NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 59

MATERIALS LICENSE

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.

Licensee	
1. Muhlenberg Regional Medical Center	In accordance with the letter dated May 28, 1997, 3. License Number 29-02575-01 is amended in its entirety to read as follows:
2. Park Avenue and Randolph Road Plainfield, New Jersey 07061	4. Expiration Date December 31, 2001
	5. Docket or Reference No. 030-02449

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 included in 10 CFR 35.100	A. Any radiopharmaceutical included in 10 CFR 35.100	A. As needed
B. Any byproduct material included in 10 CFR 35.200	B. Any radiopharmaceutical included in 10 CFR 35.200 except generators and gas	B. As needed
C. Any byproduct material included in 10 CFR 35.300	C. Any radiopharmaceutical included in 10 CFR 35.300	C. As needed
D. Any byproduct material included in 10 CFR 35.400	D. Any brachytherapy source included in 10 CFR 35.400	D. As needed
E. Any byproduct material included in 10 CFR 31.11	E. Prepackaged kits	E. As needed

9. Authorized use

A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.
B. Any imaging and localization procedure approved in 10 CFR 35.200.
C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.
D. Any brachytherapy procedure approved in 10 CFR 35.400.
E. In vitro studies

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at Park Avenue and Randolph Road, Plainfield, New Jersey.

11. The Radiation Safety Officer for this license is Young Ho Park, M.D.

ML 10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-02575-01

Docket or Reference number: 030-02449

Amendment No. 59

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

Authorized Users	Material and Use
Young Ho Park, M.D.	35.100; 35.200; 35.300 In vitro studies
James J. Chen, M.D.	35.100; 35.200; 35.300 In vitro studies
Richard R. Meyers, M.D.	35.300; 35.400
Robert C. Lauer, M.D.	35.200 for cardiovascular clinical procedures
Alan Kalischer, M.D.	35.200 for cardiovascular clinical procedures

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.

14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material at a single location 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.

15. Notwithstanding the requirements of 10 CFR 35.400(d) and (g), the licensee may use iridium-192 as seeds encased in nylon ribbon and palladium-103 as a sealed source in seeds for topical, interstitial, and intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions to the extent that the instructions are not applicable to the type of use proposed by the licensee.

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

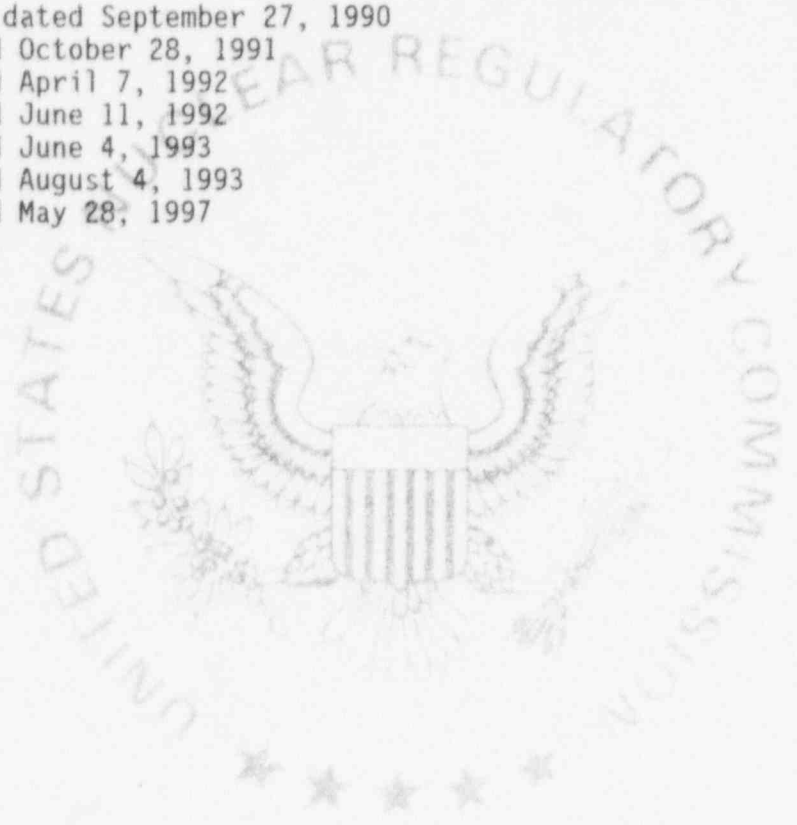
License number
29-02575-01

Docket or Reference number
030-02449

Amendment No. 59

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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The U.S. 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 September 27, 1990
B. Letter dated October 28, 1991
C. Letter dated April 7, 1992
D. Letter dated June 11, 1992
E. Letter dated June 4, 1993
F. Letter dated August 4, 1993
G. Letter dated May 28, 1997



