



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

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August 2, 1979

The Honorable Henry B. Gonzalez
United States House of Representatives
Washington, D. C. 20515

Dear Congressman Gonzalez:

Your letter to President Carter expressing concern about nuclear power in light of the Three Mile Island Unit 2 (TMI-2) accident has been referred to me. I am pleased to have the opportunity to respond to your concerns.

As you are aware, several groups are in the process of investigating the Three Mile Island accident as well as its implications on nuclear power and the regulatory process. These groups, including the President's Commission, Congressional Committees, the GAO, the Nuclear Regulatory Commission, and the nuclear industry, will be providing critical assessments from a variety of viewpoints.

As a result of the TMI-2 accident, the NRC has already taken a number of actions to improve conditions at operating plants regarding the specific items mentioned in your letter. For example, the operators of all plants designed by Babcock and Wilcox (B&W) similar to TMI-2 have received additional training to assure that they understand and can manipulate the controls properly in the event of an incident such as that which occurred at TMI-2. Immediately following the TMI-2 accident, Bulletins and Orders were issued to all pressurized water reactor facilities requiring certain specific actions and precautions be taken to avoid safety related problems identified at TMI-2. The investigations referred to above will include a hard look at a broad spectrum of operator-related issues including training, staffing, the adequacy of information available to operators, operating procedures, and various aspects of human engineering. The objective of these reviews will be to make the operator more effective in mitigating accidents. I should also emphasize that, although the B&W reactors have been our primary concern, we have taken actions to assure that the "lessons learned" from the TMI-2 accident are applied to Westinghouse and Combustion Engineering reactors as well.

With regard to emergency preparedness, a renewed examination of the emergency response capability of licensees and local, State and Federal officials is being undertaken. The Commission has recently established a Task Force on Emergency Planning which is to formulate the scope, direction and pace of the NRC's overall emergency planning activities, and to report to the Commission next month. In addition, an Advance Notice of Expedited Rulemaking

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relating to emergency planning in the vicinity of nuclear facilities has been published. (Enclosure 1) The NRC has also recently completed the installation of direct and dedicated telephone lines between operating plants, the NRC Response Center and the NRC Regional Offices. This system is currently being tested. In addition to the improvements to off-site response capability, increased priority will be given to the licensee's post-accident monitoring equipment. Such equipment will be upgraded where necessary to improve the ability of licensees to determine the magnitude of an accidental release and to inform others of it.

There are many more areas where improvements will be considered. A task force of our Office of Nuclear Reactor Regulation is analyzing the TMI-2 accident to determine what additional regulatory requirements and guidance may be needed to assure that the "lessons learned" from the accident are promptly applied to all nuclear power facilities. Requirements for design changes and operational improvements beyond those already being implemented are likely to result. These requirements will be reflected in new or revised NRC regulations, changes in review and inspection practices and procedures, new or revised industry standards, and improved and more explicit regulatory guidance.

As your letter suggests, the NRC is undertaking an extensive immediate review of all operating PWRs to assure that specific minimum design and operational measures identified as a result of the TMI-2 accident are being implemented. In the course of considering the need for such measures, all B&W designed plants were shut down or remained shut down until all such measures could be implemented. In addition, the licensees of boiling water reactors (BWR) have been asked to review the TMI-2 events and determine the implications, if any, for their plants.

As these reviews continue it is likely that the need for additional measures will be identified for implementation in the short term on operating plants. In the long term, the many investigations will likely result in the need for further changes to improve or enhance the safety of operating plants.

The TMI-2 accident also has significant implications for plants in various stages of the licensing process. These include plants currently under NRC staff review for Construction Permits or Operating Licenses and plants under construction (in the post-Construction Permit stage between the Construction Permit and Operating License reviews). The proposed design and operation of all such plants will be reviewed by the NRC staff in light of the lessons learned from the TMI-2 accident. The result of such reviews will likely be facility design modifications and changes to operation and emergency procedures for most plants.

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The timing of these reviews for individual plants will depend on many factors including the status of plant construction; the status of staff review of the application; the status of and requirements for licensing hearings and review by the NRC's Advisory Committee on Reactor Safeguards; the specific licensing requirements that are developed from the many post-TMI-2 investigations and studies and the timing of such investigations and studies. The NRC staff's highest priorities at this time are to continue those necessary activities at the Three Mile Island site and to assure that specific immediate remedial actions are implemented at operating plants as discussed above.

