TRANSMISSION VERIFICATION REPORT

TIME : 05/28/2014 21:36
NAME : USNRC REGION3 DNMS
FAX : 6305151259
TEL :
SER.# : 000A7J925770

DATE,TIME	05/28 21:33
FAX NO./NAME	13138752924
DURATION	00:02:37
PAGE(S)	13
RESULT	OK
MODE	STANDARD ECM

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

TELEFAX TRANSMITTAL

DATE May 29, 2014 NUMBER OF PAGES 13

SEND TO Avinash Rachmale - Lakeshore Global Corporation regarding Chapter 7 Bankruptcy- Lakeshore Toltest Corporation (LTC), NRC License 34-35052-01

LOCATION Highland Park, Michigan

FAX NUMBER (313) 875-2924

☑ VERIFY BY CALLING
Rec'd 5/29/14
Avinash Rachmale

FROM: Bill Reichhold
(Sender)

TELEPHONE NUMBER (630) 829-9839 FAX NUMBER (630) 515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE See accompanying documents.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
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2443 WARRENVILLE ROAD, SUITE 210
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NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank You.

It has come to our attention that Lakeshore Toltest Corporation (LTC), (Lakeshore) as filed for bankruptcy protection. NRC requirements for licensees that are the subject of a bankruptcy filing can be found in 10 CFR (U.S. Code of Federal Regulations) 30.34(h). The purpose of the regulations is to ensure that public health and safety and the environment are adequately protected and that radioactive material is properly controlled. (Please see accompanying copy of 30.34 (h)).

As a former board member of Lakeshore, please be advised you need to make sure that the radioactive materials authorized on Lakeshore's specific NRC license (NRC License 34-35052-01) and radioactive materials obtained under a general license must be controlled; (1) to prevent removal of the radioactive materials by unauthorized individuals, (2) to prevent access to radioactive materials by unauthorized individuals and (3) that the radioactive materials are in secure storage at this time. Also, make sure you comply with applicable NRC requirements.

Lakeshore's specific NRC license (NRC License 34-35052-01) authorizes radium-266 as a sealed source, not to exceed 5.5 millicuires per source, for use in Seamen Nuclear Corporation Model Nos. C-200 and C-300 portable gauging devices (moisture/density gauges). The last NRC inspection on January 2014, indicated that Lakeshore had two, Seamen Nuclear Corporation moisture/density gauges in storage at Lakeshore's offices located at 385 Midland, Highland Park, Michigan. A copy of the Lakeshore's NRC specific license can be found electronically in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Our records indicate that Lakeshore also has the following generally licensed devices:

1. Niton Corporation, Model XLP Series X-ray analyzer containing a nominal 4.5 microcuries of americium-241 as a sealed source, and

2. Niton Corporation, Model XLP Series X-ray analyzer containing a nominal 40 millicuries of cadmium-109 as a sealed source.

From our telephone discussion yesterday 28 May 2014, it is our understanding that radioactive materials and/or devices containing radioactive materials authorized on Lakeshore's NRC specific license and general license are secured from unauthorized access, unauthorized removal, and unauthorized use in the facilities at 385 Midland, Highland Park, Michigan. If your understanding is different from the above, please immediately contact Bill Reichhold at 630-829-9839.

Also, please provide the following additional information:

1. Please identify what radioactive materials and/or devices containing radioactive materials are possessed at the facilities at 385 Midland, Highland Park, Michigan.

2. Please specify any other companies affiliated with Lakeshore that may also have radionuclides that require an NRC license. If so what radionuclides do they possess and specify the license number and location of the company.

3. Please confirm that you will be the contact person for information regarding that status of the nuclear gauges/devices at the facilities at 385 Midland, Highland Park, Michigan. Please make sure you immediately contact the NRC of any change in status of use, security and/or storage of the radionuclides and any change in the individual(s) responsible for the radionuclides.

4. As we discussed by telephone on 28 May 2014, it is our understanding that Lakeshore Global Corporation may be interested in purchasing the Seamen Nuclear Corporation Model Nos. C-200 and C-300 portable gauging devices (moisture/density gauges). You can find a copy of the guidance document NUREG-1446, Volume 1, Revision 1 for completing an application for portable moisture/density gauges on the NRC website at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v1/r1/. I have also attached a copy of the application form and a copy of the application checklist for your review. Please also contact fees on the NRC website at http://www.nrc.gov/about-nrc/regulatory/licensing/fees.html.

