

From: "Stephanie Jones" <stephanie.jones@qynergy.com>
To: "Joshua Palotay" <JXP5@nrc.gov>
Date: 1/22/2008 1:28:20 PM
Subject: RE: Qynergy Response to RAI dated November 6, 2007

Mr. Palotay,

I have attached three JPEGs that I believe will fill the requirements. If you have any trouble with them or if you need any other information, please let me know.

Stephanie

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

From: Joshua Palotay [mailto:JXP5@nrc.gov]
Sent: Friday, January 18, 2008 8:15 AM
To: Stephanie Jones
Cc: John Jankovich; Tomas Herrera
Subject: Qynergy Response to RAI dated November 6, 2007

Ms. Jones,

Thank you for your response to our Request for Additional Information (RAI) dated November 6, 2007. Your response dated December 4, 2007 answered most of our questions; however, a few more clarifications need to be made.

A) In our RAI, question 6.1 (in regard to labeling) asked you to "Provide an illustration of the device, showing the information that is discussed in the application (Section 3 "Labeling," Page 5)." The images of the device labeling you submitted, both with your original application and in the response to the RAI, are missing two components for adequate labeling. The images do not show: 1) Activity, and 2) Date of assay. As per Section "3 Labeling" (page 5) of your original application, indicates that these two components are part of the label. This would be consistent with the requirements shown in NUREG-1556 Vol. 3, Rev.1.

Please submit a picture of the devise that displays all required components of a label, as described in NUREG - 1556, Vol.3, Rev. 1 (page 10-9), to include: 1) Activity, and 2) Date of assay.

B) In our RAI, question 3.2 asked you to "Provide non-proprietary copies of Figure 1 (Page 6) and Figure 2 (Page 7) in electronic form. We intend to use these illustrations in the registration certificate." However, we are unable to extract Figure 2 from the page without disturbing the part labels, as Figure 2 is not a single image file.

Please submit these pictures (Figure 1 and Figure 2) as separate JPEG files which include all appropriate labeling and schematics as part of the image file.

You may submit any information requested above as an e-mail attachment. Please contact me if you have any questions.

Sincerely,

Joshua Palotay

Joshua A. Palotay, M.S.
Health Physicist

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CC: "John Jankovich" <JPJ2@nrc.gov>, "Tomas Herrera" <TXH1@nrc.gov>,
"Chris Eiting" <Chris.Eiting@qynergy.com>, "Viswanath Krishnamoorthy"
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Mail Envelope Properties (479635B7.4CA : 8 : 38090)

Subject: RE: Qynergy Response to RAI dated November 6, 2007
Creation Date 1/22/2008 1:19:09 PM
From: "Stephanie Jones" <stephanie.jones@qynergy.com>
Created By: stephanie.jones@qynergy.com

Recipients

nrc.gov
TWGWPO03.HQGWDO01
JXP5 (Joshua Palotay)

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Wish CC (Viswanath Krishnamoorthy)
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TXH1 CC (Tomas Herrera)
JPJ2 CC (John Jankovich)

Post Office

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OWGWPO04.HQGWDO01

Route

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Files	Size	Date & Time
MESSAGE	2879	1/22/2008 1:19:09 PM
QynCell.jpg	40022	
QynCell Cutaway.JPG	65442	
QynCell Reverse Side Label.JPG		14648
Mime.822	169683	

Options

Expiration Date: None
Priority: Standard
ReplyRequested: No
Return Notification: None

Concealed Subject: No
Security: Standard