

THURSDAY,

JANUARY 13, 1977  
PART VII

ENVIRONMENTAL  
PROTECTION  
'AGENCY  
RADIATION PROTECTION  
PROGRAMS  
Environmental Radiation Protection  
- Standards For  
Nuclear Power Operations

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RULES AND REGULATIONS

Title 40-Protection of Environment  
CHAPTER I-ENVIRONMENTAL  
PROTECTION AGENCY  
SUBCHAPTER F-RADIATION PROTECTION  
'PROGRAMS  
[IF 659-6]

PART 190-ENVIRONMENTAL RADIATION  
PROTECTION STANDARDS FOR NU-  
CLEAR POWER OPERATIONS

On May 10, 1974, the Environmental  
Protection Agency (EPA) published an  
advance notice of intent to propose en-  
vironmental radiation'protection stand-  
ards for the uranium fuel cycle (39 FR  
16906) and invited publi'c participation.  
On May 29, 1975, EPA proposed regu-  
lations setting forth such standards (40  
FR 23420) pursuant to the Atomic En-  
ergy Act, as amended, and Reorganiza-  
tion Plan No. 3 of 1970 (35 FR 15623).  
Numerous written comments were re-  
ceived, and a public hearing was held on  
March 8-10, 1976 (41 FR 1124 and 41  
FR5349).'

These regulations setting forth envi-  
ronmental radiation standards are here-  
by promulgated in final form. The stand-  
ards specify the levels below which  
normal operations of the uranium fuel'  
cycle are determined to be eniironmen-  
tally acceptable. A number of changes  
have been made in the proposed regu-  
lations in response to comments received.  
These changes modify and clarify the  
areas of applicability of the standards  
and their effective dates, and expand  
the conditions under which variances  
may be granted. The numerical levels of  
the standards have been retained as  
proposed.

The Agency has benefited from exten-  
sive public participation during the  
course of the development of these regu-  
lations. Sixteen comment letters were  
received in response to the Agency's May  
10, 1974,. notice of intent to propose

standards, and 82 comment letters following the publication of proposed regulations. In this connection the Agency received requests on behalf of Allied-General Nuclear Services (AGNS) on October 4 and December 2, 1976, for a supplemental hearing on certain aspects of this rulemaking, on the grounds that the Agency is, in part, relying upon information acquired subsequent to the public hearing which, in the view of AGNS, would be an essential basis for the rulemaking but is erroneous. The Agency has reviewed the materials submitted in support of this request and concluded that they would not provide a sufficient basis for altering its conclusions. A response to new matters addressed by this material has been appended to the Agency's commentary on testimony received in connection with the public hearing on these standards. In addition it is noted that the Agency has previously (40 FR 23420) made public its intent " \* \* \* to maintain a continuing review of the appropriateness of these environmental standards \* \* \* and to revise them, if necessary, on the basis of information that develops in the interval." In view of the above, the Agency has concluded that it is neither necessary nor appropriate to grant now the additional public hearing requested. We will, of course, welcome the submission of additional factual data on the matters concerned as it becomes available.

Letters on May 29, 1975. Letters were received from a broad cross-section of representatives of the general public, the industry, professional groups, the States, and Federal agencies. In addition, 17 parties participated in three days of public hearings and, in many cases, submitted extensive additional written testimony. In all, the contributed record comprises over 3500 pages. Comment letters, a transcript of the public hearing, and all submitted testimony are available for viewing and copying in the Agency's Public Information Reference Unit, Room 2922, U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460. The Agency has considered all of this record in reaching its conclusions for these final regulations. At the time these standards were proposed, EPA released a Draft Environmental Statement and solicited public comments. A Final Environmental Statement is being made available concurrently with the promulgation of these standards. This statement contains the comments received on both the proposed standards and the draft statement, and EPA's response to these comments. Single

copies of the Final Environmental Statement and an additional document containing EPA's detailed responses to testimony received in connection with the public hearing are available from the Director, Criteria and Standards Division (AW-460), Office of Radiation Programs, Environmental Protection Agency, Washington, D.C. 20460. Persons interested in a summary discussion of the background, rationale, interpretation, and significance of these standards should consult the notice proposing these regulations and, for greater detail, the Final Environmental Statement.