Date JUN 12 1997

For the U.S. Nuclear Regulatory Commission

By Original Signed By:
Michelle Beardsley

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

JUN 12 1997

John R. Kopicki
President and CEO
Muhlenberg Regional Medical Center
Park Avenue and Randolph Road
Plainfield, NJ 07061

Dear Mr. Kopicki:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the license.

Please note that some conditions on your license have been changed/deleted/added in order to reflect current NRC licensing policies.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:
Michelle Beardsley

Michelle R. Beardsley
Division of Nuclear Materials Safety

License No. 29-02575-01
Docket No. 030-02449
Control No. 123726

Enclosure:
Amendment No. 59

OFFICIAL RECORD COPY

ML 10

DOCUMENT NAME: R:\WPS\MLTR\L2902575.01

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Beardsley							
DATE	06/12/97		06/ /97		06/ /97		06/ /97	

OFFICIAL RECORD COPY

MUHLENBERG REGIONAL MEDICAL CENTER, INC.

Park Avenue & Randolph Road
Plainfield, NJ 07061

MS-16
J1

John R. Kopicki
President & Chief Executive Officer
(908) 668-2240

May 28, 1997

Ms Michelle R. Beardsley
Nuclear Regulatory Commission
Licensing Assistance Team
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406

Re: Control No.: 123726

Dear Ms Beardsley:

Pursuant to your conversations with Mr. Raymond E Robinson and Mr. James Donlan, we have decided to use the gadolimium-153 sealed sources as reference standards. This use is permitted as stated in 10 CFR 35.49.

The two sources are listed below;

1) Gd-153, NEN model NER-430, sn G199, current activity 0.005 mCi
2) Gd-153, Amersham, model GDCCY1, sn 3194LN, current activity 11.46 mCi

We will perform leak tests on the source(s), as required, in accordance with the magnitude of their activities. The sources will be inventoried on a quarterly basis.

Thank you for your attention to this matter.

Sincerely,

John R. Kopicki
President and CEO

OFFICIAL RECORD COPY ML 10

123726

JUN - 9 1997

U. S. Nuclear Regulatory Commission Telephone or Verbal Conversation Record		Date:6-2-97 Time:8:00 am
___ Incoming Call _x__ Outgoing Call ___ Visit		
Person Calling: Michelle Beardsley	**Office:** USNRC Region I	**Phone #:**(215) 337-6942
Person Called: Jim Donlan, HP consult.	**Office:**	**Phone #:**
Conversation		
Subject:TAR response for Muhlenberg Reg. Med Ctr./License No.29-02575-01 Control No. 123726 Docket NO. 030-02449		
Summary: I explained to Mr. Donlan that their request to decay their Gd-153 sealed source in storage was denied. He said that they would then keep it as a calibration source and would amend their license stating such.		
Referred to:		
Action Requested: Letter		
Action Taken:		

MS 16
J-1

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 2, 1997

MEMORANDUM TO: Mohamed Shanbaky, Chief
Nuclear Materials Safety Branch
Division of Nuclear Materials Safety, RI

FROM: Larry W. Camper, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: MUHLENBERG REGIONAL MEDICAL CENTER, PLAINFIELD, NEW JERSEY, LICENSE NO. 29-02575-01, TECHNICAL ASSISTANCE REQUEST DATED JANUARY 22, 1997

I am responding to your technical assistance request (TAR) dated January 22, 1997, (attached) wherein Muhlenberg Regional Medical Center, Plainfield, New Jersey, requests an exemption from the requirements of 10 CFR 35.92(a) in order to permit them to decay a gadolinium-153 (Gd-153) sealed source in storage. This source is stated to have a nominal activity of 17 millicuries and, if approved, will be decayed-in-storage in a shielded storage container which is located within a locked storage module within the Hot Lab.

