

VALUE IMPACT STATEMENT

REGULATION: LABELING REQUIREMENTS FOR GAS AND AEROSOL
DETECTORS CONTAINING RADIOACTIVE MATERIAL

REGULATORY GUIDE: IMPLEMENTATION OF RADIATION PROTECTION
STANDARDS FOR SMOKE DETECTORS CONTAINING
RADIOACTIVE MATERIAL

BACKGROUND

Smoke detectors containing small amounts of radioactive material, usually Americium 241, are distributed and used extensively. About 10,000,000 units per year currently are distributed in the U.S. The user, usually a homeowner, is exempt from regulatory requirements as provided in 10 CFR 30.20 or equivalent regulations of an Agreement State. The manufacturer/distributor possesses a specific license that is granted by the NRC under 10 CFR 32.26. Section 32.26 became effective early in 1969. A license is issued by the NRC if the applicant satisfies certain general requirements and demonstrates that handling, storage, use and disposal of the detectors will not cause radiation doses in excess of values identified in 10 CFR 32.26. The exemption and the provisions of 10 CFR 32.26 apply to detectors for both industrial and home use.

In December 1977, the Nuclear Energy Agency, OECD, issued a standard for smoke detectors which is intended to promote harmony between national policies concerning the approval, distribution, use and disposal of detectors to ensure adequate protection of the public against any radiation or contamination hazards. This would be achieved by setting limits on the quantity of radioactive material in a detector, by providing certain test and design specifications, and by making recommendations about administrative controls. The recommendations include a procedure for control of smoke detectors that are used outside the country in which they are manufactured. This procedure involves the issuance of design

and quality assurance certificates of approval by regulatory authorities in the country where the detector is manufactured and acceptance of those certificates by the authorities in the country where the detector is used. The NEA standard notes that function (i.e., the ability to detect smoke) is not covered in the standard but should be considered by the individual countries. NRC regulations do not address function. The U.S. is a member of the Nuclear Energy Agency.

The method of labeling provided in the NEA standard for single station (homeowner-type) smoke detectors is summarized below:

- (1) The label must bear the name or symbol of the radionuclide; the quantity of activity; and the trefoil warning symbol or the words "This smoke detector contains radioactive material which presents no significant hazard to health if used in accordance with the instructions," or similar wording.
- (2) The label must be clearly visible when the smoke detector is removed from its mounting. If access to the radioactive source can be gained without prior removal of the detector from its mounting, a further label possessing the trefoil symbol and the word "radioactive" should be clearly visible on removing the cover, before access to the source.
- (3) The label must remain clearly legible during the expected lifetime of the unit.
- (4) The labeling of smoke detector packaging is not addressed although the standard contains a general recommendation that regulatory

authorities ensure that all relevant information on the presence and utilization of radioactive sources is brought to the attention of users of the smoke detectors.

The NRC requires that smoke detectors be labeled or marked with the name of the manufacturer or importer of the detector and the byproduct material within the detector. It is the present practice of manufacturers to locate the label inside the cover of the smoke detector. The purchaser, therefore, may not become aware that he has purchased a device containing radioactive material until after he arrives home and prepares to install the detector. This practice has raised criticism of a regulatory program that does not require readily visible labeling or marking information that the unit contains radioactive material.

I. THE PRESENT ACTIONS

A. Description

The actions underway provide guidance to manufacturers/distributors on the use of the NEA smoke detector standard in NRC's regulatory program, and provide revised regulatory requirements for manufacturer/distributors on the labeling of smoke detectors. The revised regulations will require labeling of the external surface of the detector with: (1) the name of the radionuclide and the quantity of activity, (2) a statement that the device contains radioactive material, and (3) an identification of the person licensed by NRC to distribute the detector. The revised regulations will require labeling of the external surface of the point-of-sale packaging with: (1) the name of the radionuclide and the quantity of activity, (2) an identification of the person

licensed by the NRC to distribute the detector, and (3) a statement that the detector contains radioactive material and has been manufactured in compliance with U.S. NRC safety criteria in 10 CFR 32.27 and that the purchaser is exempt from any regulatory requirements. The existing regulatory provision for specifically considering the requiring of disposal instructions in the labels will be deleted. The revised regulations will not require any statement on the label that the user of the detector return the detector to the manufacturer/distributor for disposal at the end of its useful life. The revised regulations become effective January 1, 1981.

B. Need for the Present Actions

Paragraph 32.29(b) provides that each licensee under §32.26 shall:

"Label or mark each unit so that the manufacturer or importer of the product and the byproduct material in the product can be identified; and provide such other information with each unit as may be required by the Commission, including disposal instructions when appropriate;"

Further, the applicant for license is required by § 32.26(b)(10) to propose how he will label or mark each unit. Under those provisions for labeling, it has been common practice for manufacturers/distributors to place the label inside the detector cover and also to recommend in the label that the user return the detector to the manufacturer/distributor for disposal at the end of its useful life. Since the user is exempt from NRC regulatory requirements, detectors used in the home are likely to be discarded into ordinary household trash. Analysis of the consequences of such disposal into ordinary waste systems

indicates that this does not result in a safety problem; thus, a statement on the label concerning the return of the detector for disposal appears to be unwarranted. However, these practices of the user ignoring a label recommendation on a device approved for distribution by NRC, and the manufacturer/distributor using a labeling system which does not permit a potential purchaser to know, in advance of his purchase, that the smoke detector contains radioactive material have caused criticism of NRC's regulatory program.

