

From: Larry Camper
To: Eric Compton, John Jankovich, John Lubinski, Se...
Date: Fri, Jan 22, 1999 8:02 AM
Subject: Fwd: accepting ISO certifications

Please implement this policy immediately. Thanks.

Mail Envelope Properties (36A876EB.563 : 18 : 22078)

Subject: Fwd: accepting ISO certifications
Creation Date: Fri, Jan 22, 1999 8:02 AM
From: Larry Camper

Created By: TWFN_DO.TWF4_PO:lwc

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Files	Size	Date & Time
Mail		
MESSAGE	599	Friday, January 22, 1999 8:02 AM

Options

Expiration Date: None
Priority: Standard
Reply Requested: No
Return Notification: None

Concealed Subject: No
Security: Standard

From: Michele Burgess
To: Larry Camper
Date: Tue, Jan 19, 1999 12:26 PM
Subject: accepting ISO certifications

Please see attached file - for your review and comment.

I drafted the attachment for you to send to the SSD staff regarding the change to accept ISO certs in the SSD review.

Re: New policy regarding acceptance of ISO-9000 certification during approval of SSD QA/QC

In the past, it has been policy to not allow applicants to submit commitments regarding their ISO-9001 certification in lieu of submitting QA/QC procedures to meet the QA/QC requirements for an SSD review. Due to increased use of ISO-9000 certification, and in an effort to reduce licensee burden, this policy has been changed. Since this new policy is not contained in NUREG-1556, Volume 3, this email serves as notice of the change in policy until we have an opportunity to issue additional guidance on this topic.

We are allowing the following for Perkin-Elmer (PE):

The device is an ECD in an GC. The ECD components are manufactured under PE Connecticut. PE Connecticut kits them and sends them to NRD. At NRD, the parts are assembled and the source installed. The completed ECD is sent to PE Singapore for assembly into the GC. The remaining GC components are manufactured under PE Singapore.

PE Connecticut commits to use an acceptable level of removable contamination of " <0.005 microcurie (185 Bq)".

In lieu of submitting procedures demonstrating QA/QC performed, PE Connecticut commits to the following:

- a. PE Singapore will manufacture all units in accordance with a current ISO-9001 or ISO-9002 program, and PE Connecticut will manufacture and distribute all units in accordance with a current ISO-9001 program.
- b. The procedures will ensure, prior to initial distribution:
 1. design conformity in accordance with information submitted in support of the application (including materials, dimensions within stated tolerances, manufacturing methods, assembly methods, labeling), using sampling methods that meet the minimum sampling rates in 10 CFR 32.110.
 2. all units are leak test less than 0.005 microcurie (185 Bq)
 3. all units tested for proper operation of all safety features
 4. all units verified that radiation levels do not exceed maximums stated in application.

PE Connecticut submitted copies of PE Connecticut's ISO-9001, and PE Singapore's ISO-9002 certificates.

PE Connecticut will audit PE Singapore on an annual basis. Included in the audit will be the following:

- ensure that approved and controlled procedures are in use and understood.
- ensure that critical paperwork (wipe test results, serial numbers, etc.) is processed properly and is on file.
- ensure that the sealed source is obtained from only those vendors list on our registration
- ensure that radiation test results are within acceptable levels and units are shipped within the 6-month wipe test period.

- ensure that the VOYAGER hardware and labeling meets NRC registration documentation
- ensure that shipments include proper paperwork

All units will shipped to PE Connecticut prior to initial distribution.

Prior to initial distribution, for all units, PE Connecticut will review the associate paper work from PE Singapore documenting QA/QC, and will review leak testing to ensure that all required was done and that leak test was within 6 months.

Prior to initial distribution, all units distributed for use under a general license, PE Connecticut will perform the following checks:

- correct labeling on device and inclusion of correct user manual/materials
- tamper resistant hardware in the locations as described in the device application
- overall unit appearance

If you receive an application that includes reliance on the applicants ISO-9000 certification to demonstrate that they have an acceptable QA/QC program, you should evaluate whether the submittal is adequate based on the approach taken in the Perkin-Elmer case, then discuss the issue with me for approval. In the near future, we will discuss and finalize general guidance for accepting ISO certification. Note that this only includes British ISO certification.