#### MAJOR ISSUES RAISED DURING REVIEW

Three major issues were raised by commenters. These were: (1) concern that procedures for implementation of the standards would be unnecessarily conservative or costly, (2) disagreement over the need for and cost-effectiveness of control of environmental releases of krypton-85 and other long-lived radionuclides, and (3) disagreement over the form of the relationship between effects on health and radiation dose assumed in deriving these standards.

A large number of commenters expressed the view that implementation would lead to more restrictive control of effluents than intended due to the use of unnecessarily conservative models for source terms, control capability, and environmental transport, and due to requirements for unreasonably large margins between normal operating levels and the standards, especially at sites containing a number of facilities. The authority to regulate fuel cycle facilities under these standards resides in the Nuclear Regulatory Commission (NRC), or, in some cases, the States, under agreements with NRC. The standards have been expressed in terms of the dose to members of the public, rather than to hypothetical receptors, in order to encourage the use of realistic models by the regulatory agency. In addition, the

Agency has made its intent regarding realistic implementation clear, as, for example, in the discussion of these matters in the Final Environmental Statement and will continue to do so if necessary as implementation proceeds, to assure that unnecessary conservatism does not occur. In this regard, the NRC has recently issued a revised set of regulatory guides for light-water-cooled reactors which implement their announced intent to use the most realistic models available when adequate experimental data exist to per-

mit a prudent and scientific determination. These models are intended for use in implementing the recently-issued Appendix I to 10 CFR Part 50, which defines design and operating criteria for single reactor units. EPA has examined Appendix I and the accompanying regulatory guides and agrees that they provide the basis for realistic implementation of these standards for single reactor units. The existence of these requirements, coupled with the realization that most existing reactor licenses are for no more than one or two units on a site, makes it unnecessary, in the Agency's judgment, to reexamine the license conditions of these licensees for compatibility with these standards, unless the nearest neighboring site covered by this standard is within ten miles. In these latter cases small adjustments may be necessary. However, in the vast majority of situations, the sum of all reasonably postulated contributions from sources other than the immediate site will be small compared to these standards and should be ignored in assessing compliance. It would not be reasonable to attempt to incorporate into compliance assessment doses which are small fractions of the uncertainties associated with the determination of doses from the primary source of exposure. The Agency has also concluded that, except under highly improbable circumstances, conformance to these criteria should provide reasonable assurance of compliance with these standards for up to five units on a site. This conclusion is based, among other considerations, upon realistic consideration of anticipated site sizes and the relative location of individual units, as well as the stochastic nature of effluent releases.

A number of commenters, including the NRC, also noted that shutdown of nuclear facilities for minor deviations from the standards would not be reasonable. The Agency agrees, and notes that the use of such an extreme measure is not required under present compliance procedures for licenses issued pursuant to the Atomic Energy Act, and that these regulations do not add such a requirement. A graded scale of action is an appropriate regulatory response for achieving conformance. This may include, for example, requirements for corrective actions, appropriate penalties, and, in extreme cases, cessation of operations. The Agency is confident that the NRC will implement these standards in such a reasonable manner.

Some commenters expressed the view that it was not feasible to monitor con-

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 forinance with these standards through the use of environmental measurements, The Agency agrees that routine monitoring based exclusively upon environmental measurements would not be a reasonable means for assuring conformance and the regulations do not contain such a requirement. Environmental objectives are generally best achieved through controls exercised at the source. For this reason effluent monitoring is generally preferable and such measurements, when combined with regulatory models for environmental transport, would provide quite adequate demonstration of conformance with the standards for the vast majority of situations, based, upon existing experience. However, since varying degrees of conservatism and uncertainty exist in all environmental models, the Agency believes it will often be appropriate to supplement effluent monitoring with confirming environmental measurements, as is now the regulatory practice. In the case of light water reactors, models and monitoring requirements for demonstrating conformance with Appendix I of 10 CFR Part 50 are generally adequate for demonstrating conformance with these standards. Similar models and measurements would, in general, be appropriate for most other types of facilities.

