NRC FORM 313 (03-2013)
10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 05/31/2016

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 Information Services 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

RECEIVED DEC 20 2013

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
- [x] B. AMENDMENT TO LICENSE NUMBER 17-14996-01
- [ ] C. RENEWAL OF LICENSE NUMBER

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

National Hansen's Disease Programs,
Laboratory Research Branch at LSU-SVM
Skip Bertman Drive
Baton Rouge, Louisiana 70803

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

National Hansen's Disease Programs,
Laboratory Research Branch at LSU-SVM
Skip Bertman Drive
Baton Rouge, Louisiana 70803

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Ramanuj Lahiri

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
(225)578-9844	

BUSINESS EMAIL ADDRESS

rlahiri@hrsa.gov

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, 39, AND 40, AND THAT ALL INFORMATION CONTAINED 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 CRIMINAL 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
Renee Painter, Director in Temporary Charge, NHDP.	Renee Painter	12/19/2013

FOR NRC USE ONLY

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

PUBLIC
- [ ] Immediate Release
- [x] Normal Release

NON-PUBLIC
- [ ] A.3 Sensitive-Security Related
- [ ] A.7 Sensitive Internal
- [ ] Other:

Reviewer: MTC Date: 12-26-13

ML 582743

NRC FORM 313 (03-2013)

Department of Health and Humans Services

DHHS/HRSA/Healthcare System Bureau
Division of National Hansen's Disease Programs
Louisiana State University
School of Veterinary Medicine
Skip Bertman Drive
Baton Rouge, La. 70803
Michelle Hammond
Health Physicist,
NRC.

Request for amendment to License No.:17-14996-01

Dear Ms. Hammond,

We are requesting the following amendment to our NRC material license number 17-14996-01:

Dr. Ramanuj Lahiri will replace Mr. J. P. Pasqua as the Radiation Safety Officer (RSO).

A copy of Dr. Lahiri's CV highlighting his training and experience working with radioisotopes is attached along with completed NRC 313 form. RSO will be responsible for ensuring the safe use of radioactive materials including managing NHDP radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. We hereby delegate the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by users who do not meet the necessary requirements and shutting down operations involving the use of radioactive materials where justified by radiation safety. In addition, he will be free to raise issues with NRC and other local or State authorities at any time concerning NHDP radiation safety program.

Please feel free to contact us if you have any questions.

Sincerely,

Richard W. Truman, Ph.D.
Acting Chief, Laboratory Research Branch
National Hansen's Disease Program
225-578-9848
rtruman@hrsa.gov

Renee Painter,
Director in Temporary Charge,
National Hansen's Disease Program
225-756-3773,
rpainter@hrsa.gov

PUBLIC
☐ Immediate Release
☒ Normal Release

NON-PUBLIC
☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:

Reviewer: RTT Date: 12-26-13

582743

Curriculum Vitae

Ramanuj Lahiri, Ph.D.
Microbiologist,
National Hansen's Disease Program
Voice: (225) 578-9844
Email: rlahiri@hrsa.gov

Training: Received theoretical training in radiation biology as part of Biophysics course in both Undergraduate (1992) and Master (1994) level in Department of Physiology, University of Calcutta, India. Basic radioisotope use and safety training as part of Master level (1994) Immunology & Microbiology laboratory course taught in the Department of Physiology, University of Calcutta, India. Advanced training in use of radioisotopes in biological research as part of Ph.D. level (1997) Research Methodology course in Department of Biotechnology, Jawaharlal Nehru University, New Delhi, India. Received on-the-job-training from NRC licensed user, James L. Krahenbuhl (2002). Received radiation safety training (2007) at Center for Advances Microstructures & Devices (CAMD), Louisiana State University and get re-certified every year since 2007.

Experience: 15 years of experience in using radioisotopes ^{3}H (10 mCi), ^{32}P (<1mCi), ^{14}C (>10 mCi), ^{51}Cr (<1 mCi), & $^{131}1$ (<1 mCi) in various biological assays in the laboratory (since 1997).

