

RES INDEPENDENT REVIEW BOARD

VOTING SHEET

TO: F. P. GILLESPIE, CHAIRMAN, RIRB

FROM: W. M. Morrison, Member, RIRB

TITLE OF RULEMAKING: *Revision to 10 CFR 20, 32, 40 and 70 -
licensing of sources and devices*

☐

AGREE WITH RECOMMENDATIONS
IN RES RULEMAKING REVIEW
PACKAGE

☐

REQUEST RIRB
MEETING.

☐

MODIFY RECOMMENDATIONS IN
RES RULEMAKING REVIEW
PACKAGE AS INDICATED BELOW

☒

NOT PARTICIPATING.

COMMENTS AND SUGGESTIONS:

It is not possible to conduct an independent review of this rulemaking, as requested by the RAMRB Staff, because insufficient information is provided. Missing information, most of which is required to be included in the package by the May 1984 Procedures for Conducting RES Independent Review, includes the following:

- (1) The NRC Regulatory Agenda entry;
- (2) The rulemaking as currently proposed;
- (3) The items listed in I.E.1.d. of the Procedures for Conducting RES Independent Review;
- (4) The regulatory analysis;
- (5) The memorandum identified as "Attachment 1" in the draft Minogue to Dircks memorandum, subject "Draft Recommendations to EDO Concerning ...". (It is not clear why the "draft" is in the subject.)

W. M. Morrison

W. M. Morrison
MEMBER, RIRB

8/30/85

DATE

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PDR PR
30 52FR2540 PDR

8703230244

ROUTING AND TRANSMITTAL SLIP

Date

TO: (Name, office symbol, room number,
building, Agency/Post)

Initials

Date

1. W. M. Morrison, Member, RIRB

2. K. R. Goller, Member, RIRB

3. G. A. Arlotto, Member, RIRB

4.

5.

<input checked="" type="checkbox"/> Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

LICENSING OF SOURCES AND DEVICES

RIRB members are requested to conduct an independent review of the attached RES rulemaking review package and provide the Chairman, RIRB, with their voting sheets indicating their positions on the rulemaking.

Responses by c.o.b. September 3, 1985 will be appreciated. RAMRB will use the voting sheets to assemble the complete RES review package for eventual transmittal to the OEDO and the Director of the user office.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)

Room No.—Bldg.

RAMRB staff

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8041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

* GPO: 1983 O - 381-529 (232)

RES TASK LEADER PACKAGE

RESEARCH OFFICE REVIEW OF PROPOSED REVISIONS TO
COMMISSION RULES GOVERNING THE LICENSING OF
SOURCES AND DEVICES (10 CFR 30, 32, 40 and 70)

The subject rulemaking package has been reviewed in accordance with the guidance provided in R. B. Minogue's memorandum to staff dated May 10 1984.

Basically, this rulemaking proposes that manufacturers and distributors of sealed sources or devices containing sealed sources be required, as a condition of licensing, to submit information on the characteristics and proposed uses of their products. NRC and the Agreement states would, in procedures not fully documented, review and "approve" such devices for the uses proposed in the license application. Currently, product information of this type has been provided by manufacturers on a voluntary basis since it facilitates the subsequent licensing of the users (purchasers) of their products. Such product information is catalogued and published by NRC and distributed to the Agreement States for their use in licensing reviews of applicants proposing to use a given product. Where no prior product review has been made or where no product data is on hand, information is obtained from the user-applicant as part of his licensing review.

In addition, this proposed rulemaking would establish a system which classifies sources and devices according to end-use and source characteristics. Further, the rule would also permit licensee-users of such products to employ any one of a number of sources or devices which have previously been "reviewed" by NRC or the Agreement States without the need for a specific amendment to their license as is currently the case under existing regulations.

After considering the information provided in this rulemaking package (Statement of Considerations, Regulatory Analysis, etc) we are of the opinion that,

in its present form, this rulemaking action should be terminated. This judgment is based on the following:

- (a) the health and safety of the public is not affected by the imposition of these proposed changes. Current regulatory requirements and procedures are adequate to ensure public and occupational safety in this activity.
- (b) No abuses of the voluntary system having an impact on public safety have been cited to support the need for improved regulatory control in this area .
- (c) The principal benefits cited in support of this rule are administrative in nature. These benefits flow principally to the subsequent user of these devices rather than to the manufacturer or distributor upon whom these new licensing requirements are being imposed. The administrative burden appears to be a small reduction for the user and a small increase to the supplier.
- (d) Legal redress is currently available to NRC (under 10 CFR 2.200) in situations where it can be shown that manufacturers or distributors have, through negligence, or fraud, adversely impacted on licensees' compliance with NRC regulations and, indirectly, on public health and safety.
- (e) The net cost impact of these proposed changes is small; a slight increase in manufacturers costs and reduction in users costs could occur. Cost and other impact estimates provided in the Regulatory Analysis are inconclusive. It would seem that the manufacturers/distributors would be required to apply for a license amendment for each new or unique product they produce. No assessment of this impact is given.

These opinions are, we believe, consistent with those of ELD and ADMIN who provided extensive and substantive comments on the draft rulemaking package.