AC.69-2.
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MAY 20 1988

MEMORANDUM FOR: Victor Stello, Jr.
Executive Director
for Operations

FROM: Hugh L. Thompson, Jr., Director
Office of Nuclear Material Safety
and Safeguards

SUBJECT: DIAGNOSTIC MISADMINISTRATION REPORT FORM

This is to request your approval of a minor rulemaking to require that medical use licensees submit diagnostic misadministration reports on a special form.

When it approved the revision of 10 CFR Part 35, the Commission directed that the form be developed. The revised rule was published without the form number. The Office of Management and Budget has approved the form, and a NRC form number has been assigned and printed. This rulemaking will require that licensees use the form.

The Office of Administration and Resources Management concurs in this action and the Office of the General Counsel has no legal objection.

[Signed] Robert M. Bernero for
Hugh L. Thompson, Jr., Director
Office of Nuclear Material Safety
and Safeguards

Enclosure:
NRC Form 473

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

Diagnostic Misadministration Report Form

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations for the medical use of byproduct material to indicate the form to be used for reporting diagnostic misadministrations. This action is intended to inform the public of the development and availability of the form that medical licensees must use to meet this reporting requirement.

EFFECTIVE DATE: (upon publication in the FR)

ADDRESSES: A copy of Form NRC 473 may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, DC. Single copies are available from James H. Myers, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492-0635.

FOR FURTHER INFORMATION CONTACT: James H. Myers, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492-0635.

SUPPLEMENTARY INFORMATION:

The NRC amended its regulations for the medical use of byproduct material to require licensees to report certain diagnostic misadministrations to the NRC on a special NRC form. This matter was discussed in the final rule revising 10 CFR Part 35 (51 FR 36932, October 16, 1986).

The NRC staff has developed the form, and the Office of Management and Budget (OMB) has approved its use. The NRC is amending its regulations to insert the form number in the regulatory text. A copy of the form will be mailed to NRC medical use licensees.

This amendment is a minor administrative change to an existing final rule. It merely adds the form number for an NRC form to the codified rule. The number had been omitted because OMB had not completed its review. Based on this, good cause exists to find that the notice and public procedure provisions of the Administrative Procedure Act are unnecessary pursuant to the exemption provision found in 5 U.S.C. 553(b)(B). Therefore, the amendment is effective upon publication in the Federal Register.

Administrative Statements

Environmental Impact: Categorical Exclusion

The NRC has determined that this regulation is the type of action described in categorical exclusion 10 CFR 51.22(c)(3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget under OMB Number 3150-0140.

List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

Regulatory Text

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553 the NRC is adopting the following amendment to 10 CFR Part 35.

Part 35--Medical Use of Byproduct Material

1. The authority citation for Part 35 continues to read as follows:

AUTHORITY: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

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§ 35.33 [Amended]

2. In § 35.33, paragraph (c) is amended by removing footnote 1 and by inserting "Form NRC 473" in place of "Form NRC ___" in the second sentence.

Dated at Rockville, MD, this 27th day of May 1968.

For the Nuclear Regulatory Commission.

Victor Stello, Jr.
Executive Director for Operations

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Approved for Publication

The Commission has delegated to the EDO (10 CFR 1.40(c) and (d)) the authority to develop and promulgate rules as defined in the APA (5 U.S.C. 551(4)) subject to the limitations of NRC Manual Chapter 0103, Organization and Functions, Office of the Executive Director for Operations, paragraphs 0213, 038, 039, and 0310.

The enclosed final rule, entitled "Diagnostic Misadministration Report Form," would amend 10 CFR Part 35 to indicate the form to be used for reporting diagnostic misadministrations. This action is intended to inform the public of the development and availability of the form that medical licensees must use to meet this reporting requirement.

This final rule does not constitute a significant question of policy, nor does it amend regulations contained in 10 CFR Parts 7, 8 or 9 Subpart C concerning matters of policy. I therefore find that this rule is within the scope of my rulemaking authority and am proceeding to issue it.

