

Nemours Alfred I. duPont
Hospital for Children

January 7, 2018

Dennis Lawyer
Licensing Assistance Team
US Nuclear Regulatory Commission, Region 1
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

RE: Mail Control No. 610746

Subject: Amendment to NRC License # 07-16199-01/03010568

Dear Dr. Lawyer:

This is in reference to your letter dated December 27, 2018, regarding your request for additional information for our amendment to Nuclear Regulatory Commission License No. 07-16199-01, Docket No. 03010568.

1. Question: Need documentation regarding Dr. Barwe's specific experience using licensed materials.

Answer: Please see the attached document "Barwe_Isotope_Experience".

2. Question: Your request did not make any request to change license condition 11. This is the list of authorized users and the material that they are authorized. The current Radiation Safety Officer, Robert Mason, Ph.D., is listed as an authorized user. Should Dr. Mason be removed and Dr. Barwe added? If so, is Dr. Barwe being requested to be added for all licensed material or just certain isotopes? Please follow guidance in section 8.7.2 of NUREG-1556, Volume 7, Rev. 1, when responding.

Answer: Dr. Robert Mason should be removed as an authorized user. Dr. Barwe should be listed as Authorized User / Radiation Safety Officer. Attached is a form requesting the addition of Dr. Barwe as Authorized User for the use of the specific radioisotopes listed in the attached document. We are not requesting to add Dr. Barwe as Authorized User for other radioisotopes covered under our license, only the ones listed.

Please contact me if you have any questions or concerns. Thank you.

Sincerely,



Vicky L. Funanage, Ph.D.
Operational Vice President of Research, Nemours Children's Health System
Associate Professor of Pediatrics, Jefferson Medical College
Adjunct Professor, College of Health Sciences, University of Delaware
vicky.funanage@nemours.org
302-651-6819

Enclosures:

1. Barwe_Isotope_Experience (pdf)
2. Barwe Authorized User Form (doc)

NUREG/REG MATERIALS-002

Rec'd. in LAT- 1/8/2019

**Alfred I. duPont Hospital for Children
Nemours Biomedical Research
Radiation Safety**

Statement of Training and Experience

Name: Sonali Barwe

Date: 10/17/07

Name of Authorized User: ~~Robert Mason~~

Raj

On the Job Training by an Authorized User:

| | Yes | No | Where trained | Dates | Length (in hours) |
|--------------------------------------------------------------------------------|-----|----|---------------|---------|-------------------|
| Principles and Practices of Radiation Protection | X | | UCLA | 4/21/01 | 1 |
| Radioactivity Measurement, Monitoring Techniques, and Instruments | X | | UCLA | 4/21/01 | 1 |
| Mathematics and Calculations Basic to the Use and Measurement of Radioactivity | X | | UCLA | 4/21/01 | 1 |
| Biological Effects of Radiation | X | | UCLA | 4/21/01 | 1 |

Training provided by a Radiation Safety Office:

| | Yes | No | Where trained | Dates | Length (in hours) |
|--------------------------------------------------------------------------------|-----|----|---------------|---------|-------------------|
| Principles and Practices of Radiation Protection | X | | UCLA | 4/20/01 | 3 |
| Radioactivity Measurement, Monitoring Techniques, and Instruments | X | | UCLA | 4/20/01 | 3 |
| Mathematics and Calculations Basic to the Use and Measurement of Radioactivity | X | | UCLA | 4/20/01 | 3 |
| Biological Effects of Radiation | X | | UCLA | 4/20/01 | 3 |

Formal courses (for credit):

| Title/Description of Course | Credits | College/University | Dates and Duration |
|-----------------------------|---------|--------------------|--------------------|
| | | | |
| | | | |
| | | | |

**Alfred I. duPont Hospital for Children
Nemours Biomedical Research
Radiation Safety**

Previous Isotope Handling Experience (if you need more room, attach a page):

| Isotope | Amount handled per experiment | Estimated number of expts per yr | Dates | Where | Type of experiment |
|---------|-------------------------------|----------------------------------|-----------|-------|-------------------------------------|
| P-32 | 0.1 mCi | 6 | 2001-2007 | UCLA | Southern/Northern blotting |
| H-3 | 0.05 mCi | 3 | 2001-2007 | UCLA | CAT Assays |
| S-35 | 0.05 mCi | 2 | 2001-2007 | UCLA | In vitro transcription, translation |
| Rb-86 | 0.1 mCi | 2 | 2001-2007 | UCLA | Rubidium uptake assay |
| I-125 | 0.05 mCi | 1 | 2001-2007 | UCLA | Antibody labeling |
| | | | | | |

Have you taken the Alfred I. duPont Hospital Initial Radiation Safety Training Course? ___ Yes

Request to End Probationary Status of Sonali Barwe

Name the radioisotopes for which this person has received training from you:

Has this person received training from you in the following areas? Yes

- Type(s) of radiation from the nuclide(s) used ^{35S}, ^{86Rb}
- Energy of radiation for the nuclide(s) used ✓
- Storage areas and areas of the lab where nuclides can be used ✓
- Security of nuclide(s) ✓
- External and internal hazards from the nuclide(s) ✓
- Special handling problems of the nuclide(s) ✓
- Proper use of survey equipment ✓
- Proper contamination control techniques ✓
- Proper disposal of radionuclide(s) ✓

Have you observed that this person handles radioactive materials safely and in accordance with NRC regulations and our rules and regulations? Yes

I request that the Radiation Safety Committee end the probationary status.

