[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[Docket No. 030-10047; NRC-2012-0097]

Environmental Assessment and Finding of No Significant Impact for Exemption Request for Franciscan St. Anthony Health-Crown Point, Crown Point, Indiana

AGENCY: Nuclear Regulatory Commission

ACTION: Notice of availability.

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SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is considering the renewal of Material License No. 13-15933-01 issued to Franciscan St. Anthony Health-Crown Point, Crown Point, Indiana. The license renewal would include an exemption to Title 10 of the *Code of Federal Regulations* (10 CFR) 35.400, and related rules to permit the continued use of brachytherapy sealed sources that do not have an approved Sealed Source and Device Registry (SSDR).

The NRC has determined that the license renewal qualifies for a categorical exclusion under 10 CFR 51.22(c)(14) and therefore does not require an Environmental Assessment (EA). Issuance of an exemption to 10 CFR 35.400 is not covered by a categorical exclusion. Therefore, an EA of the proposed exemption is required under 10 CFR Part 51. Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate. The license renewal with the authorization for an exemption to 10 CFR 35.400 and related rules will be issued following the publication of this Notice.

II. Environmental Assessment

The proposed action is the issuance of an exemption to NRC rules at 10 CFR 30.32(g), 35.49 and 35.400 pursuant to 10 CFR 30.11 and 35.19. The purpose of the proposed exemption is to authorize the licensee, Franciscan St. Anthony Health-Crown Point, to continue the use of brachytherapy sealed sources previously authorized by the NRC, but that have not been approved in the Sealed Source and Device (SSD) Registry.

The licensee was authorized by the NRC on April 8, 1974, to possess and use byproduct materials for medical use at its facility in Crown Point, Indiana. While reviewing the licensee's license renewal application dated October 26, 2010, the NRC staff determined that fourteen sealed brachytherapy sources have been in its possession and use since September 18, 1986 (25 years), including cesium-137 sealed sources, model numbers 1862, 1864 and 1866, manufactured by Radiation Therapy Resources, Inc. The cesium-137 sealed sources are not approved in the SSD Registry as required by the NRC regulations at 10 CFR 35.400(a).

Provisions in 10 CFR 35.400(a) require that sealed sources for manual brachytherapy medical use must be approved in the SSD Registry. The SSD Registry was established in 1989, as a formalized database to be used both by the NRC and the Agreement States in order to serve as a "clearing house" for sources and devices that meet the regulatory requirements. Under NRC rules at 10 CFR 30.32(g), normally an applicant for a specific license to use

byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number as registered in the SSD Registry, or provide the information described in 10 CFR 32.210(c) (*i.e.*, information necessary to enable a review to determine whether the device should be added to the Registry). In this case, however, use of the cesium-137 sources predates the SSD Registry. Current registration is not possible because the manufacturer of the sources, Radiation Therapy Resources, Inc., is no longer in business and the licensee does not have sufficient information to permit the normally-required SSD Registry review.

After telephone discussions with the NRC staff, the licensee, in letters dated May 3, 2011, and June 16, 2011, submitted a request for an exemption to 10 CFR 35.400(a) to possess the cesium-137 sealed sources for therapeutic medical use. The licensee stated that continued use of the cesium-137 sealed sources would be medically beneficial. Specifically, the sealed sources would be used to provide brachytherapy procedures to patients with early state of gynecological cancer or to give boost dose post external beam therapy without radiating the dose to extra normal tissue. The licensee also stated that the cesium-137 sealed sources have been used for 25 years with no occurrence of a medical event. Quarterly inventory checks have been conducted and the sources have been accounted for and stored safely and securely between the uses. The licensee conducted six-month leak tests on the sealed sources as required by the license, with no incidence of a leaking source.

The NRC staff reviewed the licensee's exemption request, information pertaining to the structural integrity of the cesium-137 sources, and historical records on the use of the cesium-137 sealed sources. Historical use of the sealed sources, which predates the existence of the SSD Registry, has been conducted safely, without environmental releases, and there are no indications that the structural integrity of the sources would be adversely affected if the current type of use continues.

The NRC staff's review also found that (1) the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment, with appropriate procedures, to safely use and handle the requested quantity of radioactive material in unshielded form, and has the necessary financial assurance; and (2) there is historical evidence extending to over two decades that the licensee has handled this and similar types of sources without incident. Based on its findings, the NRC staff concludes that granting the exemption is authorized by law, will not endanger life, property, or the common defense and security, and is otherwise in the public interest. The NRC plans to renew the license with the exemption provided in a special license condition that states, "Notwithstanding the requirements of 10 CFR 30.32(g), 35.49, and 35.400, the licensee may use Radiation Therapy Resources, Inc., Model Nos. 1862, 1864, and 1866 manual brachytherapy sources for medical uses authorized under the provisions of 10 CFR 35.400."

The staff consulted with the State of Indiana, and the State had no comments on the proposed action.

III. Finding of No Significant Impact

On the basis of the EA, the NRC has concluded that there are no significant environmental impacts from the issuance of the exemption to the NRC rules at 10 CFR 30.32(g), 35.49 and 35.400, and has determined not to prepare an environmental impact statement.

IV. Further Information

Documents related to this action, including the proposed exemption request and supporting documentation, are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession numbers for the documents related to this notice are:

(1.) Franciscan St. Anthony Health-Crown Point, Licensee exemption request, May 3, 2011, (ML111230830);

(2.) Franciscan St. Anthony Health-Crown Point, Licensee exemption request, June 16, 2011, (ML111801256);

(3.) Franciscan St. Anthony Health-Crown Point, Licensee Background information, (ML111470614); and

(4.) Franciscan St. Anthony Health-Crown Point, License Number 13-15933-01, (ML120800176).

If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by email to *pdr.resource@nrc.gov*.

These documents may also be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O 1 F21, One White Flint North, 11555 Rockville Pike Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Lisle, Illinois this 18th day of April 2012.

For the Nuclear Regulatory Commission.

/RA/

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[FR Doc. 2012-10191 Filed 04/26/2012 at 8:45 am; Publication Date: 04/27/2012]