

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Dept of HHS, NI of Diabetes &
Digestive & Kidney Diseases

License No.: 02-13990-01

Docket No.: 030-01211

Mail Control No.: 471283

Type of Action: Amend

Date of Requested Action: 02-22-07

Reviewer
Assigned:

ARM reviewer(s): Torres

| Response | Deficiencies Noted During Acceptance Review |
|----------|--|
| | <ul style="list-style-type: none">[] Open ended possession limits. Limit possession. Submit inventory.[] Submit copies of most recent leak test results.[] Add - delete IC license condition. Add IC paragraph in cover letter.[] Split license from cover letter. Add SUNSI marking to license.[] Ask the licensee if they have any type-amount of EPAct Material. |
| | |

Reviewer's Initials: _____

Date: _____

- ☐ Yes ☐ No Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.
- ☐ Yes ☐ No Decommissioning notification should be completed within 30 days.
- ☐ Yes ☐ No Termination request < 90 days from date of expiration
- ☐ Yes ☐ No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
- ☐ Yes ☐ No TAR needed to complete action.

Branch Chief's and/or Sr. HP's Initials: _____

Date: _____

SUNSI Screening according to RIS 2005-31

☐ Yes ☒ No **Non-Publicly Available, Sensitive** if any item below is checked

General guidance:

- _____ RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
- _____ Exact location of RAM (whether = or > than Category 3 or not)
- _____ Design of structure and/or equipment (site specific)
- _____ Information on nearby facilities
- _____ Detailed design drawings and/or performance information
- _____ Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

- _____ RAM quantities and inventory
- _____ Manufacturer's name and model number of sealed sources & devices
- _____ Site drawings with exact location of RAM, description of facility
- _____ RAM security program information (locks, alarms, etc.)
- _____ Emergency Plan specifics (routes to/from RAM, response to security events)
- _____ Vulnerability/security assessment/accident-safety analysis/risk assess
- _____ Mailing lists related to security response

Branch Chief's and/or Sr. HP's Initials: RTT

Date: 3-8-07

Pre-Licensing Screening

Applicant Information:

Control No. 471283

| | |
|---|---|
| Name: Dept of HHS, NI of Diabetes & Digestive & Kidney Diseases | Type of Request: Amend Program Code(s): |
| Location: AZ | License No.: 02-13990-01 Docket No.: 030-01211 |

STEP 1—Radioactive Materials and Quantities Requested:

| | |
|---|-----------|
| Instructions for Step 1: Complete Step 1 for all applications. If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay. | Yes or No |
| A. The request is from a new applicant. | N |
| B. NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit. | N |
| C. The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been "highlighted" by the reviewer | N |

Table of Risk Significant Quantities

(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

| Radionuclide | Risk Significant Quantity (TBq ¹) | Risk Significant Quantity (Ci ¹) | Radionuclide | Risk Significant Quantity (TBq ¹) | Risk Significant Quantity (Ci ¹) |
|--------------|---|--|---------------------|---|--|
| Am-241 | 0.6 | 16 | Pm-147 | 400 | 11,000 |
| Am-241/Be | 0.6 | 16 | Pu-238 | 0.6 | 16 |
| Cf-252 | 0.2 | 5.4 | Pu-239/Be | 0.6 | 16 |
| Cm-244 | 0.5 | 14 | Ra-226 ² | 0.4 | 11 |
| Co-60 | 0.3 | 8.1 | Se-75 | 2 | 54 |
| Cs-137 | 1 | 27 | Sr-90 (Y-90) | 10 | 270 |
| Gd-153 | 10 | 270 | Tm-170 | 200 | 5,400 |
| Ir-192 | 0.8 | 22 | Yb-169 | 3 | 81 |

¹ The primary values are TBq. The curie (Ci) values are for informational purposes only.

