MATERIALS LICENSE

Amendment No. 28

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.

301726

Licensee	
1. Marshfield Clinic	In accordance with letter dated August 12, 1996
2. 1000 North Oak Avenue Marshfield, WI 54449	3. License Number 48-10966-03 is amended in its entirety to read as follows:
	4. Expiration Date December 31, 2001
	5. Docket or Reference No. 030-08688

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 with Atomic Numbers 3-83, inclusive	A. Any	A. 200 millicuries per radionuclide. Total possession not to exceed 2000 millicuries; except as listed below: Iodine-131 1000 millicuries
B. Hydrogen-3	B. Any	B. 200 millicuries
C. Molybdenum-99	C. Any	C. 20 curies
D. Technetium-99m	D. Any	D. 20 curies
E. Xenon-133	E. Gas in Saline	E. 2000 millicuries
F. Hydrogen-3	F. Foil sources	F. 150 millicuries
G. Cesium-137	G. Sealed sources (ORNL-RAMCO 5000 or 150-1000)	G. 720 curies
H. Cesium-137	H. Sealed Sources (Technical Operations Model 77032)	H. 150 millicuries

D/1

060016

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 48-10966-03
Docket or Reference Number: 030-08688
Amendment No. 28

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
I. Uranium (Depleted in Uranium-235)	I. Cadmium plated metal	I. 350 kilograms
J. Any byproduct material with atomic Nos. between 3-83, inclusive	J. Analytical samples	J. See Item 9.J. below
K. Gadolinium-153	K. Sealed sources (North American Scientific, Inc. Model 3601)	K. 4 sources, not to exceed 250 millicuries each

9. Authorized Use:

A. through E. Medical diagnosis, therapy, and research in humans. Research and development as defined in Section 30.4 of 10 CFR Part 30 including animal studies.

F. For use in Gas Chromatographs for sample analysis.

G. To be used in a Nordion Gammacell Elite irradiator for irradiation of blood and blood products (excluding flammable and explosive materials).

H. To be used in a Technical Operations Model 773 calibrator for instrument calibrations.

I. Shielding in a linear accelerator.

J. For possession incident to the performance of tests for leakage and/or contamination on customer sources and devices.

K. Two sources to be used in ADAC Laboratories Transmission Line Source Housing in VANTAGE devices for medical radiography in humans. Two sources in shipping containers for replacement of the sources.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-10966-03

Docket or Reference Number
030-08688

Amendment No. 28

CONDITIONS

10. Licensed material shall be used at licensee's facilities located at:

    A. 1000 N. Oak Avenue, Marshfield, Wisconsin and St. Joseph Hospital, 611 St. Joseph Avenue, Marshfield, Wisconsin.

    B. Licensed material listed in Subitem G. shall be used only at the Joint Venture Laboratory, St. Joseph's Hospital, 611 North St. Joseph Avenue, Marshfield, Wisconsin.

11. The Radiation Protection Officer for the activities authorized by this license is Douglas J. Walraven.

12. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Thomas Gallant, M.D., Chairperson. The licensee shall maintain records of individuals designated as users.

    B. Physicians designated to use licensed material in or on humans shall meet the training criteria established in Subpart J. of 10 CFR Part 35.

    C. Individuals designated to use licensed material for research and development (excluding human use) shall meet the training and experience requirements in 10 CFR Part 33, Section 33.15(b), (1) and (2).

13. The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 10 CFR Part 35 except sections 35.49(a) and (b), 35.100, 35.200, and 35.300.

14. Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 10 CFR 35.200 and 10 CFR 35.300, the licensee may use for medical use any byproduct material or reagent kit. The licensee shall possess and use byproduct material for medical use in accordance with the prescriptive and performance criteria in the other sections of 10 CFR 35. This does not relieve the licensee from complying with applicable Food and Drug Administration (FDA) and other Federal and State requirements.

15. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material, and shall further restrict the possession of unsealed licensed material to quantities less than 10* times the applicable limits in Appendix C of 10 CFR 20. as specified in 10 CFR 30.35(d).

MATERIALS LICENSE
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Amendment No. 28

16. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration, referred to in 10 CFR 32.210 or a certificate of registration issued by an Agreement State.

B. Notwithstanding Paragraph of this Condition sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made, a sealed source or detector cell received from another person shall not be put into the use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources need not be leak tested if:

(i) they contain only hydrogen-3; or

(ii) they contain only krypton-85; or

(iii) the physical half-life of the isotope is 30 days or less; or

(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 5 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

G. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

17. Pursuant to 10 CFR 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.

18. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding that specified by the manufacturer and approved by NRC.

B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

19. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), of 10 CFR Part 20, the licensee is hereby authorized to label detector cells, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.

20. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.

21. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

D. A record of each disposal permitted under this license condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

MATERIALS LICENSE
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22. Experimental animals, or the product from experimental animals, administered licensed materials shall not be used for human consumption.

23. This license does not authorize commercial distribution of licensed material.

24. 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."

25. The licensee shall maintain records of information important to safety and effective decommissioning at the Marshfield Clinic, 1000 North Oak Avenue, Marshfield, Wisconsin per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

26. The licensee shall conduct a physical inventory every three months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 10 CFR 35.400, and 10 CFR 35.500 and every six months for all other sources and/or devices. Records of inventories shall maintained for 5 years from the date of each inventory, and shall include the information required in 10 CFR 35.59(g).

27. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

28. The licensee shall ensure that all individuals who work with or in the vicinity of radioactive materials will be provided with the necessary instructions as described in application dated June 4, 1990 before assuming duties with radioactive materials and whenever there is a significant change in personnel duties, regulations, or the terms of the license.

29. The licensee shall ensure that the quorum of the Radiation Safety Committee consists of the chairman, radiation safety officer, a management representative and committee person(s) representing the department/area from whom the radioactive material request originated.

30. Individuals who handle radioactive material will be required as a minimum, to wear film badges, or thermoluminescent dosimeters.

31. The licensee shall follow procedures contained in Appendix N, "Model Procedure for Area Surveys" of Regulatory Guide 10.8, Revision 2, August 1987 for all areas where radioactive materials will be utilized and stored.