In a reply to a TAR from the Division of Industrial and Medical Nuclear Safety, NMSS, dated January 12, 1994, (synopsis contained within TAR response dated February 18, 1994 (attached)), the Division of Waste Management supported approval of decay-in-storage disposal for nuclides with half-lives less than 120 days and supported inclusion of Gd-153 under the same conditions pursuant to 10 CFR 20.2001(a)(2). The rationale given for the inclusion of Gd-153 is:

1. That the amount to be disposed of needs to be less than the smallest value for the annual limits on intake for this nuclide - 5000 microcurie ingestion and 100 microcurie inhalation. This TAR, specifically, requests approval for decay-in-storage of Gd-153 source with an activity on the order of 17 millicuries, which, after a ten half-life decay period would result in a remaining activity of less that 17 microcuries. This value, being less than both the smallest values for intake and inhalation limits, would thus satisfy this criterion for approval.

2. Survey of the waste, without shielding, using an appropriate radiation survey instrument and technique must indicate no readings distinguishable from natural background.

CONTACT: Robert L. Ayres, IMNS/NMSS
(301) 415-5746

123726

MAY - 5 1997

OFFICIAL RECORD COPY ML 10

3. The licensee must comply with the Environmental Protection Agency regulations on hazardous waste management.

To support the disposal of this material via 10 CFR 20.2001(a)(2), the licensee must establish a reasonable expectation that the radiation survey performed after 10 half-lives of decay will indicate no readings above natural background. With the expected residual activity remaining being of the order of 17 microcuries, it would be reasonable to expect that this criterion would not be met. Based on the expected failure of the source to meet the criteria of no readings above background after 10 half-lives of decay, the request for decay-in-storage should be denied.

Attachment: 1. TAR dated 1/22/96
2. TAR response dtd 2/18/94

DISTRIBUTION: Closes IMNS5687

IMNS Central Files	NRC File Ctr	NMSS r/f	PCVacca
BR&SL	REGSL	REGCHFS	

G:\IMNS5687.RLA
*See previous concurrence

OFC	IMAB*		IMAB*		IMAB*		
NAME	RAyres		CHaney		LCamper		
DATE	4/15/97		4/15/97		4/28/97		

To support the disposal of this material via 10 CFR 20.2001(a)(2), the licensee must establish a reasonable expectation that the radiation survey performed after 10 half-lives of decay will indicate no readings above natural background. With the expected residual activity remaining being of the order of 17 microcuries, it would be reasonable to expect that this criterion would not be met. Based on the expected failure of the source to meet the criteria of no readings above background after 10 half-lives of decay, this request for decay-in-storage should be denied.

Attachment: Tar dtd 1/22/96

DISTRIBUTION: Closes IMNS5687

IMNS Central Files	NRC File Ctr	NMSS r/f	PCVacca
BR&SL	REGSL	REGCHFS	

G:\IMNS5687.RLA

*See previous concurrence 4-15-97

OFC	IMAB*		IMAB*		IMAB		
NAME	RAyres		CHaney		LCamper		
DATE	4/15/97		4/15/97		4/[illegible]/97		

To support the disposal of this material via 10 CFR 20.2001(a)(2), the licensee must establish a reasonable expectation that the radiation survey performed after 10 half-lives of decay will indicate no readings above natural background. With the expected residual activity remaining being of the order of 17 microcuries, it would be reasonable to expect that this criterion would not be met. Based on the expected failure of the source to meet the criteria of no readings above background after 10 half-lives of decay, this request for decay-in-storage should be denied.

Attachment: Tar dtd 1/22/96

DISTRIBUTION: Closes IMNS5687

IMNS Central Files	NRC File Ctr	NMSS r/f	PCVacca
BR&SL	REGSL	REGCHFS	

G:\IMNS5687.RLA

OFC	IMAB	IMAB	IMAB	
NAME	RAyres	CHaney	LCamper	
DATE	4/ /97	4/ /97	4/ /97	

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM TKT 1/24/97

Date: January 22, 1997

Mail or E-Mail to: Donald A. Cool (DAC), Mail Stop: T8-F5 **If E-mail, cc:** CLE
Division of Industrial and Medical Nuclear Safety, NMSS

From: Mohamed Shanbaky, Region I
Chief, Nuclear Materials Safety Branch 1

Licensee: Muhlenberg Regional Medical Center, Inc. **License No.:** 29-02575-01

x☐ **Control No.:** 123726 (if applicable)

x☐ **Letter dated:** January 6, 1997, January 21, 1997

☐ **Suggested change in licensing procedure (enclosed):** _____

x☐ **Problem/Issue:** The licensee requests an exemption from the requirements of 10 CFR 35.92(a) in order to permit them to decay their gadolinium-153 sealed source in storage (T 1/2 = 242 days).

x☐ **Action Required:** Review and deny or give generic approval.

