



Sisters of Charity of Leavenworth Health System

January 4, 2010

United States Nuclear Regulatory Commission
611 Ryan Drive, Suite 400
Arlington, TX 76011-8064

LicenseNumber:25-13173-02

Gentlemen:

St James Healthcare submits its response to the violations identified during a routine visit by of the NRC staff on October 27, 2009.

Item A. Possession of unidentified sealed sources I-125 and Pd-103 and Sr-90.

St. James Healthcare has requested the NRC Licensing Division to Amend its Byproduct Materials License to include I-125, Pd-103 and Sr-90. The source manufacturer and its model number were included with that request. A copy of that amendment request is included with this letter.

Item B. Sealed Source Inventory

A therapeutic sealed source inventory reminder is included with the Nuclear Medicine Departments recordkeeping program as a 'tickler' to remind the individual responsible for inventorying therapeutic seal sources. The recordkeeping computer is located in a separated location and used by an individual separated from the Department Radiation Oncology

Item C. Sealed Source Leak Testing

A therapeutic sealed source leak testing reminder is included with the Nuclear Medicine Departments recordkeeping program as a 'tickler' to remind the individual responsible for leak testing therapeutic seal sources. The recordkeeping computer is located in a separated location and used by an individual separated from the Department Radiation Oncology

IE07



Sisters of Charity of Leavenworth Health System

Root Cause Analysis

It is important to identify the cause of the errors made that resulted in the violations cited by the NRC representative. . Failure to advise the NRC of sealed source names and model numbers is a failure on the part of its Radiation Safety Officer. To correct that failure the RSO will review all current rules and regulations applicable this license. Such review is expected to be completed by the end of January 2010.

A detailed and comprehensive review by the RSO concluded that sealed source violations cited by the NRC's staff would have been avoided by automatic reminders for the execution of routine time defined tasks for radioactive material accountability and safety. To that end the Nuclear Medicine Department recordkeeping computer will be utilized for the necessary 'ticklers' to remind staff of necessary tests and inventories as they arise. Such ticklers shall be in place by the end of January 2010.

It is the intention of St. James Healthcare to transfer all of its Cs-137 sources as well as its Sr-90 eye applicator sealed source applicator to a disposal agent licensed and authorized to possess these materials.

If there are any questions please do not hesitate to contact me by phone (406) 788-0477 or e-mail rodwimmer@lycos.com.

Sincerely,

Rod Wimmer Ph.D.
RSO St. James Healthcare.



Sisters of Charity of Leavenworth Health System
January 4, 2010

United States Nuclear Regulatory Commission
611 Ryan Drive, Suite 400
Arlington, TX 76011-8064

LicenseNumber:25-13173-02

Gentlemen:

St James Healthcare requests an amendment to its byproduct materials license to include sealed sources identified in CFR 35.400 to include palladium-103, iodine-125 and strontium-90. The sealed sources are manufactured by Theragenics. Two source types are requested I-125 (Model 125.S06) and Pd-103 (Model 200). Source types are sold under trade mark and registered names as TheraStrand, TheraLoad and TheraSleeve. As a condition of possession of these sources St. James Healthcare agrees to follow Appendix O and P for ordering, receipt and opening the package containing these materials, require a written directive prior to the administration, return unused sources to the manufacturer and conduct radiation protection surveys following their administration. The radiation surveys shall include but not be limited to: OR room utilized for the implant; recovery room used by the patient prior to their release.

St. James Healthcare requests licensure for possessing a Sr-90 eye applicator manufactured by Isotope Products Laboratories Therapy Source Model 4-850. Initial activity on 5/1/1987 was 125 mCi.

St. James Healthcare request the removal of the use of Iotrex material from its Byproduct Materials License. Iodine-125 labeled Iotrex procedures are no longer performed at St. James Healthcare.

If there are any questions please do not hesitate to contact me by phone (406) 788-0477 or e-mail rodwimmer@lycos.com.

Sincerely,

Rod Wimmer Ph.D.
RSO St. James Healthcare.