NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION



# MATERIALS LICENSE

Amendment No. 03

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.

301697

| Licensee | |
|---|---|
| 1. Bloomfield Cardiology | In accordance with letters dated July 19, 1996 and September 16 and 23, 1996 |
| 2. 2520 S. Telegraph<br>Suite 105<br>Bloomfield Hills, MI 48302 | 3. License Number 21-26170-01 is amended in its entirety to read as follows: |
| | 4. Expiration Date July 31, 2000 |
| | 5. Docket or Reference No. 030-31656 |

| 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, aerosols and generators) | B. As needed |

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200 (excluding xenon-133, aerosols and generators).

## CONDITIONS

10. Location of use: 2520 S. Telegraph, Suite 105, Bloomfield Hills, Michigan.

11. Radiation Safety Officer: Lawrence G. Wayburn, M.D.

D/1

210076





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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-26170-01

Docket or Reference Number
030-31656

Amendment No. 03

12. Authorized Users:

A. Lawrence G. Wayburn, M.D., for material in 10 CFR 35.100 and 35.200 (excluding xenon-133, aerosols and generators).

B. Yash K. Shah, M.D., for material in 10 CFR 35.100 and 35.200 (excluding xenon-133, aerosols and generators).

13. The licensee is not required to have a Radiation Safety Committee described in 10 CFR 35.22. The Radiation Safety Officer may make radiation safety program changes permitted by 10 CFR 35.31 with the advise and consent of the licensee's management.

14. The licensee will establish and implement the model procedure for a multidose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2.

15. This license is based on the licensee's statements and representations listed below:

A. Application dated March 28, 1990; and

B. Letters dated May 17, 1990 (with attachments), July 19, 1996, September 16, 1996 and September 23, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 4 October 1996

By William P. Kriddold
Nuclear Materials Licensing Branch, Region III

COPY

S7

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02201
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 20000731
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: BLOOMFIELD CARDIOLOGY GROUP, P.C.
RECEIVED DATE: 960807
DOCKET NO: 3031656
CONTROL NO.: 301697
LICENSE NO.: 21-26170-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 440.00
CHECK NO.: 10734

3. COMMENTS

SIGNED
DATE 8/12/96

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 SC
DATE 8/14/96

1996 AUG 12 AM 8:59

RECEIVED
AUG 19 1996
REGION III

Log Aug 6 III
Remitter
Check No. 10734
Amount $440
Fee Category 7C
Type of Fee Amd
Date Check Rec'd 8/12/96
Date Completed 8/14/96
By: SC

AUG 19 1996

BLOOMFIELD CARDIOLOGY GROUP, P.C.
2520 S. TELEGRAPH
SUITE 105
BLOOMFIELD HILLS, MICHIGAN 48302

July 19, 1996

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

Subject: Request for Amendment to Bloomfield Cardiology License #21-26170-01

Dear Reviewer,

Please amend our NRC License (#21-26170-01) to update our Procedure for Calibrating the Dose Calibrator. See the Attachment for the revised procedure.

Also as a point of information, we replaced our Pho/Gamma scintillation Camera System with a General Electric SPECT camera. The partition between the Imaging Room and Exam Room was removed to allow adequate space for the SPECT camera, console and collimator stand.

The amendment fee (Category 7c) of $440.00 is included.

If you have any question or concerns, please contact me at (810) 645-2010.

Sincerely,

Charles G. Arminja, M.D., FACC
Physician - Owner

cc. Dr. Wayburn, RSO



PDR; 8-1-96

## ITEM 9.3 PROCEDURE FOR CALIBRATING THE DOSE CALIBRATOR

The following tests shall be performed at the indicated frequencies to verify proper calibration of the dose calibrator.

a. Constancy at least once each day prior to assay of patient dosages (±10%).

b. Linearity at installation, and at least quarterly thereafter (±10%). The assayed activities, exact date and exact time of measurement shall be forwarded to a certified or NRC approved medical physicist for evaluation and generation of the final report record.

c. Geometry dependence at installation (±10%).

d. Accuracy at installation and at least annually thereafter (±10%).

