



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

August 8, 2008

Docket No. 03037158
Control No. 142612

License No. 52-31137-01

Tomas Irizarry, M.D.
Owner
Imagia Corporation
105 Mendez Vigo
Mayaguez, PR 00680

SUBJECT: IMAGIA CORPORATION, LICENSE RENEWAL, CONTROL NO. 142612

Dear Dr. Irizarry:

This refers to your request for renewal of your NRC license as discussed between you and Lizette Roldan, Ph.D. of our staff on July 2, 2008. Enclosed with this letter is the renewed license. 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.

During the discussion between you and Dr. Roldan, she indicated that a corrected copy would be issued for the full ten-year term resulting in an expiration date of June 30, 2016. After a review of all pertinent documents, it was determined that the license reviewers responsible for issuing your license followed all of the proper procedures. Specifically, a license issued for "installation and storage only" is given a two-year term to allow the licensee time to obtain the licensed material and training necessary to operate a safe licensed program. Based on Dr. Roldan's inspection and your continuing construction problems, the Commission has opted to extend your license for a one-year term. In order to fully activate your license and begin nuclear medicine procedures, you must request an amendment to your license after having the required training from the manufacturer in the use of the patient attenuation device and receive the amended license from the Commission.

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
 - a) when you decide to terminate all activities involving materials authorized under the license; or
 - b) if you decide not to acquire or possess and use authorized material.
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;
 - 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.

You will be periodically inspected by the NRC. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and the 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, imposition of a civil penalty, or an order suspending, modifying or revoking your license.

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 included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Steve Courtemanche

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

Enclosure
Amendment No. 1

cc:
David Rhoe, Ph.D., Radiation Safety Officer

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