

CONVERSATION RECORD  
(time) (date)

TIME | DATE  
1/18/08

VISIT      CONFERENCE      TELEPHONE X

INCOMING  
 OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT      ORGANIZATION (OFFICE, DEPT. ETC.)      TELEPHONE NO  
Pam Barton      Aptuit      816-767-6020

SUBJECT  
C/N's 316665 and 316804

SUMMARY

This was a follow-up call to the conversation that I had with Pam on 1/9/08.

I asked her about the status of her response to my request that she provide additional info with regard to the proposed RSO's qualifications. She said that due to a lack of experience in his use of high energy beta emitters, they will be withdrawing their request for approval of P-32. Also, Pam stated that she will e-mail me a copy of the Kansas license that listed Mr. Gregg as the RSO. She stated that the license issued by Kansas was a broad scope license that authorized the same type of synthesis activities that Aptuit is requesting in C/N 316804. Pam stated that she will submit a written response withdrawing their request for P-32, and will also reference the Kansas license number that has Mr. Gregg named as the RSO.

Given the significant program change that Aptuit is proposing, I suggested that Aptuit consider modifying its program to delete authorization for the RSO to approve users and areas. This would be a true limited scope R&D program, and hence require that the licensee amend its license to name users and approve radioactive material use areas. Ms. Barton agreed. This element of the program change will be addressed with C/N 316804. Currently, the use of material at Aptuit includes I-125 and C-14 by approximately 10 RSO approved users in 3 laboratories.

I also informed Ms. Barton that at this time NRC does not have jurisdiction in the State of Missouri for NARM material, which includes I-129. The waiver will terminate for Missouri in late summer/early fall 2008. Therefore, I cannot approve Aptuit's request to add I-129 to their NRC license.

We also discussed C/N 316804. This action will be significant due to the large requested increase in H-3 and C-14, from both technical (including a programmatic change to authorize radiosynthesis as an authorized use) and financial assurance (which will now require that the licensee submit a DFP) standpoints. This action will require a site visit, and will most likely result in a deficiency letter that addresses technical and financial assurance issues. As a result, this action will not be completed by the end of February, as was requested by the licensee.

ACTION REQUIRED

C/N 316665: Issue amendment to change RSO approve modified facility.  
C/N 316804: Initiate technical review per R&D NUREG-1556, volume 7, and await licensee's DFP and prepare TAR for HQ.

NAME OF PERSON DOCUMENTING CONVERSATION      SIGNATURE      DATE  
Kevin Null      *Kevin Null*      1/18/08

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CONVERSATION RECORD

4/4/08

|TIME |DATE

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VISIT

CONFERENCE

TELEPHONE

INCOMING

OUTGOING

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NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

Clint Gregg, RSO

Aptuit

816-767-6000

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SUBJECT

C/N 316804

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SUMMARY

In reference to your 4/1/08 response to our 2/20/08 deficiency letter, please submit the following:

1. **Response to Item 9 of our 2/20/08 def. letter:** Define the word "routinely." Also, please be more definitive about the NRC guidance that you will use to determine individual participation in your bioassay program.

ANSWER: Mr. Gregg will resubmit his response and remove the word "routinely."

2. **Response to Item 10 of our 2/20/08 def. letter:** In attachment 7 to your response, please make a definitive commitment to follow NUREG-1556, Volume 7 for conducting surveys.

ANSWER: Mr. Gregg will resubmit his response and commit to follow Appendix Q to Volume 7.

3. **Response to Item 11 of our 2/20/08 deficiency letter:** Please submit a calculation to show that expected air effluent concentrations will be less than 10% of Part 20 limits to further support that stack release monitoring is not necessary. This will also provide additional support to Item 12.B. of our letter to demonstrate that an EA is not necessary for this licensing action.

ANSWER: Mr. Gregg will submit a calculation to demonstrate that air effluent will be < 10% of Part 20 limits.

4. Submit make and model number of Barium-133 and Cesium-137 sources.

ANSWER: Mr. Gregg will submit make and model numbers.

5. Clarify if Clint Gregg, RSO, is also to be listed as an authorized user.

ANSWER: Mr. Gregg will only be authorized for items 6.F. and 6.G., sealed sources used in the LSC's.

6. The description of experience in using nuclides for several a number of proposed authorized users does not include experience in chemical synthesis with radionuclides. Most of these individuals have experience in using lower levels of C-14 and H-3 for either analytical operations or analytical synthesis. Please clarify your request for authorization for these individuals.

ANSWER: Individuals who will be doing analytical operations will be testing synthesized compounds. Therefore, they should only be granted authorization for R&D. The individual who was listed as conducting "analytical synthesis" will be conducting analytical operations, not synthesis. Mr. Gregg will submit a correction.

