



STATEMENT OF POLICY

*Attachment 18*

The Nuclear Regulatory Commission has instituted a Special Inquiry to review and report on the accident which took place at the Three Mile Island Nuclear Station No. 2 beginning on March 28, 1979. The primary objective of the inquiry will be to prepare a report which makes factual determinations concerning the actual events which occurred and their causes, and the actions of utility and Commission personnel before and during the accident. The inquiry will also identify areas of deficiency revealed by the accident and areas in which further investigation is warranted.

The Commission will contract with the law firm of Rogovin, Stern and Huge, Washington, D.C., to conduct the Special Inquiry. The inquiry will be headed by a Director, Mitchell Rogovin. Mr. Rogovin will have the authority to designate a staff of his choosing, including both NRC personnel, and staff and consultants from outside the Commission. It is expected that in assembling a staff, the Director will draw substantially on senior Commission staff, including Commission personnel and consultants currently engaged in conducting an interim inquiry into the matter. The Director will possess full independence in carrying out the inquiry and will be removable only for malfeasance or neglect of duty. To further such independence the Director will maintain records of all discussions bearing on the inquiry between those conducting the inquiry and any member of the Commission or a Commissioner's personal staff. The Commission will designate a senior NRC official to whom it will delegate its statutory power

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to conduct investigations, issue subpoenas, and administer oaths in order that these powers will be available to further the Special Inquiry. The Commission will grant to the Director access to any and all documents and employees of the Commission that he deems necessary to conduct a full and complete inquiry, and will provide appropriate administrative support for carrying out the inquiry. It is expected that reports issued and analyses performed by other persons and organizations will be utilized where useful. It is anticipated that the Special Inquiry will take approximately six months.

The Special Inquiry represents a major phase of the Commission's evaluation of the accident and its implications. It is not intended to duplicate the efforts of the President's Commission on the Accident at Three Mile Island. It is designed instead so that the Nuclear Regulatory Commission, in order to fulfill its own regulatory responsibilities, will have the fullest possible understanding of the events at Three Mile Island, both from the technical standpoint and from the standpoint of how its regulatory processes functioned. The purpose of that evaluation is to permit the Commission to take whatever further steps may be necessary to prevent any similar accident in the future, and to improve the NRC's ability to respond to accidents.

The specific areas which the Special Inquiry will examine include the following:

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- the sequence of events during the accident, what was happening to the reactor and the plant, including, where feasible, an assessment of important alternative sequences; the response of the operating personnel; radioactive releases and exposures; events at the plant before the accident that might be related to the accident.
  
- the history of the NRC review of the utility's application for a license to operate Three Mile Island No. 2; NRC license conditions on TMI-2 operations, including technical specifications; the operating and inspection history at TMI-2; the operating and inspection histories of other Babcock & Wilcox plants, focused on any indications of the types of problems that arose in the TMI-2 accident; a summary of NRC past consideration of such problems; the extent to which financial or tax considerations influenced conditions in the plant in any way that might have contributed to the accident; any other precursor events or analyses relevant to the accident.
  
- the susceptibility of Babcock & Wilcox plants to accidents; unique features of TMI-2 that may have increased or decreased the severity of the accident; other design effects related to the TMI-2 accident.

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- TMI-2 operations, including training and qualifications of personnel, operating procedures and management overview; technical support to operating personnel and management.
- emergency response to the TMI-2 accident by the utility, other utilities and utility groups, and industrial organizations, including coordination with NRC and other Federal, State, and local officials, and assessment and dissemination of information.
- emergency planning by, and emergency response plans approved by, the NRC; actual emergency response to the accident by NRC, including staff, ACRS and Commissioners, on site and at headquarters; NRC coordination with Federal, State, and local officials, the utility, industry sources, and the national laboratories; NRC assessment and dissemination of information; communications and chain of command within NRC.

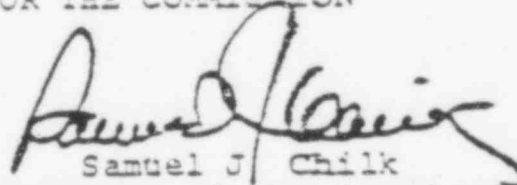
The Special Inquiry will also assess the possible implications of the accident at TMI-2 (including design of the facility, operations, regulatory actions, emergency preparedness) for other nuclear power plants and identify areas where further study is recommended. Based on these assessments and recommendations, the Commission will undertake such additional investigations, analyses and actions as it considers appropriate in the discharge of its responsibilities.

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The Director will keep the Commission informed on a periodic basis of the progress of the inquiry. Any information of immediate public health or safety significance will be reported promptly to the Commission. The Commission emphasizes that it will take whatever regulatory action it deems necessary at any time, based on information available to it at that time. By instituting the Special Inquiry, the Commission intends no suggestion that it will withhold regulatory action with respect to identified deficiencies until the inquiry is completed.

