

From: Bruce Glick <bglick@II-VI.com>
To: "Seung Lee" <SJL@nrc.gov>
Date: 07/12/2001 12:55:06 PM
Subject: RE: Request for Additional Information, 07/12/01

Hello Dr. Lee:

Firstly, thank you for the feed back on our application. We will carefully review and address the items and questions.

Secondly, I want to give you an overview of our organization to make sure we do not cause confusion with our responses and interactions.

I am the General Manager of eV PRODUCTS and I have and will continue to review and sign the documents as an Officer of the company.

Kevin Parnham is our Staff Physicist and also serves as our Radiation Protection Officer

Fred Ferraro is our Engineering and Quality Assurance Manager (including all regulatory affairs).

Kevin is the lead person on formulating, submitting and following up this application and as such, he has been and will continue to be the prime interface with you.

I am certainly keenly aware of this process and I will stay close to the matter as we proceed with responding to items and any additional follow-up.

Again, we appreciate your feed-back and support and look forward working through this process with you.

Best Regards,
Bruce Glick

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

From: Seung Lee [mailto:SJL@nrc.gov]
Sent: Thursday, July 12, 2001 8:41 AM
To: bglick@ii-vi.com; kparnham@ii-vi.com
Cc: John Jankovich
Subject: Request for Additional Information, 07/12/01

Good morning, Mr. Glick!

We are in the process of reviewing your application for the Model CPC-48 thickness gauge. In order to continue our review of your application for registration certificate, we need the following information:

1. The complete QA/QC procedures are not included. We do not review

incomplete application. Please provide the final and complete QA/QC procedures.

2. On Page 23 of Enclosure 1, the drawing is draft. We do not review the draft drawings. Please provide the final and complete drawings.

Please provide assembly drawings that show the source holder in relation to the shielding and the shutter. The drawings should also indicate how the shutter operates to close the radiation beam.

3. On Page 1 of Enclosure 1, the certifying officer's name and title, date, and signature are not shown.

4. On Page 3 of Enclosure 1, CUC.D1 has ANSI Classification of 43333 based on ANSI N43.6-1997. However, IL-136-S-211-S states that it has ANSI Classification of C64344 based on ANSI N542-1977. Please clarify this discrepancy.

5. On Page 5 of Enclosure 1, the application stated that "The CPC-48 is shipped in a separate package to the user's facility."

On Page 20 of Enclosure 1, the application stated that radiation surveys of the completed device will be performed as a final quality inspection when fabrication completed.

Please explain how and why the completed device is separated when it is shipped to user's facility.

6. On Page 7 of Enclosure 1, the application stated that the Cd-109 source is replaced every two years and leak test every six months.

On Page 19 of Enclosure 1, the application stated that "Given Cd-109's short half-life, sources will be procured on a "just-in-time" basis, so additional, once accepted by eV Products, leak testing will not be required."

Based on these two statements, it is not clear whether the leak test is performed when the source is replaced or installed.

Also, please provide the acceptance criteria for the leak test, and provide the location for the source installation and replacement.

7. On Page 8 of Enclosure 1, please provide the technical specifications for the tamper-proof screws and their locations used for the device and the label.

8. On Page 9 of Enclosure 1, you have described the design process for the shutter return spring. Please provide information, test data, or operational experience, that the spring will not be clogged up in the paint booth environment and still will be able to maintain its function of

returning the shutter into the closed position in case of air pressure failure. Please also address the time duration for which trouble-free operation of the return spring can be expected.

9. On Page 16 of Enclosure, two units (mR/hour and mrem/hour) are used. Does mR represent milliRoentgen?

10. On Page 11 of Enclosure 1, you have described operational tests. Please provide prototype test information regarding likely accident scenarios, such as dropping the device during installation or the device colliding with equipment during robotic arm operations. Please note that criteria for likely accident conditions are described in NRC report NUREG-1556, Vol. 3, Section 10.5 (please note paragraph 3, page 10-13).

11. On Page 10 of Enclosure 10, the label should have actual activity, not nominal activity.

12. Enclosures 6 and 8 have drawings with proprietary information. Please provide a waiver regarding the proprietary nature of these drawings or, if you wish to maintain the proprietary classification, please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.790. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. For each document or page, please submit two copies. One copy should be an unmarked copy containing all information. The second copy should have removed from it, all information that you wish to be held proprietary. This second copy will be placed in the NRC's public document room. While it is allowable, please refrain from submitting proprietary information in support of a registration unless necessary. Keep in mind that all registration certificates in the Sealed Source and Device Registry, and all NRC licenses are considered to be in the public domain, and are therefore may be viewed by any member of the public who requests to see them.

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 e-mail, 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 contact me at (301) 415-5787 and sjl@nrc.gov, or Dr. John Jankovich at (301) 415-7904.

PS: Please reply immediately to this e-mail for your confirmation.

CC: John Jankovich <JPJ2@nrc.gov>, "Fred A. Ferraro" <fferraro@II-VI.com>, "Kevin B. Parnham" <kparnham@II-VI.com>

Mail Envelope Properties

(3B4DD65C.BFD : 16 : 35837)

Subject: RE: Request for Additional Information, 07/12/01
Creation Date: 07/12/2001 12:48:16 PM
From: Bruce Glick <bglick@II-VI.com>

Created By: bglick@II-VI.com

Recipients

nrc.gov

twf4_po.TWFN_DO

JPJ2 CC (John Jankovich)

SJL (Seung Lee)

II-VI.com

kparnham CC (Kevin B. Parnham)

fferraro CC (Fred A. Ferraro)

Post Office

twf4_po.TWFN_DO

Route

nrc.gov

II-VI.com

Files

MESSAGE

Header

Size

6578

940

Date & Time

12:48:16 PM 07/12/2001

Options

Expiration Date: None

Priority: Standard

Reply Requested: No

Return Notification: None

Concealed Subject: No

Security: Standard