With regard to licensing reviews, the NRC staff is initially focusing its efforts on plants that are in the final stages of operating license review. At a minimum, these plants will be reviewed in the same manner as plants already operating with regard to needed remedial actions. As the TMI-2 studies and investigations proceed, it is likely that additional actions that must be implemented in the short term prior to issuance of an operating license will be identified. The staff will complete the necessary reviews and report its findings related to whether such short-term actions must also be implemented prior to a decision to issue an operating license for each plant. Although no formal moratorium has been declared, it is anticipated that it will take at least three months for such reviews to be completed and for the necessary pre-licensing changes to be implemented.

These studies and investigations will likely also identify actions that should be implemented in the longer term after Operating License issuance. The necessary actions, if clearly identified at the time, can be included as license conditions requiring action at various stages of operation, e.g., actions required prior to fuel loading; actions required prior to criticality; actions required prior to power operation; actions required by the first refueling; etc.

With regard to Construction Permits, a similar process will be utilized. Those staff reviews necessary before Construction Permit issuance will be conducted for each application. Additional reviews will likely be necessary in the post-Construction Permit stage or as part of the NRC staff's Operating License review. Such reviews can be left to the Operating License stage only if the required (by regulation) Construction Permit findings can be made and it is reasonable to do so, i.e., if waiting until the Operating License stage will not foreclose implementing design modifications necessary to assure safe operation of the facility.

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With regard to the resolution of other safety questions referred to in your letter, the NRC reports to Congress in accordance with Section 210 of the Energy Reorganization Act of 1974, as amended, on its plans to resolve "Unresolved Safety Issues." The report, "Identification of Unresolved Safety Issues Relating to Nuclear Power Plants" (NUREG-0510, Nov. 1978), describes the issues being examined to determine whether our requirements should be modified for new and operating plants (Enclosure 2). A copy is enclosed. An unresolved safety issue is considered on a generic basis only after the staff has made an initial evaluation for individual plants and determined that the safety significance of the issue does not prohibit continued operation or require licensing actions while the longer term generic review is underway. The most recent report on the unresolved safety issues is included in Chapter 2 of the 1978 NRC Annual Report (Enclosure 3). The report defines an "Unresolved Safety Issue", identifies and discusses each issue and discusses the NRC staff's plans for and status of resolution of each.

The "Unresolved Safety Issues" Program has been impacted to some extent by the diversion of manpower to work on Three Mile Island related issues. However, steps are being taken at this time to reallocate the necessary resources to revitalize the "Unresolved Safety Issues" Program with the objective of restoring the schedules to those reported in the 1978 NRC Annual Report. In addition, quite clearly, additional technical issues that qualify as "Unresolved Safety Issues" will be identified in the months ahead. These issues will be identified and discussed in the 1979 Annual Report.

To ensure that waste management is given increased attention, earlier this year we created a Division of Waste Management within our Office of Nuclear Material Safety and Safeguards. We are placing a great deal of emphasis on organizing, consolidating, and staffing this new division so that we can be fully responsive to concerns such as those you have raised in the waste management area.

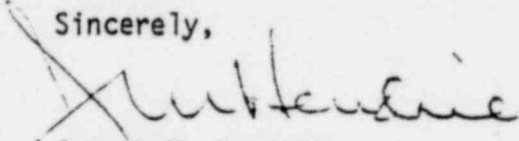
I fully agree that this is a serious moment for nuclear power in the United States. As I remarked to the Congress in testimony shortly after the accident, it is my view, as I am sure it is yours, that we cannot have an acceptable nuclear power program in this country if there is any appreciable risk of events of the Three Mile Island kind occurring at nuclear power plants. I am confident that the necessary changes to plant design and operations and licensing requirements and practices can be identified and implemented as necessary to maintain that risk at an acceptably low level.

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In your letter to President Carter you recommend that the Commission should have a policy of shutting down nuclear power plants when there are questions concerning safety. Let me assure you that the Commission's policy is to order whatever action may be necessary, including shutdown, to protect public health and safety. Our actions earlier this year in shutting down five plants because of seismic design deficiencies and our more recent actions with respect to the B&W plants clearly indicate our commitment to protecting public health and safety.

Carlton Kammerer of our Office of Congressional Affairs has acknowledged the receipt of your letters to me of April 3, 1979 and April 5, 1979. My comments above discuss some of the information requested in those letters. My staff is working to respond to all of the information requests received over the past several months as expeditiously as possible. Specific responses to your letters of April 3 and 5 will be provided shortly.

