thermometers, emesis and wash basin, admission kit, set of chux, stethoscope, nursing instruction sheet in room and one on chart
   f. Vital signs taken only as ordered. (Daily will be the standard if not ordered otherwise by MD.)

      Key Note: Teach patient to take own temperature with disposable thermometer.
      - Use wall blood pressure cuff
      - leave stethoscope in room
   g. Instruct patient to do as much as possible of own self care using disposable emesis basins or toilet for mouth care. I&O, calorie counts will not be ordered or done routinely.
      Key Note: Emphasize that assistance will be provided if needed. Discard oral care and bath water in toilet rather than sink (secretions and excretions may contain radioactive iodine).
   h. Personal items

C. Order diet immediately through Clinstar. Use paper tray code under modifier and call Food & Nutrition also. Food & Nutrition will call the patient for menu selections. Nursing staff will deliver. Document amount taken.
Key Point: MD will probably order patient NPO for two hours prior to I-131 administration. (The patient may remain NPO for a period of time post I-131 --- to be determined by the Radiologist.)

D. Nuclear Medicine will review the procedure and get a signed consent from the patient.

E. Administration of I-131

1. The Nuclear Medicine staff will brief the patient, administer the dosage, take proper measurement, post the door with three radiation precaution signs.

F. Assess patients' needs and interests. Provide occupational materials PRN.
Key Note: All materials must be left in room post discharge unless otherwise approved by the RSO at the time of discharge.

INDEX	SUBJECT I-131 RADIO-ISOTOPES

G. Spillage of Excreta

1. If the patient has an emesis, is incontinent, or spills excreta, notify the Radiation Safety Officer at any time and follow directions.
   Key Note: Telephone number of RSO will be on chart. While awaiting directives, immediate steps should include, marking off the entire region of potential contamination. Any person who enters the contaminated area should not leave without being monitored. Contaminated skin should be scrubbed.

H. Documentation:

1. Precaution Code - I-131
2. Diet - with modifier for paper tray
3. Standard - Radioisotope I-131
4. Chart at the Nurses Station - Documentation as per Collaborative Practice

5. Identified patient specific P/G (knowledge, isolation, anxiety, age if minor, etc.)

I. The RSO will remove contaminated items prior to the cleaning of room. The room will have to be kept vacant until levels are safe. After clearance, routine discharge cleaning takes place. (This can be two-three post patient's discharge from the hospital.

I. Patient written discharge instructions will include:

1. Avoid close contact with children and pregnant women.

2. Use separate eating utensils.

3. Flush toilet two times after use and clean the bathroom area thoroughly when finished.

4. Avoid mouth to mouth contact (tooth brush, glasses, etc.)

5. Personal items

These precautions should be taken for 5-7 days following release from the hospital.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Dave Pynonnen		11/1/93		722-501-13
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Kamrad		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kruidenier		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: HIGH DOSE I-131 THERAPY				

PURPOSE:

To safely administer therapeutic I-131 sodium iodide of quantities greater than 30.0 mCi.

POLICY/PROCEDURE:

The following instructions shall occur prior to administration of therapy:

1) A written directive (prescription) signed by the authorized user is required and identifies the activity of I-131.

2) Therapeutic doses of I-131 will be ordered from reputable suppliers in a calibrated unit dose form for ease of administration.

3) The dose shall be measured in dose calibrator, compared to the manufacturer calibration, and recorded in log and check in document. The dose shall measure within the prescribed dose range (±10%) before being administered to the patient.

4) The technologist will follow quality management program by identifying the patient by at least two methods (see written directive form).

5) Women of childbearing age (menses to menopause) will have a recent pregnancy test (within the prior 48 hours).

6) A consent form will be signed by patient (and parent, if patient is under 18 years of age).

7) No one except the Nuclear Medicine technologist, physicist, and physician should be present during administration.
(exception - unless patient needs immediate care from a nurse)

Index: 722-501-13	SUBJECT: HIGH DOSE I-131 THERAPY

CONSENT FORM:

This shall be signed by patient prior to administering therapy. If patient is under 18 years old, the parent must also sign consent form.

DELIVERY OF DOSE TO ROOM:

The Nuclear Medicine technologist will deliver dose to designated room while maintaining proper shielding. The exposure shall not exceed 2 mR/hr at 3 feet from the surface of the container. A stable cart with additional shielding should be used to secure the dose from accidental breakage.

ADMINISTRATION OF ISOTOPE:

The patient should drink the I-131 solution using a straw (unless capsule form is used). Plenty of absorbing materials (Chux) will be used in case of spillage. The vial will be carefully rinsed at least 2 times with deionized water to ensure proper dosing.

CLEANUP:

The Nuclear Medicine technologist shall return all dosing materials and store all which are contaminated for 10 half lives in an appropriate decay in storage location with proper labelling. If accidental contamination occurs then notify the medical physics department staff for proper cleanup. Immediately isolate any potentially contaminated area to prevent the spread of contamination.

BIOASSAY:

The Nuclear Medicine Department staff shall do baseline and post administration thyroid counts on the personnel present. The baseline should be done prior to therapy. Post administration measurements should be done within 3 days after therapy.

ST. ELIZABETH HOSPITAL
Appleton, Wisconsin 54915

DEPARTMENT OF NUCLEAR MEDICINE

INFORMED CONSENT FOR RADIOACTIVE IODINE THERAPY

PATIENT: _____ AGE: _____

DATE: _____ TIME: _____ A.M. / P.M. PLACE: _____

I hereby request and authorize Dr _____ to administer radioactive iodine to myself in a dosage he deems advisable.

I understand that I may in the future develop hypothyroidism (underactive thyroid gland) secondary to the radioactive iodine therapy for which replacement thyroid hormone therapy may be necessary.

I understand that retreatment at a later date may be necessary.

Dr _____ has explained the procedure to my satisfaction and all my questions have been answered.

Signed: _____

The foregoing consent was read, discussed and signed in my presence, and in my opinion, the person so signing did so freely with full knowledge and understanding.

Witness: _____

ST. ELIZABETH HOSPITAL
Appleton, Wisconsin 54915

NUCLEAR MEDICINE THERAPY PATIENT INSTRUCTIONS

Name: _____

Date: _____

1. You must remain in the room for the duration of the therapy. You should remain in bed until the morning following administration except when at toilet.

2. Visitors are not allowed inside restricted zone (tape on floor).

3. If you feel nauseous or if vomiting or incontinence occur, please notify the nurse.

4. Careful bathroom habits are important. Flush toilet 3 times after use and wash hands thoroughly. Do not use the shower until restrictions are lifted.

5. You have been given two containers for "Radioactive" waste disposal, one for trash and one for linen. Eating utensils, dishes, straws, kleenex, and other items having direct contact with saliva or other body secretions should be disposed of in the container marked "Radioactive"-Trash. All linen will have to be saved so please use provided hospital clothing and place used items in container marked "Radioactive"-Linen.

   Please follow these additional steps to minimize waste storage:

   a. Pour milk and other liquids down the sink.

   b. Flush uneaten (easily dissolvable) food items down the toilet whenever possible.

   c. Discard newspapers, disposable meal trays/lids and snack food wrappings in the wastebasket for non-radioactive items.

6. Upon release from the hospital:

   a. Avoid close contact with children and pregnant women; this results in unnecessary radiation exposure. An occasional hug is not harmful, but prolonged contact is discouraged.

   b. Use separate eating utensils.

   c. Flush the toilet 2 times after use and clean the bathroom area thoroughly when finished.

   d. Avoid mouth to mouth contact. Items that contact your mouth should be kept from use by other individuals (toothbrush, glass, etc.).

These precautions should be taken for 5-7 days following release from the hospital.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Renee Vertin, RD August, 1993		Nov., 1993	None	801-262
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Margie Rankin 10-25-93		
Division Head		Michael L. Thomas 10-27-93		
Management Staff				
Medical Advisor				
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: HANDLING OF MENUS AND TRAYS FOR PATIENTS RECEIVING NUCLEAR MEDICINE THERAPY (HIGH DOSE I-131 THERAPY)				

POLICY:

Menus and trays for patients receiving nuclear medicine therapy in Room 437 will be handled by the Food and Nutrition Services Department according to the established guidelines.

PURPOSE:

1) To ensure proper diet order and menu processing.
2) To ensure proper documentation of nutrition-related information.
3) To minimize possible exposure to potentially hazardous conditions.

PROCEDURE:

1. Nursing will communicate diet order to Food and Nutrition Services (FNS) through Clinstar, and will use "paper tray" modifier.

2. The diet office will call the patient for menu selections throughout the patient's admission.

3. The patient's menu will be stamped "paper tray" to generate use of disposable food tray, plate cover, dishes, and eating utensils at each meal. The tray will be placed on top of the unit's hot cart.

4. The tray will be delivered to the unit according to the guidelines of regular meal service. Nursing will deliver the tray to the room.

5. The door leading into the room will be posted with a "Caution - Radioactive Materials" sign to alert FNS employees that entry is prohibited.

6. Nursing will document the amount of the meal consumed by the patient. Nursing will also be responsible for documenting information required for I&O and calorie counts.

INDEX: 801-262	SUBJECT: HANDLING OF MENUS AND TRAYS FOR PATIENTS RECEIVING NUCLEAR MEDICINE THERAPY (HIGH DOSE I-131 THERAPY)

7. The patient or nursing staff will dispose of waste food and paper tray according to procedure.

8. In the event that a FNS employee is accidently exposed to the patient or tray, the employee needs to be screened by the Radiation Safety Officer and Incident Report needs to be completed.

CLERICAL INSTRUCTIONS FOR NUCLEAR MEDICINE THERAPIES

1. The patient should be located in shielded room (436 or 437). This reduces the exposure to patients in adjacent rooms.

2. The patient isolation includes the ordering of:

   Disposable trays and eating utensils
   Linen hamper

3. a. The patient is <u>not</u> to be scheduled for other studies during the therapy unless authorized by medical physicist.

   b. <u>No</u> biological samples (blood, urine, etc.) are to be taken unless authorized by medical physicist.

4. Only medical physicist may release room to admitting office.

5. Housekeeping is not to enter the room unless supervised by the medical physicist, or unless the room has been checked and cleared upon patient release.

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPHORUS-32 OR SR-89 (METASTRON)

Patient Name: _____ Patient Room: _____

Dose: _____mCi of _____ as _____ was administered at ____:____ am pm

Signature: _____ Date: ____-____-____

RADIATION EXPOSURE RATES

Unrestricted areas: door- _____ _____mR/hr; rm _____-_____mR/hr; rm _____-_____mR/hr
Patient supine in bed or _____

Date	Time	Bedside	3 ft from bed	Door	_____
___-___-___	___:___ am pm	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm		_____mR/hr		

INSTRUCTIONS

Visitor Restrictions:

- ☐ No visitors.
- ☐ No visitors under 18 or pregnant.
- ☐ ____ minutes each day maximum for each visitor.
- ☐ Visitors must stay behind line on floor at all times.
- ☐ Other instructions: _____

Nursing Restrictions:

- ☐ Patient is restricted to room.
- ☐ No nurses who are pregnant may render care.
- ☐ ____ minutes each day per nurse in the room.

Patient Care:

- ☐ Wear disposable gloves and discard in marked container. Wash your hands after caring for patient.
- ☐ Discard urine and feces in toilet. Flush three times.
- ☐ Housekeeping personnel are not permitted in the room.
- ☐ Only RSO may release room to admitting office.
- ☐ Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
- ☐ Hold any material (linen, dressings, bedclothes, etc.) that may contain blood or body excrements and store in the marked container in the room.
- ☐ _____ _____
- ☐ _____

In case of emergency, or if you have a question, call:

RSO: _____ Work: _____ Home: _____ Pager: _____
MD: _____ Work: _____ Home: _____ Pager: _____

CONTROL ID 396604

Attachment 10.14.24

ST. ELIZABETH HOSPITAL
NUCLEAR MEDICINE DEPARTMENT
I-131 RECORD

A. Type of Procedure (circle one): 1 - I-131 Therapy

2 - I-131 Thyroid Scan

3 - I-131 Whole Body Scan

B. Patient's Name: _____ Age: _____

Patient's identity verified by more than one method (circle two or more).

1 - Name response/repeated

2 - Able to state home address - address correlated

3 - Wrist band

4 - Verification of patient's identity with companions

5 - Inpatient chart record/information

6 -

C. Radiology I.D. No.: _____

D. Referring Physician(s): _____

E. Diagnostic Iodine-123 Uptake Values

Date I-123 Given: _____

6 Hour Uptake: _____

24 Hour Uptake: _____

F. Scan Appearance: _____

_____

G. Date Patient is to be Administered I-131: _____

H. Activity of I-131 to be Administered: _____ mCi ± _____

I. Patient is Pregnant: Y / N / NA _____

J. Female Patient May Not Nurse Until (List Date/Time): _____: N/A

_____
Authorized User

_____
Date

Attachment 10.14.25

ST. ELIZABETH HOSPITAL
NUCLEAR MEDICINE DEPARTMENT
RADIOPHARMACEUTICAL THERAPY RECORD

A. Type of Procedure (circle one): 1 - P-32

2 -

B. Patient's Name: _____ Age: _____

Patient's identity verified by more than one method (circle two or more).

1 - Name response/repeated

2 - Able to state home address - address correlated

3 - Wrist band

4 - Verification of patient's identity with companions

5 - Inpatient chart record/information

6 -

C. Radiology I.D. No.: _____

D. Referring Physician(s): _____

E. Date Patient is to be Administered Radiopharmaceutical A: _____

F. Activity of Radiopharmaceutical to be Administered:

_____ mCi ± _____

G. Patient is Pregnant: Y / N / NA _____

H. Female Patient May Not Nurse Until (List Date/Time): _____: N/A

_____
Authorized User

_____
Date

Attachment 10.14.26

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		725-501-15
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Kamratt		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kuide MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: THERAPEUTIC USE OF SEALED SOURCES				

POLICY:

Therapeutic use of sealed sources shall follow appropriate safety precautions to maintain personnel and public exposure as low as reasonably achievable.

PROCEDURE:

I. Radiation Safety Precautions:

a. Sealed sources are handled and stored in a specially designated room (Cesium-137 storage, see Attachment 10.15.8) located in the Radiation Therapy Department. The Cs-137 sources are stored in a locked lead safe (4 inches of lead shielding) which limits the measured exposure rate to a maximum of .15 mR/hr at the outside surface with our full Cs-137 stock present.

b. All sealed sources are handled with long forceps behind a 2" L-Block lead shield with a lead glass window providing over eight HVL of shielding for Cs-137. Sources are handled for the shortest time possible with the hands and arms being the only parts which are not shielded.

c. The Radiation Safety Officer or a Medical Physicist is responsible for loading all afterloading inserts with the correct sources. If they are unavailable, then the physician in charge will load the sources. A ring TLD badge in addition to the body film badge is worn at all times while transferring sealed sources by all personnel responsible for the loading of the applicator.

d. Sealed sources (excluding I-125) are transported in a commercially made Heyman carrier with a cart. This carrier has 1" lead shielding and a four foot handle for maintaining distance while transporting. In addition, extra shielding is provided with at least 3/4" lead equivalent molded alloy surrounding the carrier. This shielding keeps exposure levels below 1.0 mR/hr at one meter when loaded with our maximum amount of clinical

radioactive material. This carrier is kept in the patient's room, if possible, in order to provide a readily accessible shielding place for dislodged applicators or sources.

We have a 1.0" x 24" x 36" portable lead shield used at bedside to help reduce visitor and nursing personnel exposures and a 36" x 48" x 0.5" lead shield under the bed for additional protection for the room below.

e-f. All sources taken from our sealed source storage safe are logged on our sealed source accountability form (see Attachment 10.15.9) at the time of removal or return. Sources are removed, transported or returned only by the Radiation Safety Officer, Medical Physicist or the physician in charge. A quarterly inventory is taken for all sealed sources in excess of .1 uCi and recorded on our inventory form (Attachment 10.15.10).

The size of our department allows for only a few individuals to handle sealed radioactive sources and the Radiation Safety Officer and Medical Physicists have the responsibility of maintaining the accountability of our sources. The Radiation Safety Officer or qualified designee is generally present for all sealed source removals and immediately upon transferring the sources to the shielded carrier, a Geiger counter survey is performed before applicators or bandages are removed. The carrier is brought to the Cs-137 storage room and all sources are counted and returned to the safe and a record is maintained. The patient is not discharged until all sources are accounted for on our record and a predischarge radiation survey has been completed.

Surveys are performed (see Attachment 10.15.11) for all brachytherapy patients immediately upon insertion of radioactive material. Measured dose rates are recorded for selected areas within the patient's room and outside the patient's door. Dose rates are not measured in the adjacent room since these brachytherapy rooms were specially shielded to prevent dose rates from exceeding 1.0 mR/hr when loaded with our maximum expected activity. An experiment was performed with an unshielded applicator to verify the shielding design (see Attachment 10.15.14). Specially shielded rooms were constructed in order that radiation surveys would not be necessary and would not unnecessarily alarm patients and family members in the adjacent room. Nursing personnel are reminded of precautions necessary for dealing with these patients and all appropriate labelling is done. Full-time nursing personnel working with brachytherapy patients are assigned a permanent body film badge and other personnel have available a pocket dosimeter with a log sheet located on the patient's door. Brachytherapy procedures are only performed in two specially shielded rooms l[illegible]d on 4 West (436/437). Permanent I-125 implant patients will have c[illegible]rent precautions (see Attachment 10.15.12) and nursing personnel will be instructed accordingly for radiation safety procedures. Attachments 10.15.5 - 10.15.7 are nursing procedures on file for brachytherapy patients and also cover general radiation safety for nursing.

Loss of any sealed source will initiate an immediate investigation by the Radiation Safety Officer and appropriate authorities will be notified dependent on the incident.

MANAGEMENT OF BRACHYTHERAPY PATIENTS

Patient Name _____ Room No. _____ Date _____

Effective Until: _____ Isotope: _____

Temporary Intracavitary: ___ Temporary Interstitial: ___ Permanent Implant: ___

GENERAL INSTRUCTIONS

1. Visiting time is limited to 30 minutes per day unless otherwise stated. In any event, the maximum permissible dose equivalent for those persons not occupationally exposed shall be 500 mrem per year.

2. Children and pregnant women, including nurses, should not be allowed to visit the patient unless otherwise indicated.

3. Visitors must stay at least 6 feet from the patient and preferably directed to the chair in the most distant corner of the room.

4. The patient must be confined to their room except in the case of an emergency.

5. Appropriate tags or labels shall be affixed to:
a) the door; b) the bed; c) the chart

6. All employees entering the room must wear a pocket dosimeter or a film badge to monitor exposure levels. Those employees not assigned a film badge shall record the results on the radiation monitoring record located on the patient's door.

