



Food and Drug Administration  
Mail Stop HFS-657  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

03036120

October 15, 2012

Docket No. ~~0306120~~ *Nw*  
Control No. 578109

License No. 19-30771-01

Dennis Lawyer, Health Physicist  
U.S. Nuclear Regulatory Commission  
Region 1  
2100 Renaissance Blvd, Suite 100  
King of Prussia, PA 19406-2713

J6

03036120

REC'D OCT 18 12 PM 11:13

Subject: DHHS, Response to Request for Additional Information Concerning Application  
for Amendment to License, Control No. 578109

Dear Mr. Lawyer,

This is in reference to your letter dated August 29, 2012. The information you have requested is noted below:

- 1) Letter enclosed as "Attachment A"
- 2) We do **NOT** wish to have "HSF-657" removed from our mailing list. This was left off in error.
- 3) Badaruddin Shaikh and Badar Shaikh **IS** the same person, please disregard Badaruddin Shaikh on the submitted application. This duplication of proposed Authorized Users was done in error.
- 4) Proposed Authorized Users, the radioisotopes to be authorized, and the experience related to using the radioisotope is enclosed as "Attachment B"
- 5) Instructions to ancillary personnel frequenting restricted areas – All personnel visiting or frequenting any portion of the restricted areas will receive instructions concerning the hazards of the area, accident and emergency procedures, and their responsibility to report violations. Other topics may include storage and use of radioactive material, the hazards associated with exposure to radioactive material in the area, means to reduce exposure, and appropriate responses to warning signs and labels. The extent of this instruction shall be commensurate with potential radiological health protection hazards in the restricted area. Training will be conducted or arranged for by the RSO and may be held in a classroom setting or be provided via computer-based, video, or other format, as appropriate.
- 6) Generic laboratory room diagram enclosed as "Attachment C"

578109

Do to a change in current research plans the following proposed Authorized Users do not require approval at this time and may be removed form the license application:

Charles Gieseke  
Cynthia Stine  
Kristina Williams  
Girdhari Sharma

Please continue your review of this information in regards to requesting the amendment of Nuclear Regulatory License No. 19-30771-01. Please contact me at (240) 402-2105 or [michael.spady@fda.hhs.gov](mailto:michael.spady@fda.hhs.gov) if you have any further questions about this information.

Sincerely,



10/12/2012

Michael A. Spady, M.S.  
Radiation Safety Officer, FDA - CFSAN



Food and Drug Administration  
Mail Stop HFS-657  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

September 28, 2012

Dennis Lawyer  
Health Physicist  
Nuclear Regulatory Commission  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
2100 Renaissance Boulevard, Suite 100  
King of Prussia, PA 19406-2713

Subject: Request for Additional Information Concerning Application for Amendment to License, Control NO. 578109

Dear Mr. Lawyer,

As the Executive Management Representative, I have reviewed the application to amend Nuclear Regulatory License Number 19-30771-01 and concur with the statements and representations contained therein.

Please continue with your review and feel free to contact me or our Radiation Safety Officer, Mr. Michael Spady at (240) 402-2105 with any further questions regarding this application.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles Sabatos".

Charles Sabatos  
Deputy Executive Officer  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

PERSONAL INFORMATION WAS REMOVED  
 BY NRC. NO COPY OF THIS INFORMATION  
 WAS RETAINED BY THE NRC.

