NRC FORM 374 (4-94)

U.S. NUCLEAR REGULATORY COMMISSION



# MATERIALS LICENSE

Amendment No. 47

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.

301667

| Licensee | |
|---|---|
| 1. Lakeland Medical Center, St. Joseph | In accordance with letter received September 26, 1996<br>3. License Number 21-04177-01 is amended in its entirety to read as follows: |
| 2. 1234 Napier Avenue<br>St. Joseph, MI 49085 | 4. Expiration Date January 31, 2005 |
| | 5. Docket or Reference No. 030-02049 |

| 6. Byproduct, Source, and/or Special Nuclear Material | 7. Chemical and/or Physical Form | 8. Maximum Amount that Licensee May Possess at Any One Time Under This License |
|---|---|---|
| A. Any byproduct material identified in 10 CFR 35.100 | A. Any radiopharmaceutical identified in 10 CFR 35.100 | A. As needed |
| B. Any byproduct material identified in 10 CFR 35.200 | B. Any radiopharmaceutical identified in 10 CFR 35.200 (excluding Tc-99m aerosols) | B. As needed |
| C. Any byproduct material identified in 10 CFR 35.300 | C. Any radiopharmaceutical identified in 10 CFR 35.300 | C. As needed |
| D. Any byproduct material identified in 10 CFR 35.400 | D. Any brachytherapy source identified in 10 CFR 35.400 | D. As needed |
| E. Gadolinium-153 | E. Sealed Sources (North American Scientific Mode 3601) | E. 4 sources not to exceed 250 millicuries each |

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200 (excluding Tc-99m aerosols).

C. Medical use described in 10 CFR 35.300.

220035

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**MATERIALS LICENSE**
**SUPPLEMENTARY SHEET**

D. Medical use described in 10 CFR 35.400.

E. Two sources to be used in Adac Laboratories Transmission Line Source Housing VANTAGE device for medical radiography in humans. Two sources in shipping containers for replacement of the sources.

CONDITIONS

10. Location of use: 1234 Napier Avenue, St. Joseph, Michigan.

11. Radiation Safety Officer: Alexander Bogda, M.S.

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 |
|---|---|
| A. Gene E. Maddock, M.D. | 10 CFR 35.100, 35.200 (excluding Tc-99m aerosols) and 35.300 and gadolinium-153 in VANTAGE device for medical radiography. |
| B. William F. Leahey, M.D. | 10 CFR 35.100, 35.200 (excluding Tc-99m aerosols), and 35.300 (excluding iodine-131 for thyroid carcinoma therapy) and gadolinium-153 in VANTAGE device for medical radiography. |
| C. Walter M. Decker, M.D. | 10 CFR 35.100 and 35.200 (excluding Tc-99m aerosols) and gadolinium-153 in VANTAGE device for medical radiography. |
| D. Anwar Ahmad, M.D. | 10 CFR 35.400. |
| E. Muhammad Z. Iqbal, M.D. | 10 CFR 35.400. |
| F. Roman Hyszczak, M.D. | 10 CFR 35.100 and 35.200 (excluding Tc-99m aerosols) and gadolinium-153 in VANTAGE device for medical radiography. |
| G. Daniel F. Kreider, M.D. | 10 CFR 35.100, 35.200 (excluding Tc-99m aerosols) and 35.300 and gadolinium-153 in VANTAGE device for medical radiography. |
| H. Kent T. Lancaster, M.D. | 10 CFR 35.100 and 35.200 (excluding Tc-99m aerosols) and 35.300 and gadolinium-153 in VANTAGE device for medical radiography. |