After repair, after being disconnected from electrical outlet for more than 24 hours, repeat the above tests as appropriate.

A. CONSTANCY means reproducibility in measuring a constant source over a long period of time. Assay a long-lived source of Cs-137.

Required Source - 50 microcurie or more of Cs-137

1. Check the background activity recorded on each of the reference source settings and adjust the reading to zero by removing extraneous sources of activity or dialing out background readings in excess of 1 microcurie.

2. Assay the reference source using the appropriate dose calibrator setting for Cs-137, Tc-99m and other commonly used radionuclide settings.

3. Record the results in the log book or on the daily record form.

4. Compare the recorded measurement of Cs-137 with the decay chart provided by the source manufacturer or calculated by a certified medical physicist. Any measurement greater than or less than 10% of chart value should be reported to the Radiation Safety Officer. NRC regulations require replacement or repair of the dose calibrator if the error exceeds 10 percent.

B. LINEARITY means that the dose calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done by using a unit dose syringe of Tc-99m whose initial activity is at least as large as the maximum activity normally assayed in the dose calibrator for preparation or administration of patient doses.

Required Source - Tc-99m activity at least as large as the maximum activity administered to a patient.

DECAY METHOD:

1. Assay the Tc-99m syringe or vial in the dose calibrator and subtract background to obtain the net activity in millicuries. Record the date, exact time to the nearest minutes, and net activity. This first assay should be performed as early in the work day as possible.

2. Repeat the assay at a minimum of two times each day for three days (a minimum of 2 hours between each reading) until the assay activity is less than 10 microcuries.

3. Submit the recorded data to a certified or NRC approved physicist for calculation and submission of the final report. The final report shall include, as a minimum, calculation of appropriate correction factors and the percent deviation of each assayed measurement from the expected value. Each report shall contain a recommendation statement.

SHIELD METHOD:

1. The Shield Method shall be initially calibrated and instituted simultaneous with performance of the linearity test using the Decay Method.

2. The manufacturer's instructions and reporting forms shall be utilized for performance and record keeping of these results. Only NRC approved manufacturers of attenuator sleeves for calibration of linearity of dose calibrator response shall be used.

C. ACCURACY:

Sources - Cs-137 dedicated source of at least 50 uCi and
Co-57 or Ba-133 dedicated source of at least 50 uCi

1. Assay the calibrated source on the appropriate setting.

2. Remove the source from the calibrator and measure the background reading on the same setting.

3. Subtract the background reading from the measured activity to obtain the net activity.

4. Repeat this procedure for the other calibrated sources.

D. GEOMETRY DEPENDENCE:

Sources - Tc-99m between 1 and 10 mCi/ml

Syringe Method - for all licensees

1. Draw 0.5 ml of Tc-99m liquid into a syringe of the size normally used for patient doses.

2. Place the syringe in the dose calibrator in a reproducible geometry.

3. Assay the syringe; record the measured value and the volume.

4. Draw an additional 0.5 ml of non-radioactive saline or water into the syringe. Special care must be taken that none of the original radioactive liquid is released from the syringe during the process.

5. Assay and record the measured value and volume.

6. Repeat this procedure until a volume of 2.0 ml has been assayed.

7. Select as a standard the volume that is closest to that used most frequently for patient doses.

8. Divide all measured valued by the standard activity. The quotient is the volume correction factor.

Vial Method - for using generators or radiopharmaceutical kits (<u>in addition</u> to the above method).

1. Begin the test with 1 ml of Tc-99m in a vial of the size most frequently used for elutions and kits.

2. Assay the vial and record the measured value and the volume.

3. Add 2.0 ml of non-radioactive saline or water to the vial.

4. Assay and record the measured activity and volume.

5. Repeat this procedure until a 19 ml volume has been assayed.

6. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits.

7. Divide all measured activities by the standard activity. This is the volume correction factor.

E. The Radiation Safety Officer must review and sign all of the above tests except the constancy tests.

<u>Action Levels</u>

Linearity or geometry errors in excess of 10% shall be mathematically corrected for in measurement of doses greater than 10 uCi.

