

NEBRASKA

Good Life. Great Mission.

DEPT. OF HEALTH AND HUMAN SERVICES



Pete Ricketts, Governor

July 22, 2021

The Nebraska Medical Center
987400 Nebraska Medical
Omaha, NE 68198

ATTN: Mark Theis
Radiation Safety Officer

Dear Mr. Theis:

This refers to the inspection conducted by Becki Harisis and Travis Smith of this office, and Lizette Roldan-Otero, PhD, of the Nuclear Regulatory Commission, on June 24, 2021 of activities authorized by Nebraska Radioactive Material License No. 01-88-01. Our findings were discussed with Frank Rutar, Carrie Carson, Amy Pitzew, Kelly Emrick, Patrick Wortmann, Sumin Zhou, Thomas Lane, and you at the conclusion of this inspection.

This inspection was an examination of the activities conducted under your license, a selective examination of procedures and representative records, observations and interviews with personnel as they relate to radiation safety and to compliance with the Department's rules and regulations, and the conditions placed on the license.

Please note that any material with a half-life equal to or greater than 120 days may not be held for decay-in-storage. Specifically, Y-90 TheraSpheres® and Y-90 SirSpheres® determined to contain impurities with a physical half-life of greater than 120 days that can be distinguished from the background radiation level with an appropriate radiation detection survey meter will need to be returned to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres, or transferred to an authorized recipient. A copy of NRC Information Notice 2007-10 is enclosed which addresses disposing of microspheres.

The inspection also included a review of the actions described in your letter dated August 27, 2018, regarding items of noncompliance identified during our July 11 and 12, 2018 inspection. We have no further questions regarding this matter.

Based on the results of this inspection certain of your activities were not conducted in full compliance with Title 180, as set forth in the Notice of Noncompliance enclosed herewith.

The Nebraska Medical Center
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This is to advise you that you are required to post a notice of violation of radiological working conditions (see enclosure). Any noncompliance item with respect to the Regulations or the conditions of the license is considered a violation of working conditions per 180 NAC 10-002.01, item 4.

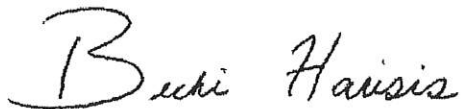
Submit a written statement or explanation in reply including:

- (1) Corrective actions, which have been taken by you and the results, achieved.
- (2) Corrective actions, which will be taken to avoid, further items of noncompliance.
- (3) The date when full compliance will be achieved.

This report shall be received by this office before **August 22, 2021**.

If you have any questions or concerns regarding this inspection, please contact me, at (402) 471-0385.

Sincerely,

A handwritten signature in cursive script that reads "Becki Harisis".

Becki Harisis, Program Manager
Office of Radiological Health
DHHS - Division of Public Health

Encl. Notice of Noncompliance

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NOTICE OF NONCOMPLIANCE
The Nebraska Medical Center
Radioactive Material License No. 01-88-01

Based on the results of the Nebraska Department of Health & Human Services Division of Public Health inspection conducted on June 24, 2021, certain of your activities are in noncompliance with Title 180 (Control of Radiation) and the conditions of your Radioactive Material License No. 01-88-01 as indicated below:

1. 180 NAC 13-005.01 requires that each licensee who transports licensed material outside of the site of usage, as specified in the Department license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, must comply with the applicable requirements of the U. S. Department of Transportation (DOT) regulation in 49 CFR part 107, 171 through 180, and 390 through 397 appropriate to mode of transport.

49 CFR 173.428(d) requires that a radioactive materials packaging which previously contained radioactive material and has been emptied of contents as far as practical must not contain internal contamination that exceeds 100 times the limits in 173.443(a).

Contrary to the above, on June 24, 2021, the licensee prepared a package labeled as excepted package-empty packaging, UN2908, but the package was not prepared for shipment, as required, in accordance with 49 CFR 173.428. Specifically, the licensee did not determine that the internal contamination levels did not exceed 100 times the limits in 173.443(a).

This is a Severity Level IV violation.