

From: Coffin, Tim [Tim.Coffin@astrazeneca.com]
Sent: Wednesday, November 30, 2011 11:33 AM
To: Lawyer, Dennis
Cc: Walsh, Shaun; Gobris, David M
Subject: Modification/Updates to NRC Form 314 Extra Pages (License Termination Package)
Attachments: USBC_OW1B07_EXCHANGE_11302011-111119.pdf

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Mr. Dennis Lawyer,

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Attached please find a signed PDF file copy of the requested changes to the NRC Form 314 pages that were part of the AstraZeneca (AZ) License (#07-03990-01) Termination Package. Additional statements have been included on how AZ handled exempt H3/C14, LSC/animal tissue wastes addressed in 10 CFR 20.2005; and the status of AZ Holding Tank Analysis Records for liquid released to the sewer from Lab L326.

Hope these additional statements satisfy your inquiry.

Respectfully,

Timothy Coffin
Radiation Safety Officer
AstraZeneca Pharmaceuticals, LP
Wilmington, DE



NRC FORM 314 (continued)

NRC 314 SUMMARY NOTES

SEALED SOURCES:

AstraZeneca (AZ) had no specifically licensed sealed sources.

All AZ generally licensed sealed sources (i.e., calibration standards, ECDs, staticmasters, equipment sources, etc.) have been returned to the original manufacturer or transferred to another licensee. The confirmation receipts for all transferred sealed sources have been received.

No generally licensed sealed sources held by AZ were ever found to be leaking.

ZERO RADIOACTIVE INVENTORIES:

All radioactive materials (i.e., compounds, waste, equipment standards, etc.) have been disposed or transferred to another licensee. The confirmation of receipt for all disposed or transferred radioactive materials has been received.

SPILLS:

AZ has not experienced any major leaks or spills of radioactive material.

DISPOSAL OF SPECIFIC WASTES:

AZ did not use the exemption under 10 CFR 20.2005 for disposing of liquid scintillation counting medium or animal tissue, 0.05 microcurie or less of H3 and C14, as if it were not radioactive. All of these types of waste were always manifested and disposed as radioactive wastes.

SEWER RELEASE:

The only RSO approved AZ lab that controlled and released nuclides (H3 and C14) to the sewer was the radiosynthesis lab (L326). The radiosynthesis lab was in operation from September 16, 2003 to April 2011.

The holding tank contents in Lab L326 were checked to confirm that all activity readings were below the AZ Action Level of 25,000 dpm/ml before the tank contents could be released to the sewer. The AZ Action Level was well below the quantity and concentration limit requirements listed in the 10 CFR 20.2003. The one time activity readings were found to be above the AZ Action Level resulted in the tank contents being pumped out and contained for disposal as radioactive aqueous waste.

NRC 314 SUMMARY NOTES

SEWER RELEASE: (continued)

Further confirmation of the sewer release limits being met was shown by being in compliance with the Delaware, New Castle County, AZ Waste Water Discharge Permit (0.12 maximum curies per year). Under the AZ Waste Water Discharge Permit, Beta Testing was done of the sewer effluent. The highest level recorded resulted in less than 0.003 curies per year.

The holding tank analysis records were maintained in a black binder, on a shelf over the wash sink, in the gowning area leading into Lab L326. Unfortunately, the actual black binder of analysis records is not available for inspection. The binder was misplaced, lost, disposed, or accidentally destroyed during the transfer and storage of files to close Lab L326. A thorough search did not result in locating the missing records.

RECORDS TRANSFER AND RETENTION:

AZ will transfer and maintain all radioactive program records for permanent storage in accordance with the AZ File Retention Policy. Records will be maintained at a, company approved, archive records storage facility.



Shaun Walsh
Vice President, Business Services
AstraZeneca Pharmaceuticals, LP
Wilmington, DE