Education:

Degree	Year	Institution	Subject	Grade
Ph.D.	2001	Jawaharlal Nehru University	Immunology	Awarded
M.Sc.	1995	University of Calcutta	Physiology	I
B.Sc.	1993	University of Calcutta	Physiology Major	I

Position Held:
January 2011 – Present: Microbiologist, NHDP, HSB, HRSA.
August 2008 – January 2011: Senior Postdoctoral Researcher, Department of Pathobiological Sciences, Louisiana State University, USA.
March 2004 – August 2008: Postdoctoral Researcher, Department of Pathobiological Sciences, Louisiana State University, USA.
January 2002 – March 2004: Research Associate, Department of Pathobiological Sciences, Louisiana State University, USA.
July 1998 – August 2001: Senior Research Fellow, School of Biotechnology, Jawaharlal Nehru University, India.
July 1996 – June 1998: Junior Research Fellow, School of Biotechnology, Jawaharlal Nehru University, India.

Awards:

1. Post Doctoral Fellowship (January 2002 to January 2004) from American Leprosy Mission. Greensville, USA.
2. Awarded Senior Research Fellowship, in 1998 from Council for Scientific and Industrial Research, Govt. of India to pursue research in biological sciences in any Indian University or Institute
3. Awarded Junior Research Fellowship, in 1996 from Council for Scientific and Industrial Research, Govt. of India, to pursue research in biological sciences in any Indian University or Institute.

Research Support:

Heiser Foundation Grant. 07/01/12 – 06/30/14.
Ramanuj Lahiri – Principal Investigator.
Thomas P. Gillis & Linda B. Adams – Co- Investigators.
Functional characterization of effector T cells eliciting protective immune response in mouse foot pad against *Mycobacterium leprae*.

American Leprosy Mission Grant. October 2011 – September 2014
Ramanuj Lahiri – Principal Investigator.
Thomas P. Gillis – Co-Principal Investigator.
Provision of highly viable nu/nu mouse derived *Mycobacterium leprae* as a unique leprosy research reagent.

Heiser Foundation Grant. 07/01/09 – 06/30/10.
James L. Krahenbuhl - Principal Investigator.
Ramanuj Lahiri – Co-Investigator.
Modulation of apoptosis by viable *Mycobacterium leprae* as an intracellular survival strategy.

Heiser Foundation Grant. 07/01/07 – 06/30/09.
James L. Krahenbuhl - Principal Investigator.
Ramanuj Lahiri – Co-Investigator.
Development of a mouse model for early detection of sub clinical leprosy.

Professional Memberships:

2004 – Present	Member American Society of Microbiology.
1999 – Present	Member Indian Immunology Society.
1994 – Present	Member Physiological Society of India.

Publications:

1. Davis GL, Ray NA, **Lahiri R**, Gillis TP, Krahenbuhl JL, Williams DL, and Adams LB. Molecular Assays for Determining *Mycobacterium leprae* Viability in Tissues of Experimentally Infected Mice. *PLoS Negl Trop Dis*, 2013, 7(8): e2404. doi:10.1371/journal.pntd.0002404.

