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May 29, 1979

(17)

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

DOCKET NUMBER
PETITION RULE PRM-35-1 (44FR26817)

Attn.: Docketing and Service Branch

Gentlemen:

In regard to the petition for rule making submitted by George B. Taplin, M.D. as published in the Federal Register Vol. 44 No. 89, Monday May 7, 1979 page 26817, I wish emphatically to support this petition.

Dr. Taplin, one of the leaders in the field of nuclear medicine and an individual who in his lifetime has developed many important radiopharmaceuticals which have given great benefit to sick patients throughout the world, objects to a limitation of the Nuclear Regulatory Commission which requires that physicians rigidly follow the package insert of the Food and Drug Administration regarding the chemical and physical form of the agent, route of administration and dosage range in carrying out clinical procedures which have not been approved by FDA.

This requirement is not one imposed by FDA; in fact, they have specifically stayed away from the area of impeding the judgment of the physician in regard to these drugs.

This matter is of extreme importance since in addition to the specific concern of Dr. Taplin in regard to technetium-99m labeled DTPA it applies broadly to all radioactive drugs used in the field of nuclear medicine.

Having studied this broad question for a number of years I am unaware of any judgment exercised either by the NRC or the FDA which demonstrates that the judgment of either of these agencies is an improvement over the judgment of a physician in the care of an individual patient. The argument purportedly advanced by NRC could be extended to mandate the length of a surgical incision or the number of days for which a patient requires antibiotics or other drugs in the treatment of a specific illness.

I attach to this letter a statement by the Nuclear Regulatory Commission concerning their goal of minimizing such needless interference with the development of regulatory procedures issued in the Federal Register Vol. 43 No. 150 of Thursday, August 3, 1978 in response to a request of President Carter.

It is essential that those of us concerned with teaching, patient care and clinical research be protected from this type of harrassment as it is a serious threat to the health of the citizens of the United States.

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Sincerely,

Eugene L. Saenger

Eugene L. Saenger, M.D.
Professor of Radiology
Vice-Chairman, Department of Radiology

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ELS/swh
enclosure
cc: Senator John Glenn
Senator Howard Metzenbaum
Representative Bill Gradison

[7590-01]

NUCLEAR REGULATORY COMMISSION

IMPROVING NRC REGULATIONS

Response to Executive Order 12044

AGENCY: Nuclear Regulatory Commission.

ACTION: Progress report to the President and Congress.

SUMMARY: The NRC is making public its response to the President and Congress dated July 21, 1978 (copy attached), outlining the plans for voluntarily implementing Executive Order 12044, "Improving Government Regulations." Comments from the public are invited.

DATE: Comment period expires September 5, 1978.

ADDRESS: Interested persons should send their comments and suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

FOR FURTHER INFORMATION CONTACT:

William M. Shields, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 2055, 202-634-3215.

Dated at Washington, D.C., this 31st day of July 1978.

For the Nuclear Regulatory Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

[7590-01]

U.S. NUCLEAR REGULATORY COMMISSION,
Washington, D.C., July 21, 1978.

THE PRESIDENT,
The White House,
Washington, D.C.

DEAR MR. PRESIDENT: I am pleased to transmit the NRC report of progress in improving its regulations as requested by your letter of March 23 accompanying Executive Order 12044. We fully support the basic objectives of the order and believe that the preparation of clearer and less complex regulations is a necessary prerequisite for satisfying these objectives.

We have carefully examined the provisions of the Executive Order 12044 to determine how current NRC procedures compare. We have found that, for the most part, our procedures appear to satisfy the requirements of the order, or at least will satisfy its intent upon suitable modification. In one area (section 4) further study is needed to determine our position.

The NRC is fully cognizant of the importance of eliminating unnecessary burdens upon those being regulated, and of reducing as far as possible the economic cost of Government regulation. The following quote from the NRC's Value-Impact Guidelines, adopted by the Commission in January 1978, illustrates our commitment to these ideals:

> The policy of the Nuclear Regulatory Commission is that value-impact analysis be conducted for any proposed regulatory actions that might impose a significant burden on the public (where the term public is defined in its broadest sense). Such policy is not to be construed to mean that cost considerations take precedence over considerations of health, safety, environment, or national security. These factors remain paramount. However, where there are alternative means of realizing equivalent benefits in regulatory matters, cost should be a prime consideration.

Enclosed is a section-by-section response to the provisions of Executive Order 12044. In each case we outline briefly our current procedures and plans for some future changes in certain areas. In our comments on section 4 we indicate why further study is needed.

Respectfully,

JOSEPH M. HENDRIE.

Enclosure: Analysis.

SECTION-BY-SECTION ANALYSIS OF EXECUTIVE ORDER 12044

SECTION 2(a)

Requirements

Publish semi-annual agenda of regulations under development or review. Each item should include a staff contact.

Comment

The NRC now employs four separate procedures which seek to achieve the goals of this section:

(1) NRC publishes an agenda of petitions for rulemaking currently under review;

(2) NRC publishes proposed regulations for public comment;

(3) A status summary report listing, among other things, those regulations under development by the Office of Standards Development (the "Green Book") is published quarterly and is available to the public on request; and

(4) Commission staff papers, which are discussed in Commission meetings open to public attendance, are placed in the Washington Public Document Room on the day of the Commission meeting.

