

REQUEST FOR ADDITIONAL INFORMATION

Department of Commerce – National Institute of Standards and Technology

SNM-362 License Renewal Application

November 8, 2012

During the conference call held on November 8, 2012, between NIST staff (Richard Kayser and Tom O'Brian) and NRC staff (Robert Johnson, Betsy Ullrich and Richard Thompson) to clarify NIST's response to NRC's request for additional information dated September 10, 2012, NIST was asked to clarify their RAI response provided on October 25, 2012 under RAI #2 related to manufacturing of sources under 10 CFR Parts 30 and 32. NIST stated that they manufacture exempt quantities for distribution to persons who are exempt from licensing pursuant to 10 CFR 30.18, and distributes these items under License No. 19-23454-01E. This license authorizes exempt quantities in the form of calibration solutions and sealed sources. NRC staff further understands that NIST occasionally manufactures custom sources for distribution to persons who will possess them under a specific license. NIST's license renewal application (LRA) does not fully address the activities to fabricate sealed sources using licensed material for calibration standards and calibration sources and the service activities performed using such sources or other licensed materials to calibrate instruments. The LRA also does not address quality assurance and quality control procedures used during these activities to confirm that the material meets approved design requirements for sealed sources.

10 CFR Parts 30.33 and 32.18/19/20 provide the requirements for manufacturing of exempt quantities for distribution to persons who are exempt from licensing. 10 CFR Part 30 and Subpart D of 10 CFR Part 32 provide the requirements for manufacturers of specifically-licensed sealed sources. Accordingly, NIST will provide the following:

- a. A brief description of its activities to fabricate sealed sources using licensed material for calibration standards and calibration sources and the service activities performed using such sources, or other licensed materials to calibrate instruments. NIST should address both the exempt quantity items as well as sources distributed to persons who hold specific licenses.
- b. 10 CFR 32.19(c) provides the requirements for the marking and labeling of exempt quantity items. NIST will provide a description of how their manufacturing program meets these requirements.
- c. 10 CFR 32.19(d) provides the requirements for instructions to be provided to users of exempt quantity items. NIST will provide a description of the instructions provided to users of sealed sources in meeting these requirements.
- d. 10 CFR 32.210(c) provides the information needed for NRC review of sealed sources or devices for transfer to persons who are specifically-licensed. NIST will provide a description of how its manufacturing program meets these requirements.