NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 19

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.

302500

Licensee	
1. Trinity Health System Trinity West D/B/A Trinity Medical Center West 2. 4000 Johnson Road Steubenville, OH 43952	In accordance with letter dated April 1, 1997 3. License Number 34-06578-02 is amended in its entirety to read as follows:
	4. Expiration Date July 31, 2000
	5. Docket or Reference No. 030-02760/030-07576

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 (excluding xenon-133)	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
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. As needed
E. Uranium depleted in Uranium-235	E. Cadium plated metal	E. As needed

D/1

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 34-06578-02

Docket or Reference Number: 030-02760/030-07576

Amendment No. 19

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200 (excluding xenon-133).

C. Medical use described in 10 CFR 35.300.

D. Medical use described in 10 CFR 35.400.

E. Shielding in a linear accelerator at Trinity Medical Center East, 380 Summit Avenue, Steubenville, Ohio.

CONDITIONS

10. Locations of Use: Trinity Medical Center West, 4000 Johnson Road, Steubenville, Ohio and Trinity Medical Center East, 380 Summit Avenue, Steubenville, Ohio.

11. A. Radiation Safety Officer: William Hunter Vaughan, M.D.

B. Assistant Radiation Safety Officer: Ronald I. Veatch, M.D.

12. Authorized Users:

A. William Hunter Vaughan, M.D., for material in 10 CFR 35.100 and 35.200 (excluding xenon-133).

B. Ronald I. Veatch, M.D., for material in 10 CFR 35.100, 35.200 (excluding xenon-133) and 35.300.

C. Conrad S. Revak, M.D., for material in 10 CFR 35.100, 35.200 (excluding xenon-133) and 35.300.

D. Marshall S. Carlin, D.O., for material in 10 CFR 35.100, 35.200 (excluding xenon-133) and 35.300.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
34-06578-02

Docket or Reference Number
030-02760/030-07576

Amendment No. 19

12. Authorized Users (Continued)

E. Heung Joon Yoo, M.D., for material in 10 CFR 35.100 and 35.200 (excluding xenon-133).

F. Mark G. Trombetta, M.D., for material in 10 CFR 35.400.

G. Gerald R. Medwick, D.O., for material in 10 CFR 35.400.

H. John A. Hyland, M.D, for material in 10 CFR 35.400.

I. James M. Hughes, M.D., for material in 10 CFR 35.400.

J. Tarit K. Dutta, M.D., for material in 10 CFR 35.400.

K. Marcel M. Szal, M.S., for material in 10 CFR 35.400, for survey instrument calibration only.

L. Frank P. Ottino, M.S., for material in 10 CFR 35.400, for survey instrument calibration only.

M. Rajiv Shingal, Ph.D., for material in 10 CFR 35.400, for survey instrument calibration only.

N. Tony G. Combine, M.S., for material in 10 CFR 35.400, for survey instrument calibration only.

O. David Wonderly, M.S., for material in 10 CFR 35.400, for survey instrument calibration only.

13. 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.

14. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 34-06578-02

Docket or Reference Number: 030-02760/030-07576

Amendment No. 19

15. This license is based on the licensee's statements and representations listed below:

A. Application dated April 11, 1990; and

B. Letters dated April 16, 1991, June 18, 1991, May 23, 1996, October 4, 1996, October 9, 1996 and April 1, 1997 (excluding the Quality Management Program).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAY 2 9 1997

By Charles F. Dill
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20000731
Fee Comments:
Decom Fin Assur Reqd: N

58

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: TRINITY HEALTH SYSTEMS
   Received Date: 970403
   Docket No: 3002760
   Control No.: 302500
   License No.: 34-06578-02
   Action Type: Amendment

2. FEE ATTACHED
   Amount: X * ADDL INFO
   Check No.: X 301956-58

3. COMMENTS

Signed D. Hersey
Date 4-25-97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered X /)

FEE NOT REQUIRED

1. Fee Category and Amount: 7C

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed SC
Date 4/14/97

APR 25 1997

Log Apr 5 10
Remitter
Check No.
Amount
Fee Category 7C
Type of Fee AMD
Date Check Rec'd
Date Completed 4/14/97
By: SC

97 APR 14 AM 9:23

TRINITY
HEALTH SYSTEM

380 Summit Avenue
Steubenville, Ohio 43952

April 1, 1997

Charles Gill
U.S.N.R.C.
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Re: Control Numbers: 301966 & 301967

Mr. Gill,

This correspondence is written in response to your request for additional information dated March 6, 1997. All of the requested information is listed below. All responses are numbered to correspond with the noted request.

1. Authorized Materials, Uses, and Places of Use.

   a. Depleted Uranium

   We confirm our request for the use of Uranium depleted in Uranium-235 as Cadmium plated metal, as needed, for use as shielding in a linear accelerator at the Trinity Medical Center East facility located at 380 Summit Avenue, Stubenville, Ohio. This material will remain in exactly the same location including the room number and location within the room as represented in correspondence with the NRC regarding past authorizations for license number ~~34-13317-02~~.

   The Linear Accelerator Manufacturer is Varian Oncology Systems.

   The Linear Accelerator Model Number is Clinac 6/100.

   Information regarding the type, dimension, thickness, and weight of the depleted Uranium shielding is attached.

   The linear Accelerator is registered with the State of Ohio.

   The Accelerator room diagram is attached.

b. Material Identified in 10 CFR 31.11

We confirm that the materials identified above are or were used only under a general license. (Total possession quantities not to exceed 200uCi. total for iodine 125, iodine 131, selenium-75 and iron 159 at any one time).

c. Carbon 14

Carbon 14 is not now in use. We also confirm that Carbon 14 was used only in quantities requiring a general license.

d. Molybdenum-99 Generator Depleted Uranium Shielding

We confirm that we do not request the use of depleted uranium in generator shielding. Please delete License Condition No. 13.

e. Material Identified in 10-CFR 35.400

We confirm that we request full authorization for the use of 10 CFR 35.400 materials for brachytherapy at both the Trinity East and Trinity West locations. Trinity West currently has had no brachytherapy use or possession. In the past, Trinity East possessed and used I-125 Seeds. These seeds were stored in the Nuclear Medicine Department Hot Lab (a restricted area)for > 10 half-lives until decayed to background, surveyed and disposed. Currently, no I-125 seeds are possessed. We do not request that the Hot Lab be released for unrestricted use therefor, no close-out survey was performed.

f. Material Identified in 10 CFR 35.100, 35.200, and 35.300

We confirm that we are requesting full authorization for materials identified in 10 CFR 35.100 and 35.300 at both the East and West location. It has been decided that no Xenon-133 will be used at either location therefor, we are requesting authorization for materials identified in 10 CFR 25.200 excluding Xenon-133. We confirm that we are requesting authorization for the use of aerosols and generators.

2. Facility Diagrams

Facility diagrams for all restricted areas are attached.

We confirm that surveys have been taken of all areas surrounding the restricted

areas to assure that no individual members of the public will receive doses in excess of those specified in 10 CFR 20.1301.

3. Survey Meter Calibrations

The name of the current instrument calibration facility is R.U.F. License No. 34-26693-01.

4. Radiation Safety Committee

Radiation Safety Program Manager and Site Representatives (by position title) who are members of the Radiation Safety Committee:

a. Director of Radiology - Radiation Safety Program Manager
b. Site Representative Trinity East
c. Site Representative Trinity West

We confirm that the Radiation Safety Committee Membership will include the following:

Radiation Safety Officer - W. Hunter Vaughan, M.D. (or in his absence, Ronald I Veatch, M.D., assistant RSO)
Member of Administration - David Arnold (or equivalent title)
Director of Radiology - Radiation Safety Program Manager
Nursing Representative - Trinity East (RN)
Nursing Representative - Trinity West (RN)
Site Radiation Safety Representative Trinity East
Site Radiation Safety Representative Trinity West
Authorized user for materials identified in 35.100 & 25.200 - W. Hunter Vaughn, M.D. (or equivalent 35.100 & 35.200 authorized user)
Authorized user for material identified in 35.300 - Ronald I Veatch, M.D. (or equivalent 35.300 authorized user)
Authorized user for material identified in 35.400 - Mark G. Trombetta, M.D. (or equivalent 35.400 authorized user)

5. Laboratory Instructions

Attachment No 14 has been corrected to read "Do not use the dosage if it is more than 10 percent off from the prescribed dosage, except for prescribed

dosages who's activity is less than 10 uCi." A corrected Attachment No. 10.4 is attached.

6. Area Survey Procedures

We confirm that we will commit to Regulatory Guide 10.8 Appendix N for area survey procedures.

7. Spilled Gas Clearance Times

We do not request the use of Xenon-133 at either location.