7. All brachytherapy patients shall be assigned to a private room that has a toilet. Temporary intracavitary and interstitial patients shall be assigned to rooms 436 or 437.

8. The portable lead shields should be used whenever possible for temporary implant/ intracavitary procedures.

BRACHYTHERAPY INSTRUCTIONS - TEMPORARY BRACHYTHERAPY PROCEDURES

1. Nurses should spend only the minimum time necessary near a patient for routine nursing care.

2. Never touch needles, capsules or containers holding brachytherapy sources. If a source or applicator becomes dislodged, use a long forceps and put it in the shielded container provided and immediately contact the Radiation Safety Officer or the physician in charge. If there are any questions concerning this procedure, contact the Radiation Safety Officer (Ext. 2190 or 2184).

3. Limit bathing to washing hands and face while sources are in place unless special physician orders indicate otherwise.

4. Perineal care is not given during gynecological treatment; the perineal pad may be changed when necessary unless orders to the contrary have been written.

5. Surgical dressings and bandages used to cover the area of an interstitial implant may be changed only under the direction of the physician in charge. Dressings shall not be discarded until it has been verified that no sources are contained in the bandages. Special orders will be written for oral hygiene for patients with oral implants.

6. No precautions are needed for sputum, urine, vomitus, stools, dishes, instruments or utensils unless specifically ordered. If it is suspected that a source has become dislodged or inadvertently displaced, hold all items until checked by the Radiation Safety Officer.

7. At the conclusion of the treatment, the Radiation Safety Officer will survey the room and remove all radiation signs. All sources will be accounted for prior to discharging the patient. If any permanent implants are to remain in the patient, the Radiation Safety Officer will instruct the patient on radiation safety precautions.

8. Emergency Procedures:
   a) If a source or applicator appears dislodged, or
   b) If the patient dies while sources are in place, or
   c) If the patient requires emergency surgery, immediately call the physician and Radiation Safety Officer.

Physician: _____ Ext: 2184 Home Phone: _____

Radiation Safety Officer: _____ Ext: 2190 Home Phone: _____

PURPOSE:

1. To provide guidelines when caring for patients with radiation implants.

2. Minimize radiation exposure to hospital personnel and visitors.

3. To provide maximum therapeutic environment while patient is receiving therapy.

4. Minimize psychological trauma incurred during radiation therapy.

DEFINITIONS:

1. Dosimeter - Two types of dosimeters are generally used for our radiation procedures. The pocket dosimeter shall be used by employees not assigned a film badge. Readings from the pocket dosimeter are logged on the designated form located on the brachytherapy patient's door. The film badge is specifically assigned to an individual and worn during this procedure.

2. Mrem - The measurement used to measure cumulative dose of radiation your body receives (a permanent record is kept by the Radiation Safety Officer; please inquire if there are any questions).

3. mg Ra Eg (MRE) - The amount of radioactivity coming from a source measured in milligrams radium equivalent.

4. Holder or Applicator - Container in which the radiation source is placed.

GENERAL INFORMATION:

1. Personnel responsible for providing care should minimize radiation exposure by keeping in mind two factors: distance and time.

   Distance: Work as far from the radiation source as you can. The intensity of radiation you will receive decreases by the square of the distance between you and the source (inverse square law).

   Thus, if you are standing 2 feet from the source and move back 2 more feet (double the distance), the radiation you receive drops by a factor of 4 (2 squared).

   Time: The less time you spend near the patient, the less radiation you will receive. The best way to reduce your time near the patient is to make your work as efficient as possible. Plan what you are going to do before you do it. The amount of time you can spend near the patient depends on how close you are to the patient.

2. a) All nursing personnel must wear a radiation dosimeter when caring for brachytherapy patients.

   b) Pregnant nursing personnel will not be assigned to care for patients with sealed radiation sources. However, if you care for a patient with radiation implants, following the guidelines to minimize exposure, and later discover you are pregnant, do not be alarmed.

3. Only designated rooms (436 and 437) will be utilized as radiation therapy rooms. Do not admit two patients with radiation implants to the same room simultaneously.

4. The holder may be implanted in surgery; but the radiation source will not be placed in holder until after the patient is returned to the room. This will prevent unnecessary radiation exposure in the hospital. The radiation source will usually remain in place 48-72 hours.

5. The radiotherapist will instruct and discuss procedure and general instructions with the patient. However, it is the nurses' responsibility to reinforce these and answer any further questions the patient may have.

6. The Radiation Safety Officer will be responsible for:

   a. The proper number and display of Radiation Area signs.
   b. Verification that adequate radiation monitoring devices are readily available.
   c. General radiation precautions.
   d. Transportation and handling of radioactive material.
   e. Notifying nursing personnel if linens, eating utensils, secretions are to be monitored before releasing.

NURSING ORDERS (GENERAL): The following orders are frequently observed, however, the physician may modify these when necessary; see physicians orders.

A. On admission:

   1. Anti-embolic stockings.
   2. General consent for hospitalization and procedure.

B. Evening before procedure:

   1. Codeine and/or Imodium - constipating agents.
   2. Betadine vaginal douche (gyn).
   3. Fleets enema (gyn).

C. On return from procedure: (If ordered by physician)

   1. Resume analgesics as prescribed.
   2. Heal pads.
   3. Propek pad for bed.
   4. Prophylactic Heparin.
   5. An indwelling ('Silastic') Foley catheter will be inserted prior to source insertion. Foley care is not to be given while radiation sources are in place. The patient's Intake and Output must be recorded. The patient may be taught how to record his own intake. The nurse shall check the patency of the Foley catheter q. 8° and chart the output.
   6. Have radiation shields in the patient's room.

D. Upon insertion of radioactive sources:

   1. Observe radiation precautions and visitor restrictions. Each visitor is limited to 30 minutes or less per day. The visitors shall be instructed to remain at least 6 feet from the patient or as directed (see General Instructions). ONLY IMMEDIATE FAMILY MEMBERS OVER 18 YEARS OF AGE MAY VISIT.

2. Activity: Complete bedrest is necessary to prevent any movement or dislodging of radiation sources. Patient 'log rolling' may be allowed (consult physician prior) however, lower body motion which may cause a change in the original source position shall be avoided.

3. Vital Signs: Temperature should be taken q. 8° (once each shift); PR and BP once daily. The patient may be instructed prior to the implantation to do TPRs.

4. Hygiene: Back care and oral care may be given as necessary for patient comfort. AM and PM sponge bath (waist up) should not be given unless ordered otherwise.

5. Diet: The patient will be allowed foods and fluids as tolerated in most cases.

6. Linen should be changed only when necessary. If there is a possibility that the linen, gowns, or dressings may have contamination or a radiation source then these items must remain in the room until released by the Radiation Safety Officer.

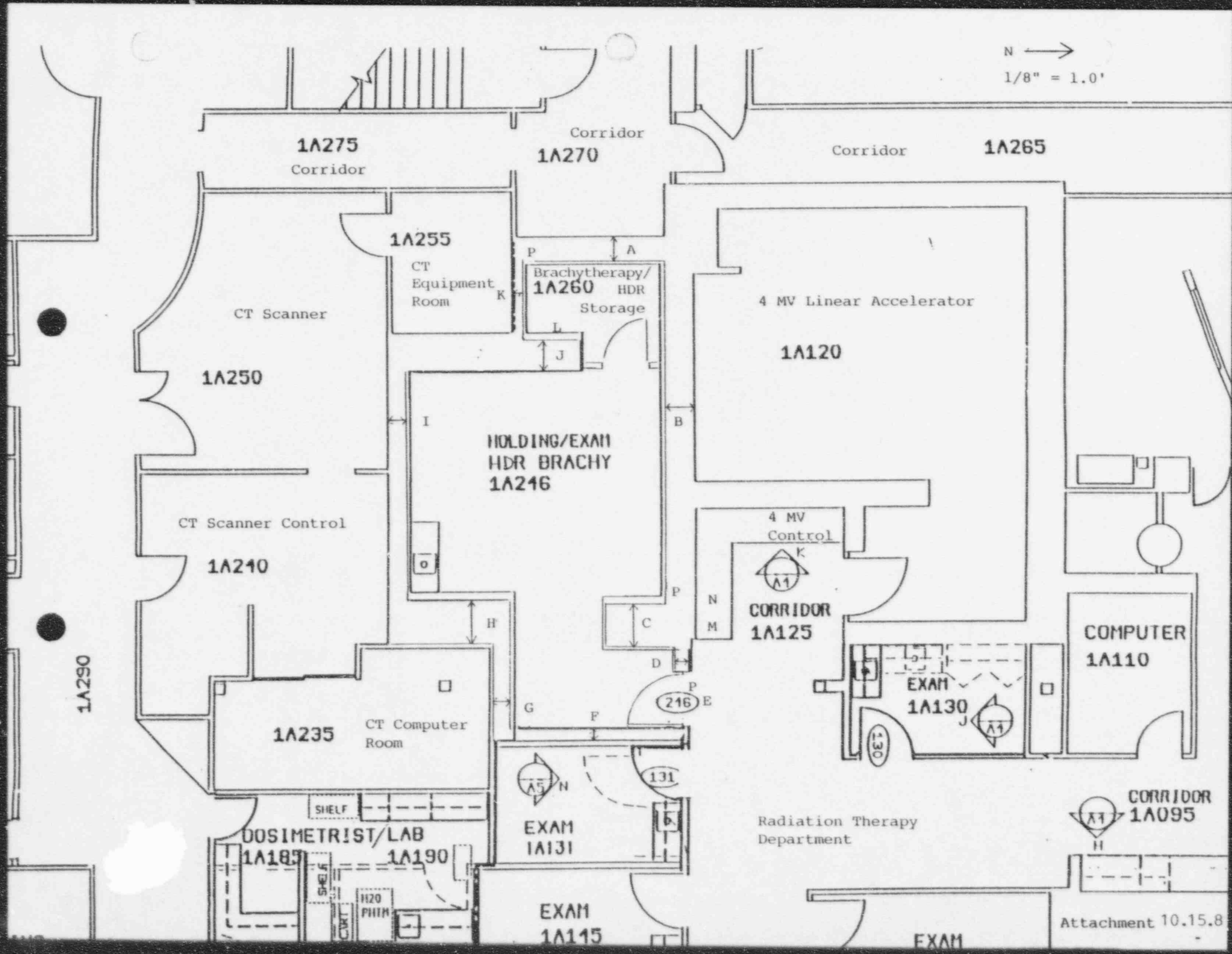
7. If an implant is dislodged and found outside the patient, the nursing personnel should use ring forceps (attached to lead transport containers) to pick up implant and place in lead transport container. DO NOT TOUCH. Notify Dr. Chessin or Dr. Reinke and Stanley A. Reed (telephone numbers noted on General Instructions) immediately. If radiation source is dislodged and you cannot find it in the room, clear the room of all personnel; contact the Radiation Safety Officer and the radiation therapy physician in charge (see General Instructions).

8. Codeine will be routinely administered during this treatment to provide pain relief and reduce action of bowel.

   If the patient needs to defecate, a fracture pan should be used. Care must be taken to prevent dislodging of implant. Stool may be disposed of in the toilet.

9. A nurse may be requested to remain in room while radiation sources are inserted. Procedure, physician and time is to be noted in the nursing notes.

10. Document nursing orders on cardex and identify appropriate problems or potential problems on the Care Plan. Refer to Standard of Care for implants.


N
1/8" = 1.0'
1A275
Corridor
Corridor
1A270
Corridor
1A265
1A255
CT
Equipment
Room
Brachytherapy/
1A260 HDR
Storage
4 MV Linear Accelerator
1A120
CT Scanner
1A250
HOLDING/EXAM
HDR BRACHY
1A246
CT Scanner Control
1A240
4 MV
Control
CORRIDOR
1A125
COMPUTER
1A110
EXAM
1A130
1A290
1A235
CT Computer
Room
EXAM
1A131
CORRIDOR
1A095
Radiation Therapy
Department
SHELF
DOSIMETRIST/LAB
1A185
1A190
H2O
PATH
EXAM
1A115
EXAM
Attachment 10.15.8

CESIUM SEALED SOURCE ACCOUNTABILITY

	Total Number Available		2	5	4	4	4	2	Patient	Room #	Initials
	Source Color		Blue	Green	Old Yellow	New Yellow	Orange	Red			
	Nominal Activity (MRE)		5	10	15	15	20	25			
	Date	Time									
Sources in Clinical Use											
Sources in Storage											
Sources Returned											
Sources in Storage											
Sources in Clinical Use											
Sources in Storage											
Sources Returned											
Sources in Storage											
Sources in Clinical Use											
Sources in Storage											
Sources Returned											
Sources in Storage											
Sources in Clinical Use											
Sources in Storage											
Sources Returned											
Sources in Storage											
Sources in Clinical Use											
Sources in Storage											
Sources Returned											
Sources in Storage											
Sources in Clinical Use											
Sources in Storage											
Sources Returned											
Sources in Storage											

Attachment 10.15.9

SEALED SOURCE INVENTORY

DATE: _____ Max Level in BSR (Sr-90 applicator): _____ mR/hr

SURVEYOR: _____ BSR Doorway: _____ mR/hr

OBSERVATIONS: In Front of Cs-137 safe: _____ mR/hr

# of Sources	Activity mg-Ra-equiv.	Color Code	# In Safe	# In Use	
2	(11-7-80) 5.10	Blue			
5	9.92	Green			
4	14.69	(old) Yellow			
4	19.51	Orange			
2	24.66	Red			
4	(1-7-86) 16.25	(new) Yellow			
Total: 21					

BSR: (Brachytherapy Storage Room)
NMHL: (Nuclear Medicine Hot Lab)

Radioactive Sources	Source Identification	Original Activity	Date	Location	#	Accountability Yes	Accountability No
Co-60	4014 MR	.091 uCi	3-6-78	BSR	1		
Cs-137	3048 MR	.085 uCi	11-29-77	NMHL Pb-box	1		
Co-57	5035 MR	.099 uCi	5-26-78	BSR	1		
Ba-133	6006 MR	.099 uCi	5-26-78	BSR	1		
Cs-137	77325	418 uCi	5-31-78	NMHL Pb-box	1		
Eu 152/154	Stored in glass container	.5 uCi	1978?	BSR	1		
Cs-137	Model 184010	.11 uCi	April 1966	BSR	1		
Cs-137	G3048	.1 uCi	? before 1980	BSR	1		
Cs-137	658-194	.8-.1 uCi	? before 1980	BSR	1		
Sl-I	1052	.1 uCi	? before 1980	BSR	1		
Co-60	77323	.515 mCi	8-11-78	BSR	1		
Co-57	77320	.465 mCI	8/78	BSR	1		
Co-57	Plastic syringe	.91 mCi	8-28-78	BSR	1		
Sr-90	751331	.9 mCi	4-84	BSR	1		
Sr-90	1835	80 mCi	7-4-77	BSR	1		
Am-241		5 mCi	?	BSR	1		
I-125	seeds	.5 mCi each	before 11-84	BSR	46		
Ba-133	3580185A-04	271 uCi	1-18-85	BSR	1		
Co-57	NES Reference	.121 uCi	11-5-85	BSR	1		
Co-57 ruler	Broken stored in glass	70 uCi	5-6-85	BSR	1		
Co-57	67-231/SN 1527	230 uCI	1-27-89	NMHL Pb-box	1		
Co-57	S206034-077	5.1 mCi	1-12-89	BSR	1		
Co-57	S260012-29	50 uCi	12-88	BSR	1		
Co-57	NES 392230-05 flood	10 mCi	2-28-91	NMHL	1		

RADIATION PROTECTION SURVEY

Patient: _____

Applicator: _____

Source: _____

Source #: _____

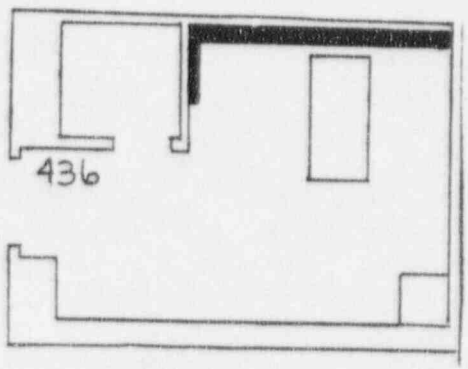
Room #: _____

Surveyor: _____

Total Activity: _____

Procedure: Date: Time:

Location:		Exposure Rate (mR/hr)
a	@ 1 meter from bedside	
b	bedside	
c	chair	
d	doorway	
e	end of bed	



Final Survey:

Date: _____ Surveyor: _____

Location	Exposure Rate (mR/hr)	

Source Removal: Date: Time:

#Sources Returned: _____

Observations:

RADIATION PROTECTION SURVEY

Patient: _____

Applicator: _____

Source: _____

Source #: _____

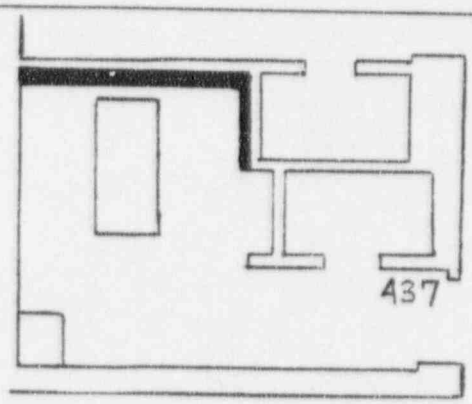
Room #: _____

Surveyor: _____

Total Activity: _____

Procedure: Date: Time:

Location:		Exposure Rate (mR/hr)
a	@ 1 meter from bedside	
b	bedside	
c	chair	
d	doorway	
e	end of bed	



Final Survey:

Date: _____ Surveyor: _____

Location	Exposure Rate (mR/hr)	

Source Removal: Date: Time:

#Sources Returned: _____

Observations:

RECOMMENDATIONS FOR DISCHARGED PATIENTS WITH RADIOIODINE-125 IMPLANTS

1) NAME: _____ has received a sealed source implant containing _____seeds for a total activity of _____mCi of I-125 on (date) _____. The measured radiation exposure rate at this date was _____mR/hr.

2) Precautions: (All circled statements below apply)

a. Because of low radiation levels, no special precautions are required.
b. A special protective shield shall be used until _____ (date) whenever the patient is closer than three feet from another person for a length of time exceeding five minutes.
c. Do not get within three feet for times exceeding five minutes for persons who may be pregnant or under the age of 18.
d. other (list):

3) If the patient has been treated for a superficial lesion (one near the surface of the skin), it is possible that one or more of the radioactive seeds might slough off or become detached as the tumor regresses or becomes smaller. To prevent loss of the seeds in the home, examine the bandages, dressings, or linens that come into direct contact with the implant site for small metallic seeds (about 1/4 inches long and about as thick as a straight pin), similar to the "dummy" seed shown to you. If seed(s) are found, place in the lead vial given to you for this purpose. Cover the vial and place it in some inaccessible place in the home. (Do not handle the seed(s) again). At your next appointment return the vial containing the seed(s) to the undersigned physician for proper disposal.

