ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Scela, Inc. **License No.:** 11-27664-01MD

Docket No.: 030-35366 **Mail Control No.:** 471071

Type of Action: Amend **Date of Requested Action:** 08-03-06

Reviewer Assigned: **ARM reviewer(s):** Cook

Response	Deficiencies Noted During Acceptance Review
	[ ] 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: JJC **Date:** 8/9/06

ADAMS # ML062270226
Template _____
Date 8/15/06 QC'd by SM

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

CardinalHealth

www.cardinalhealth.com

July 31, 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 11-27664-01MD, Boise, ID

Attention Licensing:

Please amend the above referenced license(s) to revise the frequency required for required bioassay for handlers of I-131. This change only affects the frequency of bioassay for I-131, and not I-123, and more accurately mirrors the guidelines in NRC Regulatory Guide 8.20. Please see the attached Bioassay Program Proposed Revision.

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

Sincerely,

Dave Breuning
Health Physicist
Nuclear Pharmacy Services

CC: PRSO, Loc 3306 (Boise)
License File Loc 3306 (Boise) (3)

Encl: Bioassay Program Proposed Revision

Bioassay Program Proposed Revision

In a continuing effort to improve our radiation safety program, the bioassay program was reviewed.

Our current bioassay program states that the following individuals must perform a bioassay:

a) All individuals that handle an open form of quantities of radioactive iodine greater than or equal to those quantities shown in Table 1 of NRC Regulatory Guide 8.20 (see Appendix C for a copy)
b) Any employee sufficiently close to the handling process (within a few meters, and in the same room as the worker handling the material).

The bioassays should be performed at this frequency:

a) Individuals compounding I-131 capsules must perform bioassays weekly and individuals compounding I-123 must perform bioassays between 6 and 24 hours post-handling.
b) Individuals who are not on a regular bioassay program, but have assisted in decontamination, for example after a spill, shall complete a bioassay between 6 and 24 hours post-exposure.

Upon review of NRC Regulatory Guide 8.20 we have determined that the bioassay frequency schedule can be modified. The proposed changes are as follows:

Individuals whom handle I-131 will be divided into two categories, **frequent and infrequent** handlers. A frequent handler is defined as an individual whom handles I-131 or is sufficiently close to the handling process once every two (2) weeks or more often. An infrequent handler handles I-131 less frequently than, once every two (2) weeks.

Frequent handlers must follow the following bioassay schedule:

a) Between 6-72 hours after initial handling of I-131, a bioassay must be performed.
b) After the initial bioassay, a biweekly bioassay schedule will be maintained. A bioassay must be performed once every 2 weeks.
c) After 3 months of the biweekly bioassay schedule an individual can change their bioassay schedule to monthly if they meet the following condition.
   - During the three month biweekly period, they do not exceed thyroid burden action level one for I-131 (0.04 μCi).
d) If at some point during the monthly bioassay schedule an individual exceeds the thyroid burden action level one. They will revert to the biweekly schedule until three consecutive months have passed with a thyroid burden less than action level one.

Infrequent handlers must perform one bioassay with in 6-72 hours following handling I-131.

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02500
Status Code: 0
Fee Category: 3C 2B
Exp. Date: 20100930
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: SCELA, INC.
   Received Date: 20060803
   Docket No: 3035366
   Control No.: 471071
   License No.: 11-27664-01MD
   Action Type: Amendment