MATERIALS LICENSE
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32. 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. 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. Application dated June 4, 1990; and

B. Letters dated October 14, 1991 (excluding reference to compacting radioactive wastes in Item 18 "Waste Disposal"), June 1, 1992, June 2, 1992, September 2, 1992, November 23, 1994, February 9, 1995, May 12, 1995, June 15, 1995 (with attachments), August 12, 1996 (excluding reference to the Quality Management Program) and September 25, 1996 (excluding reference to the Quality Management Program).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date October 23, 1996

By Cassandra F. Joyner
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

R3

PROGRAM CODE: 02110
STATUS CODE: 0
FEE CATEGORY: 7B 3P 3E 2B
EXP. DATE: 20011231
FEE COMMENTS: CAL. & LT SERV.
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   APPLICANT/LICENSEE: MARSHFIELD CLINIC
   RECEIVED DATE: 960815
   DOCKET NO: 3008688
   CONTROL NO.: 301726
   LICENSE NO.: 48-10966-03
   ACTION TYPE: AMENDMENT

2. FEE ATTACHED
   AMOUNT: 470
   CHECK NO.: 481158

3. COMMENTS

SIGNED D. Hersey
DATE 8-16-96

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

1. FEE CATEGORY AND AMOUNT: 7B 3P 3E 2B

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

3. OTHER

SIGNED SC 8/23/96
DATE

1996 AUG 19 PM 4:07

Log Aug 10 III
Remitter
Check No. 481158
Amount $470
Fee Category 7B 3P 3E 2B
Type of Fee Amd
Date Check Rec'd 8/20/96
Date Completed 8/23/96
By: SC

AUG 26 1996

1000 North Oak Avenue
Marshfield, WI 54449-5777

Fax 715-387-5240

715-387-5511

MARSHFIELD CLINIC

August 12 1996

Unites States Nuclear Regulatory Commission
Region III, Materials Licensing Section
801 Warrenville Road
Lisle, IL 60532-4351

RE: LICENSE 48-10966-03

AMENDMENT REQUEST

We are requesting the following amendments to our license:

1. We have purchased a ADAC Vantage gamma camera system which is designed to provide nonuniform attenuation correction using a sealed gadolinium-153 line source. The source (Model MED 3601, Registration number CAS510S1218) is supplied by North American Scientific supplies. Nominal activity is 200 to 250 mCi per source, and two sources are used. Enclosed is a one page flyer from ADAC describing the source. We are requesting the addition of a line item to our license allowing possession of up to 800 mCi of Gadolinium-153. This limit should be sufficient to cover possession of expired sources during source exchanges.

2. The chairperson of our Radiation Safety Committee has retired from committee service. Dr. Thomas Gallant has been appointed to replace Dr. Russ as chairperson. His *curriculum vitae* is enclosed.

Also enclosed, please find a revised Quality Management Plan for our Radiation Oncology Department. We are providing this updated plan to you as required by 10 CFR 35.32(e).

A check in the amount of $470 for license amendment fees is enclosed. Thank you for your assistance with these matters. If you have questions, or need further information, please contact me at (715) 387-9349.

Sincerely,

Douglas J. Walraven
Radiation Safety Officer

PM; 8-13-96

301726

To: ADAC Vantage Customer

Subject: Gadolinium-153 Licensing Requirements

Date: August 25, 1995

You must amend your radioactive materials license to accommodate a total of 800 millicuries of Gd-153 before you can receive the Vantage.Nonuniform Attenuation Correction system into your department. (A limit of 800 millicuries is necessary when replacing the line sources.) In order to amend your radioactive materials license, please refer to your specific license information or contact your Radiation Safety Officer. All amendment procedures must follow NRC or agreement state agency policies.

North American Scientific supplies the Gd-153 for ADAC Laboratories (Model # MED 3601 - Registration # CA5105121S). Mike Cutrer, the North American Scientific representative, can be contacted at (818) 503-9201 if you have additional questions regarding the line sources or amendment procedures.

The Vantage system design is consistent with the ALARA (As Low As Reasonably Achievable) principles of radiation exposure. For a 40 minute acquisition (a typical acquisition time is less than 20 minutes), the patient exposure at the maximum source strength of 200 mCi with two sources is less than 5 mR (2 millirems - confirmed by TLD and survey meter measurements).

When the line source is in use, radiation emits from a 1 mm collimated aperture on the line source housing. When the line source is not in use, the lead housing completely shields the line source. This housing reduces patient and operator radiation exposure to a safe level (the exposure reading at the housing surface is less than 0.2 mR/hr). The line source housings can be left on the gantry at all times or removed and placed in a storage area, if desired.

The line sources are sealed sources that must be leak tested every six months. The leak test procedure is described in the operator's manual.

When it is time to replace the line sources, please contact your ADAC field service engineer who will arrange for the source disposal with North American Scientific.

Vantage Gd-153 line source specifications

- Quantity: 2 Line sources per system
- Activity: 200-250 mCi line source x 2 for a total of up to 500 mCi/system
- Active length: 508 ±3 mm
- Overall length: 521.7 ±3 mm
- Active diameter: 1.5 ±0.1 mm
- Overall diameter: 3.05 ±0.1 mm
- Uniformity: ±5% over entire surface area
- Contaminants: Eu-152, Eu-153, Eu-154 < 0.05% of total content

Quality Management Program
Brachytherapy with Sealed Sources
Radiation Oncology

Saint Joseph's Hospital - Marshfield Clinic

Marshfield, Wisconsin

April 1996

QUALITY MANAGEMENT PROGRAM
BRACHYTHERAPY WITH SEALED SOURCES
RADIATION ONCOLOGY DEPARTMENT

1. Policies and Procedures for Teletherapy:

1.1 Cobalt-60 Teletherapy devices are not used at our facility.

2. Policies and Procedures for Brachytherapy:

2.1 High-dose-rate remote afterloading devices are not used at our facility.

2.2 All other Brachytherapy Applications:

2.2.1 An authorized user dates and signs a written directive prior to the administration of any brachytherapy dose.

2.2.2 Before administering a brachytherapy dose, the identity of the patient is verified as the individual named in the written directive by more than one method. The procedure used to identify the patient is 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: birthdate, address, social security number, signature, the name on the patient's ID bracelet or hospital card, the name on the patient's medical insurance card or the photograph of the patient's face.

2.2.3 Prior to implantation, the brachytherapy written directive must include the radionuclide, number of sources, and source strengths.

2.2.4 All workers are asked to seek guidance if they do not understand the written directive.

2.2.5 A qualified person under the supervision of the authorized user verifies that the radionuclides, number of sources, source strengths and loading sequence of the sources to be used are in agreement with the written directive before implanting the radioactive sealed sources. Verification methods include using color-coded sealed sources and using clearly marked storage locations.

2.2.6 For temporary brachytherapy implants, radiographs of brachytherapy sources of nonradioactive "dummy" sources are used as the basis for verifying the position of the sources and calculating the exposure time or total dose. Whenever possible, nonradioactive "dummy" sources are used before inserting the radioactive sources. Radiographs may not be necessary provided the position of the sources is known prior to inserting the radioactive sources and calculating the exposure time or total dose.

2.2.7 For permanent brachytherapy implants, radiographs of brachytherapy sources are used as the basis for verifying the position of the sources and calculating the total dose. Radiographs may not be necessary for some procedures when fixed geometry applicators are used to establish the location of the sources.

2.2.8 After insertion of the temporary implant brachytherapy sources, the authorized user records the actual load in sequence of the radioactive sources implanted and signs or initials the patient's chart or appropriate record.

2.2.9 After insertion of the permanent implant brachytherapy sources, the authorized user records the actual number of radioactive sources implanted and signs or initials the patient's chart or appropriate record.

2.2.10 The dose calculations are checked before the total prescribed brachytherapy dose has been administered. A qualified person under the supervision of the authorized user who, whenever possible, did not make the original calculations, checks the dose calculations.

