

**From:** Elizabeth Ullrich  
**To:** [dorie.waddick@cfsan.fda.gov](mailto:dorie.waddick@cfsan.fda.gov)  
**Date:** Mon, Aug 25, 2003 11:23 AM  
**Subject:** additional information needed for the inspection

Dorie,

Constance was to follow up to find additional information about the following issue that was identified late Friday morning, after our decommissioning discussion. This is related to the receipt and surveys of incoming packages.

Two packages were recorded, in what Ron said was his handwriting, as being received on May 9, 2003 at 2:10 pm. This is also recorded on the "Receipt for Radioactive Material Inventory" in his handwriting in blue ink. These were packages 07-03 (PO 039620) and 08-03 (PO 039620) which were actually two vials in one package. Below that, in a line which was later crossed out, was package 09-03 with PO 445448, dated May 21, 2003. After several lines stating a correction which we still do not quite understand, is package 09-03 for a different package with PO 312627 which is listed as received on May 9, and the survey paper for this package also says May 9, 2003 at 2:10 pm but is in a different hand-writing, not Ron's. [Although we noted that Ron keeps copies of blank forms with his signature available, and this "Receipt of Radioactive Materials Report" appeared to be one of those with his xeroxed signature.] Package 10-03 (PO 445448) is listed as received on May 21, 2003 in what appears to be the same handwriting as the second 09-03 package with PO 312627 (which Constance said was hers) but with no time recorded. [The May 21 package also has Ron's xeroxed signature, but Constance signed her name under his signature.] According to Constance and Ron, Constance did packages on May 21 because Ron was out on sick leave. It seems to us that PO 312627 may actually have been surveyed on May 21, not May 9. This is further confounded by the ship date of May 8 on the incoming package shipping paper for PO 312627.

Constance was going to get copies of the Shipping/Receiving paperwork for May 9 and May 21. This is paperwork which she says Ron or she must sign when they collect packages from Shipping/Receiving. Constance had planned to fax us that information on Friday. As she is out for the next two weeks, we would appreciate it if someone else could get us that information.

There are several concerns with package receipt and surveys which may result in another violation: surveys were not always done, sometimes only radiation level surveys were done but not wipe surveys, OR perhaps records are not being maintained. Also, if this package was received on May 9 but not surveyed until May 21, there is a violation of the requirement to perform surveys within 3 hours of receipt.

The other unfinished business is that of Hewlett-Packard ECD Serial NO. H2571 . This was tested, and re-tested, in September and October 2002 as suspected of leaking. It was not apparently leak-tested in 2003 and its location could not be verified before we left. Constance believes it was disposed of, but that it will take some time to track the disposal record. If it is located before she returns, it would help us to know that also.

thanks,

Betsy (610) 337-5040 or [exu@nrc.gov](mailto:exu@nrc.gov)  
Donna (610) 337-5371) or [dmj@nrc.gov](mailto:dmj@nrc.gov)

**CC:**

Donna Janda

**From:** "Waddick, Doris E" <Doris.Waddick@cfsan.fda.gov>  
**To:** "Elizabeth Ullrich" <EXU@nrc.gov>  
**Date:** Mon, Aug 25, 2003 1:35 PM  
**Subject:** RE: additional information needed for the inspection

Thanks for providing an update on Friday morning's record review. We continued to meet with our contractors until after 2:00 pm Friday on the FB-8 Decommissioning project. So, Ron went out to MRC this morning to get copies of the shipping and receiving paperwork. Beth or I will take a look at what he brings back and fax it to you, if not today, tomorrow.

Beth called from FB-8 in DC this morning and indicated that she apparently found the missing monthly surveys for March, April, May, June, and July 2001 packed up in a blue tote.

Beth will track the ECD tomorrow. We will notify you as soon as we can verify the ECD location.

Dorie Waddick  
Chief, OMS/Safety Management Staff  
Wiley Building, Room 4C-007, HFS-657  
5100 Paint Branch Parkway  
College Park, MD 20740  
(301) 436-2176 phone  
(301) 436-2629 fax

-----Original Message-----

From: Elizabeth Ullrich [mailto:EXU@nrc.gov]  
Sent: Monday, August 25, 2003 11:24 AM  
To: Waddick, Doris E  
Cc: Donna Janda  
Subject: additional information needed for the inspection

Dorie,

Constance was to follow up to find additional information about the following issue that was identified late Friday morning, after our decommissioning discussion. This is related to the receipt and surveys of incoming packages.

Two packages were recorded, in what Ron said was his handwriting, as being received on May 9, 2003 at 2:10 pm. This is also recorded on the "Receipt for Radioactive Material Inventory" in his handwriting in blue ink. These were packages 07-03 (PO 039620) and 08-03 (PO 039620) which were actually two vials in one package. Below that, in a line which was later crossed out, was package 09-03 with PO 445448, dated May 21, 2003. After several lines stating a correction which we still do not quite understand, is package 09-03 for a different package with PO 312627 which is listed as received on May 9, and the survey paper for this package also says May 9, 2003 at 2:10 pm but is in a different hand-writing, not Ron's. [Although we

noted that Ron keeps copies of blank forms with his signature available, and this "Receipt of Radioactive Materials Report" appeared to be one of those with his xeroxed signature.] Package 10-03 (PO 445448) is listed as received on May 21, 2003 in what appears to be the same handwriting as the second 09-03 package with PO 312627 (which Constance said was hers) but with no time recorded. [The May 21 package also has Ron's xeroxed signature, but Constance signed her name under his signature.] According to Constance and Ron, Constance did packages on May 21 because Ron was out on sick leave. It seems to us that PO 312627 may actually have been surveyed on May 21, not May 9. This is further confounded by the ship date of May 8 on the incoming package shipping paper for PO 312627.

Constance was going to get copies of the Shipping/Receiving paperwork for May 9 and May 21. This is paperwork which she says Ron or she must sign when they collect packages from Shipping/Receiving. Constance had planned to fax us that information on Friday. As she is out for the next two weeks, we would appreciate it if someone else could get us that information.

There are several concerns with package receipt and surveys which may result in another violation: surveys were not always done, sometimes only radiation level surveys were done but not wipe surveys, OR perhaps records are not being maintained. Also, if this package was received on May 9 but not surveyed until May 21, there is a violation of the requirement to perform surveys within 3 hours of receipt.

The other unfinished business is that of Hewlett-Packard ECD Serial NO. H2571 . This was tested, and re-tested, in September and October 2002 as suspected of leaking. It was not apparently leak-tested in 2003 and its location could not be verified before we left. Constance believes it was disposed of, but that it will take some time to track the disposal record. If it is located before she returns, it would help us to know that also.

thanks,  
Betsy (610) 337-5040 or exu@nrc.gov  
Donna (610) 337-5371) or dmj@nrc.gov

**CC:** "Reed, Elizabeth" <Elizabeth.Reed@cfsan.fda.gov>, "Rosser, Constance" <Constance.Rosser@cfsan.fda.gov>