



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
June 8, 2000

David Petrella, M.D.
Radiation Safety Officer
Mid-Michigan Radiology Associates, P.C.
211 S. Crapo Road
Suite F
Mt. Pleasant, MI 48858

Dear Dr. Petrella;

Enclosed is Amendment No. 03 to your NRC Material License No. 21-26346-01 in accordance with your request. Please note that the changes made to your license are printed in **bold** font.

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 at this time we updated and reformatted your license to conform with current NRC policies. These were administrative changes only that should have no effect on your license and they are described below.

We deleted former Condition No. 13, as it appeared on Amendment No. 02, because the regulations in 10 CFR 30.35(g) contain the same provisions, making the Condition unnecessary.

We updated Condition Nos. 12. and 14. and added a new Condition No. 13. Condition No. 13 was added to restrict your possession of licensed material, chiefly iodine-131 in 10 CFR 35.300, to quantities below the limits specified in 10 CFR 30.72 (ten curies for iodine-131), which would require consideration of the need for you to submit an emergency response plan for responding to a release of licensed material.

If you would prefer to have this Condition removed in a future amendment, you should specify the maximum activity of iodine-131 in 10 CFR 35.300 that you wish to possess, including waste activity, and your possession limit must be less than ten curies. Your proposed possession limit should also reflect a realistic quantity of iodine-131 that you could possess at any one time.

In addition, we approved Roger W. Hynes, M.D. as an authorized user and deleted Drs. Boss and Scherock as authorized users in accordance with your letter dated December 23, 1998.

Please note that at this time we were unable to approve your request to inject radioactive drugs at remote sites because the information submitted in your letter dated March 13, 2000, was insufficient for us to complete our review.

If you wish to pursue this authorization please address the information requested in the Enclosure and submit it to us as "additional information to Control No. 306237." We will then

continue our review. Be advised that if you request anything other than this authorization, a separate amendment may be required to permit each requested action a timely review.

If you have any questions concerning this amendment please contact me at either (800) 522-3025 or (630) 829-9841.

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.
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 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,

/RA/

Colleen C. Casey
Materials Licensing Branch

License No. 21-26346-01
Docket No. 030-32468

Enclosures:

1. Amendment No. 03
2. Enclosure - Remote Site Injections
3. 10 CFR Part 19
4. 10 CFR Part 20
5. 10 CFR Part 30
5. 10 CFR Part 35
6. 10 CFR Part 71

ENCLOSURE - REMOTE SITE INJECTIONS

Your request to inject radioactive drugs at physician's offices remotely located from your address of use was not approved. Please submit the following information, commitments and clarifications:

1. Please justify why this authorization is necessary. If patient care will benefit from this authorization, please so state and briefly explain why.
2. Please state whether you will be providing remote site injections at physicians' offices already subject to another NRC license for human use and, if so, explain how you will comply with 10 CFR 35.29(c).
3. Please indicate where the physician's offices are located where the patients to be injected are being stressed for cardiac studies, such as an approximate radius from your present location of use. Please state whether these patients will subsequently be imaged at your address of use. If they will not, please explain why and justify why another licensee would be imaging these patients.
4. Please describe in greater detail how your proposed remote site injection program would work, beginning with dose ordering, receipt and preparation, through transport and administration and concluding with waste disposal.
5. Please provide us with copies of letters signed by the management of each physician's office for whom remote site injection services will be rendered initially, that authorizes the use of byproduct material, limited to injections only, at the physician's office - "address of use." (After you submit these letters and your remote-site injection program is approved and operational, you may keep on file records of letter from newly acquired client/physicians, i.e., you do not need to request an amendment for new clients to be added for this service).

Please note that we are asking for these specific commitments because your request for remote-site injections is very similar to a request to provide mobile nuclear medicine services, except that you will not be performing remote-site imaging as well and you will be conducting these injections at physicians' offices, not hospitals.