4) There are no radioactive contamination problems associated with this treatment. Dishes, tableware, clothing, linens, toilet apparatus, etc. used or touched by the patient may be used by anyone else without any special precautions. Touching the patient will not contaminate anyone.

5) Should the patient (or family member) have any questions about safety, please call the undersigned physician.

6) If the patient sees any other physician or is admitted to this or another hospital during the next six months, be sure to show these instructions to the doctor.

_____ _____
Physician

_____ _____
Physicist

_____ _____
Date of Interview

_____
Persons at Interview

Attachment 10.15.12

RADIATION MONITORING RECORD

All nursing personnel entering a radioactive patient's room (designated by radioactive material sign on the door) shall wear a pocket dosimeter and shall record the readings on this sheet. Dosimeters and the radiation safety manual are kept at the nursing station.

In order to read the pocket dosimeter, hold the tube up to a light and a scale will be illuminated. A small wire should be visible indicating a numerical reading. Record the value before and after entering the room. Always orientate the tube in the same direction while reading. (Call the Radiation Safety Officer if there are any questions - ext. 2184).

Date	Name	Chamber Number	Reading Before	Reading After	Net Reading	

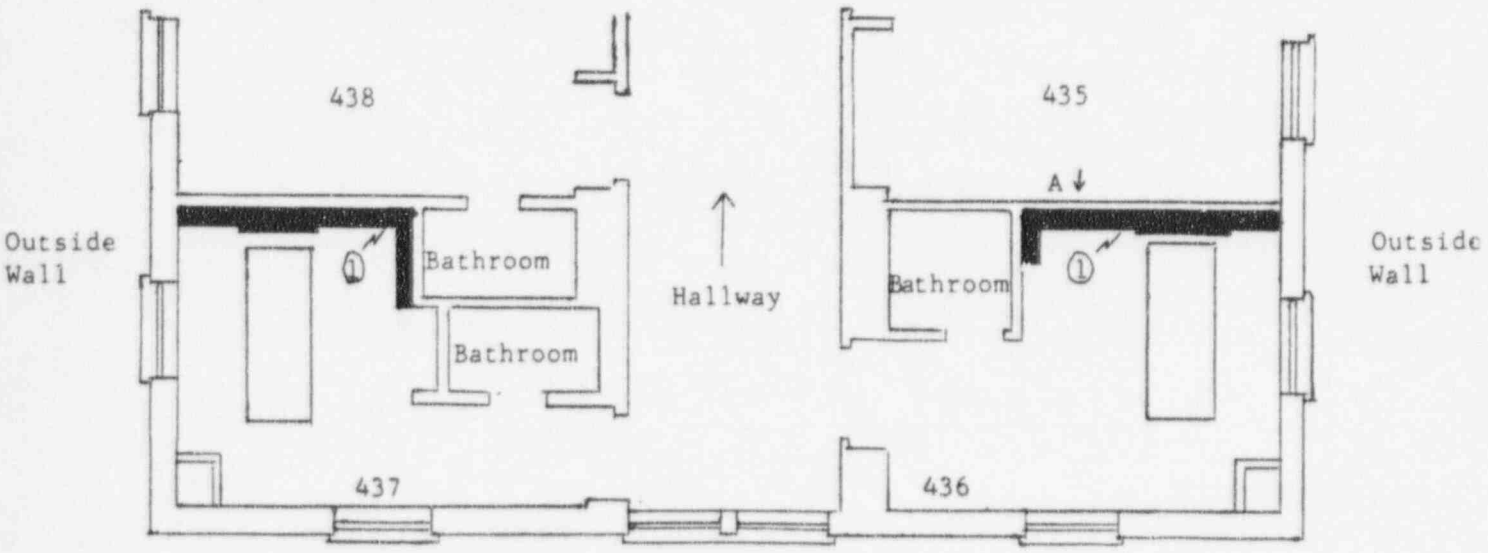
BRACHYTHERAPY SURVEY 4-WEST

DATE: July 31, 1984
SURVEYOR: Stanley A. Reed, Medical Physicist
RADIATION CONDITION: 83.4 MRE Cs-137 was afterloaded for an intracavitary procedure and the adjacent room was unoccupied with the results listed below.
EQUIPMENT: Victoreen Model 493 Geiger Counter S/N 1427

Survey Location	Readings mR/hr	Recommendations
Room 435 Wall A 1½' 6' above floor	typical .25→.35 maximum .45	Well below 2.0 mR/hr limits
Room 435 Wall A below 1½'	maximum 1.0	
Hallway outside 436 door	.35	
Room 336, 3' above floor in line with bed above	maximum .5→.7	The 3rd floor may have pediatric patients or newborn mothers, an additional floor shield (2 HVL) can easily be installed
Room 536, 3' above floor in line with bed below	.5→.8	
Room 536, at finished floor level	maximum 1.0→1.1	

Conclusion: This brachytherapy patient had a loading which we would not significantly exceed in total activity. All accessible areas had measured values below regulatory limits. However, it would be easy to install a 2 HVL lead sheet below each brachytherapy bed to reduce exposure levels in rooms below. This recommendation will be followed (ALARA) in the near future.

Shielding: ① The existing wall has 1.0" of plaster as an exterior covering (2.0" total) over 6.0" clay tile, hollow brick. The brick would have a solid thickness of approximately 1.0". An additional 13 sheets (5/8"/sheet) of gypsum wall board was installed starting 1½' above finished floor height. An initial survey prior to any patients indicated that maximum limits may be reached for a few areas, therefore a lead panel 3/8" thick, 4'x4' was attached to the wall in line with each bed (starting 1½' above floor level).



SAFE HANDLING OF STRONTIUM-90 EYE APPLICATOR

Source:	Sr-90/Y-90		
Manufacturer:	Amersham Corporation		
Source Number:	1835	Catalogue Code:	SIA 20
Activity (listed):	80 mCi	Dose Rate:	60.5 rads/sec 6-29-77
Active Area:	56 mm^2		

The Sr-90 ophthalmic applicator is stored in our locked brachytherapy storage room and will be stored and transported in its specially designed container until clinically used. The following procedures will be followed:

1) The radiation safety officer or NRC approved radiotherapist will be responsible for handling the Sr-90 applicator.

2) A portable shield will be used when cleaning/sterilizing the applicator. The applicator shall always be manipulated using the shielded handle end of the applicator. The applicator is rinsed in an alcohol solution, then in a sterile water bath prior to use. The end is dried by wiping on a sterile pad.

3) The treatment end should be directed away from personnel at all times and not touched by hands or other portions of the body.

4) Radiation monitors shall be worn and the extremity monitor (TLD) shall be worn with the detector on the palm side of the hand.

5) The eye to be treated shall have mechanical assistance to allow the applicator to come in contact with the desired area and prevent personnel extremity exposures. The eyelid shall not be held open with fingers.

6) The applicator will be checked for leakage every six months. In the event of apparent or probable damage immediately confine the applicator in its storage container or equivalent and contact the RSO.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		October 1991		721-501-5 722-501-10
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Kamrath		2-22-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kridel via		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: ADMINISTRATION OF RADIOISOTOPES AND/OR BRACHYTHERAPY SEALED SOURCES TO PATIENTS				

PURPOSE:

Guidelines as outlined for the administration of radioactive materials to patients and how this quality management program will be evaluated.

PROCEDURE:

A. Diagnostic Nuclear Medicine (including I-125 and I-131):

1) All patients will have less than 30 millicuries (1.11 GBq) of radioactive material for diagnostic procedures. Outpatients with less than 30 millicuries of a diagnostic nuclear medicine radioisotope may be discharged from the hospital.

2) All doses will be assayed in the dose calibrator prior to administration. The administered patient dose shall be within 10% of the prescribed dose range if the dose is greater than 10 microcuries. Doses less than 10 microcuries need only be verified that they are less than 10 microcuries.

3) Before administering a dose the patient's identity will be verified by more than one method. The radionuclide, chemical form, and the activity/dosage will also be checked for accuracy with the exam ordered.

B. Therapeutic Nuclear Medicine and Additional Requirements for I-125 or I-131:

1) Prior to the administration of more than 30 microcuries (1.11 MBq) of I-125 or I-131, or any quantity of therapeutic radiopharmaceutical (i.e. P-32), a written directive will be prepared. If a delay caused by waiting for the written directive would jeopardize the patient's health, then an oral directive or an oral revision to an existing written directive will be acceptable as long as the revision is documented immediately in the patient's record and then signed by the authorized user within 24 hours. The administration of the radioisotope shall be in accordance with the written directive(s).

2) A written revision to an existing written directive may occur provided the revision is dated and signed by the authorized user prior to administration.

3) Prior to administration of therapeutic radiopharmaceuticals, or I-125/I-131 in quantities exceeding 30 microcuries the patient's identity will be verified by more than one method as the individual named in the written directive.

C. Brachytherapy:

1) Prior to the use of brachytherapy sealed sources a written directive will be prepared. If a delay, caused by waiting for the preparation of the written directive, would jeopardize the patient's health, then an oral directive or an oral revision to an existing written directive will be acceptable as long as the revision is documented immediately in the patient's record and then signed by the authorized user within 24 hours. All plans shall be in accordance with the written directive(s).

2) A written revision to an existing written directive may occur provided the revision is dated and signed by the authorized user prior to administration.

3) Prior to the use of brachytherapy sealed sources the patient's identity is verified by more than one method as the individual named in the written directive.

D. Program Evaluation/Audits:

1) Verification of diagnostic and therapeutic nuclear medicine procedures are performed on a quarterly basis at the time of the overall quarterly review. Diagnostic doses are reviewed for complete documentation and appropriate activity ranges. I-131, I-125 and other therapeutic doses will also be checked that the written directive corresponds to the actual administration. Any recordable events or misadministrations will be documented and responded to as described in CFR 10, Part 35 §35.2, §35.32 and §35.33. Any corrective actions taken will be documented.

2) The brachytherapy program will have an annual audit performed in which at least 50% of the cases will be reviewed for completeness and accuracy in accordance with the written directive. Any recordable event or misadministration will be documented and responded to as described in CFR 10, Part 35 §35.2, §35.32 and §35.33. Any corrective actions taken will be documented.

ANNUAL ALARA AND QUALITY MANAGEMENT PROGRAM REVIEW

Date: _____ Annual Review Monitoring Time Period: _____

Reviewer: _____

This document is designed to provide an overview of the radiation safety program for the Radiation Safety Committee, management representatives, radiation safety officer and NRC representatives.

1) ALARA/Radiation Safety Program Review:

a) Changes/improvements during the last year:

b) Radiation Safety Officer's Annual Summary:

c) Summary of all exposures exceeding 125 mrem annually:

Monitoring period: _____

Annual Exposure Range (mrem)	Number of Individuals G_1 - Total Body Exposures				Number of Individuals U_3 - Extremity Exposures			
	AMC		SEH		AMC		SEH	
M								
10 - 125								
125 - 250								
250 - 375								
375 - 500								
500 - 750								
750 - 1000								
1000 - 1500								
1500 - 2000								
2000 - 3000								
3000 - 4000								
4000 - 5000								
> 5000								
Totals:								

U_3 reading less than G_1: SEH _____ : AMC _____

2) Quality Management Program Review:

a) Approximately half of the brachytherapy cases will be reviewed by checking:

1) that the written directive corresponds to the actual treatment
2) that the computer plan has the correct data input
3) that all radiation sources were appropriately surveyed and accounted for

Total cases: _____ number reviewed: _____ results:

b) Therapeutic radioisotopes and I-125 or I-131 in quantities >30 microcuries:

1) All administrations will be checked for documented accuracy (i.e. written directive corresponds to the actual treatment) on a quarterly basis.

1st quarter:	
2nd quarter:	
3rd quarter:	
4th quarter:	

2) All recordable events and misadministrations will be reviewed and modifications to our quality management made as required.

Type of Event	Description/Action Taken

3) Summary of NRC inspections and responses taken by licensee.

ST. ELIZABETH HOSPITAL
NUCLEAR MEDICINE DEPARTMENT
I-131 RECORD

A. Type of Procedure (circle one): 1 - I-131 Therapy

2 - I-131 Thyroid Scan

3 - I-131 Whole Body Scan

B. Patient's Name: _____ Age: _____

Patient's identity verified by more than one method (circle two or more).

1 - Name response/repeated

2 - Able to state home address - address correlated

3 - Wrist band

4 - Verification of patient's identity with companions

5 - Inpatient chart record/information

6 -

C. Radiology I.D. No.: _____

D. Referring Physician(s): _____

E. Diagnostic Iodine-123 Uptake Values

Date I-123 Given: _____

6 Hour Uptake: _____

24 Hour Uptake: _____

F. Scan Appearance: _____

_____

G. Date Patient is to be Administered I-131: _____

H. Activity of I-131 to be Administered: _____ mCi ± _____

I. Patient is Pregnant: Y / N / NA _____

J. Female Patient May Not Nurse Until (List Date/Time): _____: N/A

_____
Authorized User

_____
Date

Attachment 10.14.25

ST. ELIZABETH HOSPITAL
NUCLEAR MEDICINE DEPARTMENT
RADIOPHARMACEUTICAL THERAPY RECORD

A. Type of Procedure (circle one): 1 - P-32

2 -

B. Patient's Name: _____ Age: _____

Patient's identity verified by more than one method (circle two or more).

1 - Name response/repeated

2 - Able to state home address - address correlated

3 - Wrist band

4 - Verification of patient's identity with companions

5 - Inpatient chart record/information

6 -

C. Radiology I.D. No.: _____

D. Referring Physician(s): _____

E. Date Patient is to be Administered Radiopharmaceutical A: _____

F. Activity of Radiopharmaceutical to be Administered:

_____ mCi ± _____

G. Patient is Pregnant: Y / N / NA _____

H. Female Patient May Not Nurse Until (List Date/Time): _____: N/A

_____
Authorized User

_____
Date

Attachment 10.14.26

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		725-501-16
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Ramsdell		2-28-94
Division Head				
Management Staff				
Medical Advisor		Henry Thomas, MD 2/25/94		
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: HIGH DOSE RATE AFTERLOADING THERAPY PROGRAM				

POLICY:

The use of a high dose rate afterloading therapy treatment system shall follow appropriate procedures (see below) to ensure safe operation.

PROCEDURE:

I. Prior to Clinical use
II. Use of HDR System
III. Periodic Quality Control

I. Prior to Clinical Use:

A. Training:

1) All operators of the HDR equipment shall be trained by qualified individuals (from Nucletron or a trained medical physicist) prior to use. This training will include, machine safety and interlocks, radiation protection, control console and equipment operation, emergency procedures which include dry runs, and use of applicators and accessories. This training will be repeated at least annually for all users.

B. Radiation Survey/Source Calibration:

1) A complete radiation survey of the areas surrounding the treatment room will be made prior to clinical use. The survey will take into account the possible treatment geometries and various source positions. The survey will account for source strength, occupancies, and type of workers that may be present near the treatment room. This survey will be performed at initial installation and prior to clinical use, and repeated if a significant change is made in surrounding areas or shielding.

2) Whenever a source is installed and prior to clinical use the source will be calibrated by a qualified medical physicist (§35.961).

II. Use of HDR System:

A. General Security:

1) The HDR source unit will be stored when not in use in the locked brachytherapy storage room which is adjacent to the treatment room. The unit will have power at all times while in use or storage. Keys to operate the control console will not be kept with the control unit.

B. Treatment Room Security:

1) The treatment room door has a "Caution-High Radiation Area" sign and a red warning light which indicates when a source is in use. The operator for the system is next to the entry door and is responsible for monitoring unauthorized access into the room while a source is in use. The entry door is interlocked to the system and the source will retract to a shielded position when the door is opened and the source is in use. Only the patient will be in the treatment room when a clinical procedure is being performed. All tests will be conducted without individuals being in the treatment room.

2) Two continuous viewing systems (CCTV) will be used to observe the patient while the clinical treatment is occurring. At least one system must be operational during the treatment. A permanent radiation monitor with an indicator near the control console and one in the treatment room shall be operational on all days of HDR use. If the permanent system fails then a temporary radiation monitoring system could be utilized as long as the operator is able to determine the source position from the control console location and the system provides the same information as the permanent radiation monitor.

C. Clinical Treatment/Use:

1) The operator of the HDR unit for clinical use must be appropriately trained (see I.A.). The operator shall verify that only the patient is in the treatment room while radiation treatments are occurring. A written prescription will be made by the authorized user prior to source administration and the prescription will be correlated with the treatment plan as being in accordance with the written directive and signed by the authorized user. During clinical use, both the authorized user and a qualified medical physicist shall be physically present (within audible range of normal human speech).

2) Prior to each administration the patient's identity will be verified by more than one method. Unintended deviations (administered dose differs by more than 10% of the prescribed dose) from the written directive will be evaluated and appropriate action taken.

3) A microSelectron-HDR Ir-192 User Guide which summarizes the control console operation shall be kept near the control console.

4) The source use location shall not allow the source to be in a direct line to the entrance door. The applicator, catheters and guide tubes shall be visually checked for damage and proper orientation prior to initiating treatment.

5) A shielded container shall be present near the high dose procedure to provide a location to put an applicator or cable with an unretracted source in the event of an emergency. Cable cutters shall be stored conveniently for emergency use.

6) After treatment completion the patient will be surveyed by an appropriate radiation detector to verify that the source has not accidentally become separated from the drive cable. The room radiation monitor shall also be observed as not detecting a radiation signal before the patient leaves the treatment room.

D. Emergency Procedure:

1) If the Ir-192 fails to return to the safe then the emergency procedure posted at the control console and in the front of the quality control book shall be implemented. All users shall be familiar with performing the emergency procedures and these shall be reviewed on an annual basis. Refer to the policy 'Emergency Procedures for High Dose Rate (HDR) Afterloader' (Attachments 10.17.7-10.17.9) for specific details.

III. Periodic Quality Control:

A. Each day of clinical use the following items shall be checked for proper operation and documented: (see Attachment 10.17.5 for outline of procedure)

1) Door interlock
2) Proper channel is recognized as having an applicator
3) Radiation warning lights are operational
4) Treatment interrupt
5) Autoradiograph for verification of programmed source position
6) Total source retraction
7) Timer ends therapy treatment
8) Inspection of source guide tubes (II.C4)

B. 1) Each time a source is replaced it shall be calibrated prior to clinical use and updated and verified in the treatment planning system. The original manufacturer will perform a preventative maintenance survey at the time of each source replacement. At the time of source replacement the power fail back-up system will be tested.

