



# Spectrum Health

Department of Radiology  
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Grand Rapids, MI 49503

## FAX TRANSMITTAL

Date 3/26/07 Time 10:45 Number of Pages (includes this one) 3

To USNRC Matt's Licensing Fax # 630-515-1078 Phone # 630-829-9887

From Bruce Hesselquist Fax # 616-391-2665 Phone # 616-391-3646

RE License Amendment Request

### Confidential Information

Message Please route to Licensing.

Thanks!

BH

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## Spectrum Health

*Butterworth Campus*

100 MICHIGAN STREET NE GRAND RAPIDS MI 49503-2560  
616 391 1774 FAX 391 2745 [www.spectrum-health.org](http://www.spectrum-health.org)

March 20, 2007

United States Nuclear Regulatory Commission  
Region III, Nuclear Materials Licensing  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

License Number: SNM-1432 (Spectrum Health Hospitals)  
Docket #070-01486

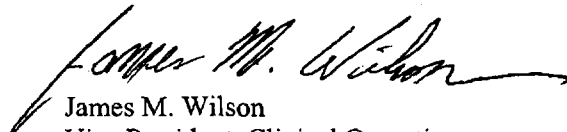
Dear Sir or Madam:

We would like to request an amendment to Item 14 of our USNRC license number SNM-1432 to allow flexibility in the disposal of explanted pacemakers. The current license condition requires "Procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer shall be followed upon the death of the patient." One of our pacemakers, which was recently explanted, was manufactured by Coratomic (note misspelling in Item 9.A.) which, to the best of our knowledge, no longer exists as a business. I have attached a letter from the BICO, Inc / Biocontrol Technology, Inc. RSO dated March 27, 2003 stating that BICO, Inc was filing for bankruptcy and would no longer be able to receive and dispose of Coratomic brand pacemakers. His recommendation for alternate disposal means at the time appears to be the OSRP program at LANL. Our RSO has contacted the OSRP program and has been informed that they are still taking nuclear pacemakers for disposal. We continue to track four additional nuclear powered pacemakers which were manufactured by Cordis. It is our understanding that Radiological Health Services (RHS) in Jacksonville, FL is the manufacturer's authorized disposal agent for the Cordis units. RHS has informed us that the current charge for disposal of the Cordis units is \$3000 per unit.

We would therefore like to amend our license to allow the flexibility for all of our remaining pacemakers of either disposal by return to the manufacturer or disposal by transfer to the LANL OSRP program upon the death of the patient or removal of the device for other reasons. We will continue to securely store any explanted pacemakers at the location of use for this license pending disposition of this request.

If you have any questions regarding this amendment request, please contact Bruce E. Hasselquist, Ph.D., RSO at 616-391-2498.

Sincerely,

  
James M. Wilson  
Vice President, Clinical Operations

Enclosure

cc: Bruce E. Hasselquist, Ph.D., RSO  
Larry Genzink, Director, Radiology  
Thomas Getz, MD, Chair, RSC

*Talk to Tom  
in Cath lab.*

**Biocontrol Technology, Inc.**

625 Kolter Drive

Indiana, PA 15701

Phone: (724) 349-1811

Fax: (724) 349-8610

March 27, 2003

Tom Vitalis, M.S., RSO  
Butterworth Hospital  
Radiation Oncology Department  
100 Michigan NE  
Grand Rapids, MI 49503

Dear RSO,

Biocontrol Technology, Inc. records indicate your hospital is responsible for following, under your NRC or Agreement State License, one or more patients with a Coratomic brand isotopic powered pacemaker, model C-100, C-101, C-101-P, or Pulsar-N1. This letter updates the current business condition of Biocontrol, and discusses how that condition may affect your licensed activities.

On February 28, 2003, the NRC issued an order revoking Biocontrol's NRC license SNM-1319 following an immediately effective 30-day suspension, due to non-payment of the annual NRC license fee. On March 18, 2003, BICO, Inc., the parent company of Biocontrol Technology, Inc., filed for Chapter 11 bankruptcy protection at the U.S. District Court in Pittsburgh, PA. As of March 26, 2003, Joseph N. Klingensmith no longer performs Radiation Safety Officer services on a contract basis for Biocontrol Technology, Inc. license number SNM-1319. Hospitals should contact BICO, Inc., for all questions regarding license number SNM-1319.

BICO, Inc.  
2275 Swallow Hill Road  
Bldg. 2500, 2nd Floor  
Pittsburgh, PA 15220

phone# 412-429-0673  
fax# 412-279-1367  
Tony Pattera, x206  
Stan Cottrell, xunknown

While the ultimate outcome of bankruptcy is unknown at this time, it appears almost certain that BICO, Inc. / Biocontrol Technology, Inc. will not retain an NRC license. Therefore, Biocontrol will not be able to receive and dispose explanted Coratomic brand isotopic powered pacemakers. Hospitals will need to temporarily store and then dispose these pacemakers. RSOs should review their hospital's NRC or Agreement State license to see if a license amendment is required to temporarily store and then dispose explanted Coratomic brand isotopic powered pacemakers.

The Department of Energy (DOE) through Los Alamos National Labs (LANL) has a program for storage and disposal of unwanted pacemaker isotopic sources. DOE/LANL contacts are:

→ J. Andrew Tompkins, jatompkins@lanl.gov, 770-517-4320  
Shelby Leonard, sleonard@lanl.gov, 505-667-6701, <http://osrp.lanl.gov>  
Jerry McAlpin, mcAlpin@lanl.gov, fax: 505-665-7913

Sincerely,

*Joseph N. Klingensmith*  
Joseph N. Klingensmith, former RSO

cc: BICO, Inc. c/o Tony Pattera  
NRC Region I