Recommended Action: Recommend approval on a one-time basis since this type of source/device is obsolete and if properly shielded and accounted for in storage, the source poses a minimally significant safety hazard.

Remarks: _____

Headquarter Reviewer: _____
Regional Reviewer: M. Beardsley
Reviewer Code: J-1
Reviewer Phone No.: (610) 337-6942 **FAX No.:** (610) 337-5269
Request Needed by: _____ (date)

MUHLENBERG REGIONAL MEDICAL CENTER, INC.

Park Avenue & Randolph Road
Plainfield, NJ 07061

M56
J-1

John R. Kopicki
President & Chief Executive Officer
(908) 668-2240

January 6, 1997

Nuclear Regulatory Commission
Licensing Assistance Team
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Re: 29-02575-01

Control No.: 123726

Dear Sir/Madam:

The following request is a continuation of our license amendment dated September 9, 1996. A fee in the amount of $440.00 was submitted with that request.

> We hereby request an exemption from the requirements of 10 CFR 35.92(a). Specifically, paragraph (a) has established 65 days as the maximum physical half-life for byproduct materials to be held for decay-in-storage. We are requesting a one-time exemption of the 65 day limit in order to permit a gadolinium-153 sealed source with a 243 day half-life to be stored for decay to background levels.
>
> This exemption, if granted, will alleviate the financial burden of disposal, as we decay every other radioactive material to background levels for disposal in the ordinary trash. It will also be similar to the maximum half-life for decay-in-storage established by the Department of Environmental Protection of the State of New Jersey. This half-life is 300 days, allowing us to store cobalt-57 sources for decay to background levels. Cobalt-57 has a half-life of 271 days.

123726

JAN 13 1997

Nuclear Regulatory Commission
Licensing Assistance Team
Division of Nuclear Materials Safety

Furthermore, the storage of the gadolinium-153 source for decay to background levels does not pose any increased risk of radiation exposure to workers or the public, nor is it an environmental hazard. The source is in a shielded storage container which is located in a locked storage module within the Hot Lab. The current nominal activity of the source is 17 millicuries.

Thank you for your attention to this matter.

Sincerely,

John R. Kopick

John Kopick,
President and CEO

MUHLENBERG REGIONAL MEDICAL CENTER, INC.

Park Avenue & Randolph Road
Plainfield, NJ 07061

(908) 668-2000
Direct Dial (908) 668-_____

M516
J-1

January 21, 1997

Nuclear Regulatory Commission
Licensing Assistance Team
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406 - 1415

Re: 29-02575-01
Control No.: 123726

Attn.: Michelle R. Beardsley

As per our phone conversation of January 17, regarding the storage and accountability for the gadolinium-153, for which we requested an exemption from the requirements of regulation 10 CFR 35.92 (a).

> The gadolinium-153 is currently maintained with all of our sealed sources. Each source is contained in an individual lead container, which is appropriately labeled on the outside indicating isotope, date of calibration and original activity. All sealed sources are maintained in an "ammo" case, which itself is secured in one of our lead lined storage modules located in our dose preparation room. [Access to this room is limited to staff, with security having one [1] key to allow deliveries to be made. The lock on the door is off the master key system to exclude access to unauthorized personnel].
>
> The gadolinium-153 has been maintained on our quarterly inventory of sealed sources and will continue to be accounted for in this manner. The gadolinium-153 shall be allowed to decay for a minimum of ten half lives. The material shall be monitored before disposal as ordinary trash and determined that its radioactivity cannot be distinguished from background radiation levels. At that time all labels shall be obliterated and a record of its disposal shall be maintained by the medical center.

Thank you for your attention to this matter. If I can be of further assistance, please let me know.

Sincerely,

Raymond E Robinson, CNMT, RT(N)
Manager, Department of Nuclear Medicine

JAN 29 1997

JAN 22 1997
FAX REC'D_____

Most recent guidance on decay-in-storage.

slm

Response to Technical Assistance Request

You have NOT BEEN ASSIGNED to approve this TAR

Switch to Approval Mode

Response Section

From: Cool

Date Completed: 02/15/95

Images:   1215b001 1215b002

Response:

I am responding to a technical assistance request dated December 15, 1993, regarding the Department of **Veterans Affairs Medical Center (VAMC), Boise, Idaho** request for authorization for decay-in-storage of sulfur-35 and for extended storage of carbon-14 and hydrogen-3. In a memorandum dated April 11, 1994, the Medical, Academic, and Commercial Use Safety Branch (IMAB) stated that the staff could not provide a recommendation on this request until a generic dose assessment was completed by the Division of Low-Level Waste Management (now the Division of Waste Management) (copy attached).

