NRC FORM 699
(11-2017)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
Gregory S. Hiatt Radiation Safety Officer	12/14/2018	☐ E-MAIL ☑ TELEPHONE ☐ INCOMING ☑ OUTGOING
E-MAIL ADDRESS tarqy@sbcglobal.net	**TELEPHONE NUMBER** (574) 298-9616	
ORGANIZATION Spectron mrc, LLC, 17490 Douglas Dr., South Bend, IN 46635	**DOCKET NUMBER(S)** 030-38044	
LICENSE NAME AND NUMBER(S) 13-32726-01MD	**MAIL CONTROL NUMBER(S)** **610131**	

SUBJECT
Additional Information Request concerning the licensee's request to amend the referenced U.S. NRC radioactive materials license, including to add iodine (I-123, I-124, and I-131) capsule compounding operations, with possession limits exceeding those requiring an emergency plan per 10 CFR 30.32

SUMMARY AND ACTION REQUIRED (IF ANY)

This record concerns the licensee's October 4, 2018 letter (NRC Accession No. ML18277A326) requesting to add line item iodine-123, iodine-124, and iodine-131 authorizations to Item No. 6 to the referenced radioactive materials license, including to the update Item 9 authorized uses for the referenced license to allow compounding of iodine-131 capsules.

Upon review, we have noted that this request is lacking some details needed to complete the review. First, it requests possession limits exceeding those in Title 10 of the *Code of Federal Regulations* (CFR) Section 30.72, and therefore - without providing reduced possession limits - would need to provide, for a release of radioactive materials, either an (i) evaluation showing that the maximum dose to a person offsite due to the release would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or (ii) emergency plan for responding to the release. Second, the request for an authorization for compounding would require additional facility information including specific ventilation system details as well as monitoring locations. As discussed, please see attached for information needed to complete our review of your request.

Please resubmit your amendment request as described. Include a signed and dated cover letter transmitting your response. Submission of your response via facsimile to 630-515-1078 or as a pdf file attached to an email will allow for the quickest processing. Please call or email me with any questions you may have, or if you are unable to respond within the next few days. If you are unable to fully respond at this time, you may withdraw your request without prejudice to resubmission. Thank you for your prompt attention to this matter.

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
Sara A. Forster	12/14/2018

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)	MAIL CONTROL NUMBER(S)
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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

ADDITIONAL INFORMATION NEEDED FOR CONTINUED REVIEW

I. For increasing the possession limit for iodine-131:

As discussed, in accordance with NUREG 1556, Vol. 13, rev. 1, "Program-Specific Guidance About Commercial Radiopharmacy Licenses," either:

A. Please reduce the requested iodine-131 possession limit from the requested 9.9 curies to one that does not (e.g. 5 curies) - when combined with possession limits for alpha emitters listed on the license (e.g. actinium-225 and astatine-211) - exceed that listed in 10 CFR 30.72;

OR

B. Please provide either an:

1. Evaluation showing that the maximum dose to a person offsite due to the release would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid including one or more of the following:

(i) The radioactive material is physically separated so that only a portion could be involved in an accident;
(ii) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
(iii) The release fraction in the respirable size range would be lower than the release fraction shown in 10 CFR 30.72 due to the chemical or physical form of the material;
(iv) The solubility of the radioactive material would reduce the dose received;
(v) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 10 CFR 30.72;
(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in 10 CFR 30.72; or
(vii) Other factors appropriate for the specific facility. OR

2. Emergency plan for responding to the release including the following information:

(i) A brief description of the licensee's facility and area near the site.
(ii) An identification of each rad. materials accident type for which protective actions may be needed.
(iii) A classification system for classifying accidents as alerts or site area emergencies.
(iv) Identification of the means of detecting each type of accident in a timely manner.
(v) - (vii) Brief descriptions of the:
- means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.
- methods and equipment to assess releases of radioactive materials.
- responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the NRC; also responsibilities for developing, maintaining, and updating the plan.

CONVERSATION RECORD (continued)

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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

(vii) A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the NRC operations center immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

(ix) - (xi) Brief description of the:

- Types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the NRC.
- Frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.
- Means of restoring the facility to a safe condition after an accident.

(xii) Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(xiii) A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct material.

NOTE: Prior to submitting its emergency plan to the NRC, the licensee must allow all offsite response organizations expected to respond in case of an accident 60 days to comment on its plan. The licensee shall provide any comments received within the 60 days to the NRC with the emergency plan.

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)	MAIL CONTROL NUMBER(S)
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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

II. Facility Information:

As discussed, in accordance with NUREG 1556, Vol. 13, rev. 1, please provide the following:

A. Descriptions of the area(s) assigned for the receipt, storage, preparation - including compounding of measurement, and distribution of iodine-123, iodine-124, and iodine-131 and the location(s) for radioactive iodine-123, iodine-124, and iodine-131 waste storage;

1. The revised facility diagram should be drawn to the scale of an 8 1/2 " x 11" sheet of paper, showing dimensions and highlighting any changes to the facility specifically designated for radioiodine use
2. The facility diagram should show sufficient detail to show any shielding added specifically for the compounding of radioiodine or other items added for radiation safety
3. The facility diagram should be in sufficient detail to indicate locations of shielding, the proximity of radiation sources- to unrestricted areas.
4. The facility diagram should show what is above, below and adjacent to the area where the radiodines will be compounded, dispensed, and stored.

