(4)

September 30, 1997

QUALITY MANAGEMENT PROGRAM

NOTE

Following Commission approval of the staff's program to revise 10 CFR Part 35 and associated guidance documents, the NRC staff initiated development of draft rule language, using a modality-based approach. As directed by the Commission, the staff has developed alternatives, with draft rule text, for the more significant issues associated with the regulation of the medical use of byproduct material. These alternatives to regulation in specific areas are intended to help focus the discussion during the NRC's public meetings and the meetings with medical professional societies during the Fall of 1997 and to assist the staff in developing the proposed rule language. The alternatives represent a broad range of possibilities and are being provided to stimulate input from members of the public in an effort to encourage all interested parties to provide input into the development of the revised regulation. The NRC staff has not selected any alternative at this time, and is open to additional alternatives which might be proposed that are consistent with the guidance provided by the Commission.

9/29/97

PART 35 - QUALITY MANAGEMENT PROGRAM

Summary of Alternatives

1. Maintain current requirements in §35.32.

2. Only require a written quality management program.

3. Require written quality management program, retain each written directive and a record of each dosage requiring a written directive, and perform audits.

4. Require written quality management program, retain each written directive and a record of each dosage requiring a written directive, and maintain a record of recordable events.

NOTE: Section 6 of the SRM dated, March 20, 1997, states:

> [Staff should consider...]
> The Quality Management Program provisions (10 CFR Part 35.32) should be re-evaluated and revised to focus on those requirements that are essential for patient safety, e.g. confirming patient identity, requiring written prescriptions and verifying dose. To the maximum extent possible, the requirements should be revised to be risk informed. Given this objective, a mixed approach of performance-based rules and otherwise prescriptive regulations should be pursued.
>
> Section 4 of the SRM dated, March 20, 1997, states:
>
> [Staff should consider...]
> Changing the nomenclature from "misadministration" to "medical event" or comparable terminology.

ALTERNATIVE 1

Maintain current requirements in §35.32.

Pros

1. No additional regulatory burden to licensees.

2. No additional NRC resources would be needed for modifications to licensing or inspection procedures.

3. §35.32(a) would continue to require licensee to establish and maintain a written quality management program (QMP) to provide confidence that byproduct material or radiation therefrom will be administered as directed by the authorized user.

4. §35.32(b) would continue to require that licensees audit their QMP's to determine the effectiveness of their program and retain records of the audit.

5. §35.32(c) would continue the concept of "recordable event" to be used to identify precursor events.

6. §35.32(d) would continue to require licensees to retain each written directive and record each administered dose or dosage requiring a written directive.

Cons

1. Does not reduce regulatory burden to licensees.

2. Does not make the regulation more performance-based.

3. §35.32(e) would continue to require licensees to submit modifications of their QMP's to NRC, which continues regulatory burden.

4. §35.32(f) would continue to require licensees to submit their QMP's to the NRC, which continues regulatory burden.

5. Rule is inconsistent with Commission direction (SRM on DSI 7) to focus on those requirements that are essential for patient safety e.g., confirming patient identity, requiring written prescriptions, and verifying dose.

Current Rule Text

Section 35.32 Quality management program.

(a) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

(1) That, prior to administration, a written directive [1] is prepared for:

(I) Any teletherapy radiation dose;

(ii) Any gamma stereotactic radiosurgery radiation dose;

(iii) Any brachytherapy radiation dose;

(iv) Any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; or

(v) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(2) That, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(b) The licensee shall:

(1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

(I) A representative sample of patient and human research subject administrations,

(ii) All recordable events, and

(iii) All misadministrations

to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of paragraph (a) of this section; and

(3) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

(c) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(1) Assembling the relevant facts including the cause;

(2) Identifying what, if any, corrective action is required to prevent recurrence; and

(3) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

(d) The licensee shall retain:

(1) Each written directive; and

(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in paragraph (a)(1) above, in an auditable form, for three years after the date of administration.

(e) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the appropriate NRC Regional Office within 30 days after the modification has been made.

(f)(1) Each applicant for a new license, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 a quality management program as part of the application for a license and implement the program upon issuance of the license by the NRC.

(2) Each existing licensee, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 by January 27, 1992 a written certification that the quality management program has been implemented along with a copy of the program.

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[1] If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

[56 FR 34121, July 25, 1991, as amended at 59 FR 61783, Dec. 2, 1994]

ALTERNATIVE 2

Only require a written quality management program.

Pros

1. Reduces regulatory burden to licensees (no audits or records).

2. Makes the regulation performance-based.

3. §35.32(a) would continue to require licensee to establish and maintain a written quality management program (QMP) to provide confidence that byproduct material or radiation therefrom will be administered as directed by the authorized user.

4. §35.32(e) would be deleted, discontinuing the requirement for licensees to submit modifications of their QMPs to the NRC which would decrease regulatory burden.

