UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

March 06, 2000

NRC INFORMATION NOTICE 2000-05: RECENT MEDICAL MISADMINISTRATIONS RESULTING FROM INATTENTION TO DETAIL

Addressees:

All medical licensees.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to remind addressees of the importance of following written directives and procedures, and the need to pay attention to detail, especially when verifying patient identity, programming treatment devices and preparing treatment doses. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

The NRC has become aware of a number of medical misadministrations over the past year, because of licensees not following written directives or procedures, and a lack of attention to detail. The following are brief summaries of misadministrations, caused by inattention to detail, that have occurred since January 1999:

1. A patient received an underdose to an intended site and a dose to an unintended site during a high dose rate afterloader (HDR) treatment. An error, made by a technologist when programming the parameters into the HDR, was not detected by the physicist required to verify the information keyed into the console. The technologist responsible for setting up the HDR was unfamiliar with the skip process and did not program the skip into the HDR, even though it was clearly marked on the written directive. The skip process, in this particular remote afterloader, involves the sending of the source to the end of the catheter as a starting point and then moving the source back to the designated first radiation point. Because the skip was not programmed, the source started the radiation treatment from the end of the catheter, resulting in a dose to an unintended site. Ineffective training and inattention to detail were considered the root causes of this misadministration.

2. A patient received a cobalt-60 teletherapy treatment instead of a linear accelerator treatment, after being misidentified by the technologist, when the patient mistakenly responded to the name announced by the technologist. The technologist had reviewed the written directive and the photograph of the individual to be treated as per procedures, but did not compare the photograph to the individual and did not ask for additional identification.

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3. A misadministration, resulting in an approximate 32 percent overdose, occurred when the treatment dosage, ordered before the preparation of a written directive, was greater than the dosage later prescribed in the written directive. The technologist administering the dosage failed to compare it to the correctly prescribed dosage in the written directive. The technologist also failed to obtain second party verification of the dosage, before treatment, as required by procedure.

4. A patient received an underdose to the intended site and a dose to an unintended site during an HDR treatment. After several unsuccessful attempts to electronically transfer a patient's treatment plan to the HDR treatment system, the licensee manually entered the treatment plan directly into the treatment system's control station. While manually entering changes to the source dwell times, an unintended change to the source step size occurred. The licensee did not notice this change and the patient was treated using the incorrect step size resulting in the misadministration. The licensee attributed this unintended and unnoticed change in step size to a software problem. However, had the licensee properly reviewed the complete final treatment plan, which clearly showed the changed step size, this misadministration could have been prevented.

5. A patient received an overdose while participating in a new protocol that recommended a lower dosage for a whole body scan using Iodine-131. The dosage administered to the patient was the licensee's standard dosage for a whole body scan and was not verified against the written directive, resulting in a dosage 25 percent greater than that prescribed in the written directive. The failure to check the written directive prior to treatment resulted in this misadministration.

6. A licensee reported a teletherapy misadministration when a technician left a 30-degree wedge out of the treatment site, which resulted in a weekly total dose 33 percent greater than that prescribed for the teletherapy series. The misadministration occurred during daily treatments for 5 consecutive days. The root cause of this misadministration was inattention to detail and failure to follow the licensee's written Quality Management Program procedures.

7. A medical misadministration was reported when a patient was administered a smaller dosage instead of the intended therapeutic dosage, resulting in a 33 percent underdose. The investigation determined that the dosage ordered from the radiopharmacy was less than the dosage prescribed in the written directive. The root causes of this incident were the failure to verify that the administered dosage was in accordance with the written directive and the failure to order the correct dosage from the radiopharmacy.

8. A patient received a 12.3 percent therapeutic underdose during a treatment involving gamma sterotactic radiosurgery. While inputting the treatment data into the planning computer, an incorrect date, "1/6/1998," was entered rather than the actual date, 1/6/1999, resulting in a difference in the decay calculation for the source. Contributing factors to the event included: 1) a failure to recognize a treatment planning computer warning that the entered treatment date differed from the system date; 2) a decision not to repeat the daily treatment planning computer test after the computer had gone down; and, 3) a failure to ensure that the treatment date was accurate before dose administration.

Discussion:

The guidance in 10 CFR 35.32(a)(1) requires that written directives be prepared before administration for brachytherapy, teletherapy, gamma sterotactic radiosurgery, quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, and any therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131. 10 CFR 35.32(a)(3)& (4) require that final treatment plans and related calculations and administration are in accordance with the respective written directives. It is important that written directives and procedures are kept up to date and provide adequate information. It is also important that management place a high premium on staff following all procedures and directives, that all staff are trained, and that training programs are effective in relaying necessary information. In all of the cases noted above, written directives and procedures were in place. However, failure to adhere to the procedures and directives, a lack of attention to detail, or a failure to perform adequate, independent verification of treatment plans, patient identities, and treatment doses contributed to all of these misadministrations.

Licensees should ensure that personnel are aware of and understand the requirements for written directives, procedures and policies; and that personnel review written directives (during pre-planning and prior to administration); confirm patient identity; review parameters entered for treatment planning computers; and verify patient doses. Additional time and effort spent in verifying calculations, patient identities, and treatment parameters, before a procedure or an administration, will help to ensure that the physician's written directive is carried out.

Related Generic Communications:

NRC IN 95-39: Brachytherapy Incidents Involving Treatment Planning Errors; and NRC IN 88-93: Teletherapy Events.

This IN requires no specific action nor written response. If you have any questions about the information in this notice, please contact the technical contacts listed below or the appropriate regional office.

/RA/
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Attachments:
1. List of Recently Issued NMSS Information Notices

2. List of Recently Issued NRC Information Notices

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All licensees should remind personnel that written directives, procedures and policies are required; and that personnel must review written directives (during pre-planning and prior to administration); confirm patient identity; review parameters entered for treatment planning computers; and verify patient doses. Extra time and effort spent in verifying calculations, identities, etc., before a procedure/administration can save a lot of time and effort in dealing with misadministrations; and more importantly, reduce the potential for patient injury.

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