2. Sharma R, **Lahiri R**, Scollard DM, P, Williams DL, Adams LB, Figarola J and Truman RW. The armadillo: a model for the neuropathy of leprosy and potentially other neurodegenerative diseases. *Disease Models & Mechanisms*, 2013, 6: 19-24.
3. **Lahiri R**, Randhawa B, Franken KLMC., Duthie MS, Spencer JS, Geluk A, and Krahenbuhl JL. Development of a Mouse Food Pad Model for Detection of Sub Clinical Leprosy. *Leprosy Review,* 2011, 82: 432-444.
4. **Lahiri R**, Randhawa B, Krahenbuhl JL. Infection of mouse macrophages with viable Mycobacterium leprae does not induce apoptosis. *Journal of Infectious Diseases*, 2010; 201:1736-1742.
5. Raman VS, O'Donnell J, Bailor HR, Goto W, **Lahiri R**, Gillis TP, Reed SG, Duthie MS. ML0276 vaccination reduces local inflammation, but not bacterial burden, during experimental *M. leprae* infection. *Infect Immun*, 2009; 77: 5623-5630.
6. Martinez AN, **Lahiri R**, Pittman TL, Scollard D, Truman R, Moraes MO, and Williams DL. Molecular Determination of Mycobacterium leprae Viability Using Real-Time PCR. *J Clin Microbiol.* 2009; 47: 2124-2130.
7. **Lahiri R**, and Krahenbuhl JL. The Role of Free-Living Pathogenic Amoeba in the transmission of Leprosy: A Proof of Principle. *Leprosy Review*, 2008; 79: 401-409.
8. **Lahiri R**, Sandoval FG, Krahenbuhl JL, and Shannon EJ. Activation of Complement by *Mycobacterium leprae* requires disruption of the bacilli. *Leprosy Review*, 2008; 79: 311-314.
9. Duthie MS, Reece ST, **Lahiri R**, Goto W, Raman VS, Kaplan J, Ireton GC, Bertholet S, Gillis TP, Krahenbuhl JL and Reed SG. Antigen-specific cellular and humoral responses are induced by intradermal *Mycobacterium leprae* infection of the mouse ear. *Infect Immun*, 2007; 75: 5290-5297.
10. Mohanty BP, **Lahiri R**, Misra-Bhattacharya S, and Kar SK. *Brugia malayi* adult low molecular weight IgG4-reactive antigens induce differential cytokine response in lymphocytes of endemic normal and asymptomatic microfilariae carriers *in vitro*. *Journal of Clinical Immunology*, 2007; 27: 397-408
11. Manjunatha UH, **Lahiri R**, Randhawa B, Dowd CS, Krahenbuhl JL, and Barry CE III. *Mycobacterium leprae* is naturally resistant to PA-824. *Antimicrobial Agents and Chemotherapy*, 2006; 50: 3350-3354.
12. **Lahiri R**, Randhawa B, Krahenbuhl JL. Effects of purification and fluorescent staining on viability of *Mycobacterium leprae*. *International Journal of Leprosy and Other Mycobacterial Diseases*, 2005; 73: 194-203.
13. **Lahiri R**, Randhawa B, Krahenbuhl JL. Application of a viability staining method for *Mycobacterium leprae* derived from the athymic (nu/nu) mouse foot pad. *Journal of Medical Microbiology*, 2005; 54: 235-242.

Oral presentations:

1. Host response to *M. leprae* infection. 2010, Invited lecture, School of Biotechnology, Jawaharlal Nehru University, New Delhi, India.
2. Early influx of CD4+ cells in the foot pads of vaccinated mice following challenge with live Mycobacterium leprae as a surrogate marker of protection. 2009, 44th Meeting of U.S.-Japan Joint Cooperative Medical Sciences Program in Tuberculosis and Leprosy, Fukuoka, Japan.
3. Immunological response in foot pads and lymph nodes of vaccinated mice following challenge with live *Mycobacterium leprae*. 2008, 43rd Meeting of U.S.-Japan Joint Cooperative Medical Sciences Program in Tuberculosis and Leprosy, Baltimore, USA.

4. *Mycobacterium leprae*: The well behaved pathogen. 2007, Invited lecture, School of Biotechnology, Jawaharlal Nehru University, New Delhi, India.
5. Further definition of viability of *Mycobacterium leprae* as a research resource. 2003, 38th Meeting of U.S.-Japan Joint Cooperative Medical Sciences Program in Tuberculosis and Leprosy, Newark, USA.
6. *Mycobacterium leprae* and Programmed cell death. Annual General Meeting of the South Central Branch of American Society for Microbiology. 2006. Lafayette, USA.
7. Dissecting host–parasite interaction in lymphatic filariasis. 2001, International Conference on New Horizons of Biotechnology, Trivandrum, India.