We will use only single use devices for aerosol studies and collect spent aerosols in a shielded trap thus, in accordance with Regulatory Guide 10.8 Appendix O Item 10.13.2 , monitoring of the trap effluent is not required.

We will not directly vent spent aerosols to the atmosphere therefore in accordance with Regulatory Guide 10.8 Appendix O, no effluent estimation is necessary.

8. Radiopharmaceutical Therapy
   a. Bioassay Program

Thyroid bioassay is to be performed on any individual who administers or helps administer an iodine-131 therapy dose with an activity greater than 30 millicurie. Bioassays will be performed between 6 and 72 hours post exposure.

Procedure

1. A microcurie size I-131 capsule (10-20uCi) should be used to determine a calibration factor. If liquid I-131 is used for therapy, the residual activity can be used for determining a calibration factor.

2. Place I-131 capsule in thyroid phantom. Set parameters to detect Iodine-131. Count capsule for two minutes at the face of the collimator. From this count and assay from the dose calibrator, determine efficiency factor.

$$\text{efficiency Factor} = \frac{\text{Activity of source (uCi)} \times (2.2 \times 10^6 \text{ dpm/uCi})}{\text{net CPM of source}}$$

3. Count individual's thyroid on same parameters as Step #2. Count for two minutes. Place knee area in front of probe and count for two minutes. Subtract knee count from thyroid count in order to determine net thyroid count. Document thyroid count in cpm.

4. Multiply thyroid count (cpm) by calibration factor (uCi/cpm) in order to determine thyroid exposure.

$$\text{uCi in thyroid} = \frac{\text{net CPM of thyroid x efficiency factor}}{2.2 \times 10^6 \text{ DPM/uCi}}$$

5. If thyroid exposure is greater than .04 uCi, an investigation should be initiated by the RSO as to the cause of the exposure. A repeat thyroid bioassay should be done within two weeks of the previous measurement.

Note Change:

The evaluation level for bioassays as described in Regulatory Guide 8.9 (NRC) is 0.133 uCi (2% of the annual limits on intake, ALI). The investigational level as described in the same document is 0.665 uCi (10% of the ALI). These values are based upon an ALI value of 50 uCi, and a thyroid intake retention factor (IRF) for I-131 at 24 hrs of 0.133 (NUREG 4884).

The instruments used for bioassays are as follows:

East Unit - Capintec S/N 20163-1
West Unit - AtomLab - 930 S/N 1282005

Efficiency Evaluations on both units are attached.

Action levels (0.04 uCi.) and actions are noted above.

b. The useful range of the pocket dosimeter (model number 415-A) is 1 mR - 9999 mR.

We confirm that the pocket dosimeter will be calibrated annually by our survey meter calibration company in accordance 10 CFR 20.2106 (b).

We confirm that records of individual monitoring results for individuals for whom monitoring was required pursuant to 20.1502 and records of doses received during planned special exposures, accidents, and emergency conditions will be kept in accordance with 10 CFR 20.1206.

We confirm that dosimeter exposures will be recorded after a nurse exits the patient's room.

9. Brachytherapy

a. We confirm that we will commit to Regulatory Guide 10.8 Revision 2 Appendix Q for Radiation Safety during Implant Procedures.

b. We confirm that all personnel caring for patients undergoing implant therapy will be instructed in accordance with 10 CFR 35.410.

c. The useful range of the pocket dosimeter is (model number 415-A) is 1 mR - 9999 mR

We confirm that the pocket dosimeter will be calibrated annually by our survey meter calibration company in accordance 10 CFR 20.2106 (b).

We confirm that records of individual monitoring results for individuals for whom monitoring was required pursuant to 20.1502 and records of doses received during planned special exposures, accidents, and emergency conditions will be kept in accordance with 10 CFR 20.1206.

We confirm that dosimeter exposures will be recorded after a nurse exits the patient's room.

d. We confirm that we will commit to Regulatory Guide 10.8 Revision 2 Appendix M.4 for maintaining implant source accountability. Exhibit 15 or a similar form will be used for documentation.

e. We confirm that exhibit 20 of Regulatory Guide 10.8 Revision 2 or similar form will be used to document implant therapies.

A sample Written Directive is attached. These records will be kept for NRC review for a minimum of 3 years following treatment.

f. **NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH TEMPORARY IMPLANT SOURCES**

Patient Name:_____ Patient Number:_____

Attending:_____ Phone:_____ Pager:_____ Patient Room: _____

Dose:_____mCi of _____ as _____ individual sources was loaded on ____-____-____.

Sources will be removed at approximately ____:____ am pm on ____-____-____.

RADIATION EXPOSURE RATES

Unrestricted areas: door-_____mR/hr; room____-____mR/hr; room____-____mR/hr

Patient supine in bed or _____

Date	Time	Bedside	1 m from patient Door		_____
____-____-____	____:____ am pm	_____mR/hr	_____mR/hr	_____mR/hr	_____mR/hr

Release certification: Patient may not be released from the hospital until the following certification is signed and dated by the RSO or the attending physician.

I have removed and counted ___ individual sources from this patient. A low-range GM survey of the patient failed to indicate any remaining sources in the patient.

Signature_____ Date _____

g. We confirm that we will commit to:

M.4 Keeping an Inventory of Implant Sources

MODEL PROCEDURE

1. Use a locking installe. cabinet or safe to store all implant sources.

2. Make a list of names of those individuals you allow to handle implant sources and have them initial beside their names.

3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.

4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.

5. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use or patient's name, and the time and date they were removed from storage; initial the record.

6. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Then make a record of the number and activity of sources returned, the room number of use or patient's name, and the time and date they were returned to storage; initial the record.

7. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

We confirm that we will modify our Cs-137 implant source log to mimic Exhibit 21 of Regulatory Guide 10.8 Revision 2.

h. A diagram of the implant source storage area including radiation safety equipment is attached.

i. We confirm that the brachytherapy source storage room will remain locked at all times.

The following individuals will have access to the keys to the room:

1. Any authorized user for materials in 10 CFR 35.400.
2. Any Physicist listed as an authorized user on the materials license.

j. A standard commercially available portable source transport safe with at least one inch of lead shielding will be used to transport sources from the storage room to the area of use.

k. All personnel handling brachytherapy sources will wear TLD finger dosimeters.

l. We confirm that inventories will be performed in accordance with 10 CFR 35.59(g)and(h).

m. We confirm that all brachytherapy bed linens will be checked with a radiation survey meter before being removed from the patient's room to assure that no dislodged sources are removed.

n. A standard commercially available source safe including front lead glass L will be used. Example 3M safe model 6624 with four inches of lead shielding and an L shield one and three quarters inches lead or equivalent.

We confirm that stainless steal remote handling tongs will be used to handle sources.

o. Victoreen Panaramic Survey Meter

See attached equipment list.

10. Quality Management Program for both Trinity East and West:

QUALITY MANAGEMENT PROGRAM

POLICIES AND PROCEDURES FOR DIAGNOSTIC AND THERAPEUTIC RADIOPHARMACEUTICAL USES

1. A written directive must be prepared prior to the administration of any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 uCi of either sodium iodide I-125 or I-131. Each written directive will be issued as an order for a specific patient, dated and signed prior to an administration by an authorized user or a physician under the supervision of an authorized user. The written directive for sodium iodide I-125 or I-131 will include the dosage to be administered. The written directive for all other therapeutic radiopharmaceuticals will include the dosage to be administered, the radiopharmaceutical to be administered, and the route of administration.

   Procedures for oral directive or revisions to written directive are as follows.

   If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and revised written directive is dated and signed by the authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision.

   Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user or physician under the supervision of an authorized user prior to the administration of the radiopharmaceutical dosage.

   If, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

2. Before administering a radiopharmaceutical dosage, the licensed user or designee will verify by more than one method the identity of the patient as the individual named in the written directive. The procedure used to identify the patient will be to ask the

patient's name and confirm the name and at least one of the following by comparison with corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, or the name on the patient's medical insurance card.

3. The licensed user or designee will verify, before administering the radiopharmaceutical, that the specific details of the administration are in accordance with the written directive. The radiopharmaceutical, dosage, and route of administration will be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive. For photon emitting radiopharmaceuticals, the dosage will be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive. For pure beta emitters, the manufacturer's assay of the radiopharmaceutical, as well as any calculations to correct for decay and volume, will be compared with the prescribed dosage in the written directive or the dosage will be measured in the dose calibrator using a setting and/or correction factor previously determined.

4. The licensed user will direct all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers will ask for clarification if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

5. The authorized user or a qualified person under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist, or technologist), after administering a radiopharmaceutical, will make, date, and sign or initial a written record that documents the administered dosage in an auditable form.

6. Should an unintended deviation from a written directive be identified, it shall be brought to the attention of the Radiation Safety Officer. The RSO will have the deviation investigated, will evaluate the need for corrective action and shall cause such corrective action to be implemented.

