(20)

State of Alabama
Department of Public Health

State Office Building
Montgomery, Alabama

Claude Earl Fox, M.D., M.P.H.
State Health Officer

P. O. Box 303017
Montgomery, Alabama 36130-1701

March 20, 1990

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D. C. 20555

ATTN: Docketing and Service Branch

Dear Sirs:

The attached comments pertain to NRC's proposed rule on basic quality assurance in nuclear medicine as they appeared in Federal Register, Vol. 55, No. 10, Tuesday, January 16, 1990, page 1439.

My comments are offered in a spirit of cooperation and support. These comments are my personal concerns and do not necessarily reflect the views of my employer.

I currently serve as Chairman of the Conference of Radiation Control Program Director's Committee on Nuclear Medicine. Several comments have been given to me, the ones in writing are also attached with this letter and represent each writer's viewpoint.

Thank you for the opportunity to comment.

Sincerely,

Kirksey E. Whatley

Kirksey E. Whatley, Director
Radioactive Material Licensing
Division of Radiation Control
Bureau of Environmental & Health
Service Standards

KEW:psc

Attachment

DS 10

Comments on Proposed Rule Change
Basic QA Program - Medical Use
By Kirksey E. Whatley

1. 35.35(a) Support requirement for licensees to establish a written basic quality assurance program to detect, prevent, and correct the cause of errors in medical use.

2. 35.35(a)(2) Prescriptions should be made for any therapy procedure and any diagnostic procedure.

3. 35.35(a)(3) A diagnostic referral can be made by any physician, including those who have no training in nuclear medicine. The selection of patients to receive radioactive material should be done by a physician having the training required for physicians to practice nuclear medicine. Recommend dropping the concept of "diagnostic referral".

4. 35.35(a)(3) Assume a patient arrives at a nuclear medicine clinic under referral of a "diagnostic referral physician" who has no training in nuclear medicine. The technician takes the diagnostic referral and administers the radiopharmaceutical. The nuclear physician (authorized user) is yet to be involved. If for diagnostic studies, the authorized user's responsibility is solely to interpret studies, it appears that much of the current training requirements for physicians is unnecessary.

5. 35.2 Definitions. "Diagnostic Referral". Recommend concept be dropped as it legitimatizes the practice of nuclear medicine (selection of patients) by physicians who have no training in nuclear medicine. If the purpose of misadministration rules are to prevent errors in medical use, it would appear that the first place to start is to assure that the physician selecting patients has minimal knowledge in nuclear medicine. The technician, who who may have no formal training, should not be the one judging whether or not to administer a radiopharmaceutical to a patient.

6. 35.2 Definitions. "Prescription," Supervision should be defined as it applies to a physician receiving training "under the supervision of an authorized user". The physician under the supervision of an authorized user should not be allowed to (1) select patients, (2) prescribe isotope and dose to be administered nor (3) interpret results. The "supervised" physician may have no training in nuclear medicine, yet he/she can "prescribe" diagnostic and therapy doses without approval of the authorized user. Such a concept does not appear consistent with the intent of the misadministration rule. The physician in training should obtain prior aproval from an authorized user before administering radiopharmaceuticals. Training should be "pre-dose" not "post-dose".

7. Other comments were offered in a meeting with John Telford on March 14, 1990, including these discussed in this letter.

For illustration purposes, please refer to page 4 of NUREG-0090, Vol. 12, No. 3, July-September, 1989, Report No. 89-9, Medical Diagnostic Misadministration.

In this case the referring physician phoned an order to a scheduling secretary who wrote down the wrong order. The technologist then took the order and administered a therapeutic dose of I-131 instead of a diagnostic dose of I-123. The authorized user was not involved prior to such administration apparently.

The "diagnostic referral" concept by-passes the only individual who has received training in the medical use of radiopharmaceuticals. If the proposed rules are an attempt to "detect and prevent" errors in nuclear medicine it does not seem logical to consider by-passing the one individual who should, by virtue of training and experience, be able to "detect and prevent" the error-namely the authorized user. This applies to both therapeutic and diagnostic uses.

