



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 2, 2004

Department of Environment & Conservation
ATTN: Mr. Charles Arnott
Health Physicist
Division of Radiological Health
3rd Floor
L&C Annex
401 Church Street
Nashville, TN 37243-1532

Dear Mr. Arnott:

This is in response to your letter dated July 15, 2004; requesting removal of registration certificate TN-1004-D-101-S from NRC's registry and website.

Please note we have removed the registration certificate from the system as you requested in your letter.

If I can be of further assistance, please feel free to contact me at 301-415-8140.

Sincerely,


Traci Kime, Licensing Assistant
Division of Industrial
and Medical Nuclear Safety
Office of Nuclear Material
Safety and Safeguards

cc: Jim Melchore, Director
Technical Operations
Bracco Diagnostics, Inc.
107 College Road., East
Princeton, NJ 08543

Gloria Caton
1060 Commerce Park, 139
MS 6480
Oak Ridge, TN 37830



STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION

3rd Floor, L & C Annex
401 Church Street
Nashville, TN 37243-1532

July 15, 2004

U. S. Nuclear Regulatory Commission
Sealed Source Safety Section
Mail Stop T-8 F5
Washington, D.C. 20555

Attention: Traci Kime

Dear Ms. Kime:

We wish to have removed from the Registry of Sealed Sources and Devices Registration Number TN-1004-D-101-S dated February 6, 1996, issued to Bristol-Myers Squibb Company. This is at the request of Bracco, the company that markets the registered CardioGen-82 System which consists of a radionuclide generator and infusion system for medical use. See their attached letter dated July 5, 2004. The parent radionuclide is Strontium 82 which is accelerator produced (NARM). This system will not become inactive.

Due to certain circumstances, we made the decision to include this product in the Registry even though it was a radionuclide generator and not a sealed source or device containing a sealed source. We now believe it be best to remove this registration. The product is not required to be registered, the registration is no longer accurate, and we do not have control over its manufacture or distribution.

Please contact me at (615) 532-0378 if I can provide further information.

Sincerely,

A handwritten signature in cursive script that reads "Charles Arnott".

Charles Arnott
Health Physicist
Division of Radiological Health



THE IMAGE OF INNOVATION

CWA

July 5, 2004

Mr. Charles Arnott
Division of Radiological Health
Tennessee Department of Environment and Conservation
L&C Annex, Third Floor
401 Church Street
Nashville, TN 37243-1532

Dear Mr. Arnott:

The purpose of this letter is a follow-up the June 30, 2004 telephone conversation between yourself and Mr. Tim Fralix of Shaw Environmental & Infrastructure, acting on behalf of Bracco. This conversation was concerning one of our products, the CardioGen-82[®] which is currently listed in the Nuclear Regulatory Commission's "Registry of Radioactive Sealed Sources and Devices" under a State of Tennessee registration number, TN-1004-D-101-S.

As related to you by Mr. Fralix, Bracco is interesting in, if possible, having the CardioGen-82[®] removed from registration. The identification of the CardioGen-82[®] in the NRC's registry has led to confusion among Bracco's clients regarding its regulatory status and has adversely affected Bracco's ability to market the system. Discussions with regulators from NRC Region I have, ultimately, brought us to the conclusion that inclusion of the system in the registry is not required, or appropriate.

This basis of our request to remove the system from registry is that the system does not contain a sealed source or calibration/reference standard. Additionally, the generator component, which contains the radioactive Strontium-82 used in the Rubidium-82 elution process was, in fact, approved by the Food and Drug Administration, in 2001, as a "Drug" under existing regulation.

To further support this request, I am including recently updated technical information regarding the CardioGen-82[®] along with documentation of its FDA approvals.

Please contact me at (609-514-2370) if you require additional information. I appreciate your willingness to consider this request.

Sincerely,

James A. Melchore

Jim Melchore
Director, Technical Operations

Attachments:
Rb-82 Infusion System User's Guide
FDA Approval Letters

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