5. §35.32(f) would be deleted, discontinuing of the requirement for licensees to submit their QMPs to the NRC which would decrease regulatory burden.

6. Dose based rule.

7. *Requirements in draft rule language is consistent with Commission direction (SRM on* DSI 7) to focus on those requirements that are essential for patient safety, e.g., confirming patient identity, requiring written prescriptions, and verifying dose

Cons

1. Additional NRC resources would be needed for modifications to licensing or inspection procedures.

2. May increase on-site inspection time (no audits or records of recordable events are available for inspector review).

3. No requirement (§35.32(b)) for licensees to audit their QMPs to determine the effectiveness of their program and retain records of the audit.

4. §35.32(c) would be deleted, discontinuing of the concept of "recordable event" which is used to identify precursor events.

5. No requirement (§35.32(d)) for licensees to retain each written directive and record each administered dose or dosage requiring a written directive, thus these records would not be available for inspection.

6. Guidance would need to be developed to assist licensees in determining when a QMP/written directive is necessary

Draft Rule Text

Section 35.32 Quality management program.

(a) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

(1) That, prior to administration, a written directive [1] is prepared when the dose to any organ or tissue exceeds 50 rem:

(2) That, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(3) That each administration is in accordance with the written directive; and

(4) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

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[1] If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

ALTERNATIVE 3

Require written quality management program, retain each written directive and a record of each dosage requiring a written directive, and perform audits.

Pros

1. Reduces regulatory burden to licensees.

2. Makes the regulation more performance-based.

3. §35.32(a) would continue to require licensee to establish and maintain a written quality management program (QMP) to provide confidence that byproduct material or radiation therefrom will be administered as directed by the authorized user.

4. Retain a requirement (§35.32(b)) for licensees to audit their QMP to determine the effectiveness of their program and retain records of the audit.

5. Retains requirements (§35.32(d)) for licensees to retain each written directive and record of each administered dose or dosage requiring a written directive.

6. §35.32(e) would be deleted, discontinuing the requirement for licensees to submit modifications of their QMP to the NRC.

7. §35.32(f) would be deleted, discontinuing of the requirement for licensees to submit their QMP's to the NRC.

8. Requirements in draft rule language is consistent with Commission direction (SRM on DSI 7) to focus on those requirements that are essential for patient safety, e.g., confirming patient identity, requiring written prescriptions, and verifying dose, with the exception of the requirement for an audit.

Cons

1. Additional NRC resources would be needed for modifications to licensing and inspection procedures.

2. §35.32(c) would be deleted, discontinuing of the concept of "recordable event" to be used to identify precursor event.

3. Guidance would need to be developed to assist licensees in determining when a QMP/written directive is necessary

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(3) That each administration is in accordance with the written directive; and

(4) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(b) The licensee shall:

(1) Develop procedures for and conduct a review of the quality management program at intervals no greater than 12 months.;

and

(2) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

(c) The licensee shall retain:

(1) Each written directive; and

(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in paragraph (a)(1) above, in an auditable form, for three years after the date of administration.

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[1] If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

ALTERNATIVE 4

Require written quality management program, retain each written directive and a record of each dosage requiring a written directive, and maintain a record of recordable events.

Pros

1. Reduces regulatory burden to licensees (no required audits).

2. Makes the regulation more performance-based.

3. §35.32(a) would continue to require licensee to establish and maintain a written quality management program (QMP) to provide confidence that byproduct material or radiation therefrom will be administered as directed by the authorized user.

4. §35.32(c) would continue the concept of "recordable event" to be used to identify precursor events.

5. Retains requirements (§35.32(d)) for licensees to retain each written directive and records of each administered dose or dosage requiring a written directive.

6. §35.32(e) would be deleted, discontinuing the requirement for licensees to submit modifications of their QMP to the NRC.

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8. Requirements in draft rule language is consistent with Commission direction (SRM on DSI 7) to focus on those requirements that are essential for patient safety, e.g., confirming patient identity, requiring written prescriptions, and verifying dose.

Cons

1. Additional NRC resources would be needed for modifications to licensing and inspection procedures.

2. May increase on-site inspection time.

3. §35.32(b) would be deleted, thus there would be no requirements for licensees to audit their QMP to determine the effectiveness of their program and retain records of the audit.

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(1) Assembling the relevant facts including the cause;

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QUALITY MANAGEMENT OVERVIEWS

	ALTERNATIVES			
KEY ITEMS FOR CONSIDERATION	1	2	3	4
Licensee establish and maintain QMP [objectives identified in regulation]	X	X	X	X
Licensee required to perform audits and record results	X		X	
Licensee required to retain written directives and records of administered doses	X		X	X
Licensee required to submit QMP modifications to NRC	X			
Licensee required to maintain recordable events	X			X