7. Upon discovery of a recordable event, the RSO will have the event evaluated by assembling the relevant facts including the cause. The RSO will identify what, if any, corrective actions are required to prevent recurrence and will retain a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken. The above action will be performed within 30 days after discovery of the recordable event.

8. Reviews of the radiopharmaceutical QM program will be performed at intervals not to exceed twelve months. The review will include a representative sample of patient administrations, all recordable events, and all misadministrations for the previous 12

months (or last review). Patient cases will be selected at random to eliminate any bias in the sampling procedure. The number of patient cases to be sampled will be based on the principles of statistical acceptance using acceptance sampling tables of 10CFR32.110, assuming an error rate (Lot Tolerance Percent Defective) of 10 percent. (See table.) For each patient case, a comparison will be made between what was administered versus what was prescribed in the written directive, relative to radiopharmaceutical dosage and route of administration. Program reviews will be documented and distributed to all appropriate management and departments.

Lot Tolerance Percent Defective
10.0 Percent:

Lot Size	Sample Size	Acceptance Number
1 to 20	All	0
21 to 50	17	0
51 to 100	20	0
101 to 200	22	0
201 to 800	23	0
801 to 100,000	39	1

Lot Tolerance Percent Defective
5 Percent:

Lot Size	Sample Size	Acceptance Number
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2,000	45	0
2001 to 100,000	75	1

Should either a misadministration or a recordable event be uncovered during a review of the QMP, the number of cases sampled will be increased to those indicated by using the acceptance sampling table of 10CFR32.110 for a Lot Tolerance Percent Defective rate of 5%.

Each review of the QMP will be evaluated to determine the effectiveness of the program. Should the number of deviations discovered in the review not exceed the appropriate Acceptance Number specified by the Lot Tolerance Percent Defective table, the program will be considered effective. Should the number of deviations exceed the appropriate Acceptance Number, the program may be ineffective. In this case, the RSO shall make such modifications as necessary to meet the objectives of the program as defined in 10CFR35.32(a).

9. Modifications to the QMP may be made to increase the program's efficiency provided the program's effectiveness is not decreased. The modified program will be submitted to the NRC Regional Office within 30 days after the modification is made.

10. Written records of each administered radiopharmaceutical dosage and each written directive will be maintained for three years. Records of each QMP review and evaluation will be maintained for three years.

11. The radiation safety training program has been modified to include instruction in the Quality Management Program.

QUALITY MANAGEMENT PROGRAM

POLICIES AND PROCEDURES FOR BRACHYTHERAPY

(Excluding high dose-rate remote afterloading brachytherapy)

1. A written directive must be prepared prior to the administration of any brachytherapy treatment. Each written directive will be issued as an order for a specific patient, dated and signed by an authorized user or a physician under the supervision of an authorized user. The written directive will include the radioisotope, number of sources and source strengths. After implantation but prior to the completion of the procedure, the authorized user will amend the written directive to add the radioisotope, treatment site, total source strength, and total exposure time (or, equivalently, the total dose).

   Procedures for oral directives and revisions to written directives are as follows:

   If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.

   Also, a written revision to an existing written directive may be made for this therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the brachytherapy dose.

   If, because of the emergent nature of the patient's medical condition, a delay in order

to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

2. Before administering a brachytherapy dose, the licensed user or designee will verify by more than one method the identity of the patient as the individual named in the written directive. The procedure used to identify the patient will be to ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name of the patient's medical insurance card, or the photograph of the patient's face.

3. The person administering the brachytherapy treatment will verify, before administering the brachytherapy treatment, that the specific details of the brachytherapy administration are in accordance with the written directive and plan of treatment. In particular, the radioisotope, number of sources, source strengths, treatment site, loading sequence and total dose will be confirmed to verify agreement with the written directive and plan of treatment.

4. The licensed user will direct all workers to seek guidance if they do not understand how to carry out the written directive. Workers will ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

5. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist) will verify that the radioisotope, number of sources, source strengths, and, if applicable, loading sequence of the sources to be used are in agreement with the written directive and plan of treatment before implanting the radioactive sealed sources.

   Verification methods, such as checking the serial number of the sealed sources behind an appropriate shield, using a radiation detector, using a dose calibrator, using color-coded sealed sources, or using clearly marked storage locations, i.e., one location for each source strength will be used. In the case of Ir-192, the sources are usually in color coded strands for identification purposes. If not color-coded, the different strength sources are in different lead containers. In these cases, the activity of the sources will be based on the manufacturer's calibration, subject to accounting for decay.

6. For temporary brachytherapy implants, the licensed user or designee will use

radiographs or other comparable images (e.g. computerized tomography) of brachytherapy radioactive sources or nonradioactive "dummy" sources in place as the basis for verifying the position of the sources and calculating the exposure time (or, equivalently, the total dose). Whenever possible, nonradioactive "dummy" sources will be used before inserting the radioactive sources (e.g., cesium-137 sealed sources used for intracavitary applications). However, in brachytherapy procedures requiring the use of various fixed geometry applicators (e.g., appliances or templates) radiographs or other comparable images will not be necessary provided the position of the sources is known prior to inserting the radioactive sources and calculating the exposure time (or, equivalently, the total dose).

7. For permanent brachytherapy implants, the licensed user or designee will use radiographs or other comparable images (e.g., computerized tomography) of brachytherapy radioactive sources in place as the basis for verifying the position of the sources and calculating the total dose, if applicable, after inserting the sources (e.g., iodine-125 sealed sources used for interstitial applications). However, in brachytherapy procedures requiring the use of various fixed geometry applicators (e.g., templates) radiographs or other comparable images will not be necessary.

8. After administering a brachytherapy treatment using a temporary implant, the authorized user or a qualified individual under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist) will promptly make a written record of the treatment. The record will include the radioisotope, the treatment site, the actual loading sequence (the strength of each source and its location in its applicator), and the total exposure time or the total dose. The individual will sign or initial the record. The record will be maintained in an auditable form.

9. After administering a brachytherapy treatment using a permanent implant, the authorized user or a qualified individual under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist) will promptly make a written record of the treatment. The record will include the radioisotope, the treatment site, the actual number of sources implanted, the strength of each source, and the total dose. The individual will sign or initial the record. The record will be maintained in an auditable form.

10. The licensed user or designee will check the dose calculations before the total prescribed brachytherapy dose has been administered. Whenever possible, an authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who did not make the original calculation will check the dose calculations. Manual dose calculations will be checked for:

- Arithmetic errors,
- Appropriate transfer of data from the written directive, plan of treatment, tables and graphs,
- Appropriate use of nomograms (when applicable), and
- Appropriate use of all pertinent data in the calculations.

Computer-generated dose calculations will be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations (e.g., position of the applicator or sealed sources, number of sources, total source strength, or source loading sequence). Alternatively, the brachytherapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. When the manual dose calculations are performed using computer-generated outputs (or vice versa), particular emphasis will be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual).

11. If the authorized user determines that delaying treatment in order to perform the checks of dose calculations would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations will be performed within two working days of completion of the brachytherapy treatment.

12. Acceptance testing by a qualified person (e.g., a teletherapy physicist) will be performed on each treatment planning or dose calculating computer program used for brachytherapy dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for brachytherapy dose calculations. The licensee will assess each treatment planning or dose calculating computer program based on specific needs and applications.

13. Should an unintended deviation from a written directive be identified, it shall be brought to the attention of the Radiation Safety Officer. The RSO will have the deviation investigated, will evaluate the need for corrective action and shall cause such corrective action to be implemented.

14. Upon discovery of a recordable event, the RSO will have the event evaluated by assembling the relevant facts including the cause. The RSO will identify what, if any, corrective actions are required to prevent recurrence and will retain a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken. The above action will be performed within 30 days after discovery of the recordable event.

15. Reviews of the brachytherapy QM program will be performed at intervals not to exceed 12 months. The review will include a representative sample of patient

administrations, all recordable events and all misadministrations for the previous 12 months (or last review). Patient cases will be selected at random to eliminate any bias in the sampling procedure.

The number of patient cases to be sampled will be based on the principles of statistical acceptance using acceptance sampling tables of 10CFR32.110, assuming an error rate (lot tolerance percent defective) of 10 percent. (See table) For each patient case, a comparison will be made, prior to implantation between what was administered versus what was prescribed in the written directive relative to the radioisotope, number of sources and source strengths; and after implantation but prior to completion of the procedure: the radioisotope, treatment site and total source strength and exposure time (or, equivalently, total dose). Program reviews will be documented and distributed to all appropriate management and departments.