MAY 27 1988
(date)

Victor Stello, Jr.
Executive Director
for Operations

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NRC FORM 473
(5-88)
10 CFR Parts 35 .33

U.S. NUCLEAR REGULATORY COMMISSION
Approved by OMB
3150-0140
Expires 5/31/91

DIAGNOSTIC MISADMINISTRATION REPORT

(N1) LICENSEE NAME

(N2) LICENSE NUMBER

(N3) CITY

(N4) STATE

(N5) EVENT DATE — MONTH DAY YEAR

(N6) REPORT DATE — MONTH DAY YEAR

(N7) TYPE OF MISADMINISTRATION
- (01) WRONG RADIOPHARMACEUTICAL
- (02) DOSAGE DIFFERING FROM PRESCRIBED BY 50%
- (03) WRONG PATIENT
- (04) WRONG ROUTE?

(N8) DID THE MISADMINISTRATION INVOLVE AN ISOTOPE OF IODINE
- (999) YES
- (111) NO

(N9) NUMBER OF PATIENTS WHO RECEIVED A MISADMINISTRATION UNDER THIS REPORT

(N10) INTENDED
- (05) NO CLINICAL PROCEDURE
- (06) NUCLEAR MEDICINE STUDY (Complete (N10A) INTENDED and (N11) GIVEN)
- (07) X-RAY STUDY
- (08) ULTRASOUND STUDY
- (09) CT STUDY
- (10) NMR STUDY
- (11) OTHER

(N10A) INTENDED				(N11) GIVEN			
MILLICURIES	ISOTOPE	CHEMICAL FORM	STUDY	MILLICURIES	ISOTOPE	CHEMICAL FORM	STUDY

(N12) PRECIPITATOR
- (71) REFERRING PHYSICIAN
- (72) WARD NURSE
- (73) WARD CLERK
- (74) NUCLEAR PHARMACY
  - NAME OF NUCLEAR PHARMACY | CITY | STATE
- (75) AUTHORIZED USER
- (76) HOT LAB TECHNOLOGIST
- (77) IMAGING TECHNOLOGIST
- (78) CLINIC RECEPTIONIST
- (79) SCHEDULING TECHNOLOGIST
- (80) PATIENT
- (81) OTHER

(N13) ERROR

HOT LAB
- (11) MISLABELED A SYRINGE
- (12) MISLABELED A VIAL OR VIAL SHIELD
- (13) RECONSTITUTED WRONG REAGENT KIT
- (14) PLACED RECONSTITUTED VIAL IN WRONG SHIELD
- (15) SELECTED WRONG VIAL WHEN DRAWING DOSAGE
- (16) SET DOSE CALIBRATOR IMPROPERLY
- (17) MISREAD DOSE CALIBRATOR
- (18) MISUNDERSTOOD RADIOPHARMACEUTICAL OR DOSAGE ORDER

REFERRAL
- (20) MISUNDERSTOOD REFERRING PHYSICIAN'S REQUEST
- (21) REQUESTED WRONG STUDY
- (22) REQUESTED STUDY FOR WRONG PATIENT

ADMINISTRATION
- (30) SELECTED WRONG PATIENT
- (31) ANSWERED WAITING ROOM PAGE INTENDED FOR OTHER PATIENT
- (32) BROUGHT WRONG PATIENT TO CLINIC
- (33) SELECTED WRONG SYRINGE FROM DOSAGE CART

OTHER
- (40) Specify

(N14) CONTRIBUTING FACTORS
- (80) STUDENT TECHNOLOGIST
- (81) NEW EMPLOYEE
- (82) FOREIGN LANGUAGE
- (83) PATIENT INCOHERENT OR UNCONSCIOUS
- (84) ID BRACELET NOT CHECKED
- (85) REQUISITION NOT CHECKED
- (86) PATIENT CHART NOT CHECKED
- (87) NEW PROCEDURE
- (88) HEAVY WORKLOAD
- (89) OTHER