7. Confirm that Michael Sadick is the only proposed user of Iodine and sulphur-35.

ANSWER: Yes, Mr. Sadick is the only person who will be authorized for iodine and sulphur radionuclides.

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ACTION REQUIRED

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NAME OF PERSON DOCUMENTING CONVERSATION

Kevin Null

SIGNATURE

*Kevin A. Null*

DATE

4/4/08

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ACTION TAKEN

SIGNATURE

TITLE

DATE

APPENDIX C

Item No.	Suggested Response	Yes	Description Attached
5.	<p><b>RADIOACTIVE MATERIAL</b></p> <p><b>Unsealed and/or Sealed Sources</b></p> <ul style="list-style-type: none"> <li>For unsealed materials:                             <ul style="list-style-type: none"> <li>Provide element name with mass number, chemical and/or physical form, and maximum requested possession limit.</li> <li>For potentially volatile materials (e.g., I-125, I-131, H-3), specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form.</li> </ul> </li> <li>For sealed materials:                             <ul style="list-style-type: none"> <li>Identify each Radionuclide (element name and mass number) that will be used in each source.</li> <li>Provide the manufacturer's (distributor's) name and model number for each sealed source and device requested.</li> <li>Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State.</li> <li>Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State.</li> </ul> </li> <li>Provide an Emergency Plan (if required). <i>Not required</i></li> </ul> <p><b>Financial Assurance and Recordkeeping for Decommissioning</b></p> <p>No response is needed from most applicants. If F/A or a DFP is required, submit the required documents as described in Regulatory Guide 3.66.</p>	<p>*</p> <p>*</p> <p>N/A</p>	<p>[ ]</p> <p>[ ]</p> <p>[ ]</p>
6.	<p><b>PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED</b></p> <p>List the specific use or purpose of each radioisotope.</p>	<p>*</p>	<p>[ ]</p>

*Requesting 7 m<sup>3</sup> H-3 from 1ci to 500ci  
 # C-14 from 1ci to 500ci  
 # S-35 from 20mc to 15ci  
 per 1/21/08, 1 hr. withdrawal  
 result to add p-32  
 I also informed because  
 that we do not request  
 I was [in] not just  
 waive is terminated  
 no, it is 8/2008.*

*Will need to re-submit RA in form of a DFP see 1/19/08 detail*

*Changing A-use from R+D for H-3, C-14 + S-35 from No D to radiopharmaceuticals. C-2*

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Item No.	Suggested Response	Yes	Description Attached
7.	<p><b>INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE</b></p> <p><b>RSO</b> <i>new RSO approved in previous amendment who has exp. in radiology and radioisotopes</i></p> <p>Provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.</p> <p><b>AUs</b></p> <p>Provide the name of each proposed AU, with the types and quantities of licensed material to be used. Also provide information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials.</p>	*	[ ]
8.	<p><b>TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (Occupationally Exposed Individuals and Ancillary Personnel)</b></p> <p>Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.</p> <p><i>instructor? Qualifications?</i></p>	*	<p>[ ]</p> <p><i>Items 8, AH-3</i></p> <p><i>Define criteria for hrs of "New category" &amp; limited experience</i></p> <p><i>E??</i></p>

→ Was RSO for similar license with ~~position~~ was licensed for radioisotopes in a Kansas license

MW  
Lst:  
Clint  
Gross

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\*  
*[Signature]*

→ Currently, RSO approves users. Due to have a new RSO & licensing request for significant ↑ in activity & to be approved for radioisotopes, will suggest that the license modify program to ~~request~~ remove authorization for RSO to approve users (LIC # 12) & list specifically list users on their license. This would require an amendment request & NRC approval for all new authorized users. → Also need to verify license's → over

Describe methods used to evaluate filtration systems for effluents from synthesis labs to determine if filters are saturated. Describe how wd. effluent to determine not exceeding Part 20 limits for release to environment.

APPENDIX C

Item No.	Suggested Response	Yes	Descripti Attache
9.	<b>FACILITIES AND EQUIPMENT</b> Describe the facilities and equipment to be made available at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage, preparation and measurement of radioactive materials. Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.	*	[ ]
10.	<b>RADIATION SAFETY PROGRAM</b> <b>Audit Program</b> The applicant is not required to, and should not, submit its audit program to the NRC for review during the licensing phase.	N/A	N/A

\* Change  
to item 9. This  
will not be a R.S.  
license of this time  
Use with not appropriate  
users/uses/facilities  
NRC will review  
+ Grand  
license.  
Also needs Part 20  
No 1. ATT 5

\* ATT 5 P. 1  
change in NPP  
to be filed  
require  
down per  
CRP in ATT 7  
N/A, vol. 7  
5/1/02  
N/A

Once request for significant Q in IT-3, C-14 & S-35, + authorization to conduct radio-synthesis, ~~but~~ license needs to describe microstructure to facilities + eqpt needed to safely conduct radio-synthesis operations &/or handle & store material for operations use & waste that is generated. Any changes to ventilation systems, monitoring of effluents released to environment, how many synthesis labs? special eqpt in these labs? I.D. all synthesis labs & waste storage area.