Lot Tolerance Percent Defective
10.0 Percent:

Lot Size	Sample Size	Acceptance Number
1 to 20	All	0
21 to 50	17	0
51 to 100	20	0
101 to 200	22	0
201 to 800	23	0
801 to 100,000	39	1

Lot Tolerance Percent Defective
5 Percent:

Lot Size	Sample Size	Acceptance Number
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2,000	45	0
2001 to 100,000	75	1

Should either a misadministration or a recordable event be uncovered during a review of the QMP, the number of cases sampled will be increased to those indicated by using the acceptance sampling table of 10CFR32.110 for a Lot Tolerance Percent Defective rate of 5%.

Each review of the QMP will be evaluated to determine the effectiveness of the program. Should the number of deviations discovered in the review not exceed the appropriate Acceptance Number specified by the Lot Tolerance Percent Defective table, the program will be considered effective. Should the number of deviations exceed the appropriate Acceptance Number, the program may be ineffective. In this case, the RSO shall make such modifications as necessary to meet the objectives of the program as defined in 10CFR35.32(a).

16. Modifications to the QMP may be made to increase the program's efficiency provided the program's effectiveness is not decreased. The modified program will be submitted to the NRC Regional Office within 30 days after the modification is made.

17. Written records of each administered brachytherapy treatment and each written directive will be maintained for three years. Records of each QMP review and evaluation will be maintained for three years.

18. The radiation safety training program has been modified to include instruction in the Quality Management Program.

Thank you for your attention to this matter.

David Arnold 4/2/97

David Arnold
Vice President, Administration

ATTACHMENTS

MINIMUM DETECTABLE ACTIVITY

EFFICIENCY / CALCULATION

FACILITY: Trinity - East DATE: 3/24/97

INSTRUMENT:Capintec : S/N: 20163-1

SOURCE:

NUCLIDE: I-131 TYPE Capsule ACTIVITY: 11.52 uCi

ASSAY DATE: 3/21/97

TEST DATE: 3/24/97

ELAPSED TIME
FROM ASSAY DATE: 3 days

CALCULATED CURRENT ACTIVITY: $A = A_o e^{\left(\frac{-.693t}{T_{1/2}}\right)}$

CURRENT ACTIVITY: 8.90 uCi (uCi X 2.22E6 dpm/uCi = dpm)

CURRENT ACTIVITY: 1.98 E7 dpm

EFFICIENCY

% EFFICIENCY = cpm/dpm x 100

DETECTOR USED: Capintec Uptake Probe

Bkg: 265.5 cpm Std: 23075.4 cpm

EFFICIENCY = .12 %

MINIMUM DETECTABLE ACTIVITY

$$MDA = 3\frac{\sqrt{R_b / t}}{Eff}$$

R_b = RATE OF BKG in cpm
t = TIME IN MIN.

MDA = 40735 dpm
MDA = 0.019 uCi.

MINIMUM DETECTABLE ACTIVITY

EFFICIENCY / CALCULATION

FACILITY: Trinity - West DATE: 3/20/97

INSTRUMENT: AtomLab 930 : S/N: 1282005

SOURCE:

NUCLIDE: I-131 TYPE Capsule ACTIVITY: 12.58 uCi

ASSAY DATE: 3/20/97

TEST DATE: 3/20/97

ELAPSED TIME
FROM ASSAY DATE: 0 days

CALCULATED CURRENT ACTIVITY: $A = A_o e^{\left(\frac{-.693t}{T_{1/2}}\right)}$

CURRENT ACTIVITY: 12.58 uCi (uCi X 2.22E6 dpm/uCi = dpm)

CURRENT ACTIVITY: 2.79 E7 dpm

EFFICIENCY

% EFFICIENCY = cpm/dpm x 100

DETECTOR USED: Capintec Uptake Probe

Bkg: 69 cpm Std: 21560 cpm

EFFICIENCY = .08 %

MINIMUM DETECTABLE ACTIVITY

$$MDA = 3\frac{\sqrt{R_b/t}}{Eff}$$

R_b = RATE OF BKG in cpm
t = TIME IN MIN.

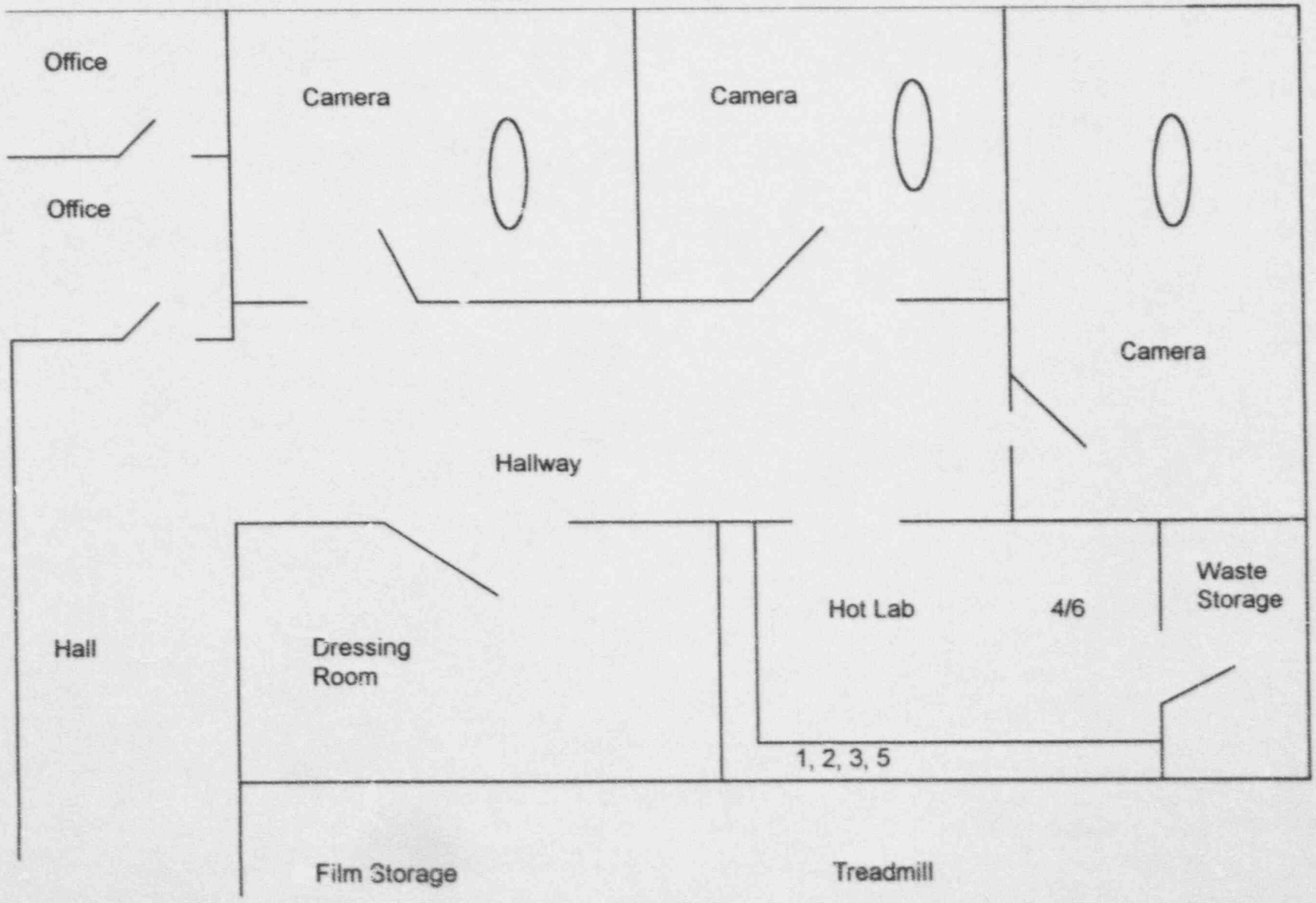
MDA = 31150 dpm
MDA = 0.014 uCi.