2) The proper source positioning will be verified by using autoradiographs after each source replacement.

3) A radiation survey of the HDR unit shall be performed with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 milliroentgen per hour.

IV. Waste Disposal/Source Exchange:

The reduced activity I-192 source is transferred to the original shielded source container at the time of source exchange by service personnel employed by the original manufacturer. The customer contacts the original manufacturer with proper information concerning the Ir-192 source (activity, transport index, source serial number) in order that proper paperwork is prepared for transportation of dangerous goods. Labelling is then performed by a medical physicist or the RSO and a proper carrier is contacted. The reduced activity source is then shipped back to the original manufacturer.

HIGH DOSE RATE AFTERLOADER QUALITY CONTROL PROCEDURE

Frequency: Each day of clinical use and before any clinical application

A. Position HDR source unit in treatment room and attach the source position ruler to the appropriate adaptor and connect to channel #2.

B. Program channel #1 at a length of 900 mm and time = 10 sec.

1) Leave open the treatment room door and try to start the treatment; DOOR OPEN should be indicated, record result (A).

2) Close door and try to start treatment again, an error code 14 should appear - record result (B).

C. Reprogram the source for channel #2 at three positions: 950 mm, time $\cong$ .2 sec : 900 mm, time = .2 sec : 850 mm, time = .2 sec. Position the source position ruler on a film (Kodak TL Ready Pack film) which has been appropriately exposed (80 kVp/16 mAS) by diagnostic x-ray with the check source properly inserted.

1) The treatment time should compensate for source decay. Complete the programmed technique in (C-above). Observe that radiation warning lights and the radiation monitor are properly operating and record (C-D).

D. Take film out of treatment room to be developed and reprogram unit for channel #2, 900 mm length and 15 sec.

1) Initiate treatment and use treatment interrupt button to stop the treatment before the timer ends. Restart the treatment and open the door (door interrupt), restart, and verify the treatment stops when the timer ends - record (E)(F).

2) Evaluate radiograph for proper source positioning $\pm$1 mm accuracy - record (G).

3) Use the survey meter to check for complete source retraction by measuring at the front of the unit and at the reference location at the side cover and record (H). If any of the above tests fail, no clinical treatments will be given until the problem is corrected and the test is repeated and acceptable.

Initiator/Date		Effective Date	Supersedes	Index
Stanley A. Reed/May 1993		6/25/93	721-501-18	721-501-18A
Required Approval By:	(X)	Signature and Date		Annual Review Date
Department Director	X	Faye E. Komsatz		1.
Division Head				2.
Management Staff				3.
Medical Advisor	X	Henry Chu MD		4.
Med. Staff Exec. Comm.				5.
President				6.
Board of Directors				7.

SUBJECT: EMERGENCY PROCEDURES FOR HIGH DOSE RATE (HDR) AFTERLOADER

PURPOSE:

To establish operational guidelines in the event that the high dose rate Ir-192 source does not return to a proper shielded position.

POLICY:

1. During all patient treatments both an authorized user, and a trained medical physicist or approved operator recognized by the NRC as able to institute proper radiation safety and emergency procedures, will be physically present. Physically present is defined as within audible range of normal human speech.

2. All personnel shall be trained in both routine use and emergency procedures associated with the HDR afterloader. Training shall be provided to all personnel prior to their independent use of the HDR system. Periodic retraining will occur at yearly intervals for all personnel.

3. A radiation survey will be performed on all patients receiving high dose rate treatments immediately after completion of the therapy procedure with an appropriate survey meter (in addition to the area monitor).

4. In the event of an apparent malfunction, which may require an emergency response, the medical physicist or an approved operator with the authorized user will be responsible for implementing the emergency response outlined in the procedure section of this policy. An outline of this procedure will be available near the control console.

5. All personnel involved with HDR procedures shall wear a radiation monitor.

INDEX	SUBJECT
721-501-18A	EMERGENCY PROCEDURES FOR HIGH DOSE RATE (HDR) AFTERLOADER

PROCEDURE: EMERGENCY RESPONSES:

1. All clinical procedures shall have a shielded container present in the procedure room near the patient which is large enough to allow the largest clinical template and needles to be placed inside. The container shall provide at least five half value layers of equivalent shielding material.

2. A portable radiation shield shall be located in the treatment room and positioned to provide a shield for persons entering into a possible radiation field caused by a malfunction of the treatment unit.

3. The closed circuit television shall be positioned to allow observation of the patient, pertinent patient monitors, and the source transport motors. The lid to see the source transport motors and manual drive levers shall be open while the unit is in use. Cable cutters and long forceps shall be available at the HDR unit at all times.

4. Possible malfunctions and responses:

   Emergency Procedure/Clinical Response Flow Chart

SARmmm

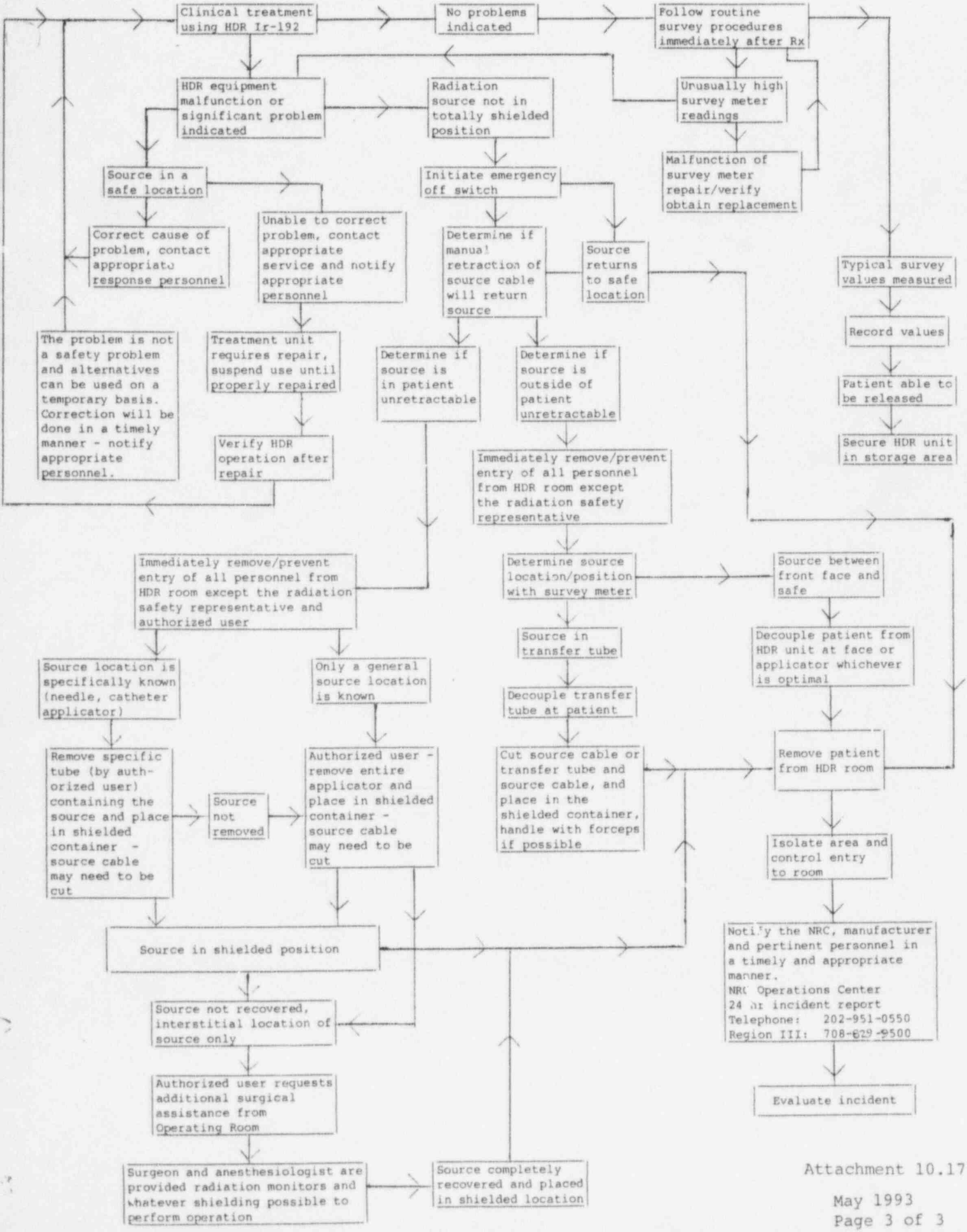
PHYSICS/DOSIMETRY HDR RECORD

Patient Name: _____

Treatment Site: _____

Date	Treatment Number	Time	Prior to Rx-Verification-Parameters Correspond to Plan					Survey of Patient
			dwell positions	distal dwell length	step size	patient name	initial set-up for films mimic treatment set-up	time/initials
								Ref: Pat:
								Ref: Pat:
								Ref: Pat:
								Ref: Pat:
								Ref: Pat:
								Ref: Pat:
								Ref: Pat:

[redacted]GENCY PROCEDURES/CLINICAL RESPONSE FLOW CH[redacted]



ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed		June 1989		722-501-27
Required Approval By:	(X)	Signature and Date		Review Date
Department Director		Faye E. Kamrath		2-28-94
Division Head				
Management Staff				
Medical Advisor		Robert R Kruck MD		2-25-94
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: RADIOACTIVE WASTE DISPOSAL RECORD GUIDELINES				

POLICY:

All radioactive or potentially radioactive waste shall be handled in accordance with proper radiation safety procedures and disposed properly.

I. Guidelines for Decay-in-Storage (DIS) Disposal:

1) All radioactivity labels must be defaced or removed from containers and packages prior to disposal as in-house waste. All materials shall have been surveyed and measured at background prior to release.

2) Consider occupational and public exposure to radiation as well as other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability). After the radiation hazard has decayed, assure that proper disposal for other possible hazardous substances occurs.

3) When the container is nearly full, seal it and label the outside with information that indicates the longest-lived radioisotope inside, the date sealed, and the initials of the person sealing the container. Exchange nearly waste containers after waiting overnight or after a weekend.

4) Decay for at least 10 half-lives (only material with a half-life of less than 65 days may be disposed of by DIS).

5) Prior to disposal as in-house waste monitor each container as follows:

a) Check survey meter for proper operation.

b) Monitor in low background area (<.05 mR/hr).

c) Remove shielding and monitor all surfaces of each container.

d) Discard as in-house waste only those containers that are at background levels. Record (see Attachment 11.1.2) the date on which the container

was sealed, the disposal date, and type of material. Verify that no radiation labels are visible. Hazardous non-radioactive waste disposal should be evaluated for all materials to assure the proper disposal route.

II. Generator (Mo-99/Tc-99m) Return to Manufacturer:
(As of September 1993, generators discontinued)

1) Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.

2) Assemble label and complete the shipping papers for the package in accordance with the manufacturer's instructions.

3) Assure that the container (package) has no radioactive material on its surfaces. (A survey meter check of all surfaces is acceptable.)

III. Release to Sanitary Sewer: (§20.2003(a))

A) At present (1994) no significant release of radioactive material occurs in the sanitary sewer system except for I-131 therapy patient's excreta which is not subject to limitations described in §20.2003(a).

B) §20.2003(a) states that licensed material may be discharged into sanitary sewerage if each of the following conditions is satisfied:

(1) The material is readily soluble (or is readily dispersible biological material) in water; and

(2) The quantity of licensed or other radioactive material that is released into the sewer in one month divided by the average monthly volume of water released into the sewer does not exceed the concentration listed in Table 3 of Appendix B to §§20.1001-20.2401; and

(3) If more than one radionuclide is released, the following conditions must also be satisfied:

(i) Determine the fraction of the limit in Table 3 of Appendix B to §§20.1001-20.2401 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released into the sewer by the concentration of that radionuclide listed in Table 3 of Appendix B to §§20.1001-20.2401; and

(ii) The sum of the fractions for each radionuclide required by paragraph (a)(3)(i) of this section does not exceed unity; and

(4) The total quantity of licensed and other radioactive material released into the sanitary sewerage system in a year does not exceed 5 Ci of H-3, 1 Ci of C-14, and 1 Ci of all other radioactive materials combined.

RADIOACTIVE WASTE DISPOSAL RECORD

(Decay-in-Storage)
(Refer to the Guidelines for Appropriate Radioactive Waste Disposal)

Type of Material and Lot Numbers if Applicable	Date Storage Container was Sealed	Disposal Date from Storage	All Surfaces @ Background	Tech

JAN 3 1 1997

Stanley Reed
Radiation Safety Officer
St. Elizabeth Hospital
1506 South Oneida Street
Appleton, WI 54915

Dear Mr. Reed:

Enclosed is Amendment No. 56 renewing your NRC Material License No. 48-10219-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that per conversation with Gidget Watson, of our staff and yourself on January 30, 1997, we have added Condition 19. to your license, requiring monthly safety checks on the brachytherapy unit as well as retained Condition 17.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

396604

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;

   b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;

   c. Change Radiation Safety Officers;

   d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   f. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements,

prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Gidget Watson
Nuclear Materials Licensing Branch

License No.: 48-10219-01
Docket No.: 030-03466

Enclosure: Amendment No. 56

DOCUMENT NAME: M:\03003466.CL7

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII								
NAME	GWATSON:jaw								
DATE	01/30/97GHW								

OFFICIAL RECORD COPY

CONVERSATION RECORD

TIME 9:55 AM DATE 1/30/97

O VISIT O CONFERENCE x TELEPHONE

O INCOMING
x OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT: Stan Reed, RSO

ORGANIZATION (OFFICE, DEPT.ETC.): St. Elizabeth Hospital

TELEPHONE NO.: 414/738-2190

SUBJECT

License No. 48-10219-01 Renewal Issuance

SUMMARY

I informed Mr. Reed that at long last the renewal request that had been in Region III's possession for nearly 3 years would be issued. I informed Mr. Reed that the information that was submitted on a Tar in February '96 was still under review by our H.Q.'s Office and that we obtained permission to issue the license, as long as we conditioned the license. I informed him that the license would be issued with one Special Condition which pertained to "monthly checks being performed on the HDR unit" as well as retaining the Condition which pertained to "surveys being performed on the unit prior to initiation of a treatment program and subsequent to each source exchange". Mr. Reed stated that he did not object to the aforementioned information and that he was happy to receive "good news" regarding the issuance of the license. He further stated that the issues in the TAR could be discussed after H.Q.'s completed the review.

ACTION REQUIRED

Richard Wilson — 1/30/97

NAME OF PERSON DOCUMENTING CONVERSATION — SIGNATURE — DATE

ACTION TAKEN

SIGNATURE — TITLE — DATE

From: Gidget M. Watson (GMW)
To: RXA1
Date: Friday, June 28, 1996 8:41 am
Subject: St. Elizabeth TAR

Hi Bob,

Per conversation with Stan Reed, physicist, St. Elizabeth Hospital (48-10219-01) on June 27, 1996, I am requesting that the TAR that was closed out on June 18, 1996 be reactivated. The hospital has decided to keep the HDR authorization on their license.

I sincerely apologize for any inconvenience this may have caused you. Your efforts in this matter are greatly appreciated.

G. Watson
Region III

From: Gidget M. Watson (GMW)
To: CH1:HMS3:TTR:THUB1:TWD2.TWP8:RXA1
Date: Tuesday, June 18, 1996 3:50 pm
Subject: St. Elizabeth TAR -Reply

Bob,

Per letter dated June 3, 1996 from Stan Reed, RSO/Medical Physicist of St. Elizabeth Hospital (48-10219-01), as of
August 5, 1996 the facility will discontinue their remote afterloading program. Thus, the TAR is no longer needed. Mr. Reed is aware that he will have to formally amend the license.

Sorry for any inconvenience this may have caused you,

G. Watson

St. Elizabeth Hospital
A MEMBER OF AFFINITY HEALTH SYSTEM, INC.

June 17, 1996

Gidget Watson
United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

NRC License No. 48-10219-01
Control No. 396604

Dear Ms. Watson:

St. Elizabeth Hospital requests an amendment to its byproduct material license to delete the use of our Micro-Selectron HDR afterloading brachytherapy system as of August 5, 1996. The existing treatment room, which is located in our Radiation Oncology Department, is expected to be used by Radiology/Radiation Therapy employees and patients. The room was designed originally as a cobalt teletherapy treatment room and has an adjacent locked storage room which will continue to store brachytherapy sources and supplies.

After the current source is removed, the HDR system will be surveyed to assure no radioactivity is remaining. It is intended that this HDR system will be transferred to another user as a resale using the original equipment manufacturer in the resale process.

Please contact Stanley A. Reed (414-738-2190) for questions concerning this amendment request.

Respectfully submitted,

Jeffrey Jenkins
Vice President-Clinical Services

Stanley A. Reed, MD
Medical Physicist, RSO

SAR/saw

RECEIVED
JUN 25 1996
REGION III
JUN 25 1996

1506 S. Oneida Street
Appleton, Wisconsin 54915
(414) 738-2000 • FAX: (414) 738-0949

St. Elizabeth Hospital
A MEMBER OF AFFINITY HEALTH SYSTEM, INC.

June 3, 1996

United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

NRC License No. 48-10219-01
Control No. 396604

Dear Medical License Reviewer:

In February 1994, St. Elizabeth Hospital submitted its license for renewal. As of this date the renewal has not been approved, and it appears that the slow progress has been related to the remote afterloading brachytherapy portion of the license. Recently, due to local changes in the healthcare delivery system, the administration of our hospital has concluded to discontinue our remote afterloading brachytherapy program as of August 5, 1996. The current published regulations that we have do not seem to address the notification requirements necessary to discontinue a remote afterloading (HDR) brachytherapy program.

Please advise us on the proper procedures to follow so that we can modify our license. Thank you for your attention on this matter.

If there are any questions please contact me (414-738-2190).

Respectfully submitted,

Stanley A. Reed

Stanley A. Reed, RSO, Medical Physicist

SARmmm

1506 S. Oneida Street
Appleton, Wisconsin 54915
(414) 738-2000 • FAX: (414) 738-0949

CONVERSATION RECORD | TIME | DATE 2/6/96

O VISIT O CONFERENCE X TELEPHONE

O INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT: Stan Reed, RSO
ORGANIZATION (OFFICE, DEPT.ETC.): St. Elizabeth Hospital
TELEPHONE NO.: 414/738-2190

SUBJECT
License No. 48-10219-01

SUMMARY
Conference Call: Sandy Frazier, Senior Licensing Reviewer
Gidget Watson, Licensing Reviewer

Renewal Deficiency Response dated July 27, 1995 was discussed.

