



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Office of the Secretary
Public Health Service
GA

Food and Drug Administration
Rockville MD 20857

LOCAL NUMBER
PROPOSED RULE PR 52,54100
45 FR 79820

Mr. James J. Henry
Office of Standards Development
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Henry:

The Notice of Intent to prepare an Environmental Impact Statement for Revision of the Regulations Governing the Siting of Nuclear Power Plants has been reviewed by the Bureau of Radiological Health, Food and Drug Administration.

Since this Notice is based on the July 29, 1980 Advance Notice of Rulemaking (45 FR 50350) and the August 1979, Report of the Siting Policy Task Force, our comments will be related to recommendations common to both documents.

Recommendation 1. Specification of Minimum Distances and Population Densities

The numerical requirements of minimum exclusion distance have been developed. It is difficult to conceive that an all-inclusive distance can be developed which could be applicable to all reactors. Such a criterion could preclude consideration of a site even though it is more desirable from an overall safety standpoint. Further, we believe that the present method of determining an acceptable exclusion distance based on performing radiation exposure calculations to assure that the maximum exposure at the exclusion distance boundary meets an acceptable dose criterion should not be removed. This methodology provides a needed assurance that the maximally exposed individual and the public health generally is adequately protected.

We believe that incorporating specific population density and distribution limits outside the exclusion area that are dependent upon average population of the region is a desirable objective. However, further study of population in selected regional areas and estimates of risk of siting a reactor in these areas should be undertaken before establishment of such a criterion. This study could form the basis of the rationale for numerical requirements given in the discussion on page 49 of NUREG 0625.

The NRC should adopt the emergency planning zone (EPZ) proposed in NUPEC-0396. We believe that a fixed value for the EPZ should not be established by regulations but should be sufficiently flexible to take into consideration siting characteristics and emergency planning requirements. In particular, the EPZ should accommodate the Food and Drug Administration's responsibilities for providing guidelines and recommendations to be taken in the event of a radiological incident resulting in accidental contamination of food and animal feed (Proposed Rulemaking, 43 FR 58790, December 15, 1978). Provision for greater EPZ distance than about 10 miles would permit advance planning to identify the critical pathways that could lead to contaminated human food and animal feed. Federal and State agencies would need to have plans in place that would provide for protection of the public health and safety in the event of an accident. Such plans would include establishing procedures for diverting food products or water supplies from consumption by humans or domestic animals in the food chain.

Acknowledged by card... 2/3/81

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Recommendation 2, Establish Minimum Stand-off Distances from Potential Hazards Posed by Man-Made Activities

The concept of establishing minimum stand-off distances from airports, LNG terminals, gas pipelines, faults and large quantities of explosives or toxic materials does contain an adequate basis and sufficient rationale to justify the need for the requirement. The present practice of examining specific off-site potential hazards on a site basis would appear to be a more appropriate methodology.

Recommendation 3, Interdictive Measures to Limit Ground Water Contamination from Class 9 Accidents

We cannot comment specifically on this recommendation. However, for accidents in the immediate site area, it is important to provide reasonable assurance that interdictive measures would limit ground water transport of radioactivity and would assure protection of the public health and safety.

Recommendation 4, Reflect Evolving Technology in Assessing Seismic Hazards

We have no specific comments.

Recommendation 5, Post Licensing Changes to Off-Site Activities

We support the proposed requirement for the NRC staff to inform local authorities and other Federal agencies involved in off-site activities.

Recommendation 6, Continue Current Approach Relative to Site Selection

We have no specific comments.

Recommendation 7, Specify Site Approval at the Earliest Decision Point

We support the concept that would specify that site approval is established at the earliest decision point in the review.

Recommendation 8, Provide a Final Decision Disapproving a Proposed Site Agency Whose Approval is Fundamental to the Project and Would Be Sufficient Basis for NRC to Terminate Review

We have no specific comments.

Recommendation 9, Develop Common Bases for Comparing Risks for All External Events

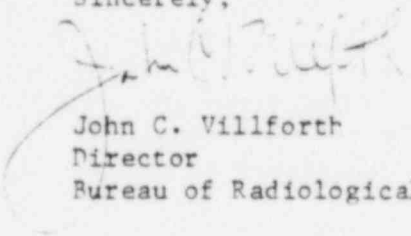
We believe this task should be undertaken to provide a quantitative risk comparison of external events and natural phenomena. The examples cited in NUREG-0625 have shown how regulatory agencies use risk assessment to develop safety criteria. For instance, it was considered by the Food and Drug Administration in developing its guidelines and recommendations for accidental radioactive contamination of human food and animal feeds.

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The tentative Table of Contents (Appendix B), as shown in the subject Notice of Intent, has adequately addressed the issues under consideration for this rule-making.

Thank you for the opportunity to review and comment on this Notice of Intent.

Sincerely,



John C. Villforth
Director
Bureau of Radiological Health