² The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

| | |
|--|---------------------------------|
| Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. NOTE—If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s). | Yes, No, or Not Applicable (NA) |
| Total Activity—multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide | — |
| Unity Rule—multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g., [(total activity for radionuclide A) ÷ (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) ÷ (risk significant quantity for radionuclide B)] ≥ 1.0. | — |

Signature and Date for Step 1:

RTZ 3-8-07
License Reviewer and Date



National Institutes of Health
National Institute of Diabetes and
Digestive and Kidney Diseases
4212 North 16th Street
Phoenix, Arizona 85016
(602) 263-1556

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DNMS

February 22, 2007

Regional Administrator
US Nuclear Regulatory Commission
Region IV, Material Radiation Protection Section
611 Ryan Plaza Dr, Ste 400
Arlington, TX 76011-4005

RE: License #02-13990-01

Dear Sirs:

ATTN
This letter is a request to amend our license. We request removal of items 6A (chromium 51), 6B (iodine-125) and 6E (phosphorus-32) from our list of licensed materials. In addition, we wish to remove Michal Prochazka as an authorized user and replace him with Shannon Parrington as an authorized user of all licensed materials on the requested revised license. A copy of the Radioisotope Training and Experience form for Shannon Parrington is enclosed.

Thank you for your consideration of this matter.

Sincerely,

David M Mott, PhD
Radiation Safety Officer
Obesity and Diabetes Clinical
Research Section
PECRB, NIDDK, NIH, DHHS
Tel 602-200-5300
Fax 602-200-5335
Email dmott@mail.nih.gov

Richard M Bryan
Administrative Officer
Phoenix Epidemiology and Clinical
Research Branch
NIDDK, NIH, DHHS
Tel 602-400-6588
Fax 602-253-4140
Email mbryan@mail.nih.gov

Radiation Training and Experience

Candidate
Shannon Parrington

Date
2/22/07

Training

| Field of Training | Location and Dates | Lecture/Laboratory (hrs) |
|--|--|---------------------------------|
| Basic Radiation Protection Course | University of Arizona, 9/10/01 | Lecture, 4.5 hours |
| Radiation Control Officer, Elizabeth Vierling Laboratory | University of Arizona, 2002-2003 | 2 years |
| Radiation Safety | ODCRS, PECRB, NIDDK, NIH, Phoenix, Arizona, 7/03-present | Lecture, 5 total hours, 1 hr/yr |

Isotopes

| Isotope | Maximum Amount | Where Experience Gained | Duration of Experience | Type of Use |
|-----------------|--------------------------|------------------------------|------------------------|---|
| ^3H | 200 μCi -5mCi | University of Arizona | 2002-2003 | Waste Management |
| ^3H | 5mCi | PECRB, NIH, Phoenix, Arizona | 2003-present | Analysis of Hepatic Glucose Production; Metabolic (Tracer) Assays |
| ^{14}C | 5mCi | University of Arizona | 2002-2003 | Waste Management |
| ^{14}C | 250 μCi | PECRB, NIH, Phoenix, Arizona | 2003-present | Enzymatic Assays |
| ^{32}P | 100 μCi -5mCi | University of Arizona | 2002-2003 | Waste Management |
| ^{35}S | 1mCi-5mCi | University of Arizona | 2002-2003 | Waste Management |

MAR - 8 2007

DATE

This is to acknowledge the receipt of your letter/application dated 2-22-07, and to inform you that the initial processing, which includes an administrative review, has been performed.

☒ There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card:

The action you requested is normally processed within 90 days.

☐ A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 471283.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Colleen Murnahan

Licensing Assistant

(FOR LFMS USE)
INFORMATION FROM LTS

```
.....
Program Code: 02410
Status Code: 0
Fee Category: 7C
Exp. Date: 20140531
Fee Comments:
Decom Fin Assur Req'd: N
.....
```

Decom Fin Assur Req: N

Decom Fin Assur Req: N

- Applicant/Licensee: **HEALTH & HUMAN SERVICES, DEPT. OF**

20070305

3001211

471283
02 12000 01

~~Termination~~ AMEND

- Amount:

The graph shows a coordinate system with a horizontal x-axis and a vertical y-axis. Two vertical lines are drawn at constant x-values. A smooth, downward-sloping curve starts from the left, crosses the first vertical line at a high y-value, and crosses the second vertical line at a lower y-value, continuing to slope downwards to the right.

- Signed Colleen M. Bradburn
Date 3-8-07

Colleen M. Macdonald
3-8-07

- CH (Check when milestone 03 is entered / __/)

- 10

- Amendment _____

-

Date _____

[illegible]

Obesity & Diabetes Clinical Research Section
National Institutes of Health
Department of Health & Human Services
4212 N 16th St Rm 541
Phoenix AZ 85016 USA

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*Regional Administrator
US Nuclear Regulatory Commission
Region IV, Material Radiation Protection Section
611 Ryan Plaza Dr. Ste. 400
Arlington, TX 76011-4005*

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