DEPARTMENT OF THE NAVY
NAVY ENVIRONMENTAL HEALTH CENTER
2510 WALMER AVENUE
NORFOLK, VIRGINIA 23513-2617

6470
Ser 31/ 4158
9 SEP '93

From: Commanding Officer, Navy Environmental Health Center

Subj: NAVY RADIOACTIVE MATERIAL PERMIT INFORMATION NOTICE 93-8

Encl: (1) Nuclear Regulatory Commission letter dated 4 August 1993 "Revision to the NRC Enforcement Policy Regarding the Quality Management Rule"

1. I am forwarding enclosure (1) for your information. The enclosure discusses revisions to the Nuclear Regulatory Commission (NRC) Enforcement Policy regarding the Quality Management Program and Misadministration (QM) rule.

2. The Enforcement Policy is contained in Title 10 Code of Federal Regulations Part 2 (10 CFR 2) and is used by this Command to help determine the safety and regulatory significance of violations of NRC regulations. You should note that the change in emphasis reflected in the Enforcement Policy is intended to focus attention on the need to evaluate compliance with QM program requirements and to take prompt, effective action when violations are discovered.

3. You are reminded that 10 CFR 35.25(a)(1) includes a requirement to provide instruction in the QM program to all personnel who work under the supervision of the authorized users.

4. I recommend that the enclosure be reviewed by your Radiation Safety Officer and Radiation Safety Committee.

5. For further information, please call LCDR G. I. Snyder, MSC, USN, Head, Radiation Health Department (NEHC-31), DSN 564-4657, (804) 444-4657, Ext. 413.

/s/ G. I. Snyder
G. I. SNYDER
By direction

Distribution:
NATNAVMEDCEN Bethesda MD
(Attn: LCDR G. Higgins, MSC, USN)
NAVHOSP Bremerton WA
(Attn: LCDR D. Dunn, MSC, USN)
NAVHOSP Camp Lejeune NC
(Attn: LCDR V. J. Catullo, MC, USN)
NAVHOSP Camp Pendleton CA
(Attn: LCDR L. Canavan, MC, USNR)
NAVHOSP Charleston SC
(Attn: LT E. Wittenbach, MSC, USNR)
NAVHOSP Great Lakes IL
(Attn: LCDR R. K. Fong, MSC, USN)

NAVHOSP Groton CT
(Attn: LCDR J. Pomerville, MSC, USN)
NAVHOSP Guam
(Attn: LT M. P. Buetow, MC, USNR)
NAVHOSP Jacksonville FL
(Attn: LT P. L. Liotta, MSC, USN)
NAVHOSP Long Beach CA
(Attn: LCDR B. K. Bertrand, MC, USNR)
NAVHOSP Millington TN
(Attn: LCDR D. R. Mitchell, MC, USNR)
NAVHOSP Newport RI
(Attn: CAPT G. Mathews, MC, USN)
NAVHOSP Oakland CA
(Attn: LCDR G. Gorsuch, MSC, USN)
NAVHOSP Okinawa JA
(Attn: LCDR W. Smith, MC, USN)
NAVHOSP Orlando FL
(Attn: LT J. W. Elliott, MSC, USN)
NAVHOSP Pensacola FL
(Attn: LT S. Riahi, MSC, USN)
NAVHOSP Portsmouth VA
(Attn: LCDR S. Kirtland, MSC, USN)
NAVHOSP San Diego CA
(Attn: LCDR D. Taylor, MSC, USN)
NAVENVIRHLTHCEN DET Bethesda MD
NAVUSEAMEDINSTITUTE Groton CT
(Attn: LT T. Naquin, MSC, USN)

Copy to:
CNO (N455)
BUMED (MED-211)
NAVSEADET RASO Yorktown VA
NSHS Bethesda MD
(Attn: Clinical Nuclear Medicine School)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

AUG 4 1993

TO: ALL NRC MEDICAL LICENSEES

SUBJECT: REVISIONS TO THE NRC ENFORCEMENT POLICY REGARDING THE QUALITY MANAGEMENT RULE

This letter is to inform all medical use licensees of recent revisions to the U.S. Nuclear Regulatory Commission "Enforcement Policy" regarding the "Quality Management Program and Misadministrations" (QM) rule.

On April 2, 1993, the enclosed change to the NRC "Enforcement Policy" (Title 10, Code of Federal Regulations, Part 2, Appendix C, Supplement VI) was published in the Federal Register (58 FR 17321). The change modified examples that help the NRC staff determine the safety and regulatory significance of various violations of the QM rule for medical licensees. Enforcement decisions will focus on violations that are indicative of a programmatic deficiency. The change also reflects the fact that violations that represent isolated mistakes, of limited consequence, that are not associated with a programmatic weakness of the licensee's quality management (QM) program[1], will be considered less significant than previously.