Sincerely,


Joseph M. Hendrie

Enclosures:

1. Federal Register notice (44FR 4183)
"Adequacy and Acceptance of Emergency
Planning Around Nuclear Facilities"
2. NUREG-0510
3. 1978 NRC Annual Report

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installation information shall be submitted as soon as possible and the applicant shall permit verification by the International Atomic Energy Agency and take such other action as may be necessary to implement the US/IAEA Safeguards Agreement, in the manner set forth in §§ 75.8, 75.11-75.14 of this chapter. The Commission will grant an exemption from this requirement, upon application, if it determines that the installation will not be included on the United States eligible list.

Part 170—Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended

12. Section 170.11 is amended by adding a new paragraph (a)(10) to read as follows:

§ 170.11 Exemptions.

(a) No application fees, licensee fees, renewal fees, or inspection fees shall be required for:

(10) Activities of the Commission undertaken, pursuant to Part 75 of this chapter, solely for the purpose of implementation of the US/IAEA Safeguards Agreement.

Dated at Washington, DC this 12th day of July, 1979.

For the Nuclear Regulatory Commission,

Samuel J. Chalk,

Secretary of the Commission.

(FR Doc. 79-2207 Filed 7-15-79; 8:45 am)

BILLING CODE 7590-01-01

Adequacy and Acceptance of Emergency Planning Around Nuclear Facilities

[10 CFR Part 50]

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Advance Notice of Proposed Rulemaking.

SUMMARY: The Nuclear Regulatory Commission is considering the adoption of additional regulations which will establish as conditions of power reactor operation increased emergency readiness for public protection in the vicinity of nuclear power reactors on the part of both the licensee and local and state authorities. The Commission is interested in receiving public comment on objectives for effective plans, acceptance criteria for State/local emergency plans, NRC concurrence in State and local plans as a requirement for issuance of an operating license or

for continued operation of a nuclear facility, and coordination between the licensee plan and State and local plans. The Commission seeks written comments on what items should be included in the rule.

DATES: Comments are due no later than August 31, 1979.

ADDRESSES: Written comments concerning these issues should be submitted to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Patricia A. Comella, Site Designation Branch, Office of Standards Development, Nuclear Regulatory Commission, Washington, DC 20555, 301-443-5981.

SUPPLEMENTARY INFORMATION: The NRC requires that power reactor licensee applicants plan for radiological emergencies within their plant sites and make arrangements with State and local organizations to respond to accidents that might have consequences beyond the site boundary. In this way off-site emergency planning has been related to the nuclear licensing process. See 10 CFR Part 50, Appendix E (1979), see also additional guidance in U.S. NRC, Regulatory Guide 1.101, "Emergency Planning for Nuclear Power Plants," (Rev. 1, 1977).

To aid State and local governments in the development and implementation of adequate emergency plans, the NRC, in conjunction with seven other Federal agencies, has attempted, on a cooperative and voluntary basis, to provide for training and instruction of State and local government personnel and to establish criteria to guide the preparation of emergency plans. However, the NRC has not made NRC approval of State and local emergency plans a condition of nuclear power plant operation.

The accident at Three Mile Island has raised a number of questions about the adequacy of radiological emergency response plans. Even before the accident the GAO had recommended that NRC not license new power plants for operation unless off-site emergency plans have been approved by the NRC. GAO, Report to the Congress, "Areas Around Nuclear Facilities Should Be Better Prepared For Radiological Emergencies," March 30, 1978. The Commission is also considering new guidance to State and local governments on emergency planning, based on an analysis of a joint NRC-EPA Task Force Report, "Planning Basis for Development of State and Local Government Radiological Emergency Response Plans

in Support of Light Water Nuclear Power Plants," NUREG-0396/EPA 520/1-78-016, December 1978. See 43 Fed. Reg. 58658 (December 15, 1978), see also 44 Fed. Reg. 23137 (April 18, 1979). Furthermore, a number of organizations, including Critical Mass and Public Interest Research Groups, have renewed and supplemented a petition for rulemaking, previously denied by the Commission, concerning the operational details of evacuation planning. See 44 FR 32486 (June 6, 1979).

The Commission has decided to initiate an expedited rulemaking procedure on the subject of State and local emergency response plans and those of licensees. The Commission is soliciting public comments in this area, particularly on the following issues:

1. What should be the basic objectives of emergency planning?

a. To reduce public radiation exposure?

b. To prevent public radiation exposure?

c. To be able to evacuate the public?

To what extent should these objectives be quantified?

2. What constitutes an effective emergency response plan for State and local agencies? For licensees? What are the essential elements that must be included in an effective plan? Do existing NRC requirements for licensees (10 CFR Part 50, Appendix E) and guidance for States (NUREG-75/111) lack any of these essential elements?