Manual dose calculations are checked for:

1) Arithmetic errors
2) Appropriate transfer of date from the written directive, plan of treatment, tables and graphs
3) Appropriate use of nomograms when applicable and
4) Appropriate use of all pertinent data in the calculations

Computer-generated dose calculations are checked by examining the computer printout to verify that the correct data for the patient is used in the calculations.

2.2.11 The authorized user dates and signs a written directive in the patient chart. Prior to treatment completion, the radionuclide, treatment site, and total source strength and exposure time or total dose will be made a part of the written directive.

2.2.12 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.

2.2.13 A qualified person performs acceptance testing on each treatment planning or dose calculations computer that could be used for brachytherapy dose calculations. Acceptance testing is performed before the first time use of the treatment planning or dose calculating computer program for brachytherapy dose calculations.

3. Gamma Stereotactic radiosurgery is not being used at our facility.

4. Oral Directives and Revisions to Written Directives:

4.1 If because of the patient's medical condition a delay in order to provide a written revision to an existing directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user prior to the administration of the brachytherapy dose.

5. Review of Written Directives:

Review of all brachytherapy procedures will be conducted by the authorized users and physicist. The review will include a representative sample of patient administrations, all recordable events and all misadministrations. For each patient's case, a comparison is made between what was administered versus what was prescribed in the written directive. The persons conducting the review will not review their own cases. An annual review will be given to the Radiation Safety committee to ensure that the Quality Management Program is effective.

For each patient case reviewed, we will determine whether the administered dose was in accordance with the written directive or plan of treatment, as applicable. The following will be checked:

1) For brachytherapy prior to implantation: the radionuclide, number of sources and source strengths; after implantation but prior to completion of the procedure; the radionuclide, treatment site and total source strength and exposure time.

2) For each patient case reviewed, we will identify deviations from the written directive, the cause of each deviation, and the actions required to prevent recurrence. The actions may include new or revised procedures, additional training or increased supervisory review of work.

3) The Radiation Safety Committee will reevaluate the Quality Management Program's policies and procedures after each annual review to determine whether the program is effective or to identify actions required to make the program more effective.

   Program review results will be documented and will be available for the Nuclear Regulatory Commission's inspections. The program review will be distributed to all members of the Radiation Safety Committee and appropriate management. Corrective actions for deficient conditions will be implemented within a reasonable time after identification of the deficiency.

4) Records of brachytherapy will be kept in auditable form for at least 3 years.

Procedure Brachytherapy - Cesium Gyn implants

1. Informed consent is obtained.

2. Appliance is inserted.

3. After the patient is released from the recovery room, dummy sources are loaded in the applicator and orthogonal films are taken. Ideally these films should have the central axis at the top of the lowest tandem source and be taken at the same magnification.

4. The initial directive is completed on the "LOW DOSE RATE BRACHYTHERAPY DIRECTIVE AND TREATMENT RECORD" form. This directive shall describe the type of brachtherapy, the radionuclide, the prescription point, the anticipated dose and doserate, the approximate duration of implantation and a diagram of the source loading including source strength for each source. The time and date of the directive are written. The written directive and the associated loading diagram are both signed by the authorized user. The individual loading the sources into the carriers shall require this signature and date.

5. A dose distribution and any necessary reference point doses are calculated using the positional information of the orthogonal sources and the loading information from the loading diagram. The authorized user and dosimetrist (or physicist) will sign and date the dose distributions and reference point calculations. If the dose rate, dose or time interval are altered by 10% from the original directive, the written directive shall be amended, dated and signed by the authorized user.

6. The source carriers are loaded with an additional observer present. The loading diagram will be copied to the "RADIATION SOURCE CERTIFICATE" and used by the loader. The loader will call out the sequence of sources as they are loaded for confirmation by the observer who will compare the indicated sources with the original loading diagram. The loader and the authorized user will sign and date the "RADIATION SOURCE CERTIFICATE" which is filed in the Radioactive Safe Log. The sources are transported to the patients room in a lead shielded transporter. Sources shall not be released from the source storage area until the written directive is complete.

7. Ideally the patients will be housed in rooms 815 or 816. Implant patients may share a room with another implant patient, but not with an I131 patient. Limiting criteria for alternate room selection and for visitation shall be a maximum permissible instantaneous dose rate to the visitor or non-implant patient of 2

mR/hr and a maximum annual dose of 100 mR. The 100 mR annual dose objective is conservatively met by limiting the total exposure from a single implant to 20 mR.

8. The identity of the patient is verified by at least two methods which are recorded on the "LOW DOSE RATE BRACHYTHERAPY DIRECTIVE AND TREATMENT RECORD" form.

9. The source carriers are inserted in the applicators. A radiation exposure survey of the treatment room and adjacent rooms is performed. Records of this survey detailing the date, survey instrument, room number, patient name, radiation exposure rates are maintained in the PATIENT SURVEY log.

9a. The authorized user will complete the "RADIATION PRECAUTIONS" form or write specific radiation precautions for insertion in the medical record as a physician order. This form describes the radiation source, form and quantity, the extra precautions required, the duration of the planned implant, the time of implant and the planned explant time and date.

9b. The authorized user will complete the "INTRODUCTION OF RADIATION SOURCES" form for insertion in the medical record as patient history. This form describes the radiation source, form, quantity, location and applicator, the duration of the planned implant, the time of implant, the planned explant time and date, radiation exposure rates for nursing staff and any special radiation precautions.

9c. The authorized user will enter the implant time and date and planned explant time and date on the "LOW DOSE RATE BRACHYTHERAPY DIRECTIVE AND TREATMENT RECORD" form.

10. A verification of the treatment directive and plan will be performed. This verification shall be performed by someone other than the authorized user and shall include;

10a. the correspondence between the source loading diagram and the computer treatment plan,

10b. the accurate use of the derived dose rate information to determine the desired implant duration and

10c. the accuracy of the calculation of explant time.

The individual verifying this information shall initial the source loading diagram, the prescription or amendments and the log of application.

11. It will be the responsibility of the authorized user to inform the physics/dosimetry staff of any amendments, additions or alterations of the "LOW DOSE RATE BRACHYTHERAPY DIRECTIVE AND TREATMENT RECORD" form that would impact on the verifications of section 10.

12. The radiation sources are removed from the applicator. A radiation survey of the patient after explant shall be performed and logged in the PATIENT SURVEY log. The sources are returned to the storage area and logged in to the radiation safe.
A verification that all sources are accounted for is performed. The authorized user will sign and date the return element of the "RADIATION SOURCE CERTIFICATE" which is filed in the radiation safe log.

13. Within two working days of the completion of the implant, the log of dose component of the "LOW DOSE RATE BRACHYTHERAPY DIRECTIVE AND TREATMENT RECORD" will be verified by the physics staff.

14. In the event of a misadministration, the NRC Operations Center will be notified by phone within 24 hours at 301-951-0550. The Region III office number is 708-829-9500.

CURRICULUM VITAE

NAME: Thomas E. Gallant, M.D.

