

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

February 2, 1993

NRC INFORMATION NOTICE NO. 93-10: DOSE CALIBRATOR QUALITY CONTROL

Addressees

All Nuclear Regulatory Commission medical licensees.

Purpose

This notice is provided to alert recipients to problems concerning dose calibrator quality control tests, identified by NRC inspectors during inspections of medical programs, and also to emphasize the importance of quality control procedures for equipment used to assay patient doses. It is expected that licensees will: review this information for applicability to their programs; distribute this notice to those responsible for radiation safety and medical quality assurance, including technologists; and consider actions to preclude similar situations from occurring at their facilities. However, the suggestions contained in this notice do not constitute any new NRC requirements, and no written response is required.

Description of Circumstances

During recent NRC inspections of medical facilities, inspectors found deficiencies and irregularities in the performance and recording of dose calibrator quality control tests. The most frequently occurring deficiencies involve the constancy checks and linearity tests. However, there have also been citations for failure to perform accuracy tests and determine geometric independence. In some instances, the licensee did identify a malfunctioning dose calibrator, but no corrective action was taken even though the error or deviation exceeded allowable limits. Other problems included: failure to instruct supervised individuals in the proper use of the dose calibrator; failure to perform constancy checks when emergencies required the dose calibrator to be used during non-routine periods such as weekends and holidays; and failure to analyze the data, as required.

Discussion

Quality control checks of dose calibrators used to assay patient dosages are essential to ensure that the dosage administered to a patient is the same as the prescribed dosage. Medical personnel administering dosages should be aware of the applicable NRC regulations (10 CFR 35.50) and any specific related license conditions. Licensees are encouraged in Regulatory Guide 10.8, Rev. 2, to develop procedures that provide an even higher level of confidence that the correct dosage is administered. For example, Regulatory Guide 10.8, provides a model procedure for meeting the requirement. The guide proposes a smaller percent deviation as a trigger level, so the licensee can

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take action before the regulatory limit is reached. However, if it committed to the regulatory guide procedures as part of a license application, the licensee must comply with the more restrictive requirement. Licensees are responsible for the instruction and supervision of individuals to ensure that they know and follow the proper procedures for dose calibrator checks.

1. Constancy Checks

Constancy means reproducibility in measuring the activity of a known source over a long period of time. The dose calibrator is required (10 CFR 35.50(b)(1)) to be checked for constancy with a dedicated check source at the beginning of each day of use. This includes weekends and holidays, if radiopharmaceuticals are administered to a patient. During recent NRC inspections, inspectors determined that licensees had failed to perform these required checks because part-time technologists who worked only on weekends or staff technologists called in on weekends had not been properly instructed by the licensee and did not know that these checks were to be performed on weekends.

The reference source used for the constancy check must be assayed at a frequently used setting. Regulatory Guide 10.8 suggests using two or more sources with different photon energies and activities, although one source meets the requirement. The rule requires that the licensee determine the constancy of the dose calibrator under an actual condition of use. Since most medical licensees use technetium-99m for patient-dosage administrations more frequently than any other isotope, such licensees should check the technetium-99m setting, on each day of use, with a dedicated check source. It is recommended that dose calibrators having both pre-adjusted controls (i.e., push buttons) and variable potentiometers be tested on both the variable potentiometer technetium-99m (or other frequently used isotope) setting and the pre-adjusted control. Discrepancies or fluctuations between the two controls, when tested for constancy with the same check source, may be indicative of equipment malfunction. Licensees must plot or log (10 CFR 35.50(e)(1)) the measured activity of each source and compare it to the calculated activity, based on decay of the dedicated check source. If the error between the two values exceeds 10 percent, the dose calibrator must be repaired or replaced (10 CFR 35.50(d)).

2. Accuracy Test

The accuracy test ensures that the activity is within 10 percent of a given calibrated reference source whose activity has been determined by the manufacturer to be within 5 percent of the activity stated by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by NIST. At least two sealed sources with different principal photon energies, one of which has a principal energy between 100 keV and 500 keV, must be used to determine accuracy upon installation, and at least annually thereafter (10 CFR 35.50(b)(2)). The regulations require that the activity is at least 10 μCi for Ra-226 and 50 μCi for any other photon-emitting radionuclide. For best accuracy, the lower energy reference standards should be in vials of similar thickness to those for actual samples. As with the constancy check

and linearity tests, Regulatory Guide 10.8 suggests a trigger level of 5 percent difference but the requirement states that if the error exceeds 10 percent then the dose calibrator must be repaired or replaced.

3. Linearity Tests

The linearity test ensures that the dose calibrator can indicate the correct activity over the range of use between the highest dose that will be administered to a patient and 10 microcuries. The dose calibrator is to be tested for linearity upon installation and at least quarterly thereafter (10 CFR 35.50(b)(3)). Licensees have frequently not determined linearity over the entire range of use. Technetium-99m is most frequently used for the linearity test because of its availability and short half-life, and it is relatively inexpensive. If the percent deviation exceeds 10 percent, dosage readings must be mathematically corrected. Regulatory Guide 10.8 suggests a trigger level of ± 5 percent but unless the licensee commits to this level in the license application, the requirement allows for a 10 percent variation.