Please send a facsimile (630- 515-1078) of your response to the above as soon as possible. Please call me at 630-829-9839 if you have any questions.
Please call me at 630-829-9839 if you have any questions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this facsimile and the attached documents will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

From the desk of:
Bill Reichhold
Bill Reichhold

NRC FORM 313 (03-2014) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 05/31/2015**

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- ☐ A. NEW LICENSE
- ☐ B. AMENDMENT TO LICENSE NUMBER _____
- ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

BUSINESS TELEPHONE NUMBER

BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS EMAIL ADDRESS

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY _____ AMOUNT ENCLOSED $ _____

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A C RIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE

SIGNATURE

DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

Appendix B

Suggested Format for Providing Information Requested in Items 5 through 11

ITEMS 5 AND 6: MATERIALS TO BE POSSESSED AND PROPOSED USES

Yes	No	Radioisotope	Manufacturer or Distributor Model No.	Quantity	Use As Listed on SSD Certificate	Specify Other Uses Not Listed on SSD Certificate
		Cesium-137	Sealed source manufacturer or distributor and model number: _____ Device manufacturer or distributor and model number: _____	Not to exceed either the maximum activity per source or maximum activity per device as specified in Sealed Source and Device Registration Certificate	Yes ❒ Specific description of the gauge use: _____	❒ Not applicable _____ ❒ Uses are: _____ (Submit safety analysis supporting safe use)
		Americium-241	Sealed source manufacturer or distributor and model number: _____ Device manufacturer or distributor and model number: _____	Not to exceed either the maximum activity per source or maximum activity per device as specified in Sealed Source and Device Registration Certificate	Yes ❒ Specific description of the gauge use: _____	❒ Not applicable _____ ❒ Uses are: _____ (Submit safety analysis supporting safe use)

Yes	No	Radioisotope	Manufacturer or Distributor Model No.	Quantity	Use As Listed on SSD Certificate	Specify Other Uses Not Listed on SSD Certificate
		Californium-252	Sealed source manufacturer or distributor and model number: _____ Device manufacturer or distributor and model number: _____	Not to exceed either the maximum activity per source or maximum activity per device as specified in Sealed Source and Device Registration Certificate	Yes ❒ Specific description of the gauge use: _____	❒ Not applicable _____ ❒ Uses are: _____ (Submit safety analysis supporting safe use)
		Other Isotope (Specify):	Sealed source manufacturer or distributor and model number: _____ Device manufacturer or distributor and model number: _____	Not to exceed either the maximum activity per source or maximum activity per device as specified in Sealed Source and Device Registration Certificate	Yes ❒ Specific description of the gauge use: _____	❒ Not applicable _____ ❒ Uses are: _____ (Submit safety analysis supporting safe use)
		Financial Assurance Required and Evidence of Financial Assurance Provided				

ITEMS 7 THROUGH 11: TRAINING AND EXPERIENCE, FACILITIES AND EQUIPMENT, RADIATION SAFETY PROGRAM, AND WASTE DISPOSAL

Item No. And Title	Suggested Response	Yes	Alternative Procedures Attached
7. **INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE – RADIATION SAFETY OFFICER** Name:_____	Before obtaining licensed materials, the proposed RSO will have successfully completed one of the training courses described in Criteria in the section entitled "Individual(s) Responsible for Radiation Safety Program and Their Training and Experience – Radiation Safety Officer" in NUREG-1556, Vol. 1, Rev. 1, dated November 2001.	❒	❒
8. **TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS**	Before using licensed materials, authorized users will have successfully completed one of the training course described in Criteria in the section entitled "Training for Individuals Working In or Frequenting Restricted Areas" in NUREG-1556, Vol. 1, Rev 1, dated November 2001.	❒	❒
9. **FACILITIES AND EQUIPMENT**	No information needs to be submitted in response to this item; key issues are addressed under "Radiation Safety Program – Public Dose" and "Radiation Safety Program – Operating and Emergency Procedures."	**Separate Item 9 Response** **Need Not Be Submitted With Application**	
10. **RADIATION SAFETY PROGRAM – AUDIT PROGRAM**	The applicant is *not* required to, and should not, submit its audit program to NRC for review during the licensing phase.	**Need Not Be Submitted With Application**	
10. **RADIATION SAFETY PROGRAM – TERMINATION OF ACTIVITIES**	The applicant is *not* required to submit a response to the termination of activities section during the initial application. However, when the license expires when the licensee ceases operation, NRC Form 314 must be submitted.	**Need Not Be Submitted With Application**	
10. **RADIATION SAFETY PROGRAM – SURVEY INSTRUMENTS**	We will either possess and use, or have access to and use, a radiation survey meter that meets the Criteria in the section entitled "Radiation Safety Program – Instruments" in NUREG-1556, Vol. 1, Rev. 1, dated November 2001.	❒	❒