The above concerns are reflected by NRC on page 1440 of Federal Register, Vol, 55, No. 10, Tuesday, January 16, 1990, center column, last paragraph as follows:

> "Many of the misadministrations demonstrated that the authorized user failed to review the medical history of the referred patient to determine the suitability of a particular clinical procedure. In many misadministrations, the referring physician, who is not a nuclear medicine expert, and the nuclear medicine technologist, who is not a medical expert, determine which radiopharmaceutical should be administered."

The diagnostic referral concept only legitimatizes by-passing the only person who is a medical expert, and it does nothing to prevent the cause of many misadministrations as stated above.

STATE OF FLORIDA
DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES

March 12, 1990

TO: Kirksey Whatley, Director, RAM Licensing
Division of Radiation Control
Alabama Department of Public Health

FROM: Ray Dielman, PHP. Supervisor
Western Regional Field Office
Florida Department of HRS
Office of Radiation Control

SUBJECT: Part "G" Committee Proposed 10CFR35 Changes "REVISED"

I endorse, in principle, the subject proposed rule requiring medical use licensees to establish and implement a basic quality assurance program as it would enhance patient safety and efficacy; offer the following recommendation and commentary:

Proposed 35.2 Definitions

Delete "Diagnostic Referral"

This provides a vehicle for referring physicians to order procedures without benefit of authorized user training and clinical experience.

Delete Prescribed Dose "(b)"

(b) - Dependent upon "Diagnostic Referral".

Proposed 35.33(2); (3)(b)(1); (3)(e)(1)

Delete....."Diagnostic Referral"

Comment: All nuclear medicine procedures are currently done by Diagnostic Referral, i.e. requested or ordered by the patients physician.

The problem is that the authorized user is not evaluating the patient and prescribing the dose in diagnostic use. All drugs require a prescription. Why the exception for radiopharmaceuticals? There is no hardship to hospitals or physicians by requiring prescription, although the Radiologist practicing nuclear medicine may see it as such due to the economic impact.

Proposed 35.35 (2)(3)

Delete...involving more than 30 microcuries of 125 I and 131 I.

Kirksey Whatley
Part "C" Committee
Continued/March 12, 1990

35.35 (4)(5)(6)(7)

Delete...."Diagnostic Referral"

Comment: The rule should apply to all radiopharmaceutical administrations not just "more than 30 microcuries of 125 I and 131 I". 99m Tc radiopharmaceuticals provide approximately the dose as iodine radionuclides.

Commentary:

In my experience, there are two models of nuclear medicine practice - the "Radiology Model" and the "Nuclear Medicine Model". In the "Radiology Model" (80% of nuclear medicine practice) the referring physician orders a procedure and it is implemented by a technologist. The authorized user does not see the patient, review the medical history to determine suitability of the procedure or prescribe the dose, but most often interperts the result. In the "Nuclear Medicine Model" (10% of nuclear medicine practice) the referring physician refers the patient to the authorized user who evaluates the patient, prescribes the dose and interperts the result.

All rules, regulations and policies since 1954 have been predicated on the assumption that nuclear medicine is practiced using the "Nuclear Medicine Model", i.e. adequately informed physicians (authorized users) making decisions on "their" patients interests.

Cognizant that existing rules, regulations and policies require the prospective authorized user to acquire RAM training and clinical experience - examination of patients to determine the suitability for a procedure, it seems a natural extention to require the application of this training and experience in practice.

STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY
GEORGE DEUKMEJIAN, Governor

DEPARTMENT OF HEALTH SERVICES
714/744 P STREET
P.O. BOX 942732
SACRAMENTO, CA 94234-7320

(916) 323-2754

February [illegible] 1990

Kirksey E. Whatley
Conference of Radiation Control Program Directors, Inc.
Part G Committee Chairman
C/O State of Alabama
Department of Public Health
434 Monroe Street
Montgomery, Alabama 36104

Dear Mr. Whatley:

I have reviewed in detail the proposed changes to 10CFR35. Although I agree with the concept of requiring a "Basic Quality Assurance Program", I disagree with the NRC's reasoning. The belief that the "establishment" of a Quality Assurance Program will reduce the number of misadministrations, whether therapeutic or diagnostic, is absurd. In California, all of our medical licensee's have Quality Assurance Programs, but unfortunately, we still have misadministrations. My analysis of the misadministrations which have occurred in California, as well as those detailed in the Federal Register, Volume 55, Number 10, Table 1, indicates that the causes were due to human error not a system problem.

