UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352

FEB 20 2008

Pamela Barton
Facilities North America Director
Aptuit, Inc.
10245 Hickman Drive
Kansas City, MO 64134-0708

Dear Ms. Barton:

We have completed our review of your request for an amendment to NRC License Number 24-15595-01, and find that we will need additional information as follows:

1. Financial Assurance

As a result of Aptuit's request to increase its possession limit of hydrogen-3 from 1 curie to 5000 curies, and carbon-14 from 2 curies to 500 curies, Aptuit will need to resubmit financial assurance in the form of a decommissioning funding plan (DFP), as required in 10 CFR Part 30, Section 30.35.

Upon receipt of the DFP we will review it for adequacy to supply funds for future decommissioning, as applicable.

2. Programmatic Changes

From our review of your application it appears that you are requesting that Aptuit's license be upgraded to a broad scope program. Evidence of this appears in Attachment 7 to the Radiation Protection Program where reference was made to Radiation Safety Committee (RSC) duties and responsibilities that include, for example, approval of users and uses of license material, and modifications of facilities and equipment.

Given Aptuit's request to significantly increase possession limits of hydrogen-3 and carbon-14, expand its authorized use from research and development (R&D) to radiosynthesis, and the recent change in the Radiation Safety Officer (RSO), the NRC feels very strongly that at this time Aptuit's license should continue to be written as a limited scope R&D.

During telephone conversations that we held on January 18 and 28, 2008, you stated your agreement with our proposal. Therefore, it will be necessary for Aptuit to review its October 25, 2007, application in its entirety and make the necessary modifications to the application in accordance with the enclosed NUREG-1556, Volume 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope", and submit the revisions for our review.

3. Authorized Use

A. Describe the purpose for conducting radiosynthesis, and confirm that you will not be engaged in commercial distribution of end product.

B. Describe the types of radiosynthesis studies that will conducted. Include nuclides involved, frequency of studies performed, and typical quantities of each radionuclide that will be used at any one time.

4. Authorized Users

Your current license authorizes the Radiation Safety Officer (RSO) to approve users of licensed material. As we discussed during our telephone conversation on January 18, 2008, the NRC feels that given the recent change in Aptuit's RSO, request for a significant increase in possession limits for hydrogen-3 and carbon-14, and a programmatic change from research and development to radiosynthesis, Aptuit's license should be modified to list the authorized users. Therefore, please provide a complete list of authorized users with a description of radionuclides that you would like each to be approved to use. Also, include a description of their experience in using each nuclide (include maximum quantities used per study and types of studies conducted).

5. Training Program

A. Item 8, Attachment 3 to your October 25, 2007, amendment request states that "new employees with limited experience must work under supervision of an Authorized User." Provide more detail on the criteria that will be used to evaluate new employees in order to assess their ability to work safely with licensed material.

B. Provide us with the name of the instructor(s) for your training program, and include their qualifications to provide the training.

6. Facilities and Equipment

A. Please describe in detail all modifications that were made to your facility, and submit a list of radiation safety equipment that will be used to ensure that radiosynthesis operations are conducted safely. Include any changes in ventilation systems, air/water effluent monitoring programs/equipment, etc. Submit diagrams and locations of all synthesis labs, and include the location of any specialized safety-related equipment for each lab, e.g., fume hoods, glove boxes, waste storage areas, etc.

B. Describe equipment used to filter radioactively contaminated air/water before effluents are released to the environment. Include a description of the methods that will be used to evaluate these filtration systems for saturation.

C. Identify the location of all areas that are dedicated for the storage of radioactive waste. Include a description of provisions taken to ensure that these areas will be secured from unauthorized access.

7. Radiation Monitoring Instruments

Please address Item 8.10.2 of the enclosed NUREG-1556, Volume 7, and submit a more detailed description of the radiation monitoring instruments that Aptuit will possess and use.

8. Occupational Dose

Please address occupational dose by submitting a response to Item 8.10.4 of the enclosed NUREG-1556, Volume 7.