OFFICE ADDRESS: Department of Radiology, 2B
Marshfield Clinic
1000 North Oak Avenue
Marshfield, WI 54449

OFFICE TELEPHONE: (715) 389-3474

BIRTHDATE: December 3, 1949

SOCIAL SECURITY NUMBER: 004-48-8559

BIRTHPLACE: Philadelphia, Pennsylvania

EDUCATION: Colby College, B.A., 1971
Waterville, Maine

Baylor College of Medicine, M.D., May 24, 1974
Houston, Texas

POSTGRADUATE TRAINING:

Internship: University Hospital of Vermont, Burlington, VT
Internal Medicine, 1974-1975

Residency: University Hospital of Vermont, Burlington, VT
Diagnostic Radiology, 1975-1978
Rotations at :
Armed Forces Institute of Pathology
Children's Hospital Medical Center, Boston, MA

Fellowship: Massachusetts General Hospital, Boston, MA
Cardiac Radiology, 1978-1979
Vascular Radiology, 1979-1980

BOARD CERTIFICATIONS:

National Board of Medical Examiners #142863	07-01-75
American Board of Radiology	07-01-78
Certificate of Added Qualification in Interventional Radiology,	02-26-95
Fellow, American College of Cardiology	03-01-91
ACLS (American Heart Assn.) #2222626	09-09-94

LICENSES:

Vermont	5506	06-26-75 *
New York	130296	03-18-77 *
Massachusetts	45866	06-06-80 *
Indiana	30008	07-14-80 *
Ohio	47328	04-20-82 *
Kentucky	22011	06-10-82 *
Wisconsin	27629	07-01-86
DEA	AG1613555	07-08-86

* Inactive

PROFESSIONAL APPOINTMENTS:

1980-1982 Cardiovascular Radiologist
St. Vincent Hospital and Health Care Center,
Indianapolis, Indiana

1980-1982 Faculty Member
Tutorials in Percutaneous Angioplasty
Alexandria Hospital
Alexandria, Virginia

1982-1985 Assistant Professor of Radiology
University of Cincinnati College of Medicine

1985-1986 Associate Professor of Radiology
University of Cincinnati College of Medicine

1982-1986 Co-Director of Cardiac Catheterization Laboratory
Co-Director of Vascular Radiology
University Hospital, Cincinnati, Ohio

1986-Present Cardiovascular Radiologist
The Marshfield Clinic
Marshfield, Wisconsin

1990-Present Co-Director, Cardiovascular Laboratories
St. Joseph's Hospital
Marshfield, Wisconsin

1995-Present Assistant Chair, Radiology Department
St. Joseph's Hospital
Marshfield, Wisconsin

HOSPITAL STAFF:

1980-1982 Staff Radiologist
St. Vincent's Hospital and Health Care Center
2001 West 86th Street
Indianapolis, Indiana 46240

1982-1986 Staff Radiologist
University Hospital
234 Goodman Street
Cincinnati, Ohio 45267

Courtesy Staff
William Booth Hospital
7380 Turfway Road
Florence, Kentucky 41042

Courtesy Staff
Veterans Administration Hospital
3200 Vine Street
Cincinnati, Ohio 45220

Courtesy Staff
The Jewish Hospital
3200 Burnett Avenue
Cincinnati, Ohio 45229

1986-Present Staff Radiologist
Co-Director, Cardiac Catheterization Laboratories
St. Joseph's Hospital
411 St. Joseph's Avenue
Marshfield, Wisconsin 54449

UNIVERSITY OF CINCINNATI COMMITTEES:

The Medical Center Committee for Human Research
The Cardiology Chair Search Committee
The Air Ambulance Committee
Medical Student Advisor

MARSHFIELD CLINIC COMMITTEES:

1988-1993 Clinic Computer Committee
1989-1991 Chair, Standards Subcommittee
1991-1993 Medical Transcription Taskforce

1987-1990 Emergency Room / Disaster Preparedness Committee

1988-Present Radiation Safety Committee
1995 Ad-hoc Committee, Review of Brachytherapy Practice

1989-Present Cardiac Cath Lab Steering Committee

1991-1992 Executive Committee
Ad-hoc Committee, Review of Director of Research and Education

1989-Present Quality Improvement Committee
1990 IV Standards Taskforce

1995-Present Medical Records Committee

PROFESSIONAL SOCIETY MEMBERSHIP

Alpha Omega Alpha
American College of Radiology
Cardiovascular Radiology Council
American Heart Association
Radiological Society of North America
The Society for Cardiac Angiography
Society of Thoracic Radiology
Society of Cardiovascular and Interventional Radiology
Fellow, American College of Cardiology
American Medical Association
Wood County Medical Society
Wisconsin State Medical Society

JOURNAL EDITORIAL BOARDS:

Chest 1980
Radiology 1985-1992

Abstract Reviewer of Circulation

Ameri an Heart Association, Scientific Session, 1986
Reviewer of Submitted Abstracts

HONORS: COLBY COLLEGE

Phi Beta Kappa
Magna Cum Laude
Honors in Chemistry
Senior Scholar in Chemistry

BAYLOR COLLEGE OF MEDICINE

Cum Laude
Alpha Omega Alpha

POSTGRADUATE

Honorable Mention,
Cardiovascular Radiology Exhibits
69th Scientific Sessions
Radiological Society of North America
Chicago, Illinois
November 14-18, 1983

PATENTS:

Radiographic Film Inclinometer
Shinozaki T, Gallant TE, Deane RSD, Cunningham D:
U.S. Patent 4,267,642
May 19, 1981

PUBLICATIONS:

1. Maier, GE, Kusiak JW, Higgins, GL, Gallant TE: Pressor Activity in Bovine Kidney Homogenate: Enhancement by Cadmium and Zinc Ions. Arch Environ Health 1974; 29: 110-114.

2. Gallant TE, Malinak LR, Gump DW, Mead PB: Hemophilus Para-Influenza Peritonitis Associated with an Intrauterine Contraceptive Device. Am J Obstet Gynecol 1977; 129: 702-703.

3. Gallant TE, Hunziker RJ, Gibson TC: Primary Chylopericardium: the Role of Lymphangiography. AJR 1977; 129: 1043-1045.

4. Gallant TE, Dietrich PA, Shinozaki T, Deane RSD: Simple Device to Measure Patient Position on Portable Chest Radiographs. AJR 1970; 131: 169-170.

5. Gallant TE, Athanasoulis CA: Regional Infusion of Thrombolytic Enzymes. In Athanasoulis CA, Greene RE, Pfister RD, Roberson GH, (eds.): Interventional Radiology, Boston, W.B. Saunders, 1981, pp. 374-378.

6. Gallant TE, Greenfield AJ, Athanasoulis CA: Angiography in Diagnosis and Control of Bleeding. In Jirsch DW (ed.): Frontiers in General Surgery, Lancaster, England, MTP Press Ltd., 1982, pp. 85-122.

7. Pinkerton CA, Slack JD, Schwarten DE, Gallant TE: Percutaneous Transluminal Coronary Angioplasty: Successful Application in a Community Hospital. The Community Hospital. The Journal of the Indiana State Medical Association 1982; 75: 258-261.

