



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
2100 RENAISSANCE BOULEVARD, SUITE 100  
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

February 15, 2013

Docket No. 03004675

License No. 20-08361-01

Brian Baker  
Center Director, WEAC  
Department of Health & Human Services  
Public Health Service, FDA  
Winchester Engineering & Analytical Center  
109 Holton Street  
Winchester, MA 01890-1197

SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUEST FOR  
ASSISTANCE CONCERNING MATERIAL RELEASE

Dear Mr. Baker:

This letter is in response to your request for assistance in your letter dated January 24, 2013. Responses to each of the five questions asked are as follows.

1. The material you described is licensed material, regardless of the current quantity. Licensed material can only be disposed of pursuant to 10 CFR Part 20. The Health Physics Position Paper 43 (<http://www.nrc.gov/about-nrc/radiation/protects-you/hppos/hppos043.html>), "Disposal of Exempt Quantities of Radioactive Material," states, "It is an OELD (Regional Operations and Enforcement) opinion that radioactive material held under license can only be disposed of pursuant to 10 CFR Part 20, even when the quantity disposed is less than that listed in 10 CFR 30.71, Schedule B." Please see the website for detailed information.
2. A licensee must determine if the radioactive material meets the definition of licensed material. The definition is listed in 10 CFR 20.1003. If the material is determined to be licensed material then see the answer to item 1. If it is not licensed material, the Nuclear Regulatory Commission does not regulate this material. An example similar to your issue may be found in the following Health Physics Position Paper (<http://www.nrc.gov/about-nrc/radiation/protects-you/hppos/hppos150.html>) about disposing of specifically licensed and exempt licensed smoke detectors.
3. If the material you described is licensed material, please see the answer to item 1. As authorized in 10 CFR 20.2005, a licensee may dispose of licensed material consisting of 0.05 microcuries or less of hydrogen 3 or carbon 14 per gram of medium used for liquid scintillation counting as if it were not radioactive. For this type of disposal, the licensee shall maintain records in accordance with 10 CFR 20.2108.
4. If the liquid waste stream contains licensed material, please see the answer to item 1. You may dispose of licensed byproduct material with a half life of less than 120 days without regard of radioactivity, following the procedure in your License Condition 21.

5. You may purchase NRC exempt standards only from a person who distributes the material in accordance with a license issued under 10 CFR 32.18, which states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State. As stated in 10 CFR 30.18(d), "No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in 10 CFR 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons, exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under 10 CFR 32.18 of this chapter, which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State." If you received material under your license, because a license was required to possess the material, then it is 'licensed' material regardless of the quantity remaining.

You may request a specific exemption for any of the items that you described. The guidance for submitting specific exemptions can be found in NUREG-1556, Volume 20 (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v20/>), "Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures." See sections 4.13 and Appendix K.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

If you have any further question about this letter, please contact me at 610-337-5366.

B. Baker

3

Thank you for your inquiry.

Sincerely,

***Original signed by Dennis R. Lawyer***

Dennis R. Lawyer  
Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

cc:  
Edmond J. Baratta, Radiation Safety Officer

B. Baker

3

Thank you for your inquiry.

Sincerely,

**Original signed by Dennis R. Lawyer**

Dennis R. Lawyer  
Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

cc:  
Edmond J. Baratta, Radiation Safety Officer

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