

Kime, Traci

From: Jankovich, John
Sent: Wednesday, February 20, 2013 9:28 AM
To: Sean C. Chapel; Kotzalas, Margie
Cc: Sepulveda, Lymari; Bhachu, Ujagar; George Gleason; Herrera, Tomas; Xu, Shirley
Subject: RE: Bruker Detection Corporation Amendment to add uRAID Device

Mr. Chapel,

This is a response to your e-mail below, sent to Ms. Margie Kotzalas, Chief, Licensing Branch/NRC, requesting a conference call. The objective of the call was to be to discuss the status of the safety evaluation of your client's, Bruker Detection Corporation's, amendment application.

Regarding the status of the application, please note that the NRC staff has proceeded in a timely manner with the review of the application since its receipt. However, please also note that we have received two requests from Mr. George Gleason/Bruker Detection Corporation, for extension of the due dates for responses to our questions. Specifically, a short overview of the history of the events and dates may help you to understand the status of the review and provide the answer to your question:

- On 11/9/2012, the NRC requested additional information with a response due in 30 days;
- On 11/21/2012, Mr. Gleason requested an extension of the due date to 12/21/2012, the NRC granted the extension;
- On 12/14/2012, Mr. Gleason requested a second extension to 1/25/2013, the NRC granted the second extension;
- On 12/19/2012, the NRC informed Mr. Gleason that we would resume the review of the application when we receive the response;
- On 1/11/2013, we received Mr. Gleason's response, we resume the review, and the response referred to the operator's manual in attachment D. However, attachment D showed a designation "Version Draft 0.1:"
- On 1/15/2013, we called Mr. Gleason about this issue, and he said that the operator's manual can only be changed by the overseas manufacturer;
- On 1/17/2013, Mr. Gleason responded in an e-mail, but his response still referred to a "final draft" of the operator's manual. Please note that a draft document is not an acceptable basis for the issuance of a device registration certificate.

Currently, the only open issue is the "final draft" of the operator's manual. The NRC staff has drafted the registration certificate for the device, but we cannot issue it we receive a copy of the operator's manual which is final. Please provide confirmation that the designation "Version Draft 0.1" could be interpreted as the final for the manual and the reasons why the manual designation cannot be changed to the final version at this time. When we receive such confirmation, we can proceed expeditiously to issue the amendments which Bruker Detection Corporation requested in the application.

Thus, if you still see the need for a conference call, please let us know the date and time so that we could schedule it on the calendars of those who need to participate.

John P. Jankovich, Ph.D.
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From: Sean C. Chapel [mailto:schapel@irsc-inc.com]
Sent: Tuesday, February 19, 2013 3:39 PM
To: Kotzalas, Margie
Cc: Sepulveda, Lymari; Jankovich, John; Bhachu, Ujagar; George Gleason
Subject: Bruker Detection Corporation Amendment to add uRAID Device

Hi Ms. Kotzalas,

Bruker Detection Corporation is requesting a conference call to discuss any remaining questions the NRC may have regarding the amendment request to add the uRAID device to their existing NRC exempt device registration and distribution license.

Bruker recently received a notice that it may take an additional 180 days to complete this amendment after the initial period which has already expired. It is urgent that this amendment be completed by the end of this month in order to accommodate customer needs.

We suggest having the call this Thursday Feb 21st at 9AM Eastern Time. If this is a good time for you we send you the call information for our conference line.

If you have any questions please let me know.

Thanks

Sean

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