

GENOMESYSTEMS, INC8620 Pennell Drive
St. Louis, Missouri 63114

a specialized resource for genetic research

Telephone:
1-800-430-0030
(314) 692-0033
Facsimile:
(314) 692-0044
www.genomesystems.com

June 9, 1997

United States Nuclear Regulatory Commission
Regional Administrator
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Sir/ Madam:

I am responding in accordance with 10 CFR 2.201, Notice of Violation for Genome Systems, Inc. License No. 24-26778-01, Docket No. 030-34332, inspection date March 24, 1997, **Reply to a Notice of Violation.**

1. "...licensee has receive radioactive labeled packages not exempt from the contamination monitoring requirement, and the licensee has failed to monitor each package for radioactive contamination."

Pre-inspection, our radioactive material check in procedure consisted of monitoring package both prior to opening and after the source container had been removed, before discarding in either radioactive waste or regular trash.

The inspecting officer pointed out this procedure did not follow the procedure outline in our license item 10 (b) (2). Since, I have updated the Radioactive Material Check In Procedure to reflect that of item 10 (b)(2) in our license. This form now requires interactive responses from the individual who is checking in the radioactive material and provides a written record. This has been in service since 12 May 97.

2. "...orders for radioactive material had been placed by other individuals rather than the Radiation Safety Officer as required."

Pre-inspection, radioactive material orders had been place by individuals other than the Radiation Safety Officer(RSO). This occurred primarily due to the RSO primarily being assigned to and supervising the second shift here at Genome Systems.

Post-inspection, I have set up as many standing- orders as possible. I have also add a column to the Radionuclide Purchasing Log for RSO Approval and then I place the order the following day. Any standing orders requiring changes must be done through the RSO as well. This more accurately reflects item 10 (a)(1) in our license. This has been in service since 1 May 97.

If you have any question, please call me.

Sincerely,

William E. Nash
Radiation Safety Officer
Mapping Shift Supervisor
Genome Systems, Inc.

Radioactive Material Check In Procedures:

1. Put on double gloves, lab coat, and eye protection. Visually inspect the outside of package for damage. Monitor package, if acceptable, remove packing slip, open package:
 - a) Do packing slip and vial labels agree?
 - b) Does the source container appear intact? Inspect for cracked vials, broken seals, loss of liquid, discoloration of packing material, ect.
2. Monitor the empty package and any packing materials for contamination. Discard any contaminated materials as **RADIONACTIVE WASTE. IF NOT CONTAMINATED,** remove or obliterate any radiation labels and discard the materials in the regular trash.

Signature

Date

~~Pre~~ Pre-Inspection Form, This is Page 2 of Radionuclide
Accountability Form

Radioactive Material Check In Procedures:

1. Put on double gloves, lab coat, and eye protection. Place carton on bench designated for radioactive usage and visually inspect the outside of package for any signs of damage.
 - a) Describe the condition of packaging: _____
 - b) If NO visible damage, if visible damage, wet package, discoloration, notify the RSO immediately @ Home 314-894-8563, pager 314-509-3594.
2. Measure and record exposure rate at 1 meter from package surface: _____ mR/hr.
 - a) If >10 mR/hr, stop and notify RSO immediately @ Home 314-894-8563, pager 314-509-3594.
3. Measure and record exposure rate at surface of package surface: _____ mR/hr.
 - a) If >200 mR/hr, stop and notify RSO immediately @ Home 314-894-8563, pager 314-509-3594.
4. Open package.
 - a) Remove packing slip, verify contents match packing slip, *Yes/No (circle one)*
 - b) Check source container for cracks, or broken seal loss of liquid ect. Note the condition of source container: _____
 - c) Wipe external surface of source container with a moistened filter paper held with forceps and assay with survey meter record: _____ mR/hr.
5. Monitor packing material and packages for contamination before discarding. If not contaminated, obliterate radiation labels before discarding in regular trash. If contaminated, treat as radioactive dry waste.

Signature

Date

Post-inspection form, This is Page 2 of Radionuclide
Accountability form.