Subsequent guidance was sent to the regions in Policy and Guidance Directive 94-05, "Updated Guidance on Decay-In-Storage." This guidance states that the regions may authorize decay-in-storage of byproduct material with half-lives up to, and including, 120 days, provided the waste is held for a minimum of 10 half-lives, and other procedures for decay-in-storage are followed, as described in 10 CFR 35.92. Based on this guidance, Jacqueline Burks, of your staff, has issued an amendment to the license for the VAMC in Boise, Idaho, authorizing the licensee to hold sulfur-35 for decay-in-storage.

The licensee also requested extended storage of carbon-14 and hydrogen-3 in the event that access to the Northwest Compact site is denied. NRC believes that licensees should exhaust all possible alternatives for disposal of radioactive waste and rely upon on-site storage of low-level waste as a last resort measure. The protection of the public health and safety is enhanced by disposal rather than storage of wastes. Accordingly, as the licensee has access to the Northwest Compact Site, we cannot approve extended storage at this time. If the licensee is informed that it will no longer have access to the waste site, we can reconsider the request for extended storage.

Attachment(s):

TEXT OF MEMO DTD 4/11/94

This branch has reviewed the technical assistance request (TAR) (Enclosure 1), dated December 15, 1993, regarding the Department of **Veterans Affairs Medical Center (VAMC), Boise, Idaho**, request for an exemption to 10 CFR 35.92 authorizing decay-in-storage of sulfur-35 (S-35). We have also reviewed the TAR (Enclosure 2) dated March 17, 1993, regarding the Department of VAMC, Los Angeles, CA, request for an exemption to 10 CFR 35.92 authorizing the disposal of iodine-125 after 5 half-lives and sulfur-35 after 10 half-lives.

The Division of Low-Level Waste Management and Decommissioning (LLWM) will perform a dose assessment to ensure 10 CFR Part 20 limits will not be exceeded by our proposed disposal methods. We cannot give a recommendation on this issue until we have received the results of the dose assessment from LLWM. Upon receipt, we will forward a response to all regions.

---

last modified by Pat Vacca/usnrc on 26-Apr-96 at 12:51 PM

Response to
Technical Assistance Request

You have NOT BEEN ASSIGNED to approve this TAR

Switch to Approval Mode

Response Section

From: Glenn

Date Completed: 11/23/93

Images:  
0913b001 0913b002

Response:

This Branch has reviewed your Technical Assistance Request dated September 13, 1993, (copy enclosed) regarding Madigan Army Medical Center's request to dispose of medical research waste containing Gadolinium (Gd-153), Tin (Sn-113), Cerium (Ce-141), and Sulfur (S-35).

Based on the information submitted stating that byproduct material with half-lives less than 120 days, (i.e. Ce-141, Sn-113, and S-35) were held for a minimum of 10 half-lives, and that the survey of the byproduct material was monitored with an appropriate survey meter, the request to dispose of the byproduct material as ordinary trash may be granted. However, a record of each disposal permitted shall be retained for three years pursuant to 10 CFR 30.51. The record must include the date of the disposal, the date on which the byproduct material 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.

Regarding the request to dispose of Gd-153 with a half-life of 241 days, the licensee will need approval for alternative disposal methods pursuant to 10 CFR 20.302. Therefore, this request cannot be granted without the additional information required by 10 CFR 20.302. We plan to take no further action unless the licensee requests approval pursuant to 10 CFR 20.302.

