



An OSI Systems Company

July 22, 2013

Katie Wagner
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs
U.S Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

RE: Request for Additional Information- Amendments to Sealed Source and Device Registration Certificate and Exempt- Distribution License (July 9, 2013).

Dear Ms. Wagner:

We are in receipt of your letter dated July 9, 2013, requesting more information to support our amendment request of May 13, 2013 for Sealed Source and Device Registration Certificate No. NR-1267-D-102-E and the associated exempt- distribution materials license No. 04-24011-01E. This letter serves as a response to your request for more information. Enclosed are the questions and confirmations requested in your letter followed by Rapiscan's response. If you have any questions please call me at 310.349.2494 or 424.236.0314 or email at MAbdu@rapiscansystems.com .

Sincerely,

A handwritten signature in blue ink that reads "Mershad Shahabidin".

Mershad Shahabidin
Radiation Safety and Compliance
Rapiscan Systems Inc.
2805 Columbia Street
Torrance, CA 90503

ATTACHMENT A
Requested Information and Responses

A. Questions regarding your sealed source and device registration certificate application/amendment request per 10 CFR 32.20.

1.1 In your letter dated May 8, 2013, you indicated that the addresses in Torrance, CA and Hawthorne, CA will be used for manufacturing and testing; please indicate which facility will be used for manufacturing and which will be used for testing.

Rapiscan requests that manufacturing of the HE50 be approved at both the Hawthorne and Torrance facilities, with testing of all final products being performed at the Torrance, CA facility.

1.2 Please confirm that no changes were made to the product since its last registration certificate amendment on April 9, 2012.

Rapiscan confirms that no changes have been made to the product since the last registration amendment on April 9, 2012.

1.3 Please confirm that the previous commitments made for the North Andover, Massachusetts location will not change with the move of the manufacturing facility to California.

Rapiscan confirms that all previous commitments made for the North Andover, Massachusetts location will not change with the move of manufacturing facility to California.

1.4 Please confirm that the quality assurance program has not changed and that it will be implemented as approved by the NRC.

Rapiscan confirms that the quality assurance program has not changed and it will be implemented in California as it was approved by the NRC.

1.5 Please provide information on the label which will be used on the devices distributed from Torrance, CA.

Attachment A.1 of this response contains a picture of the label that was approved by the USNRC for manufacture of the HE50 in North Andover, MA. As you can see that the label does not identify the location of manufacture. It only identifies Rapiscan as the Manufacturer of the HE50. Therefore Rapiscan intends to use this label, unchanged, on the HE50 units that will be manufactured and distributed from Torrance, CA

B. Question pertaining to your Exempt-Distribution Materials License

- 1. In your application you indicated that you wish the material to be distributed from your location at Torrance, CA. Please indicate if you want to list the address at Hawthorne, CA as a distribution location as well. Also, confirm that you wish to remove the address at North Andover, MA from your distribution license.**

Rapiscan does not want the Hawthorne CA address listed as a distribution address on our distribution license. All products manufactured at the Hawthorne location will be transferred from that location to the Torrance location for final testing prior to distribution.

On further consideration, Rapiscan requests that the North Andover facility remain on the distribution license for now to insure a smooth transition during this change period. We will submit a separate request to remove the North Andover, MA facility once the move has been completed in its entirety. This will insure continuity of services to our customers.

ATTACHMENT A.1
MANUFACTURING LABEL FOR THE HE50

CONTAINS RADIOACTIVE MATERIAL,
RADIONUCLIDE: AM-241
ACTIVITY: 20 μ Ci



DISTRIBUTED BY RAPISCAN SYSTEMS, INC.
UNDER U.S. LICENSE AND IN COMPLIANCE WITH
NRC 10CFR 32.26

THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL
AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH
U.S. NRC SAFETY CRITERIA IN 10CFR 32.27

THE PURCHASER IS EXEMPT FROM ANY
REGULATORY REQUIREMENTS