The NEA smoke detector standard has been recommended to member countries for use in establishing national policies that adequately protect the public yet do not unnecessarily restrict international trade in smoke detectors. There is extensive international trade in smoke detectors at the present time.

In the NEA standard, there are certain provisions which are not presently covered in NRC's regulatory program. For example, the NEA standard provides for the National Authorities in a country where a smoke detector is manufactured to certify that the manufacturer has followed particular quality assurance procedures. That certificate is then recognized by the National Authorities in the importing country where the detector is to be used. Also, the National Authorities in the country of origin may certify that the detector meets all the requirements of the NEA standards and the National Authorities in the user country may then allow distribution within the user country without requiring further information about the detector. These provisions for recognition of certificates issued by foreign regulatory groups are not part of NRC's regula-

tory program for smoke detectors; and the NRC intends to maintain its current practice of review of all smoke detectors intended for distribution in the United States.

The NEA standard recommends that industrial type detectors which usually contain larger quantities of radioactive material should be recovered for controlled disposal. It should be noted that the NEA standard does not call for recovery of single station (homeowner-type) smoke detectors.

C. Value/Impact of the Present Actions

1. NRC Operations - Implementing the revised regulatory requirements for the labeling of smoke detectors should reduce current criticism of a labeling system that may not inform prospective purchasers that a detector contains radioactive material. The revised requirements may also reduce criticism of the user's failure to follow disposal instructions contained in the label.

Endorsement of the NEA standard in a regulatory guide, clearly spelling out any exceptions that NRC might take to its specific provisions, would clarify NRC's position with respect to international trade in smoke detectors. This one-time clarification may help avoid numerous inquiries which would otherwise require case-by-case response.

Laboratory temperature testing of certain currently distributed detectors and sources used in detectors was performed at Oak Ridge National Laboratory. This work was done under an NRC contract and is reported in NUREG/CR-0403. It used the temperature tests described in the NEA standard. Additional laboratory testing is not expected to be needed in order to evaluate the NEA temperature tests.

Implementing revised regulatory requirements for labeling and recognizing the NEA standard in a regulatory guide initially will cause a minor expenditure of additional NRC time and resources; however, it is expected that NRC staff efforts will be reduced in answering questions raised by potential licensees and others concerning the regulation of smoke detectors.

2. Other Government Agencies - The Bureau of Radiological Health (BRH) and the States are involved in the review and regulatory approval of smoke detectors containing radium sources. The role of BRH is to advise the States. BRH has expressed strong interest in adopting the NEA standard, to the extent possible, in its activities for smoke detectors containing radium.

BRH's suggestion that NRC require that smoke detector packages be labeled in a manner similar to that required by BRH for television sets, prompted the new NRC requirement (to be effective 1/1/81) whereby the consumer is informed that the detector satisfies safety criteria in 10 CFR 32.27.

Implementation of the NRC's revised requirements for labels and development of a regulatory guide on the NEA standard may influence the actions by BRH and the States on detectors using radium.

3. Industry - In October 1976, the American National Standards Institute (ANSI) called a meeting of the smoke detector manufacturers and others in order to determine their interest in developing an ANSI standard for smoke detectors. The group was apprised of then on-going work on the NEA standard and the status of NRC regulations. The group elected not to develop an ANSI standard for smoke detectors. The industry, particularly those manufacturers involved in international trade, kept informed of developments in the NEA standard. Some

manufacturers are now testing their detectors against the prototype tests set out in the NEA standard. Recognition of the NEA standard by NRC would help standardize prototype testing by manufacturers and eliminate uncertainty as to how much testing is required to support an application for license.

A clear regulatory requirement on labeling should reduce uncertainty about minimum labeling requirements. The revised regulatory requirements will result in modification of presently used labels and could cause stock-piled labels to be discarded. The revised regulations allow until January 1, 1981, for use of existing stocks of labels. Both the labeling or marking method for the detector and the point-of-sale package will have to be redesigned at a significant one-time cost. The amortized price of a single unit should not increase by more than a few cents.

Location of labels so as to be visible to prospective purchasers may provide a certain resistance to and, therefore, loss of sales; however, manufacturers should no longer encounter complaints from dissatisfied customers who contend they did not know the detector contained radioactive material. For presently distributed detectors, a change in NRC labeling requirements will be implemented by January 1, 1981, to allow for the depletion of existing stock. The change may be implemented sooner for new models that are proposed for distribution. Relabeling of detectors that have been completely fabricated or that have been distributed is not contemplated.

