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**Henry Ford Hospital
Henry Ford Medical Group**

Facsimile Transmittal

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 From: Alan M. Jackson Dept: Radiation Safety Office
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 Pages: 4 Date: 9/17/10

Urgent For Review Per your request Please Reply

• **Comments:**

See you Monday.

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DEPARTMENT OF RADIOLOGY
Henry Ford Hospital & Medical Centers

Radiation Safety Office

September 17, 2010

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Deborah Piskura
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Ms. Piskura:

I am directing this report to your attention as this will certainly provide information relevant to the upcoming inspection of event 46230.

During a routine radiation safety audit on September 3, 2010 Alan Jackson, MS, CHP at Henry Ford - Wyandotte Hospital (License: 21-12930-01 Docket: 030-002140) discovered that Michael F. Zydek, MD had signed written directives for the use of iodine-131 and that he was not authorized for this type of work on this license. While Dr. Zydek is an authorized user for 10 CFR § 35.100 and 35.200 uses, he is not authorized for 35.300 use. These cases are clearly a violation of the license terms and were judged by us to be potential medical events because there were not valid written directives and some administrations resulted in a dose in excess of 50 rem to the thyroid. This information was communicated by Alan Jackson through a phone call to the NRC operations center and Region III on September 3, 2010. This letter describes additional evaluation and corrective actions taken by Henry Ford - Wyandotte Hospital.

Six cases of 10 CFR § 35.300 usage by Dr. Zydek were originally reported to the NRC. Dr. Zydek was added to the radioactive materials license in 2005. All written directives from that date until the present were reviewed. As a result of this review, a total of 16 cases of improper use by Dr. Zydek were identified. No other cases were identified of any other individual violating their license permissions. The following cases were identified:

Administration Date	Dose Delivered	Treatment Type
4/24/08	2.0 mCi I-131	Thyroid Cancer Scan
4/20/08	9.24 mCi I-131	Hyperthyroid
6/17/08	2.0 mCi I-131	Thyroid Cancer Scan
6/20/08	101.5 mCi I-131	Ablation
10/22/08	2.0 mCi I-131	Thyroid Cancer Scan
7/9/09	2.4 mCi I-131	Whole Body
7/17/09	100 mCi I-131	Thyroid Cancer Therapy
8/3/09	14.69 mCi I-131	Hyperthyroid
8/4/09	1.98 mCi I-131	Thyroid Cancer Scan
8/7/09	100.5 mCi I-131	Thyroid Cancer Therapy
4/27/10	2.1 mCi I-131	Thyroid Cancer Scan
6/15/10	2.0 mCi I-131	Thyroid Cancer Scan
6/17/20	12 mCi I-131	Hyperthyroid
6/18/10	99.8 mCi I-131	Thyroid Cancer Therapy
8/24/10	2.0 mCi I-131	Thyroid Cancer Scan
8/27/10	100 mCi I-131	Thyroid Cancer Therapy

Our investigation revealed that Dr. Zydek thought that he had authorization for this work. Part of his reasoning is that his medical education in Nuclear Medicine was identical to his radiology business partners. He obtained the requisite training hours in the proper subjects by a valid preceptor to become authorized in 10 CFR § 35.300 use. In addition, Dr. Zydek asked a Wyandotte Nuclear Medicine technologist if he was a valid authorized user and she confirmed that he was on the license but failed to recognize that his authorized user status did not include the part 300 use. To compound this error, radiation safety audits missed earlier opportunities to identify this license violation.

Upon discovery of this situation the Radiation Safety Office notified the hospital administration and Nuclear Medicine technologists that Dr. Zydek could not sign any written directives. A summary sheet of valid Authorized Users was generated and posted in Nuclear Medicine Department making it clear who can legitimately write written directives.

We asked Kastytis Karvelis, MD who is an authorized user at Henry Ford Hospital, for 10 CFR § 35.300 use and is not a business partner with Dr. Zydek to review the 16 cases listed above. According to Dr. Karvelis, "In each of the cases reviewed ... the administered amounts of diagnostic and therapeutic radioiodine appear to have appropriate indications, and the dosages are consistent with current standards at our institution". Thus we conclude that there was no harm done to any of these patients. Based on that conclusion we have decided to notify only the referring physicians so they may decide if notification to their patients is warranted.

We appreciate your assistance in this matter. Please contact Alan Jackson by phone at (313) 916-2739 or via e-mail at AlanJ@rad.hfh.edu if you have any questions or concerns.

Sincerely,



Donald Peck, PhD, DABR
Radiation Safety Officer



Alan M. Jackson, MS, CHP
Senior Health Physicist