Attachment(s):

N/A

last modified by Eric Bazerghi/usnrc on 21-Sep-95 at 03:25 PM

Response to
Technical Assistance Request

You have NOT BEEN ASSIGNED to approve this TAR

Switch to Approval Mode

Response Section

From: Glenn

Date Completed: 02/18/94

Images:

Response:

This is a final response to your Technical Assistance Request (TAR) dated September 13, 1993 (Enclosure 1), regarding a request from Madigan Army Medical Center, Tacoma, Washington, for disposal of byproduct material as ordinary trash pursuant to 10 CFR 20.302. A request, dated November 17, 1993 (Enclosure 2), was made to the Decommissioning and Regulatory Issues Branch (LLDR) for review of the disposal of the gadolinium-153 (Gd-153). In a reply, dated January 12, 1994 (Enclosure 3), LLDR supported approval of decay-in-storage disposal for nuclides with half-lives less than 120 days and supported inclusion of Gd-153 under the same conditions. LLDR suggested such approval should include appropriate survey requirements and/or limits on nuclide quantities. Subject to such conditions, the region may grant the licensee's request for disposal of the Gd-153. This guidance supersedes that provided in a memorandum dated November 23, 1993 (Enclosure 4), regarding the Gd-153 disposal, which, in part, directed the region to gather the additional information required by 10 CFR 20.302.

The following is the text of a 1/12/94 memorandum from JAustin, LLWM to JGlenn:

On November 17, 1993, you forwarded a Technical Assistance Request regarding the Madigan Army Medical Center's request to dispose of byproduct material as ordinary trash pursuant to 10 CFR 20.302 [10 CFR 20.2002]. Since new Part 20 is now mandatory, it may be more appropriate, in this case, to use the provisions of Paragraph 20.2001(a)(2). This paragraph states that, "A licensee shall dispose of licensed material only ... (b)y decay in storage; or ...". While the phrase "decay in storage" is not defined in the regulations, disposal under this provision of the regulations could be approved without the specific analyses and evaluations required under Section 20.2002.

The byproduct material, in question, includes Sn-113, Ce-141, S-35, and Gd-153. The first

three nuclides have half-lives less than 120 days while the half-life for Gd-153 is 242 days. You specifically asked for our review of the proposed Gd-153 disposal, involving an assayed activity of 500 μCi on March 6, 1987, which, after about a ten half-life decay period results in a current activity of less than 0.5 μCi.

We concur with your plan to instruct Region V to approve the requested "decay-in-storage" disposal for the nuclides with half-lives less than 120 days and would support inclusion of Gd-153 under the same conditions. Our rationale for the inclusion of Gd-153 is similar to yours and the Region's; that is:

1. The amount to be disposed of (i.e., 0.5 μCi) is substantially less than the smallest value for the annual limits on intake for this nuclide - 5000 μCi ingestion and 100 μCi inhalation [minor correction from the 500 μCi value cited in your memorandum]. As a result, the projected dose, if an individual were to ingest the total activity, is less than 0.5 mrem (inhalation of the total quantity is not considered a credible event).

2. Survey of the waste without shielding using an appropriate instrument and survey technique indicates no readings distinguishable from natural background.

3. Licensee will comply with the Environmental Protection Agency regulations on hazardous waste management.

We, therefore, support disposal of the subject material via 10 CFR 20.2001(a)(2). This, and other similar approvals, should include appropriate survey requirements and/or limits on nuclide quantities.

Attachment(s):

N/A

---

last modified by Pat Vacca/usnrc on 15-Apr-96 at 01:56 PM

REGION[redacted] TECHNICAL ASSISTANCE REQ[redacted]ST FORM TKT 1/24/97

Date: January 22, 1997

Mail or E-Mail to: Donald A. Cool (DAC), Mail Stop: T8-F5 **If E-mail, cc:** CLE
Division of Industrial and Medical Nuclear Safety, NMSS

From: Mohamed Shanbaky, Region I
Chief, Nuclear Materials Safety Branch 1

Licensee: Muhlenberg Regional Medical Center, Inc. **License No.:** 29-02575-01

x☐ **Control No.:** 123726 **(if applicable)**

x☐ **Letter dated:** January 6, 1997, January 21, 1997

☐ **Suggested change in licensing procedure (enclosed):** _____

x☐ **Problem/Issue:** The licensee requests an exemption from the requirements of 10 CFR 35.92(a) in order to permit them to decay their gadolinium-153 sealed source in storage (T 1/2 = 242 days).

x☐ **Action Required:** Review and deny or give generic approval.

Recommended Action: Recommend approval on a one-time basis since this type of source/device is obsolete and if properly shielded and accounted for in storage, the source poses a minimally significant safety hazard.

Remarks: _____

Headquarter Reviewer: _____
Regional Reviewer: M. Beardsley
Reviewer Code: J-1
Reviewer Phone No.: (610) 337-6942 **FAX No.:** (610) 337-5269
Request Needed by: _____ **(date)**

OFFICIAL RECORD COPY ML 10

Form TAR-10 (G:\TARS\TARFORM)
9/93

MUHLENBERG REGIONAL MEDICAL CENTER, INC.

