



CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU		DATE OF CONTACT	TYPE OF CONVERSATION	
James C. Hatten Radiation Safety Officer		09/21/2018	<input type="checkbox"/> E-MAIL <input checked="" type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING	
E-MAIL ADDRESS		TELEPHONE NUMBER		
jhatten@sahci.com		(815) 370-6538		
ORGANIZATION		DOCKET NUMBER(S)		
Eurofins Scientific		030-38742		
LICENSE NAME AND NUMBER(S)		MAIL CONTROL NUMBER(S)		
24-35149-01		609379		
SUBJECT				
Additional Information Request concerning the licensee's request to amend the referenced U.S. NRC radioactive materials license, including to remove Nann Green as an Authorized User (AU), to release one area of use, to remove the bioassay requirement, and to add 3 new AUs - A. Irvin, N. Steele & D. Werth				
SUMMARY AND ACTION REQUIRED (IF ANY)				
<p>This record concerns the licensee's July 9, 2018 letter (NRC Accession No. ML18198A226) requesting changes to the above referenced licenses including to: (I) remove Nann Green as an Authorized User (AU) listed in Condition No. 11 of the referenced license; (II) revise the tie-down commitments in Condition No. 16 of the referenced license to release an area of use located in a building at the 15 Research Park Dr. location of use listed in Condition No. 10.A. to the licensee's license; (III) revise the tie-down commitments in Condition No. 16 of the referenced license to remove a "bioassay requirement;" and (IV) list Angela Irvin as an AU for iodine-125 use; Nancy Steele as an AU for iodine-125 use; and list Diane Werth as an AU for iodine-125, carbon-14, hydrogen-3, phosphorus-32, phosphorus-33, and sulfur-35 uses in Condition No. 11 of the referenced license.</p> <p>Upon review, we have noted that this request is lacking some details needed to complete the review. As discussed, please see attached for information needed to complete our review of your request.</p> <p>Please provide the requested information within 14 days of this message (on or before October 5, 2018). Include a signed and dated cover letter transmitting your response. Submission of your response as a pdf file attached to an email or via facsimile to 630-515-1078 will allow for the quickest processing. Please call or email me with any questions you may have, or if you are unable to respond by the date suggested above. Thank you for your prompt attention to this matter.</p>				
NAME OF PERSON DOCUMENTING CONVERSATION				
Sara A. Forster, M.S., Health Physicist, Materials Licensing Branch, DNMS, RIII office, sara.forster@nrc.gov				
SIGNATURE			DATE OF SIGNATURE	
<i>Sara A. Forster</i>			09/21/2018	

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

MAIL CONTROL NUMBER(S)

24-35149-01

609379

SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

ADDITIONAL INFORMATION NEEDED FOR CONTINUED REVIEW

I. For Removal of Nann Green as an Authorized User:

No additional information need be submitted to complete the review.

II. For removing the area of use listed in your letter:

(1) Please indicate whether your request to remove one area of use is limited to removal of the referenced area of use, currently included in the 15 Research Park Dr. location of use, under Condition No. 10.A. to the referenced license.

A. If the request is also meant to limit the authorization in Condition No. 10.A. to licensed material listed in Subitem Nos. 6.A. through 6.F. to Subitem No. 6.A. only, please confirm the same.

B. If the new authorization in Condition No. 10.A. will remove previous authorizations listed in Subitem Nos. 6.B. through 6.F., please provide a complete history of use for authorizations being removed (of carbon-14, tritium, phosphorus-32, phosphorus-33, and sulfur-35) for the 15 Research Park Dr. location of use, including maximum possession by isotope and form, last use date, final disposition date, and confirmation that all materials used or stored at the 15 Research Park Dr. under this license have been disposed or otherwise transferred to another authorized location or recipient.

(2) If all primary activities - involving radioactive materials other than iodine-125 - at 15 Research Park Dr., have stopped, please provide final status surveys for all areas where such licensed radioactive materials were used or stored under the license including wipe test and area survey results, instrument calibration documentation, and names of individuals performing the final surveys.

