NORTH DAKOTA
DEPARTMENT *of* HEALTH

ENVIRONMENTAL HEALTH SECTION
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701.328.5200 (fax)
www.ndhealth.gov

MEMO TO : North Dakota Radioactive Material Medical Licensees

FROM : Terry L. O'Clair, P.E.
Director
Division of Air Quality

RE : NRC Information Notice 2007-38: Ensuring complete and accurate information in the documentation of training and experience for individuals seeking approval as medical authorized users

DATE : January 28, 2008

The North Dakota Department of Health is forwarding this U.S. Nuclear Commission (NRC) Information Notice to inform licensees of the importance of verifying the completeness and accuracy of information provided by individuals seeking authorization for medical use from the NRC under the alternate pathway(10 CFR Part 35).

Recently, NRC has identified several instances where licensees have provided documentation of training and experience for proposed authorized individuals that contained false or inaccurate information. It is the preceptor's responsibility to ensure the training documented is accurate and complete. If the preceptor statement is not accurate and complete, "Completeness and accuracy of information", it is a violation of 10 CFR 30.9.

If you have any questions, please contact the North Dakota Department of Health Radiation Control Program at (701)328-5188.

LR:csc
Enc:

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, DC 20555-0001

December 14, 2007

NRC INFORMATION NOTICE 2007-38: ENSURING COMPLETE AND ACCURATE INFORMATION IN THE DOCUMENTATION OF TRAINING AND EXPERIENCE FOR INDIVIDUALS SEEKING APPROVAL AS MEDICAL AUTHORIZED USERS

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The NRC is issuing this information notice (IN) to inform addressees of the importance of verifying the completeness and accuracy of information provided by individuals seeking authorization for medical use from the NRC under the alternate pathway. Approval under the alternate pathway is based on an evaluation of an individual's training and experience against the requirements specified in Title 10 of the *Code of Federal Regulations* Part 35, "Medical Use of Byproduct Material," (10 CFR Part 35) for the particular authorization being sought. Recipients should review the information for applicability to their facilities and consider actions, as appropriate, to ensure the completeness and accuracy of the information provided in support of individuals seeking authorization under the alternate pathway. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action or written response is required. The NRC is providing this IN to the Agreement States for their information and for distribution to their medical licensees as appropriate.

DESCRIPTION OF CIRCUMSTANCES

Recently, NRC has identified several instances where licensees have provided documentation of training and experience for proposed authorized individuals (i.e., physician authorized users (AUs) or authorized medical physicists (AMPs)) that contained false or inaccurate information. In each case, the proposed authorized individuals sought authorization by the alternate pathway.

In the first case, a licensee submitted an amendment request to add a number of medical physicists to its license as AMPs and included a preceptor statement for a Junior Medical Physicist who was seeking authorization under the alternate pathway. An AMP who was listed on the licensee's license completed the Junior Physicist's preceptor statement. Based on an investigation by the NRC Office of Investigations (OI), the NRC determined that the preceptor statement was inaccurate in that it documented dates of clinical training that exceeded the dates of actual training received by the Junior Medical Physicist. The NRC concluded that the actions of the preceptor AMP were deliberate, in that he knew that the preceptor statement was inaccurate at the time it was submitted to the licensee and then subsequently to the NRC. The

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licensee is responsible for the acts and omissions of its employees and contractors and their employees, and thus the agency determined that the submission of the inaccurate information by the licensee to the NRC was a deliberate violation of 10 CFR 30.9(a). This section of the regulations requires, in part, that information provided to the Commission by a licensee or an applicant for a license shall be complete and accurate in all material respects. As a result, the NRC cited the licensee for a Severity Level III violation of 10 CFR 30.9(a) and levied a civil penalty of $3,250.00. Severity Level III violations are causes for significant regulatory concern. Furthermore, the NRC determined that the AMP, who was a contractor or employee of the licensee, deliberately provided inaccurate information to the licensee that caused the licensee to violate NRC regulations. Therefore, the agency issued the AMP a Severity Level III Notice of Violation for violation of 10 CFR 30.10, "Deliberate misconduct." This regulation requires, in part, that an employee, contractor (including a consultant or supplier), or subcontractor of a licensee or applicant for a license may not engage in deliberate misconduct that causes a licensee or applicant for a license to violate any requirement, and may not deliberately submit to the NRC, the licensee, or the license applicant, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