3. Should NRC concurrence in the associated State and local emergency response plans be a requirement for continued operation of any nuclear power plant with an existing operating license? If so, when should this general requirement become effective?

4. Should prior NRC concurrence in the associated State and local emergency response plans be a requirement for the issuance of any new operating license for a nuclear power plant? If so, when should this general requirement become effective?

5. Should financial assistance be provided to State and local governments for radiological emergency response planning and preparedness? If so, to what extent and by what means? What should be the source of the funds?

6. Should radiological emergency response drills be a requirement? If so, under whose authority: Federal, State or local government? To what extent should Federal, State, and local governments, and licensees be required to participate?

7. How and to what extent should the public be informed, prior to any

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emergency, concerning emergency actions it might be called upon to take?

8. What actions should be taken in response to the recommendations of the joint NRC/EPA Task Force Report (NUREG-0096/EPA 520/1-78-016)?

9. Under what circumstances and using what criteria should a licensee notify State, local, and Federal agencies of incidents, including emergencies?

10. How, to what extent, and by what means should the public be notified of major incidents?

The comments received will be solicited and evaluated by the NRC staff, which will, in turn, submit recommendations on proposed rules to the Commission. Based on the comments it receives from the public and the analysis of the problem presented by the NRC staff, the Commission will determine whether to proceed with a proposed rule for notice and comment and/or whether to make such rule immediately effective. The Commission anticipates completion of this expedited rulemaking in approximately six months.

The NRC staff is presently conducting a comprehensive review of all aspects of the NRC emergency planning and preparedness program. Therefore, the Commission is also interested in receiving comments on all other aspects of emergency planning, including issues raised in the Critical Mass/PIRG petition for rulemaking and questions such as the following:

10. How and to what extent should the concerns of State and local governments be incorporated into Federal radiological emergency response planning?

11. How should Federal agencies interface with State and local governments and the licensee during emergencies?

12. Should the licensees be required to provide radiological emergency response training for State and local government personnel? If so, to what extent? Should the Federal government provide such training? If so, to what extent?

13. To what extent should reliance be placed on licensees for the assessment of the actual or potential consequences of an accident with regard to initiation of protective action? To what extent should this responsibility be borne by Federal, State or local governments?

14. Would public participation in radiological emergency response drills, including evacuation, serve a useful purpose? If so, what should be the extent of the public participation?

Dated at Washington, D.C., this 12th day of July, 1979.

For the Commission,
Samuel J. Chalk,
Secretary of the Commission.
(FR Doc. 79-32978 Filed 7-17-79; FR 445 445)
BILLING CODE 7930-01-2

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 620]

[Doclet No. 79N-0425]

Bacterial Products; Additional Standards for Typhoid Vaccine

AGENCY: Food and Drug Administration.
ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics Typhoid Vaccine regulations to ensure further the antigenic integrity of the Ty 2 strain of bacteria used in vaccine production and to require that licensed manufacturers obtain the U.S. Opacity Standard from the Bureau of Biologics. The FDA is also proposing to amend these regulations by establishing new standards for the performance and results of the potency test for each lot of manufactured Typhoid Vaccine.

DATE: Comment by September 17, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Michael L. Hooton, Bureau of Biologics (HFB-020), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, MD 20014, 301-443-1306.

SUPPLEMENTARY INFORMATION: The Commissioner is proposing to amend the biologics regulations for manufacturing Typhoid Vaccine by setting potency standards for the Ty 2 strain of *Salmonella typhosa* used in the manufacture of Typhoid Vaccine and by revising the potency test under § 620.13 (21 CFR 620.13) consistent with new scientific knowledge derived from past experience with the product.

In the United States, typhoid disease has been in decline in recent years and routine typhoid vaccination is no longer recommended. However, immunization is indicated if a person has come into contact with a known typhoid carrier, if there is an outbreak of typhoid fever in the community, or if a person plans to travel to an area where typhoid fever is endemic.

Under section 351 of the Public Health Service Act (42 U.S.C. 262), Typhoid Vaccine offered for sale, barter, or exchange in interstate commerce must be licensed and meet certain standards that ensure its continued safety, purity, potency, and effectiveness. Minimum requirements for Typhoid Vaccine were first established on December 8, 1953, and revised on September 30, 1966. Additional standards were published in the Federal Register on June 4, 1969 (34 FR 8914) and recodified as §§ 620.10 through 620.15 (21 CFR 620.10 through 620.15), on November 20, 1973 (38 FR 32048). Under § 620.14(c) of the additional standards (21 CFR 620.14(c)), Typhoid Vaccine shall not be issued by the manufacturer until written notification of official release is received from the Director, Bureau of Biologics (BOB). Official written release is issued only after the Director has reviewed the protocol and tested samples to ensure the continued safety, purity, potency, and effectiveness of Typhoid Vaccine.