A. Pursuant to Title 10 of the *Code of Federal Regulations* Section 30.36(j)(2)(i), for areas where licensed material other than iodine-125 was used or stored, report levels of gamma radiation in units of millisieverts (microrentgen) per hour (mSv/hr; μ R/hr) at 1 meter from surfaces and report levels of radioactivity, including alpha and beta, in units of disintegrations per minute per 100 square centimeters (dpm/100 cm²).

B. For any additional surveys submitted, please provide a facility diagram, keyed to the results.

(3) Please provide a history of non-exempt sealed sources removed from the 15 Research Park Dr. location of use. If such sources have been disposed or transferred to another licensee, please include documentation (e.g. letter confirming receipt; waste manifest; etc.), demonstrating their final removal from the facility.

(4) Please provide a history of leaking sources - if any - for materials used or stored at the 15 Research Park Dr. location, under the license. Attach copies of the most recent leak test results for sources identified in the transferred inventory, above.

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

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24-35149-01

609379

SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

III. For Revision of the bioassay requirement currently required by the license:

As discussed, please clarify the change that is being requested.

IV. For Addition of Authorized Users Angela Irvin, Nancy Steele, and Diane Werth:

As discussed, in accordance with NUREG 1556, Vol. 7, rev. 1, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers," please provide additional details as to uses to be authorized and training and experience for each proposed Authorized User, as noted on attached sheets

8.7.2 Authorized User

Regulations: 10 CFR 20.1101(b), 10 CFR 30.33(a)(3), 10 CFR 40.32, 10 CFR 70.22

Criteria: Authorized users (AU) must have adequate training and experience with the types and quantities of licensed material they propose to use.

Discussion: An AU (also known as "principal investigator," "permit holder," "source custodian," or by other licensee designations) is an individual whose training and experience have been reviewed and approved by the NRC, who is named on the license, and who uses or directly supervises the use of licensed material. The AU's primary responsibility is to ensure that radioactive materials used in his or her particular lab or area are used safely and according to regulatory requirements (see Figure 8-5). The AU is also responsible for ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

- (1) (a) For each radionuclide (iodine-125, carbon-14, tritium, phosphorus-32, phosphorus-33, and sulfur-35), please provide a description of the forms (i.e. any, non-volatile, prepackaged kits, etc.), purpose of use, and maximum quantities (amount per container, quantity per use, and overall limits, in microcuries or millicuries, as appropriate) of material that you are requesting that Diane Werth be authorized to use, under NRC Lic. No. 24-35149-01.
- (b) For Ms. Steele and Ms. Irvin, please provide a description of the forms, i.e. any, non-volatile, prepackaged kits, etc.), purpose of use, and maximum quantities (amount per container, quantity per use, and overall limits, in microcuries or millicuries, as appropriate) of material that you are requesting that they be authorized to use, under NRC Lic. No. 24-35149-01.

AUs must have adequate and appropriate training to provide reasonable assurance that they will use licensed material safely. Training for AUs should include: maintaining security of, and controlling access to, licensed material; and responding appropriately to events or accidents involving licensed material to prevent the spread of contamination.

- (2) Please provide a description of training Ms. Steele, Ms. Irvin, and Ms. Werth have had (formal training courses; hands-on training; RSO training courses; etc.) in:
 - (a) Maintaining security of, and controlling access to radioactive material, and
 - (b) Responding appropriately to events or accidents involving licensed material to prevent the spread of contamination

An AU should have (i) a college degree at the bachelor's level or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (ii) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities
- radiation detection instrumentation
- biological hazards of exposure to radiation (appropriate to the types and forms of byproduct material to be used)

(4) For each proposed new AU (Ms. Steele, Ms. Irvin, and Ms. Werth), please provide the date(s), format (lecture, online, etc.), and provider of training in the five radiation safety topics outlined above.

- hands-on use of radioactive materials

The amount of training and experience needed will depend upon the type, form, quantity, and proposed use of the licensed material requested, but it should cover the subjects stated.

