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DNMS

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April 5, 2016

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 40-10683-01 Docket No. 030-03235

Dear Mr. Kellar:

This is in response to a notice of a violation discovered during NRC routine inspection of our facility on January 28, 2016 and a final phone exit interview on March 17, 2016. We sincerely regret that all the components which were required by 10 CFR part 35.40 were not complied with on written directive. The specific item noted was the signature of the authorized user prior to administration of radiopharmaceutical.

We have since have met with all the individuals responsible for the administration of dose in Nuclear medicine and emphasized the need to complete the necessary items in a timely manner. A root cause analysis indicates that we need to perform a thorough inspection of these forms after the administration of the dose. In addition all the forms completed during the previous quarter will be reviewed by RSO to ensure compliance.

We have developed the appropriate forms which are attached with this letter for your records. We are in full compliance effective immediately with this item of noncompliance. We appreciate the time and effort of your staff in bringing this item to our attention.

Sincerely;



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: _____ Visit Number: _____

Diagnosis: _____

Patient Weight: _____ Route of Administration: _____

☐ **RADIUM 223-XOFIGO**

Isotope: Ra-223 Dose: _____ uCi

☐ **I-131 SODIUM IODIDE > 30 mCi**

Isotope: I-131 Dose: _____ uCi

☐ **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. Ralph Tullo, M.D., CPE, Radiologist

Date: _____ **Time:** _____

Nuclear Medicine Technologist: _____