



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
WASHINGTON, D.C. 20555-0001

February 1, 2018

Rapiscan Systems, Inc.  
ATTN: Varti Vartanian, Ph.D.  
Senior Director of Global Radiation Safety  
2805 Columbia Street  
Torrance, CA 90503

SUBJECT: RAPISCAN SYSTEMS, INC., REQUEST FOR ADDITIONAL INFORMATION  
REGARDING REQUEST FOR AMENDMENT TO EXEMPT DISTRIBUTION  
LICENSES 20-23904-01E AND 04-24011-01E AND SEALED SOURCE AND  
DEVICE REGISTRATION CERTIFICATE NR-0399-D-101-E

Dear Mr. Vartanian:

This letter refers to your license amendment letter dated December 28, 2017 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML18003A276). In reviewing your application, we have determined additional information is required to complete our review. In order to continue our review, please address the issues listed in the enclosure to this letter. This information is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.26, "Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer," and 10 CFR 32.210, "Registration of product information."

We will continue our review upon receipt of this information. If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in 10 CFR 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390 (b)(1).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's ADAMS. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions regarding your exempt distribution license, you may contact me at (301) 415-7640, or by e-mail at [Shirley.Xu@nrc.gov](mailto:Shirley.Xu@nrc.gov). Any correspondence regarding your exempt distribution license should reference mail control number 602077. Any questions regarding your sealed source and device registration certificate should be directed to Celimar Valentin-Rodriguez at (301) 415-7124, or by e-mail at [Celimar.Valentin-Rodriguez@nrc.gov](mailto:Celimar.Valentin-Rodriguez@nrc.gov).

Sincerely,

**/RA/**

Shirley S. Xu  
Materials Safety Licensing Branch  
Division of Material Safety, States, Tribal  
and Rulemaking Program  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 030-36457  
Mail Control No. 602077

Enclosure:  
Request for Additional Information

RAPISCAN SYSTEMS, INC., REQUEST FOR ADDITIONAL INFORMATION REGARDING  
REQUEST FOR AMENDMENT TO EXEMPT DISTRIBUTION LICENSES 20-23904-01E AND  
04-24011-01E AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE  
NR-0399-D-101-E

Date: February 1, 2018

**ML18032A520**

<b>OFC</b>	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB
<b>NAME</b>	Shirley Xu	Deborah Weaver	Celimar Valentin-Rodriguez	Tomas Herrera	Shirley Xu
<b>DATE</b>	2/1/18	2/1/18	2/1/18	2/1/18	2/1/18

OFFICIAL RECORD COPY

**Rapsican Systems, Inc.**  
**Request for Additional Information**

1. In your letter you stated that Rapsican Systems, Inc. (Rapsican) will no longer distribute certain models listed in Registration Certificate NR-0399-D-101-E. Please indicate if Rapsican will continue to provide services to previously distributed models, including those models no longer being distributed. Also, indicate if you have identified an entity that will provide the necessary services. Additionally, for each model Rapsican is no longer distributing, provide the total number of units sold and the estimated number of units still in use.
2. You stated in your letter that the following models will be distributed under Rapsican. Please provide information regarding how you plan to re-label these devices before distribution.
  - Entryscan 4
  - Itemiser DX
  - Itemiser 3 Enhanced
  - MobileTrace
  - Hardened MobileTrace
3. The Quality Assurance (QA) Program submitted by Rapsican states that it is compliant with ISO 9001:2008. If Rapsican is ISO 9001:2008 certified please provide a copy of the certificate. In addition, confirm that the Rapsican's QA Program ensures that:
  - a. There is full design conformity in accordance with the statements and commitments submitted in support of the application (including materials of construction, dimensions within stated tolerances, manufacturing methods, assembly methods, and labeling).
  - b. All units are leak tested to 185 Bq (0.005  $\mu$ Ci).
  - c. All units are tests for proper operation of all safety functions.
  - d. All units are verified that the radiation levels do not exceed the maximum values stated in the application.

If Rapsican is not ISO 9001:2008 certified, please confirm the following:

- a. the final product is leak tested;
- b. the materials of construction and the final assembly meet the design specifications;

Enclosure

- c. a final radiation profile is performed;
  - d. a test is performed to verify that the product operates as intended, including all safety functions; and
  - e. a visual and mechanical inspection is performed of components that are considered related to safety or are expected to be susceptible to failure under extreme or unusual conditions.
4. Indicate if Rapiscan's corporate headquarters location at Torrance, CA should be included in your Registration Certificate NR-0399-D-101-E.
  5. Indicate if the Andover, MA location will maintain records custody of records pertaining to Registration Certificate NR-0399-D-101-E.
  6. In order to keep license condition 12. B of Exempt Distribution License 20-23904-01E on the merged license, provide a copy of your possession license(s) to reflect that you are authorized to use radioactive material in other States for instruction and training purposes.