B. Descriptions of the ventilation systems, including gloveboxes or fume hoods, with pertinent airflow rates, area differential pressures, filtration equipment, and monitoring systems for the use or storage of iodine-123, iodine-124, and iodine-131 likely to become airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions;

1. Include a description of the glove box in which the compounding will occur (manufacturer, model, etc.)
2. Describe how the glove box is connected to the main ventilation or other exhaust system.
3. Show where filtration equipment will be place and where the airborne radiation levels will be monitored
4. Show additional details sufficient to demonstrate ventilation system is adequate.

AND

C. Verification (e.g. calculation or other evaluation demonstrating that flow rates are adequate for procedures as proposed) that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within constraints for air emissions established under 10 CFR 20.1101(d).

III. Procedure for compounding of iodine-123, iodine-124, and iodine-131

As discussed, please provide additional details as to the procedure that will be used for compounding.

1. Describe how the radioiodine will be transferred to the glove box.
2. Provide a typical and maximum quantity that will be in an open vial, during the compounding
3. Include a description of any special handling and emergency equipment to be used and/or available during the compounding, including personal protective monitoring equipment, area monitors, etc.
4. Describe handling procedures, including for compounding, waste, and transferring finished capsules
5. Provide additional detail as needed to demonstrate that work will be done safely, without releases exceeding regulatory limits, and with exposures to workers as low as reasonably achievable.

Forster, Sara

From: Gregory Hiatt <tarqy@sbcglobal.net>
Sent: Monday, December 17, 2018 2:08 PM
To: Forster, Sara
Subject: [External_Sender] Re: Additional information requested re Spectron mrc, LLC amendment to add iodine compounding; Lic. 13-32726-01MD; CN610131

Sounds good.

Thanks

Greg

On Monday, December 17, 2018, 2:43:46 PM EST, Forster, Sara <Sara.Forster@nrc.gov> wrote:

Great! Thank you. I will call you at 3:30 eastern, if that is okay with you.

Sara Forster

From: Gregory Hiatt [mailto:tarqy@sbcglobal.net]
Sent: Monday, December 17, 2018 1:32 PM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] Re: Additional information requested re Spectron mrc, LLC amendment to add iodine compounding; Lic. 13-32726-01MD; CN610131

Sara,

I am available after 3pm eastern today if that is more convenient for you.

Thanks,

Greg

On Friday, December 14, 2018, 2:18:53 PM EST, Forster, Sara <Sara.Forster@nrc.gov> wrote:

Great. Thank you.

From: Gregory Hiatt [mailto:targy@sbcglobal.net]
Sent: Friday, December 14, 2018 1:00 PM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] Re: Additional information requested re Spectron mrc, LLC amendment to add iodine compounding; Lic. 13-32726-01MD; CN610131

Ms. Forster:

I will make myself available for your suggested call on Monday December 17, 2018 between the hours of 1000 eastern and 1500 eastern.

If you need to make any changes just let me know since I will be around all day on Monday and Tuesday.

Take care,

Greg Hiatt

On Friday, December 14, 2018, 1:06:47 PM EST, Forster, Sara <Sara.Forster@nrc.gov> wrote:

Dear Mr. Hiatt:

We have reviewed your October 4, 2018 letter (ML18277A326) requesting to add radioiodine compounding (I-123, I-124, and I-131) to the above-referenced licenses. Note that this letter may not be available electronically due to its containing sensitive facility information. As noted in the attached conversation record, additional information is needed to complete our review. Accordingly, please provide additional details to items noted in the attached conversation record, including:

1. Possession limit adjustment(s) as needed for iodine-131, actinium-225, and astatine-211 in order that limits in Title 10 of the *Code of Federal Regulations* Section 30.72 are not exceeded;

2. If possession limits are not adjusted, an evaluation showing that dose criteria in 10 CFR 30.32(i)(1)(i) are met;

3. If neither possession limits are adjusted nor a 10 CFR 30.32(i)(1)(i) dose evaluation provided, an emergency plan including elements specified in 10 CFR 30.32(i)(3) – no sooner than 60 days after allowing offsite response organizations to comment on that plan;

4. Revised facility diagram for areas where the radioiodines will be used or stored;

5. Detailed description of the ventilation system;

6. Verification (calculation or other evaluation) that ventilation system is adequate for radioiodine compounding as proposed; and

7. Detailed description (such as a procedure) of radioiodine compounding use authorizations that are requested.

I would like to call you the morning of Monday, December 17, 2018, between 9 am and 2 pm central (between 10 am and 3 pm eastern) to discuss this message. Please let me know your availability for a call, and a good time to reach you.

Following our discussion, we would appreciate if you could please submit additional information on or before the close of business Wednesday, December 19, 2018. If additional time is needed, please let us know when you will be able to provide a response; you may also withdraw your request without prejudice for resubmission. Additional guidance may be found in NUREG 1556, Volume 13, revision 1, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Commercial Radiopharmacy Licenses."

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Any response must be submitted under a signed and dated cover letter. Do not hesitate to call me with any questions you may have, or if you will need additional time to complete your response.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer

U.S. Nuclear Regulatory Commission - Region III

Division of Nuclear Materials Safety

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