8. Clark RA, Gallant TE, Alexander ES: Angiographic Management of Traumatic Arteriovenous Fistulas: Clinical Results. Radiology 1983; 147: 9-13.

9. Schwarten DE, Gallant TE: Transluminal Renal Angioplasty, In Castaneda W (ed.): Percutaneous Transluminal Angioplasty, New York, Thieme Stratton, 1983, pp. 62-70.

10. Clark RA, Gallant TE: Acute Mesenteric Ischemia: Angiographic Spectrum. AJR 1984; 142: 555-562.

11. Iannaccone ST, Gallant TE, Colon UF: The Medical Center Committee of Human Research: Investigator's Handbook. University of Cincinnati College of Medicine, 1985, Revised June 1986.

12. Gallant TE, Clark RA: Principles of Arteriography for Lower Extremity Ischemia, In Kempczinski RF (ed.): The Ischemic Leg, Chicago, Year Book Medical Publishers, Inc., 1985, pp. 145-159.

13. Schneider, JF, Gallant TE: Late Total Occlusion Following Coronary Angioplasty: Incidence and Significance. Circulation 1986; 74 (Supp II): 489.

14. Hermoni Y, Engel PJ, Gallant TE: Sequelae of Injury to the Heart Caused by Multiple Needles. J Am Coll Cardio 1986; 8: 1226-1231.

15. Clark RA, Gallant TE: Bile Duct Strictures Associated with Hepatic Arterial Infusion Chemotherapy. Gastroint Radio 1987; 12: 148-151.

16. Schneider JF, Wilson M, Gallant TE: Percutaneous Balloon Aortic Valvuloplasty for Aortic Stenosis in Elderly Patients at High Risk for Surgery. Ann Intern Med 1987; 106: 696-699.

17. Sutton TM, Gallant TE, Griese G: Balloon Aortic Valvuloplasty for Treatment of Severe Congenital Aortic Stenosis in Children: Report of Two Cases. Wisc Med J 1987; 86: 13-15.

SCIENTIFIC PRESENTATIONS AND EXHIBITS:

1. Waltman AC, Athanasoulis CA, Greenfield AJ, Novelline RA, Gallant TE, Jensen SR: Detachable Mini-Balloons as Embolic Materials: Limited Applications and Clinical Usefulness. Presented at the Radiological Society of North America, Scientific Sessions, Dallas, 1980.

2. Gallant TE: Intrapulmonary Urokinase for Massive Pulmonary Emboli: Preliminary Data. Presented at Angiography Refresher Course, Massachusetts General Hospital, Boston, May 3-6, 1982.

3. Gallant TE: Coronary and Renal Percutaneous Angioplasty. Presented at Angiography Refresher Course, Massachusetts General Hospital, Boston, May 3-6, 1982.

4. Gallant TE: Ethanol as an Embolic Agent. Presented at Angiography Refresher Course, Massachusetts General Hospital, Boston, May 3-6, 1982.

5. Gallant TE: Workshop on Angioplasty. Presented at Angiography Refresher Course, Massachusetts General Hospital, Boston, May 3-6, 1982.

6. Linnemeier TJ, Gallant TE: Intrapulmonic Urokinase for Massive Pulmonary Embolus with Hemodynamic Compromise. Presented at Midwest Meeting, American College of Physicians, October 29, 1982.

7. Gallant TE: Particulate Therapeutic Embolization. Presented at Uroradiology Course, Division of Urology, University of Cincinnati Medical Center, January 14, 1983.

8. Gallant, TE: Two Dimensional Echocardiography in Acute Myocardial Infarction. Presented at Annual Refresher Course for Practitioners, Holzer Medical Center, Gallipolis, OH, April 23, 1983.

9. Gallant TE: Percutaneous Coronary Angioplasty. Presented at Annual Refresher Course for Practitioners, Holzer Medical Center, Gallipolis, OH, April 23, 1983.

10. Gallant, TE: Massive Pulmonary Embolism: Treatment Options. Presented at Annual Refresher Course for Practitioners, Holzer Medical Center, Gallipolis, OH, April 23, 1983.

11. Gallant TE: Hemodynamic Response to Centrally Administered Fibrinolytic Agents for Massive Pulmonary Emboli. Presented at Ohio State Radiological Society, May 20-22, 1983.

12. Gallant TE: Percutaneous Coronary Angioplasty. Presented at Ohio State Radiological Society, May 20-22, 1983.

13. Gallant TE: Renal Angiography. Presented at the 25th Annual Refresher Course in Diagnostic Radiology, University of Cincinnati Department of Radiology, Ft. Mitchell, KY, May 26, 1983.

14. Gallant TE: Cardiopulmonary Angiography. Presented as the 25th Annual Refresher Course in Diagnostic Radiology, University of Cincinnati Department of Radiology, Ft. Mitchell, KY, May 26, 1983.

15. Yoshizumi T, Thomas SR, Clark RA, Gallant TE, Kereiakes JG: Clinical Evaluations of Image Enhancement Algorithms as Applied on Digital Radiography Images. Presented at the American Association of Physicists in Medicine, New York, July 31-August 4, 1983.

16. Gallant TE, Lubbers DJ, Kereiakes JG: Compound Angulation in Coronary Arteriography: Anatomy and Radiation Considerations. Exhibit at 69th Scientific Assembly and Annual Meeting of the Radiological Society of North America (Honorable Mention), Chicago, November 14-18, 1983.

17. Gallant TE: Renal Arteriography. Presented at the Annual Refresher Course in Urology, Cincinnati, OH, January 12, 1984.

18. Gallant TE: The Role of Fibrinolysis in Massive Pulmonary Emboli. Presented at the University of Pittsburgh School of Medicine, Pittsburgh, PA, January 20, 1984.

19. Schneider JF, Gallant TE: Coronary Angioplasty: The U.C. Experience. Medical

Grand Rounds, University of Cincinnati Medical Center, Cincinnati, OH, April 11, 1984.

20. Gallant TE: Coronary Angioplasty: Perspectives in Medicine Lecture Series, University of Vermont College of Medicine, Burlington, VT, May 11, 1984.

21. Gallant TE: Coronary Fibrinolysis and Angioplasty: An Update. Presented at Ohio State Medical Association Annual Meeting, Cincinnati, OH, May 21, 1984.

22. Gallant TE: Renal Angiography. Presented at the 26th Annual Refresher Course in Diagnostic Radiology, University of Cincinnati Department of Radiology, Cincinnati, OH, May 24, 1984.

23. Gallant TE: Cardiac Angiography. Presented at the 26th Annual Refresher Course in Diagnostic Radiology, University of Cincinnati Department of Radiology, Cincinnati, OH, May 25, 1984.

24. Gallant TE, Staubach LB, Clark RA: Renal Vein-Inferior Vena Caval Renin Ratio: A Sensitive and Specific Marker for Renal Hypertension. Presented at the 70th Scientific Assembly and Annual Meeting of the Radiological Society of North America, Washington, DC, November 25, 1984.

25. Gallant TE, Shipley RT, Engel PJ, Clark RA: CT Assessment of Anomalous Coronary Arteries. Presented at the 2nd Annual Scientific Session, Society of Thoracic Radiology, Bal Harbour, FL, March 24, 1985.