NRC believes that programmatic deficiencies are likely to have a broader impact on the licensee's program, in terms of the probability of a misadministration occurring, than would an isolated mistake, involving human error, made in the treatment of an individual patient. The revised examples in the NRC "Enforcement Policy" reflect this difference, by a reduced severity level being assigned to an isolated error, of limited consequence, that is associated with a violation of the QM Rule. Such violations may be associated with a reportable misadministration, but do not indicate any programmatic failure or weakness and, thus, may be classified as less significant under this change to the NRC Enforcement Policy.

Licensees should also note that the change in emphasis reflected by the NRC "Enforcement Policy" is intended to focus attention on the need for medical licensees to evaluate their compliance with QM program requirements and to take prompt, effective corrective action when violations are discovered. By

---

[1]The QM Program is described in Title 10, Code of Federal Regulations, Section 35.32, and requires, in part, that medical licensees establish and maintain a written QM program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The QM program must include written policies and procedures for administering quantities of sodium iodide I-125 or I-131 in excess of 1.11 megabecquerel (30 microcurie) for diagnostic or therapeutic procedures, or for administering any other radiopharmaceutical or radiation from byproduct material for therapeutic purposes.

auditing compliance and implementing corrective action, licensees may eliminate violations and programmatic deficiencies.

Finally, NRC has also been asked questions about QM training for personnel. 10 CFR 35.25(a)(1) includes a requirement to provide instruction in the QM program to technologists and other individuals (e.g., temporary, student, nurse) who work under the supervision of a physician named on the NRC license. NRC interprets this requirement to apply to those individuals whose duties involve activities covered by the QM rule. If the licensee determines that an individual such as a temporary, student, or weekend technologist **is not ever** involved in therapy procedures **and does not ever** prepare or administer quantities of I-131 or I-125 covered by the QM rule, instruction in the QM program is not required.

If you have any questions about the revised "Enforcement Policy" or the QM rule, you may contact the responsible individual, listed below, in the appropriate regional office:

Region I:	Judith A. Joustra	(215) 337-5257
Region II:	Earl G. Wright	(404) 331-5607
Region III:	Cassandra F. Frazier	(708) 790-5704
Region IV:	Charles L. Cain	(817) 860-8186
Region V:	Beth A. Prange	(510) 975-0250

Carl J. Paperiello

Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Changes to NRC "Enforcement Policy"

Rules and Regulations

Federal Register
Vol. 58, No. 62
Friday, April 2, 1993

NUCLEAR REGULATORY COMMISSION

10 CFR Part 2

RIN 3150-AE59

Policy and Procedure for NRC Enforcement Actions; Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement: Modification and request for comments.

SUMMARY: The NRC is modifying Supplement VI of its Enforcement Policy to revise certain of the examples of severity levels for violations associated with the quality management program required by 10 CFR 35.32. The examples of severity levels are used in the enforcement process to provide guidance in determining the safety and regulatory significance of a particular violation.

DATES: This revised policy statement is effective on April 2, 1993. Submit comments on or before May 3, 1993. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date. Comments may be considered in future revisions of the statement of policy.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, ATTN: Docketing and Service Branch. Deliver comments to One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m., Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street, NW., (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: James Lieberman, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, (301) 504-2741.

SUPPLEMENTARY INFORMATION: On July 25, 1991, the Commission published in the Federal Register (56 FR 34121) a final rule, effective January 27, 1992, requiring persons subject to the requirements of 10 CFR Part 35 to establish a quality management program and meet certain reporting requirements for misadministrations. As part of that Notice, the Commission modified its Enforcement Policy to provide examples in Supplement VI of severity levels for potential violations associated with the new requirements. The examples of severity level are used in the enforcement process to provide guidance in determining the safety and regulatory significance of a particular violation. The enforcement action taken is, in part, based upon the severity level decision. As a result of comments on the rulemaking, NRC has reconsidered the severity level examples for misadministrations.

The NRC is revising examples B.3, C.6, and D.4 of Supplement VI, which are the examples of violations of Severity Levels II, III, and IV, respectively. The basic purpose and thrust of the revisions is to provide greater emphasis, and attach greater importance, to violations which are indicative of or flow from deficiencies of a programmatic nature. Such deficiencies are preventable and are more likely to have a widespread or severe impact than are isolated mistakes involving human error made in the treatment of individual patients. The revisions also reflect a reduced Severity Level assignment for individual violations which represent isolated mistakes or errors of limited consequences that qualify as reportable misadministrations but are not indicative of or due to any programmatic failure or weakness.

The current examples for Severity Levels II and III, examples B.3 and C.6, reflect the assignment of Severity Level based on whether or not a misadministration occurred and the magnitude of overdose involved. Under the current examples, any failure to follow quality management program procedures resulting in an overdose of 50 percent or more is automatically a Severity Level II event; any misadministration not involving an overdose of 50 percent or more is automatically a Severity Level III event, regardless of whether there is an overexposure or underexposure.