Trinity - West

Nuclear Medicine

1. Survey Equipment
2. Receipt Area
3. Kit/Dose Prep
4. Generator
5. Dase Calibrator
6. Isotope Storage

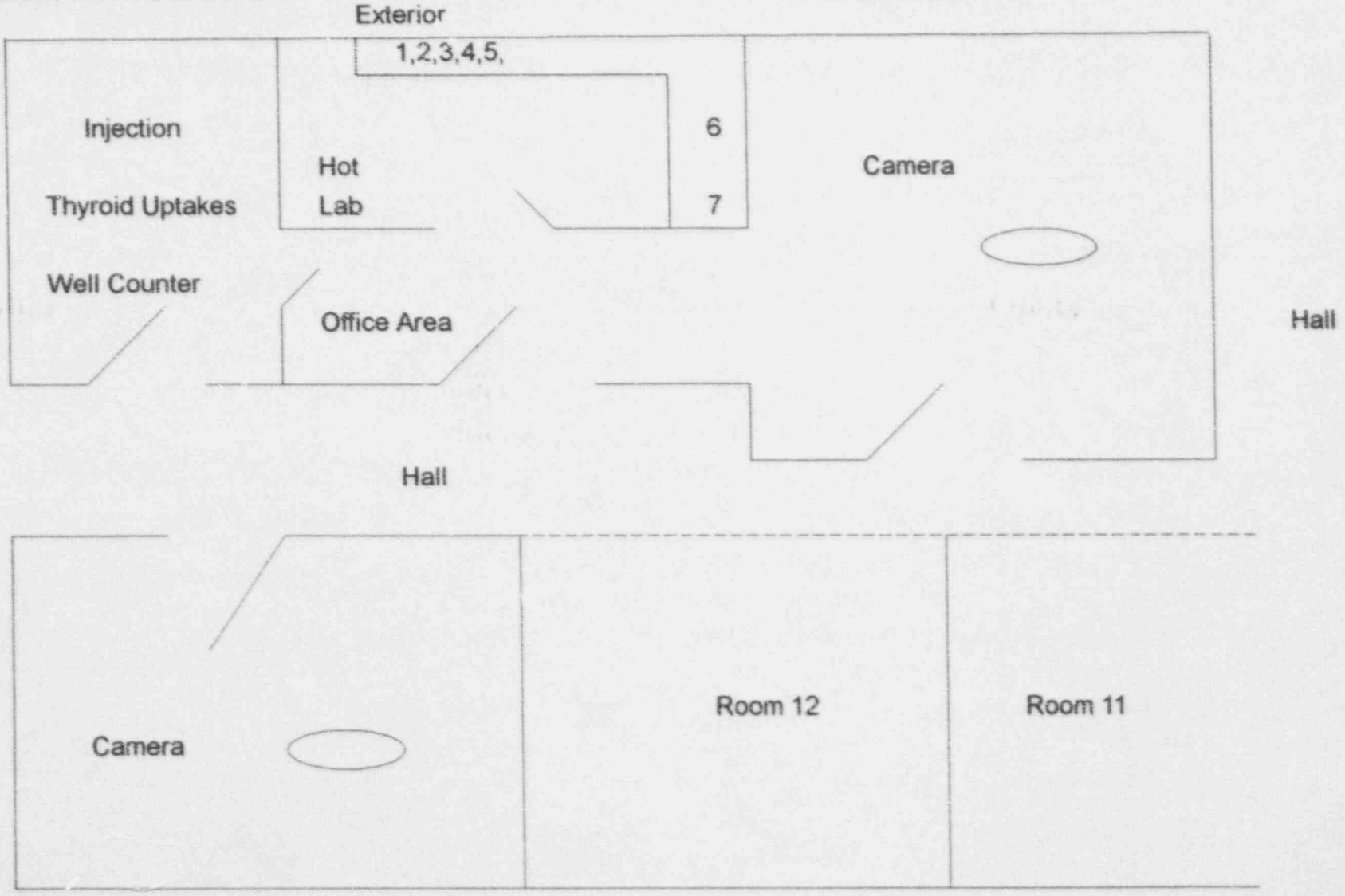
Hot Lab Shielding - Standard 2" Lead Bricks, L. Block, ~1/8
Storage Containers - All lLockable Doors in Restricted Areas



Trinity - East

Nuclear Medicine

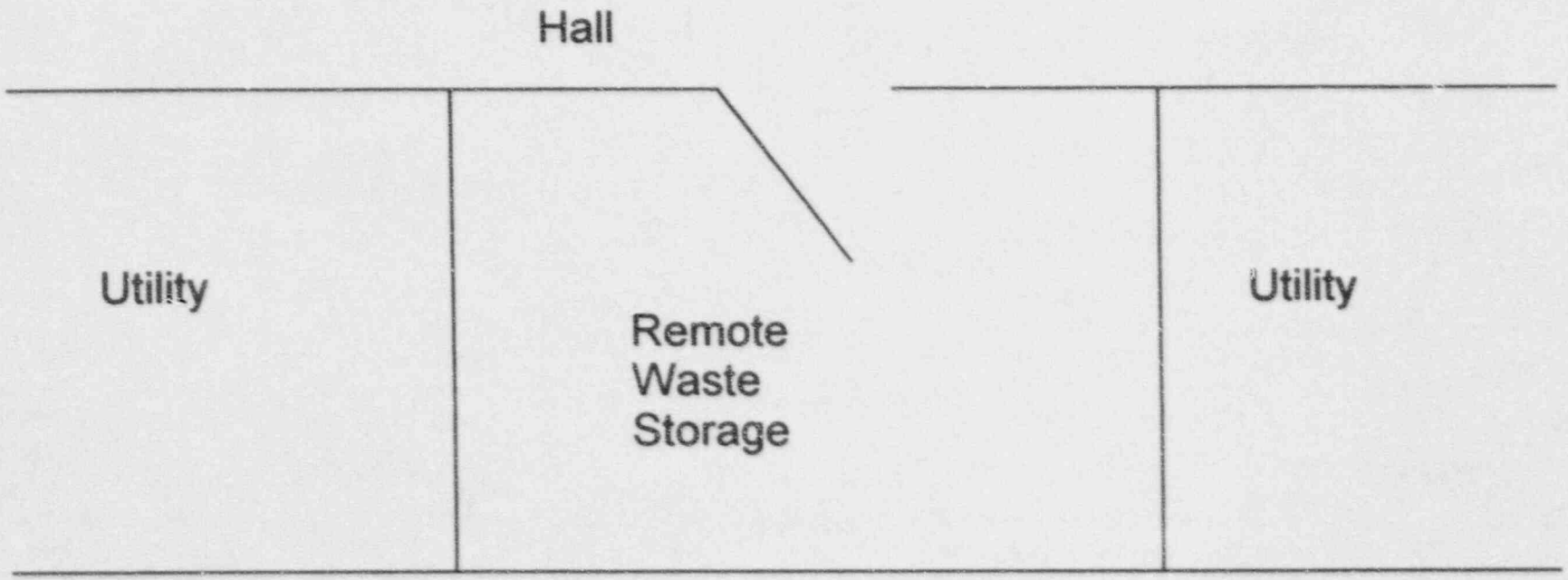
1. Survey Equipment
2. Receipt Area
3. Kit/Dose Prep
4. Generator
5. Dose Calibrator
6. Isotope Storage
7. Waste Storage