26. Anderson ML, Hanslits ML, Clark RA, Shipley RT, Gallant TE: CT Diagnosis of Pelvic and Lower Extremity Venous Thrombosis. Presented at the ARRS 85th Annual Meeting, Boston, April 21-26, 1985.

27. Gallant TE: Renal Angiography. Presented at the 27th Annual Refresher Course in Diagnostic Radiology, University of Cincinnati Department of Radiology, Ft. Mitchell, KY, May 30, 1985.

28. Gallant TE: Cardiopulmonary Angiography. Presented at the 27th Annual Refresher Course in Diagnostic Radiology, University of Cincinnati Department of Radiology, Ft. Mitchell, KY, May 31, 1985.

29. Clark RA, Gallant TE: Refresher Course in Vascular and Interventional Radiology. Presented at the ARRS 86th Annual Meeting, Washington, DC, April 14, 1986.

30. Gallant TE: Renal Angiography. Presented at the 28th Annual Refresher Course in Diagnostic Radiology, University of Cincinnati Department of Radiology, Ft. Mitchell, KY, May 29, 1986.

31. Gallant TE: Cardiopulmonary Angiography. Presented at the 28th Annual Refresher Course in Diagnostic Radiology, University of Cincinnati Department of Radiology, Ft. Mitchell, KY, May 30, 1986.

32. Schneider JF, Gallant TE: Late Total Occlusion Following Coronary Angioplasty: Incidence and Significance. Presented at 59th Scientific Sessions, American Heart Association, Dallas, TX, November 18, 1986.

33. Gallant TE: Percutaneous Aortic Valvuloplasty. Marshfield Clinic-Wide CME Program, Marshfield, WI, March 5, 1987.

34. Schneider JF, Wilson M, Gallant TE: Percutaneous Balloon Aortic Valvuloplasty in Elderly Patients with Severe Calcific Aortic Stenosis Who are Poor Candidates for Valve Replacement Surgery. Poster Presentation at American College of Cardiology 36th Scientific Sessions, New Orleans, LA, March 10 1987.

35. Gallant TE: Pulmonary Emboli: Diagnosis and Therapy with Special Emphasis on Treatment of Massive Emboli. Sheboygan Clinic Educational Exchange Program, Sheboygan, WI, May 19, 1987.

36. Gallant TE: Clinical Use of Nonionic Contrast Agents, Physicians' Forum Lecture Series, Columbus, IN, August 5, 1987.

37. Gallant TE: Nonionic Contrast Agents: Review and Recommendations. Presented at Wisconsin Society of Radiological Technologists, Region 4, Marshfield, WI, September 9, 1987.

38. Gallant TE: Nonionic Contrast Agents: Use and Indications. Presented as Rusk County Medical Society Meeting, Rice Lake, WI, April 11, 1989.

39. Therapy Options For Pulmonary Emboli: Fibrinolysis For Massive Emboli. Presented at Gunderson Clinic-Marshfield Clinic Exchange Program, September 20, 1989.

40. Gallant TE: Clinical Application of CT: Current State of The Art. Presented at American College of Physicians, XIII Regional Meeting of Central America and Panama, Panama City, Panama, January 25-26, 1991.

41. Gallant TE: MRI: Development and Current Applications. Presented at American College of Physicians, XIII Regional Meeting of Central America and Panama, Panama City, Panama, January 25-26, 1991.

42. Gallant TE: Peripheral and Renal Angioplasty: State of the Art. Presented at American College of Physicians, XIII Regional Meeting of Central America and Panama, Panama City, Panama, January 25-26, 1991.

43. Gallant TE: Coronary Angioplasty: Current State of the Art. Presented at American College of Physicians, XIII Regional Meeting of Central America and Panama, Panama City, Panama, January 25-26, 1991.

44. Gallant TE: Inferior Vena Caval Filters: Review of Marshfield Experience. Wisconsin Society of Radiological Technologists, Region 4, Stevens Point, WI, September 20, 1991.

45. Otters, AA, Gallant, TE: An Unusual Cause of Homonomous Hemianopsia. Wisconsin Society of Internal Medicine, Waukesha, WI, September 18, 1992.

46. Gallant, TE: Regional Fibrinolysis. Wisconsin Society of Radiological Technologists, Region 4, Stevens Point, WI, May 1995.

WORKS IN PROGRESS:

1. Gallant TE: Angiographic Embolization to Control Massive Post Partum Hemorrhage.

2. Gallant TE, Davis JS, Carlson RD: Clinical Experience With Currently Available IVC Filters: Comparison of Bird's Nest, Titanium Greenfield, and Simon Nitinol Devices.

3. Gallant TE, Swanson MK: Embolization of Duodenal Varices to Control Recurrent Massive GI Hemorrhage.

4. Gallant TE, Choucair AK, Karanjia PN: Angiographic Diagnosis of Coccidiomycotic Arteritis.

5. Gallant TE, Davis JS, Carlson RD: The Micropuncture Sheath: A Nontraumatic One-Step Vascular Access System.

6. Gallant TE, Vidaillet HJ Jr: MRI Characterization of a Right Ventricular Fibroma in a Patient with Gorlin's Syndrome.

7. Gallant TE, Vidaillet HJ Jr: Cardiac MRI in Patients with Active Lyme Disease and Electrocardiagraphic Abnormalities.

8. Gallant TE, Vidaillet HJ Jr, Zavaro SH, Grierson DS: Critical Mitral Stenosis and a Large Pulmonary Arteriovenous Fistula: Clinical and Hemodynamic Improvement After Closure of the Fistula with Embolic Coils.

9. Gallant TE, Balian A: MRI Diagnosis of Cardiac Sling

10. Gallant TE: Lymphangiographic Demonstration of Chyluria, Report of a Case.

GRANT SUPPORT:

1. Gallant TE, Clark RA: Digital Subtraction Angiography of Abdominal Aorta and Peripheral Vessels by Intravenous Injection: Randomized Double-Blind Comparison of Iohexol and Renograffin-76 in Adult Patients. Sterling Winthrop Research Institute, 1984.

2. Gallant TE, Engel PJ, Clark: Digital Cardioangiography. Medical Center Clinical Development Grant, 1984.

RESEARCH PROTOCOLS:

1. HRC #84-2-10-7. Gallant TE, Clark RA: Digital Subtraction Angiography of Abdominal Aorta and Peripheral Vessels by Intravenous Injection: Randomized Double-Blind Comparison of Iohexol and Renograffin-76 in Adult Patients. Sterling Winthrop Research Institute, 1984. Completed January 1, 1986.

2. Maxon HR, Gallant TE, Clark RA: A Comparison of Radionuclide and Conventional Arthrography in Evaluation of Painful Cemented and Non-Cemented Hip Prostheses.

3. HRC #84-7. Clark RA, Thomas SR, Lukin RR, ...Gallant TE,et al: Development and Evaluation of Magnetic Resonance Technology for Medical Analysis of Anatomic and Biochemical Abnormalities.