Park Avenue & Randolph Road
Plainfield, NJ 07061

M56
J-1

John R. Kopicki
President & Chief Executive Officer
(908) 668-2240

January 6, 1997

Nuclear Regulatory Commission
Licensing Assistance Team
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Re: 29-02575-01

Control No.: 123726

Dear Sir/Madam:

The following request is a continuation of our license amendment dated September 9, 1996. A fee in the amount of $440.00 was submitted with that request.

> We hereby request an exemption from the requirements of 10 CFR 35.92(a). Specifically, paragraph (a) has established 65 days as the maximum physical half-life for byproduct materials to be held for decay-in-storage. We are requesting a one-time exemption of the 65 day limit in order to permit a gadolinium-153 sealed source with a 243 day half-life to be stored for decay to background levels.
>
> This exemption, if granted, will alleviate the financial burden of disposal, as we decay every other radioactive material to background levels for disposal in the ordinary trash. It will also be similar to the maximum half-life for decay-in-storage established by the Department of Environmental Protection of the State of New Jersey. This half-life is 300 days, allowing us to store cobalt-57 sources for decay to background levels. Cobalt-57 has a half-life of 271 days.

123726

JAN 13 1997

Furthermore, the storage of the gadolinium-153 source for decay to background levels does not pose any increased risk of radiation exposure to workers or the public, nor is it an environmental hazard. The source is in a shielded storage container which is located in a locked storage module within the Hot Lab. The current nominal activity of the source is 17 millicuries.

Thank you for your attention to this matter.

Sincerely,

John R. Kopicka

John Kopicka,
President and CEO

MUHLENBERG REGIONAL MEDICAL CENTER, INC.

Park Avenue & Randolph Road
Plainfield, NJ 07061

(908) 668-2000
Direct Dial (908) 668-_____

M516
J-1

January 21, 1997

Nuclear Regulatory Commission
Licensing Assistance Team
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406 - 1415

Re: 29-02575-01
Control No.: 123726

Attn.: Michelle R. Beardsley

As per our phone conversation of January 17, regarding the storage and accountability for the gadolinium-153, for which we requested an exemption from the requirements of regulation 10 CFR 35.92 (a).

> The gadolinium-153 is currently maintained with all of our sealed sources. Each source is contained in an individual lead container, which is appropriately labeled on the outside indicating isotope, date of calibration and original activity. All sealed sources are maintained in an "ammo" case, which itself is secured in one of our lead lined storage modules located in our dose preparation room. [Access to this room is limited to staff, with security having one [1] key to allow deliveries to be made. The lock on the door is off the master key system to exclude access to unauthorized personnel].
>
> The gadolinium-153 has been maintained on our quarterly inventory of sealed sources and will continue to be accounted for in this manner. The gadolinium-153 shall be allowed to decay for a minimum of ten half lives. The material shall be monitored before disposal as ordinary trash and determined that its radioactivity cannot be distinguished from background radiation levels. At that time all labels shall be obliterated and a record of its disposal shall be maintained by the medical center.

Thank you for your attention to this matter. If I can be of further assistance, please let me know.

Sincerely,

Raymond E Robinson, CNMT, RT(N)
Manager, Department of Nuclear Medicine

JAN 29 1997

JAN 22 1997
FAX REC'D_____

MUHLENBERG REGIONAL MEDICAL CENTER, INC.

Park Avenue & Randolph Road
Plainfield, NJ 07061

(908) 668-2000
Direct Dial (908) 668-_____

M516
J-1

January 21, 1997

Nuclear Regulatory Commission
Licensing Assistance Team
Division of Nuclear Materials Safety
Region I
475 Allendale Road
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Control No. : 123726

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Thank you for your attention to this matter. If I can be of further assistance, please let me know.

Sincerely,

Raymond E Robinson, CNMT, RT(N)
Manager, Department of Nuclear Medicine

OFFICIAL RECORD COPY

ML 10 JAN 29 1997

JAN 22 1997

FAX REC'D_____

MUHLENBERG REGIONAL MEDICAL CENTER, INC.

