

## RI - DNMS Licensee Event Report Disposition

Licensee: Wyeth Research  
 Event Description: Improper Transfer of Generally Licensed Items  
 License No: 37-0040103 Docket No: 03005990 MLER-RI: 2007-013  
 Event Date: 05/17/07 Report Date: 06/25/07 HQ Ops Event #: \_\_\_\_\_

1. REPORTING REQUIREMENT

<input type="checkbox"/>	10 CFR 20.1906 Package Contamination	<input type="checkbox"/>	10 CFR 30.50 Report
<input checked="" type="checkbox"/>	10 CFR 20.2201 Theft or Loss	<input type="checkbox"/>	10 CFR 35.3045 Medical Event
<input type="checkbox"/>	10 CFR 20.2203 30 Day Report	<input type="checkbox"/>	License Condition
<input type="checkbox"/>	Other _____		

2. REGION I RESPONSE

<input type="checkbox"/>	Immediate Site Inspection	Inspector/Date	_____
<input type="checkbox"/>	Special Inspection	Inspector/Date	_____
<input type="checkbox"/>	Telephone Inquiry	Inspector/Date	_____
<input type="checkbox"/>	Preliminary Notification/Report	<input type="checkbox"/>	Daily Report
<input checked="" type="checkbox"/>	Information Entered in RI Log	<input checked="" type="checkbox"/>	Review at Next Inspection
<input type="checkbox"/>	Report Referred To: _____		

3. REPORT EVALUATION

<input checked="" type="checkbox"/>	Description of Event	<input checked="" type="checkbox"/>	Corrective Actions
<input checked="" type="checkbox"/>	Levels of RAM Involved	<input type="checkbox"/>	Calculations Adequate
<input checked="" type="checkbox"/>	Cause of Event	<input type="checkbox"/>	Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

<input type="checkbox"/>	Release w/Exposure > Limits	<input type="checkbox"/>	Deliberate Misuse w/Exposure > Limits
<input type="checkbox"/>	Repeated Inadequate Control	<input type="checkbox"/>	Pkgng Failure > 10 rads/hr or Contamination > 1000x Limits
<input type="checkbox"/>	Exposure 5x Limits	<input type="checkbox"/>	Large# Indivs w/Exp > Limits or Medical Deterministic Effects
<input type="checkbox"/>	Potential Fatality	<input type="checkbox"/>	Unique Circumstances or Safeguards Concerns
<input type="checkbox"/>	If any of the above are involved:		
<input type="checkbox"/>	Considered Need for IIT	<input type="checkbox"/>	Considered Need for AIT
	Decision/Made By/Date: _____		

5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only)

<input type="checkbox"/>	Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
<input type="checkbox"/>	Medical Consultant Used-Name of Consultant/Date of Report: _____
<input type="checkbox"/>	Medical Consultant Determined Event Directly Contributed to Fatality
<input type="checkbox"/>	Device Failure with Possible Adverse Generic Implications
<input type="checkbox"/>	HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

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Non-Public                      Inspector Signature: Michael C. Reischer                      Date: 07/10/2007  
 Public-SUNSI REVIEW COMPLETE                      Branch Chief Initials: [Signature]                      Date: 7/10/2007

# Wyeth

**Wyeth Research**  
Mail Stop COL RS 1149  
500 Arcola Rd.  
Collegeville, PA 19426

**Robert C. Wickline**  
Radiation Safety Officer  
Radiation Safety  
484—865-5546 tel

June 29, 2007

USNRC Region 1  
475 Allendale Rd.  
King of Prussia, PA 19406-1415

2007 JUL -2 PM 2:36  
RECEIVED  
REGION 1

Attn: Michelle Beardsley

Subject: Improper transfer of generally licensed items

Dear Ms. Beardsley:

This report is pursuant to the requirement in 10 CFR 20.2201 regarding the loss of licensed material. This matter was reported to the NRC Operations Center in Washington, DC on June 25<sup>th</sup>.

Wyeth Research in Collegeville, PA operates under NRC license number 37-00401-03.

1. Description of the licensed material involved, including kind, quantity, and chemical and physical form:

The material in question is generally licensed material and is contained within a Berger Supercritical Fluid Chromatography (SFC) instrument.

- <sup>63</sup>Ni electron capture detector (ECD), 14.09 mCi;
- Manufactured by Agilent,
- Sealed Source and Device Registry number G1223A,
- Serial number K4879.

2. Description of the circumstances under which the loss occurred:

Chemistry lab personnel wishing to upgrade the capabilities of the SFC identified Accelapure Corporation, 3 Kinross Court, Newark, Delaware as the vendor that would perform this service. Accelapure performs contract laboratory services utilizing SFC, in addition to servicing and upgrading SFC instruments. During the time that the SFC was in their possession Accelapure was re-organized and is now conducting

business under the name of Lotus Separations. Accelapure/Lotus Separations does not have a license to possess  $^{63}\text{Ni}$ .

On May 17, 2007 the SFC was sent, without the RSO's knowledge, to Accelapure for upgrades and modifications. This work did not include activities that would involve the removal of the ECD or the need to access the ECD. The portion of the instrument containing the ECD remained intact.

The transfer off-site was discovered on Wednesday June 13, 2007 as follows. Wyeth Radiation Safety personnel visited the laboratory location where the SFC is normally used on Wednesday June 13<sup>th</sup>, to perform a sealed-source leak test and inventory. The Radiation Safety Officer was notified that day that the SFC was unaccounted for. The RSO visited the lab Wednesday afternoon and was informed that the SFC had been sent out for modifications. The respondent was unaware of further details and suggested that the RSO return to the lab on Thursday June 14<sup>th</sup> when the responsible party would return to work. The RSO sent an e-mail to the responsible party on the 13<sup>th</sup> requesting the company name, contact name, and contact information of the recipient of the SFC. Details of the transfer to Accelapure were communicated to the RSO on Thursday June 14<sup>th</sup>.

3. Statement of disposition of the licensed material involved:

The SFC and generally licensed sealed source within were returned to Wyeth on Friday June 29<sup>th</sup>.

4. Exposures of individuals to radiation:

Doses to personnel are not expected, since the licensed material will remain in the sealed source.  $^{63}\text{Ni}$  is a weak beta emitter and the radiation will not escape through the metallic body of the sealed source.

5. Actions that have been taken to recover the material:

The RSO contacted Ken Klein of Accelapure who confirmed that the SFC would be returned to Wyeth as scheduled, which was 3 days after my conversation with him.

6. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss of licensed material.

Wyeth's Radiation Safety Office ships all specifically licensed material. Instruments such as a gas chromatograph or liquid scintillation counter that contain generally licensed material within will be posted with a label indicating that the Radiation Safety Office must be contacted prior to making arrangements for a transfer of such a device.

Sincerely,

A handwritten signature in cursive script, appearing to read "Robt C Wickline".

Robert C. Wickline, RSO

Cc: Mary Dorman  
Paul Linsalata