

MATERIALS LICENSE

Amendment No. 39

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.

302626

<p>Licensee</p> <p>1. General Electric Company Medical Systems</p> <p>2. P. O. Box 414 Milwaukee, Wisconsin 53201</p>	<p>In accordance with letter dated April 30, 1997</p> <p>3. License Number 48-00337-05 is amended in its entirety to read as follows:</p> <p>4. Expiration Date August 31, 2001</p> <p>5. Docket or Reference No. 030-06709</p>	
<p>6. Byproduct, Source, and/or Special Nuclear Material</p> <p>A. Americium-241</p> <p>B. Barium-133</p> <p>C. Cesium-137</p>	<p>7. Chemical and/or Physical Form</p> <p>A. Sealed sources (which have been registered pursuant to 10 CFR 30.32(g) or equivalent Agreement State regulations)</p> <p>B. Sealed sources (which have been registered pursuant to 10 CFR 30.32(g) or equivalent Agreement State regulations)</p> <p>C. Sealed sources (which have been registered pursuant to 10 CFR 30.32(g) or equivalent Agreement State regulations)</p>	<p>8. Maximum Amount that Licensee May Possess at Any One Time Under This License</p> <p>A. 25 sources not to exceed 10 millicuries each</p> <p>B. 135 sources not to exceed 3 millicuries each</p> <p>C. 10 sources not to exceed 1 millicurie each</p>

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C PDR



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MATERIALS LICENSE
SUPPLEMENTARY SHEET

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48-00337-05

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6. Byproduct, source,
and/or special nuclear
material

D. Iron-55

E. Molybdenum-99

F. Technetium-99m

G. Gadolinium-153

H. Strontium-90/Yttrium-90

7. Chemical and/or physical
form

D. Sealed sources
(which have been
registered pursuant
to 10 CFR 30.32(g)
or equivalent
Agreement State
regulations)

E. Elution Generator

F. Any

G. Sealed sources
(which have been
registered pursuant
to 10 CFR 30.32(g)
or equivalent Agreement
State regulations and which
are installed in shielded
collimators)

H. Sealed source

8. Maximum amount that
licensee may possess at
any one time under this
license

D. No single source to
exceed 100
microcuries. Total
not to exceed
10 millicuries.

E. 2 curies

F. 2 curies

G. 4 sources
not to exceed
500 millicuries each

H. One source not
to exceed
15 millicuries

9. Authorized Use:

A. through F. To be used in the calibration and testing of gamma cameras, image tubes, positron emission tomography equipment, and other electronic equipment.

G. Two sources installed in collimators to be used for research and development of a device for attenuation correction on medical imaging equipment. Two sources installed in collimators for possession as necessary for replacement of sources in the attenuation correction device.

H. For storage only, incident to disposal.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located in the Milwaukee Metropolitan area.

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11. A. Licensed material shall only be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, David F. Knight, Chairperson.
- B. The Radiation Safety Officer for the activities authorized by this license is David F. Knight.
12. 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.
- B. Notwithstanding Paragraph A 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 within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Sealed sources need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the 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 10 years without being tested for leakage and/or contamination.
- E. 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, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The 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, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

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- F. 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.
13. Sealed sources containing licensed material shall not be opened or removed from their respective source holders by the licensee.
14. Licensed material shall not be used in or on human beings or in products distributed to the public.
15. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71. "Packaging and Transportation of Radioactive Material."
16. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 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.
17. 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 February 20, 1995 (Items 1 through 4 only); and
 - B. Letters dated August 8, 1996 (with attachments), October 22, 1996, February 10, 1997 and April 30, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 13 1997

By

Loren J. Hester
Nuclear Materials Licensing Branch, Region III

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(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

Program Code: 03620
Status Code: 0
Fee Category: 3M
Exp. Date: 20010831
Fee Comments:
Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: GENERAL ELECTRIC COMPANY
Received Date: 970512
Docket No: 3006709
Control No.: 302626
License No.: 48-00337-05
Action Type: Amendment

2. FEE ATTACHED

Amount: 610
Check No.: 1005567

3. COMMENTS

Signed
Date

D. Hersey
5/13/97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / 1 /)

1. Fee Category and Amount: *3M* *610*

2. Correct Fee Paid. Application may be processed for:

Amendment ☒
Renewal ☐
License ☐

3. OTHER

Signed
Date

SC *5/17/97*

MAY 21 1997

Log	<i>May 7 7M</i>
Remitter	
Check No.	<i>12164027</i>
Amount	<i>610</i>
Fee Category	<i>3M</i>
Type of Fee	<i>AMD</i>
Date Check Rec'd	<i>5/14/97</i>
Date Completed	<i>5/14/97</i>
By	<i>SC</i>

