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April 13, 2016

DNMS

Ray L Kellar, PE Chief
Nuclear Material Safety Branch A
Division of Nuclear Material Safety
US Nuclear Regulatory Commission
Region IV
1600 E Lamar Blvd
Arlington TX 76001-4511

Reply to a Notice of Violation: EA-16-036
Ref: License 40-01683-01 Docket No. 030-03235

Dear Mr. Kellar:

This is in response to a follow up phone conversation with Janine Katanic Phd, CHP and Jason Vonehr with the NRC office and Kevin Pistulka RTR from Avera Sacred Heart Hospital in regards to our formal response to our Notice of Violation: EA-16-036.

A recommendation was made to modify our Written Directive Form to insure accurate documentation of NRC requirements. We have implemented the changes to the form and have included copies of them with this letter for your review.

We will also be submitting a license amendment to remove William C. Doeblor MD as an authorized user on our license.

We appreciate the time and effort of your staff in assisting us in making sure that we meet all the NRC requirements.

Sincerely;

A handwritten signature in black ink, appearing to read "D. Ekeren".

Douglas Ekeren, FACHE
Regional President and CEO



WRITTEN DIRECTIVE (NRC 35.40)
ADMINISTRATION OF THERAPEUTIC RADIOPHARMACEUTICAL

This form must be completed before administration of all therapeutic doses

Patient Name: _____ MR Number: _____

Diagnosis: _____

Patient Weight: _____ Route of Administration: _____

☐ **RADIUM 223-XOFIGO**

Isotope: Ra-223 Dose: _____ uCi

☐ **I-131 SODIUM IODIDE > 30 uCi**

Isotope: I-131 Dose: _____ mCi

☐ **Sm-153 SAMARIUM**

Isotope: Sm-153 Dose: _____ mCi

☐ **Sr-89 STRONTIUM**

Isotope: Sr-89 Dose: _____ mCi

☐ **OTHER** _____

Isotope: _____: _____ mCi /uCi

COMMENTS: _____

Signature of Authorized User: _____
Dr. Ralph Tullo, M.D., CPE, Radiologist

Date: _____ **Time:** _____

Nuclear Medicine Technologist: _____



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☐ **BRACHYTHERAPY RADIATION FROM BYPRODUCT MATERIAL**

Before Implantation:

Treatment site: _____

Radionuclide: _____

Prescribed Dose: _____

After Implantation: (before completion of procedure)

Treatment site: _____

Radionuclide: _____

Number of Sources: _____

Total Source Strength and Exposure Time: _____

Signature of Authorized User: _____
Dr. Michael Peterson, MD Radiation Oncologist

Date: _____ **Time:** _____

Nuclear Medicine Technologist: _____