[Signature]
Signature

SIGRID RAMSEKARAN, Ph.D
Print your name

2/23/11
Date

February 27, 2013

Alfred I. duPont Hospital for Children
Radiation Safety

Current Status

Authorized User: Ayyappan Rajasekaran, PhD/Sigrid Langhans, PhD

RSO signature: 

Procedures:

| | Date approved |
|--------------------------------------------|---------------|
| Paracellular permeability assay | 8/22/08(NRC) |
| Peptidase activity assay | 8/22/08(NRC) |
| Proliferation assay | 8/22/08(NRC) |
| Hybridization blotting . | 8/22/08(NRC) |
| Metabolic labeling of cultured cells . | 8/22/08(NRC) |
| Metabolic labeling of proteins | 8/22/08(NRC) |
| Radioligand binding assay (not iodination) | 8/22/08(NRC) |
| Rubidium uptake | 8/22/08(NRC) |

Radionuclides:

| Nuclide | Chemical/Physical form | Maximum activity on hand at any one time | Date approved |
|---------|-------------------------------------|------------------------------------------|----------------|
| H-3 | Peptide; polysaccharide; nucleotide | 40 mCi (20 each) | 8/22/2008(NRC) |
| P-32 | NTPs | 40 mCi (20 each) | 8/22/2008(NRC) |
| S-35 | Amino acids | 160 mCi (80 each) | 8/22/2008(NRC) |
| I-125 | Peptides | 10 mCi (5 each) | 8/22/2008(NRC) |
| Rb-86 | Salt | 10 mCi (5 each) | 8/22/2008(NRC) |

Participating personnel:

| Names | Degree | Supervisor | Probation | Approved |
|--------------------------------|--------|------------|-----------|--------------|
| Ayyappan Rajasekaran | Ph.D. | | | 8/22/08(NRC) |
| Sigrid Langhans | Ph.D. | | | 8/22/08(NRC) |
| Seung Joon Lee | Ph.D. | Sigrid | 9/18/09 | 6/4/10 |
| Sonal Barwe | Ph.D. | Raj | 6/4/10 | 2/23/11 |
| Justin David | | Raj | - | 5/18/11 |
| *Sona Lakshme Balasubramaniam | | Sigrid | | 2/13/13 |
| *Anilkumar Gopalakrishnapillai | | Sigrid | | 2/13/13 |

Locations of use:

| Building | Room No. | Date approved |
|------------|----------|---------------|
| Rockland I | 225 | 8/22/08(NRC) |

Alfred I. duPont Hospital for Children
Nemours Biomedical Research
Radiation Safety

Isotope Handling Experience at A I duPont Hospital for Children – Sonali Barwe, PhD

| Isotope | Amount handled per experiment | Estimated number of experiments per year | Dates | Where | Type of experiment |
|------------------|-------------------------------|------------------------------------------|-----------|----------------------------------------|---------------------------------------------|
| ⁸⁶ Rb | 20 μ Ci | 2 | 2011-2015 | Alfred I. duPont Hospital for Children | Paracellular permeability assay |
| ³² P | 100 μ Ci | 5 | 2011-2018 | Alfred I. duPont Hospital for Children | DNA/RNA labeling for hybridization blotting |
| ³⁵ S | 100 μ Ci | 2 | 2014-2018 | Alfred I. duPont Hospital for Children | Metabolic labeling of cultured cells |

**Alfred I. duPont Hospital for Children
Nemours Biomedical Research**

Requesting addition of Authorized User: Sonali Barwe, PhD for the radioisotopes listed below.

Dr. Sonali Barwe completed required radiation safety training and on-the-job training during her postdoctoral fellowship at UCLA (see Statement of Training and Experience attached). Additionally, she completed probationary period during which hands-on radioisotope use and training was documented (see Request to Probationary Status attached). Dr. Grace Hobson (RSO at the time) granted Dr. Barwe authorization to work with radioisotopes under the Authorized Users – Drs. Rajasekaran/ Langhans (see attachment dated Feb 27, 2013). Her isotope handling experience at A. I. duPont Hospital for Children is listed below. Dr. Barwe successfully completed the 40 hour technical short course entitled Radiation Safety Officer on Aug 31 2018. Therefore, Dr. Barwe has training and experience with use of radioactive materials that is appropriate to the types and forms of material of her proposed use.

Dr. Barwe's proposed type, form, quantity and use:

| Type | Form | Quantity | Uses |
|------------------|-------------------------------------|----------|---------------------------------------------|
| ³² P | NTPs | 20 mCi | DNA/RNA labeling for hybridization blotting |
| ³⁵ S | Amino acids | 20 mCi | Metabolic labeling of protein/cells |
| ³ H | Peptide, polysaccharide, nucleotide | 20 mCi | DNA/RNA labeling for hybridization blotting |
| ¹²⁵ I | Peptides | 5 mCi | Antibody labeling |
| ⁸⁶ Rb | Salt | 5 mCi | Paracellular permeability assay |