

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

April 23, 2013

Sean C. Chapel, President International Radiation Safety Consulting, Inc. 7 Cabot Place, 3rd Floor Stoughton, MA 02072

SUBJECT:

REQUEST FOR REGULATORY OPINION FOR SERVICE PROVIDERS IN

SEALED SOURCE/DEVICE REGISTRATIONS

Dear Mr. Chapel:

This is a response to your e-mail dated January 18, 2013, requesting a regulatory opinion on whether a service provider must be listed on a sealed source and device (SS&D) registration certificate in order to service the product. In addition, you also stated your understanding that it is common practice to list "secondary manufacturers" on SS&D registration certificates in addition to "primary manufacturers."

The U.S. Nuclear Regulatory Commission (NRC) regulations do not require that service providers be listed by name, license, or by other means of identification in SS&D registrations. See, for example, the following regulations, which apply to conducting service on SS&D registered products:

- For exempt products 10 CFR 32.32(a)(iv)
- For generally licensed products 10 CFR 31.5(c)(8)(iii)(C), 10 CFR 31.6,
 10 CFR 31.6(b), 10 CFR 31.10(b)(1), 10 CFR 32.51(a)(3)(i), 10 CFR 32.51(c),
 10 CFR 32.51a(a)(3), 10 CFR 32.51a(b)(2), 10 CFR 32.61(d)
- For specifically licensed products 10 CFR 32.210(c)

None of these regulations require listing of service providers on registration certificates. Similarly, the applicable guidance document, NUREG-1556, Vol. 3, Rev. 1, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," does not indicate that such listing is required (see in particular Section 10.8, Appendix A, and Appendix D).

Regarding your statement about "primary" and "secondary manufacturers," please note that the NRC does not use this terms. You may be referring to multiple listings of addresses for manufacturers on Page 1 of some registration certificates. These multiple listings indicate that the product is manufactured at more than one location and do not imply that one manufacturer is primary and another is secondary.

We note that you also requested that "these questions be reviewed by the NRC legal office." In accordance with NRC practice, the NRC Office of General Counsel has reviewed the staff's response in this letter.

If you have further questions, please contact me again.

Sincerely,

John P. Jankovich, Ph.D.

SS&D Team Leader, Licensing Branch

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Division of Materials Safety and State Agreements

Office of Federal and State Materials

and Environmental Management Programs