4. HRC #86-2-241EE. Gallant TE, Lubbers DJ, Clark RA: Double Blind Randomized Comparison of Iohexol, Iopamidol, and Ioxaglate for Peripheral Angiography: A Comparison of Patient Tolerance.

5. HRC #86-4. Schneider JF, Gallant TE: Balloon Valvuloplasty for Senile Calcific Stenosis in Patients Who are Poor Candidates for Surgical Valve Replacement. IND Froposal to the FDA From Mansfield Scientific Company, July 1986.

6. MMF IRB #0337-01086. Reinhart, RA, Grierson DS, Gallant TE: Cook Thin-Walled Balloon Catheters for Aortic Valvuloplasty.

7. MMF. Karanjia P, Principal Marshfield Investigator: Asymptomatic Carotid Atherosclerosis Study.

8. MMF. Karanjia P, Principal Marshfield Investigator: North American Symptomatic Carotid Endarterectomy Trial.

9. MMF. Goldhaber SZ: Friedenberg WF, Pricipal Marshfield Investigator: Pulmonary Emboli Study 4: Two Hour Infusion of TPA vs. Urokinase.

10. MMF. Goldhaber SZ: Friedenberg WF, Principal Marshfield Investigator: Pulmonary Emboli Study 5A: Bolus TPA vs 2-Hr TPA Infusion.

11. MMF. Vidaillet HJ Jr: Lyme Disease: Cardiac Manifestations in an Endemic Area.

OCT 23 1996

Douglas J. Walraven
Radiation Safety Officer
Marshfield Clinic
1000 North Oak Avenue
Marshfield, WI 54449

Dear Mr. Walraven:

Enclosed is Amendment No. 28 to your NRC Material License No. 48-10966-03 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 note that the expiration date on your NRC licensee was extended 5 years in accordance with 10 CFR 30.36(2) and now reads December 31, 2001.

Please also note that License Condition No. 32 excludes reference to changes made in your quality management program (QMP). 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.

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).

301726

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
James R. Mullauer, M.H.S.
Health Physicist
Nuclear Materials Licensing Branch

License No.: 48-10966-03
Docket No.: 030-08688

Enclosure: Amendment No. 28

DOCUMENT NAME: M:\03008688.CL6

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	JRMULLAUER:jaw		C FRAZIER					
DATE	10/21/96		10/22/96					

OFFICIAL RECORD COPY

1000 North Oak Avenue
Marshfield, WI 54449-5777

Fax 715-387-5240

715-387-5511

MARSHFIELD CLINIC

September 25, 1996

Mr. James Mullauer
Unites States Nuclear Regulatory Commission
Region III, Materials Licensing Section
801 Warrenville Road
Lisle, IL 60532-4351

RE: LICENSE 48-10966-03

MAIL CONTROL NUMBER: 301726

Per our telephone conversation last week, I am providing you with the following information:

1. Enclosed is a letter from ADAC Laboratories indicating that they will be providing on-site training on the use and maintenance of their attenuation correction sources. Only ADAC personnel will install or exchange these sources.

2. Only physicians who meet the training requirements for Imaging and Localization studies under 10 CFR 35.920 will be authorized by our Radiation Safety Committee to oversee use of this equipment.

3. I have enclosed a highlighted copy of the previous version of our Radiation Oncology Department's Quality Management Program document, indicating what sections have changed.

If you have questions, or need further information, please contact me at (715) 387-9349.

Sincerely,

Douglas J. Walraven

Douglas J. Walraven
Radiation Safety Officer

PM: 9-26-96

ADAC

ADAC LABORATORIES

September 21, 1996

Ms. Joan Priem
Department Manager
St. Joseph's Hospital
611 St. Joseph Avenue
Marshfield, WI 54449-1898

Dear Joan,

This letter is written in regards to the Vantage Attenuation Correction for your Vertex camera. In response to your question regarding responsibility for the removal and replacement of the line sources, ADAC will come in and remove the old line sources and bolt on the new line sources when the they have expired. St. Joseph's will not be responsible for the shipment and installation of the line sources

In addition, ADAC will provide St. Joseph's Hospital with training on the use and maintenance of the line sources. If you have any questions, please page me at 1-800-791-3558. I am looking forward to talking with you soon.

Sincerely,

Robert T. Gemuenden

Robert T Gemuenden
Territory Manager

D-D

QUALITY MANAGEMENT PROGRAM
RADIATION THERAPY

1. Policies and Procedures for Teletherapy:

1.1 Cobalt-60 teletherapy devices are not used at our facility.

2. Policies and Procedures for Brachytherapy:

2.1 High-dose-rate remote afterloading devices are not used at our facility.

2.2 All Other Brachytherapy Applications:

2.2.1 An authorized user dates and signs a written directive prior to the administration of any brachytherapy dose.

2.2.2 Before administering a brachytherapy dose, the identity of the patient is verified as the individual named in the written directive by more than one method. The procedure used to identify the patient is 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: birthdate, address, social security number, signature, the name on the patient's ID bracelet or hospital card, the name on the patient's medical insurance card or the photograph of the patient's face.

2.2.3 Before administering the brachytherapy dose, the specific details of the brachytherapy administration are verified to be in accordance with the written directive and plan of treatment. In particular, the radionuclide, number of sources and source strengths are confirmed to verify agreement with the written directive and plan of treatment.

2.2.4 All workers are asked to seek guidance if they do not understand the written directive.

2.2.5 A qualified person under the supervision of the authorized user verifies that the radionuclides, number of sources, source strengths and loading sequence of the sources to be used are in agreement with the written directive and treatment plan before implanting the radioactive sealed sources. Verification methods include using color-coded sealed sources and using clearly marked storage locations.

2.2.6 For temporary brachytherapy implants, radiographs of brachytherapy sources of nonradioactive "dummy" sources are used as the basis for verifying the position of the sources and calculating the exposure time or total dose. Whenever possible, nonradioactive "dummy" sources are used

before inserting the radioactive sources. Radiographs may not be necessary provided the position of the sources is known prior to inserting the radioactive sources and calculating the exposure time or total dose.

2.2.7 For permanent brachytherapy implants, radiographs of brachytherapy sources are used as the basis for verifying the position of the sources and calculating the total dose. Radiographs may not be necessary for some procedures when fixed geometry applicators are used to establish the location of the sources.

2.2.8 After insertion of the temporary implant brachytherapy sources, the authorized user records the actual load in sequence of the radioactive sources implanted and signs or initials the patient's chart or appropriate record.

2.2.9 After insertion of the permanent implant brachytherapy sources, the authorized user records the actual number of radioactive sources implanted and signs or initials the patient chart or appropriate record.

2.2.10 The dose calculations are checked before the total prescribed brachytherapy dose has been administered. A qualified person under the supervision of the authorized user who, whenever possible, did not make the original calculations, checks the dose calculations.

Manual dose calculations are checked for:

1) Arithmetic errors
2) Appropriate transfer of date from the written directive, plan of treatment, tables and graphs
3) Appropriate use of nomograms when applicable and
4) Appropriate use of all pertinent date in the calculations

Computer-generated dose calculations are checked by examining the computer printout to verify that the correct data for the patient is used in the calculations.