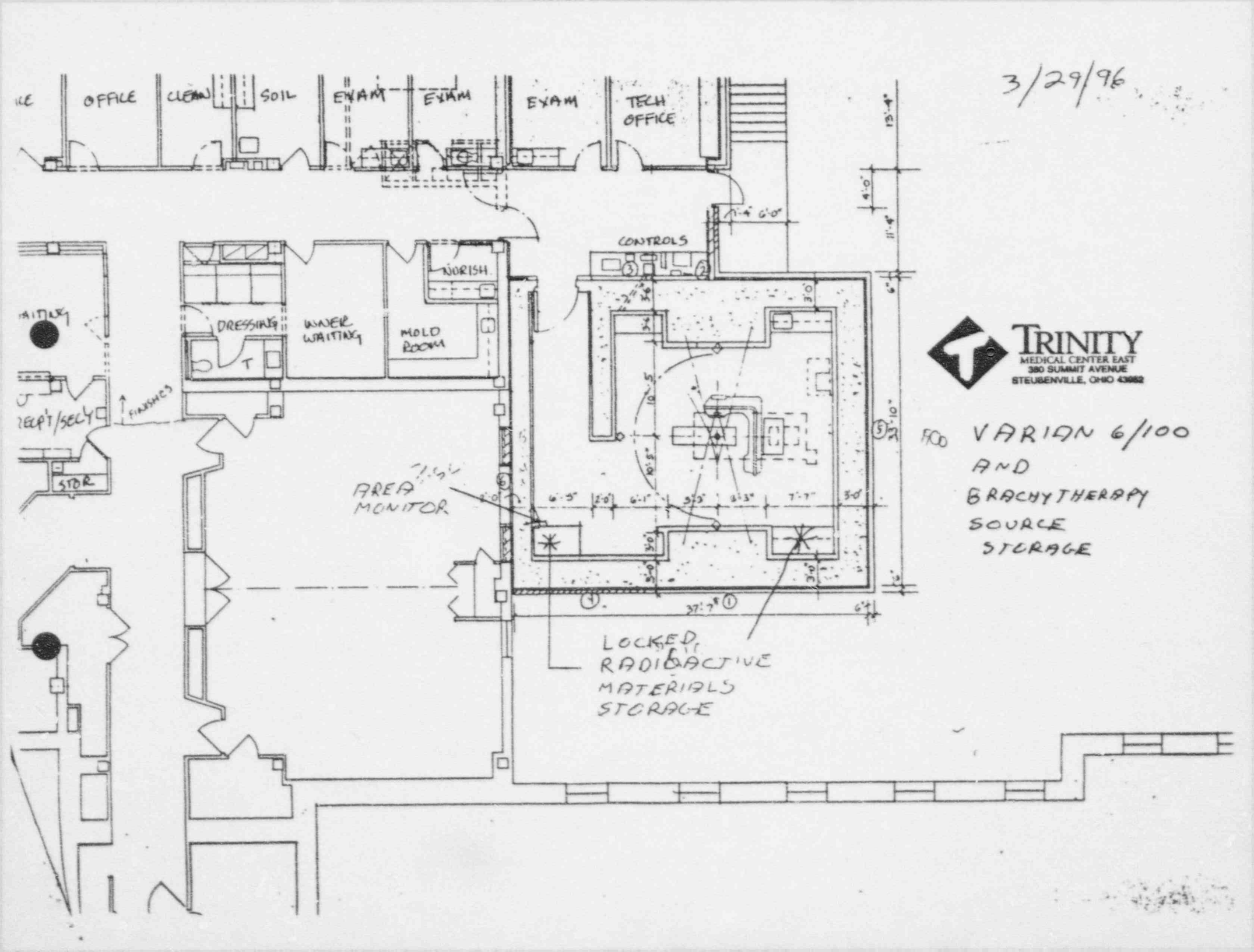


Hot Lab Shielding - Standard 2" thick lead bricks, Standard L Block, ~1/8" Storage Containers
All Lockable Doors in the Restricted Areas

Trinity - East

Remote Waste Storage Area
2nd Central West




3/29/96
OFFICE
CLEAN
SOIL
EXAM
EXAM
EXAM
TECH OFFICE
CONTROLS
NOURISH.
DRESSING
WAIVER WAITING
MOLD ROOM
T
STOR
FINISHES
AREA MONITOR
LOCKED RADIOACTIVE MATERIALS STORAGE
TRINITY
MEDICAL CENTER EAST
380 SUMMIT AVENUE
STEUBENVILLE, OHIO 43952
FOR VARIAN 6/100 AND BRACHYTHERAPY SOURCE STORAGE

varian

DEPLETED URANIUM COMPONENTS IN THE CLINAC 4, 4S, 6X, 4/100, 6/100, AND 600C

Clinac 4, 4S and 6X

Part Containing Uranium	No. of Parts	(pounds) Unit Weight	Total Weight
Primary collimator	1	68	68
Upper jaw	2	31	62
Lower jaw	2	53	106
Face plate shield	2	8.5	17
Gun shield	1	18.5	18.5
Gun shield disks	-	-	-
Total Pounds:			271.5

Clinac 4/100, 6/100 and 600C

Part Containing Uranium	No. of Parts	(pounds) Unit Weight	Total Weight
Primary collimator	1	96	96
Upper jaw		Tungsten replacement	
Lower jaw		Tungsten replacement	
Face plate shield	2	8.5	17
Gun shield	-	-	-
Gun shield disks	3	40	120
Total Pounds:			233

Element and Mass Number: U-238
Physical Form: Metal Alloy U-0.75 titanium
Specific Activity: 3.6×10^{-7} Ci/gm
Purpose of Use: Shielding

2.4 SAFETY PROCEDURES

In establishing operating procedures for the Clinac installation, the hospital administration should include the following items to help assure safety and reduce the likelihood of injury to personnel and damage to the equipment.

1. Cease machine operation immediately if any equipment malfunction is detected or suspected. Never continue patient treatment. Always call maintenance personnel to service the machine.

2. If a power failure or emergency stop should shut the machine down during treatment, remove the patient from the treatment room and perform the daily checkout procedure before resuming treatment.

3. When performing the daily checkout procedure, record each time designated in the daily log. Also record any unusual behavior or observations noted at that time or throughout the treatment day.

4. When entering the treatment room at any time, the operator should always take the X-RAYS key. The machine will remain ON, but X-rays cannot be generated.

5. Before rotating the gantry, always make certain that the PSA and treatment couch are positioned so as to eliminate the possibility of collision.

6. When attempting to lower the PSA, if there is no response to commands from the hand pendant, make certain that all motions are locked and remove the patient with great care.

7. Under no circumstances should interlocks or other devices intended for personnel or machine protection be bypassed or jumpered.

8. Whenever the machine is in standby overnight or for a weekend, or is otherwise unattended, always remove the X-RAYS key from the console and deposit it in a designated secure storage place so that no unauthorized activation of the machine can occur.

VARIAN 6/100

2.5 DEPLETED URANIUM SHIELDING

In order to minimize radiation leakage, certain shielding components in the Clinac 6/100 and 4/100, including the primary collimator and the four movable collimators, may have been fabricated from depleted uranium.

Depleted uranium is a naturally occurring, processed radioactive material, and should be handled with caution. A major portion of the radiation emanates from alpha and beta particles, with only a small fraction being gamma rays. External radiations are well below those generally considered as hazardous. The surface beta-plus-gamma dose rate from depleted uranium (at the collimators) is approximately 200 mrem/hr. Twenty centimeters (approximately 7.8 inches) from the surface of the collimators, the beta-plus-gamma decreases to below 20 mrem/hr while the gamma dose rate is less than 1 mrem/hr.

The Clinac contains up to approximately 400 pounds of depleted uranium. Each piece is stamped with the following identifying symbols: CAUTION – RADIOACTIVE MATERIAL – DEPLETED URANIUM.

Bare uranium oxidizes easily and the oxide powder could become a minor radiation problem. All pieces are nickel cadmium plated to prevent oxidation. Care should be taken to assure that the protective coating is not damaged.

Uranium oxide poisoning to personnel can result from oxidation of depleted uranium components if the protective coating is damaged. Under no circumstances should anyone attempt to machine, file, drill, scrape, scratch, or break the protective coating of the depleted uranium components. By law only the original manufacturer or other specifically licensed facility may machine, rebore, replate, or may perform modifications to uranium.

In case of disposal of a Clinac 6/100 or 4/100, this material must not be processed as normal scrap but rather must be returned either to Varian or to a licensed commercial supplier of uranium, or to the U.S. Nuclear Regulatory Commission.

