



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

January 15, 2013

Docket No. 030-36179
Control No. 579387

License No. 06-30764-02MD

James Matons
President
Biocompatibles, Inc.
115 Hurley Road Bldg3
Oxford, CT 06478

SUBJECT: BIOCOMPATIBLES, INC., REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO.
579387

Dear Mr. Matons:

This is in reference to your application dated November 1, 2012 requesting to amend Nuclear Regulatory Commission License No. 06-30764-02MD. In order to continue our review, we need the following additional information:

1. Please confirm that your products that you distribute to specific licensees will meet the labeling requirements of 10 CFR 32.74(a)(2)(vii) & 32.74(a)(3). 10 CFR 32.74(a)(viii) requires that a brochure or leaflet accompany the sources that are distributed to licensees that includes radiation safety instructions for handling, storing, and sterilizing the radiation sources as well as the information specified in 32.74(a)(3). Please submit a copy of the leaflet or brochure that accompanies your sealed sources to your customers.
2. Do you accept returned sources from the licensees to which you distribute? If you do, please submit the guidance that you provide your customers for shipping sealed sources back to your facility to ensure they are compliant with DOT/IATA regulatory requirements.
3. Describe your procedure to ensure that sources in a stranded or loose configuration are not contaminated. Provide the monitoring techniques and your action levels to assure that patients of your customers receive optimal protection.
4. Please describe your quality control procedures for determining that the correct activity and radioisotope in the loose or stranded configuration of sealed sources are sent to your customers.

Current NRC regulations and guidance are included on the NRC's website at 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).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 579387. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5303.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Thomas K. Thompson

Thomas K. Thompson
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Wayne Richardson, Radiation Safety Officer

DOCUMENT NAME: G:\WordDocs\Current\Lic Def Letter\L06-30764-02.579387.doc

SUNSI Review Complete: TThompson

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI			
NAME	JJMiller / <i>JJM</i> /		TThompson / <i>TKT</i> /					
DATE	1/15/2013		1/15/2013					

OFFICIAL RECORD COPY