Peer-Reviewed Conference Papers:

1. **R. Lahiri**, and J. L. Krahenbuhl. Free-living pathogenic amoebae as potential reservoirs / vectors in leprosy transmission. 2008, 17th International Congress, Hyderabad, India.
2. **R. Lahiri**, and J. L. Krahenbuhl. Provision of fresh, viable *Mycobacterium leprae* as a research reagent. 2008, 17th International Congress, Hyderabad, India.
3. **R. Lahiri**, B. Randhawa and J. L. Krahenbuhl. Viable *Mycobacterium leprae* does not Induce Apoptosis in Infected Murine Macrophages. 2008, 17th International Congress, Hyderabad, India.
4. **R. Lahiri**, F. Sandoval, J. L. Krahenbuhl, and E. J. Shannon. Activation of complement by *Mycobacterium leprae* requires disruption of the bacilli. 2008, 17th International Congress, Hyderabad, India.
5. **R. Lahiri**, B. Randhawa and J. L. Krahenbuhl. Contrasting apoptotic effects of *Mycobacterium leprae* and *Mycobacterium tuberculosis* on infected murine macrophages. 2005, 40th Meeting of U.S.-Japan Joint Cooperative Medical Sciences Program in Tuberculosis and Leprosy. Seattle, USA.
6. **R. Lahiri**, B. Randhawa and J. L. Krahenbuhl. *Mycobacterium leprae* does not induce apoptosis *in vitro* in mouse peritoneal macrophages. 2005, 105th Annual General Meeting of American Society for Microbiology. New Orleans, USA.
7. **R. Lahiri**, B. Randhawa and J. L. Krahenbuhl. A rapid and reliable method to measure viability in *Mycobacterium leprae*. 2003, 103rd Annual General Meeting of American Society for Microbiology. Washington D.C., USA.
8. **R. Lahiri**, B. Randhawa and J. L. Krahenbuhl. Viable *Mycobacterium leprae* as a research resource: evaluation of fluorescent staining for live and dead *Mycobacterium leprae*. 2002, 16th International Leprosy Congress. Salvador, Brazil.
9. B.P. Mohanty, **R. Lahiri**, S. Bhattacharya, and S. K. Kar. *Brugia malayi* adult <24kd antigens preferentially induce Th1 cytokine response in endemic normal individuals. 2001, Abstract A6. *Scandinavian J. Immunol.* **54** (Suppl.1): 88

The J. Bennett Johnston, Sr.
CAMD
Center for Advanced Microstructures and Devices

August 21st; 2013

To Whom It May Concern:

This letter certifies that Dr. Ramanuj Lahiri has successfully been re-certified in radiation safety each year since he became a CAMD user in 2007. In addition, he completed a rigorous written test that generally requires multiple attempts to achieve a passing grade. Since becoming a member of the CAMD Synchrotron Ring user community, Dr. Lahiri has always completed his radiation safety training in a diligent and timely matter.

Should you have any additional questions that I may answer, please fill free to contact me.

Sincerely,

Marie-Lorraine Morreau-Day

Lorraine Day, PhD
CAMD RSO
6980 Jefferson Hwy
Baton Rouge, LA 70806
225-578-4616

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 03620
Status Code: Pending Amendment
Fee Category: 3M
Exp. Date: 02/29/2012
Fee Comments: 170.11(A)(5)
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee:	HEALTH & HUMAN SERVICES, DEPT. OF
Received Date:	12/20/2013
Docket Number:	3008380
Mail Control Number:	582743
License Number:	17-14996-01
Action Type:	Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: Colleen Murnahan

Date: 12-27-2013

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER _____

_____

Signed: _____

Date: _____