NEW RADIONUCLIDE USER TRAINING AND EXPERIENCE RECORD

USER NAME (must be clearly printed): Monday, Steven R.		PHONE: 240-402-2012 ----- BLDG : CPKI                      RM: 3E-015	MAILCODE: HFS 711	
DIVISION: MMDB	JOB TITLE: Research Microbiologist	BIRTH DATE: [REDACTED]	SSAN (last 4 digits only): [REDACTED]	
LIST RADIONUCLIDES EXPECTED TO BE USED: 32P		CFSAN/CVM PRINCIPAL INVESTIGATOR NAME (print): Monday, Steven R.		
TRAINING AND EXPERIENCE				
TYPE OF TRAINING AND COURSE TITLE		SPONSOR/LOCATION	DATE(S)	LENGTH
PRINCIPLES AND PRACTICES OF RADIATION PROTECTION (COURSE TITLE: <i>RADIATION SAFETY IN THE LABORATORY (RSL)</i> )		University of California Riverside	[REDACTED]	2 hours/ session
RADIOACTIVITY MEASUREMENTS AND MONITORING TECHNIQUES (COURSE TITLE: <i>RSL</i> )			'Rad Safety training'	
MATHEMATIC/CALCULATIONS BASIC TO THE MEASUREMENT OF RADIOACTIVITY (COURSE TITLE: <i>RSL</i> )		University of Idaho	[REDACTED]	'Rad Safety training'
BIOLOGICAL EFFECTS OF RADIATION (COURSE TITLE: <i>RSL</i> )				
		CFSAN	2005- present 'RSL courses' inclusive	
RADIONUCLIDE	MAXIMUM ACTIVITY USED	NAME OF ORGANIZATION	HOW LONG USED?	TYPE OF USE
32P	250 uCi	CFSAN	7 years	labeling experiments
3H, 32P	1 mCi	University of Idaho	4 years	labeling experiments, cellular metabolic experiments
32P, 35S	250 uCi	University of California Riverside	6 years	labeling experiments, DNA sequencing

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SUPERVISOR'S SIGNATURE:

*[Handwritten Signature]*

DATE:

*10/15/12*

PRINCIPAL INVESTIGATOR'S SIGNATURE:

*[Handwritten Signature]*

DATE:

*10/15/12*

s/a training and experience record.doc (23-10)

QUALIFICATIONS OF RADIONUCLIDE USERS

DATE: 9-12-12	PHONE: 301-827-817	MAILCODE: HFV-512	DIVISION: Residue Chemistry
NAME: BADAR SHAIKH	JOB TITLE: RESEARCH CHEMIST	BIRTHDATE: [REDACTED]	SSN: [REDACTED]
LIST RADIONUCLIDES TO BE USED: <sup>14</sup> C, 3H		PRINCIPAL INVESTIGATOR: B. Shaikh	

TRAINING AND EXPERIENCE

TYPE OF TRAINING AND COURSE TITLE	SPONSOR/LOCATION	DATES	LENGTH
A. PRINCIPLES AND PRACTICES OF RADIATION PROTECTION COURSE TITLE: 1) Radioisotopes in Biology 2) Basic Radiation Safety in the Lab.	1) Hood Collag 2) FDA/CFSAN	[REDACTED] 1987	one Semester (4 credits) 24 HOURS
B. RADIOACTIVITY MEASUREMENTS AND MONITORING TECHNIQUES COURSE TITLE: Same as above	Annual Refresher FDA/CFSAN	1993 - Present	Annual 3-4 HRS.
C. MATHEMATIC / CALCULATIONS BASIC TO THE MEASUREMENT OF RADIOACTIVITY COURSE TITLE: Same as above			
D. BIOLOGICAL EFFECTS OF RADIATION COURSE TITLE: Same as above			

RADIONUCLIDE	MAXIMUM ACTIVITY USED	WHERE	DATES USED	TYPE OF USE
<sup>14</sup> C -	200 µCi	FDA/CVM	1994-1999	Metabolism
<sup>14</sup> C -	500 µCi	FDA/CVM	1983-1985	Method Development, HPLC, etc.
3H.	1 mCi	FCRC, Frederick, MD	1977-1979	Methods Development, HPLC, etc. Drug Interaction
<sup>14</sup> C -	500 µCi	FCRC, Frederick, MD	1977-1979	

PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

SUPERVISOR'S SIGNATURE

PRINCIPAL INVESTIGATOR'S SIGNATURE

*Michael D. Thompson*  
*B. Shaikh*

9/12/12

**QUALIFICATIONS OF RADIONUCLIDE USERS**

PERSONAL INFORMATION WAS REMOVED  
BY NRC. NO COPY OF THIS INFORMATION  
WAS RETAINED BY THE NRC.  
DIVISION: DVA

DATE: 04/27/2011	PHONE: 301-210-7503	MAILCODE: HFS-025	DIVISION: DVA
NAME: Uma S. Babu, Ph.D.	JOB TITLE: Research Biologist	BIRTHDATE: [REDACTED]	SSN: [REDACTED]
LIST RADIONUCLIDES TO BE USED: Cr51, Tritium		PRINCIPAL INVESTIGATOR: Uma S. Babu	