In the special case of possible wind-blown effluents from mill tailings, the existence of operational measures (e.g., temporary or permanent stabilization) should normally be the criterion used for verifying compliance, in lieu of effluent and environmental monitoring, because of the difficulty associated with such measurements. It should be noted that doses resulting from exposure to radon and its daughters, which are discharged from a mill site (or result from material which has been discharged), are excluded, but that gamma radiation crossing site boundaries from any on-site source is covered.

In situations where members of the public are actually exposed, these standards, in effect, preempt those regulations which are based upon the Federal Radiation Protection Guides (25 FR 4402) Insofar as exposure of the public is due

to operations- defined to be included in the uranium fuel cycle. For example, the dose limits in 10 CFR Part 20 would not be the limiting consideration regarding exposure of members of the public as a result of uranium fuel cycle operations. These standards do not, however, replace application of the Radiation Protection Guides to the regulation of sources not included within the scope of the uranium fuel cycle. Finally, the graded scale of actions established in 1961 (26 FR 9057) for use in implementing the Radiation Protection Guides do not apply to implementation of these standards, but would remain in effect -for implementation of radiation protection guides for other radiation sources.

Several commenters expressed the view that a requirement for control of the unrestricted release of krypton to the environment from fuel cycle operations

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was: (a) beyond the Jurisdiction of EPA, (b) unreasonably costly, (c) not achievable by 1983, the proposed Implementation date (or, In the view of some commenters, was achievable prior to 1983), or (d) not a reasonable requirement of domestic Industry until International agreements are achieved to restrict emissions from foreign sources.

The Agency has concluded that Its jurisdiction Is clear. Reorganization Plan No. 3 of 1970 specifically transferred to EPA from the Atomic Energy Commission the authority to establish standards for-"\* \* quantities of radioactive materials In the environment \* \* " and attaches no conditions to this authority except a requirement that the standards apply outside the boundaries of licensees. EPA has carefully reexamined the costs of control systems for krypton and has concluded that a substantial portion of the additional costs presented at the public hearings is correct. This analysis is reviewed in the Final Environmental Statement. However, in spite of these increased costs, the installation of controls for krypton-85 is believed to be justified by the public health benefits achievable. In today's dollars, the cost per unit radiation dose reduction at future reprocessing facilities will be \$50-\$75 per man-rem for whole body doses, and considerably less than this for doses to other organs. These values are more than an order of magnitude lower than limiting costs now specified in regulations governing the licensing of individual nuclear power reactors. It is recog-

nized that the cost of retrofitting one facility which is expected to be in operation before 1983 will involve greater costs, and the regulatory agency is encouraged to explore means to minimize costs to this facility in its implementation of the standard for this pilot case. Regarding the achievability of control over the release of krypton-85 to the environment by 1983, it is noted that this or similar control technology is already being offered commercially for nuclear reactors and fuel reprocessing facilities, and is currently being installed, or is on order, at several U.S. reactors and at a foreign fuel reprocessing facility by U.S. suppliers. The Agency, therefore, believes that 1983 is an achievable implementation date. However, a more accelerated schedule is not considered justified. In view of the small amount of reprocessing that will occur before that date and the present lack of operating experience with krypton controls.

Finally, we have examined arguments concerning the need for international agreement prior to the establishment of standards and do not find them persuasive. EPA fully supports the development of international agreements, and is presently participating in the development of international guidance for control of radioactive effluents from the fuel cycle under the auspices of the International Atomic Energy Agency. A number of countries are already committed to or are in the process of committing themselves to control of krypton releases. The Agency supports this trend and has con-

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cluded that the control of U.S. releases of krypton-85 is warranted on the basis of reducing its potential worldwide public health impact. In initiating a requirement for this control, the United States fulfills its responsibility, as the world's largest user of nuclear power, to provide leadership in this matter.

A number of commenters suggested that the proposed regulations should be amended to include standards for carbon-14 and, in some cases, other long-lived radionuclides. The Agency has studies of sources and controls for these materials underway and anticipates that proposals for appropriate environmental standards for carbon-14 can be made shortly, with consideration of proposals for other materials following at a later date. However, the knowledge base is not yet sufficient to permit incorporation into these standards now.

