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

January 12, 2017

Rapiscan Systems Inc.
ATTN: Mershad Shahabidin
Radiation Safety Officer
2805 Columbia Street
Torrance, CA 90503

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Shahabidin:

This letter refers to your license renewal application request dated September 29, 2016 (Agencywide Documents Access and Management System [ADAMS] No. ML16278A072) for U.S. Nuclear Regulatory Commission (NRC) exempt-distribution license number 04-24011-01E.

We do not have sufficient information to complete the review of your application. 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, 32.27, 32.28, and 32.29. You may provide previously submitted documents as long as they are current. These should be provided as attachments to your response to this letter.

Please note that an application for an exempt-distribution license, including renewals, should not contain information concerning the possession and use of radioactive material since that is covered in your separate possession license.

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

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).

Any correspondence regarding this renewal application should reference control number 592058.

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, please feel free to contact me at (301) 415-5477, or by e-mail at Richard.Struckmeyer@nrc.gov.

Sincerely,

**/RA/**

Richard K. Struckmeyer
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No.: 030-38542
License No.: 04-24011-01E

Enclosure:
Request for Additional Information

If you have any questions, please feel free to contact me at (301) 415-5477, or by e-mail at Richard.Struckmeyer@nrc.gov.

Sincerely,

**/RA/**

Richard K. Struckmeyer
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No.: 030-38542
License No.: 04-24011-01E

Enclosure:
Request for Additional Information

Certified Mail No. 7015 0640 0003 2910 1498

**ML16278A066 (pkg.)** **ML16349A063 (Letter)**

| **OFC** | NMSS/MSTR/MSLB | NMSS/MSTR/MSLB | NMSS/MSTR/MSLB | NMSS/MSTR/MSLB |
|---|---|---|---|---|
| **NAME** | RStruckmeyer | Debra Miller | HGonzalez | RStruckmeyer |
| **DATE** | 1/11/2017 | 12/14/2016 | 1/12/2017 | 1/12/2017 |

OFFICIAL RECORD COPY

## Request for Additional Information for Renewal of Rapiscan Systems, Inc., License Number 04-24011-01E

The information requested in the following paragraphs is required by Title 10 of the *Code of Federal Regulations*, Chapter 32 (10 CFR Part 32). Each paragraph is derived from a section within this chapter.

1. Section 32.26(b)(3) requires the applicant to submit information concerning the chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.

   Although you provided information concerning the chemical and physical form of the byproduct material in the product, we do not see that you provided information concerning changes in chemical and physical form that may occur during the useful life of the product. Please provide this information or state where it can be found in your application.

2. Section 32.26(b)(4) requires the applicant to submit information concerning the solubility in water and body fluids of the forms of the byproduct material contained in the product.

   We do not see that you provided information concerning the solubility in water and body fluids of the forms of the byproduct material contained in the product. Please provide this information or state where it can be found in your application.

3. Section 32.26(b)(5) requires the applicant to submit information concerning details of construction and design as related to containment and shielding and other safety features under normal and severe conditions of handling, storage, use, and disposal.

   Although you provided information concerning construction and design as related to containment and shielding and other safety features under normal use and disposal, we do not see that you provided information concerning severe conditions of handling, storage, and use. Please provide this information or state where it can be found in your application.

4. Section 32.26(b)(6) requires the applicant to submit information concerning maximum external radiation levels at 5 and 25 cm from external surface of product and the method of measurement.

   Although you provided the following statement under Section 11, Design Futures [sic] and System Operation: "The external radiation levels from Model Detectra HX and Detectra HN are slightly above background radiation level as provided in Section 12 …," radiation levels are not discussed in that section, but in Section 14. Section 14 refers to Appendix D, "Prototype Testing Records," but the items 1 through 3 listed on that page could not be found. Please provide the information concerning maximum external radiation levels at 5 and 25 cm from external surface of product and the method of measurement as required by 10 CFR 32.26(b)(6).

Enclosure

5. Section 32.26(b)(8) requires the applicant to submit information concerning the total quantity of byproduct material expected to be distributed annually.

   We do not see that you provided information concerning the total quantity of byproduct material expected to be distributed annually. Please provide this information or state where it can be found in your application.

6. Section 32.26(b)(11) requires the applicant to submit information concerning the procedures for prototype testing (containment, shielding and other safety features) under both normal and severe conditions of handling, storage, use, and disposal of the product.

   We do not see that you provided information concerning the procedures for prototype testing as required by this regulation. Please provide this information. Section 13, "Prototype Testing" refers to Attachment D, "Prototype Testing Records." Attachment D lists three items (documents): (1) "Detectra HX Radiation Survey Report," (2) "HE50 ANSI Radiation Safety Profile Testing," and (3) "Contamination Leak Test Results Certificates Before and After the ANSI Testing." These documents were not found in your application.

   Also, in Section 6, "Leak Test Frequency," of your application, you indicate that this is not required because the product contain[s] gamma-emitting material of no more than 3.7 MBq (100 µCi). However, this appears to be a misinterpretation of 10 CFR 32.59, "Same: Leak testing of each source," which applies to requirements for license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226 for distribution to persons generally licensed under § 31.8.

7. Section 32.26(b)(12) requires the applicant to submit information concerning the results of prototype testing including any change in form, extent of release to environment, increase in radiation levels and changes in safety features.

   We do not see that you provided information concerning the results of prototype testing as required by this regulation. Please provide this information.

8. Sections 32.26(b)(13) and (14) require the applicant to provide a detailed evaluation which demonstrates that the product will meet the safety criteria of 10 CFR 32.27 and 32.28. These sections require that the applicant demonstrate that under normal conditions of handling, storage, use, and disposal, it is unlikely that the dose commitments for an exposed individual would exceed the values in 32.28.

   a. Section 32.26(b)(13) requires the estimated dose commitments relevant to the safety criteria in Section 32.27 and the basis for such estimates.

   b. Section 32.26(b)(14) requires a determination that the probabilities in Section 32.27(c) (related to scenarios such as bulk storage and fires) will not be exceeded with respect to the dose commitments referred to in Section 32.28, Column II. This is usually done using a methodology and scenarios similar to those found in Section 2, Exemptions for Byproduct Material, of NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials."

We do not see that you provided information concerning the detailed evaluation which demonstrates that the product will meet the safety criteria of 10 CFR 32.27 and 32.28. Please provide an evaluation which demonstrates that the product will not exceed the probabilities in10 CFR 32.27(c) and will not exceed the dose commitments in 32.28, Column II.