**TRAINING AND EXPERIENCE**

TYPE OF TRAINING AND COURSE TITLE	SPONSOR/LOCATION	DATES	LENGTH
A. PRINCIPLES AND PRACTICES OF RADIATION PROTECTION COURSE TITLE: Basic principles of radiation protection	NIH	1991	8 hrs
B. RADIOACTIVITY MEASUREMENTS AND MONITORING TECHNIQUES COURSE TITLE: Basic principles of radiation protection	NIH	1991	8 hrs
C. MATHEMATIC / CALCULATIONS BASIC TO THE MEASUREMENT OF RADIOACTIVITY COURSE TITLE: Radiation units and decay laws	FDA	1995, 2003	4 hrs
D. BIOLOGICAL EFFECTS OF RADIATION COURSE TITLE: Annual refresher courses	FDA	Yearly	4 hrs

RADIONUCLIDE	MAXIMUM ACTIVITY USED	WHERE	DATES USED	TYPE OF USE
Tritium	50 mCi	India	1981-85	Cell labeling
Tritium	50 mCi	USDA, MD	1986-90	Cell labeling
Chromium 51	300 mCi	FDA	1995-Present	Cell labeling
Tritium	100 mCi	FDA	1999-Present	Cell labeling

SUPERVISOR'S SIGNATURE: *Christina M. Williams*  
 PRINCIPAL INVESTIGATOR'S SIGNATURE: *Uma S. Babu*

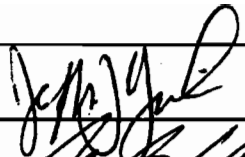
PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

## NEW RADIONUCLIDE USER TRAINING AND EXPERIENCE RECORD

USER NAME (must be clearly printed): Margaret Kraeling, M.S.		PHONE: 301-210-6076 <hr/> BLDG: MOD 1      RM: 2008		MAILCODE: HFS-025	
DIVISION: Toxicology		JOB TITLE: Research Biologist		BIRTH DATE: ██████████	
SSAN: ██████████		LIST RADIONUCLIDES EXPECTED TO BE USED: <sup>3</sup> H, <sup>14</sup> C		CFSAN/CVM PRINCIPAL INVESTIGATOR NAME (print): Margaret Kraeling, M.S.	
<b>TRAINING AND EXPERIENCE</b>					
TYPE OF TRAINING AND COURSE TITLE			SPONSOR/LOCATION	DATE(S)	LENGTH
PRINCIPLES AND PRACTICES OF RADIATION PROTECTION COURSE TITLE: 1) Certification for Use of Radiation 2) Radiation Safety Training 3) Radiation Safety in the Laboratory			1) University of Cincinnati	██████████	8 hours 1 day
RADIOACTIVITY MEASUREMENTS AND MONITORING TECHNIQUES (COURSE TITLE: <i>RSL</i> ) see above			2) DHHS, NIH, Bethesda, MD	4/19/90	1 day
MATHEMATIC/CALCULATIONS BASIC TO THE MEASUREMENT OF RADIOACTIVITY (COURSE TITLE: <i>RSL</i> ) see above			3) FDA/CFSAN continuing refresher training	1994 – present	58 hours
BIOLOGICAL EFFECTS OF RADIATION (COURSE TITLE: <i>RSL</i> ) see above			4) FDA-DOT Requirements for Transportation of Radioactive Materials	3/13/2000	4 hours
RADIONUCLIDE	MAXIMUM ACTIVITY USED	NAME OF ORGANIZATION	HOW LONG USED?	TYPE OF USE	
<sup>3</sup> H	5 uCi	University of Cincinnati	1989-1990	Research	
<sup>3</sup> H, <sup>14</sup> C	20 uCi	USFDA	1990-present	Research	




SUPERVISOR'S SIGNATURE:



DATE:

10/12/12

PRINCIPAL INVESTIGATOR'S SIGNATURE:



DATE:

