



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION IV
1600 E. LAMAR BLVD
ARLINGTON, TX 76011-4511

March 28, 2017

Ms. Traci Hollingshead, Radiation Safety Officer
Nuclear Medicine Department
Avera McKennan
1325 South Cliff Avenue
Sioux Falls, SD 57117-5046

SUBJECT: LICENSE AMENDMENT

Dear Ms. Hollingshead:

Please find enclosed Amendment Number 68 to NRC License Number 40-16571-01 adding locations of use, adding another manufacturer and model of a High Dose Rate afterloader unit, and deleting an authorized medical physicist, as requested. An environmental assessment for this licensing action is not required since this action is categorically excluded under 10 CFR 51.22(c)(10) (v) and (14)(iv). You should review this license carefully and be sure that you understand all conditions. You can contact me at 817-200-1132 if you have any questions about this license.

Note that your license and license conditions have been updated in a new format. Please review your license and notify this office if you have any discrepancies or questions.

Please note that the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance was revised on February 12, 2016, Rev. 9 (<https://www.nrc.gov/docs/ML1535/ML15350A099.pdf>). Please note that you are currently authorized to use these products (microspheres) committed by license condition to following provisions in a previous revision of this guidance. Therefore, you may request a license amendment to commit to following the more recent revision (Rev. 9) of the guidance instead. Please note that you must apply for and receive this license amendment in order to make program changes to conform to this revision of the guidance.

**The enclosure transmitted
herewith contains Official Use
Only – Security-Related
Information. When separated
from this enclosure, this
document is decontrolled.**

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The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's expectations for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant. Since the NRC also accepts a letter requesting amendment of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available on the following internet address: <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

An electronic version of the NRC's regulations is available on the NRC Web site at www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

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The NRC medical list server has been set up. The list server will send automatic e-mail notifications of medical-related generic communications, Federal Register Notices, and NMSS/FSME newsletters as they are published. Anyone may subscribe/unsubscribe to the new medical list server by sending an e-mail to medical-gc@nrc.gov with “Subscribe” or “Unsubscribe” in the subject line.

NRC’s Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through the NRC’s Agencywide Documents Access and Management System (ADAMS). The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/>. Pursuant to NRC’s RIS 2005-31, this letter and its enclosed materials license will not be made publicly available.

Thank you for your cooperation.

Sincerely,

/RA/

Jacqueline D. Cook, Senior Health Physicist
Nuclear Materials Safety Branch B

Docket: 030-11252
License: 40-16571-01
Control: 592576
592645

Enclosure: As stated

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