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.

302576

Licensee	
1. Mohamad S. Kassir, M.D.	In accordance with letter dated April 24, 1997 3. License Number 34-26383-01 is amended in its entirety to read as follows:
2. 1330 Timkin Mercy Drive, N.W. Suite 200 Canton, OH 44708	4. Expiration Date November 30, 2002
	5. Docket or Reference No. 030-32947

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 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 and generators) limited to cardiovascular clinical procedures.

CONDITIONS

10. Location of use: 1330 Timkin Mercy Drive, N.W., Suite 200, Canton, Ohio.

11. Radiation Safety Officer: Mohamad S. Kassir, M.D.

12. Authorized User 120115 — Material and Use

A. Mohamad S. Kassir, M.D. — 10 CFR 35.100 and 35.200 (excluding xenon-133 and generators), limited to cardiovascular clinical procedures.

COPY

9706120357 970520
PDR ADOCK 03032947
C PDR

Printed on recycled paper

License Number
34-26383-01

Docket or Reference Number
030-32947

Amendment No. 03

MATERIALS LICENSE
SUPPLEMENTARY SHEET

Authorized User	Material and Use
B. Todd L. Johnson, M.D.	10 CFR 35.100 and 35.200 (excluding xenon-133 and generators), limited to cardiovascular clinical procedures.
C. Patricia J. Rubin, M.D.	10 CFR 35.100 and 35.200 (excluding xenon-133 and generators), limited to cardiovascular clinical procedures.

13. The licensee may not possess and use materials authorized in Items 6, 7, and 8 until:

    A. The licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and

    B. The U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Materials Licensing Section, 801 Warrenville Road, Lisle, Illinois 60532-4351 has been notified that activities authorized by the license will be initiated.

14. Within 30 days of the date of a decision not to complete the facility, acquire equipment, or possess and use authorized material, the licensee must notify the Commission in writing, of the decision.

15. 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 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. Applications dated January 26, 1992, and November 6, 1996; and

    B. Letters dated September 22, 1992, December 6, 1995, May 23, 1996, and December 19, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAY 20 1997

By Deborah D. A. Abeira
Nuclear Materials Licensing Branch, Region III

COPY

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: 20021130
Fee Comments:
Decom Fin Assur Reqd: N

S4

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
Applicant/Licensee: KASSIR, MOHAMAD S., M.D.
Received Date: 970428
Docket No: 3032947
Control No.: 302576
License No.: 34-26383-01
Action Type: Amendment

2. FEE ATTACHED
Amount: 440
Check No.: 3131

3. COMMENTS

Signed D. Hersey
Date 4-30-97

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 5/2/97

1997 MAY -1 AM 11:39

MAY 07 1997

Log May 1 AM
Remitter Cardiology One, Inc
Check No. 3131
Amount $440
Fee Category 7C
Type of Fee AMD
Date Check Rec'd 5/1/97
Date Completed 5/2/97
By: SC

Cardiology One

STEVEN C. HIRSCH, M.D., FACC
MOHAMAD S. KASSIR, M.D., FACC
BRIAN E. SIMMONS, M.D., FACP, FACC, FCCP
JOHN C. TSAI, M.D., FACC
PATRICIA J. RUBIN, M.D.
TODD L. JOHNSON, M.D.

April 24, 1997

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

Re: License No. 34-26383-01

Gentlemen:

Please amend our Materials License to add Todd L. Johnson, MD and Patricia J. Rubin, MD to the list of authorized users. Documentation of training and experience is attached for review.

If there are any questions, please contact me at 330-489-1386.

Thank you for your attention to this matter.

