1/11 NC

2245971

[redacted]

073007

YOUSSEF KHAWAJA, M.D.
16 CORNERSTONE COURT
PLANTSVILLE, CT 06479
(860) 621-9353 TEL
(860) 621-1815 FAX
DEA # BK 0758776

NAME [redacted] AGE
ADDRESS DATE 11/11/05

Rx ILLEGAL IF NOT SAFETY BLUE BACKGROUND

℞

Total body I131 stun
(after therapy)
Dx: thyroid cancer

Refill _____ times

(Signature)

To ensure brand name dispensing, prescriber must handwrite "BRAND MEDICALLY NECESSARY" on the prescription

5IIM0297608

Pt: [redacted]

Appts on Wed 11/16/06 8:45AM and
Fri 11/18/06 SAME TIME

ATTN: Celeste in Nuclear Medicine

FROM: YOUSSEF B. KHAWAJA, M.D.
INTERNAL MEDICINE ENDOCRINOLOGY
16 CORNERSTONE CT.
MAIN STREET
PLANTSVILLE, CT 06479

note: 1-11-06 WRITTEN DIRECTIVE misplaced (JS)
Dr Stein notified

copy

NEW BRITAIN GENERAL HOSPITAL
100 GRAND ST.
NEW BRITAIN , CONN. 06050

NRC LICENSE # 06-02388-01

DATE OF REPORT: JANUARY 12,2006
DATE OF INCIDENT: JANUARY 11,2006

PATIENT MEDICAL RECORD # 073007 WAS SCHEDULED WITH THE ORDERING PHYSICIAN'S OFFICE (DR. YOUSSEF KHAWAJA) FOR AN IODINE 131 WHOLE BODY SCAN USING THE THYROGEN PROTOCOL. A NOTE WAS LEFT ON THE ACTIVE FILE OF PATIENT ORDERS THAT ORDERS FROM DR. KHAWAJA AND A WRITTEN DIRECTIVE WERE NEEDED. THE 4 (FOUR) MILLICURIE IODINE-131 DOSE WAS ORDERED THE NIGHT BEFORE USING THE PROTOCOL , KNOWING THE THYROGEN PROTOCOL DOSE WAS 4 MILLICURIES OF IODINE 131.
THE TECHNOLOGIST WHO DOSED THE PATIENT, KNOWING THE DOSE WAS ORDERED, ASSUMED THE WRITTEN DIRECTIVE HAD BEEN FILLED OUT PRIOR. AFTER ASKING THE PATIENT THE LIST OF QUESTIONS AND IDENTIFYING HER, (SEE ATTACHED) THE PATIENT WAS ADMINISTERED 4.1 MILLICURIES OF IODINE 131 ORALLY. IT WAS AT THIS TIME , AS THE TECHNOLOGIST WENT TO COMPLETE THE PAPAERWORK,IT WAS DISCOVERED THERE WAS NO WRITTEN DIRECTIVE.
THE TECHNOLOGIST IMMEDIATELY NOTIFIED THE NUCLEAR MEDICINE SUPERVISOR. AS THE RSO/PHYSICIST WAS NOT IN THE STATE, A CALL WAS PLACED TO THE RADIATION SAFETY ASSISTANT. AS THIS WAS A DIAGNOSTIC STUDY AND THE APPROPRIATE DOSE WAS GIVEN, IT WAS FIRST DETERMINED TO SEE IF THE WRITTEN DIRECTIVE WAS MISPLACED. THURSDAY MORNING (1/12/06) UPON REVIEW, IT APPEARS NO WRITTEN DIRECTIVE WAS EVER GENERATED. A MESSAGE WAS LEFT WITH THE RSO/PHYSICIST VOICEMAIL AT 8:25AM. THE RSO/PHYSICIST RETURNED THE PHONE CALL SHORTLY BEFORE 9 AM SAYING HE WAS UNSURE ABOUT WHETHER THE MISTAKE WAS RECORDABLE; HE WOULD CHECK THE REGS AND GET BACK TO US. HE CALLED BACK AROUND 9:40 AM SAYING HE HAD SPOKEN TO PAM HENDERSON FROM THE NRC WHO ENCOURAGED FILING A REPORT. THE RADIATION SAFETY ASSISTANT IMMEDIATELY CALLED PAM HENDERSON(9:55 AM) WHEN THE NUMBER THE RSO/PHYSICIST GAVE US KEPT GOING TO VOICE MAIL. MS. HENDERSON VERIFIED THE NUMBER TO CALL AND AT 10:15 AM JOHN MACKINNON FROM THE NRC WAS NOTIFIED OF THE WRITTEN DIRECTIVE ISSUE.
MR. MACKINNON WAS GIVEN THE FOLLOWING INFORMATION:

1. PHYSICIAN'S ORDER WAS IN HAND
2. PATIENT RECEIVED 4.1 MCI IODINE -131 FOR A DIAGNOSTIC PROCEDURE

3. THE WRITTEN DIRECTIVE WAS NOT COMPLETED
4. APPROPRIATE DOSE WAS GIVEN PER DEPARTMENT PROTOCOL
5. NOTIFICATION WAS NOT MADE IMMEDIATELY BECAUSE IT WAS A DIAGNOSTIC PROCEDURE
6. REPORT WILL BE GENERATED BY THE HOSPITAL.

CORRECTIVE ACTIONS:

1. **NO** IODINE 131 DOSE WILL BE ORDERED WITHOUT THE WRITTEN DIRECTIVE IN FRONT OF THE ORDERING TECHNOLOGIST
2. WRITTEN DIRECTIVE WILL BE CHECKED FOR **ALL** IODINE 131 PATIENTS **PRIOR** TO THE ADMINISTRATION OF THE DOSE
3. THE RADIATION SAFETY TECHNOLOGIST AND THE RSO/PHYSICIST WILL REVIEW THE REGULATIONS TO UPDATE.

NEW BRITAIN GENERAL HOSPITAL
100 GRAND ST
NEW BRITAIN, CT. 06050

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ADDENDUM TO REPORT DATED JANUARY 12,2006 REGARDING INCIDENT JANUARY 11,2006

On January 19, 2006 at approximately 11:30 am, Donna Janda (610-337-5371) from NRC headquarters called and spoke to Celeste Majek, radiation safety technologist.

Ms. Janda had reviewed the report dated January 12, 2006 regarding the administration of Iodine 131 to a patient for a diagnostic whole body scan without a written directive.(see report dated 1/12/06 for details). It is her opinion that this is not considered a medical event and therefore does not require a report submitted to the NRC. Ms. Janda further states that the issue and hospital report will be reviewed at the hospital's next NRC inspection for potential violation of a regulation.

At Ms. Janda's direction, Ms. Majek called the NRC to retract the event report. (event report # 42253)

At 12:45pm Ms. Majek spoke to Stuart Korchin, hospital physicist and radiation safety officer, advising him of the phone call with Ms. Janda. He asked for the phone number to speak to her regarding the details.

At 1:05pm Ms. Majek contacted Bill Gott (301-816-5100) at the NRC, outlining the conversation with Ms. Janda and formally requesting a retraction of the report submitted on January 12,2006.

Mr. Gott indicated he would mark the report as retracted, but stated the report would stay in existence.

The entire matter is on the agenda for the next radiation safety committee meeting for review and discussion.