(N15) ACTION TAKEN TO PREVENT RECURRENCE
- IMPLEMENT NEW PROCEDURES FOR
  - (C1) VERIFICATION OF REQUEST
  - (C2) RADIOPHARMACEUTICAL LABELING AND HANDLING
  - (C3) VERIFICATION OF PATIENT IDENTIFICATION
  - (C4) REINSTRUCT PERSONNEL
  - (C5) REPRIMAND PERSONNEL
- (C6) IMPROVE SUPERVISION OF PERSONNEL
- (C7) NO ACTION
- (C8) OTHER

(N16) EFFECT ON PATIENTS
- NONE APPARENT
- SEE ABSTRACT

(N17) ABSTRACT *(If more space is required, attach additional sheets.)*

RADIATION OFFICER (Printed Name) | SIGNATURE | TELEPHONE | DATE

NUCLEAR REGULATORY COMMISSION USE

(N18)	(N19) AS	(N20) REGIONAL LOG NUMBER	(N21) ACCESSION NUMBER	(N22) INITIALS
(999) YES (111) NO				

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NOTES ON MISADMINISTRATION REPORT FORM:

5APR88 CONTACTED SAM PETTYJOHN (AEOD) ABOUT "AUTHORIZED USER" BLOCK 75 AND AUTHENTICATION STATEMENT IN ABSTRACT SECTION. AEOD HAS NO PROBLEM WITH ADDITION OF THE INFORMATION.

CONTACTED B. MARTIN (ARM) TO SEE IF PROPOSED ADDITIONS ARE OK. THEY ARE CHECKING TO SEE IF THE ADDITIONS ARE OK AND ON THE OMB CLEARANCE REINSTATEMENT. FORM IS UP FOR RENEWAL, PACKAGE HAS BEEN SENT TO OCONNELL (NMSS). SHOULD NOT BE A PROBLEM IN GETTING SMALL ITEMS ADDED TO THE FORM. MARK-UP FORM BEING SENT TO ARM.

RON SMITH (OGC) HAS NO OBJECTIONS TO ADDITIONS.

BOB OCONNELL (NMSS) WILL PROCESS FORM FOR NEW CLEARANCE. GIVEN COPY OF DRAFT FORM FOR HIS USE.

COPY OF DRAFT FORM SENT TO B. REIDLINGER, RV, FOR REVIEW.

14APR88 CALLED HERB PARKOVER (ARM) TO CHECK ON FORM. ARM HAS AGREED TO PRINT A MINIMUM NUMBER UNTIL CLEARANCE IS GRANTED. THIS IS TO GET FORM OUT ASAP TO LICENSEES AND AVOID A 3 MONTH DELAY.

5MAY88 CALLED ARM, FORM SENT TO PRINTER ON 19APR88. AWAITING PRINTING

9MAY88 COPY OF AMENDED FORM GIVEN TO R. E. CUNNINGHAM (NMSS) FOR REVIEW AND APPROVAL.

10MAY88 APPROVAL FOR AMENDED FORM RECEIVED FROM R. E. CUNNINGHAM (NMSS)

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NOTES ON MISADMINISTRATION FORM: 6APR88

THE FOLLOWING INFORMATION AND COMMENT WAS RECEIVED FROM B. REIDLINGER, RV, FOLLOWING DISCUSSION OF THE NEW FORM DURING A REGIONAL CONFERENCE CALL.

1. THE FORM DOES NOT INDICATE WHEN IT IS TO BE USED ON THE FORM, IE., 5X PRESCRIBED DOSE, ORGAN DOSE OF 2 REM OR GREATER, OR WHOLE BODY DOSE OF 500mREM OR GREATER.

THE ABOVE INFORMATION IS INCLUDED IN 10CFR35.

2. THE PRECIPITATOR SECTION ONLY ALLOWS ONE PERSON TO BE IDENTIFIED. WHAT IF THERE ARE MORE? NEED TO EMPHASIZE THAT NO NAMES ARE REQUIRED.