In the second case, involving the same AMP and Junior Medical Physicist and the same inaccurate preceptor statement, a different licensee submitted an amendment request to add the Junior Medical Physicist to its license. However, in this case, before submitting the amendment request to the NRC, the licensee's Radiation Safety Officer (RSO) conducted interviews with the AMP and the Junior Medical Physicist in an attempt to verify the accuracy of the information contained in the preceptor statement. Both the AMP and the Junior Medical Physicist informed the RSO that the information in the preceptor statement was accurate. The licensee subsequently submitted the amendment request with the inaccurate preceptor statement. As in the first case, the NRC concluded that the actions of the AMP and the Junior Medical Physicist were deliberate. However, because the licensee's RSO did attempt to verify the accuracy of the information contained in the preceptor statement by interviewing both individuals, before submitting it to the NRC, the agency classified the violation of 10 CFR 30.9(a) as a Severity Level IV violation and did not propose a civil penalty. Severity Level IV violations are less significant than Severity Level III violations. The NRC determined that the AMP and the Junior Medical Physicist, who were both contractors or employees of a licensee, deliberately provided materially inaccurate information to the licensee and caused the licensee to violate 10 CFR 30.9(a). The AMP and the Junior Physicist both received Severity Level III Notices of Violation for violation of 10 CFR 30.10.

In the third case, a diagnostic nuclear medicine licensee provided a proposed AU with a copy of a sample preceptor letter that contained blank spaces to be completed by the proposed AU and a preceptor AU. The blank spaces were for the documentation of the number of hours of supervised clinical and work experience in diagnostic nuclear medicine received by the proposed AU and for the signature of the supervising preceptor AU. The blank spaces of the preceptor letter were filled in, the letter was signed by the preceptor AU and the proposed AU, and the letter was returned to the licensee. The licensee did not question the authenticity or accuracy of the number of hours of supervised clinical and work experience identified in the preceptor letter. The licensee submitted a license amendment application to add the proposed AU to its license and included the preceptor letter as supporting documentation. The NRC approved the amendment and added the physician to the license as an AU. However, based on an OI investigation, the NRC determined that the preceptor letter was materially inaccurate. Specifically, the preceptor admitted to signing the letter without reading the details and acknowledged that the number of hours of supervised clinical work experience was inaccurate. As a result, the AU was subsequently removed from the license. The NRC issued separate

Severity Level III Notices of Violation to the licensee and proposed AU for having violated 10 CFR 30.9(a).

DISCUSSION

In the first and third cases described above, the licensees did not fulfill their responsibility to take reasonable steps to verify that the proposed AU or AMP had actually received the training and experience claimed before submitting their license amendment applications to the NRC. NRC regulations in 10 CFR 30.9(a) require, in part, that information provided to the Commission by a licensee or applicant for a license shall be complete and accurate in all material respects. It is the licensee's and applicant's responsibility to ensure the completeness and accuracy of all information it provides to the NRC. Licensees and applicants for a license should consider contacting preceptors as well as training program directors and continuing medical education providers to verify that the training and experience submitted by proposed individuals (i.e., AUs, AMPs, authorized nuclear pharmacists and radiation safety officers) is accurate and commensurate with the training and experience required by the applicable sections of 10 CFR Part 35.

Whether or not a licensee is aware of the incompleteness or inaccuracy of the information it submits to the NRC, a violation of 10 CFR 30.9, "Completeness and accuracy of information," occurs when inaccurate or incomplete information is submitted because licensees are responsible for the completeness and accuracy of the information they submit to the NRC. In addition, if the licensee willfully submits inaccurate or incomplete information to the NRC, or if inaccurate or incomplete information submitted to the NRC is determined to have been willfully supplied to the licensee by an employee, contractor, consultant, supplier, or subcontractor of the licensee, the licensee's violation of 10 CFR 30.9 may also be considered willful as the licensee is responsible for the conduct of its agents. Such violations will result in the consideration of escalated enforcement action against the licensee, including possible civil penalties. In addition, individuals who deliberately provide materially incomplete or inaccurate information to licensees or applicants for a license in connection with a submission to the NRC may be subject to NRC enforcement action under 10 CFR 30.10 and to criminal prosecution.

CONTACT

This IN requires no specific action or written response. If you have any questions about the information in this notice, please contact the technical contact below, or the appropriate regional office.

/RA/

Janet R. Schlueter, Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Technical Contact: Tara Weidner, RI
(610) 337-5272
E-mail: tlw@nrc.gov

Enclosure:
"Recently Issued FSME/NMSS Generic Communications"

Severity Level III Notices of Violation to the licensee and proposed AU for having violated 10 CFR 30.9(a).

