

## UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, DC 20555 - 0001

October 8, 2013

VEGA Americas, Inc. ATTN: Mr. John F. Birch 4241 Allendorf Drive Cincinnati. OH 45209 Mail Control No. 581320

SUBJECT: INTENT TO VOID VEGA AMERICA'S APPLICATION FOR AN EXEMPT

DISTRIBUTION LICENSE PURSUANT TO TITLE 10, CODE OF FEDERAL

REGULATIONS, PART 32, SECTION 32.14

Dear Mr. Birch:

This letter refers to your application for an exempt distribution license dated June 24, 2013. After careful consideration, we have concluded that we cannot process your license application to distribute the Fibertrac31 incorporating Eu-152, to persons exempt from licensing under Title 10, Code of Federal Regulations, Part 32, Section 32.14. That section describes the requirements for a license to apply byproduct material to, or to incorporate byproduct material into, the products specified in Section 30.15. The device you described in your application (Agencywide Document and Management System (ADAMS) Accession No. ML13191B329) and in your September 12, 2013, response (ADAMS Accession No. ML13281A058) to our Request for Additional Information (ADAMS Accession No. ML13233A270) is not used for the purpose intended by Section 30.15.

Given that the device is only to be used by specific or general licensees for use as part of a specifically or generally licensed measuring system, it should be licensed for distribution (and registered in the Sealed Source and Device Registry) in conjunction with the devices that form the remainder of the measuring systems of which the Fibertrac31 is a part.

The Fibertrac31 can only be categorized, in regulatory terms, within the scope of Title 10, Code of Federal Regulations, Section 30.22 (10 CFR 30.22), which states:

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material 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 an ionized atmosphere, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, 30 through 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.30 of this chapter, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

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(b) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under paragraph (a) of this section, should apply for a license under § 32.30 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

If you do not incorporate byproduct material into your device, you do not need to apply for a license from the U.S. Nuclear Regulatory Commission (NRC). However, in order to distribute such a device incorporating any quantity of byproduct material, such as Eu-152, to persons exempt from licensing, you must apply for and obtain a license under § 32.30 and for a certificate of registration in accordance with § 32.210.

We are voiding the active control for your application. This means that no further action will be taken on your June 24, 2013 application. This action is without prejudice to the resubmission of another application with the required information. Generally, if an applicant reapplies within one year of the date of our void letter, no additional fee need be submitted for the license application. However, an additional fee is normally required for an application for a certificate of registration (Sealed Source and Device review) in accordance with § 32.210. For information about the fees required for applications to the NRC, you should contact the License Fee and Debt Collection Branch, at SSD ELicense.Resource@nrc.gov.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at <a href="http://www.nrc.gov/NRC/ADAMS/index.html">http://www.nrc.gov/NRC/ADAMS/index.html</a> (the Public Electronic Reading Room).

Any correspondence regarding your amendment application should reference the control number specified above.

If you have any questions, please feel free to contact Richard Struckmeyer of my staff at (301) 415-5477 or electronic mail: <a href="mailto:richard.struckmeyer@nrc.gov">richard.struckmeyer@nrc.gov</a>.

Sincerely,

## /RA/

Margie Kotzalas, Chief
Licensing Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Docket No. 030-38665

J Birch 2

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Sincerely,
/RA/
Margie Kotzalas, Chief
Licensing Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Docket No. 030-38665

<u>DISTRIBUTION</u>: MKotzalas TKime KButler JOHara LFARB RIII/DNMS MSSA r/f

ML13191B321 (pkg.)

OFC	FSME: MSSA	FSM	IE: MSSA			
NAME	RStruckmeyer		MKotzalas			
DATE	10/8/2013		10/8/2013			