

From: [Arribas-Colon, Maria](#)
To: [BOA - Hannig, Markus](#)
Cc: [Jankovich, John](#)
Subject: RE: Request for Additional Information - In response to your letter dated May 10, 2013
Date: Wednesday, August 07, 2013 12:16:08 PM
Attachments: [Corrected page- NR-0122-D-101-B.pdf](#)

Good Afternoon Mr. Hanning,

Please find attached the NR-0122-D-101-B corrected page dated August 7, 2013.

Let me know if you have any questions.

Thank you,
-Maria

From: BOA - Hannig, Markus [mailto:BOA@bst-procontrol.com]
Sent: Thursday, July 18, 2013 4:52 PM
To: Arribas-Colon, Maria
Cc: Jankovich, John; Sepulveda, Lymari; Schlemm, Hans; Blecher, Frank
Subject: RE: Request for Additional Information - In response to your letter dated May 10, 2013

Hello Maria,

I received the new certificates and reviewed them.

You must have misunderstood me with item# 5 saying, '...The other two labels with information on the sealed source and service interval remain the same.'

With 'remain the same", I meant as they are listed in the previous certificate NR-0122-D-101-B from March 9, 2010, attachment 3 of 5 (label testing interval information) and 5 of 5 (label with nuclide information)

I have attached the label for the testing interval, as it was and will remain.

This reflects betacontrol of America, Inc. as the distributor of the device.

Again BST ProControl GmbH is the manufacture.

I hope that makes everything clear now.

If you have any question, please feel free to contact me.

Kindest Regards,

Markus Hannig

betacontrol of America, Inc.

425 Main Road
Towaco, NJ 07082
Phone 973-263-8053
Fax 973-263-0477
Email: boa@bst-procontrol.dcom
Internet: www.bst-procontrol.com

Pflichtangaben nach §125a HGB:

BST ProControl GmbH
Am Weidekamp10
57258 Freudenberg, Germany

UID: DE 252 654 873, HRB Nr.9870
Amtsgericht / District Court: Siegen
Geschäftsführer/ CEO: Michael Hecht

From: BOA - Hannig, Markus
Sent: Friday, July 05, 2013 11:47 AM
To: 'Arribas-Colon, Maria'
Cc: Jankovich, John; Sepulveda, Lymari; Schlemm, Hans; Blecher, Frank
Subject: RE: Request for Additional Information - In response to your letter dated May 10, 2013

Hello Maria,

Here is my second attempt answering your question.

- 1) The correct postal address is: 425 Main Road, Towaco, NJ 07082, the physical location of our office has not changed
- 2) Postfach 1225, Am Weidekamp 10
D-57258 Freudenberg, Germany
- 3) Also the licensing purpose, overall design, and the integrity of both Model MK 1.0 and Model MK 2.0 will not be affected by this name change.
- 4) It is just a name change.
- 5) Please find attached the label with the US distributor name and address for both MK 1.0 and MK 2.0 models. The other two labels with information on the sealed source and service interval remain the same.

I again apologize for the confusion caused by submitting the wrong labels.

Please don't hesitate contacting me for any further question.

Kindest Regards,

Markus Hannig

From: Arribas-Colon, Maria [<mailto:Arribas-Colon@nrc.gov>]
Sent: Tuesday, June 25, 2013 9:09 AM
To: BOA - Hannig, Markus
Cc: Jankovich, John; Sepulveda, Lymari

Subject: Request for Additional Information - In response to your letter dated May 10, 2013

Mr. Hanning,

As you requested, we are currently amending your Registration Certificates No.: NR-0122-D-101-B and NR-0122-D-102-S to reflect the Manufacturer's name change. We noted that there are discrepancies in the Registration Certificates regarding the exact addresses for both the Manufacturer and Distributor. Please see the discrepancies and additional questions for additional information listed below:

- 1) Please clarify the exact Distributor address to be used in the Registration Certificate.
 - o Registration Certificate NR-0122-D-101-B indicates that the Distributor address is the following:

*P.O. Box 18
425 Route 202
Towaco, NJ 07802*
 - o Registration Certificate NR-0122-D-102-S indicates that the Distributor address is the following:

*425 Main Road,
Towaco, NJ 07802*
- 2) Please clarify the exact Manufacturer address to be used in the Registration Certificate.
 - o Registration Certificate NR-0122-D-101-B indicates that the Manufacturer address is the following:

*P.O. Box 1225, Am Weidekamp 10
D-5905 Freudenberg, Germany*
 - o Registration Certificate NR-0122-D-102-S indicates that the Manufacturer address is the following:

*meß-und regeltechnik
Postfach 1225, Am Weidekamp 10
D-57258 Freudenberg, Germany*
- 3) In letter dated May 10, 2013 you stated that the name change will have no effect on the licensing, overall design, and the integrity of the Model MK 1.0 (new and old version). Please **confirm** that the licensing purpose, overall design, and the integrity of both Model MK 1.0 and Model MK 2.0 will not be affected by this name change.
- 4) Please clarify if this change is as a result of a change of control/ownership or just a name change. If this change is as a result of a change of control/ownership, please provide the information listed in Section 13.6 of Volume 3 of the NUREG 1556 series.
- 5) Provide a copy of the label with the US Distributor name and address for both MK 1.0 and MK 2.0 Models.

Please submit the requested information within 30 days of the date of this email. If we have not received complete information within 30 days of the date of this email, we will consider your application as having been abandoned by you. This is without prejudice to

the submission of a complete application.

Thank you,

María del Mar Arribas-Colón, M.S.

Project Manager

U.S. Nuclear Regulatory Commission

FSME/MSSA/LB

Phone: (301) 415-6026

Email: María.Arribas-Colon@nrc.gov

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