

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

February 9, 1989

NRC INFORMATION NOTICE NO. 89-12: DOSE CALIBRATOR QUALITY CONTROL

Addressees:

All NRC medical licensees.

Purpose:

This notice is provided to alert recipients to a frequent problem 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 have found deficiencies and irregularities in the performance and recording of dose calibrator quality control tests. The most common deficiency is a failure to evaluate the recorded measurements against expected values, in order to validate proper dose calibrator operation within the tolerances specified in NRC regulations, licensee operating procedures, and license conditions. Technologists often base their dose calibrator acceptance criteria solely on the lack of any sudden or large changes in the recorded measurements, rather than using the approved, required NRC standards. NRC inspectors have documented several instances where measured readings have gradually deviated from expected values; yet, licensees have failed to detect, and therefore correct or repair, malfunctioning dose calibrators. In some instances, a dose calibrator was later determined to be functioning properly, but the test itself had been performed improperly. In all of these instances, prompt evaluation of recorded results would have assured proper performance of tests and validation of measured patient doses.

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Other types of problems related to the use of dose calibrators have also been identified. In some cases, licensees have identified a malfunctioning dose calibrator, but then failed to take action to correct the problem. In one particular instance, the licensee's consultant made initial arrangements for a replacement dose calibrator after a linearity test demonstrated non-linearity, but the licensee did not act on the consultant's recommendation and waited one month before retesting the dose calibrator. In other cases, technologists failed to perform constancy checks when emergencies required the dose calibrator to be used during periods such as weekends, when radiopharmaceuticals are not normally administered to patients.

Of serious concern to the NRC is the finding, during several inspections, that false information was recorded for dose calibrator tests. In one case, a consultant requested a technologist to repeat the linearity test. Instead of repeating the test, the technologist created a record using the results of a linearity test performed 30 months before the recorded date. In another case, an NRC inspection at a hospital revealed records indicating that a cobalt-57 check source (half life of 271 days) had not shown any decay in two months, resulting in a 15% discrepancy.

#### Discussion:

All medical licensees are reminded of the importance of making accurate quality control checks of dose calibrators used to assay patient dosages. NRC believes that the performance and evaluation of these dose calibrator checks are necessary to ensure that the dosage administered is the same as the dosage that was prescribed for the patient. These checks are essential steps for assuring safety and quality in the medical use of byproduct material. Therefore, licensees should assure that technologists or other individuals performing dose calibrator checks understand:

- a) the applicable NRC regulations and specific license conditions;
- b) the purpose, method, and importance of these tests; and
- c) when follow-up actions are necessary.

Licensees may wish to consider some type of audit or verification program to detect performance errors, including: failure to perform a test, inadequate evaluation of a test, or falsification of test records. Audits should include interviews with and observations of personnel performing their duties, as well as reviews of records to determine that the recorded results are correct. Licensees are reminded that they are held responsible for the acts of their employees and contractors. Willful failure to perform required dose calibrator tests and falsification of records have resulted in civil penalties and orders modifying licenses to prohibit the involvement of individuals responsible for licensed activities. Willful violations can also result in criminal prosecution against both the licensee and individual employees.

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.



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

Technical Contact: Sam Jones, NMSS  
(301) 492-0571

Attachments:

1. List of Recently Issued  
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LIST OF RECENTLY ISSUED  
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| Information Notice No. | Subject  | Date of Issuance | Issued to   |
|------------------------|--|------------------|---|
| 89-03                  | Potential Electrical Equipment Problems  | 01/11/89         | All Fuel Cycle and major nuclear materials licensees  |
| 89-02                  | Criminal prosecution of licensee's former president for intentional safety violations                                | 01/09/89         | All holders of NRC specific license   |
| 88-100                 | Memorandum of understanding between NRC and OSHA relating to NRC-licensed facilities (53 FR 43950, October 31, 1988) | 12/23/88         | All major nuclear materials licensees and utilities holding CPs and OLs.  |
| 88-93                  | Teletherapy Events   | 12/2/88          | All NRC medical licensees   |
| 88-90                  | Unauthorized removal of industrial nuclear gauges  | 11/22/88         | All NRC licensees authorized to possess, use, manufacture, or distribute industrial nuclear gauges  |
| 88-66                  | Industrial radiography inspection and enforcement  | 08/22/88         | All NRC industrial radiography licensees  |
| 88-62                  | Recent findings concerning implementation of quality assurance programs by suppliers of transport packages           | 08/12/88         | All holders of NRC quality assurance program approvals for radioactive material packages  |
| 88-33                  | Recent problems involving the model Spec 2-T radiographic exposure device  | 05/27/88         | All Agreement States and NRC licensees authorized to manufacture, distribute or operate radiographic exposure devices and source changers |

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| 89-11                  | Failure of DC Motor-Operated Valves to Develop Rated Torque Because of Improper Cable Sizing   | 2/2/89           | All holders of OLs or CPs for nuclear power reactors.              |
| 89-10                  | Undetected Installation Errors in Main Steam Line Pipe Tunnel Differential Temperature-Sensing Elements at Boiling Water Reactors.   | 1/27/89          | All holders of OLs or CPs for BWRs.                                |
| 89-09                  | Credit for Control Rods Without Scram Capability in the Calculation of the Shutdown Margin   | 1/26/89          | All holders of OLs or CPs for test and research reactors.          |
| 89-08                  | Pump Damage Caused by Low-Flow Operation   | 1/26/89          | All holders of OLs or CPs for nuclear power reactors.              |
| 89-07                  | Failures of Small-Diameter Tubing in Control Air, Fuel Oil, and Lube Oil Systems Which Render Emergency Diesel Generators Inoperable | 1/25/89          | All holders of OLs or CPs for nuclear power reactors.              |
| 89-06                  | Bent Anchor Bolts in Boiling Water Reactor Torus Supports  | 1/24/89          | All holders of OLs or CPs for BWRs with Mark I steel torus shells. |
| 89-05                  | Use of Deadly Force by Guards Protecting Nuclear Power Reactors Against Radiological Sabotage  | 1/19/89          | All holders of OLs for nuclear power reactors.                     |

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CP = Construction Permit

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