Enclosure

Information Needed for Amendment of
Exempt-Distribution License No. 29-27907-01E

Your application does not sufficiently address the requirements in Title 10 of the Code of Federal Regulations, Part 32, Section 32.14, "Certain items containing byproduct material; requirements for license to apply or initially transfer," and Section 32.15, "Same: Quality assurance, prohibition of transfer, and labeling." Please provide the information requested below.

Questions 1 and 2 refer to NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 3, Rev. 2, "Applications for Sealed Source and Device Evaluation and Registration," which is intended as guidance to applicants for requests for sealed source or device safety evaluations and registrations; however, the sections concerning prototype testing (Section 10.5) and quality assurance / quality control (Section 10.7) provide guidance relevant to applicants for licenses under 10 CFR 32.14; such guidance is either limited or not currently available in NUREG-1556, Volume 8, "Program-Specific Guidance About Exempt Distribution Licenses." Please be aware that these sections describe various methods for meeting the requirements; therefore the applicant should read and understand each section carefully to enable selection of the methods that will best satisfy the regulatory requirements of 10 CFR 32.14(b)(4) and 10 CFR 32.14(b)(5).

1) Title 10, Code of Federal Regulations, Section 32.14(b)(4) requires that the applicant provide procedures for and results of prototype testing to demonstrate that the byproduct material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product.

   Some of the information you provided in your application under the heading "Testing" is relevant to this requirement, but it does not fully address its intent. Acceptable approaches to satisfy the requirement for prototype testing are described in NUREG-1556, Volume 3, Rev. 2, Section 10.5, "Prototype Testing." Not all approaches require the submission of written procedures.

   This document is available on the NRC's external web site at:
   http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v3/r2/.
   (or, type www.nrc.gov in the web address area of your browser; then choose the "NRC Library" tab; choose "Document Collections"; choose "NUREG-series Publications"; choose "Publications Prepared by NRC Staff"; choose "NUREG-1556"; choose "Volume 3, Revision 2," then download the complete document.)

2) Title 10, Code of Federal Regulations, Section 32.14(b)(5) requires the applicant to submit quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

   The information submitted under 10 CFR 32.14(b)(5) on quality control must demonstrate that the applicant/licensee will comply with the requirements of:

- Paragraph (a) of 10 CFR 32.15, which requires each person licensed under 10 CFR 32.14 to:
  (1) Maintain quality assurance practices;
  (2) Subject inspection lots to acceptance sampling procedures; and
  (3) Visually inspect each unit, except electron tubes containing byproduct material, in inspection lots.

- Paragraph (b) of 10 CFR 32.15, which states that no person licensed under 10 CFR 32.14 shall transfer to other persons:
  (1) Any part or product tested and found defective; or
  (2) Any part or product contained within any lot that has been sampled and rejected.

The regulations do not specifically define "inspection lots" or "acceptance sampling." These terms are generally used in connection with the production of items in large quantities, and may not be applicable to situations in which a small number of items are produced and distributed. Under such circumstances where acceptance sampling is not appropriate, the applicant may satisfy this regulation by inspecting each item and otherwise following the requirements of 10 CFR 32.15.

Guidance about quality control is available in NUREG-1556, Volume 8, "Program-Specific Guidance About Exempt Distribution Licenses," Section 9.1.3, "Quality Assurance/Quality Control Programs." The guidance concerning Regulatory Guide 6.9 is outdated, but the rest of this section remains relevant. Within section 9.1.3, reference is made to NUREG-1556, Volume 3. Section 10.7 of Volume 3 indicates that as an alternative approach to meeting the requirement of 32.14(b)(5), the NRC staff may consider a QA program that is part of a QA program designed and intended to meet another established standard or requirement, including programs established to meet ISO or ANSI QA program standards, …"

In addition, the applicant should be aware of the paragraphs in section 10.7 concerning foreign vendors.

To satisfy the requirements of 32.14(b)(5) and 32.15, please either (1) provide a copy of your quality control procedures, or (2) if applicable, confirm that your quality control procedures are part of a QA program designed and intended to meet another established standard or requirement, and indicate which standard or requirement is used.

If relevant, please confirm that the volume of production of your product is sufficiently small that you do not subject inspection lots to acceptance sampling procedures. If you utilize inspection lots and acceptance sampling procedures, please describe how you comply with the requirements of Section 32.15(a)(2) and 32.15(b)(2).

3) Title 10, Code of Federal Regulations, Section 32.14(b)(6) requires a description of the proposed method of labeling or marking each unit and its container with the identification of the manufacturer or initial transferor and the byproduct material in the product.

   Please provide a copy of the proposed label.

4) Title 10, Code of Federal Regulations, Section 32.14(d) requires that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

It does not appear that you provided information in your application to demonstrate how this requirement will be met. Please describe how the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

5) Title 10, Code of Federal Regulations, Section 32.15(b)(1) requires that no person licensed under Section 32.14 shall transfer to other persons for use under Section 30.15 of this chapter or equivalent regulations of an Agreement State any part or product tested and found defective under the criteria and procedures specified in the license issued under Section 32.14, unless the defective part or product has been repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria.

   It does not appear that you provided information in your application to demonstrate how this requirement will be met. Please describe how you shall prevent transfer to other persons any part or product tested and found defective under the criteria and procedures specified in the license, unless the defective part or product has been repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria.