



CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU Michael Levy, Radiation Safety Officer (RSO)	DATE OF CONTACT 09/23/2019	TYPE OF CONVERSATION <input checked="" type="checkbox"/> E-MAIL <input type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING
E-MAIL ADDRESS michael.levy@sodie.com	TELEPHONE NUMBER (412) 716-6900	
ORGANIZATION Sodie Network, Inc. d/b/a Sodie, 21000 Atlantic Blvd., STE. 730, Dulles, VA 20166	DOCKET NUMBER(S) 030-38460	
LICENSE NAME AND NUMBER(S) 24-32827-01MD	MAIL CONTROL NUMBER(S) 615342	
SUBJECT Additional Information Request concerning the licensee's request to amend its radioactive materials license , including to add authorizations for the use of IRE GalliEo germanium-68/gallium-68 generators for preparation of radiopharmaceuticals		
SUMMARY AND ACTION REQUIRED (IF ANY) <p>This record concerns the licensee's September 12, 2019 letter requesting use of the germanium-68/gallium-68 generators a commercial radiopharmacy. The referenced letter is non-publicly available due to sensitive security related information but is stored in NRC's Agencywide Document and Management System (ADAMS) at Accession No. ML19260G225.</p> <p>Upon review, we have noted that the application omits certain Radiation Safety Program information requested in the NRC's Germanium-68/Gallium-68 Pharmaceutical Grade Generators Licensing Guidance dated July 25, 2019, issued pursuant to Title 10 of the <i>Code of Federal Regulations</i> Section 35.1000. The referenced guidance document is publicly available and may be found in ADAMS at Accession No. ML19106A367. As discussed, please see attached for information needed to complete our review of your request.</p> <p>As we will discuss in the next 2 to 5 business days, please provide the requested information within 14 days of this message (on or before October 7, 2019). Include a signed and dated cover letter transmitting your resubmitted application. 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 09/23/2019	
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CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

24-32827-01MD

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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

ADDITIONAL INFORMATION NEEDED FOR CONTINUED REVIEW

ITEM 10: RADIATION SAFETY PROGRAM:

Sofie commitments were reviewed with respect to the referenced 10 CFR 35.1000 guidance. Upon review, the following commitments - found on pages 5 through 6 of the NRC guidance - were provided only in part or otherwise were not fully consistent with the guidance:

- *After installation, [the above referenced licensee shall] perform the conditioning procedure following the manufacturer's instructions properly disposing of the conditioning eluates prior to the first use of eluate for testing or human use;*
- *During the course of breakthrough testing, if the eluate exceeds the manufacturer's breakthrough limits, the eluate will not be distributed or administered to a patient or human research subject;*
- *[The above referenced licensee shall] send a written report to the appropriate NRC Regional Office within 30 days after discovery of a generator that is unable to meet the manufacturer's stated breakthrough limits of Ge-68 on multiple occasions rendering the generator unusable in human patients and research subjects; and*
- *[The above referenced licensee shall] conduct surveys of all areas of licensed material use, including the generator storage and kit preparation areas, for contamination each day of use;*

- (1) For initial conditioning of the generator, the amendment request contained a commitment to conduct properly dispose of eluate after the first use. However, the licensee does not appear to have committed to following the manufacturer's conditioning procedure, etc. **In accordance with suggested commitments, please provide the initial conditioning procedure commitment provided in the guidance or otherwise explain the adequacy of the limited disposal of eluate prior to first use commitment originally provided.**
- (2) For limitations on distributing eluate that exceeds breakthrough testing limits, the amendment request contained a commitment to not knowingly administer such material. However, limitations on distribution and the expectation that any eluate exceeding breakthrough testing limits would not be administered or distributed was not reflected in the request. **In accordance with suggested commitments, please provide the no-distribution-or-administration commitment provided in the guidance or otherwise explain the adequacy of the limited commitment originally provided.**
- (3) For written reporting of eluates that exceed breakthrough testing, there appears to be an exclusion of eluates from flushing the generator if in accordance with manufacturer procedures. It is unclear why such an exclusion would apply. **In accordance with suggested commitments, please provide the written reporting commitment provided in the guidance or otherwise explain the adequacy of the commitment - with exclusions - originally provided.**
- (4) For survey procedures, the amendment request contained a commitment to conduct wipe tests. However, other types of area surveys were not addressed in the request. **In accordance with suggested commitments please provide the survey commitment provided in the guidance or otherwise explain the adequacy of the wipe-test-only commitment originally provided.**

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