On the basis of new scientific knowledge derived from product release data accumulated and analyzed by BOB for the past several years, FDA is proposing amendments to the additional standards for Typhoid Vaccine, including the following:

(1) Strain Ty 2 of *Salmonella typhosa* is used in the manufacture of Typhoid Vaccine. To ensure the antigenic integrity of the Ty 2 strain, FDA is proposing to amend § 620.11 (21 CFR 620.11) to require that antigenic integrity be verified by the agglutination of living bacteria by a Ty 2 antiserum.

(2) To clarify the source for obtaining necessary reference materials, FDA proposes to amend § 620.12 (21 CFR 620.12) to require that the U.S. Standard Typhoid Vaccine and the U.S. Opacity Standard be obtained from the Bureau of Biologics.

(3) Saline is required for use in dilutions of the vaccine and challenge doses used in the potency test. The use of phosphate-buffered saline (PBS) by the BOB has not resulted in any detectable changes in the potency test. Accordingly, FDA is proposing to amend § 620.13(b)(1) and (c)(2) to permit the use of PBS for diluting the vaccine, the challenge, and virulence titrations of Strain Ty 2 of *Salmonella typhosa*.

(4) Based on statistical methods used in, and results derived from, Typhoid Vaccine potency tests performed at the BOB, FDA is proposing to amend § 620.13(e) to require that new statistical methods be used for determining the validity of the potency test. For consistency, FDA proposes to amend

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Congress of the United States
House of Representatives
Washington, D.C. 20515

April 23, 1979

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GENERAL OVERSIGHT AND RENEGOTIATION

The Honorable James E. Carter
The President of the United States
The White House
Washington, D. C. 20500

FILE NO. AJEC:1979
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APR 27 1979
cc: TMI Comm., Eisenhower

Dear Mr. President:

I believe that there should be a moratorium on the issuance of licenses for new nuclear power plants; that all plants now in operation should be carefully reviewed for safety; and that no new plants be licensed for operation until questions concerning safety and the integrity of the Nuclear Regulatory Commission safety program can be significantly improved.

As a person of training and experience in nuclear power, you know the risks better than most people. You know, for example, that engineering that is amply safe can be rendered unsafe by improper operation. You also know that some designs are safer than others and that some regulatory agencies are more effective than others.

It is clear that certain nuclear power plants are less safe than others. I have had reports that Pilgrim (Boston) is not particularly safe; that Indian Point (New York) poses problems; and you know, of course, about accidents at Browns Ferry (Alabama) and others. The Nuclear Regulatory Commission rates plants on relative safety, and I believe that wherever there is any question about plant safety that plant should be shut down. You should ask the Commission to make clear that you would support such a policy.

It is also clear that a good part of the problem at Three Mile Island was caused by improper operation. As time passes, it is becoming evident that operator training programs are notable by their absence; that emergency procedures are woefully inadequate; and that the self-regulation of the industry cannot be counted upon to prevent lax or improper operation. Commissioner Bendrie, him-

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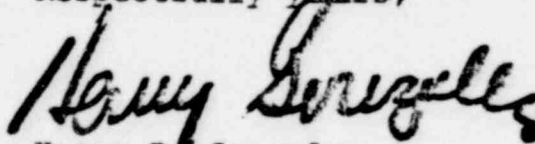
self, recognizes that NRC regulation has been inadequate. Until that can be corrected, there should be no further granting of operational licenses for nuclear power plants.

There is also growing evidence that not all safety questions have been successfully addressed. The NRC itself has repudiated its previous estimates on plant safety (the Rasmussen report) and listed a large number of unresolved safety issues.

Further, the problem of waste disposal has yet to be solved. Until that is done, the nuclear power industry is, in fact, operating only on an ad hoc basis. It seems unreasonable to expand the industry further at a time when its longest lasting problem, waste disposal, is only now being addressed and is long from being resolved. Not even the most placid community in the country would welcome a permanent waste facility, and as you know, temporary sites are subject to growing controversy.

This is a serious moment for the nuclear power industry. It is not a time for reassurances; it is a time for reassessment. Anything less only begs the real issue. Your leadership in providing a reassessment will resolve questions that have been growing for years, and were dramatized by the incident at Three Mile Island.

Respectfully yours,



Henry B. Gonzalez
Member of Congress

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