

NMSBZ

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

August 31, 2007

Re: Amendment Request for Materials License No. 10-06772-01

U.S. Nuclear Regulatory Commission
Licensing Assistance Team
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, PA 19406

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REGION 1

Dear Sir,

We request amendment of our current Materials License (No. 10-06772-01) to include the removal of Source Uranium and Source Thorium, which are naturally occurring radioactive materials, from the CDC Materials License. The concentration of the source uranium and source thorium, which are used by the Centers for Disease Control and Prevention (CDC) are pure analytical reagents and therefore contain no radium byproduct material. The source materials are not purposely increased, but in fact are diluted, and therefore, are not federally regulated radionuclides, as explained in the following two paragraphs.

In accordance with the EPAct, Section 651(e) the definition of byproduct material has been expanded by: (1) adding any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity (Section 11e.(3) of the AEA); or any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity (Section 11e.(3) of the AEA); and (2) adding any discrete source of naturally occurring radioactive material, **other than source material**, that the Commission, in consultation with the Administrator of the Environmental Protection Agency (EPA), the Secretary of the Department of Energy (DOE), the Secretary of the Department of Homeland Security (DHS), and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and is extracted or converted after extraction before, on, or after the date of enactment of the EPAct for use in a commercial, medical, or research activity (Section 11e.(4) of the AEA).

Additionally, in accordance with the SECY-07-0062 – Final Rule: Requirements for Expanded Definition of Byproduct Material (RIN: 3150-AH84), the term “discrete source” was defined as: “a radionuclide that has been processed so that its **concentration** within a material has been **purposely increased** for use for commercial, medical, or research activities.”

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When Source Uranium and Source Thorium are received at the CDC they are received at levels far below NRC requirements for labeling. A 100 mL natural thorium standard (NIST 3159) with a magnitude of 0.1 microcurie is 1/1000 of the NRC labeling requirement published in Appendix B to 10 CFR Part 30. A 100 mL natural uranium standard (NIST 3164) with a magnitude of 0.7 microcurie is less than 1/100 of the NRC labeling requirement published in Appendix B to 10 CFR Part 30. Further, they are not concentrated, but instead, they are used in analytical methods in which they are further diluted to less than 1/1,000,000 of the concentrations as received to the order of urine concentrations, as explained in the following paragraphs.

For Quality Control Materials two levels of urinary uranium and thorium quality control solutions are prepared by spike addition of approximately 10 ng/L (low spike), and 425 ng/L thorium and natural uranium (high spike) from **diluted NIST SRMs 3164 and 3159** to base urine. A U-238 and Th-232 check standard for accuracy determination is **prepared by dilution** of SPEX CRMs PLU2 and PLTH2 to 10 ng/L of Uranium and Thorium into 5% nitric and hydrofluoric acids.

Calibration Standards are prepared for analyses with magnetic sector inductively coupled plasma-mass spectrometry by **dilution** of NIST SRMs 3159 and 3164 into a diluent solution 5% (v/v) in nitric and hydrofluoric acids. The five standard solutions are prepared to 5, 20, 100, 200, and 500 ng/L Th-232 (natural thorium) and natural uranium levels. Calibration standards for analyses by quadrupole inductively coupled plasma-mass spectrometry are prepared to 25, 75, 250 and 500 ng/L natural uranium.

In summary, we request the removal of Source Uranium and Source Thorium from our Materials License (No. 10-06772-01) on the basis that these radioactive materials do not meet the expanded definition of "byproduct material", as provided in the EPCRA, Section 651(e). Additionally, the Source Uranium and Source Thorium used at the CDC are not included in the definition of a "discrete source" since each radionuclide's concentration is purposely diluted, rather than its concentration being purposely increased.

We have an existing Radiation Safety Program, which is well equipped to monitor area surveys and personnel exposure, ensure that all radiation safety practices are followed, maintain accurate inventories and safeguard these radionuclides from unauthorized access and removal. Please contact us as necessary for questions or additional information.

Sincerely yours,



Paul D. Simpson Jr., RSO
Radiation Safety Team
Office of Health and Safety

This is to acknowledge the receipt of your letter/application dated

8/31/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 10-06772-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 141025.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.