Sincerely,

Mohamad S. Kassir, MD
Radiation Safety Officer

Pm: 4-25-97

RECEIVED
APR 28 1997
REGION III

Cardiology One, Incorporated, 1330 Mercy Drive, N.W., Suite 200, Canton, OH 44708 Fax 330-489-1258 Telephone 330-489-1386
Massillon Office: 830 Amherst Road, N.E., Suite 104, Massillon, OH 44646 Fax 330-830-6934 Telephone 330-830-6934
Dover Office: 2620 N. Wooster Avenue, Dover, Ohio 44622 Telephone 330-363-3505

APR 28 1997
312576

THE CLEVELAND CLINIC FOUNDATION

A National Referral Center An International Health Resource

February 3, 1997

Raymundo T. Go, M.D.
Chairman
Department of Nuclear Medicine / Gb8
216/444 2065

TO WHOM IT MAY CONCERN:

This is to certify that Todd L. Johnson, M.D. gained clinical experience in nuclear cardiology in the Department of Nuclear Medicine at the Cleveland Clinic during the period August - September 1993, October - November, 1994, and one week in June 1996. During that time, Dr. Johnson actively participated in the following number of procedures:

461	Thallium stress imaging/function procedures
93	PET studies - either Rb-82 perfusion or F-18-FDG metabolic imaging, or both
12	Ejection fraction calculation procedures

During this time, Dr. Johnson acquired experience in health physics, radiopharmaceutical preparation, technical, and administrative procedures of our facility, as well as general operations as stipulated by our license conditions.

While spending approximately 14 hrs in the nuclear pharmacy laboratory, Dr. Johnson gained experience in the preparation of radiopharmaceutical kits during this period, and eluted the $^{99m}Tc/^{99}Mo$ generator.

The hours of nuclear cardiology clinical and work experience accrued during this period total more than 1000 hours.

Sincerely,

Raymundo T. Go, M.D.

Raymundo T. Go, M.D.
Chairman Cleveland Clinic Foundation Nuclear License No. #34-0046601

/rmb

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion and Competency

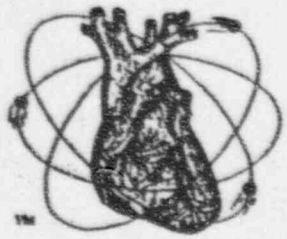
This document is to attest that

TODD L. JOHNSON, MD

has successfully completed the didactic program

PRINCIPLES OF RADIATION PHYSICS

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination. This program provides the following levels of accomplishment:



50 Didactic Instructional Hours (DIH)
(In compliance with 10CFR35 and Agreement States)

5 Continuing Education Units (CEU)

50 Technical/Professional Credit specified by the American Pharmaceutical Association and the American Association of Health Physicists*

*additional documentation will be provided to Regulatory Agencies upon participant request

14 September 1996
Date Class Commenced

Charles H Rose
Authorized Signature

191724
Affidavit of Competency

Institute for Nuclear Medical Education

5660 Airport Blvd., Suite 101, Boulder, Colorado 80301 — 800-548-4024

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

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MEDICAL RADIATION INSTRUMENTATION

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22 September 1996
Date Class Commenced

Charles H. Roe
Authorized Signature

191771
Affidavit of Competency

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MEDICAL RADIATION PROTECTION

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June 15, 1996
Date Class Commenced

Charles H Rood
Authorized Signature

0131575
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RADIOPHARMACEUTICALS AND CHEMISTRY

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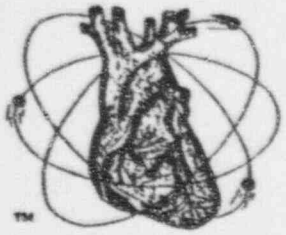

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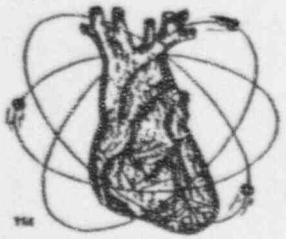

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Authorized Signature

0191533
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LITHO IN U.S.A.

Washington
WASHINGTON UNIVERSITY IN ST. LOUIS
School of Medicine

Division of Radiation Safety

June 26, 1996

Patricia Rubin, M.D.
Division of Cardiology

Dear Dr. Rubin:

The institutional Radiation Safety Committee unanimously voted to approve you as an authorized medical user at the meeting held June 26, 1996. The approval was based on the statement of training and experience and signed preceptor statement presented on your behalf at the meeting by Barry Siegel, M.D. The approval permits you to be the responsible nuclear physician for cardiovascular diagnostic procedures involving radioactive materials, including materials licensed by the US Nuclear Regulatory Commission (NRC) for the categories of use specified in 10CFR35.910 (uptake, dilution and excretion studies) and 35.920 (imaging and localization studies).

Your use of NRC-licensed materials for medical uses is authorized by NRC Ma[illegible]s License 24-00167-11.

Copies of the preceptor and training/experience statements are enclosed.

Sincerely,

John Eichling

John Eichling, Ph.D.
Secretary
Radiation Safety Committee

JE:fi

cc: Barry A. Siegel, M.D.

Washington University School of Medicine
at Washington University Medical Center
Campus Box 8131, 660 S. Euclid Ave
St. Louis, MO 63110-1093
(314) 362-2988 FAX (314) 362-5333
(Location 510 S. Kingshighway)

U.S. NUCLEAR REGULATORY COMMISSION

FORM NRC-313M-SUPPLEMENT A
(8-78)

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Patricia J. Rubin, M.D.	Missouri, Ohio

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Internal Medicine		Sept. 1989
Cardiovascular Dis		Nov. 1995

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Mallinckrodt Inst. of Rad. 7/1/93-1/31/96	84	16
b. RADIATION PROTECTION	Mallinckrodt Inst. of Rad. 7/1/93-1/31/96	24	6
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Mallinckrodt Inst. of Rad. 7/1/93-1/31/96	20	
d. RADIATION BIOLOGY	Mallinckrodt Inst. of Rad 7/1/93-1/31/96	20	
e. RADIOPHARMACEUTICAL CHEMISTRY	Mallinckrodt Inst. of Rad 7/1/93-1/31/96	20	10

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
C-11	45 mCi	MIR	Jul 93-present	PET
O-15	100 mCi	MIR	Jul 93-present	PET
F-18	14 mCi	MIR	Jul 93-present	PET
In-111	250 uCi	MIR	Nov 93-Dec 95	Planar
Tl-201	5 mCi	Univ. Hosp. Cleveland	Jul 91-Jun 93	SPECT
Tc-99m	30 mCi	Univ. Hosp. Cleveland	Jul 91-Jun 93	SPECT

FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Patricia J. Rubin, M.D.

STREET ADDRESS

CITY | STATE | ZIP CODE

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING	333	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER	Tc-99m Myocardial Imaging	311	

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	6	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	4	
Other			
Tl-201	Myocardial Imaging	453	
C-11	Myocardial Imaging	125	
O-15	Myocardial Imaging	107	
F-18	Myocardial Imaging	97	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

7/1/94-6/30/95 (>1000 hours) during fellowship in cardiovascular nuclear medicine and clinical PET.

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Barry A. Siegel, M.D.

b. NAME OF INSTITUTION
Mallinckrodt Institute of Radiology

c. MAILING ADDRESS
510 S. Kingshighway Blvd.

d. CITY
St. Louis, MO 63110

5. MATERIALS LICENSE NUMBER(S)
24-00167-11

6. PRECEPTOR'S SIGNATURE
Barry A Siegel MD

7. PRECEPTOR'S NAME *(Please type or print)*
Barry A. Siegel, M.D.

8. DATE
5/8/96

FORM NRC-313M-SUPPLEMENT B
(8-78)

MAY 20 1997

Mohamad S. Kassir, M.D.
1330 Timkin Mercy Drive, N.W.
Suite 200
Canton, OH 44708

Dear Dr. Kassir:

Enclosed is Amendment No. 03 to your NRC Material License No. 34-26383-01 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 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. (No fee is required if the location of byproduct material remains the same.)

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.

302576

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 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,

Original Signed By
Deborah A. Piskura
Nuclear Materials Licensing Branch

License No.: 34-26383-01
Docket No.: 030-32947

Enclosure: Amendment No. 03

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

April 30, 1997

Mohamad S. Kassir, M.D.
Radiation Safety Officer
Suite 200
1330 Timken Mercy Drive, N.W.
Canton, OH 44708

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated April 24, 1997)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

__ New License X Amendment __ Renewal
__ Termination __ Auth User (Amendment not required) __ Other

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No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302576
License No. 34-26383-01