MATERIALS LICENSE

Amendment No. 10

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.

3024160

Licensee	
1. Bay Area Medical Center Marinette Facility	In accordance with application dated February 28, 1997
2. 3100 Shore Drive Marinette, WI 54143	3. License Number 48-25971-01 is amended in its entirety to read as follows:
	4. Expiration Date: February 28, 2004
	5. Docket or Reference No.: 030-30818/21-18523-01

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200 (excluding xenon-133 and generators that require uranium, depleted in uranium-235, for shielding)	B. As needed
C. Any byproduct material identified in 10 CFR 35.500	C. Sealed sources identified in 10 CFR 35.500	C. As needed
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits	D. As needed
E. Strontium-89	E. As included in 10 CFR 35.300	E. As needed
F. Gadolinium-153	F. Sealed sources (North American Scientific Inc. Model 3601)	F. 4 sources, not to exceed 250 millicuires each

120123

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-25971-01

Docket or Reference Number
030-30818/21-18523-01

Amendment No. 10

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200 (excluding xenon-133 and generators that require uranium, depleted in uranium-235, for shielding).

C. Medical use described in 10 CFR 35.500 in devices which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.

D. In vitro studies.

E. Palliative treatment of bone.

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

CONDITION

10. Location of Use: Bay Area Medical Center
Marinette Facility
3100 Shore Drive
Marinette, WI 54143

11. Radiation Safety Officer: Thomas M. Gates, M.D.

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. Thomas M. Gates, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.500, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.
B. William J. Mallory, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.500, strontium-89 as included in 10 CFR 35.300, 31.11 and gadolinium-153 in VANTAGE devices for medical radiography.

13. 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.

E. 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.

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, 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.

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

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

15. For ventilation studies the licensee shall collect spent technetium-99m DTPA aerosol in a single use shielded trap.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-25971-01

Docket or Reference Number
030-30818/21-18523-01

Amendment No. 10

16. 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 July 30, 1993 (with attachments) and February 28, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAY 30 1997

By _____
Nuclear Materials Licensing Branch, Region III

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: 20040228
Fee Comments:
Decom Fin Assur Regd: N

55

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: BAY AREA MEDICAL CENTER
   Received Date: 970325
   Docket No: 3030818
   Control No.: 302460
   License No.: 48-25971-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 440
   Check No.: 030972

3. COMMENTS

Signed D. Hersey
Date 3-28-97

1997 MAR 31 PM 4:25

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

1. Fee Category and Amount: 7C 2B $440

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

3. OTHER

Signed JC
Date 4/1/97

APR 03 1997

Log Mar 13 III
Remitter
Check No. 30972
Amount $440
Fee Category 7C 2B
Type of Fee Amd
Date Check Rec'd 3/31/97
Date Completed 4/1/97
By: JC

BAY AREA
MEDICAL CENTER

February 28, 1997

Nuclear Regulatory Commission
Region III
Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: Amendment to Materials License #48-25971-01

Dear Sir or Madam:

Please amend the above referenced radioactive materials license for the following:

1. We would like to be licensed for Gd-153 under 10 CFR 35.200 for an ADAC Vantage Correction System. These sources will be used under the supervision of Thomas M. Gates, M.D. and William J. Mallory, M.D., both of which are licensed to use materials identified in 35.200. The following is specific information about the sources:

Manufacturer:	North American Scientific
Model:	MED 3601
Activity per source:	300 mCi
Maximum Activity:	1 Ci

These sources will be exchanged by an ADAC field service engineer as needed. These sources will be leak tested at least every six (6) months along with the rest of our applicable sealed sources.

2. We would like to add a second imaging room to our license. The room is adjacent to the existing department. Attached is a diagram of the new room.

Enclosed is a check for $440.00 to cover the processing fees. If you have any questions about this amendment, please contact Tim Leemon at (715) 735-4200.

