

U.S. NUCLEAR REGULATORY COMMISSION**Date:** July 9, 2012**TELEPHONE CONVERSATION RECORD****Mail Control
or Report No(s).**

577649

License No(s).

19-07538-01

Docket No(s).

03004544

Name of Licensee:

Dept. of Health and Human Services, FDA, CDRH

Name of Participant(s):Mary Walker, Radiation Safety Officer
Steven R. Courtemanche, Health Physicist NRC RI**Telephone No.**

301-796-2558, 610-337-5075

Subject:

Licensee Questions Concerning NRC RAI

(NOTE: This will be used as the
Documents Title in ADAMS)

7/6/2012 (14:25) Ms. Walker left a message for me to contact her as there were technical questions concerning the NRC's Request for Information that she needed to be answered. 7/9/2012 (07:30) I left a voice-mail message for Ms. Walker to return my call. (11:25) Ms. Walker returned my call while I was at an "All Employees" Meeting. (11:45) I spoke with Ms. Walker about her concerns. Question 2: Ms. Walker mentioned that the company taking the sealed sources performed their own leak tests. I stated that either the leak test result records from that company could be submitted for review or the licensee (HHS) would have to show that the equipment used for leak testing was capable of detecting 0.005 microcuries of removable activity for each isotope tested. The sealed sources of concern were two cobalt-57 sources, a cadmium-109 source, a carbon-14 source, and a cesium-137 source. If any of the sources were below 100 microcuries of activity of beta/gamma emitters, the license has an exemption and leak testing is not required. In your reply to Question 2, either give the methodology for the isotope or state that leak testing was not required because the sealed source's activity was below 100 microcuries. Question 3: Please account for the sources mentioned in Question 2 as towards their disposition. Ms. Walker indicated that all of the sources had been taken by a vendor except one that was still in-house and two that had been taken by the previous RSO. The manufacturer indicated that the in-house source was distributed as a specific item which would need to be disposed of prior to the termination of the license. I informed Ms. Walker that she would need to contact the previous RSO and determine if the sources qualified as transfers under 10 CFR 30.18 or would need to be transferred to the licensee for disposal. Ms. Walker stated that she would assess the situation and inform me of the actions taken by the licensee. Question 4: Ms. Walker stated that the material was ultimately disposed of through RSO, Inc. She would provide documentation with her reply to the RAI.

Action Required: None

Document Availability:

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Publicly Available

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Non-Publicly Available

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Non-Sensitive

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Sensitive – Privacy Act/ PII

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Immediate Release

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Non-Sensitive Copyright

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Sensitive – Internal

Normal Release Date: 07/17/12

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Sensitive- Proprietary

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Sensitive – Security-Related

Delayed Release Date:

SUNSI Review Completed By:

Steven R. Courtemanche

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