2.2.11 The authorized user dates and signs or initials a written record in the patient chart or in another appropriate record after insertion of the brachytherapy sources. The written record includes the radionuclide, treatment site, and the total source strength and exposure time.

2.2.12 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.

2.13 A qualified person performs acceptance testing on each treatment planning or dose calculations computer that could be used for brachytherapy dose calculations. Acceptance testing are performed before the first time use of the treatment planning or dose calculating computer program for brachytherapy dose calculations.

3. Gamma stereotactic radiosurgery is not being used at our facility.

4. Oral Directives and Revisions to Written Directives:

4.1 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 is acceptable. The oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user prior to the administration of the brachytherapy dose.

5. Review of Written Directives

Review of all brachytherapy procedures will be conducted by the authorized users and physicist. The review will include a representative sample of patient administrations, all recordable events and all misadministrations. For each patient's case, a comparison is made between what was administered versus what was prescribed in the written directive. The persons conducting the review will not review their own cases. An annual review will be given to the Radiation Safety Committee to ensure that the Quality Management Program is effective.

For each patient case reviewed, we will determine whether the administered dose was in accordance with the written directive or plan of treatment, as applicable. The following will be checked:

1) For brachytherapy prior to implantation: the radionuclide, number of sources and source strengths; after implantation but prior to completion of the procedure; the radionuclide, treatment site and total source strength and exposure time.

2) For each patient case reviewed, we will identify deviations from the written directive, the cause of each deviation, and the actions required to prevent recurrence. The actions may include new or revised procedures, additional training or increased supervisory review of work.

3) The Radiation Safety Committee will reevaluate the Quality Management Program's policies and procedures after each annual review to determine whether the program is effective or to identify actions required to make the program more effective.

Program review results will be documented and will be available for the Nuclear Regulatory Commission's inspections. The program review will be distributed to all members of the Radiation Safety Committee and appropriate management. Corrective actions for deficient conditions will be implemented within a reasonable time after identification of the deficiency.

Quality Management Program
Brachytherapy with Sealed Sources
Radiation Oncology

Saint Joseph's Hospital - Marshfield Clinic

Marshfield, Wisconsin

April 1996 NEW

QUALITY MANAGEMENT PROGRAM
BRACHYTHERAPY WITH SEALED SOURCES
RADIATION ONCOLOGY DEPARTMENT

1. Policies and Procedures for Teletherapy:

1.1 Cobalt-60 Teletherapy devices are not used at our facility.

2. Policies and Procedures for Brachytherapy:

2.1 High-dose-rate remote afterloading devices are not used at our facility.

2.2 All other Brachytherapy Applications:

2.2.1 An authorized user dates and signs a written directive prior to the administration of any brachytherapy dose.

2.2.2 Before administering a brachytherapy dose, the identity of the patient is verified as the individual named in the written directive by more than one method. The procedure used to identify the patient is 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: birthdate, address, social security number, signature, the name on the patient's ID bracelet or hospital card, the name on the patient's medical insurance card or the photograph of the patient's face.

2.2.3 Prior to implantation, the brachytherapy written directive must include the radionuclide, number of sources, and source strengths.

2.2.4 All workers are asked to seek guidance if they do not understand the written directive.

2.2.5 A qualified person under the supervision of the authorized user verifies that the radionuclides, number of sources, source strengths and loading sequence of the sources to be used are in agreement with the written directive before implanting the radioactive sealed sources. Verification methods include using color-coded sealed sources and using clearly marked storage locations.

2.2.6 For temporary brachytherapy implants, radiographs of brachytherapy sources of nonradioactive "dummy" sources are used as the basis for verifying the position of the sources and calculating the exposure time or total dose. Whenever possible, nonradioactive "dummy" sources are used before inserting the radioactive sources. Radiographs may not be necessary provided the position of the sources is known prior to inserting the radioactive sources and calculating the exposure time or total dose.

2.2.7 For permanent brachytherapy implants, radiographs of brachytherapy sources are used as the basis for verifying the position of the sources and calculating the total dose. Radiographs may not be necessary for some procedures when fixed geometry applicators are used to establish the location of the sources.

2.2.8 After insertion of the temporary implant brachytherapy sources, the authorized user records the actual load in sequence of the radioactive sources implanted and signs or initials the patient's chart or appropriate record.

2.2.9 After insertion of the permanent implant brachytherapy sources, the authorized user records the actual number of radioactive sources implanted and signs or initials the patient's chart or appropriate record.

2.2.10 The dose calculations are checked before the total prescribed brachytherapy dose has been administered. A qualified person under the supervision of the authorized user who, whenever possible, did not make the original calculations, checks the dose calculations.

Manual dose calculations are checked for:

1) Arithmetic errors
2) Appropriate transfer of date from the written directive, plan of treatment, tables and graphs
3) Appropriate use of nomograms when applicable and
4) Appropriate use of all pertinent data in the calculations

Computer-generated dose calculations are checked by examining the computer printout to verify that the correct data for the patient is used in the calculations.

2.2.11 The authorized user dates and signs a written directive in the patient chart. Prior to treatment completion, the radionuclide, treatment site, and total source strength and exposure time or total dose will be made a part of the written directive.

2.2.12 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.

2.2.13 A qualified person performs acceptance testing on each treatment planning or dose calculations computer that could be used for brachytherapy dose calculations. Acceptance testing is performed before the first time use of the treatment planning or dose calculating computer program for brachytherapy dose calculations.

3. Gamma Stereotactic radiosurgery is not being used at our facility.

4. Oral Directives and Revisions to Written Directives:

4.1 If because of the patient's medical condition a delay in order to provide a written revision to an existing directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user prior to the administration of the brachytherapy dose.

5. Review of Written Directives:

Review of all brachytherapy procedures will be conducted by the authorized users and physicist. The review will include a representative sample of patient administrations, all recordable events and all misadministrations. For each patient's case, a comparison is made between what was administered versus what was prescribed in the written directive. The persons conducting the review will not review their own cases. An annual review will be given to the Radiation Safety committee to ensure that the Quality Management Program is effective.

For each patient case reviewed, we will determine whether the administered dose was in accordance with the written directive or plan of treatment, as applicable. The following will be checked:

1) For brachytherapy prior to implantation: the radionuclide, number of sources and source strengths; after implantation but prior to completion of the procedure; the radionuclide, treatment site and total source strength and exposure time.

2) For each patient case reviewed, we will identify deviations from the written directive, the cause of each deviation, and the actions required to prevent recurrence. The actions may include new or revised procedures, additional training or increased supervisory review of work.

3) The Radiation Safety Committee will reevaluate the Quality Management Program's policies and procedures after each annual review to determine whether the program is effective or to identify actions required to make the program more effective.

   Program review results will be documented and will be available for the Nuclear Regulatory Commission's inspections. The program review will be distributed to all members of the Radiation Safety Committee and appropriate management. Corrective actions for deficient conditions will be implemented within a reasonable time after identification of the deficiency.

4) Records of brachytherapy will be kept in auditable form for at least 3 years.