DISCUSSION

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Technical Contact: Tara Weidner, RI
(610) 337-5272
E-mail: tlw@nrc.gov

Enclosure:
"Recently Issued FSME/NMSS Generic Communications"

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OFFICE	DNMS	DNMS	DNMS	RI/ORA	RI/OI	
NAME	TWeidner	PHenderson	BHolian	DHolody	EWilson	
DATE						
OFFICE	RI/RC	FSME/DMSSA	FSME/DMSSA	OE	OGC	FSME/DMSSA
NAME	KFarrar	CFlannery	SWastler	NHiltion for C.Carpenter-concurrence with	FCameron	JSchlueter
DATE		8/13/07	08/14/07	10/26/07	12/11/07	12/14/07

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Recently Issued FSME/NMSS Generic Communications

Date	GC No.	Subject	Addressees
02/02/07	IN-07-03	Reportable Medical Events Involving Patients Receiving Dosages of Sodium Iodide Iodine-131 Less Than the Prescribed Dosage Because of Capsules Remaining in Vials after Administration	All NRC medical use licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
02/28/07	IN-07-08	Potential Vulnerabilities of Time-Reliant Computer-Based Systems Due to Change in Daylight Saving Time Dates	All NRC licensees and all Agreement State Radiation Control Program Directors and State Liaison Officers.
03/13/07	IN-07-10	Yttrium-90 Theraspheres® and Sirspheres® Impurities	All NRC medical licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
04/04/07	IN-07-13	Use of As-Found Conditions To Evaluate Criticality-Related Process Upsets at Fuel Cycle Facilities	All licensees authorized to possess a critical mass of special nuclear material.
05/02/07	IN-07-16	Common Violations of the Increased Controls Requirements and Related Guidance Documents	All licensees who are implementing the NRC order imposing increased controls (EA-05-090), issued November 14, 2005, and December 22, 2005.
07/19/07	IN-07-25	Suggestions from the Advisory Committee on the Medical Use of Isotopes for Consideration To Improve Compliance with Sodium Iodide I-131 Written Directive Requirements in 10 CFR 35.40 and Supervision Requirements in 10 CFR 35.27	All NRC medical use licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
10/17/07	IN-07-35	Varian Medical Systems Varisource HDR Events: Iridium-192 Source Pulled From Shielded Position	All NRC medical use licensees and NRC master materials licensees authorized to possess or use a Varian Medical Systems VariSource High Dose Rate Remote Afterloader. All Agreement State Radiation Control Program Directors and State Liaison Officers
03/01/07	RIS-07-03	Ionizing Radiation Warning Symbol	All NRC licensees and certificate holders. All Radiation Control Program Directors and State Liaison Officers.
03/09/07	RIS-07-04	Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission	All holders of operating licenses for nuclear power reactors and holders of and applicants for certificates for reactor designs. All licensees, certificate holders, applicants, and other entities subject to regulation by the NRC for the use of source, byproduct, and special nuclear material.

Date	GC No.	Subject	Addressees
03/20/07	RIS-07-05	Status and Plans for Implementation of NRC Regulatory Authority for Certain Naturally Occurring and Accelerator-Produced Radioactive Material	All NRC materials licensees, Radiation Control Program Directors, State Liaison Officers, and NRC's Advisory Committee on the Medical Uses of Isotopes.
04/05/07	RIS-07-07	Clarification of Increased Controls for Licensees That Possess Collocated Radioactive Material During Transportation Activities	All NRC licensees issued the NRC's order imposing increased controls and all Radiation Control Program Directors and State Liaison Officers.
05/15/07	RIS-07-10	Subscriptions to New List Server for Automatic Notifications of Medical-Related Generic Communications, *Federal Register* Notices and Newsletters	All NRC medical-use licensees and NRC medical use licensees and NRC master materials licensees. All Radiation Control Program Directors and State Liaison Officers.
06/27/07	RIS-06-27, Suppl. 1	Availability of NRC 313A Series of Forms and Guidance for Their Completion	All NRC medical use licensees, commercial nuclear pharmacy licensees, and NRC master materials licensees. All Radiation Control Program Directors and State Liaison Officers.
08/31/07	RIS-07-13	Verification of the Authenticity of Materials Possession Licenses	All NRC materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
06/05/07	RIS-07-14	NRC Regulatory Issue Summary 2007-14 Fingerprinting Requirements for Licensees Implementing the Increased Control Order	All NRC licensees that have received the Increased Controls (IC) requirements. All Agreement State Radiation Control Program Directors and State Liaison Officers.
06/05/07	RIS-07-15	NRC Regulatory Issue Summary 2007-15 Unescorted Access to Materials for Non-Manufacturer and Distributor Service Providers	All NRC licensees that are non-manufacturer and distributor (non-M&D) service providers. All Agreement State Radiation Control Program Directors and State Liaison Officers.
10/04/07	RIS-07-22	Status Update for Implementation of NRC Regulatory Authority for Certain naturally-Occurring and Accelerator-Produced Radioactive Material	All NRC materials licensees, radiation control program directors, State liaison officers, and the NRC's Advisory Committee on the Medical Uses of Isotopes.
10/04/07	RIS-07-23	Date for Operation of National Source Tracking System	All licensees authorized to possess Category 1 or Category 2 quantities of radioactive materials. All Radiation Control Program Directors and State Liaison Officers.

Note: A full listing of generic communications may be viewed at the NRC public Web site at http://www.nrc.gov/reading-rm/doc-collections/gen-com.