

From: [Torres, Roberto](#)
To: [Daniel, Kimberly D \(Kimberly.Daniel@fda.hhs.gov\)](mailto:Kimberly.Daniel@fda.hhs.gov)
Bcc: [Torres, Roberto](#)
Subject: NRC verification request
Date: Friday, May 22, 2020 7:10:00 PM
Attachments: [Draft Amendment 18.pdf](#)

Ms. Daniel:

I am working on draft amendment 18 to change license 03-15093-01 from Broad Scope Type A to broad Scope Type B but before making the changes I need to coordinate with you what those changes are. Attached is draft amendment 18 containing only the sections that will be changed. The text in red colored font is the text that is going to be removed and will be replaced with the text highlighted in yellow. Please review the changes and let me know if you concur on these changes that is what makes a license a Type B broad scope.

The maximum possession limit for a Type B broad scope is listed in NRC regulation 10 CFR 33.100, Schedule A, Column 1 (see link).

<https://www.nrc.gov/reading-rm/doc-collections/cfr/part033/part033-0100.html>

If you believe that a proposed change(s) will have a detrimental effect in the conduct of your radiation safety program then propose alternate language or different alternatives.

Thank you for your cooperation.

Roberto J. Torres, M.S.
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MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70 and 71, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Department of Health and Human Services Food and Drug Administration National Center for Toxicological Research</p> <p>2. 3900 NCTR Road HFT-2 Jefferson, AR 72079</p>		<p>In accordance with application dated August 29, 2017.</p>	<p>4. Expiration Date: October 31, 2032</p>
		<p>3. License number: 03-15093-01 is renewed in its entirety to read as follows:</p>	<p>5. Docket No.: 030-08559 Reference No.:</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with Atomic Numbers 1 through 83 [proposed removal] As specified in Section 33.100, schedule A of 10 CFR 33 (Type B Broad License)</p> <p>B. Hydrogen-3</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 500 millicuries per radionuclide and 10 curies total [proposed removal] See condition 11.</p> <p>B. 5 curies total</p>	<p>9. Authorized use</p> <p>A. For use in research and development as defined in 10 CFR 30.4; biological studies (including animal studies) of pharmaceutical products, foods and food additives, pesticides, consumer products, and environmental pollutants.</p> <p>B. For use in research and development as defined in 10 CFR 30.4; biological studies (including animal studies) of pharmaceutical products, foods and food additives, pesticides, consumer products, and environmental pollutants.</p>

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
03-15093-01

Docket or Reference Number
030-08559

Amendment No. 17

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|---|----------------------------------|--|--|
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license | 9. Authorized use |
| C. Carbon-14 | C. Any | C. 1 curie total | C. For use in research and development as defined in 10 CFR 30.4; biological studies (including animal studies) of pharmaceutical products, foods and food additives, pesticides, consumer products, and environmental pollutants. |

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at 3900 NCTR Road, HFT-2, Jefferson, Arkansas, 72079.
11. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column 1. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, schedule A, Column 1, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.
11. A. Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the National Center for Toxicological Research Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material. [proposed removal]
- B. The Radiation Safety Officer (RSO) for this license is Kimberly D. Daniel. [proposed removal]
- 12.A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Officer.
- 12.B. The Radiation Safety Officer for this license is Kimberly D. Daniel.
23. Condition 23.A through 23.D. will be removed in its entirety because this condition is exclusively used for Type A broad scope licenses.

All other conditions in the license will remain the same.