9. Bioassay Program

The discussion in your application regarding monitoring for internal dose states that a "bioassay program **may** be implemented at the **discretion** of the RSO." With the increase in possession limits of both hydrogen-3 and carbon-14 and authorization to conduct radiosynthesis, you must be more definitive in your statement and develop a strict bioassay program with clear criteria for implementation. Therefore, please review the enclosed Regulatory Guides 8.9 and 8.32, and submit a comprehensive bioassay for monitoring internal dose from the intake of radionuclides.

10. Survey Program

A. The survey frequency described in your application for conducting contamination surveys is significantly higher than the frequencies recommended in NUREG-1556, Volume 7. For example, your program requires daily surveys for contamination when quantities of hydrogen-3 used are greater than, or equal to, 1000 curies. Volume 7 recommends daily surveys for contamination be conducted where quantities used are greater than or equal to 1.0 Annual Limit on Intake (ALI). The smallest ALI for hydrogen-3 is 80 millicuries. Please modify your criteria for frequency of conducting contamination surveys to be in accordance with Appendix Q to Volume 7, NUREG-1556.

B. Describe in greater detail the criteria that the RSO will use to determine the types, frequencies, and locations of routine surveys.

11. Waste Management

Describe your monitoring program for air and liquid effluents that you will implement to verify that concentrations of radioactive materials do not exceed 10 CFR Part 20 limits.

Also, describe how you will test and confirm that effluents released to the environment are within 10 CFR Part 20 limits.

12. Environmental Assessment

10 CFR Part 51, Section 51.22, describes criterion for categorical exclusion (CATX) of licensing actions that would not require an environmental assessment (EA). Section 51.22(c)(14)(v) provides a CATX for the use of radioactive materials for research and development purposes.

Research and development licensees that release radioactive material to the environment will normally not need an EA and are covered under this CATX, **provided**:

A. All releases originating on-site to the environment, such as air and liquid effluents, direct radiation from deposition of radioactive materials from the release (e.g., groundshine), comply with as low as reasonably achievable (ALARA) and 10 CFR Part 20 requirements.

B. To assist in demonstrating compliance with the requirements of 10 CFR Part 20, please set ALARA goals for air effluents at a modest fraction of the values in Appendix B, Table 2, Columns 1 and 2, to 10 CFR Part 20, Sections 20.1001-20.2401. Experience indicates that values of about 10 millirems per year from all radioactive air effluents should be practicable for almost all materials facility licensees (see Regulatory Guide 8.37). Therefore, as a first step toward demonstrating compliance with ALARA for radioactive air effluents, please demonstrate that the nearest member of the general public will receive no more than 10 millirems per year from all of Aptuit's radioactive air effluents (i.e., please demonstrate how Aptuit will meet the requirements of 10 CFR 20.1101(d)).

C. All releases on-site comply with all applicable decommissioning requirements (e.g., decommissioning recordkeeping requirements pursuant to 10 CFR 30.35(g)) and current decommissioning policies.

In order to demonstrate that your program qualifies for a CATX, please demonstrate how Aptuit meets the above criterion.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

Please submit your response to our letter within 30 days, and reference as additional information to Control Number 316804.

If you have any questions, please feel free to contact me at (630) 829-9854.

Sincerely,

Kevin G. Null
Materials Licensing Branch

Enclosures:
1. NUREG-1556, Volume 7
2. NUREG-1748
3. Regulatory Guides 8.9, 8.32, and 8.37
4. 10 CFR Parts 20, 30 and 51

cc: Clint Gregg, RSO

aptuit

April 7, 2008

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
Attn: Kevin G. Null
Materials Licensing Branch

Response: Additional Information to Control Number 316804

Dear Mr. Null:

We have completed our response to your phone call on April 7, 2008. Please find our response below:

1. Item 9. Bioassay program. Changes to the RPP reflect weekly urinalysis for all personnel involved in radio-synthesis and any other user working with an ALI. Please find amended sheet attached.

2. Item 10. Aptuit has changed its RPP to reflect compliance with NUREG 1556 Vol. 7 Appendix Q. Please find the amended sheet attached.

3. Item 11. Emissions Estimate Calculation Included. The calculations of the average stack concentrations of H-3 and C-14 are attached. Using very conservative assumptions, it demonstrated that the dose to the nearest member of the public is less than 10 mrem per year.

4. Please find the table below detailing our Liquid Scintillation Counters.

Type of Instrument	Model Number	Source	Activity	Identification Number	New Location
Liquid Scintillation Counter	Beckman LS6000LL	CS-137	30 µCi	Beckman LSC - LS6000LL	B2-119
Liquid Scintillation Counter	Perkin-Elmer Tricarb2900TR	Ba-133	18.8 µCi +/- 17 %	Perkin Elmer LSC 2900	B2-165
Liquid Scintillation Counter	Beckman LS6500	CS-137	30 µCi	Beckman LSC - LS6500	B2-166

5. AU Type of Use Change. Please find the revised "Type of use" for Peter Swan.

6. I do not find that we have any personnel experienced with I-131 and it should be removed from our license.

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Please let me know if additional information is needed.

Sincerely,

Clinton Gregg
Radiation Safety Officer

Enclosures

1. Item 9

performed by the RSO to determine the potential for the employee to exceed the regulatory exposure limit during the nine-month gestation period. The individual's potential exposure and their job functions will be reviewed by Health Services, Environmental Health and Safety (EH&S), and management. Recommendations on minimizing radiation exposure may be made on an individual basis after this evaluation. A DPW may revoke her declaration of pregnancy by submitting a letter to the RSO; however the lower dose limit for the embryo/fetus will no longer apply.

External Dose Monitoring

The RSO will determine the need for and type of personnel dosimetry in accordance with applicable NRC regulations and guidance documents (e.g. NUREG-1556, Vol. 7, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope). The personnel dosimetry program shall be conducted through a dosimetry provider that is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP).

It is the responsibility of employees who are assigned personnel dosimetry devices to wear and store them in accordance with the instructions of the RSO. Dosimetry reports will be reviewed by the RSO. Monitoring records will be maintained as part of the employee's health file. Employees will be notified of any exposures recorded above the dosimeter's minimum measurable quantity. A summary of the annual results will be provided to each employee participating in the personnel monitoring program.

Internal Dose Monitoring

Employees who perform radio-synthesis will submit weekly urine samples. Other employees using ^{3}H, ^{14}C, ^{35}S, ^{125}I, or ^{131}I, at the levels indicated in Table 1 will be required to participate in the bioassay program as determined by the RSO. The RSO will determine participation in the bioassay program based on the amount and form of the isotope, type of use, control methods and in accordance with applicable NRC Regulatory Guides. Users are required to notify the RSO before using radionuclide form/activity combinations exceeding those in Table 1. Scheduling of bioassay tests will be coordinated through the RSO. In addition, appropriate bioassay may be performed whenever an internal exposure to radioactive materials is suspected.

Records of all monitored employee exposures are maintained by the RSO and also as part of the employee's permanent health record.

2. Item 10

Type of Instrument	Radiation Detected	Sensitivity Range	Window Thickness	USE
Alarm Ratemeter with PGM	Beta , gamma	0 - 500 cpm, X1, X10, X100, X1k	1.7 +/-.03 mg/cm²	Personnel contamination monitoring
Inspector (G-M)	beta, gamma	0-300K cpm .001-1000 mR/hr	1.5-2.0 mg/cm²	Contamination surveys
Liquid Scintillation Counter	Beta	NA	NA	Removable contamination, waste and product assays
Ion chamber or microR meter	Gamma	0 – 5000 mR/hr	NA	Exposure rate, package surveys
Low energy gamma detector	Low energy gamma	0 - 500 cpm X1, X10, X100, X1000	18.4 mg/cm²	I-125 surveys
Large area gas proportional detector	Alpha, beta	X1, X10, X100, X1000 0 - 500 cpm,	0.4 – 0.8 mg/cm²	Contamination surveys

Portable survey instruments are calibrated annually or after repair by persons authorized by the NRC, an Agreement State, or a licensing State to perform that service. Calibration records are maintained in the radiation safety files. Fixed laboratory instruments used for analysis of samples are checked for satisfactory performance pursuant to vendor instruction manuals.