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 21-04177-01

Docket or Reference Number 030-02049

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| | | |
|---|---|---|
| I. | Kathleen Gafarian, M.D. | 10 CFR 35.100, 35.200 (excluding Tc-99m aerosols) and 35.300 and gadolinium-153 in VANTAGE device for medical radiography. |
| J. | Brad Bastow, M.D. | 10 CFR 35.100 and 35.200 (excluding Tc-99m aerosols) and gadolinium-153 in VANTAGE device for medical radiography. |
| K. | Don F. Brooks, M.D. | 10 CFR 35.200 (excluding generators and reagent kits), limited to cardiovascular clinical procedures only and gadolinium-153 in VANTAGE device for medical radiography. |
| L. | Dilip Arora, M.D. | 10 CFR 35.100 and 35.200 (excluding Tc-99m aerosols and generators), limited to cardiovascular clinical procedures only and gadolinium-153 in VANTAGE device for medical radiography. |
| M. | J. Christian Higgins, M.D. | 10 CFR 35.100 and 35.200 (excluding Tc-99m aerosols and generators), limited to cardiovascular clinical procedures only and gadolinium-153 in VANTAGE device for medical radiography. |
| N. | John F. Fiederlein, M.D. | 10 CFR 35.100, 35.200 (excluding Tc-99m aerosols) and 35.300 and gadolinium-153 in VANTAGE device for medical radiography. |
| O. | Shahid Latif, M.D. | 10 CFR 35.400. |

13. A. The licensee may use the Calicheck device for doing linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.

    B. The licensee may use the Lineator device for doing linearity tests of its dose calibrator provided it follows the procedures in the Atomic Products Corporation Lineator Instructions Manual dated June 20, 1983.

14. The licensee may 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 21-04177-01

Docket or Reference Number 030-02049

Amendment No. 47

15. The licensee will require the authorized user performing an iodine procedure to sign a written request that will indicate the name of the patient, isotope, radiopharmaceutical, activity, and the supplier prior to ordering the dose.

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

17. 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.

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

    A. Application dated June 20, 1994; and

    B. Letters dated June 20, 1990 (excluding the requests to change Items 7., 9.2, and 10.14) and July 12, 1996.

    C. Letter received September 26, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date Sept. 27, 1996

By Patricia M. Vacheston
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02120
STATUS CODE: 0
FEE CATEGORY: 7C 2B
EXP. DATE: 20050131
FEE COMMENTS: CODE 23
DECOM FIN ASSUR REQD: N

R7

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   APPLICANT/LICENSEE: LAKELAND MEDICAL CENTER ST. JOSEPH
   RECEIVED DATE: 960801
   DOCKET NO: 3002049
   CONTROL NO.: 301667
   LICENSE NO.: 21-04177-01
   ACTION TYPE: AMENDMENT

2. FEE ATTACHED
   AMOUNT: $440
   CHECK NO.: 43057

3. COMMENTS

SIGNED M. Mellman
DATE 8/8/96

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

1. FEE CATEGORY AND AMOUNT: 7C #440

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

3. OTHER

SIGNED SC
DATE 8/5/96

AUG 09 1996

Log A492 III
Remitter
Check No. 43057
Amount $440
Fee Category 7C
Type of Fee MD
Date Check Rec'd 8/5/96
Date Completed
By SC

96 AUG -5 AM 11:03

Lakeland
Medical Center

July 12, 1996

United States Nuclear Regulatory Commission
Region III, Materials Licensing Branch
801 Warrenville Rd.
Lisle, IL 60532-4351

Re: Amendment to Materials License No. 21-04177-01

Dear Sirs,

Please amend our Material's License 21-04177-01 as follows:
Add Radioactive Material and Use

| Item 5 | | Item 6 | |
|---|---|---|---|
| Byproduct Material | Chem. & Phys. Form | Max. Possession Activity Limit | Purpose |
| Gadolinium-153 | Sealed Source<br>North American Scientific<br>Model 3601<br>NRC Device #CA510S121S | 800 Mci<br>For two(2)<br>sources &<br>source change | ADAC Vantage<br>Attenuation<br>Correction |

ADAC confirms that the manufacturer (North American Scientific) is licensed as per 10 CFR 32.74 as required.

Also, please delete Kathleen Gafarian as an authorized user.

Enclosed is the $440.00 amendment fee. If you have any questions regarding the proposed amendment, please do not hesitate to call Cheryl Weise at (616) 983-8868.