Item No. And Title	Suggested Response	Yes	Alternative Procedures Attached
10. RADIATION SAFETY PROGRAM – MATERIAL RECEIPT AND ACCOUNTABILITY	Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.	❐	❐
10. RADIATION SAFETY PROGRAM – OCCUPATIONAL DOSIMETRY	Either we will maintain, for inspection by NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20, or we will provide dosimetry processed and evaluated by an NVLAP-approved processor that is exchanged at a frequency recommended by the processor.	❐	❐
10. RADIATION SAFETY PROGRAM – PUBLIC DOSE	The applicant is *not* required to submit a response to the public dose section during the licensing phase. This matter will be examined during an inspection.	**Need Not Be Submitted With Application**	
10. RADIATION SAFETY PROGRAM – OPERATING AND EMERGENCY PROCEDURES	We will implement and maintain the operating and emergency procedures in Appendix H of NUREG-1556, Vol. 1, Rev. 1, dated November 2001, and provide copies of these procedures to all gauge users and at each job site. **OR** Operating and emergency procedures will be developed, implemented, and maintained and will meet the criteria in the section entitled "Radiation Safety Program – Operating and Emergency Procedures" in NUREG-1556, Vol. 1, Rev. 1, dated November 2001.	❐ ❐	❐
10. RADIATION SAFETY PROGRAM – LEAK TEST	Leak tests will be performed at intervals approved by NRC or an Agreement Sate and specified in the Sealed Source and Device Registration Sheet. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services for other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the kit supplier's instructions.	❐	❐ **The information in Appendix J supporting a request to perform leak testing and sample analysis is attached.**

Item No. And Title	Suggested Response	Yes	Alternative Procedures Attached
10. RADIATION SAFETY PROGRAM – MAINTENANCE	*Routine Cleaning and Lubrication* We will implement and maintain procedures for routine maintenance of our gauges according to each manufacturer's recommendations and instructions.	❒	❒
	Non-Routine Maintenance We will send the gauge to the manufacturer or other person authorized by NRC or an Agreement State to perform non-routine maintenance or repair operations that require the removal of the source or source rod from the gauge.	❒	❒ **The information listed in Appendix G supporting a request to perform non-routine maintenance in-house is attached.**
10.RADIATION SAFETY PROGRAM – TRANSPORTATION	The applicant is *not* required to submit its response to transportation during the licensing process. However, this issue will be reviewed during inspection.	**Need Not Be Submitted With Application**	
11. WASTE MANAGEMENT – GAUGE DISPOSAL AND TRANSFER	The applicant is *not* required to submit a response to waste management during the licensing process. However, the licensee should develop, implement, and maintain gauge transfer and disposal procedures in its radiation protection program.	**Need Not Be Submitted With Application**	

30.34 Terms and conditions of licenses

(a) Each license issued pursuant to the regulations in this part and the regulations in parts 31 through 36 and 39 of this chapter shall be subject to all the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Commission.

(b)(1) No license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

(2) An application for transfer of license must include:

(i) The identity, technical and financial qualifications of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by § 30.35.

(c) Each person licensed by the Commission pursuant to the regulations in this part and parts 31 through 36 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part and parts 31 through 36 and 39 of this chapter shall carry with it the right to receive, acquire, own, and possess byproduct material. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of part 71 of this chapter.

(d) Each license issued pursuant to the regulations in this part and parts 31 through 36 and 39 shall be deemed to contain the provisions set forth in section 183b.- d., inclusive, of the Act, whether or not these provisions are expressly set forth in the license.

(e) The Commission may incorporate, in any license issued pursuant to the regulations in this part and parts 31 through 36 and 39, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of byproduct material as it deems appropriate or necessary in order to:

(1) Promote the common defense and security;

(2) Protect health or to minimize danger to life or property;

(3) Protect restricted data;

(4) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

(f) Licensees required to submit emergency plans by § 30.32(i) shall follow the emergency plan approved by the Commission. The licensee may change the approved without Commission approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the appropriate NRC Regional Office specified in § 30.6 and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Commission.

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with § 35.204 of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

(h)(1) Each general licensee that is required to register by § 31.5(c)(13) of this chapter and each specific licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against:

(i) The licensee;

(ii) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(2) This notification must indicate:

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of the filing of the petition.

(i) Security requirements for portable gauges.

Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(j)(1) Authorization under § 30.32(j) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in § 32.72(a)(4) of this chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in § 32.72(c) of this chapter.

(3) A licensee that is a pharmacy authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in § 32.72(b)(2) of this chapter, or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter.

(4) A pharmacy, authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of § 32.72(b)(5) of this chapter.