Comments were received reflecting many points of view on health effects issues. One group agreed with the Agency's primary reliance on risk estimates provided by the recent report to EPA of the National Academy of Sciences ("The Effects on Populations of Exposure to Low Levels of Ionization," Report of the Advisory Committee on the Biological Effects of Ionizing Radiation, NAS-NRC, 1972). These estimates are primarily based upon a linear interpolation between existing data on human populations and the assumption of no effects at zero dose. Another group believed this model is not sufficiently conservative to adequately protect public health, based upon several investigators' hypotheses concerning the shape of the dose-effect relationship at low doses. A third group believed these estimates to be too conservative at low doses and low dose-rates. Frequent reference was made by the third group to a report of the National Council on Radiation Protection and Measurements (Report No. 43) which implies that radiation standards should not be based upon numerical estimates of health effects, and a recent report of the Nuclear Regulatory Commission (NUREG-75/014) which presents, in addition to risk estimates based upon the National Academy of Sciences report, some lower risk estimates based upon a belief that dose-rate dependent phenomena exist for low linear energy transfer radiation (gamma rays and beta particles) which reduce the carcinogenic effect of radiation to levels lower than those predicted by the linear model. The Agency has examined the evidence for each of the above views and concluded that, while each may have validity under various assumptions or for various specific situations, the weight of currently available scientific evidence supports the continued use of a linear, nonthreshold model for deriving standards to protect public health.

#### Changes Made in the Proposed Regulations

A number of changes have been made in response to comments received on the proposed regulations. The following describes and provides the reasons for each of these changes:

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1. Paragraph 190.02(b) has been changed to delete transportation as an

operation covered by these standards and to specifically exclude waste disposal sites, which were previously not mentioned. The Agency is addressing the development of criteria and standards for management of radioactive wastes as a separate matter, as mentioned in the notice proposing these standards.

A number of commenters, including the NRC and the Department of Transportation, pointed out the difficulty of implementing these standards for transportation activities, particularly noting the problems near nuclear facilities.

In such cases an apportionment of the dose limits would appear to be necessary in order to avoid unreasonably extensive monitoring requirements for members of the public. Since studies by both EPA and NRC show that most transportation-related doses are expected to remain at small fractions of these standards in any case, the implementation difficulty does not appear to warrant their inclusion in these standards limiting doses to individuals from uranium fuel cycle operations. The Agency will instead address this matter under its broad authority inherited from the former Federal Radiation Council, through the development of more general guidance to all Federal agencies concerning radiation exposure arising from the transportation of all types of radioactive materials, not just those from the uranium fuel cycle.

2. Paragraph 190.02(d) is changed to reflect the definition of "site" implied by Reorganization Plan No. 3 of 1970.

3. Paragraph 190.02(f) is changed by adding the word "spontaneously" to reflect the Agency's original intent.

4. Paragraph 190.02(g) is deleted and subsequent paragraphs in Section 190.02 are renumbered. This paragraph defined uranium ore as ore containing 0.05% or more uranium by weight. As pointed out by one commenter, it is not desirable to exclude ores containing less than this quantity of uranium, since future demand for ore may make the use of such ores economically feasible.

5. Section 190.11 has been broadened to permit a greater degree of discretion to the regulatory agency to develop and apply conditions for the granting of variances. As pointed out by a number of commenters, it is not reasonable to predicate the justification for variances solely on public need for orderly delivery of power. For example, a facility may have installed a control system which, in spite of good faith performance on the part

of the supplier and the user, may fail to achieve operational capability on a timely basis, or, once installed may experience operational failure at some time, yet operation of the facility may not be essential to the "orderly delivery of electrical power." In addition, some portions of this standard are predicated upon the use of waste treatment systems not yet in general commercial use. Although in no case should operation continue if safety is compromised, it may easily be that excursions above these