2. FEE ATTACHED
   Amount: _____
   Check No.: _____

3. COMMENTS

Signed Colleen Murnahan
Date 8-9-06

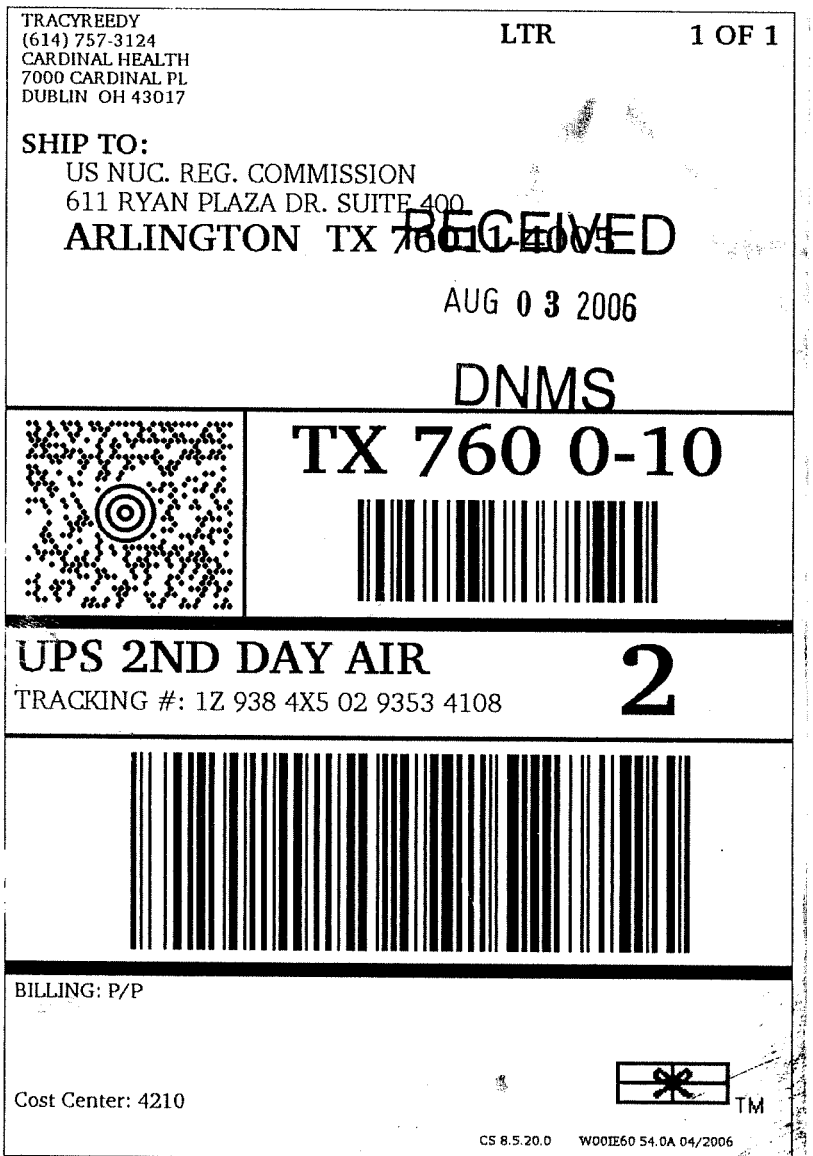
B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License _____

3. OTHER _____
   _____

Signed _____
Date _____



TRACYREEDY
(614) 757-3124
CARDINAL HEALTH
7000 CARDINAL PL
DUBLIN OH 43017

LTR 1 OF 1

SHIP TO:
US NUC. REG. COMMISSION
611 RYAN PLAZA DR. SUITE 400
ARLINGTON TX 760[illegible]

RECEIVED
AUG 0 3 2006
DNMS

TX 760 0-10

UPS 2ND DAY AIR
TRACKING #: 1Z 938 4X5 02 9353 4108

2

BILLING: P/P

Cost Center: 4210

TM

CS 8.5.20.0 W00IE60 54.0A 04/2006

Applicant Information: **Control No.** 471071

Name: Scela, Inc.	Type of Request: Amend Program Code(s):
Location: ID	License No.: 11-27664-01MD Docket No.: 030-35366

STEP 1–Radioactive Materials and Quantities Requested:

		Yes or No
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.		
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.

	Yes , No, or Not Applicable (NA)
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).**	
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:

RJTC 9/28/06

License Reviewer and Date