Sincerely,

Rick Ament
Chief Executive Officer
:gob
Enclosure

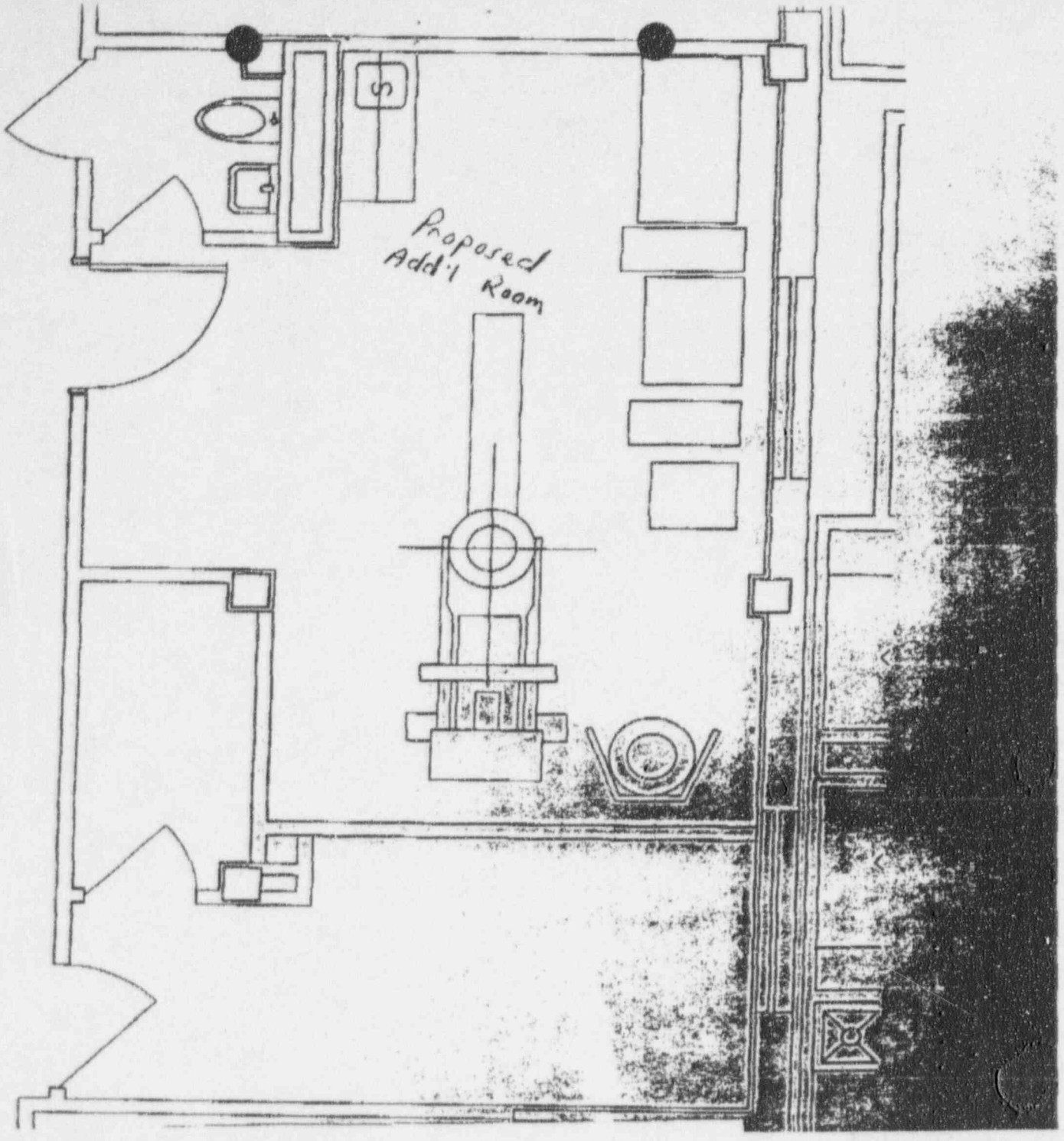
RECEIVED
MAR 2 5 1997
REGION III

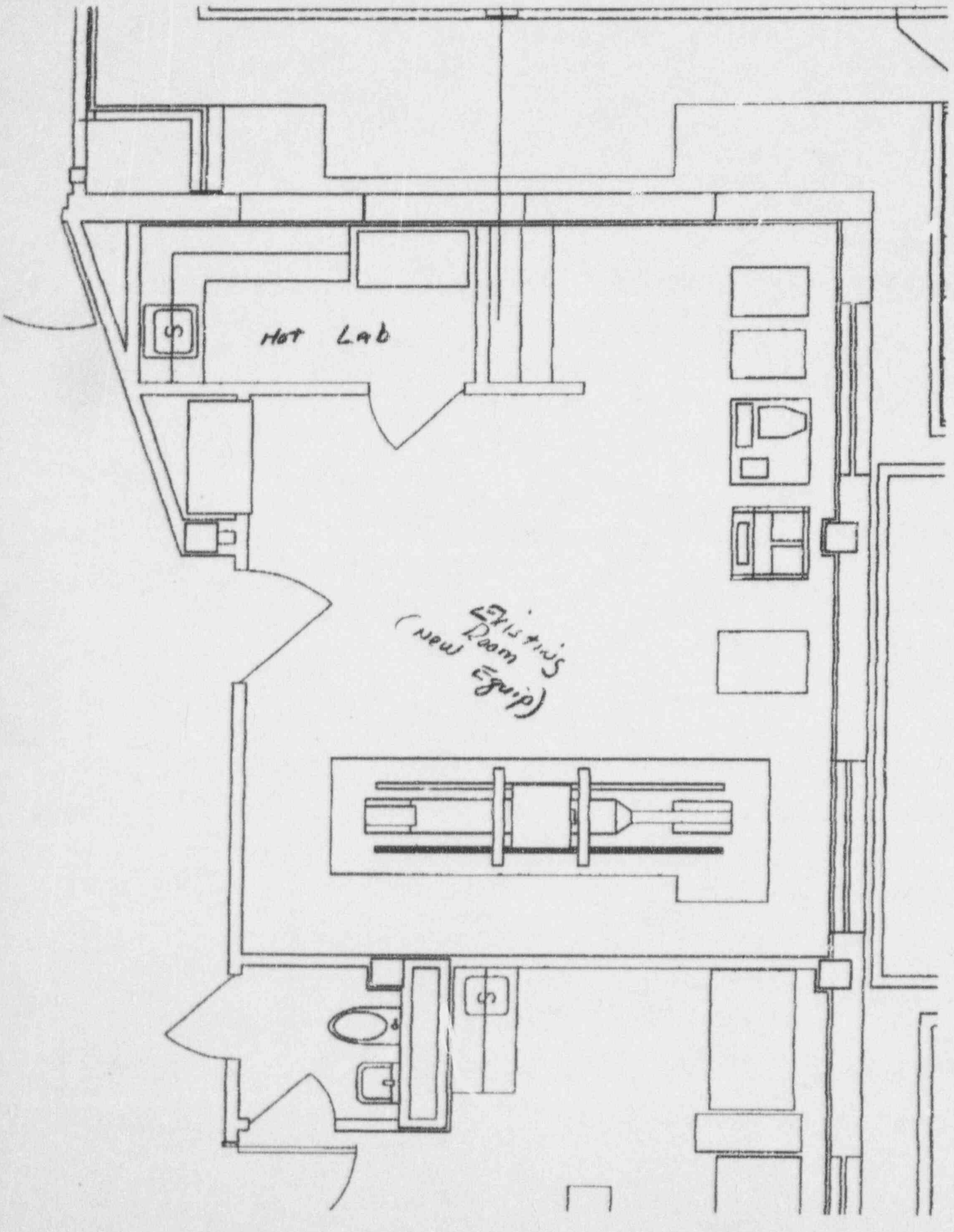
pm: 3-19-97

MAR 2 5 1997

1110 TENTH AVENUE • MENOMINEE, MICHIGAN 49858 • 906/863-5571

302460


S
Proposed
Add'l Room


Hot Lab
Existing Room (new Equip)

MAY 3 0 1997

Rick Ament, CEO
Bay Area Medical Center
Marinette Facility
3100 Shore Drive
Marinette, WI 54143

Dear Mr. Ament:

Enclosed is Amendment No. 10 to your NRC Material License No. 48-25971-01 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 at (630) 829-9887 so that we can provide appropriate corrections and answers.

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

302460

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 Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC

requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Gidget Watson
Nuclear Materials Licensing Branch

License No. 48-25971-01
Docket No. 030-30818

Enclosure: Amendment No. 10

DOCUMENT NAME: M:\03030818.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									
NAME	GWatson:brt									
DATE	05/28/97									

OFFICIAL RECORD COPY

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

March 28, 1997

Thomas M. Gates, M.D.
Radiation Safety Officer
Bay Area Medical Center
Marinette Facility
3100 Shore Drive
Marinette, WI 54143

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 02/28/97)

Dear Licensee:

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

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

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

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