Att 7, p. 17

Need to readdress as stated here

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Item No.	Suggested Response	Yes	Description Attached
10.	<p><b>RADIATION SAFETY PROGRAM (Cont'd)</b></p> <p><b>Radiation Monitoring Instruments</b></p> <p>Describe the instrumentation that will be used to perform required surveys and state that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary."</p> <p style="text-align: center;"><b>OR</b></p> <p>Describe the instrumentation that will be used to perform required surveys and state that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Additionally, we will implement the model survey meter calibration program published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary."</p> <p><b>Material Receipt and Accountability</b></p> <p>Develop and maintain procedures for ensuring material accountability,</p> <p style="text-align: center;"><b>AND</b></p> <p>State that: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license."</p>	<p>*</p> <p>*</p> <p>*</p>	<p>[ ]</p> <p>[ ]</p> <p>[ ]</p>

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**OR**

ok

ok

Att 7, p. 13.

Att 7, p. 13.   
 Note: Need to re-address this section

APPENDIX C

Item No.	Suggested Response	Yes	Description Attached
10.	<p><b>RADIATION SAFETY PROGRAM (Cont'd)</b></p> <p><b>Occupational Dose</b> <span style="float: right;">Att 7, p. 13</span></p> <p>State that: "we have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20," <del>or</del> "we will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program - Occupational Dose' in NUREG - 1556, Vol. 7, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope,'" dated December 1999." <i>Be more definitive &amp; discuss program per NUREG 1A-6. Att 7, p. 13 appears to leave it up to us. Develop a second bioassay program based upon specifically referenced NRC guidance.</i></p> <p><b>Public Dose</b> <i>to us. Develop a second bioassay program based upon specifically referenced NRC guidance.</i></p> <p>No response is required from the applicant in a license application. <i>N/A</i></p> <p><b>Safe Use of Radionuclides and Emergency Procedures</b></p> <p>Develop and maintain procedures for safe use and emergencies. State that such procedures have been developed. <i>6k</i></p> <p>If an emergency response plan is needed, submit it as a separate part of the application. <i>Att 7, p. 14-15</i></p>	<p>*</p> <p>*</p> <p>N/A</p> <p>*</p> <p>[ ]</p>	<p>[ ]</p> <p>[ ]</p> <p>N/A</p> <p>[ ]</p> <p>[ ]</p>

Note ~~however~~ fact

Review bioassay program &

Need clear program that includes baseline bioassay, emergency bioassay, etc. Refer to NUREG \_\_\_\_\_



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Item No.	Suggested Response	Yes	Description Attached
10.	<p><b>RADIATION SAFETY PROGRAM (Cont'd)</b></p> <p><b>Survey</b></p> <p>State that: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions."</p>	<p>*</p> <p>[ ]</p>	<p>[ ]</p>

OK

RESUBMIT PER ~~NUREG~~ VOL. 7, SECT. 10

APPENDIX C

Item No.	Suggested Response	Yes	Description Attached
10.	<p><b>RADIATION SAFETY PROGRAM (Cont'd)</b></p> <p style="text-align: center;"><b>OR</b></p> <p>State that: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix R to NUREG - 1556, Vol. 7, "Consolidated Guidance about Materials Licenses: 'Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope,' dated December 1999."</p> <p><b>Transportation</b></p> <p>No response is needed from applicants during the licensing phase.</p>	<p>[ ]</p> <p>N/A</p>	<p>N/A</p>

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Item No.	Suggested Response	Yes	Description Attached
10.	<p><b>RADIATION SAFETY PROGRAM (Cont'd)</b></p> <p><b>Minimization of Contamination</b></p> <p>The applicant does not need to provide a response to this item under the following condition. NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: "Radioactive Material - Unsealed and/or Sealed Sources," "Facilities and Equipment," "Radiation Safety Program - Safe use of Radioisotopes and Emergency Procedures," "Radiation Safety Program - Surveys," and "Radiation Safety Program - Waste Management."</p>	N/A	N/A
11 <del>11</del>	<p><b>WASTE MANAGEMENT</b></p> <p>State that: "We will use the model waste procedures published in Appendix T to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999."</p> <p><i>Describe how you will determine that disposal of liquid waste via sanitary sew will be in part do limits</i> OR <i>"We will use the (specify either (1) Decay-In-Storage, (2) Disposal of Liquids Into Sanitary Sewerage) model waste procedures that are published in Appendix T to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999."</i></p>	*  [ ]  [ ]	[ ]  [ ]



EA needed?

CAT\* apply?