Instruments used for radiation detection/measurement may be upgraded as necessary at the discretion of the RSO.

Radiation Safety Surveys

Aptuit will perform radiation safety surveys that are sufficient in scope to assess the radiation hazards to workers and the public. These surveys will consist of dose-rate and contamination surveys, as appropriate, in and adjacent to locations where radioactive materials are used or stored. The RSO will determine the types, locations and frequency of radiation safety surveys in accordance with NUREG-1556, Vol. 7, Appendix Q 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope'. The RSO maintains records of radiation safety surveys. General guidelines for performing surveys are presented below.

Dose-rate Surveys

Dose-rate surveys may be performed in areas where external exposure hazards are present. In general, dose-rate surveys should be performed if radiation levels could result in doses in excess of 500 mrem per year or where the dose rate in

3. Emission Calculation

Shaw Shaw Environmental & Infrastructure, Inc.

By RTG Date 4-8-08 Subject Calculation of Air Effluent Concentration Sheet No. 1 of 2

Chkd. By Date 4/8/08 in Aptwit KCM stack Proj. No. 120089.41000000
.25 In. X .25 In.

30" diameter stack
cross sectional area of stack = $\pi\left(\frac{30}{2}\right)^2$ = 707 in^2
= 4561 cm^2

Effluent exit velocity = 3000 ft/min
= 91440 cm/min

Effluent Flow rate = 4561 cm^2 × 91440 cm/min
= 4.2×10^8 cm^3/min

Total volume (effluent) per year = 4.2×10^8 cm^3/min × 5.3×10^5 min = 2.2×10^{14} cm^3
= 2.2×10^{14} ml
- assume stack runs continuously

Concentration in stack using 2007 emissions at Lenexa -
- assume C-14 emissions are in the form of CO_2
- assume H-3 emissions are in the form of HTO
- take no credit for HEPA Filtration, dispersion of plume, occupancy, wind direction

H-3 no emissions in 2007
C-14 - 0.563 mCi = 5.63×10^5 µCi

Average annual C-14 concentration in stack
= $5.6 \times 10^5 / 2.2 \times 10^{14}$ ml
= 2.6×10^{-9} µCi/ml

Effluent limit for C-14 (CO_2) = 3×10^{-7} µCi/ml Appendix B to Part 20 Table 2
Effluent limit for H-3 (HTO) = 1×10^{-7} µCi/ml
Calculated stack concentration as a percent of the annual emission limit

$$= \left(\frac{2.6 \times 10^{-9}}{3 \times 10^{-7}}\right)(100) = 0.9\ \%$$

1191A-65.22

3. Continued

Shaw Environmental & Infrastructure, Inc.

By RTG Date 4-8-08 Subject Calculation of air effluent concentrations Sheet No. 2 of 2

Chkd. By [illegible] Date 4/8/08 I.A. Optuit KCMI stack Proj. No. 120089.41000000
.25 in. X .25 in.

As a more conservative calculation, use the average H-3 and C-14 emissions from Lenexa for the last 7 years*

H-3 2001-2007 average emissions - 1.3×10^4 uCi
C-14 2001-2007 average emissions - 2.8×10^6 uCi

H-3 annual average concentration in stack

1.3×10^4 uCi / 2.2×10^{14} ml = 5.9×10^{-9} uCi/ml

C-14

2.8×10^6 uCi / 2.2×10^{14} ml = 1.3×10^{-8} uCi/ml

Using the unity rule

$$\frac{C_{C-14}}{EC_{C-14}} + \frac{C_{H-3}}{EC_{H-3}}$$

$$\frac{1.3 \times 10^{-8}}{3 \times 10^{-7}} + \frac{5.9 \times 10^{-9}}{1 \times 10^{-7}} = 0.10$$

This very conservative calculation demonstrates that the dose to a member of the public would be less than 5 mrem (0.1×50 mrem = 5 mrem, since concentration values in Table 2 of Appendix B are set to produce a dose equivalent of 50 mrem if inhaled continuously over the course of a year.)

* There were no H-3 emissions in the last 3 years. Procedures were modified in 2007 to reduce C-14 emissions.