I believe that the implementation of 35.35 will have little, if any, impact in the prevention of misadministrations. These regulations are for the most part consistent with the recommendations of the American College of Radiology, Pathology, JCAHO, et al. The small benefit that will result from implementation of these regulations is the enforceability aspect, but in reality, the regulatory threat is minimal when compared to the medical/legal threat.

Outlined below are my specific comments as related to the proposed regulations:

1. 35.2 and 35.34 - Relative to the proposal to include an error in teletherapy fractional dose as a misadministration, some consideration should be given to the specific situation. When a fractional error occurs and treatment plan modification will result in the original target and critical organ dose, this error should be considered an "event" not a misadministration. There are many ways to accomplish the same task and one way is not always better than the next. Also, the text of 35.34 is near impossible to understand.

2. 35.2 - What is the applicability of a "diagnostic referral" to parts 35.33(b)(1) and 35 in its entirety?

3. 35.2 and 35.33 - These sections are inconsistent with the requirements of many State pharmacy dispensing and physician ordering regulations. Many states do not require a physician to write a prescription prior

to the pharmacy dispensing the drug. I think that a call by a referring physician , followed by a decision by the authorized physician user is ok if proper documentation is maintained. This documentation should include who, what (isotope, form, activity, route of administration, etc.) and why (clinical indications).

4. 35.33 - I believe that the word misadministration should be restricted to situations where the patient's risk increases or their health is jeopardized. Rather than utilizing the word event, I think both the medical community and public would be best served by utilizing the word "deviation".

5. 35.33(a)(1) - I do not think the performance of diagnostic medical use not authorized under the license should automatically be classified as a misadministration/event(deviation). This type violation should be viewed as a routine violation of regulation/license condition unless the performance was inconsistent with the standard of care.

6. 35.34(b)(3)(ii)(iii) - If these errors can be compensated for, these should be classified as an event/deviation.

7. 35.34(d)(4) - In reporting a lost or leaking source during a brachytherapy procedure, what takes precedent, the reporting required under 35.34(b)(e) or that required by 20.402, 35.14 et al? Will the reporting under one section meet that required by the other?

8. 35.34(d)(e) - Why require a phone and written report of an "event"? It would appear that if you make a distinction between "misadministrations" and "events", a properly conducted and documented internal review should be adequate.

9. Relative to enforcement, I feel strongly that it is not appropriate to classify misadministrations/events, caused by human errors (excluding the failure to follow established/required procedures), into severity levels.

If you should have any questions or need clarification, please feel free to contact me at (916) 323-2754.

Sincerely,

for Stuart D. Rosenberg
Health Physicist
Radiologic Health Branch

STATE OF NEW YORK
DEPARTMENT OF HEALTH
Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

David Axelrod, M.D.
Commissioner

OFFICE OF PUBLIC HEALTH
Linda A. Randolph, M.D., M.P.H.
Director

William F. Leavy
Executive Deputy Director

March 22, 1990

Kirksey E. Whatley, Director
Radioactive Material Licensing
Radiological Health Branch
State Department of Public Health
State Office Building
Montgomery, Alabama 36130

Dear Mr. Whatley:

I do not expect to attend the Conference of Radiation Control Program Directors meeting in May due to budget and time constraints. However, the agenda indicates that you will be representing the State's position on proposed amendments to 10 CFR 35 at a panel discussion.

I submitted comments to Vandy Miller on NRC's December, 1989 draft rule in January of this year but have heard nothing since. A copy of my comments is enclosed with the hope they could be useful to you in your presentation.

I hope the March 14, 1990 meeting went well after I left and that you have received a copy of the comments I sent to Vandy Miller. Since I missed so much of the meeting, I wanted to be sure to get my two cents in. There seems to be much more consistency among the states on how to regulate medical use of materials than between the states and NRC (or between NRC central office and NRC field staff).

Very truly yours,

Rita Aldrich

Rita Aldrich, Chief
Radioactive Materials Section
Bureau of Environmental
Radiation Protection

Enclosure

RA/tw