We informed Mr. Reed that Items 3. "Compliance with Radiation Limits" and 6. "Monthly Checks" was still deficient in accordance with **Policy and Guidance Directive FC 86-4, "Information Required for Licensing Remote Afterloading Devices"**. Mr. Reed stated that he did not agree with the guide and that the response stood as is. We then informed Mr. Reed that the information would have to be sent in to our H.Q.'s Office on a Technical Assistance Request (TAR) and that it may take several months to get a response. We also informed Mr. Reed that the Renewal would not be issued until a response was received. Mr. Reed stated that he understood and would be waiting to hear from us.

ACTION REQUIRED

Gidget Watson — 2/6/96

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE | DATE

ACTION TAKEN

SIGNATURE | TITLE | DATE

St. Elizabeth Hospital
A MEMBER OF AFFINITY HEALTH SYSTEM, INC.

December 7, 1995

United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

License No. 48-10219-01

Dear Medical License Reviewer:

Enclosed is additional supporting information for Stephen M. Brink, MD to indicate his certification is complete from the American Board of Radiology. In a letter dated March 31, 1995, we had requested that he be added as an authorized user for byproduct materials listed in 10 CFR, 35.100, 35.200, and 35.300. The original preceptor statement did not apparently provide the training hours in the proper format, however, his subsequent certification by the ABR should fulfill the requirements as an authorized user.

If there are any questions concerning this request please contact me (414-738-2190).

Respectfully submitted,

Stanley A. Reed

Stanley A. Reed, MS, Medical Physicist

SARmmm
Enclosure

396604

1506 S. Oneida Street
Appleton, Wisconsin 54915
(414) 738-2060 • FAX: (414) 738-0949

The American Board of Radiology
M. Paul Capp, M.D., Executive Director

Assistant Executive Directors
Robert E. Campbell, M.D., Diagnostic Radiology
Lawrence W. Davis, M.D., Radiation Oncology

5255 E. Williams Circle
Suite 6800
Tucson, Arizona 85711

Phone (520) 790-2900
Fax (520) 790-3200

November 7, 1995

STEPHEN M. BRINK, MD
307 EAST WAYFARER LANE
APPLETON, WI 54915

38439 / DR / 16 / 225

Dear Doctor Brink:

I am pleased to inform you that you passed the oral examination held November 6-7, 1995. The American Board of Radiology grants you its Certificate of Diagnostic Radiology.

The certificate will be sent via UPS to the above address in approximately three months. Your name will appear on the certificate as shown above. If you wish your name to appear differently, please notify the Board office within thirty days.

Your name will be included in a Directory published by The American Board of Medical Specialties unless you specify otherwise in writing to the ABMS. It is your responsibility to notify your local and state medical organizations of your certification.

On behalf of the Board of Trustees of The American Board of Radiology, I congratulate you on this achievement.

Sincerely,

M. Paul Capp

M. Paul Capp, M.D.

The American Board of Radiology
M. Paul Capp, M.D., Executive Director

Assistant Executive Directors
Robert E. Campbell, M.D., Diagnostic Radiology
Lawrence W. Davis, M.D., Radiation Oncology

5255 E. Williams Circle
Suite 6800
Tucson, Arizona 85711

Phone (520) 790-2900
Fax (520) 790-3200

November 7, 1995

STEPHEN M. BRINK, MD
307 EAST WAYFARER LANE
APPLETON, WI 54915

38439 / DR / 16 / 225

Dear Doctor Brink:

I am pleased to inform you that you passed the oral examination held November 6-7, 1995. The American Board of Radiology grants you its Certificate of Diagnostic Radiology.

The certificate will be sent via UPS to the above address in approximately three months. Your name will appear on the certificate as shown above. If you wish your name to appear differently, please notify the Board office within thirty days.

Your name will be included in a Directory published by The American Board of Medical Specialties unless you specify otherwise in writing to the ABMS. It is your responsibility to notify your local and state medical organizations of your certification.

On behalf of the Board of Trustees of The American Board of Radiology, I congratulate you on this achievement.

Sincerely,

M. Paul Capp, M.D.

1506 South Oneida Street
Appleton, Wisconsin 54915
(414) 738-2000 fax: (414) 738-0949

St. Elizabeth Hospital

July 27, 1995

United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

NRC License No. 48-10219-01
Docket No. 030-03466
Control No. 396604

Dear Medical License Reviewer:

St. Elizabeth Hospital is providing additional information in response to your letter dated July 14, 1995, regarding our byproduct material license renewal. The outline below follows the same format as your July 14, 1995 letter.

1. Training Program

   a) Trainee's Competency: Please refer to Attachment 10.17.5a, II.D.1 and Attachments 10.17.13-14 which describe our written competency testing for HDR equipment.

   b) Emergency Procedure "Dry Runs": Refer to Attachment 10.17.1a, I.A.1.

   c) Training Records: Attachment 10.17.5a, II.D.2.

2. Facilities:

   a) Viewing/Intercom Backup System: Attachments 10.17.2a-3a, II.B.2 describes our redundant viewing system and that an intercom system shall be operating properly for clinical treatments to occur.

   b) Interlock Malfunction: If the electrical interlock system which monitors the single entry door position malfunctions, then the HDR system will be locked (keys removed/system off) in the off position and not used except as necessary for repair purposes. Clinical use will only occur when the door interlock and resettable interrupt function properly. These items are checked for proper operation each day of clinical use. When error codes occur we will follow the original equipment manufacturer's recommendations.

   c) One Device Only Operational: (Not Applicable) Our facility only has a dedicated HDR treatment room.

d) Inaccessible Console Keys: Console keys and the HDR source unit are stored in a locked storage room and backup console keys are also stored in an office which is locked during non-normal clinical hours. Console keys will not be left in the unit when it is not in use. In order for an individual to operate the HDR unit and get the source to be in an unshielded position prior experience is necessary, console and door keys are required, and the individual would be in an employee restricted area which has a single entry door.

e-g) Operational Radiation Monitor: As described in prior correspondence we will check that the permanent room radiation monitor is performing properly each clinical day and before clinical use (refer to IV.A/IV.B, Attachment 10.17.6b). This check may use any convenient radiation source including the HDR source which provides an expected response for the radiation monitor. This check will be maintained in written form for a period of at least three years. If the radiation monitor is found to be either inoperable or evidences intermittent failure it will be promptly repaired or replaced.

(3) Compliance with Radiation Limits:

a) Our proposed radiation survey program is described in I.B.1-6, Attachments 10.17.1a-2a. We believe that the requirement to perform a complete radiation survey of surrounding areas after source replacement (4 times per year) is unnecessary. Our ting HDR treatment room was designed for a Cobalt-60 therapy and has excess shielding. Since we would be unable to ed unrestricted regulatory limits with our HDR unit there is eason to perform a quarterly radiation survey except for the ce unit housing the source. Our replacement source is ntially the same activity and occupancies surrounding the rarely change (if significant change occurs a survey would one). A source exchange is similar to having repair ormed on a linear accelerator or an x-ray unit where a ation survey is not done because the treatment unit has not ged. We believe the requirement for a radiation survey after source replacement should be changed.

Refer to I.B.2, Attachment 10.17.2a and IV.B.3, Attachment 10.17.6b.

Refer to I.B.3, Attachment 10.17.2a. Records of surveys will be maintained for the duration of our license.

r to I.B.5, Attachment 10.17.2a.

4) Operating Procedures: (Refer to II.A,B,C,D,E, Attachments 10.17.2a-5a)

a) Treatment Room Security: Refer to II.A, Attachment 10.17.2a

b) Labelling Computer Removable Media: Refer to II.C.3, Attachments 10.17.3a-4a. At our institution the patient's name, date, and which treatment fraction or plan is identified on the removable media. We do not use patient identification numbers with our HDR system.

c-d) Procedure Survey and Record: Refer to II.C.11, Attachment 10.17.4a.

e) Decoupled/Jammed Source Procedure: The request that a "licensee shall not conduct any treatment procedure for which a decoupled or jammed source cannot be removed expeditiously from the patient" is unclear and totally subjective. Our emergency procedure II.E addressed our response in the unlikely event of an interventional and non-interventional source recovery. We intend on performing safe procedures and obviously do not want to lose control of the radiation source. This section should be deleted from the requirements, since the emergency procedure section adequately covers this area.

f) Patient Instructions: Refer to II.F, Attachment 10.17.5a.

5. Daily Checks:

a-c,g) Refer to Attachments 10.17.10a-10b for the policy regarding daily checks and Attachment 10.17.11a for the record of such tests. The permanent radiation monitor check will be done as described in 2.e-f and the referenced attachment.

d-e) Mechanical integrity of peripheral devices (applicators, source guide tubes, connectors) are visually checked prior to treatment as part of our verification process of treatment set-up (see Attachment 10.17.15).

f) Written instructions for daily checks are provided (Attachments 10.17.10a-10b). Verbal instructions are provided when necessary and our competency testing is necessary for using the system. Only trained medical physicists or dosimetrist shall perform daily checks.

6. Monthly Checks:

a) - The source position accuracy is checked through daily check procedures and prior to clinical use. This monthly check is unn[illegible] performed.

b) Tim[illegible]y is checked at three month intervals dur[illegible]ieve a three month frequency is acc[illegible]heck is of no value and should not be a [illegible]

c) Mea[illegible]e tubes is performed prior to clinical use[illegible]I.B.6). This combined with a mea[illegible] prior to each clinical use provides as[illegible] position. A request for monthly mea[illegible]de tubes is unreasonable and should be de[illegible]n.

d) Ba[illegible]AC power disconnected is performed by th[illegible]at the time of source replacement. Th[illegible]s sufficient assurance of a proper fu[illegible] The original manufacturer and our in[illegible]ss testing of this system may be more de[illegible] We believe an approximate quarterly te[illegible] replacement is appropriate and feel this recommendation should be deleted.

e) None of the monthly tests described should be required. All records are maintained for at least three years.

7. Calibration of Afterloading Device:

a) Only properly trained medical physicists (10 CFR §35.961) shall calibrate the HDR system. The qualifications are included on the curriculum vitae of Stanley A. Reed, MS, Certified Medical Physicist, and Scott D. Moon, MS, Medical Physicist. The request for specifying the medical physicist's experience with the dosimetry system used in calibration measurements is unclear. Medical physicists use many dosimetry systems and we interchange different NIST traceable electrometers with the same chamber used in our measurements. Our calibration of the source dates back to our original purchase in January 1993.

b) Our calibration method at this time uses a NIST traceable calibrated well ion chamber which was specifically designed for Ir-192 calibrations. The calibration factor is specified in Ci/A which allows us to easily derive an apparent activity for our source. The chamber is located in the center of the room and elevated without significant scattering materials close to the chamber. Our calibration procedure follows current practice and if recommendations from the AAPM or the calibration laboratories change we will adopt those recommendations.

c)(1-4) Calibration record keeping: Refer to Attachment 10.17.16 for our calibration policy. All items listed in C.1-4 are included. In C.5 our HDR output is specified in apparent activity in Curies which is the form our computer system uses for calculations. There is no reason to specify in R/hr and we do not include it in our calibration record.

d) Measured output differs more than 5%: Refer to Attachment 10.17.16, item 6.

e) Calibration frequency: Refer to Attachment 10.17.16, item 3.

f) Source homogeneity is visually verified each day before clinical use on the autoradiograph. To our knowledge there are no quantitative methods reasonably available to measure source homogeneity. This source homogeneity requirement should be performed at the manufacturer level prior to source shipment or should be deleted from these recommendations.

g) Dosimetry system-calibrations: Refer to Attachment 10.17.16, item 1,7. At present time we use a well-type (re-Entrant) chamber and various electrometers for calibrating sources. The chamber was specifically designed for Ir-192 HDR sources (Standard Imaging, Inc). We do not believe that the NRC should be specifying types of dosimetry systems and if we purchase in the future a different dosimetry system which may be a better system then we intend on using the system which meets our measurement situation and following accepted standards. Dosimetry calibration records are maintained for inspection.

h) Source inventory is maintained (10 CFR 35.59) for all sources which are on site more than four months and records are maintained for at least five years. The requirement for an Ir-192 source to be included in a quarterly inventory does not apply well with our situation. The Ir-192 source is exchanged quarterly and is checked (indirectly inventoried) at this time. Three months later it is replaced and checked (indirectly inventoried) for proper shipment back to the original manufacturer. During the three month clinical use the source is radiographed each day of clinical use. Therefore, the source is followed closely throughout its useful lifetime and a specific quarterly inventory does not provide useful information for any facility that exchanges Ir-192 sources on a quarterly basis. This recommendation should be revised to properly address HDR Ir-192 use.

8. Emergency Procedures:

a) As described in Attachment 10.17.7a all personnel involved in HDR procedures are trained on a yearly basis and have easy access to written emergency procedures near the control console.

b) Refer to Attachments 10.17.7a-9 for our emergency procedure policy for HDR. In the event where emergency source recovery is necessary during a clinical procedure then the medical physicist and authorized user will implement our emergency plan. The nurse present at the case is responsible for physically preventing unauthorized access to the HDR room. There will not be enough time nor should emergency source recovery take very long that posting the room would be possible or effective. The only time that posting the room to prevent inadvertent exposures to personnel would occur is if the source position malfunction occurs during testing. Then the medical physicist would prevent entry for the HDR room and the area would be posted. The medical physicist would be responsible for working with the original manufacturer to implement source recovery (refer to emergency policy/procedures, Attachments 10.17.7a-9).

c) Emergency source recovery equipment is located in the HDR procedure treatment room. We have a shielded storage container, long forceps, cable cutters and various routine surgical supplies which can detach any secured applicator quickly. The cable cutters are stored on the source unit. A portable radiation shield is available to provide additional shielding. One of our television cameras has remote positioning which allows visualization of a large part of the room and also has zoom capability to visualize something as small as the source itself. Refer to Attachments 10.17.7a-9 on emergency procedures.

9. Maintenance:

a) All maintenance (as defined by the NRC) and repair of the HDR unit will be performed by the manufacturer or individuals authorized by the NRC or an Agreement State. At this time only the manufacturer provides maintenance and repair for our HDR unit, if someone (in the future) other than the manufacturer provides maintenance/repair the individual's name and authorization license will be provided to the NRC.

b) Inspection service criteria: The HDR inspection and service records will be maintained for the duration of the device use. These records include the inspection/service date, the name of the service engineer, a description of service performed including components replaced and the signature of the service engineer. Our manufacturer does not include the service engineer's authorizing license number on the service record but has it as part of their NRC license.

c)(1-2) Inspection service criteria: The HDR device will be serviced at intervals recommended by the manufacturer which do not exceed 12 months and in accordance with the manufacturer's instructions.

c)(3-4) Refer to 9(a,b) above.

Please contact Stanley A. Reed, MS, Certified Medical Physicist (414-738-2190) for information concerning this response.

Respectfully submitted,

Stanley A. Reed

Stanley A. Reed, MS, Medical Physicist

SARmmm
Attachments

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed June 1989		July 1995	725-501-16A	725-501-16B
Required Approval By:	(X)	Signature and Date		Review Date
Department Director				
Division Head				
Management Staff				
Medical Advisor				
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: HIGH DOSE RATE AFTERLOADING THERAPY PROGRAM - QUALITY MANAGEMENT PROGRAM				

POLICY:

The use of a high dose rate afterloading therapy treatment system shall follow appropriate procedures (see below) to ensure safe operation.

PROCEDURE:

I. Prior to Clinical use
II. Use of HDR System/Operating Procedures
III. Records/Audits
IV. Periodic Quality Control
V. Waste Disposal/Source Exchange

I. Prior to Clinical Use:

A. Training Program:

1) All operators of the HDR equipment shall be trained by qualified individuals (from Nucletron or a trained medical physicist) prior to use. This training will include, machine safety and interlocks, radiation protection, control console and equipment operation, emergency procedures which include dry runs, and use of applicators and accessories. This training will be repeated at least annually for all users.

B. Radiation Survey/Source Calibration:

1) A complete radiation survey of the areas surrounding the treatment room will be made prior to clinical use. The survey will take into account the possible treatment geometries and various source positions. The survey will account for source strength, occupancies, and type of workers that may be present near the treatment room. This survey will be performed at initial installation and prior to clinical use, and repeated if a significant change is made in surrounding areas or shielding.

2) The radiation survey of the source unit shall indicate the maximum radiation level at 10 centimeters from the nearest accessible surface of the source safe with the source in a shielded position.

3) Radiation levels in restricted areas will be kept below the limits specified in 10 CFR 20.1201 and radiation levels in unrestricted areas will be maintained below the limits specified in 10 CFR 20.1301.

4) Whenever a source is installed and prior to clinical use the source will be calibrated by a qualified medical physicist (§35.961). Refer to the HDR calibration policy (attachment 10.17.16).

5) A conspicuous, durable label shall be affixed to at least one outer surface of the remote afterloading source unit (10 CFR 20.1904).

6) All applicators and catheters of fixed length shall be checked prior to clinical use to verify proper length and integrity.

II. Use of HDR System/Operating Procedures:

A. General Security:

1) The HDR source unit and console operating keys will be stored when not in use in the locked brachytherapy storage room which is adjacent to the treatment room. The unit will have power at all times while in use or storage. Backup keys to operate the control console will also not be stored with the control unit and will be kept in a locked area during non-normal work hours. The trained medical physicists and authorized dosimetrist are the individuals that have knowledge of control key storage and access to the keys to operate the control console.

B. Treatment Room Security:

1) The treatment room door has a "Caution-High Radiation Area" sign and a red warning light which indicates when a source is in use. The operator for the system is next to the entry door and is responsible for monitoring unauthorized access into the room while a source is in use. The entry door is interlocked to the system and the source will retract to a shielded position when the door is opened and the source is in use. Only the patient will be in the treatment room when a clinical procedure is being performed. All tests will be conducted without individuals being in the treatment room.

2) Two continuous viewing systems (CCTV) will be used to observe the patient while the clinical treatment is occurring. At least one system must be operational during the treatment. A permanent radiation monitor with an indicator near the control console and one in the treatment room shall be operational on all days of HDR use. If the permanent system fails then a temporary radiation monitoring system could be utilized as long as the operator is able to determine the source position from the control console location and the system provides the

same information as the permanent radiation monitor. A single intercom system is presently used, if this fails, it will be repaired or another intercom system will be utilized. HDR treatments will not be performed unless the intercom system is operating properly.

C. Clinical Treatment/Use:

1) The operator of the HDR unit for clinical use must be appropriately trained (see I.A.). The operator shall verify that only the patient is in the treatment room while radiation treatments are occurring. A written prescription will be made by the authorized user prior to source administration and the prescription will be correlated by the operator and authorized user with the treatment plan as being in accordance with the written directive and signed by the authorized user. The written directive shall include the total dose, dose per fraction, treatment site, overall treatment period and an order for a specific patient (see Attachment 10.17.12). The date and signature of the authorized user shall also be included in the written directive. An oral revision to a written directive is acceptable if the patient's condition might be compromised by having a delay waiting for a written directive. Oral revisions shall be documented immediately in the patient's record and the revised written directive (signed and dated by an authorized user) shall occur within 48 hours of the oral revision.