IT IS THE INTENT OF THE FORM TO IDENTIFY THE MOST LIKELY, SINGLE PRECIPITATOR OF THE EVENT. ADDITIONAL INFORMATION MAY BE SUPPLIED IN THE "ABSTRACT" SECTION OF THE FORM.

3. IN THE ABSTRACT SECTION, THERE IS NO CAUTION STATEMENT ABOUT NOT IDENTIFYING PATIENTS BY NAME.

10CFR35 IDENTIFIES THIS REQUIREMENT. IF ACCIDENTALLY INCLUDED IN THE REPORT THEY MY EASILY CENSORED FROM THE ABSTRACT.

NO COMMENTS FROM THE OTHER REGIONS WERE RECEIVED ON THE FORM.

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SUMMARY OF COMMENTS ON NRC MISADMINISTRATION FORM:

1. QUESTIONS ABOUT FORM: (R. E. CUNNINGHAM, DIRECTOR, NMSS/IMNS)

A. HAVE KATHY BLACK (AEOD) AND REGIONS REVIEWED FORM?

YES, FORM DEVELOPED BY N. L. MCELROY AND AEOD. DRAFT FORMS IN THE DRAFT REGULATORY GUIDE WERE CIRCULATED TO THE REGIONS FOR COMMENT.

B. WHY ISN'T THERE A SIGNATURE BLOCK WITH A COMMITMENT THAT THE INFORMATION IS ACCURATE?

OGC DID NOT FEEL IT WAS NECESSARY AND OTHER INITIAL REPORTS DO NOT HAVE THEM AS A RULE. FORM IS ESSENTIALLY AN ADVANCE REPORT AND CAN BE FOLLOWED UP BY THE REGIONS IF NECESSARY.

C. WHY ISN'T THE ATTENDING PHYSICIAN LISTED AS A POTENTIAL "PRECIPITATOR"?

THE PHRASE "REFERRING PHYSICIAN" AND "ATTENDING PHYSICIAN" ARE SYNONYMOUS

D. MANY BLOCKS ARE TOO SMALL TO WRITE IN THE INFORMATION.

THIS FORM IS INTENDED TO REPORT AND CATEGORIZE MISADMINISTRATION REPORT INFORMATION IN A CONCISE AND CONSISTENT MANNER. PREVIOUS REPORTS FROM LICENSERS DID NOT PROVIDE ENOUGH INFORMATION OR THE INFORMATION PRESENTED WAS CONFUSING. INFORMATION TO BE COLLECTED ON THIS FORM HAS BEEN DERIVED FROM A RETROSPECTIVE ANALYSIS OF PREVIOUS MISADMINISTRATION REPORTS AND INFORMATION REQUIRED BY 10CFR35. ADDITIONAL INFORMATION MAY BE PROVIDED IN ITEM N 17, ABSTRACT, ON THE FORM.

E. THIS IS ORIENTED TOWARD DIAGNOSIS....IS IT TO BE USED FOR THERAPY?

NO. THERAPY MISADMINISTRATIONS ARE TOO FEW IN NUMBER AND TOO COMPLEX TO REPORT USING A CHECK OFF FORMAT.

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NOTE TO FILE: 29MAR88

SUBJECT: DIAGNOSTIC MISADMINISTRATION REPORT FORM, OGC COMMENTS DTD 11FEB88, MEETING WITH RON SMITH, OGC, ON 29MAR88

1. DELETED ONE PARAGRAPH AND SUBSTITUTED RECOMMENDED PARAGRAPH.

2. CHANGE ADOPTED.

3. ITEMS LISTED DO NOT APPLY TO THIS RULE, PER M. LESAR, (ARM), REVIEW NOTES AND RECHECK WITH ARM ON 29MAR88.

4. ITEM CHANGED.

5. ITEM CHANGED PER SUGGESTION.

6. NOT CHANGED PER SUGGESTION, WILL USE SHORT FORM.

MYERS (IMAB)