10/12/12

NEW RADIONUCLIDE USER TRAINING AND EXPERIENCE RECORD

USER NAME (must be clearly printed): Jeffrey J. Yourick, Ph.D.		PHONE: 301-210-6125 ----- BLDG : MOD1 RM: 2019		MAILCODE: HFS-025	
DIVISION: Toxicology		JOB TITLE: Supervisory Toxicologist		BIRTH DATE: [REDACTED]	
SSAN: [REDACTED]		LIST RADIONUCLIDES EXPECTED TO BE USED: <sup>3</sup> H, <sup>14</sup> C			
CFSAN/CVM PRINCIPAL INVESTIGATOR NAME (print): Margaret Kraeling, M.S.					
TRAINING AND EXPERIENCE					
TYPE OF TRAINING AND COURSE TITLE			SPONSOR/LOCATION	DATE(S)	LENGTH
PRINCIPLES AND PRACTICES OF RADIATION PROTECTION COURSE TITLE: 1) Radioisotopes; 2) Radiation Protection; 3) Radiation Safety in the Laboratory			1) University of Kansas	[REDACTED]	30 hr lecture
RADIOACTIVITY MEASUREMENTS AND MONITORING TECHNIQUES (COURSE TITLE: <i>RSL</i> ) see above			2) USAMRICD, APG, MD	[REDACTED]	16 hr lab 24 hr
MATHEMATIC/CALCULATIONS BASIC TO THE MEASUREMENT OF RADIOACTIVITY (COURSE TITLE: <i>RSL</i> ) see above			3) FDA/CFSAN continuing refresher training	1994-present	58 hr
BIOLOGICAL EFFECTS OF RADIATION (COURSE TITLE: <i>RSL</i> ) see above			4) FDA-DOT Requirements for Transportation of Radioactive Materials	3/13/2000	4 hr
RADIONUCLIDE	MAXIMUM ACTIVITY USED	NAME OF ORGANIZATION	HOW LONG USED?	TYPE OF USE	
3H, 14C	20 uCi	NIH	1977-1978	Research	
14C	20 uCi	The Upjohn Co.	1979	Research	
3H	10 uCi	Western Mich. Univ.	1980-1982	Research	
3H	10 uCi	Univ. of Kansas	1984	Research	
3H, 14C	30 uCi	USFDA/CFSAN	1994-present	Research	

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SUPERVISOR'S SIGNATURE:

*Robert S. Spanda*

DATE:

*10/10/12*

PRINCIPAL INVESTIGATOR'S SIGNATURE:

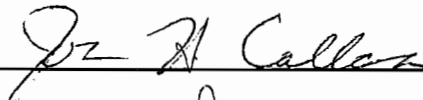

*W. J. [Signature]*

DATE:

*10/12/12*

s/a training and experience record.doc (2-3-10)

NEW RADIONUCLIDE USER TRAINING AND EXPERIENCE RECORD

USER NAME (must be clearly printed): Stacey DeGrasse		PHONE: (202) 240-1470 BLDG: CPK1 RM: BE007		MAILCODE: HFS-707
DIVISION: CFSAN/ORS/DAC		JOB TITLE: Research Biologist		BIRTH DATE: [REDACTED] SSAN: [REDACTED]
LIST RADIONUCLIDES EXPECTED TO BE USED: <sup>3</sup> H		CFSAN/CVM PRINCIPAL INVESTIGATOR NAME (print): Stacey DeGrasse		
<b>TRAINING AND EXPERIENCE</b>				
TYPE OF TRAINING AND COURSE TITLE		SPONSOR/LOCATION	DATE(S)	LENGTH
PRINCIPLES AND PRACTICES OF RADIATION PROTECTION (COURSE TITLE: <i>RADIATION SAFETY IN THE LABORATORY (RSL)</i> )		CFSAN/College Park, MD	11/18-21/2003	4 days
RADIOACTIVITY MEASUREMENTS AND MONITORING TECHNIQUES (COURSE TITLE: <i>RSL</i> )		University of Connecticut	[REDACTED]	40 hours
MATHEMATIC/CALCULATIONS BASIC TO THE MEASUREMENT OF RADIOACTIVITY (COURSE TITLE: <i>RSL</i> )		Yearly refreshers	2004-Present	
BIOLOGICAL EFFECTS OF RADIATION (COURSE TITLE: <i>RSL</i> )				
RADIONUCLIDE	MAXIMUM ACTIVITY USED	NAME OF ORGANIZATION	HOW LONG USED?	TYPE OF USE
<sup>14</sup> C	500 microCi per experiment	University of Connecticut and Bigelow Laboratory	1997-2002	Phytoplankton primary production measurements
<sup>3</sup> H	600 microCi per year	FDA Center for Food Safety & Applied Nutrition	2004-Present	Receptor binding assay for determination of paralytic shellfish poisoning toxins
SUPERVISOR'S SIGNATURE: 			DATE: 10/10/2012	
PRINCIPAL INVESTIGATOR'S SIGNATURE: 			DATE: 10/10/12	