2) Revisions to written directives for high dose brachytherapy are permissible provided that the revision is dated and signed by an authorized user prior to the administration of the brachytherapy dose or the next brachytherapy fractional dose. Initial treatments may be given using an idealized computer distribution. The authorized user will determine if the difference between the idealized plan and actual planned distribution requires treatment time or written directive modifications. All significant changes to the written directive will be documented (signed and dated by the authorized user).

3) Computerized treatment plans/dose distributions will be individually generated for each brachytherapy patient. The treatment plan will be prepared in accordance with the written directive. If an employee does not clearly understand how to perform the written directive then the individual shall timely contact a qualified user or, if necessary, the original manufacturer's training staff. All treatment plans should be checked prior to treatment by the authorized user and another trained individual who did not perform the original calculations/plan. HDR treatment plans should be verified for accuracy by intercomparing the idealized plan with the actual configuration and resolving the cause of any plan which differs by more than 10% with the idealized configuration. Computer removable media shall be clearly labelled with the patient's name, date and identify which treatment fractions/plans are on the media. In addition, the correct input data (source strength, source positions, channel numbering and sequencing, spacing, patient name, isotope) shall be independently verified (and initialed) by a qualified individual prior to clinical treatment. A log book should be

maintained which also allows intercomparison of prior plans with the new distribution. Subsequent treatments using the same program will be checked by the operator and authorized user prior to patient treatment. The patient's name, number and time of dwell positions, source activity, starting length/position, source spacing, treatment site and total dose will be verified.

4) High dose rate brachytherapy patients shall have the position of the source modeled through the use of dummy sources. The dummy sources should be checked for proper positioning and location prior to treatment planning and filming.

5) An acceptance test will be performed on the treatment planning computer to verify proper dose calculations. An independent computer system shall be used along with a manual calculation of a single source to verify that proper dose calculation is occurring. All source receiving applicators will be checked for proper length and source positioning with autoradiographs using dummy sources. Single use devices are checked for proper length and integrity prior to use.

6) During clinical use, both the authorized user and a qualified medical physicist shall be physically present (within audible range of normal human speech).

7) Prior to each administration the patient's identity will be verified by more than one method.

8) A MicroSelectron-HDR Ir-192 User Guide which summarizes the control console operation shall be kept near the control console.

9) The source use location shall not allow the source to be in a direct line to the entrance door. The applicator, catheters and guide tubes shall be visually checked by the control operator for damage and proper orientation prior to initiating treatment. An independent verification of proper cable attachment order shall occur on all treatments.

10) A shielded container shall be present near the high dose procedure to provide a location to put an applicator or cable with an unretracted source in the event of an emergency. Cable cutters shall be stored conveniently for emergency use.

11) After treatment completion the patient will be surveyed by an appropriate radiation detector to verify that the source has not accidentally become separated from the drive cable. The survey will check the applicators and guide paths traveled by the source. The survey shall also check a reproducible location on the source device and a written record with the surveyor's initials shall be maintained for at least three years for the patient and device survey. The room radiation monitor shall also be observed as not detecting a radiation signal before entering the treatment room immediately after clinical use and before the patient leaves the treatment room.

D. Training/Equipment Competency:

1) On an annual basis training will be provided for all authorized users and operators. This training will be given by qualified individuals (from the original equipment manufacturer or a trained medical physicist). Competency will be measured for all individuals operating the control console and computer treatment planning unit. A written test will be given on an annual basis and the individual shall meet the equipment competency standards identified in the attached policy (see Attachment 10.17.13-14).

2) Records of initial and refresher training for device operators and ancillary personnel will be maintained for a minimum of three years. The records shall include the instructor's name, the attender's names, date of training, and an outline of the training.

E. Emergency Procedure:

1) If the Ir-192 fails to completely return to the safe then the emergency procedure posted at the control console and in the front of the quality control book shall be implemented. All users shall be familiar with performing the emergency procedures and these shall be reviewed on an annual basis. Refer to the policy 'Emergency Procedures for High Dose Rate (HDR) Afterloader' (Attachments 10.17.7a-10.17.9) for specific details.

F. Patient Instructions:

1) All patients shall be provided with written pre and post operative instructions for HDR procedures. These instructions are also reviewed verbally with each patient.

III. Records/Audits:

A. In accordance with 10 CFR 35.32(d) each written directive and record of each administered radiation dose will be retained for at least three years after the date of administration.

B. The qualified control console operator under the supervision of an authorized user will be responsible for:

1) Transferring the proper treatment plan information to the control unit.

2) Verifying and initializing the programmed printout which indicates the programmed source positions. The control console programmed source plan shall correspond to the accepted computer plan.

3) Verify that the authorized user has initialized or signed the treatment plan and program summary prior to clinical treatment. Subsequent fractions using the accepted treatment plan shall only have each programmed control console summary initialized or signed by the authorized user and control console operator prior to treatment.

4) Checking that the control console program summary corresponds to the accepted treatment plan and that the patient's name, source spacing, treatment length, number of source positions and channels, and treatment times are correct.

5) Visually checking that the channel and applicator are properly sequenced and in accordance with the treatment plan and console programmed plan prior to treatment. A record will be maintained of the verification process (see Attachment 10.17.15).

6) Assuring that a record of the programmed treatment summary, the actual treatment summary, the written directive (Attachment 10.17.12), a complete treatment plan, and the verification record of patient setup (Attachment 10.17.15) will be placed in the patient's record within 24 hours of the last clinical treatment.

C. In accordance with 10 CFR 35.32(c) all recordable events identified will have a complete written evaluation performed within 30 days after discovery. The recordable event record will be retained in auditable form for at least three years and will contain an evaluation of the relevant facts and what corrective action, if any, was implemented to prevent a recurrence.

D. If a misadministration as defined by 10 CFR 35.2 occurs, then the NRC Operation Center shall be notified by telephone no later than the next calendar day after discovery. Records, reports and notifications of a misadministration will be performed in accordance with requirements listed in 10 CFR 35.33.

E. An annual review (Attachment 10.16.6) will be performed on approximately half of the high dose rate brachytherapy patients. This review will check that the written directive corresponds to the actual treatment, that the computer plan has the correct input data and corresponds to the written directive, and that all radiation sources were appropriately surveyed and records are complete. If a recordable event or misadministration is identified in this review process then all possible cases affected by this event will be reviewed. This review will be maintained for at least three years [10 CFR 35.32(b)(3)]. Appropriate notification will occur as described in III(C) and III(D) above.

F. The annual review and significant deviations from our Quality Management Program will be used to determine the effectiveness of our Quality Management Program. If a misadministration or recordable event is identified, then this may be an indicator that the Quality Management Program may require modifications or personnel may not be performing at an appropriate level. The annual review should indicate whether the Quality Management Program is providing a high confidence that byproduct material is administered as directed by the authorized users. Appropriate modifications will be implemented, if necessary, and any significant modifications to the Quality Management Program will be submitted to the NRC Regional Office within 30 days after the modification has been made [10 CFR 35.32(e)].

IV. Periodic Quality Control:

A. Each day of clinical use and before clinical use the following items shall be checked for proper operation and documented: (see Attachments 10.17.10a-10b for outline of procedure)

1) Door interlock and permanent radiation monitor
2) Proper channel is recognized as having an applicator
3) Radiation warning lights and intercom are operational
4) Treatment interrupt
5) Autoradiograph for verification of programmed source position
6) Total source retraction
7) Timer ends therapy treatment
8) Inspection of source guide tubes (II.C4)
9) Radiation survey instrument

B. 1) Each time a source is replaced it shall be calibrated prior to clinical use and updated and verified in the treatment planning system. The original manufacturer will perform a preventative maintenance survey at the time of each source replacement. At the time of source replacement the power fail back-up system will be tested.

2) The proper source positioning will be verified by using autoradiographs after each source replacement.

3) A radiation survey of the HDR unit shall be performed with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 milliroentgen per hour.

4) Records of all items in A above will be retained at least three years.

5) The permanent radiation monitor will be checked each clinical use day before clinical treatment for proper operation. If the monitor is found to be either inoperable or evidences intermittent failure then it will be promptly repaired or replaced prior to clinical use.

V. Waste Disposal/Source Exchange:

The reduced activity I-192 source is transferred to the original shielded source container at the time of source exchange by service personnel employed by the original manufacturer. The customer contacts the original manufacturer with proper information concerning the Ir-192 source (activity, transport index, source serial number) in order that proper paperwork is prepared for transportation of dangerous goods. Labelling is then performed by a medical physicist or the RSO and a proper carrier is contacted. The reduced activity source is then shipped back to the original manufacturer.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed May 1993		July 1995	721-501-18A	721-501-18B
Required Approval By:	(X)	Signature and Date		Review Date
Department Director				
Division Head				
Management Staff				
Medical Advisor				
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: EMERGENCY PROCEDURES FOR HIGH DOSE (HDR) AFTERLOADER				

PURPOSE:

To establish operational guidelines in the event that the high dose rate Ir-192 source does not return to a proper shielded position.

POLICY:

1. During all patient treatments both an authorized user, and a trained medical physicist or approved operator recognized by the NRC as able to institute proper radiation safety and emergency procedures, will be physically present. Physically present is defined as within audible range of normal human speech.

2. All personnel shall be trained in both routine use and emergency procedures associated with the HDR afterloader. Training shall be provided to all personnel prior to their independent use of the HDR system. Periodic retraining will occur at yearly intervals for all personnel.

3. A radiation survey will be performed on all patients receiving high dose rate treatments immediately after completion of the therapy procedure with an appropriate survey meter (in addition to the area monitor).

4. In the event of an apparent malfunction, which may require an emergency response, the medical physicist or an approved operator with the authorized user will be responsible for implementing the emergency response outlined in the procedure section of this policy. An outline of this procedure will be available near the control console. The nurse assigned to the procedure and present at the procedure will be primarily responsible for preventing access to the room where emergency source recovery is occurring. The nurse will physically stay near the only entry room door and prevent accidental entry.

5. All personnel involved with HDR procedures shall wear a radiation monitor.

Index: 721-501-18B	SUBJECT: EMERGENCY PROCEDURES FOR HIGH DOSE RATE (HDR) AFTERLOADER

PROCEDURE: EMERGENCY RESPONSES:

1. All clinical procedures shall have a shielded container present in the procedure room near the patient which is large enough to allow the largest clinical template and needles to be placed inside. The container shall provide at least five half value layers of equivalent shielding material.

2. A portable radiation shield shall be located in the treatment room and positioned to provide a shield for persons entering into a possible radiation field caused by a malfunction of the treatment unit.

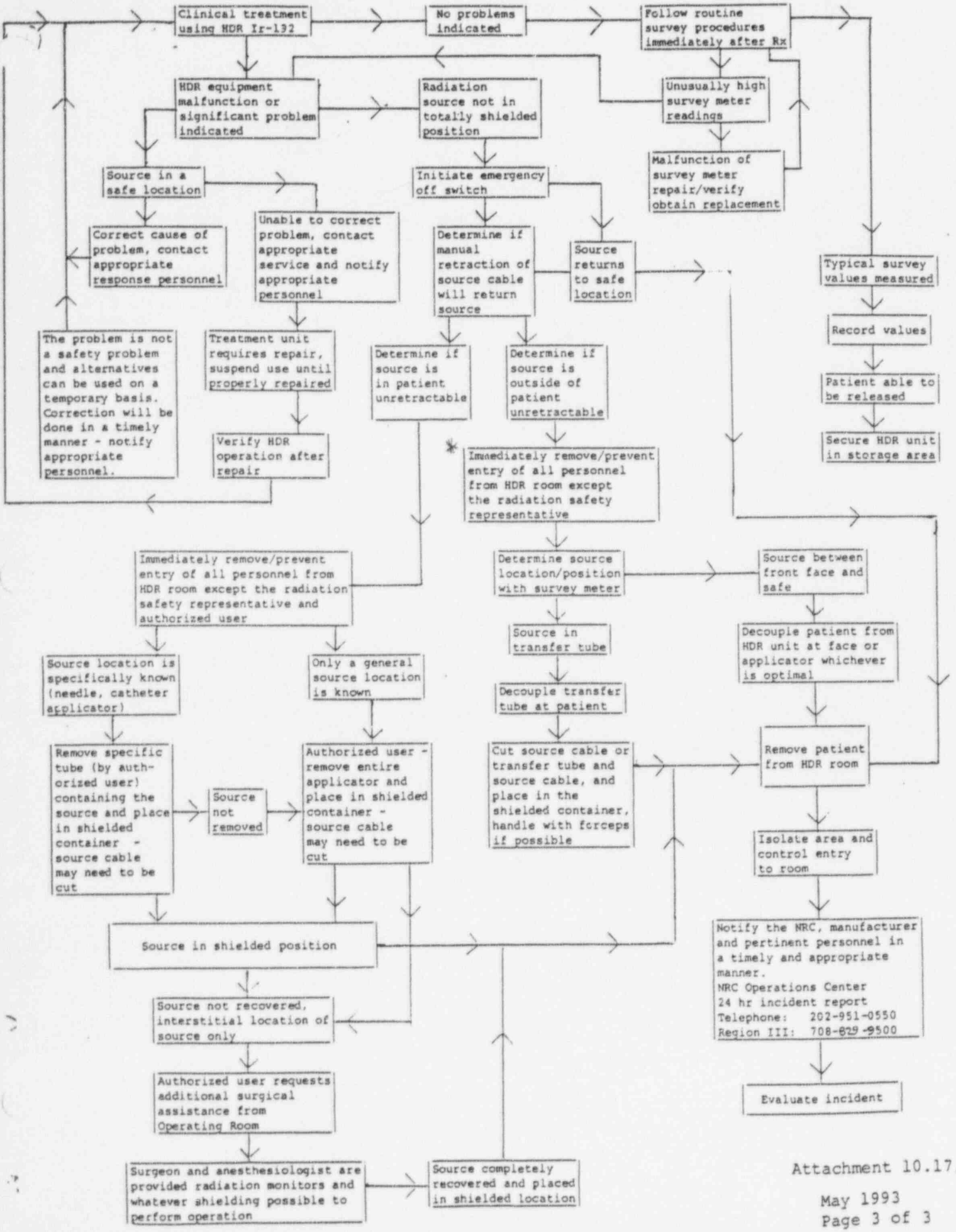
3. The closed circuit television shall be positioned to allow observation of the patient, pertinent patient monitors, and the source transport motors. The lid to see the source transport motors and manual drive levers shall be open while the unit is in use. Cable cutters and long forceps shall be available at the HDR unit at all times.

4. If the HDR source is in an exposed position and cannot be returned to the shielded safe during testing procedures with no patient/person in the treatment room then the treatment room will be posted and entry prevented by the console operator. The medical physicist in conjunction with the original manufacturer will be responsible for source recovery. Repair will occur and proper operation verified prior to clinical use.

5. Possible malfunctions and responses:

   Emergency Procedure/Clinical Response Flow Chart

EMERGENCY PROCEDURES/CLINICAL RESPONSE FLOW CHART



ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed July 1995		July 1995		725-501-19
Required Approval By:	(X)	Signature and Date		Review Date
Department Director				
Division Head				
Management Staff				
Medical Advisor				
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: HDR AFTERLOADER QUALITY CONTROL PROCEDURE				

POLICY:

Periodic tests shall be performed and appropriately documented for determining that the high dose afterloading system is performing properly.

Testing Frequency: Each day of clinical use and before any clinical application.

Action: If any of the following checks indicates a problem the system shall not be used until repaired or proper operation is verified. Console keys shall not be left with the control console unless a clinical procedure is being performed. Store console keys in the appropriate designated secure area.

PROCEDURE:

A. Take an x-ray (80 kVp/16 mAS) of the check ruler in diagnostic radiology with the dummy source position cable extended such that the first dummy is positioned at 950 mm. The ruler should be face down on Kodak TL Ready Pack Film and securely taped to prevent any movement. Prevent film shifting in the ready pack holder.

B. Position HDR source unit in treatment room (at a typical use location) and attach the source position ruler to the appropriate adaptor and connect to channel #2.

C. Program channel #1 at a length of 900 mm and time = 10 sec.

   1) Leave open the treatment room door and try to start the treatment; DOOR OPEN should be indicated, record result (A). The unit should not allow the source to be extended.

   2) Close door and try to start treatment again, an error code 14 should appear - record result (B).

Index: 725-501-19	SUBJECT: HDR AFTERLOADER QUALITY CONTROL PROCEDURE

D. Reprogram the source for channel #2 at three positions: 950 mm, time = .2 sec : 900 mm, time = .2 sec : 850 mm, time = .2 sec. Position the source position ruler on a film which has been appropriately exposed prior.

1) The treatment time should compensate for source decay. Complete the programmed technique in (C-above). Observe that radiation warning lights and the radiation monitor are properly operating and record (C-D). Verify that the intercom is working by listening to the sounds made by the HDR unit extending check and source cables and record (F). Observe that both TV monitoring systems are functioning properly and record (F).

E. Verify that the radiation monitor and the control console indicate that the source has been properly returned before entering the treatment room. Take film out of treatment room and reprogram unit for channel #2, 900 mm length and 15 sec.

1) Initiate treatment and use treatment interrupt button to stop the treatment before the timer ends. Restart the treatment and open the door (door interrupt), restart, and verify also that the treatment stops when the timer ends - record (E)(F).

2) Evaluate radiograph for proper source positioning ±1 mm accuracy - record (G).

3) Use the survey meter to check for complete source retraction by measuring at the front of the unit and at the reference location at the side cover and record (H).

4) All records shall be maintained for three years.

5) The date of survey and surveyor's initials shall be recorded on the form (attachment 10.17.11a).