FOR THE COMMISSION



Samuel J. Chilk  
Secretary of the Commission

Dated at Washington, D. C.  
this 13th day of June, 1979

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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 §§ 75.5, 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. 79-2327 Filed 7-18-79; 254 pp.)  
BILLING CODE 7890-91-8

**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 license 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 1.107, "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, "Are/Is 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 527/1-78-018, December 1978. See 43 Fed. Reg. 58658 (December 15, 1978), see also 44 Fed. Reg. 25137 (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 written 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

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-0398/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? When, how, to what extent, and by whom should the public be notified of these incidents?

The comments received will be collected 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. 79-2379 Filed 7-16-79; 9:48 am)

SELLING CODE 7599-71-8

DEPARTMENT OF HEALTH,  
EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 620]

[Docket No. 78N-9425]

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-620), 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 21, 1965. Additional standards were published in the Federal Register on June 4, 1969 (34 FR 8974) and recodified as §§ 620.10 through 620.15 (21 CFR 620.10 through 620.15), on November 29, 1973 (38 FR 32048). Under § 620.14(c) of these 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 preclinical 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 their 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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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS  
WASHINGTON, D. C. 20555

ATTACHMENT 20

April 7, 1979

Honorable Joseph M. Hendrie  
Chairman  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555

SUBJECT: INTERIM REPORT ON RECENT ACCIDENT AT THE THREE MILE ISLAND  
NUCLEAR STATION UNIT 2

Dear Dr. Hendrie

During its 228th meeting, April 5-7, 1979, the Advisory Committee on Reactor Safeguards reviewed the circumstances relating to the recent accident at the Three Mile Island Nuclear Station Unit 2. During this review, the Committee had the benefit of discussions with the NRC Staff.

Our study of the accident at Three Mile Island has shown that it is very difficult for a PWR plant operator to understand and properly control the course of an accident involving a small break in the reactor coolant system accompanied by other abnormal conditions.

The Committee recommends that further analyses be made, as soon as possible, of transients and accidents in PWRs that involve initially, or at some time during their course, a small break in the primary system. The computer codes used for these analyses should be capable of predicting the conditions observed during the accident at Three Mile Island, including thermal-hydraulic effects and clad and fuel temperatures. The range of break sizes considered should include the smallest that could be deemed significant, and should consider a range of break locations.

The Committee believes that the analyses recommended above will demonstrate, as has the accident at Three Mile Island, that additional information regarding the status of the system will be needed in order for the plant operator to follow the course of an accident and thus be able to respond in an appropriate manner. As a minimum, and in the interim, it would be prudent to consider expeditiously the provision

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April 7, 1979

of instrumentation that will provide an unambiguous indication of the level of fluid in the reactor vessel. Early consideration should be given also to providing remotely controlled means for venting high points in the reactor system, as practical.

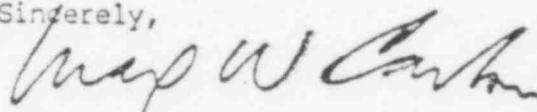
The foregoing recommendations apply to all pressurized water reactors.

The recommendations in IE Bulletin 79-05A, dated April 5, 1979, are believed to be generally suitable for Babcock and Wilcox facilities, on an interim basis. However, the Committee believes that the actions listed in Item 4b. under the heading, "Actions To Be Taken by Licensees," may prove to be unduly prescriptive in view of the uncertainties in predicting the course of anomalous transients or accidents involving small breaks in the primary system.

With regard to Three Mile Island Unit 2, the Committee believes that decisions should be made expeditiously with regard to contingency measures which may be prudent concerning containment and reactor cooldown as a backup to the currently planned cooldown procedure.

The Committee is continuing its review of these and other concerns arising from this accident and will provide further advice as it is developed.

Sincerely,



Max W. Carbon  
Chairman

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April 17, 1979

RECOMMENDATIONS OF THE NUCLEAR REGULATORY COMMISSION ADVISORY COMMITTEE  
ON REACTOR SAFEGUARDS REGARDING THE MARCH 28, 1979 ACCIDENT AT  
THE THREE MILE ISLAND NUCLEAR STATION UNIT 2

Presented orally to, and discussed with, the NRC  
Commissioners during the ACRS-Commissioners Meeting  
on April 17, 1979 - Washington, D. C.