SUPERVISOR'S SIGNATURE:

*Paddy Weisenfeld, Ph.D. Chief NIUTB*

DATE:

*10/10/12*

PRINCIPAL INVESTIGATOR'S SIGNATURE:

*[Handwritten Signature]*

DATE:

*10/10/12*

s/a training and experience record.doc (2-3-10)



# RADIATION SAFETY SURVEY FORM

Surveyor:

Date:

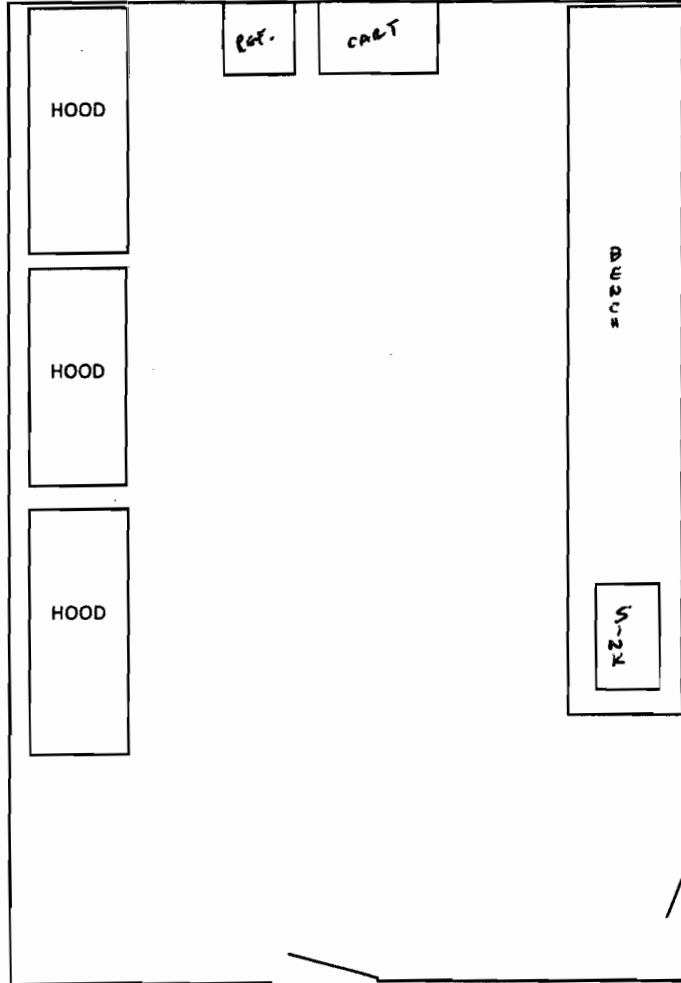
Authorized User:

Location:  
**MOD1 2315**

**COMPLIANCE:**

Yes / No / Not Evaluated

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Signs & Labels: Room/Area
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Refrigerator/Freezer/Equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LS Vials, Trays
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Source Containers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Waste Containers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Absorbent Paper on RAM Areas
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Security/Storage of RAM
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Routine use of gloves, lab coats
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radioactive waste management
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Prohibition of eating, drinking, etc.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Inventory/Disposal records complete
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Survey records current
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Contamination limits met
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Survey meters available
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Survey meters operational
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Calibration current
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other:



**RADIONUCLIDES USED:**

NUCLIDE 1:  
NUCLIDE 2:  
NUCLIDE 3:  
NUCLIDE 4:

NOTES:

**WIPE SAMPLE RESULTS:**

All samples < 100 dpm/100cm<sup>2</sup>

Sample analysis report attached

**SURVEY INSTRUMENTS USED:**

METER(S):

PROBE(S):

**COMMENTS:**

TYPICAL LAB DIAGRAM