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standards would occur in such cases to a degree that the added risk to the general public is small and the environmental impact is acceptable in comparison to the economic penalty that would be associated with cessation of operation or the anticipated public health and environmental impact of available alternative sources of power. For this reason, the variance provision has been broadened so that the regulatory agency may, if it, deems it to be in the public interest, grant a variance in such situations. It should be noted, however, that the variance provision applies only to temporary and unusual situations. It is expected, that continued operation under the variance provision will be predicated upon an approved plan to achieve compliance in an expeditious fashion, that is, in as short a time as is reasonably achievable. The requirement for public documentation of variances has been clarified and extended to apply to this broadened provision. EPA will not review individual variances or compliance plans, which will be made public in accordance with the provisions of paragraph 190.11(b), but will maintain a general overview through periodic review of the use of this Section.

6. Section 190.12(a) has been changed to provide that the effective date for the standards limiting doses to individuals shall be December 1, 1979, for all operations except the milling of uranium ore, for which the effective date shall be December 1, 1980.

The NRC has carefully examined its existing programs for implementation of Appendix I at light-water-cooled reactors, and the feasibility of integrating implementation of these standards into that on-going process, as well as, in parallel, implementing these standards at other types of fuel cycle facilities through development and promulgation

of new regulatory guides and individual license conditions. Finally, there are matters regarding reactors which will require generic treatment, such as the conditions required for compliance when there are multiple units on single sites. It is the conclusion of the NRC, and the Agency concurs, that the originally proposed two-year implementation period is insufficient and that three years will be required to complete this process. The NRC review of these matters regarding implementation has revealed that the case of mill is unique, since better information is required concerning a number of alternatives for stabilization of tailings-both as to their relative merit and the degree of periodic maintenance required. On June 3, 1976, the NRC published (41 FR 22430) a notice of intent to prepare a generic environmental statement on uranium milling operations. This effort will be completed in approximately two years, and includes field measurements with participation of both EPA and NRC personnel. In addition, the NRC issued proposed new effluent reporting requirements at mills on November 17, 1975 (40 FR 53230). In view of the above considerations, it is the jointly agreed upon conclusion of

the Agency and NRC that a four-year implementation period is required at mills, rather than the three years provided for all other fuel cycle operations. 7. Section 190.12(b) has been changed to clarify the Agency's original Intent that the standards specified in paragraph 190.10(b) apply to radioactive materials produced after the effective date. The Agency anticipates that promulgation of these standards will serve, in addition to providing for necessary protection of public health, to alleviate some of the uncertainties associated with the design of environmental controls for fuel cycle facilities, and the consequent economic penalties, through stabilizing and providing direction to the process of development of standards and regulations. The economic and inflationary impacts of these regulations have been evaluated in accordance with Executive Order 11821 and It has been determined that an Inflation Impact Statement is not required. (The estimated annual cost of additional effluent controls required by these regulations s in no case greater than ten to twenty million dollars, which is significantly less than the one-hundred million dollar annual cost cut-off established as the minimum for which

an Inflation Impact Statement is required.)

Notice is hereby given that pursuant to the Atomic Energy Act of 1954, as amended, and Reorganization Plan No. 3 of 1970 Title 40, Chapter I, of the Code of Federal Regulations is amended by adding a new Subchapter F and Part 190 as set forth below.

Dated: December 28, 1976.

RUSSELL E. TRAIN,  
Administrator.

A new Subchapter F, consisting of Part 190, is added to 40 CFR Chapter I as follows:

SUBCHAPTER F-RADIATION PROTECTION PROGRAMS

PART 190-ENVIRONMENTAL RADIATION PROTECTION STANDARDS FOR NUCLEAR POWER OPERATIONS

Subpart A--General Provisions  
Sec.

190.01 Applicability.

190.02 Definitions.

Subpart B--Environmental standards for the Uranium Fuel Cycle

190.10 Standards for normal operations.

190.11 Variances for unusual operations,

190.12 Effective date.

Authority: Atomic Energy Act of 1954, as amended; Reorganization Plan No. 3, of 1970.

Subpart A-General Provisions

§ 190.01 Applicability.

The provisions of this Part apply to radiation doses received by members of the public in the general environment and to radioactive materials introduced into the general environment as the result of operations which are part of a nuclear fuel cycle.