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

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

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

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

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

Nuclear Materials Support Branch

Mail Control No. 302460
License No. 48-25971-01

CONVERSATION RECORD

TIME | DATE 5/28/97

O VISIT O CONFERENCE X TELEPHONE

X INCOMING
O OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT | ORGANIZATION (OFFICE, DEPT.ETC.) | TELEPHONE NO.

Kris Monson, Supervisor, Nuclear Medicine Bay Area Medical Center
715/735-4200

SUBJECT

License No. 48-25971-01

SUMMARY

I requested the following additional information in regards to amendment request dated 2/28/97:

1. The number of ADAC Vantage Correction Systems requested? **1**

2. I informed Mr. Monson that the Sealed Source and Device Registry only authorized 250 mCi per source.

3. The number of sources requested? **4: 2 sources for use and 2 sources for storage in shipping containers for source exchange.**

4. I inquired as to whether onsite training would be given. **Yes, by the manufacturer on the use and maintenance of the system. Mr. Monson also stated that only ADAC personnel will install or exchange the sources.**

5. I inquired as to whether or not the ADAC System would be used in the new imaging room. **No, only a gamma camera will be used in the imaging room.**

I informed Mr. Monson that the conversation would be documented and that a written response was not necessary.

ACTION REQUIRED

Juliet Watson 5/28/97

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE | DATE