

From: Seung Lee
To: Joseph Tchira; Shane Brightwell
Date: 08/09/2001 3:37:06 PM
Subject: Request for Additional Information #3

Good afternoon, Mr. Tchira!

We found that the following information submitted have to be clarified:

1. In the original application, the labeling has (1) Model Name, (2) Distributor's Name, and (3) Distributor's Website Address. However, in the letter dated July 24, 2001, it has the radionuclide (3H) and website address. The 10 CFR 32.25 requires the byproduct material and identification of the manufacturer or initial transferor. Please provide the rationale that the distributor's name had been dropped.
2. In Page 9 of 07/24/01 letter, the audit frequency should initially be on a monthly basis; the frequency can be increased at the discretion of the QCM; a decrease in frequency should be approved by the QCD and should be based on the merit of program performance. Please provide the maximum duration between audits when the frequency decreases.

Please submit the requested information within thirty days of the date of this e-mail. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

If you have any questions, please let me know.

CC: Ask ; JPJ2

Mail Envelope Properties

(3B72E662.506 : 6 : 20584)

Subject: Request for Additional Information #3
Creation Date: 08/09/2001 3:37:06 PM
From: Seung Lee

Created By: SJL@nrc.gov

Recipients	Action	Date & Time
aol.com ProRadCon (Shane Brightwell)	Transferred	08/09/2001 3:37:21 PM
lite-pro.com jtchira (Joseph Tchira)	Transferred	08/09/2001 3:37:21 PM
nrc.gov twf4_po.TWFN_DO ASK CC (Ask)	Delivered Opened	08/09/2001 3:37:06 PM 08/09/2001 3:41:05 PM

JPJ2 CC (JPJ2)

Opened

08/09/2001 3:49:59 PM

Post Office

aol.com
lite-pro.com
twf4_po.TWFN_DO

Delivered

Route

internet
internet
08/09/2001 3:37:06 PM nrc.gov

Files

MESSAGE

Size

1985

Date & Time

3:37:06 PM 08/09/2001

Options

Auto Delete: No
Expiration Date: None
Notify Recipients: Yes
Priority: Standard
Reply Requested: No
Return Notification: None

Concealed Subject: No
Security: Standard

To Be Delivered: Immediate
Status Tracking: Delivered & Opened