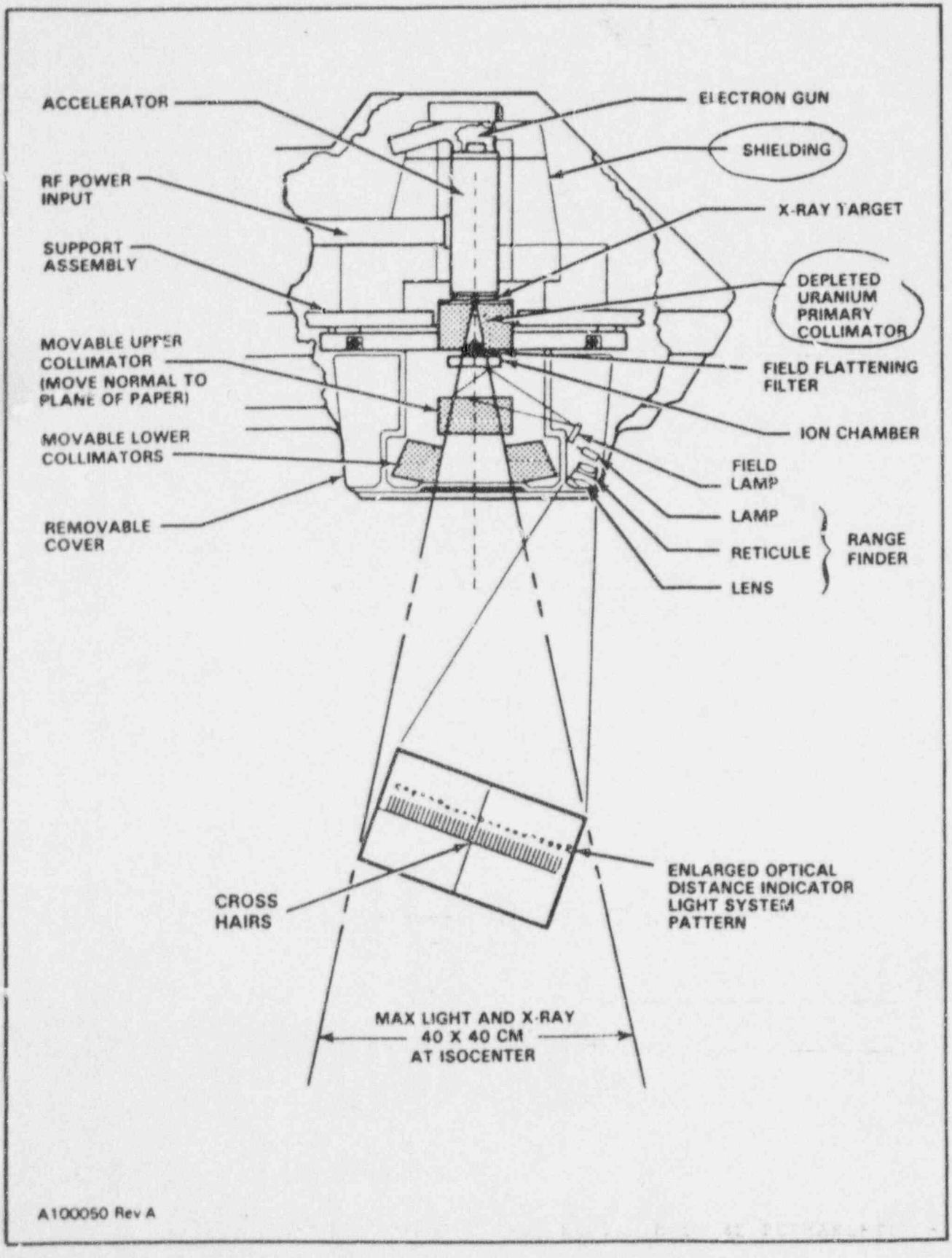


FIGURE 4-6 COLLIMATOR ASSEMBLY

Rad Techs/Physics
Check-off Procedure

FORM C

RADIATION THERAPY SOURCE USAGE RECORD

Patient _____ ID# _____ RM _____

Ordering Physician _____

Applicator(s) used _____ Sources _____

Date and time of insertion _____ AM/PM _____

	YES	SEE COMMENTS
. Patient assigned private room	( )	( )
. Exposure monitors issued to nursing personnel?	( )	( )
. Safety instruction given to nurse?	( )	( )
. Safety procedures placed in patient's chart?	( )	( )
. Caution sign placed on patient's chart?	( )	( )
. Caution signs placed on patient's room door?	( )	( )
. Nursing care rotated?	( )	( )
. Known pregnant nurses not attending patient?	( )	( )
. Pregnant visitors prohibited?	( )	( )
. Visitors under 18 prohibited?	( )	( )
. Safety survey performed and recorded?	( )	( )
. Safe line marked ?	( )	( )
. Limits of nursing care time posted?	( )	( )
. Removal notice posted in patient's chart prior to removal of all posted signs?	( )	( )
. All signs removed?	( )	( )
. Room surveyed and background radiation levels present?	( )	( )

Date/Time of Removal _____ AM/PM _____

Applicator _____ Sources _____

COMMENTS:

CERTIFIED BY: _____ Date _____

IMPORTANT: THIS RECORD MUST BE PERMANENTLY MAINTAINED

TRINITY
MEDICAL CENTER EAST
220 SUMMIT AVENUE
STEUBENVILLE, OHIO 43952

CAUTION
RADIOACTIVE MATERIA

SUMMARY INSTRUCTIONS FOR PATIENTS TREATED WITH RADIOACTIVE SOURCES

Patient's Name: _____

Room Number: _____ Physician's Name: _____

Isotope: _____ Activity: _____

Date and Time of Administration: _____

Estimated Date Sources are to be removed: _____ Isotope: _____

Exposure Rates in mR/hr

Bedside (Shielded _____/Unshielded _____) 3 feet from bed _____

Head of Bed _____ Foot of Bed _____ 10 feet from bed _____

Visitors Position

Recommended limits of nursing care time _____ positioning _____

Recommended limits of visitor time _____ positioning _____

If inadvertent source dislodgement, date/time: _____

Follow checked items:

_____1. Safety Instructions/Procedures placed in patient chart
_____2. Wear personnel monitoring device
_____3. Patient must have a private room
_____4. Wear rubber gloves
_____5. Place laundry in linen hamper in room and save
_____6. Housekeeping may not enter the room
_____7. Patient may not have visitors
_____8. No pregnant visitors or nurses
_____9. No visitors under 18 years of age
_____10. A dismissal survey must be performed before patient is discharged
_____11. Other instructions _____

_____

RSO/Designee Signature: _____

RSO Name: _____ Phone: _____ Beeper: _____
Radiation Oncologist Name: _____ Phone: _____ Beeper: _____
Physicist Name: _____ Phone: _____ Beeper: _____
Dosimetrist Name: _____ Phone: _____ Beeper: _____
Chief Technologist Name: _____ Phone: _____ Beeper: _____

TRINITY
MEDICAL CENTER EAST
360 SUMMIT AVENUE
STEUBENVILLE, OHIO 43952

Form B

Receipt/shipment record

Radiation source therapy application

Important

This record must be permanently maintained !

Patient : _____ Room # _____

PRETREATMENT INVENTORY

Drawer	#1	#2	#3	#4	
Number of sources					
Color code of sources					Total activity
Ra-226 eq. mg					in Cs-137 safe.
Total activity per drawer					

Time _____ Cesium Curator

Date _____ _____

Sources removed from the safe.

#	activity / serial number
#	_____ / _____
#	_____ / _____
#	_____ / _____
#	_____ / _____
#	_____ / _____
#	_____ / _____

POST TREATMENT INVENTORY

Time _____ Cesium Curator

Date _____ _____

Sources returned to the safe

#	activity / serial number
#	_____ / _____
#	_____ / _____
#	_____ / _____
#	_____ / _____
#	_____ / _____
#	_____ / _____
#	_____ / _____

Drawer	#1	#2	#3	#4	
Number of sources					
Color code of sources					
Ra-226 eq. mg					Total activity
Total activity per drawer					

in Cs-137 safe.

Comments :

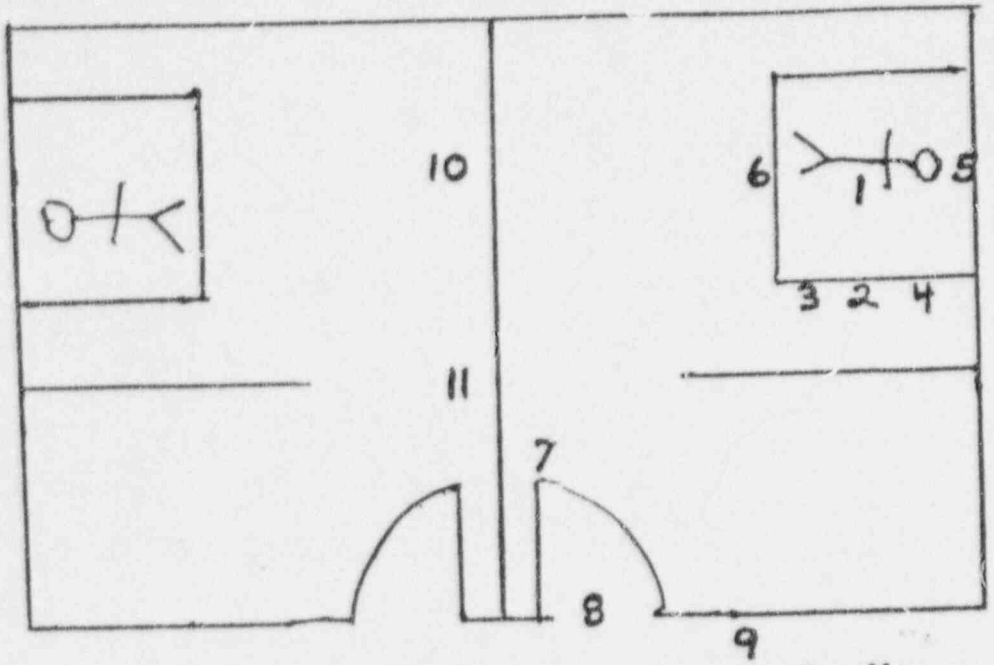
1. All sources are accounted for _____ (Yes / No)
2. Final survey results on patients _____ (mR / hr)
3. Background radiation level _____ (mR / hr)
4. Final survey of patient's room _____ (mR / hr)
5. Charge nurse contacted _____ (Name)
6. Have room/nursing restrictions

TRINITY
MEDICAL CENTER EAST
380 SUMMIT AVENUE
STEUBENVILLE, OHIO 43952

FORM B

DATE / TIME _____
ROOM # _____
PATIENT _____
ISOTOPE _____
APPLICATOR _____
ACTIVITY (mg Eq.) _____
SURVEYOR _____

Outside Area (Above Grade)



Survey Results

Comments :

Survey Meter _____
Calibration Date _____
Check Source reading _____
Background reading _____

#1	Patient On Contact	mR/hr
#2	Patient @ 1 meter	mR/hr
#3	Bed side unshielded	mR/hr
#4	Bed side shielded	mR/hr
#5	Head of bed	mR/hr
#6	Foot of bed	mR/hr
#7	Visitor's position	mR/hr
#8	Entrance	mR/hr
#9	Hall way	mR/hr
#10	Adjoining patient's room	mR/hr
#11	Adjoining patient's room	mR/hr
#12	_____	mR/hr
#13	_____	mR/hr
#14	_____	mR/hr

