

CONVERSATION RECORD

TIME | DATE

VISIT

CONFERENCE

TELEPHONE

7/26/11

INCOMING

OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

Mark Haenchen, RSO

ORGANIZATION (OFFICE, DEPT. ETC.)

St. Louis University

TELEPHONE NO.

314-977-6885

SUBJECT

New Information

SUMMARY

During the preliminary exit teleconference on 7/18/11, the inspector discussed an apparent violation of 10 CFR 35.41(a) involving failure to follow Step 1 of the licensee's "Thyroid Therapy Protocol" for providing high confidence that each administration of iodine-131 is in accordance with the written directive. Step 1 of the Procedure in the Thyroid Therapy Protocol states, "When ordering the therapeutic iodine-131 capsule from Cardinal Health nuclear pharmacy, a Quality Management Program - Prescription Form (QMP form) needs to be signed with dosage amount by one of the attending physicians." The RSO didn't recognize that step of licensee's the procedure for achieving compliance with 10 CFR 35.41(a); therefore, the RSO pursued the matter.

The RSO determined that licensee staff inadvertently provided the inspectors with a procedure that was revised on June 30, 2011, and not approved via signatures by authorized users. The RSO committed to email the inspector today the licensee's procedure that was effective on June 20, 2011, for achieving compliance with 10 CFR 35.41(a), and what should have been provided during the onsite inspection per the inspectors' request.

The inspector expressed concern that nobody attending the onsite preliminary exit meeting mentioned that the "Thyroid Therapy Protocol" wasn't the licensee's procedure that was effective on June 20, 2011, for achieving compliance with 10 CFR 35.41(a) because it infers that licensee staff were unfamiliar with the procedure that was effective on June 20, 2011.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

Bob Gattone

7/26/11

ACTION TAKEN

SIGNATURE

*Robert B. Gattone, Jr.*

DATE

SIGNATURE

TITLE

DATE