§ 190.02 Definitions.

(a) "Nuclear fuel cycle" means the operations defined to be associated with the

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production of electrical power for public use by any fuel cycle through utilization of nuclear energy.

(b) "Uranium fuel cycle" means\* the operations of milling of uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using-uranium fuel, and reprocessing of spent uranium fuel, to the extent that these directly support the production of electrical power for public use utilizing nuclear energy, but excludes mining op-

erations, -operations at waste disposal sites, transportation of any radioactive material in support of these operations, and the reuse of recovered non-uranium special nuclear and by-product materials from the cycle.-

(c) "General environment" means the total terrestrial, atmospheric and aquatic environments outside sites upon which any operation which is part of a nuclear fuel cycle is conducted.

- (d) "Site" means the area contained within the boundary of a: location under the control of persons possessing or using radioactive material on which is conducted one or more operations covered by this Part

(e) "Radiation" means any or all of the following: alpha, beta, gamma, or x-rays; neutrons; and high-energy electrons, protons, or other atomic particles; but not sound or radio waves, nor visible, infrared, or ultraviolet light.

(f) "Radioactive material" means any material which spontaneously emits radiation.

(g) "Curie" (Ci) means that quantity of radioactive material producing 37 billion nuclear transformations per second. (One millicurie (mCi) =0.001 Ci.)

(1h) "Dose equivalent" means the product of absorbed dose and appropriate factors to account for differences in blo-

logical effectiveness due to the quality of radiation and its spatial distribution in the body. The unit of dose equivalent is the "rem." (One millirem (mrem)= 0.001 rem.)

(I) "Organ" means any human organ exclusive of the dermis, the epidermis, or the cornea.

(J) "Gigawatt-year" refers to the quantity of electrical energy produced at the busbar of a generating station. A gigawatt-1s equal to one billion watts. A gigawatt-year is equivalent to the amount of energy output represented by an average electric power level of one gigawatt sustained for one year.

(k) "Member of the public" means any individual that can receive a radiation dose in the general environment, whether he may or may not also be exposed to radiation in an occupation associated with a nuclear fuel cycle. However, an individual is not considered a member of the public during any period in which he is engaged in carrying out any operation which is part of a nuclear fuel cycle.

(1) "Regulatory agency" means the the government agency responsible for

issuing regulations governing the use of sources of radiation or radioactive materials or emissions therefrom and carrying out inspection and enforcement activities to assure compliance with such regulations.

Subpart B-Environmental Standards for the Uranium Fuel Cycle

§ 190.10 Standards for normal operations.

Operations covered by this Subpart shall be conducted in such a manner as to provide reasonable assurance that:

(a) The annual dose equivalent does not exceed 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any

member of the public as the result of exposures to planned discharges of radioactive materials, radon and its daughters excepted, to the general environment from uranium fuel cycle operations and to radiation from these operations.

(b) The total quantity of radioactive materials entering the general environment from the entire uranium fuel cycle per gigawatt-year of electrical energy produced by the fuel cycle, contains less than 50,000 curies of krypton-85, 5 millicuries of iodine-129, and 0.5 millicuries combined of plutonium-239 and other alpha-emitting transuranic radionuclides with half-lives greater than one year.

§ 190.11 Variances for unusual operations.

The standards specified in § 190.10 may be exceeded if:

(a) The regulatory agency has granted a variance based upon its determination that a temporary and unusual operating condition exists and continued operation is in the public interest, and

(b) Information is promptly made a matter of public record delineating the nature of unusual operating conditions, the degree to which this operation is expected to result in levels in excess of the standards, the basis of the variance, and the schedule for achieving conformance with the standards.

§ 190.12 Effective date.

(a) The standards in § 190.10 (a) shall be effective December 1, 1979, except that for doses arising from operations associated with the milling of uranium ore the effective date shall be December 1, 1980.

(b) The standards in § 190.10(b) shall be effective December 1, 1979, except that the standards for krypton-85 and iodine-129 shall be effective January 1, 1983, for any such radioactive materials generated by the fission process after these dates.

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