6. Please confirm that you will comply with the requirements for transporting radioactive materials in 10 CFR 71.5, enclosed. Please do not submit specific transportation procedures and sample shipping papers.
7. Please confirm that you will comply with the requirements in 10 CFR 35.29(a), 35.29(b), 35.29(c) and 35.29(d). Please confirm that you will comply with the requirements in 10 CFR 35.80(b), 35.80(c), 35.80(d) (limited to survey instruments), 35.80(e) and 35.80(f). A copy of 10 CFR Part 35 is enclosed for your use.

8. Please confirm that you will limit the byproduct materials to be injected at remote sites to only technetium-99m labeled radioactive drugs for diagnostic purposes, i.e., no multi-dose vials or radioiodines will be transported off-site.
9. Please confirm that all other appropriate radiation safety procedures in 10 CFR Parts 19, 20, 30 and 35 of the regulations and in your license, including commitments and representations made in correspondence, will be followed for the remote-site injection program. These procedures should include, but not be limited to, wearing disposable gloves and protective garments during injections, using syringe shields and syringe labels, implementation of emergency procedures and having a calibrated survey instrument accompany each shipment.
10. Please confirm that you will only transport byproduct material for the remote-site injection program that is in the form of a prepared unit dose and is assayed in a calibrated dose calibrator prior to preparation for shipment.

Please confirm that you will not utilize multi-dose vials from which volumetrically calculated unit doses are prepared after transport to the remote sites.

11. Please confirm that the spill procedures in item no. 10.4 of your application dated August 1, 1991, will be followed in the event of a spill of licensed material at a remote-site location of use.
12.
 - a. Please confirm that all vehicles used to transport licensed materials will be surveyed via wipe tests and direct dose rate surveys at least once each week in which materials were transported in addition to release for unrestricted use, repairs, etc.

In the alternative, please confirm that each vehicle used for the transport of licensed materials will be surveyed after each remote-site transportation/injection or at the conclusion of each day's transport activities.
 - b. Please confirm that records of the vehicle surveys will be maintained for inspection purposes and that they will include the identity of the vehicle, the identity of the surveyor, the date, the identity of the survey instrument used, the background radiation measurement and the survey results measurements.
 - c. Please confirm that any contamination identified will be remediated and the contaminated area resurveyed prior to releasing the vehicle for unrestricted use.

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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	In accordance with letter dated December 23, 1998,
1. Mid-Michigan Radiology Associates, P.C.	3. License number 21-26346-01 is amended in its entirety to read as follows:
2. 211 S. Crapo Road Suite F Mt. Pleasant, MI 48858	4. Expiration date November 30, 2001
	5. Docket No. 030-32468 Reference No.

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 generators and xenon-133)	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300 (excluding iodine-131 for thyroid carcinoma)	C. As needed

9. Authorized Use:
- A. Medical use described in 10 CFR 35.100.
 - B. Medical use described in 10 CFR 35.200 (excluding generators and xenon-133).
 - C. Medical use described in 10 CFR 35.300 (excluding iodine-131 for thyroid carcinoma).

CONDITIONS

- 10. Location of use: 211 S. Crapo Road, Suite F, Mt. Pleasant, Michigan 48858.
- 11. Radiation Safety Officer: David Petrella, 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. David Petrella, M.D. | 10 CFR 35.100, 35.200 (excluding generators and xenon-133), and 35.300 (excluding iodine-131 for thyroid carcinoma). |
| B. Johannes J.. Buitewig, M.D. | 10 CFR 35.100, 35.200 (excluding generators and xenon-133), and 35.300 (excluding iodine-131 for thyroid carcinoma). |
| C. Alfredo P. De La Fe, M.D. | 10 CFR 35.100, 35.200 (excluding generators and xenon-133), and 35.300 (excluding iodine-131 for thyroid carcinoma). |
| D. Roger W. Hynes, M.D. | 10 CFR 35.100, 35.200 (excluding generators and xenon-133), and 35.300 (excluding iodine-131 for thyroid carcinoma). |

13. In addition to the possession limits in Item 8.C., 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.

14. 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 August 1, 1991; and
 B. Letter dated October 21, 1991.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

/RA/

Date June 8, 2000

By _____
 Colleen C. Casey
 Materials Licensing Branch
 Region III