Sincerely,

Robert P. Harrison
Chief Operating Officer

RH/vjs

pm 7-30-96

6418 Deans Hill Road • Berrien Center, MI 49102 • Phone 616/471-7761
31 North St. Joseph Avenue • Niles, MI 49120 • Phone 616/683-5510
1234 Napier Avenue • St. Joseph, MI 49085 • Phone 616/983-8300



301667

**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 # CA510S121S). 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

SEP 3 0 1996

Robert P. Harrison
Chief Operating Officer
Lakeland Medical Center, St. Joseph
1234 Napier Avenue
St. Joseph, MI 49085

Dear Mr. Harrison:

Enclosed is Amendment No. 47 to your NRC Material License No. 21-04177-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office 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 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).

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

   a. When you decide to terminate all activities involving materials authorized under the license; or

   b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.

301667

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 wo' 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, 10 CFR Part 2, Appendix C.

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
Patricia M. Vacherlon
Nuclear Materials Licensing Section

License No. 21-04177-01
Docket No. 030-02049

Enclosures:
1. Amendment No. 47
2. NRC Form 3 and 313

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| OFFICE | DRSS/RIII | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| NAME | PVacherlon:sjd | | | | | | | | | |
| DATE | 9/7/96 | | | | | | | | | |

OFFICIAL RECORD COPY

Lakeland Regional Health System

United States Nuclear Regulatory Commission
Region III, Material Licensing Branch
801 Warrenville Rd.
Lisle, Illinois 60532-4351

RE: Amendment to Materials License No. 21-04177-01; Control Number 301667

Dear Sirs:

This is in response to your letter from Mrs. Patricia M. Vacherlon, dated 9/4/96.

Response is as follows:

1. Installation of the ADAC unit will not require room changes
2. The physicians using the new ADAC unit are the same that are on the license presently with the same Material and Use . They are as follows: Gene Maddock, M.D., William F. Leahy, M.D., Walter Decker, M.D., Roman Hyszczak,M.D., Daniel F. Kreider,M.D., Kent T. Lancaster, M.D., Brad Bastow. D.O., Dilip Arora, M.D., J. Christian Higgins, M.D., John Fiederlein, M.D.,
3. The Specific Activity: A limit of 800 millicurie of Gd-153 is necessary when replacing the line source in the Vantage Nonuniform Attenuation Correction System.
   Activity of the Vantage Gd-153 line sources is 200-250 mCi per source x2 for a total of up to 500 mCi/system

If you have further questions regarding the proposed amendment, please do not hesitate to call A. Bogda at (616) 982-4873.

Sincerely,

Robert P. Harrison
Chief Operating Officer
Lakeland Medical Center

RECEIVED
SEP 2 6 1996
REGION III

f/m: 9-23-96

SEP 2 6 1996

ADAC LABORATORIES

**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 # CA5106121S). 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** – Registry of device CA102D101S

- 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 < 0.0 [illegible]% of total content

SEP 0 4 1996

Robert P. Harrison
Chief Operating Officer
Lakeland Medical Cente.
1234 Napier Avenue
St. Joseph, MI 49085

Dear Mr. Harrison:

We have reviewed your letter dated July 12, 1996 requesting an amendment to License No. 21-04177-01 and find that we will need additional information as follows:

ROOM CHANGES

State whether the addition of the ADAC unit will require any changes to the rooms for which sketches are included in your license. If room changes are necessary, your must submit updated sketches of the modified areas.

AUTHORIZED USERS

State which physicians currently listed on the license will use this device. Please note, the physicians must be qualified to use materials included in 10 CFR Parts 35.100 or 35.200.

SPECIFIC ACTIVITY

State the specific activity per source to be listed on the license. Your application implies that the max. activity would be 200 millicuries, however, the max. activity approved per source is 300 millicuries.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 301667.

Upon failure to file an answer within the specified time, we will consider that your have abandoned your request and will void this action. This is without prejudice to resubmission of the application.

If your have any questions or require clarification on any of the information stated above, your may contact us at (630) 829-9887.

Sincerely,

Original Signed By
Patricia M. Vacherlon
License Reviewer

License No. 21-04177-01
Docket No. 030-02047

DOCUMENT NAME: M:\03002047.DF6

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| OFFICE | DNMS/RIII | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| NAME | PVACHERLON:jaw | | | | | | | | | |
| DATE | 08/13/96 | | | | | | | | | |

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