Park Avenue & Randolph Road
Plainfield, NJ 07061

M516
J-1

John R. Kopicki
President & Chief Executive Officer
(908) 668-2240

January 6, 1997

Nuclear Regulatory Commission
Licensing Assistance Team
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Re: 29-02575-01

Control No.: 123726

Dear Sir/Madam:

The following request is a continuation of our license amendment dated September 9, 1996. A fee in the amount of $440.00 was submitted with that request.

We hereby request an exemption from the requirements of 10 CFR 35.92(a). Specifically, paragraph (a) has established 65 days as the maximum physical half-life for byproduct materials to be held for decay-in-storage. We are requesting a one-time exemption of the 65 day limit in order to permit a gadolinium-153 sealed source with a 243 day half-life to be stored for decay to background levels.

This exemption, if granted, will alleviate the financial burden of disposal, as we decay every other radioactive material to background levels for disposal in the ordinary trash. It will also be similar to the maximum half-life for decay-in-storage established by the Department of Environmental Protection of the State of New Jersey. This half-life is 300 days, allowing us to store cobalt-57 sources for decay to background levels. Cobalt-57 has a half-life of 271 days.

123726

JAN 13 1997

Nuclear Regulatory Commission
Licensing Assistance Team
Division of Nuclear Materials Safety

Furthermore, the storage of the gadolinium-153 source for decay to background levels does not pose any increased risk of radiation exposure to workers or the public, nor is it an environmental hazard. The source is in a shielded storage container which is located in a locked storage module within the Hot Lab. The current nominal activity of the source is 17 millicuries.

Thank you for your attention to this matter.

Sincerely,

John R. Kopicki

John Kopicki,
President and CEO

U. S. Nuclear Regulatory Commission Telephone or Verbal Conversation Record		Date:11-5-96 Time:10:00 a.m.
___ Incoming Call _x_ Outgoing Call ___ Visit		
Person Calling: Michelle Beardsley MB	**Office:** USNRC Region I	**Phone #:**(215) 337-6942
Person Called: Ray Robinson, Mgr-Rad	**Office:** 908- 668-3106	**Phone #:**
Conversation		
Subject:License amendment request-Muhlenberg Regional Med. Ctr **License No.**29-02575-01 Docket No. 030-02449 Control No.123726		
Summary: I explained to Mr. Robinson that Gadolinium-153 cannot be held for decay-in-storage due to its long half-life (242 days). He stated that they may wish to put it "in storage only" until they could arrange for disposal/transfer. He is to call back with this information.		
Referred to:		
Action Requested: Respond to above within 30 days		
Action Taken:		

ML 10

OFFICIAL RECORD COPY

MUHLENBERG REGIONAL MEDICAL CENTER, INC.

Park Avenue & Randolph Road
Plainfield, NJ 07061

John R. Kopicki
President & Chief Executive Officer
(908) 668-2240

030-02449

September 9, 1996

Nuclear Regulatory Commission
Licensing Assistance Team
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Re: 29-02575-01

Dear Sir/Madam:

Please amend our radioactive materials license to include the following change. A check in the amount of $440.00 for processing this amendment is enclosed.

> We plan to hold approximately 37 millicuries of gadolinium-153 in storage for decay to background. This material is from a dual photon bone densitometry device, licensed pursuant to 35.500(a). This source will remain in a shielded container located in a secure storage area. It will be inventoried on a quarterly basis, but it will not be leak tested unless it is put back into use. It will remain in this storage area for decay to background levels. It will not be disposed of until it decays by at least ten half-lives and it shows no measurable amount of radioactivity using a sodium-iodide type radiation detector.

When processing this request, please note these changes requested in our letter dated July 8, 1996 and include these changes in the license.

Thank you for your attention to this matter.

Sincerely,

John R. Kopicki,
President and CEO

123726

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02120
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 20011231
FEE COMMENTS: CODE 23
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MUHLENBERG REGIONAL MEDICAL CENTER
RECEIVED DATE: 960924
DOCKET NO: 3002449
CONTROL NO.: 123726
LICENSE NO.: 29-02575-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: $ 440.00
CHECK NO.: 174002

3. COMMENTS

SIGNED W. A. Perkins
DATE 9/25/96

OCT 30 AM 11:37

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

1. FEE CATEGORY AND AMOUNT: 7C $440

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

3. OTHER

SIGNED
DATE

I (FL)
Dept 2
Payer
Check No. 174002
Amount $440
Fee Category K
Type of Fee HMD
Date Check Rec'd 10/2/96
Date Completed
By SD