

February 10, 2011

William A. Passetti  
Chief, Bureau of Radiation Control  
Division of Environmental Health  
Florida Department of Health  
4052 Bald Cypress Way, Bin C21  
Tallahassee, FL 32399-1741

Dear Mr. Passetti:

This is a response to your letter to Robert J. Lewis, Director, Division of Materials Safety and State Agreements, dated June 28, 2010, regarding an application that you received for licensure for the production and distribution of a tritium battery from City Labs, Inc. (CLI). In your letter, you note that you believe that this device can be generally licensed under 64E-5.206(4) of the Florida Administrative Code which is equivalent to Title 10 of the *Code of Federal Regulations* (10 CFR) 31.5 because the battery creates an internal ionized atmosphere and request written clarification of the U.S. Nuclear Regulatory Commission's (NRC's) position.

We have reviewed the regulatory language in 10 CFR 31.5 and 10 CFR 32.51 and considered the information provided in the attachment to your letter and have concluded that NRC would not consider a tritium battery as a product that is acceptable for distribution under the general or specific licenses established in our regulations. We have come to the conclusion that the battery does not qualify for use under the 31.5 general license for the following reasons:

Section 31.5(a) provides a general license for byproduct material as follows:

Byproduct material contained in devices *designed and manufactured* for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage or qualitative or quantitative chemical composition, or *for producing* light or *an ionized atmosphere*. (Emphasis added.)

In other words, the language of the regulation clearly provides that the device must be for the purpose of producing an ionized atmosphere. It is the device that must be for that purpose, not the byproduct material that it is in the device, in order for that product to be included in the general license provided in Section 31.5. In a letter to the Florida Department of Health, dated June 18, 2010, CLI states, "The devices are designed to serve as low-power sources to electronics, microelectronics, sensors and other devices." rather than stating that the devices are designed to produce an ionized atmosphere. In so doing, it appears that CLI is confirming that the battery is not intended to serve any of the purposes for in Section 31.5(a).

In the first paragraph of its letter, CLI suggests that its product meets 31.5 criteria because the "batteries utilize a thin tritiated foil (attached to a semiconductor material) expressly for the purpose of generating an ionized atmosphere." However, we believe this is a misreading of the criteria for general licensing under Section 31.5. CLI seems to be implying that because the

particulate beta radiation emitted from tritium will ionize atoms as it passes through a media, that its product is designed and manufactured for that purpose. We note that all particulate radiation, as well as electromagnetic radiation (gamma, x-rays), that carry sufficient energy will create ions as it passes through a media.

We note that the engineering drawings attached to CLI's letter (pdf pages 13, 14, 15) do not seem to show any void or air space between the tritium foil and the semiconductor. This seems to also be supported by CLI's description of the product under item C on pdf page 9, "Tritium decay produces beta decay that impinge directly on the semiconductor P-N junction surfaces..." These documents lead one to believe that there is no "atmosphere." We believe it was the NRC's intent in using the term "ionized atmosphere," to describe a device that produces an ionized air volume surrounding the device as occurs with static eliminators whose purpose is to remove or affect the buildup of static charges or static electricity as part of a manufacturing process for some product or, perhaps, in some other process, such as some spray painting operations. In addition, as stated above, CLI itself describes the device as being "designed to serve as low-power sources to electronics, microelectronics, sensors and other devices," rather than being designed to produce an ionized atmosphere.

In sum, this product, as acknowledged by CLI, is designed to be a power source, much like any battery, not to produce an ionized atmosphere. Therefore, it does not fall within the criteria for the general license specified in 10 CFR 31.5.

If you have further questions, please contact Bruce Carrico at (301) 415-7826 or e-mail at [jbruce.carrico@nrc.gov](mailto:jbruce.carrico@nrc.gov).

Sincerely,

*/RA/*

James G. Luehman, Deputy Director  
Division of Materials Safety  
and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

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In sum, this product, as acknowledged by CLI, is designed to be a power source, much like any battery, not to produce an ionized atmosphere. Therefore, it does not fall within the criteria for the general license specified in 10 CFR 31.5.

If you have further questions, please contact Bruce Carrico at (301) 415-7826 or e-mail at [jbruce.carrico@nrc.gov](mailto:jbruce.carrico@nrc.gov).

Sincerely,

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James G. Luehman, Deputy Director  
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Office of Federal and State Materials  
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