HDR - QUALITY CONTROL RECORD

Nucletron MicroSelectron HDR: S/N 9391 Survey Meter: Victoreen 450P: S/N 640

Date/ Surveyor	Door Interrupt/ Door Open Interlock A	Proper/Cable Channel B	Source Status Light-fx's C	Radiation Monitor fx's D	Treatment Interrupt fx's E	TV Monitor/ Intercom fx's F	Proper Source Position ±1 mm G	Survey with Source Retracted H

Date	Comments

Attachment 10.17.11a

Date	ST. ELIZABETH HOSPITAL RADIATION THERAPY TREATMENT RECORD	Referring Physician

Patient Name	Patient Number	Patient Phone #
Diagnosis		

Radiation Oncology Prescription/Written Directive

HDR Ir-192 Implant

Prescription Date: Treatment Site:

Total Prescribed Dose: cGy to Location/Region:

Using Ir-192 HDR Source

Dose Per Fraction: cGy Number of Fractions:

Fractionation:

Initial fraction may be treated with an idealized plan: ☐ Yes

Authorized User Signature: Oral Revision Given: ☐ Yes

Revision to Written Directive:

Signature: Date:

Prescription Date: Treatment Site:

Total Prescribed Dose: cGy to Location/Region:

Using Ir-192 HDR Source

Dose Per Fraction: cGy Number of Fractions:

Fractionation:

Initial fraction may be treated with an idealized plan: ☐ Yes

Authorized User Signature: Oral Revision Given: ☐ Yes

Revision to Written Directive:

Signature: Date:

Prescription Date: Treatment Site:

Total Prescribed Dose: cGy to Location/Region:

Using Ir-192 HDR Source

Dose Per Fraction: cGy Number of Fractions:

Fractionation:

Initial fraction may be treated with an idealized plan: ☐ Yes

Authorized User Signature: Oral Revision Given: ☐ Yes

Revision to Written Directive:

Signature: Date:

Attachment 10.17.12

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed July 1994		July 1994		
Required Approval By:	(X)	Signature and Date		Review Date
Department Director				
Division Head				
Management Staff				
Medical Advisor				
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: COMPETENCY TESTING - PHYSICS				

POLICY:

Each medical physicist shall be evaluated annually concerning equipment competency on only equipment where the physicist provides direct patient care. The competency evaluation shall occur in conjunction with the individual's annual review or whenever new equipment is obtained or significant changes occur on an existing system. The medical physicist may occasionally utilize all equipment in the Radiology Department as well as all x-ray systems located outside of the Radiology Department and also uses many different pieces of testing equipment. Most equipment can be used with written documentation or with knowledgeable operators if operational questions occur, and written competency testing is not practical on the many occasional use systems.

PURPOSE:

To provide a written record and method of determining equipment competency on direct patient care equipment.

PROCEDURE:

1) Each medical physicist will have a written competency test on the following direct patient care equipment:

   A) Treatment Planning Computer System - Radiation Therapy
   B) High Dose Rate Treatment Planning System and Control Console

2) A score of 90% or better will be considered passing.

3) If an individual does not receive a passing score then a repeat test will be taken within 15 days.

Index:	SUBJECT: COMPETENCY TESTING - PHYSICS

4) If the individual fails the retest (3) then a written warning will occur from the department director. The employee will be allowed one final opportunity to successfully pass the competency test within 30 days of the last retest (3). The division supervisor and/or director will provide opportunity for retraining, as needed.

5) If a passing grade is not obtained on the final test or the test is not taken within 30 days then the individual will not be allowed to use the equipment without direct supervision during clinical use. The department director will contact the Human Resource Department for further action.

PHYSICS/DOSIMETRY HDR RECORD

Patient Name: _____ Nucletron MicroSelectron HDR: S/N 9391

Treatment Site: _____ Survey Meter: Victoreen 450P: S/N 640

Date	Treatment Number	Total Time	Prior to Rx-Verification-Parameters Correspond to Plan					Survey of Patient
			dwell positions	distal dwell length	step size	patient name	treatment setup/ mechanical integrity of applicator	immediately post treatment
								Ref: Pat: Bkgd:
								Ref: Pat: Bkgd:
								Ref: Pat: Bkgd:
								Ref: Pat: Bkgd:
								Ref: Pat: Bkgd:
								Ref: Pat: Bkgd:
								Ref: Pat: Bkgd:

Background/Patient Survey: The typical radiation background for the 450P survey meter is less than 30 uR/hr unless the linear accelerator in the adjacent room is treating at the 90° position. Investigate all background/patient survey readings that exceed 30 uR/hr.

ST. ELIZABETH HOSPITAL
APPLETON, WISCONSIN

POLICY AND PROCEDURE
SECTION:

Initiator/Date		Effective Date	Supersedes	Index
Stan Reed July 1995		July 1995		725-501-18
Required Approval By:	(X)	Signature and Date		Review Date
Department Director				
Division Head				
Management Staff				
Medical Advisor				
Med. Staff Exec. Comm.				
President				
Board of Directors				
SUBJECT: CALIBRATION OF Ir-192 IN A HIGH DOSE AFTERLOADING SYSTEM				

POLICY:

All replacement Ir-192 sources in the high dose afterloading system shall be properly calibrated prior to clinical use.

PROCEDURE:

1) Use an appropriately calibrated dosimetry system that has NIST traceable calibrations within the prior two years. Systems that are repaired where the calibration may change shall be appropriately calibrated prior to use.

2) The source shall be calibrated in accordance with current guidelines established by the American Association of Physicists in Medicine and the source calibration performed only by qualified medical physicists.

3) Source calibration for all replacement sources shall occur prior to clinical use or whenever there is reason to suspect a change.

4) The calibration record shall include the calibration date, manufacturer's name, and serial number for both the HDR unit and source. The record shall also identify the individual(s) performing the calibration, and the manufacturer's name and serial number of the dosimetry system used to measure the HDR source.

5) The timer accuracy and timer error shall be measured and recorded.

6) If the calibration of the Ir-192 source is not within ±5% of the manufacturer's stated activity (decay corrected) then the source will be rechecked. If the error after rechecking the source activity is still not within ±5%, the original manufacturer will be consulted. The calibration report will contain additional written information on the course of action taken when a source activity is not within ±5% of the manufacturer's activity.

7) All calibration records will be maintained for a minimum of three years.

STANLEY A. REED, M.S.

CURRICULUM VITAE

Academic History

Bachelor of Science	Zoology, University of Wisconsin-Madison, 1976
Master of Science	Medical Physics, University of Wisconsin-Madison, 1977

Professional Experience

Research Assistant	University of Wisconsin, January, 1977-February, 1978. (Research on neutron beam with DT gas target)
Medical Physicist	Columbus-Cuneo-Cabrini Medical Center, Chicago, IL, March, 1978-August, 1980. (Chief medical physicist responsible for all radiation physics including dosimetry, machine calibrations, computerized treatment planning, quality assurance in nuclear medicine and diagnostic radiology and radiation safety.)
Medical Physicist	St. Elizabeth Hospital, Appleton, WI, August, 1980 to present. (Senior medical physicist at institution and responsible for radiation safety, licensing and physics associated with nuclear medicine, diagnostic radiology, ultrasound and radiation therapy including high dose rate brachytherapy. The radiation therapy department treats approximately 50 patients/day with a 4MV linear accelerator and a dual energy accelerator (6MV and 15MV photons) with electrons. Initially I provided administrative services for the radiation therapy department, i.e., budget, personnel, policies, etc., from 1980-1985. A separate department of physics was created in 1985 and in 1993 physics and dosimetry were combined for which I am providing supervisory coverage.)

Memberships

American Association of Physicists in Medicine (AAPM), North Central Chapter, Secretary/Treasurer 1985-1987, President 1989-90.
International Society of Optical Engineering 1980-1992
Outagamie County Hazardous Waste Committee 1985-1989 (Chairman 1989)
Recycling Task Force-City of Appleton 1989-1991
Professional Information and Clinical Relations Committee-AAPM 1989-
Task Group AAPM - Role and Responsibilities of the Medical Physicist in Diagnostic Radiology 1989-1993
Consumer Advisory Panel - Wisconsin Electric Power Company 1991-1993
Revision of the State of Wisconsin Code for Use of Ionizing Radiation 1992-

Certification

American Board of Radiology - Therapeutic Radiologic Physics (1981)
American Board of Radiology - Diagnostic Radiology Physics (1992)
American Board of Radiology - Nuclear Medicine Physics (1992)

Personal Information

Home Address:	6 Timberline Court Appleton, WI 54915 (414) 733-3442
Work Address:	St. Elizabeth Hospital Radiology Department 1506 South Oneida Street Appleton, WI 54915 (414) 738-2190
Marital Status:	Married 2 daughters (ages 11 and 9)
Birth:	February 9, 1954 Joliet, Illinois

CURRICULUM VITAE

SCOTT DAVID MOON
W904 Cty. Hwy. ZZ
Kaukauna, WI 54130
Home (414) 759-0672
Work (414) 738-2221
Birthdate: May 7, 1965
Social Security #: 383-68-3703

EDUCATION:

Wayne State University, Detroit, MI. Master's Degree in Radiological Physics. Graduated December, 1992.

Ferris State University, Big Rapids, MI. Baccalaureate in Nuclear Medicine Technology. Graduated August, 1990.

Ferris State University, Big Rapids, MI. Associate Degree in Radiologic Technology. Graduated August, 1986.

Mona Shores High School, Muskegon, MI. Graduated May, 1984.

CERTIFICATIONS:

Nuclear Medicine Technology Certification Board (NMTCB): #012298
American Registry of Radiologic Technologists (ARRT): #215368
American Board of Medical Physicists (ABMP): Part I, August 27, 1992
: (Diagnostic Imaging Physics) Part II, July 24, 1994

PROFESSIONAL ASSOCIATIONS:

American Association of Physicists in Medicine (AAPM)
Society of Nuclear Medicine (SNM)

AWARDS:

Norman H. Horwitz Scientific Merit Award May 1988 for research and presentations done in the field of Nuclear Medicine. School of Allied Health, Ferris State University, Big Rapids, MI.

CLINICAL/RESEARCH EXPERIENCE:

Medical Physicist. Radiology Department/Radiation Oncology, St. Elizabeth Hospital, Appleton, WI. February 1993-present. Provide physics support to both diagnostic Radiology and Radiation Oncology departments. Responsibilities include QA and calibration of ionizing radiation producing equipment, dosimetry measurements and calculations, initiate and carry out equipment acceptance testing, High Dose Rate (HDR) and Low Dose Rate (LDR) brachytherapy treatment planning, carry out radiation safety and quality assurance programs, and evaluate, develop and initiate new programs and services.

Research Nuclear Medicine Technologist. Division of Nuclear Medicine, University of Michigan Medical Center, Ann Arbor, MI. October 1988-January 1993. Responsible for preparation, administration, imaging, and quantification of a variety of radiopharmaceuticals in studies involving both animals and humans. Other responsibilities included radiation safety, dosimetric computation and data analysis of therapeutic doses of radiolabeled monoclonal antibodies in human cancers. Served as a clinical research coordinator for patient evaluation studies involving a wide variety of radiopharmaceuticals.

Staff Radiographer. Reed City Hospital, Reed City, MI. May 1988 to September 1988. Performed radiologic procedures at a technical level. Performed other clinical duties as necessary.

Nuclear Medicine Technologist Internship. Division of Nuclear Medicine, University of Michigan Medical Center, Ann Arbor, MI. September 1987 to May 1988. Performed clinical Nuclear Medicine procedures on a technical level both under supervision and alone; intravenous administration of radiopharmaceuticals; Nuclear Pharmacy; Pediatric Nuclear Medicine; and gamma camera quality assurance testing.

Radiography Laboratory Assistant. School of Allied Health, Ferris State University, Big Rapids, MI. September 1986 to September 1987. Provided tutorial aid to students, acted as lab assistant, gathered research or lesson material, implemented quality assurance programs, and provided assistance as needed for the Department of Hospital Related Programs.

Radiographer. Immediate Care Center, Muskegon, MI. May 1986 to September 1986. Performed diagnostic radiologic procedures at a technical level on an "on call" basis. Performed other clinical duties as necessary.

Radiography Internship. Department of Radiology, Mercy Hospital, Muskegon, MI. September 1985 to August 1986. Performed diagnostic radiologic procedures, followed proper operating and file procedures, assisted physicians, performed darkroom procedures, and developed professional skills.

PUBLICATIONS IN SCIENTIFIC JOURNALS:

1. Sisson JC, Brown RS, Zasadny KR, Normolle DP, Fisher S, Moon S, Gutowski T and Wahl RL: Biodistribution and therapeutic effects of radiolabeled metaiodobenzylguanidine in a human neuroblastoma xenograft. Antibody, Immunology, Radiopharmaceuticals 1992; 5(1):23-26.

2. Kaminski MS, Fig L, Zasadny KR, Koral KF, del Rosario RB, Francis IR, Hanson CA, Normelle DP, Mudgett E, Liu CP, Moon S, Scott P, Miller RA and Wahl RL: Imaging, dosimetry, and radioimmunotherapy with iodine-131-labeled anti-CD37 (MB-1) antibody in B-cell lymphoma. J Clin Oncol 1992; 10:1696-711.

3. Kaminski MS, Zasadny KR, Francis IR, Milik AW, Ross CW, Moon SM, Crawford SM, Burgess JM, Petry NA, Butchko GM, Glenn SD and Wahl RL: Radioimmunotherapy of B-cell lymphoma with [I-131] anti-B1 (anti-CD20) antibody. N Engl J Med 1993; 329(7):459-465.

ABSTRACTS:

1. Johnson JW, Moon S, Bolgos G, Malak T, Sisson JC: SPECT imaging of adrenergic innervation and B-receptor distribution in the canine heart. Presented at the Society of Nuclear Medicine 36th Annual Meeting, June 13-16, 1989, St. Louis, MO. J Nucl Med Technol 1989; 17(2):114.

2. Fig LM, Kaminski MS, Johnson J, Moon SD, Kucharski A, Miller R, Buchsbaum D, Mudgett B, Mallette S, Wahl RL: Successful imaging of B-cell lymphomas using radiolabeled monoclonal pan B cell antibody MB1. Radiology (P) November, 1989; 173:152.

3. Sisson JC, Brown RS, Zasadny KR, Fisher S, Moon SD and Wahl RL: Neuroblastoma xenograft model to ascertain factors bearing on therapy with I-131 MIBG. Radiology (P) 1989; 173:420.

4. Wahl RL, Kaminski MS, Zasadny KR, Moon S, Fisher SJ and Kilbourn M: PET (Positron Emission Therapy) of murine lymphoma with FDG. J Nucl Med 1991; 32(5):1043.

5. Gutowski TD, Fisher SJ, Moon S and Wahl RL: Experimental studies of 18F-2-fluoro-2-deoxy-d-glucose (FDG) in infection and in reactive lymph nodes. Presented, Society of Nuclear Medicine 1992.

6. Gutowski TD, Fisher SJ, Moon S and Wahl RL: Does 18F-2-deoxy-d-glucose (FDG) accumulate into experimental bone fracture? Correlation with Tc99m MDP. Presented, Society of Nuclear Medicine 1992.

7. Koral KF, Luo J, Zasadny KR, Moon S, Kessler ML, Buchbinder S and Wahl RL: I-131 QSPECT of a phantom using transfer of CT ROIs and manual alignment-error compensation. Presented, Society of Nuclear Medicine 1992.

January 30, 1996

MEMORANDUM TO: John R. Madera, Chief
Materials Licensing Branch
Region III

FROM: Donald A. Cool, Director Original Signed by
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST: MALLINCKRODT Mo-99/Tc-99m GENERATOR

I am responding to your technical assistance request (TAR) dated December 28, 1995, requesting a sealed source and device review of Mallinckrodt Medical, Inc. (MMI) Dry Top Eluting (DTE) Mo-99/Tc-99m Generator.

The MMI DTE does not contain a sealed source. Licensing of Mo-99/Tc-99m Generators are covered under 10 CFR 34.72. We note that your TAR states that, "FDA approval is pending". Once the provisions of 10 CFR 34.72, including FDA approval, have been satisfied, a license may be issued. No sealed source and device review is necessary.

CONTACT: Robert L. Baer
301/415-8125

Distribution: TAR:95-60 (Due 1/31/96)

SCDB r/f	IMNS Central Files	NMSS r/f	SBaggett
CFrazier, RIII	CPederson, RIII	CEstep	

DOCUMENT NAME: G:\MEMO.JRM 1/25/96 c=

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	SCDB		IMAB		D:IMNS/NMSS					
NAME	RBaer:tk		LWCamper		DCool					
DATE	1/24/96		1/26/96		1/24/96					

OFFICIAL RECORD COPY

FEB 2 1995

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

95-60

DEC 2 8 1995

REQUEST FOR TECHNICAL ASSISTANCE

Date: December 22, 1995

Mail or E-Mail to: Donald A. Cool, Mail Stop: 6H3-OWFN, If E-mail, cc:CLE
Division of Industrial and Medical Nuclear Safety,
NMSS

From: for John R. Madera (JRM4), Chief
Nuclear Materials Safety Branch
Region III

Licensee: Mallinckrodt Medical, Inc. (MMI) License No.: 24-04206-05MD

☐ Control No.: 99283

☐ Letter dated: October 10, 1995

☐ Suggested change in licensing procedure (enclosed): N/A

☐ Problem/Issue: Licensee is amending their license for distribution of an upgraded generator - DTE generator. This generator is an upgrade of their present authorized Ultra - TechnaKow (UTK Generator). The upgrade consists of a repositioning of the inner components, which includes a relocation of the internal plumbing, from the bottom to the top of the generator. The elution vial is no longer attached to the generator. NOTE: FDA approval is pending, but expected soon.

☐ Action Required: Perform Sealed Source and Device review for MMI's upgraded DTE generator.

☐ Recommended Active (with revisions): X Approve or X Reject, based on information submitted by licensee.

Headquarters Reviewer:
Regional Reviewer: Cassandra Frazier (CFF)
Reviewer Code: R3
Reviewer Phone No.: (708) 829-9830 Fax No.: (708) 515-1259
Requested Needed By: 12/04/95

cc: C. Pederson

MALLINCKRODT
Nuclear Medicine

R3
95-60

October 10, 1995

Mallinckrodt Medical, Inc.
2703 Wagner Place
Maryland Heights, MO 63043
Telephone 314 [illegible]

A

Cassandra F. Frazier
Nuclear Materials Licensing Section
U.S. Nuclear Regulatory Commission,
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

030-10801

RE: License No. 24-04206-05MD

Dear Ms. Frazier:

Mallinckrodt Medical Inc. (MMI) hearby applies for an amendment of the above referenced license for the distribution of the Dry Top Eluting Mo-99/Tc-99m Generator (DTE Generator). The DTE generator is an upgrade of the Ultra-TechnaKow (UTK Generator) presently distributed by MMI. These generators will contain the various activity sizes currently used in the UTK Generator, except for the 0.25 Ci size generator which will be discontinued. Please refer to Attachment VII for activity sizes and corresponding safe sizes.

The upgrade consists of a repositioning of the inner components, which includes a relocation of the internal plumbing, from the bottom to the top of the generator. The elution vial is no longer attached to the generator. The elution vial is included as a separate component and shipped as an insert in the final generator package. Please refer to Attachments IV and V.

Mr. Ashok Dhar requested an early NRC review of the DTE license amendment application with you during a telephone conversation in the first quarter of 1995. You agreed to review this license amendment application early with a condition of MMI sending the FDA final approvable letter as soon as it was received. The preliminary approvable letter has been received; MMI is responding to the FDA comments. MMI is anticipating final FDA approval by the end of October 1995.

