



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

July 6, 2012

Docket Nos. 03000582
03038332

License Nos. 06-00183-03
06-00183-07

Tammy Stemen, C.H.P.
Radiation Safety Officer
Yale University
Radiation Safety Section - OEHS
135 College Street, First Floor
New Haven, CT 06510-2411

SUBJECT: RETURN OF DOCUMENTS MARKED CONFIDENTIAL

Dear Ms. Stemen:

On July 5, 2012, you emailed us four documents describing your corrective actions taken in response to an event at your facility on June 7, 2012 where a radiopharmaceutical for a human-use research protocol was contaminated with another radiopharmaceutical. We agree that the event was not reportable under 10 CFR 35.3045, since the additional dose to the patient was less than 500 millirem maximum organ dose and 100 millirem effective dose equivalent. The documents submitted included:

- i. Preliminary Report – Investigation of an Incident Involving Administration of Radiopharmaceuticals dated June 26, 2012
- ii. Letter to the U.S. Food and Drug Administration dated June 26, 2012, describing the event
- iii. Final Report dated June 28, 2012
- iv. Addendum to Final Report dated July 3, 2012

Thank you for describing the corrective actions taken at your facilities for the event. However, a review of the above documents indicated that you considered the documents "Confidential." Since the documents were not required to be submitted as part of a report made under 10 CFR 35.3045 and since they are marked as "confidential" without the required information under 10 CFR 2.390 submitted; the above documents submitted in electronic format have been removed from our electronic files (i.e., email). In addition, we have destroyed all paper copies of the documents. Your corrective actions described within the documents will be reviewed in detail during a future inspection of your facilities.

Thank you for your cooperation.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Thank you for your cooperation.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

DOCUMENT NAME: G:\WordDocs\Current\Misc Letter\LYale University.doc

ML12194A743

SUNSI Review Complete: PL

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