(k) As required by the Additional Protocol, each specific licensee authorized to possess and use byproduct material shall file with the Commission location information described in § 75.11 of this chapter on DOC/NRC Forms AP–1 and associated forms. The licensee shall also permit verification of this information by the International Atomic Energy Agency (IAEA) and shall take other action as may be necessary to implement the US/IAEA Safeguards Agreement, as described in part 75 of this chapter.

(l) Each licensee shall ensure that Safeguards Information is protected against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.23 of this chapter, as applicable.

[30 FR 8185, June 26, 1965, as amended at 38 FR 33969, Dec. 10, 1973; 43 FR 6922, Feb. 17, 1978; 48 FR 32328, July 15, 1983; 52 FR 1295, Jan. 12, 1987; 52 FR 8241, Mar. 17, 1987; 53 FR 19245, May 27, 1988; 53 FR 23383, June 22, 1988; 54 FR 14061, Apr. 7, 1989; 58 FR 7736, Feb. 9, 1993; 59 FR 61780, Dec. 2, 1994; 65 FR 79187, Dec. 18, 2000; 70 FR 2009, Jan. 12, 2005; 72 FR 55926, Oct. 1, 2007; 73 FR 78604, Dec. 23, 2008; 74 FR 7785, Feb. 20, 2009; 76 FR 35564, Jun. 17, 2011; 77 FR 39905, Jul. 6, 2012]

30.34 Terms and conditions of licenses

TOP

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(b)(1) No license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

(2) An application for transfer of license must include:

(i) The identity, technical and financial qualifications of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by § 30.35.

(c) Each person licensed by the Commission pursuant to the regulations in this part and parts 31 through 36 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part and parts 31 through 36 and 39 of this chapter shall carry with it the right to receive, acquire, own, and possess byproduct material. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of part 71 of this chapter.

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(e) The Commission may incorporate, in any license issued pursuant to the regulations in this part and parts 31 through 36 and 39, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of byproduct material as it deems appropriate or necessary in order to:

(1) Promote the common defense and security;

(2) Protect health or to minimize danger to life or property;

(3) Protect restricted data;

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(f) Licensees required to submit emergency plans by § 30.32(i) shall follow the emergency plan approved by the Commission. The licensee may change the approved without Commission approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the appropriate NRC Regional Office specified in § 30.6 and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Commission.

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with § 35.204 of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

(h)(1) Each general licensee that is required to register by § 31.5(c)(13) of this chapter and each specific licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against:

(i) The licensee;

(ii) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(2) This notification must indicate:

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of the filing of the petition.

(i) Security requirements for portable gauges.

Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(j)(1) Authorization under § 30.32(j) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in § 32.72(a)(4) of this chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in § 32.72(c) of this chapter.

(3) A licensee that is a pharmacy authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in § 32.72(b)(2) of this chapter, or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter.

(4) A pharmacy, authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of § 32.72(b)(5) of this chapter.

(k) As required by the Additional Protocol, each specific licensee authorized to possess and use byproduct material shall file with the Commission location information described in § 75.11 of this chapter on DOC/NRC Forms AP–1 and associated forms. The licensee shall also permit verification of this information by the International Atomic Energy Agency (IAEA) and shall take other action as may be necessary to implement the US/IAEA Safeguards Agreement, as described in part 75 of this chapter.

(l) Each licensee shall ensure that Safeguards Information is protected against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.23 of this chapter, as applicable.

[30 FR 8185, June 26, 1965, as amended at 38 FR 33969, Dec. 10, 1973; 43 FR 6922, Feb. 17, 1978; 48 FR 32328, July 15, 1983; 52 FR 1295, Jan. 12, 1987; 52 FR 8241, Mar. 17, 1987; 53 FR 19245, May 27, 1988; 53 FR 23383, June 22, 1988; 54 FR 14061, Apr. 7, 1989; 58 FR 7736, Feb. 9, 1993; 59 FR 61780, Dec. 2, 1994; 65 FR 79187, Dec. 18, 2000; 70 FR 2009, Jan. 12, 2005; 72 FR 55926, Oct. 1, 2007; 73 FR 78604, Dec. 23, 2008; 74 FR 7785, Feb. 20, 2009; 76 FR 35564, Jun. 17, 2011; 77 FR 39905, Jul. 6, 2012]

NRC FORM 313 (03-2014) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 05/31/2015**

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- ☐ A. NEW LICENSE
- ☐ B. AMENDMENT TO LICENSE NUMBER _____
- ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

BUSINESS TELEPHONE NUMBER | BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS EMAIL ADDRESS

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY _____ AMOUNT ENCLOSED $ _____

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A C RIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE | SIGNATURE | DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	