TRINITY MEDICAL CENTER
QUALITY MANAGEMENT FORM
RADIATION ONCOLOGY

PATIENT NAME:_____ DATE OF IMPLANT:_____

MEDICAL RECORD NUMBER:_____

IMPLANT DEVICE (PROPOSED)

RTD NUMBER:_____

CYL FLETCHER SUITE FREE HAND

SIZE_____

TANDEM
SOURCES_____

RIBBONS_____

SOURCES_____

SEEDS_____

OVOID
SOURCES_____

PLANES_____

DOSE REQUIRED_____ ISOTOPE_____

DOSE RATE DESIRED_____

PHYSICIAN_____

BRACHYTHERAPY SOURCE LOADING

CYL FLETCHER SUITE FREE HAND

R L

SOURCE 1_____ _____ RIBBONS_____

SOURCE 2_____ ____ _____ ____ SEEDS_____

SOURCE 3_____ _____ PLANES_____

SOURCE 4_____ _____

LOADED BY_____ VERIFIED BY_____

INSERTED BY_____ VERIFIED BY_____

BRACHYTHERAPY DOSIMETRY

INSERTED BY- _____ REMOVED BY_____

DATE_____ TIME_____ DATE_____ TIME_____

TOTAL MG RA EQ_____ TOTAL HOURS_____

RADS/HR_____ RADS/HR_____ RADS/HR_____ RADS/HR_____

AT_____ AT_____ AT_____ AT_____

TOTAL DOSE TOTAL DOSE TOTAL DOSE TOTAL DOSE

_____ _____ _____ _____

BRACHYTHERAPY PLAN RUN BY_____

BRACHYTHERAPY PLAN CHECKED BY_____

BRACHYTHERAPY PLAN APPROVED BY_____AND COMPLETE_____

ID#1_____

ID#2_____

FILM DATE_____

3M QA _____

TRINITY MEDICAL CENTER EAST 380 SUMMIT AVENUE STEUBENVILLE, OHIO 43952 NURSING DEPARTMENT GUIDELINES	Date of Origin All dates of revision must be listed Revised:	Page Section

RADIOACTIVE ISOTOPE BRACHYTHERAPY
THE USE OF THE INTEGRATING DOSIMETER

As part of the Radiation Protection Procedures established for the Nursing Personnel caring for a Radiation Therapy Patient undergoing radioactive isotope administration, an integrating dosimeter must be worn. The dosimeter is to be worn while in the room. At other times it is placed at the room's entrance. The posted log (Form D) is to include the time spent in the room as well as the exposure received while in the room.

SUPPLEMENTARY INFORMATION:

To use the integrating dosimeter:

1. Turn switch to ON
2. Push and hold black button
3. Record numerical reading upon entry into room
4. Record numerical reading upon exit from room
5. Subtract initial reading (#3) from final reading (#4) and record difference.
6. Turn switch OFF
7. Leave at entry to brachytherapy room

Whole Body Radiation Monitor Log Sheet
For Nursing Personnel

TRINITY
MEDICAL CENTER EAST
380 SUMMIT AVENUE
STEUBENVILLE, OHIO 43952

DATE: ____________________

PATIENT'S NAME: ____________________

ROOM: ____________________

Prior to entering the brachytherapy room, read "Nursing Guidelines for Patients Receiving Radioactive Isotope Brachytherapy" and document by signing under procedures read column.

Prior to entering the brachytherapy room, all nursing personnel must be wearing the film dosimeter which is issued every month. In addition, each person entering must monitor their radiation exposure by utilizing the integrating dosimeter which is made available to you.

Prior to entering the patient room, record your name, date and time, the numerical value from the integrating dosimeter in the initial reading column below. Upon leaving the room, record the numerical value from the integrating dosimeter in the final reading column and the time out. Then calculate and record your exposure.

DATE	NAME	TIME IN	TIME OUT	FINAL READING	INITIAL READING	EXPOSURE (FINAL-INITIAL)	PROCEDURES READ

TRINITY
MEDICAL CENTER EAST
380 SUMMIT AVENUE
STEUBENVILLE, OHIO 43952

PATIENT_____

RADIATION THERAPY INSERVICE EDUCATION

A BRACHYTHERAPY RADIATION SAFETY INSERVICE WAS HELD. THE FOLLOWING OUTLINE WAS UTILIZED AS A GUIDE FOR THE DISCUSSION. IT IS UNDERSTOOD THAT THE TRANSFERENCE OF THIS INFORMATION SHALL BE COMPLETED DURING THE NURSING SHIFT CHANGE REPORT.

1. SIMULATED APPLICATOR DEMONSTRATION
2. NURSING CS-137 PROCEDURES
3. FORMS A THROUGH D
4. RADIATION SAFETY PRINCIPLES OF TIME, DISTANCE AND SHIELDING
5. UNITS OF RADIATION (REM, RAD, ROENTGEN, CURIE)
6. RADIATION WARNING SIGNS
7. TIME AND VISITATION RESTRICTIONS
8. EMERGENCY PROCEDURES AND CONTACTS
9. RESPONSIBILITY OF NURSING STAFF TO REPORT UNSAFE PRACTICES
10. TYPICAL EXPOSURES ASSOCIATED WITH A TYPICAL BRACHYTHERAPY
11. QUESTIONS AND ANSWERS

NAME	DATE
----------	----------
----------	----------
----------	----------
----------	----------

THE FOLLOWING IS A LIST OF EQUIPMENT WHICH WILL BE USED FOR RADIATION SAFETY IN THE BRACHYTHERAPY AT THE TRINITY MEDICAL CENTERS

1	VICTOREEN PANARAMIC SURVEY METER	
2	VIC 290 SURVEY METER WITH	OR SIMILAR
	491-30 PROBE	OR SIMILAR
	489-110C PROBE	OR SIMILAR
	489-35 PROBE	OR SIMILAR
3	PERSONAL DIGITAL DOSIMETER NUCLEAR ASSOCIATES 06-505 OR SIMILAR	
4	L BLOCK LEAD SHIELD	
5	RADIOISOTOPE STORAGE SAFES	
6	CARRIER CART	
7	ROLLING RADIATION SHIELDS	
8	6-12 INCH HANDLING FORCEPS	
9	PRIMALERT AREA MONITOR FOR STORAGE AREA	

* MOST OF THE ABOVE ITEMS WOULD BE OR ARE SIMILAR TO THOSE FOUND IN THE NUCLEAR ASSOCIATES RADIATION THERAPY CATALOG

Attachment 10.4

Rules for Safe Use of Radiopharmaceuticals

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

2. Wear disposable gloves at all times while handling radioactive materials.

3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with a low-level G-M detector or a scintillation detector.

4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

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

6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.

7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.

8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.

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

10. Never pipette by mouth.

11. Wipe test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

12. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multi-dose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.

14. Assay each photon-emitting patient dosage in the dose calibrator before administration. Do not use the dosage if it is more than 10 percent off from the prescribed dosage, except for prescribed dosages whose activity is less than 10 uCi. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administration.

15. Flood sources, syringes, waste, and other radioactive material should be kept in shielded containers if warranted by the exposure rate.

16. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, use of a cart or wheelchair to move flood sources, waste, and other radioactive material should be considered.

MAY 2 9 1997

Angelo G. Calbone
Executive Vice President and
Chief Operating Officer
Trinity Health System
Trinity West d/b/a
Trinity Medical Center West
4000 Johnson Road
Steubenville, OH 43952

Dear Mr. Calbone:

Enclosed is Amendment No. 19 to your NRC Material License No. 34-06578-02 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 also note that License Condition No. 15 excludes reference to changes made in your Quality Management Program (QMP). In effect, excluding the Quality Management Program from the license allows you the flexibility to make changes to it without obtaining prior NRC approval. When modifications are made to your QMP program, you are required to submit the modified program to this office within 30 days after the modification is made, as required by 10 CFR 35.32(e). It appears that your QMP addresses the requirements of 10 CFR 35.32; however, the adequacy of your QMP will be reviewed during your next NRC inspection.

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.

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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 mailing address listed on the license changes. (No fee is required if the location of byproduct material remains the same.)

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.

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 Statement of Policy and Procedure 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
Charles F. Gill
Nuclear Materials Licensing Branch

License No. 34-06578-02
Docket No. 030-02760

Enclosure: Amendment No. 19

DOCUMENT NAME: M:\03002760.CL7

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

April 10, 1997

William Hunter Vaughan, M.D.
Radiation Safety Officer
Trinity Health Systems
Trinity West d/b/a
Trinity Medical Center West
4000 Johnson Road
Steubenville, OH 43952

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 04/01/97)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

___ New License _X_ Amendment ___ Renewal
___ Termination ___ Auth User (Amendment not required)
___ Other_____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302500
License No. 34-06578-02