

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Scela, Inc.

License No.: DBA Radiopharmacy of Alaska

Docket No.: 030-34105

Mail Control No.: 471047

Type of Action: Amend

Date of Requested Action: 07-13-06

Reviewer Assigned: Roberto

ARM reviewer(s): Cook

Response	Deficiencies Noted During Acceptance Review
	<input type="checkbox"/> Open ended possession limits. Limit possession. Submit inventory. <input type="checkbox"/> Submit copies of most recent leak test results. <input type="checkbox"/> Add - delete IC license condition. Add IC paragraph in cover letter. <input checked="" type="checkbox"/> Split license from cover letter. Add SUNSI marking to license. <input type="checkbox"/> Ask the licensee if they have any type-amount of EPAct Material.
<p>7/27/06 no need. Doesn't meet SUNSI criteria.</p>	<p><i>This is a change of corporate RSO in Ohio office (Nec R-III). No action to Alaska License.</i></p> <p>Reviewer: (1) Make sure proposed RSO meets T&E as specified in NUREG 1556 Vol 13. (2) Verify whether licensee was issued orders.</p>

Reviewer's Initials: RJC

Date: 7-27-06

- ☐ 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: RJC

Date: 7/27/06

Reviewer: Tie down Apr 12, 06 letter

Pre-Licensing Screening

Applicant Information:

Control No. 471047

Name: Scela, Inc.	Type of Request: Amend Program Code(s):
Location: AK	License No.: DBA Radiopharmacy of Alaska 34105
Docket No.: 030-	

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.	NO
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.	NO
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	NO

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:

 7/27/06
 License Reviewer and Date



Cardinal Health
Nuclear Pharmacy Services
7000 Cardinal Place
Dublin, OH 43017
614.757.5000 tel

www.cardinalhealth.com

July 13, 2006

U.S. Nuclear Regulatory Commission
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064


Re: Cardinal Health Nuclear Pharmacy Services, NRC Radioactive Materials License
Number 50-29096-01MD, Anchorage, AK

Attention Licensing:

This letter is to inform you of the change in Corporate Radiation Safety Officer (CRSO) from Paul Gotti to Jack Coffey. Mr. Coffey is currently listed on the US NRC Master License Number 34-29200-01MD and has previously fulfilled the duties of Corporate Radiation Safety Officer for Cardinal Health. Please see the attached Delegation of Authority letter from the Corporate Radiation Safety Committee granting Mr. Coffey authority as the new CRSO.

If you have any questions, please contact me at 614.757.3116.

Sincerely,



Dave Breuning
Health Physicist
Nuclear Pharmacy Services

CC: PRSO, Loc 3341 (Anchorage)
License File Loc 3341 (Anchorage) (3)

Encl: Delegation of Authority

4 7 1 0 4 7



To Whom It May Concern

FROM: Cardinal Health NPS, Radiation Safety Committee
Members: Jack Coffey, SVP Quality & Regulatory
Joe Zipp, SVP, Operations
Paul Gotti, VP Operations, Northeast
Jerry Costanza, VP Operations, West
Mike Mullin, VP Operations, South
Bob Medrano, SVP Human Resources
Tara Simonian, Senior Manager, Compliance Assessment

DATE: July 11, 2006

SUBJECT: Delegation of Authority - Corporate Radiation Safety Officer

Jack Coffey has been appointed Corporate Radiation Safety Officer. The Corporate Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations.

The Corporate Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities. This specifically includes having sufficient authority, organizational freedom, and management prerogative to:

1. Have unhampered access to all activities at any Cardinal Health facility involving radioactive materials to identify radiation safety problems;
2. Immediately stop, without coordination with management, any activity at any Cardinal Health facility involving the use of licensed materials by any user that might result in an unsafe situation or a violation of NRC requirements;
3. Initiate, recommend, or implement appropriate corrective actions; and
4. Verify the implementation of actions taken to correct radiation safety problems.

A handwritten signature in black ink, appearing to read "Jack L. Coffey", written over a horizontal line.

Jack L. Coffey
Senior Vice President, Quality and Regulatory
Nuclear Pharmacy Services



www.cardinalhealth.com

April 12, 2006

Re: Signature Authority for Radioactive Materials Licenses

To Whom It May Concern:

This letter authorizes the individuals listed below on behalf of Cardinal Health, its subsidiaries and affiliates, to make legally binding statements pertaining to radioactive materials licenses, permits and registrations.

Paul Gotti
Willie Regits
Chris Walters
Dave Breuning

This is to include submission of license applications, requests for changes to existing radioactive materials licenses, as well as responses to citations and notices of violations issued to radioactive materials licenses.

Sincerely,

A handwritten signature in black ink, appearing to read "Jack L. Coffey".

Jack L. Coffey
Vice President
Quality & Regulatory
Nuclear Pharmacy Services