Natural circulation is an important mode of reactor cooling, both as a planned process and as a process that may be used under abnormal circumstances. The Committee believes that greater understanding of this mode of cooling is required and that detailed analyses should be developed by licensees or their suppliers. The analyses should be supported, as necessary, by experiment. Procedures should be developed for initiating natural circulation in a safe manner and for providing the operator with assurance that circulation has, in fact, been established. This may require installation of instrumentation to measure or indicate flow at low water velocity.

The use of natural circulation for decay heat removal following a loss of offsite power sources requires the maintenance of a suitable overpressure on the reactor coolant system. This overpressure may be assured by placing the pressurizer heaters on a qualified onsite power source with a suitable arrangement of heaters and power distribution to provide redundant capability. Presently operating PWR plants should be surveyed expeditiously to determine whether such arrangements can be provided to assure this aspect of natural circulation capability.

The plant operator should be adequately informed at all times concerning the conditions of reactor coolant system operation which might affect the capability to place the system in the natural circulation mode of operation or to sustain such a mode. Of particular importance is that information which might indicate that the reactor coolant system is approaching the saturation pressure corresponding to the core exit temperature. This impending loss of system overpressure will signal to the operator a possible loss of natural circulation capability. Such a warning may be derived from pressurizer pressure instruments and hot leg temperatures in conjunction with conventional steam tables. A suitable display of this information should be provided to the plant operator at all times. In addition, consideration should be given to the use of the flow exit temperatures from the fuel subassemblies, where available, as an additional indication of natural circulation.

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The exit temperature of coolant from the core is currently measured by thermocouples in many PWRs to determine core performance. The Committee recommends that these temperature measurements, as currently available, be used to guide the operator concerning core status. The range of the information displayed and recorded should include the full capability of the thermocouples. It is also recommended that other existing instrumentation be examined for its possible use in assisting operating action during a transient.

The ACRS recommends that operating power reactors be given priority with regard to the definition and implementation of instrumentation which provides additional information to help diagnose and follow the course of a serious accident. This should include improved sampling procedures under accident conditions and techniques to help provide improved guidance to offsite authorities, should this be needed. The Committee recommends that a phased implementation approach be employed so that techniques can be adopted shortly after they are judged to be appropriate.

The ACRS recommends that a high priority be placed on the development and implementation of safety research on the behavior of light water reactors during anomalous transients. The NRC may find it appropriate to develop a capability to simulate a wide range of postulated transient and accident conditions in order to gain increased insight into measures which can be taken to improve reactor safety. The ACRS wishes to reiterate its previous recommendations that a high priority be given to research to improve reactor safety.

Consideration should be given to the desirability of additional equipment status monitoring on various engineered safeguards features and their supporting services to help assure their availability at all times.

The ACRS is continuing its review of the implications of this accident and hope to provide further advice as it is developed.

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS  
WASHINGTON, D. C. 20555

ATTACHMENT 22

April 20, 1979

Honorable Victor Gilinsky  
Acting Chairman  
U. S. Nuclear Regulatory Commission  
Washington, DC 20555

Dear Dr. Gilinsky:

This letter is in response to yours of April 18, 1979 which requested that the ACRS notify the Commissioners immediately if we believe any of our oral recommendations of April 17 should be acted upon before our next regularly scheduled meeting at which we could prepare a formal letter. The Committee discussed this topic by conference telephone call on April 19 and offers the following comments.

All of the recommendations made by the ACRS in its meeting with the Commissioners on April 17, 1979, are generic in nature and apply to all PWRs. None were intended to require immediate changes in operating procedures or plant modifications of operating PWRs. Such changes should be made only after study of their effects on overall safety. Such studies should be made by the licensees and their suppliers or consultants and by the NRC Staff. The Committee believes that these studies should be begun in the near future on a time scale that will not divert the NRC Staff or the industry representatives from their tasks relating to the cooldown of Three Mile Island Unit 2. However, the Committee believes that it would be possible and desirable to initiate immediately a survey of operating procedures for achieving natural circulation, including the case when offsite power is lost, and the role of the pressurizer heaters in such procedures.

At its meeting on April 16 and 17, 1979, the Committee discussed with the NRC Staff the matter of natural circulation for the Three Mile Island Unit 2 plant. The Committee believes that this matter is receiving careful attention by the NRC Staff and the licensee.

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Honorable Victor Gilinsky

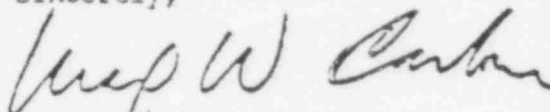
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April 20, 1979

The Committee's own recommendations to the Commission on April 17 were not intended to apply to Three Mile Island Unit 2.

We plan to write a further report on these matters at our May 10, 1979 meeting.

Sincerely,

A handwritten signature in cursive script, appearing to read "Max W. Carbon".

Max W. Carbon  
Chairman

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