Neither of these examples considers the causes of the misadministration. These examples do not provide for any assessment of the scope or magnitude of any programmatic deficiencies, nor do they depend, in any way, on whether or not the misadministration represented an isolated and inconsequential event resulting purely from human error. While the consequences of a misadministration are important, as reflected in example A.4 for Severity Level I which addresses misadministrations involving death or serious injury to a patient, it is appropriate in less consequential misadministrations to give consideration to the root cause in determining the severity level. This approach to enforcement is more likely to focus licensee attention on the need to address programmatic deficiencies with corrective action. Therefore, examples B.3 and C.6 are being revised to consider the degree of programmatic weakness in the causes of a misadministration.

Under revised example B.3, Severity Level II is assigned whenever a misadministration occurs as a result of a substantial failure to implement the quality management program required by 10 CFR 35.32, regardless of whether or not an overdose of 50 percent or more is involved. The assignment of Severity Level II is no longer dependent on the occurrence of an overdose of at least 50 percent.

Under revised example C.6, Severity Level III is assigned: (1) Whenever there is a substantial failure to implement the quality management program required by 10 CFR 35.32 even if there is no resulting misadministration; (2) if programmatic weakness in implementation of the quality management program results in a misadministration; or (3) if a misadministration is not reported.

Example D.3, the example for a Severity Level IV violation, is being revised to include instances where failure to follow the quality management program, including procedures, results in a reportable misadministration provided that such failures are isolated, have limited consequences, and do not demonstrate a

programmatic weakness in the implementation of the quality management program. A lower Severity Level may be assigned to those events where simple human error results in an isolated violation despite the development and implementation of a fully adequate quality management program as required by 10 CFR 35.32, including appropriate instruction, training, policies and procedures, written directives, and supervision. However, such violations involving misadministrations with potential for residual consequences will be considered for a Severity Level III categorization.

The Commission, nonetheless expects that all violations of NRC regulations and the licensee's quality management programs will be addressed with appropriate corrective actions so as to provide a high degree of confidence that byproduct material or radiation from byproduct material is administered to patients only as intended and directed by authorized user physicians. In this regard, the Commission emphasizes that all such violations are of concern, and that repetitive Severity Level IV violations may result in escalation of the sanctions applied, and could lead to the imposition of civil penalties or other sanctions, *e.g.*, suspension or revocation of a license, as the Commission may determine to be either necessary or appropriate to enforce compliance.

The determination of severity level based on the degree of programmatic weaknesses will be fact dependent. While generally a single failure that resulted in a misadministration would not be indicative of a programmatic weakness, depending on the circumstances, it may. For example, the failure to train one technician may indicate a programmatic weakness for a small program or where the technician not trained is the sole technician on a weekend shift.

List of Subjects in 10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Civil penalty, Enforcement, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Violations, and Waste treatment and disposal.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS AND ISSUANCE OF ORDERS

1. The authority citation for part 2 continues to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87–615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552.

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 114(f), Pub. L. 97–425, 96 Stat. 2213, as amended (42 U.S.C. 10134(f)); sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200–2.206 also issued under secs. 161b, i, o, 182, 186, 234, 68 Stat. 948–951, 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 88 Stat 1246 (42 U.S.C. 5846). Sections 2.600–2.606 also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770, 2.780 also issued under 5 U.S.C. 557. Section 2.764 and Table 1A of Appendix C also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85–256, 71 Stat. 579, as amended (42 U.S.C. 2039). Subpart K also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Subpart L also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Appendix A also issued under sec. 6, Pub. L. 91–560, 84 Stat. 1473 (42 U.S.C. 2135). Appendix B also issued under sec. 10, Pub. L. 99–240, 99 Stat. 1842 (42 U.S.C. 2021b et seq.).

2. Appendix C, Supplement VI is amended by revising examples B.3, C.6, and D.3 to read as follows:

Appendix C—General Statement of Policy and Procedure for NRC Enforcement Actions

* * * * *

Supplement VI—Fuel Cycle and Materials Operations

* * * * *

B. Severity Level II—Violations involving for example:

* * * * *

3. A substantial programmatic failure in the implementation of the quality management program required by 10 CFR 35.32 that results in a misadministration.

C. Severity Level III—Violations involving for example:

* * * * *

6. Substantial failure to implement the quality management program as required by § 35.32 that does not result in a misadministration; failure to report a misadministration; or programmatic weakness in the implementation of the quality management program that results in a misadministration.

* * * * *

D. Severity Level IV—Violations involving for example:

* * * * *

3. Failure to follow the quality management program, including procedures, whether or not a misadministration occurs, provided the failures are isolated, do not demonstrate a programmatic weakness in the implementation of the QM program, and have limited consequences if a misadministration is involved; failure to conduct the required program review; or failure to take corrective actions as required by § 35.32; or

* * * * *

Dated at Rockville, Maryland, this 26th day of March 1993.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 93–7522 Filed 4–1–93; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 92–ANM–23]

Amendment to Coppertown Control Zone; Coppertown, MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Coppertown Control Zone, Coppertown, Montana, from full-time to part-time. A reduction in personnel staffing of the Butte Flight Service Station has resulted in weather observations not being available 24 hours-a-day. This action will bring publications up-to-date giving continuous information to the aviation public.

EFFECTIVE DATE: 0901 utc May 27, 1993.