(5) (a) Please provide quantities of iodine-125 with which Ms. Steele and Ms. Irvin have had hands-on experience, at the licensee's facilities. Include dates on which such experience was obtained, as available. For any additional hands-on experience, please provide date(s), institution(s) & location(s) where Ms. Steele and Ms. Irvin had hands-on experience, applicable to iodine-125 use requested under the license. Include isotopes and quantities.

(b) Please provide quantities of iodine-125, carbon-14, tritium, phosphorus-32, phosphorus-33, and sulfur-35 with which Ms. Werth has had hands-on experience, at the licensee's facilities. Include dates on which such experience was obtained, as available. For any additional hands-on experience, please provide date(s), institution(s) & location(s) where Ms. Werth had hands-on experience, applicable to uses requested under the license. Include isotopes and quantities.

An AU is supervising the use of radioactive materials when he or she directs personnel in operations involving the licensed material. Although the AU may delegate specific tasks to supervised users (e.g., conducting surveys, keeping records), he or she is responsible for the safe use of radioactive material to ensure that areas are not contaminated.

Applicants must name at least one individual who is qualified to use the requested licensed materials. In general, AUs must demonstrate training and experience with the type and quantity of material they propose to use. For example, someone with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities may not understand the risks of working with much larger (e.g., 10 or 100 times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high-energy beta emitters.

Response from Applicant:

Applicants should provide the following:

- name of each proposed AU with the types and quantities of licensed material to be used
- information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials; information should include, as a minimum:
 - formal training or education in radiation safety [topics covered; duration of training; when training was received; identity and location of training provider (note: a course outline may be provided)]
 - experience using licensed materials (types; forms; quantities handled; activities performed; duration of experience)

Applicants should provide information about the proposed AU's training and experience relative to the licensed material requested in the application. Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, etc. Submittal of unrelated material serves only to slow the review process.

Sandrik, Lauren

From: Forster, Sara
Sent: Friday, September 21, 2018 10:25 AM
To: Song, Taehoon; Pavon, Sandy; Sandrik, Lauren
Subject: FW: Additional Information Request re your letter requesting Amendment to Eurofins Scientific., NRC Lic. No. 24-35149-01, CN609379
Attachments: 03620.609379.24-35149-01 etc. RFAI via NRC 699 RFAI Signed with attachment.pdf

Could you please scan this Request for Additional Information Conversation Record in, and return to me?

Thank you! - Sara

From: Forster, Sara
Sent: Friday, September 21, 2018 10:01 AM
To: 'jhatten@sahci.com' <jhatten@sahci.com>
Subject: Additional Information Request re your letter requesting Amendment to Eurofins Scientific., NRC Lic. No. 24-35149-01, CN609379

Dear Mr. Hatten:

As indicated via my voicemail to you on September 21, 2018, additional information is needed to complete our review of your July 9, 2018 letter, requesting to amend the above-referenced license.

For additional guidance, please refer to the following resources:

- Title 10 of the *Code of Federal Regulations*, Part 30: <https://www.nrc.gov/reading-rm/doc-collections/cfr/part030/>
- NUREG 1556, Vol. 7, rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers": <https://www.nrc.gov/docs/ML1806/ML18065A006.pdf>

Please provide the requested information within 14 days of this message (on or before October 5, 2018). Include a signed and dated cover letter transmitting your response. Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. If you are submitting via email and either (1) the message size exceeds 10 MB or (2) you do not receive confirmation that the message has been received within 5 business days, you may use the [AMRDEC Safe Access File Exchange application](#). You may access AMRDEC directly using the website: <https://safe.amrdec.army.mil/safe/Welcome.aspx>. That site will allow you to upload the file and then direct it to be sent to my email address, sara.forster@nrc.gov. When at that website, you should choose the "Non-CAC Users" button to get started. When using AMRDEC to submit information, please call or email to confirm that I am in the office, as recipients must retrieve the file within 24 hours of submission. Please call or email me with any questions you may have, or if you are unable to respond by the date suggested above. Thank you for your prompt attention to this matter.

Sara A. Forster, Health Physicist Licensing Reviewer
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