The NRC proposes to publish a semiannual list of significant regulations under review by the staff, in addition to the procedures already in place. A staff contact will be listed where possible.

SECTION 2(b)

Requirements:

Agency head must review issues and alternatives before staff initiates development of significant new regulations.

Comment:

The Commission is kept informed of current staff efforts. "Predevelopment" reviews are conducted only selectively by the Commission. However, the staff generally prepares preliminary regulatory analyses of significant regulations in early stages of their development.

SECTION 2(c)

Requirements:

1. Provide opportunity for public participation.

2. Allow 60 days for comments.

3. Notify interested parties directly if necessary.

Under present NRC procedures public comment on proposed regulations is invited upon publication in the FEDERAL REGISTER. Most Commission meetings on proposed regulations are open to the public. Current practice is to allow 45 days for public comments.

The 60-day period for public comment can be implemented without difficulty. In certain rare cases immediate action must be taken for safety, security, or other reasons, and a regulation may then be issued prior to the expiration of time for public comment. In such cases the need for immediate implementation is explained in the published notice of the new regulation.

Certain licensees who may not have immediate access to the FEDERAL REGISTER (e.g., physicians and radiographers) are generally notified by direct mail of proposed regulations affecting them.

SECTION 2(d)

Requirements:

1. Agency head or designee shall review and approve significant regulations before publication in FEDERAL REGISTER. The review shall include analysis of alternatives and impacts, including any burdens imposed by reporting requirements.

2. Agency head or designee shall determine that regulation is written in plain English and is understandable to licensees.

3. A plan shall be developed for evaluating a regulation after it has been implemented.

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omment

The Commission reviews all significant regulations prior to their publication for comment in the FEDERAL REGISTER, and would consider most of the listed factors. The NRC Office of Inspection and Enforcement takes such additional steps as directly contacting affected parties to assure that licensees correctly understand the intent of our regulations.

The Commission does not at this time require a formal plan for evaluating the regulation after its issuance (No. 8). Such evaluation is performed on a continuing basis by the regulatory and enforcement staff, particularly in regard to new regulations of uncertain impact. (See comments below on a related requirement in section 4.)

SECTIONS 2(E), 3(A), 3(B), AND 3(C)

Requirements

1. Establish criteria for evaluating regulations and analyze alternatives.

2. Publish the analyses.

Comment

Sections 2(e), 3(a)

The value-impact analysis currently performed by the NRC staff for most proposed regulations weighs many of the listed factors, where applicable to the NRC situation. The NRC does not have a formal set of criteria to determine which regulations are "significant". The guidelines for the value-impact analysis stipulate only that all proposed regulatory actions which are non-recurring or nonroutine should be examined. [Historically, value-impact analyses have been performed on about 80 percent of significant proposed regulations. Under the Commission's new value-impact guidelines, adopted in January 1978, this figure is expected to increase.] In certain cases a more extensive environmental impact assessment may be prepared which will consider the listed factors in greater detail.

Current NRC criteria for the value-impact analysis are more restrictive than those required by the order, that is, the NRC performs an analysis of many regulations whose total economic impact is far less than $100 million. Similarly an analysis may be performed on regulations having only a minor economic effect on the nuclear industry and hence on electric consumers. The Commission may, of course, order that an analysis be performed on any proposed regulation or other staff action. In our view the NRC is in compliance with this section.

[7590-01]

Section 3(b)

At this time some proposed regulations are published accompanied by the value-impact analysis. It will be NRC policy in the future to make any value-impact analyses available for public review at the time proposed or final regulations are published.

Section 3(c)

The NRC Office of Standards Development now places in the Public Document Room a final value-impact analysis if there have been any modifications or changes since the proposal was first published for comment. This procedure will be extended to all regulations subjected to value-impact analysis.

SECTION 4

Requirements

Periodically review existing significant regulations for continued need, burden, simplicity, duplication, and changes in economic or technical conditions.

Comment

The NRC does not at this time have a comprehensive plan for review of existing regulations. Some regulations are reviewed if a particular program is under review (for example, current safeguards regulations); others may be reviewed due to external events (such as petitions for rulemaking). Finally, there are staff-initiated reviews, such as the current plan to review significant fuel cycle regulations beginning in fiscal year 1978.

The Commission should be discussing with its staff reasonable and resource-effective methods, involving full opportunity for public input, for periodically reviewing our regulations as outlined in section 4.

SECTION 5

Requirements

1. Prepare a draft report outlining: (1) Process for developing regulations and any proposed changes thereon; (2) criteria for identifying significant regulations, or regulations requiring regulatory analysis; and (3) proposed criteria for identifying regulations to be included in the periodic review; publish report in FEDERAL REGISTER and send report to Office of Management and Budget.

2. After revising report in light of public comments, send to OMB for approval before final publication in FEDERAL REGISTER.

Comment

NRC will voluntarily comply with the reporting requirements of this section and submit the report to OMB for comment. With suitable modification this section-by-section analysis will constitute the draft report. Because the order does not apply to NRC, an independent regulatory agency, we do not believe that OMB approval of our report should be required.

[FR Doc. 78-21646 Filed 8-2-78; 8:45 am]

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