On October 2, 1995 during a telephone conversation with the NRC, Mr. Kevin Null, stated that it would be acceptable for MMI to submit labels and/or stats in the MMI license amendment request.

399283

Enclosed are technical data tables and copies of all the labeling and/or stats which will be located on either the generator or the generator packaging. There are five copies of the label and/or stats for your review. MMI will submit all the final labels which are currently in stat form to the NRC, after FDA approval. The technical data tables include information regarding the generator safes and the maximum precalibration activity amounts and radiation levels for all unpackaged generator sizes. Also included are drawings of the three different generator safes with the corresponding packaging.

The Attachments are as follows:

ATTACHMENT	DESCRIPTION
Attachment I	The 38mm lead safe Contains the 0.25 Ci, 0.50 Ci, and 0.75 Ci generators The 48 mm lead safe. Contains the 1.00 Ci, 1.50 Ci, 2.00 Ci, 2.50 Ci, 3.00 Ci, 4.3 Ci, 5.3 Ci, and 6.4 Ci generators
Attachment Ia	The Lead Plug for the 38 mm and 48 mm lead safe
Attachment Ib	The plastic adapter for the small lead safe
Attachment Ic	The plastic adapter for the large lead safe
Attachment II	The Depleted Uranium (DU) safe Contains the 12.00 Ci size generator
Attachment IIa	The DU/Lead Plug for the 12 Ci DU safe
Attachment III	The plastic adapter top of the DTE generator
Attachment IV	The DTE generator assembly diagram
Attachment V	The DTE generator package diagram

Attachment VI	The DTE generator labels
Attachment VIa	AS497V-Test Elution Vial Label
Attachment VIb	AS498V-Generator Eluant Bottle Label
Attachment VIc	AS507V-TechneStat Vial Label
Attachment VId	AS508V-10 ml Evacuated Collecting Vial Label (STAT)
Attachment VIe	AS509V-20 ml Evacuated Collecting Vial Label (STAT)
Attachment VIf	A784K0-10 ml Evacuated Vial Pack Label (STAT)
Attachment VIg	A785K0-20 ml Evacuated Vial Pack Label
Attachment VIh	A80010-10 ml Accessory Pack Label
Attachment VIi	A80020-20 ml Accessory Pack Label
Attachment VIj	A88010-Package Insert Label (STAT)
Attachment VIk	A880C0-Canister Label
Attachment VII	Outer shipping carton surface label
Attachment VII	Surface Radiation and TI Levels and for the Packaged DTE
Attachment VIII	Product Information for the DTE Generator

We believe that we have included all of the information you will need for your assessment of the generator upgrade except for the final approvable letter from the FDA. NRC Form 313 and a $420 check for the license amendment fee is attached.

We would appreciate your prompt attention to this amendment request. Please contact me at (314) 770-7981 if you have any questions or require additional information.

Regards,

Daniel Riemer
Health Physics Supervisor

Attachments
Amendment Fee Check

CONVERSATION RECORD

TIME | DATE 7/13/95

O VISIT O CONFERENCE X TELEPHONE

X INCOMING
O OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT: Stan Reed, RSO

ORGANIZATION (OFFICE, DEPT ETC.): St Elizabeth Hospital

TELEPHONE NO.: 414/738 2190

SUBJECT
License No. 48-10219-01

SUMMARY
Mr. Reed withdrew amendment request dated April 7, 1996.

ACTION REQUIRED

Richard Watson — 7/13/95

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE | DATE

ACTION TAKEN

SIGNATURE | TITLE | DATE

JUL 1 4 1995

St. Elizabeth Hospital
ATTN: Stanley A. Reed
Radiation Safety Officer
1506 South Oneida Street
Appleton, WI 54915

Dear Mr. Reed:

We have reviewed your letter dated February 24, 1994, requesting a renewal of NRC Material License No. 48-10219-01 and find that we will need additional information pertaining to the HDR unit as follows:

1. Training Program

   a. Please specify the method you will use to determine each trainee's competency to use the device for each type of proposed use.

   b. Confirm that your authorized user retraining will include "hands-on" training (using dummy sources) for your emergency procedures (i.e. "dry runs").

   c. Confirm that records of initial and refresher training provided for both device operators and ancillary personnel will be maintained for a period of three years. These records must include the instructor(s) name, the attenders names, the training date(s), and an outline of the topics discussed.

2. Facilities

   a. Describe the viewing and intercom backup system to be used if the primary systems fails. In lieu of a backup system, you may choose to commit to suspend further treatments until the primary system is repaired.

   b. Describe the required actions in the event of an interlock malfunction. This must include a confirmation that the device will be locked in the "off" position and not used, except as may be necessary for interlock system repair or replacement, until proper interlock system function is restored;

   c. Describe the mechanisms installed to ensure that only one device, if more than one radiation producing device is located in the treatment room, can be placed in operation at a time;

   d. Describe the method to ensure that the console keys are inaccessible to unauthorized persons

e. Confirm that the radiation monitor is checked with a dedicated check source for proper operation each day before the device is used;

f. Confirm that the operability check is documented and that these documents are maintained for a period of three years;

g. Confirm that the radiation monitor will be promptly repaired or replaced if found to be either inoperable or evidencing intermittent problems.

3. Compliance With Restricted/Unrestricted Area Radiation Level Limits

a. Describe the survey program that will be implemented to demonstrate compliance with 10 CFR 20.1501; including a requirement to conduct surveys following source replacement. These surveys must demonstrate:

(1) The maximum radiation levels at 10 centimeters from the nearest accessible surface of the source safe with the source in the shielded position;

(2) That radiation levels in restricted areas accessible to radiation workers are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.1201; and

(3) That radiation levels in unrestricted area will not result in a dose to any member of the public in excess of the limits specified in 10 CFR 20.1301.

Please confirm that records of these surveys will be maintained for the duration of the license.

b. Confirm that a conspicuous, durable label stating "Caution Radioactive Materials," will be affixed to at least one outer surface of the remote afterloading device as specified in 10 CFR 20.1904.

4. Operating Procedures

Provide a copy of your operating procedures. These procedures must require the following:

a. The treatment room to be secured when unattended;

b. Treatment planning computer removable media will be labelled with the corresponding patient's name and identification number;

c. A survey of the device will be performed immediately after each use of the device; including the connectors and applicator apparatus, the full catheter guide tube length, and the device external surface;

d. A record of the device and patient survey maintained;

e. No treatment procedure will be conducted for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in shielded container; and

f. Nursing personnel provided specific (written) instructions for patient care.

5. Daily Checks

Confirm that the following **daily** safety checks of your remote afterloader device will be performed and describe the method used to perform these checks:

a. The permanent radiation monitor check with a dedicated check source for proper operation;

b. TV monitor and intercom system check to verify proper operation;

c. Console operational function check, indicator lamp test, other status and operational displays;

d. Applicator and connector mechanical integrity check;

e. Applicators, source guide tubes, and connectors visually inspected for mechanical integrity;

f. Commitment to provide verbal as well as written instruction to individuals providing daily safety checks; and

g. Confirm that records of your daily safety checks of your remote afterloader device will be maintained for three years and will include the following information:

(1) The date of the check;

(2) The results, and

(3) The initials of the individual who performed the check.

6. Monthly Checks

Confirm that the following monthly safety checks of your remote afterloader device will be performed in accordance with the manufacturer's instructions at intervals not to exceed 30 days:

a. Source position accuracy within the catheter guide tube to within ±1 millimeter of the programmed position;

b. Timer accuracy and linearity;

c. Measurement of source guide tubes to confirm length to 1 mm accuracy;

d. Backup battery test to verify emergency source retraction capability upon power failure (i.e., a function test with the AC power disconnected); and

e. Confirm that records monthly safety checks of your remote afterloader device will be maintained for three years and will include the following information:

(1) The date of the checks;

(2) The results of the checks;

(3) For the source position accuracy check, the programmed position and actual position of the source following activation of the device; and

(4) The initials of the individual who performed check.

7. Calibration of Afterloading Device

a. Submit the name(s) and qualifications of the individual(s) who will perform the device calibrations. Specify the individuals experience with the dosimetry system which will be used to perform calibration measurements.

b. Provide a description of the method used to determine the exposure rate under specific criteria (i.e., distances used for the measurement, whether the measurement is an "in-air" measurement or done using a phantom, configuration of the chamber with respect to the source guide tube and device, scatter factors used to compute the exposure rate, etc.).

c. Specify your calibration recordkeeping requirements, including a commitment to maintain a record of calibration measurements and associated calculations for a period of three years. The records must include:

(1) The calibration date;

(2) The manufacturer's name, model number and serial number for both the HDR and the source;

(3) The manufacturer's name, model number and serial number of the instrument used to measure the HDR device output;

(4) The name of the individual who performed the measurement; and

(5) The HDR output expressed in R/hr; and the manufacturer's "expected" output value (decay corrected); these values should be within ±5%.

d. Confirm that the radiation safety officer or medical physicist will be consulted prior to performing further patient treatments if the measured output differs by greater than ±5% from the manufacturer's "expected" decay corrected output.

e. Specify the calibration frequency. Calibration is required following a new source(s) installation prior to patient treatment, and recommended morthly thereafter.

f. Describe your method for confirming source homogeneity. This may be done by autoradiography, following source replacement but prior to patient treatment.

g. Provide a description of the dosimetry system which will be used to perform calibration measurements. Confirm that the dosimetry system will be calibrated by a laboratory accredited by NIST or AAPM within the previous two years and after any servicing that may have affected the dosimetry system. Confirm that dosimetry system calibration records will be maintained for inspection.

h. Describe your method for conducting source inventories. Specify that physical source inventories will be performed quarterly (10 CFR 35.59) and records maintained in accordance with 10 CFR 35.59(g).

8. Emergency Procedures

a. Confirm that emergency procedures are provided to device operators, authorized user(s), and other personnel as necessary.

b. Specify requirements for restricting and posting the treatment area to minimize the risk of inadvertent exposure to personnel not directly involved in the emergency source recovery.

c. Identify where you will store emergency source recovery equipment and specify what equipment may be necessary for the various equipment failures described in the procedures. At a minimum, emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient, including scissors and cable cutters.

9. Maintenance

a. Confirm that all maintenance and repair of the device will be performed by the manufacturer or by individuals specifically authorized by the NRC or an Agreement State. If maintenance and repair will be performed by someone other than the manufacturer, specify the individual and provide a copy of the NRC or Agreement State license authorizing this individual for maintenance and repair activities.

Note: Maintenance and repair means installation, replacement, relocation or removal of the sealed source or an afterloading device that contains a sealed source; or any adjustment involving any mechanism on the afterloading device, treatment console, or interlocks that could expose the source, reduce the shielding around the source or affect the source drive controls.

b. Confirm that HDR inspection and service records will be maintained for the duration of device use. These records must include: the inspection/service date; the name of the individual who performed the inspection/service; the NRC or Agreement State license number authorizing the individual to perform the inspection/service; a description of the inspection/service performed, including a list of the components inspected and a list of components serviced or replaced; and the signature of the inspector.

c. Confirm the following inspection and service criteria for the HDR device:

(1) The HDR device will be fully inspected and serviced at intervals not to exceed 12 months, to ensure proper functioning of the source exposure mechanism;

(2) All scheduled service recommended by the manufacturer will be performed in accordance with the manufacturer's instructions;

(3) Inspection and service will only be performed by the manufacturer or other persons specifically licensed to do so by the NRC or an Agreement State; and

(4) Records of these inspections will be maintained.

JUL 1 4 1995

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 396604.

If you have any questions or require clarification on any of the information stated herein, you may contact us at (708) 829-9887.

Sincerely,

Original Signed By
Gidget Watson
Nuclear Materials Licensing Section

License No. 48-10219-01
Docket No. 030-03466

Enclosure: P&G Dir. FC 86-4, Rev.1

DOCUMENT NAME: M:\03003466.DF5
To receive a copy of this document, indicate in the box: "C" = Copy without attachmcnt/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DRSS/RIII								
NAME	GWatson:brt								
DATE	07/14/95								

OFFICIAL RECORD COPY

1506 South Oneida Street
Appleton, Wisconsin 54915
(414) 738-2000 fax (414) 738-0949

St. Elizabeth Hospital

March 8, 1995

John R. Madera
United States Nuclear Regulatory Commission
Region III
Nuclear Material Licensing Section
801 Warrenville Road
Lisle, IL 60532-4351

NRC License No. 48-10219-01
Control No. 396604

Dear Mr Madera:

St. Elizabeth Hospital filed a renewal medical byproduct material license which received a timely filed notice on March 11, 1994. Approximately one year has gone by without any written correspondence concerning our renewal and we are concerned that information may have been misplaced at your facility.

Please provide a written statement on the status of our license renewal. Thank you for your attention on this matter.

Sincerely,

Stanley A. Reed

Stanley A. Reed, Medical Physicist, RSO

SARmmm

1506 South Oneida Street
Appleton, Wisconsin 54915
(414) 738-2000 *fax* (414) 738-0949

St. Elizabeth Hospital

February 7, 1995

United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

License No. 48-10219-01
Docket No. 030-03466

Dear Medical License Reviewer:

This correspondence is in reference to your letter dated 1/30/95 requesting additional information concerning our response dated 5/5/93 to NRC Bulletin 93-01. As a matter of note, since our 5/5/93 letter our HDR program has been modified twice (license renewal dated 2/24/94 and QMP revision date 7/22/94).

1) Radiation Surveys/Area Monitor:

In our high dose rate (HDR) afterloading program we survey the patient after each treatment (source removal) and prior to having staff or physicians assist with the release of the patient from the treatment area. Our area monitor is supplied with emergency back-up power in the event of primary power loss. This device is checked with a radiation source for proper operation each day of use. The design of our independent area monitor is to have a radiation signal sent to a remote indication unit at the contral console. This remote signal is verified for proper operation during the quality control check on each clinical day prior to patient use. During any clinical treatment the remote radiation indicator at the console is observed for indication that the source is in an unshielded position. In our prior response we felt that the likelihood of the area monitor to fail and the failure being not due to loss of input power is just as likely as loss of power. We feel that in the event that the primary area monitor fails (whatever the reason) that a licensee should be able to temporarily use a secondary system, such as a second survey instrument to provide an acceptable level of redundancy until the primary system can be repaired. A battery operated survey

instrument may not meet the "independent source of backup power" statement and for this reason we felt the requirement was too restrictive and apparently did not address what happens in the event of an area monitor failure. We feel the requirement needs revision.

2) At all our HDR procedures we have had and will continue to have both an authorized user and a medical physicist present. In our original response we had desired the option to have a trained dosimetrist as a substitute for the medical physicist and it appears from your response that a trained dosimetrist is acceptable as a medical physicist substitute. The dosimetrist is required to have "formal radiation protection training", however, it is not clear exactly how these requirements are defined. Please outline what is considered acceptable formal radiation protection training.

Please contact Stanley A. Reed (414-738-2190) for questions concerning this response.

Respectfully submitted,

Stanley A Reed

Stanley A. Reed, MS, Certified Medical Physicist

SARmmm

1506 South Oneida Street
Appleton, Wisconsin 54915
(414) 738-2000 *fax:* (414) 738-0949

St. Elizabeth Hospital

February 7, 1995

United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

License No. 48-10219-01
Docket No. 030-03466

Dear Medical License Reviewer:

This correspondence is in reference to your letter dated 1/30/95 requesting additional information concerning our response dated 5/5/93 to NRC Bulletin 93-01. As a matter of note, since our 5/5/93 letter our HDR program has been modified twice (license renewal dated 2/24/94 and QMP revision date 7/22/94).

1) Radiation Surveys/Area Monitor:

In our high dose rate (HDR) afterloading program we survey the patient after each treatment (source removal) and prior to having staff or physicians assist with the release of the patient from the treatment area. Our area monitor is supplied with emergency back-up power in the event of primary power loss. This device is checked with a radiation source for proper operation each day of use. The design of our independent area monitor is to have a radiation signal sent to a remote indication unit at the contral console. This remote signal is verified for proper operation during the quality control check on each clinical day prior to patient use. During any clinical treatment the remote radiation indicator at the console is observed for indication that the source is in an unshielded position. In our prior response we felt that the likelihood of the area monitor to fail and the failure being not due to loss of input power is just as likely as loss of power. We feel that in the event that the primary area monitor fails (whatever the reason) that a licensee should be able to temporarily use a secondary system, such as a second survey instrument to provide an acceptable level of redundancy until the primary system can be repaired. A battery operated survey

instrument may not meet the "indopendent source of backup power" statement and for this reason we felt the requirement was too restrictive and apparently did not address what happens in the event of an area monitor failure. We feel the requirement needs revision.

2) At all our HDR procedures we have had and will continue to have both an authorized user and a medical physicist present. In our original response we had desired the option to have a trained dosimetrist as a substitute for the medical physicist and it appears from your response that a trained dosimetrist is acceptable as a medical physicist substitute. The dosimetrist is required to have "formal radiation protection training", however, it is not clear exactly how these requirements are defined. Please outline what is considered acceptable formal radiation protection training.

Please contact Stanley A. Reed (414-738-2190) for questions concerning this response.

Respectfully submitted,

Stanley A Reed

Stanley A. Reed, MS, Certified Medical Physicist

SARmmm

Colleen

ST. ELIZABETH HOSPITAL • A Member of the Wheaton Franciscan System
1506 SOUTH ONEIDA STREET • APPLETON, WISCONSIN 54915-1397

April 6, 1994

Shirley Crutchfield
License Fee and Debt Collection Branch
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Control Number: 396604

Dear Ms Crutchfield:

This correspondence is in response to our telephone conversation on April 5, 1994, concerning an additional fee for category 2B. St. Elizabeth Hospital no longer has depleted uranium as a shielding material and therefore does not require the condition on its license (48-10219-01). The depleted uranium was used in a linear accelerator which was removed (replaced) from this facility approximately six years ago. Please contact me (414-738-2190) if you have any questions regarding this request.

Sincerely,

Stanley A Reed

Stanley A. Reed, MS
Medical Physicist

SARmmm

APR 25 1994

1506 SOUTH ONEIDA STREET • APPLETON, WISCONSIN 54915-1397
PHONE (414) 738-2000 • FAX (414) 738-0949

MAR 11 1994

St. Elizabeth Hospital
ATTN: Stanley Reed, M.S.
Radiation Safety Officer
1506 South Oneida Street
Appleton, WI 54915

License No. 48-10219-01
Control No. 396604

Dear Mr. Reed:

SUBJECT: LICENSE RENEWAL APPLICATION

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified and your license number.

Sincerely,

Original Signed By
Marianne Meenan, Chief
Nuclear Materials Support Section

RIII
MM
Meenan/jaw
03/10/94