1997 MAY 14 PM 5:08

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04/30/97

To: Loren Hueter
United States Nuclear Regulatory Commission
Region III
801 Warrenville Rd.
Lisle, IL 60532-4351

Dear Loren:

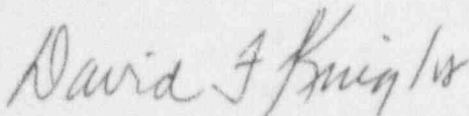
The following is an amendment requesting permission to continue on as Radiation Safety Committee Chairman for GE Medical Systems (NRC license number 48-00337-05) due to a downgrade of our program by year-end.

In previous discussions with you, I agreed to relinquish the role as Chairman, and the agreement was noted in section 7 of our letter to you dated 8/8/96, and referenced in license condition 17b. However, in order to meet the business needs resulting from the sale of the Nuclear technology, I wish to remain as Chairman until we submit a follow-up amendment about year-end. Please note that no facilities are involved in the sale of the technology.

The follow-up amendment will dramatically alter the structure of our program to meet business needs in the new year after the technology transfer to the new owners is complete. At this time, the transfer is expected to be finished by the end of 1997, or early 98. A specific license, with named users and no special provision for an RSC, will be requested in the follow-up amendment. The amendment fee of \$610.00 is enclosed.

If you have any question about my request to continue on as RSC chairman, please feel free to call me at 414-544-3166. Thank you for all of your help during this entire process.

Best Regards,



David F. Knight, GEMSAM Radiation Safety Officer

cc: Dennis Hussey, Manager, Environmental Health, and Safety
Sue Engelhardt, Radiation Consultant

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MAY 12 1997
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Pm: 5-7-97

JUN 13 1997

David F. Knight
Radiation Safety Officer
General Electric Company
Medical Systems
P.O. Box 414
Milwaukee, WI 53201

Dear Mr. Knight:

Enclosed is Amendment No. 39 to your NRC Material License No. 48-00337-05 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that 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 the 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.)

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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 a decision is made to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;
 - b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - d. 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 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

D. Knight

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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.: 48-00337-05
Docket No.: 030-06709

Enclosure: Amendment No. 39

DOCUMENT NAME: M:\03006709.CL7

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	<input checked="checked" type="checkbox"/>							
NAME	CFGill:brt	<input checked="checked" type="checkbox"/>							
DATE	06/11/97								

OFFICIAL RECORD COPY



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

May 14, 1997

David F. Knight, Manager
Radiation Safety Officer
General Electric Company
Medical Systems
P. O. Box 414
Milwaukee, WI 53201

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 04/30/97)

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 ☒ 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. 302626
License No. 48-00337-05

03/24/97

To: Loren Hueter
United States Nuclear Regulatory Commission
Region III
801 Warrenville Rd.
Lisle, IL 60532-4351

Dear Loren:

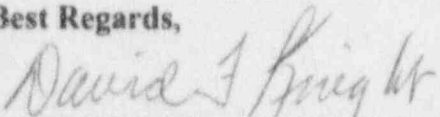
The following is a request for permission to continue on as Radiation Safety Committee Chairman for GE Medical Systems (NRC license number 48-00337-05) due to a downgrade of our program by year-end.

In previous discussions with you, I agreed to relinquish the role as Chairman, and the agreement was noted in section 7 of the license. However, in order to meet the business needs resulting from the sale of both the Nuclear and PET technologies, I must remain as Chairman until our license amendment - to be submitted by the end of the 3rd quarter - has been approved by the Commission.

The amendment will dramatically alter the structure of our program to meet business needs at the beginning of the new year (1998) when most of the technology transfer to the new owners will be complete. A specific license, with no special provision for an RSC, or an RSC approval process, will be requested.

If you have any question about my request to continue on as RSC chairman, please feel free to call me at 414-544-3166. Thank you for all of your help during this entire process.

Best Regards,



David F. Knight, GEMSAM Radiation Safety Officer

cc: Dennis Hursey, Manager, Environmental Health, and Safety
Sue Engenhardt, Radiation Consultant

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Pm: 3-25-97