Accuracy or constancy errors in excess of 10% shall be cause for repair or replacement of the dose calibrator.

OCT 0 4 1996

Charles G. Artinian, M.D., FACC
Bloomfield Cardiology
2520 S. Telegraph, Suite 105
Bloomfield Hills, MI 48302

Dear Dr. Artinian:

Enclosed is Amendment No. 03 to your NRC Material License No. 21-26170-01 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 we have extended the expiration date of the license for five years in accordance with the regulations (10 CFR 30.36).

Also note, we have removed the license condition requiring decommissioning records because this requirement is in the regulations.

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).

301697

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;

   b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;

   c. Change Radiation Safety Officers;

   d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   f. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements,

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

Sincerely,

Original Signed By
W. P. Reichhold
Nuclear Materials Licensing Branch

License No.: 21-26170-01
Docket No.: 030-031656

Enclosure: Amendment No. 03

DOCUMENT NAME: M:\0301656.CL6

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

| OFFICE | DNMS/RIII | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| NAME | WREICHHOLD:jaw | | | | | | | | | | | |
| DATE | 09/ /96 | | | | | | | | | | | |

OFFICIAL RECORD COPY

*Bloomfield Cardiology Group, P.C.*

CHARLES G. ARTINIAN, M.D., F.A.C.C. PATRICK D. POOLE, M.D., F.A.C.C.

2520 SOUTH TELEGRAPH, SUITE 105
BLOOMFIELD HILLS, MICHIGAN 48302
TEL. (810) 645-2010 or (810) 338-4177
FAX (810) 253-1606

September 23, 1996

Mr. Bill Reichhold
U.S. Nuclear Regulatoru Commission
Region III
Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

Subject: Correction to a Response Letter dated September 16, 1996

CONTROL NO:301697

Dear Mr. Reichhold,

The following is a correction to item number 2 of the letter we sent you September 16, 1996.

2. The records of checks and tests on the dose calibrator will be in accordance with 10 CFR Part 35.50(e),(1),(2),(3)and (4). Note that linearity will be tested consistent with 10CFR35.50(b)(3).

Please contact me at (810) 645-2010 if you have any further questions.

Sincerely,

Charles G. Artinian, M.D., F.A.C.C.
Physician - Owner

cc. Dr. Wayburn,RSO

RECEIVED
SEP 30 1996
REGION III

Pm: 9-26-96

SEP 30 1996

BLOOMFIELD CARDIOLOGY GROUP, P.C.
2520 S. TELEGRAPH
SUITE 105
BLOOMFIELD HILLS, MICHIGAN 48302

September 16, 1996

Mr. Bill Reichhold
U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

Subject: Response to Phone Conversation Record Dated September 5, 1996 Pertaining to the Request for Amendment to Bloomfield Cardiology License #21-26170-01

CONTROL NO: 301697

Dear Mr. Reichhold:

The following additional information is provided to complete the review of our amendment request.

1. The actual activities of our dose calibrator sources are within 5% of the activities stated on the sources.

2. The records of checks and tests on the dose calibrator will be in accordance with 10 CFR Part 35.50(e), (1), (2), (3) and (4). Note that linearity will be tested consistent with 10CFR35.5(b)(3).

3. An updated annotated drawing of our Nuclear Medicine facility is attached. The scale of the drawing is 1/4" = 1 foot. Medical office suites are located on the North and South Walls adjacent to our office suite. The East Wall is the outside wall to the building. The main corridor is located on the West Side of our office suite. All three entrances to our office suite are locked and secured when not in use. Radioactive materials are stored in the Hot Lab which is locked and secured when not in use.

Please contact me at (810) 645-2010 if you have any further questions.

Sincerely,

Charles G. Artinian, M.D., FACC
Physician - Owner

cc. Dr. Wayburn, RSO

FACILITY DIAGRAM: Bloomfield Cardiology Group, P.C.