Those manufacturers that have not performed prototype testing comparable to that contained in the NEA standard could be required to perform such testing and incur some expense, probably when they request renewal of their present license.

4. Public - If NRC recognition of the NEA standard and adoption of regulatory requirements on labeling result in increased costs to the manufacturer, those costs will be passed on to the customer. The likely increase in unit cost to the consumer for prototype testing would be negligible because of the large number of units distributed. The unit cost of the new labels could be several cents per unit.

As a benefit, the consumer would obtain a product that is labeled such that he knows in advance of purchase that the detector contains radioactive material and he knows that the detector satisfies certain Federal safety criteria. Also, if the manufacturer is able to reduce costs by NRC recognition of acceptable prototype tests, labels, etc., those savings might be passed on to the consumer.

D. Decisions on Present Action - The actions of providing revised regulatory requirements for manufacturers/distributors on the labelling of smoke detectors and guidance on the use of the NEA smoke detector standard in NRC's regulatory program should be carried out.

II. TECHNICAL APPROACH

A. Technical Alternatives

There did not appear to be a reasonable alternative to developing regulatory requirements on labeling of smoke detectors unless one considered the alternative of developing a comprehensive regulatory position on labeling of all consumer products containing radioactive material. With respect to recognition of the NEA standard, an alternative to acknowledging its prototype tests and certain specific provisions would be to develop NRC standard tests or to proceed on an ad hoc basis to evaluate license applications against the general requirements set out in 10 CFR 32.26.

B. Discussion and Comparison of Technical Alternatives

Although the development of a comprehensive regulatory position on labeling of consumer products is a desirable long term goal, the immediate and specific need is for regulatory requirements for labeling of smoke detectors. Satisfaction of this immediate need should not be delayed in order to work on a broader problem which is expected to be addressed during a general reevaluation of consumer products in the near future.

In lieu of adopting certain of the NEA standard's provisions, e.g., prototype tests, NRC could independently develop its own standard prototype tests. The time and expense involved suggest this course not to be preferred unless defects become apparent in the NEA prototype tests. Further, if U.S. and foreign manufacturers are selling both in the U.S. and in other countries that are following the NEA standard, those manufacturers could incur the expense of conducting two sets of prototype tests.

If standardized, international prototype tests are available and acceptable, evaluating ad hoc prototype tests could be an unnecessary effort.

C. Decision on Technical Approach

The action of providing revised regulatory requirements for manufacturers/distributors on the labeling of smoke detectors and guidance on the use of the NEA smoke detector standard should be carried out and the guidance should, to the extent feasible, adopt provisions of the NEA standard.

III. PROCEDURAL APPROACH

The procedural approach of issuing regulatory requirements on labeling and endorsing the NEA standard by use of a regulatory guide, appears to be a reasonable administrative approach at this time. At a later date, when experience is acquired through use of the regulatory guide and when the generic environmental assessment of consumer products is completed, other regulatory changes may be in order.

Although a Branch position could be prepared on the NEA standard, it probably would not provide the exposure and opportunity for comment that is obtainable through use of a regulatory guide.

IV. STATUTORY CONSIDERATIONS

A. NRC Authority

The revised regulatory requirements for labeling (to be effective 1/1/81) are related to the present provisions of 10 CFR Part 32.26-29. Since the NRC does not intend to consider the certification provisions of the NEA standard, questions should not arise on this subject about basic NRC authority

under the Atomic Energy Act and the Energy Reorganization Act.

This action of revising the labeling requirements in 10 CFR Part 32 is non-substantive and insignificant from the standpoint of environmental impact and does not require an environmental statement, negative declaration, or environmental impact appraisal.

As work progresses on the regulatory guide, contact may be made with the Bureau of Radiological Health (BRH) to compare NRC efforts to the BRH efforts on smoke detectors containing radium. In view of the States' interest in smoke detectors containing radium and in detectors that are distributed under NRC license and are used in the Agreement States, the States will be given opportunity to comment on the draft regulatory guide.

V. SUMMARY AND CONCLUSIONS

Revised regulatory requirements for labeling of smoke detectors (to be effective 1/1/81) and a regulatory guide on the use of the NEA smoke detector standard in NRC's regulatory program should be provided.

VI. RELATIONSHIPS TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

If smoke detector labeling is required to inform potential customers, and other persons, that the device contains radioactive material, then other products that are distributed to exempt persons may later be required to have labeling that performs a similar function.

References

1. 10 CFR Parts 30 and 32.
2. "Recommendations for Ionization Chamber Smoke Detectors in Implementation of Radiation Protection Standards," 1977, Nuclear Energy Agency, Organization for Economic Cooperation and Development.
3. Cutshall, N.H., Larsen, I.L., and Case, F.N., "High Temperature Testing of Smoke Detector Sources," NUREG/CR-0403, September 1978.
4. Notice of proposed amendments to 10 CFR 32 to revise requirements for labeling of gas and aerosol detectors (44 FR 68853).