4. Geometry Dependence

Testing for geometry independence ensures that the indicated activity does not change with volume or configuration. This test must be performed, upon installation, over the range of volumes and volume configurations for which it will be used (10 CFR 35.50(b)(4)) and, as suggested in Regulatory Guide 10.8, should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. Geometry testing performed by the manufacturer may be acceptable, provided that the manufacturer has included all volumes and volume configurations for which the dose calibrator will be used at the licensee's facility and the licensee keeps a record of this test.

Licensees are also required (10 CFR 35.50(c)) to perform appropriate checks and tests following adjustment (e.g., a constancy check after battery replacement) or repair of the dose calibrator. Whereas it is not necessary to check geometry dependence if the dose calibrator is physically relocated within the department or following minor repairs to the instrument panel, it is appropriate to do the geometry check if repairs are done that might affect the response of the chamber. It is appropriate to conduct linearity and accuracy tests following any repairs to the dose calibrator.

It is the responsibility of the Radiation Safety Officer (RSO) and Radiation Safety Committee (RSC) to ensure that these checks are performed. Licensees are reminded that 10 CFR 35.21 requires that an RSO be responsible for implementing the radiation safety program and ensuring that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. In addition, 10 CFR 35.22 requires that an RSC perform periodic reviews, to oversee the use of byproduct material.

No written response is required by this information notice. If you have any questions about this matter, please contact the appropriate NRC regional office or this office.

John E. Green (for)

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material
Safety and Safeguards

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Attachments:

1. List of Recently Issued
NMSS Information Notices
2. List of Recently Issued
NRC Information Notices

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
93-07	Classification of Transportation Emergencies	02/01/93	All Licensees required to have an emergency plan.
93-05	Locking of Radiography Exposure Devices	01/14/93	All Nuclear Regulatory Commission industrial radiography licensees.
93-04	Investigation and Reporting of Misadministrations by the Radiation Safety Officer	01/07/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-03	Recent Revision to 10 CFR Part 20 and Change of Implementation Date to January 1, 1994	01/05/93	All byproduct, source, and special nuclear material licensees.
92-84	Release of Patients Treated with Temporary Implants	12/17/92	All Nuclear Regulatory Commission Medical Licensees.
92-72	Employee Training and Shipper Registration Requirements for Transporting Radioactive Materials	10/18/92	All U.S. Nuclear Regulatory Commission Licensees.
92-62	Emergency Response Information Requirements for Radioactive Material Shipments	08/24/92	All U.S. Nuclear Regulatory Commission Licensees.
92-58	Uranium Hexafluoride Cylinders - Deviations in Coupling Welds	08/12/92	All fuel cycle licensees.

LIST OF RECENTLY ISSUED
 NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
93-09	Failure of Undervoltage Trip Attachment on Westinghouse Model DB-50 Reactor Trip Breaker	02/02/93	All holders of OLs or CPs for nuclear power reactors.
93-08	Failure of Residual Heat Removal Pump Bearings due to High Thrust Loading	02/01/93	All holders of OLs or CPs for nuclear power reactors.
93-07	Classification of Transportation Emergencies	02/01/93	All Licensees required to have an emergency plan.
93-06	Potential Bypass Leakage Paths Around Filters Installed in Ventilation Systems	01/22/93	All holders of OLs or CPs for nuclear power reactors.
93-05	Locking of Radiography Exposure Devices	01/14/93	All Nuclear Regulatory Commission industrial radiography licensees.
93-04	Investigation and Reporting of Misadministrations by the Radiation Safety Officer	01/07/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-03	Recent Revision to 10 CFR Part 20 and Change of Implementation Date to January 1, 1994	01/05/93	All byproduct, source, and special nuclear material licensees.
93-02	Malfunction of A Pressurizer Code Safety Valve	01/04/93	All holders of OLs or CPs for nuclear power reactors.
93-01	Accuracy of Motor-Operated Valve Diagnostic Equipment Manufactures by Liberty Technologies	01/04/93	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
 CP = Construction Permit

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Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material
Safety and Safeguards

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- Attachments: *In Jacket*
1. List of Recently Issued
NMSS Information Notices
 2. List of Recently Issued
NRC Information Notices

DOCUMENT NAME: 93-10.IN
E. Kraus
TechEd
11/23/92
*See previous concurrence

WR-11C

OFC	:IMAB	:IMAB*	:IMAB*	:IMOB*	:OGC*	:DD/IMNS*	:D/IMNS*
NAME	:PHolahan:rj	:LWCamper	:JEGlenn	:FCombs	:STreby	:JTGreeves	:RECunningham
DATE	:01/21/93	:12/14/92	:12/17/92	:12/18/92	:01/15/93	:01/25/93	:01/25/93

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