



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

March 29, 2005

Docket No. 03033672
Control No. 135906

License No. 29-30177-01

Peter M. Mezzacappa, M.D.
Director/Radiation Safety Officer
X-Ray Associates, P.A.
19 Mule Road
Toms River, NJ 08757

SUBJECT: X-RAY ASSOCIATES, P.A., ISSUANCE OF LICENSE RENEWAL, CONTROL
NO. 135906

Dear Dr. Mezzacappa:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the renewed license. Please note that your license was written in a format compatible with the revised 10 CFR Part 35, dated April 24, 2002. Also note that Mario Arredondo, M.D. and Janet Spector, M.D. have not been authorized for all of the procedures permitted by 10 CFR 35.300 because your license is more restrictive. Further, Jeffrey Friedenber, M.D. was not added to the license because he is not listed as an authorized user on NRC License No. 29-14966-01. You may resubmit Dr. Friedenber for consideration as an authorized user without prejudice by providing additional information about his training and experience. 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 I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. Please note that the last condition on your license indicates that "This license condition applies only to those procedures that are required to be submitted in accordance with the regulations." Therefore, any procedures submitted that were not required by regulation to be submitted, e.g., calibration of dose calibrators, will not be considered a part of your license and were not reviewed during the licensing process. These procedures will be reviewed during inspections, as necessary.

Please 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 the NRC in writing when:

- a) an authorized user, authorized nuclear pharmacist, authorized medical physicist or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;
 - b) the mailing address changes;
 - c) the name on the license changes; or
 - d) permitting an individual to function as a temporary Radiation Safety Officer in accordance with 10 CFR 35.24(c).
3. In accordance with 10 CFR 30.36(d), notify the 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) permanently change Radiation Safety Officers;
 - b) receive byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license; or
 - c) add or change the areas of use, except as allowed by 10 CFR 35.13(e) and with the appropriate notification described in 10 CFR 35.14(b)(4);
 - d) change the name or ownership of your organization;
 - e) change the address(es) of use identified on the license;
 - f) receive, prepare, or use byproduct material for a type of use that is not authorized on the license;
 - g) permit anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist, except as allowed by 10 CFR 35.13(b) and with the appropriate notification described in 10 CFR 35.14(a); or
 - h) revise procedures required by 10 CFR 35.610, 35.642, 35.643, or 35.645, as applicable, where such revision reduces radiation safety.
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.

P. Mezzacappa
X-Ray Associates, P.A.

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In addition, please note that NRC Form 313 requires the applicant, by 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 a certifying official of the licensee rather than a consultant.

You will be periodically inspected by the 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 NUREG-1600, "General Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy).

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are available at the NRC Web sites listed below or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Steven Courtemanche

Steven Courtemanche
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 6

NRC Web site addresses

NRC regulations

<http://www.nrc.gov/reading-rm/doc-collections/cfr/>

Licensing guidance

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>

General Policy and Procedure for NRC Enforcement Actions

<Http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf>

206 of the Energy Reorganization Act of 1974

<http://www.nrc.gov/who-we-are/governing-laws.html>

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| OFFICE | DNMS/RI | <input checked="" type="checkbox"/> N | DNMS/RI | <input type="checkbox"/> | DNMS/RI | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| NAME | SCourtemanche/src | | | | | | | |
| DATE | 03/29/2005 | | | | | | | |

OFFICIAL RECORD COPY

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.

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| <p style="text-align: center;">Licensee</p> <p>1. X-Ray Associates, P.A.</p> <p>2. 19 Mule Road Toms River, New Jersey 08757</p> | <p>In accordance with the applications dated October 8, 2004, and March 21, 2005,</p> <p>3. License number 29-30177-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date March 31, 2015</p> <hr/> <p>5. Docket No. 030-33672 Reference No.</p> |
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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. I-131 permitted by 10 CFR 35.300</p> <p>D. Strontium 89 permitted by 10 CFR 35.300</p> <p>E. Samarium 153 permitted by 10 CFR 35.300</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 100 millicuries</p> <p>D. 100 millicuries</p> <p>E. 100 millicuries</p> |
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9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.

B. Any imaging and localization study permitted by 10 CFR 35.200.

C. through E. Any imaging and localization study or therapy procedure permitted by 10 CFR 35.300, except thyroid carcinoma, for which the patient can be released under the provisions of 10 CFR 35.75.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
29-30177-01

Docket or Reference Number
030-33672

Amendment No. 6

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 19 Mule Road, Toms River, New Jersey.
11. The Radiation Safety Officer for this license is Peter M. Mezzacappa, M.D.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

Authorized Users

Material and Use

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|----------------------------|--|
| Peter M. Mezzacappa, M.D. | 35.100; 35.200; 35.300, except thyroid carcinoma |
| Jeffrey Chahal, M.D. | 35.100; 35.200 |
| Barry Friedenber, M.D. | 35.100; 35.200 |
| Kee Seon Kang, M.D. | 35.100; 35.200 |
| Ann M. Hughes, M.D. | 35.100; 35.200 |
| C. Stephen Keklak, M.D. | 35.100; 35.200 |
| Carlo L. Rondina, M.D. | 35.100; 35.200; 35.300, except thyroid carcinoma |
| Howard Rosenstein, M.D. | 35.100; 35.200; 35.300, except thyroid carcinoma |
| Stanley Rich, M.D. | 35.100; 35.200 |
| Beatrice Symchowicz, M.D. | 35.100; 35.200 |
| Debra M. Loeb, M.D. | 35.100; 35.200 |
| Kenneth R. Tomkovich, M.D. | 35.100; 35.200 |
| Kenneth Romano, M.D. | 35.100; 35.200 |
| Peter Kouveliotis, M.D. | 35.100; 35.200 |
| Mario Arredondo, M.D. | 35.100; 35.200; 35.300 except thyroid carcinoma |
| Janet Spector, M.D. | 35.100; 35.200; 35.300 except thyroid carcinoma |

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
29-30177-01Docket or Reference Number
030-33672

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13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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 March 21, 2005



For the U.S. Nuclear Regulatory Commission

Date March 29, 2005

By *Original signed by Steven Courtemanche*
Steven Courtemanche
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406