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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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In the Matter of)

PETITION FOR RULEMAKING BY)
SOUTHERN CALIFORNIA EDISON)
COMPANY)
_____)

DOCKET NO. _____

PETITION FOR RULEMAKING ON EMERGENCY
ARRANGEMENTS FOR MEDICAL SERVICES FOR CONTAMINATED
INJURED INDIVIDUALS, 10 C.F.R. 50.47(b)(12)

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Attachments filed in DS B

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I.

INTRODUCTION

On February 12, 1985, the United States Court of Appeals for the District of Columbia held that the Nuclear Regulatory Commission's generic interpretation of its regulations governing emergency arrangements for medical services in the event of a radiological emergency at a nuclear power reactor could not be sustained. GUARD v. Nuclear Regulatory Commission, 753 F.2d 1144, 1150 (D.C. Cir. 1985) (cited hereinafter as "GUARD v. NRC"). In the words of the Court:

"The petition for review questions whether it is rational to qualify, as a form of 'arrangements . . . made for medical services' for persons 'exposed to dangerous-levels of radiation,' mere identification of

whatever facilities happen to exist. We hold that the Commission did not reasonably interpret the section 50.47(b)(12) phrase 'arrangements . . . made for medical services' when it declared, generically, that a simple list of treatment facilities already in place constitutes such arrangements." 753 F.2d at 1146.

Accordingly, the Court vacated the Commission and Licensing Board Decisions in Southern California Edison Company, et al. (San Onofre Nuclear Generating Station, Units 2 and 3, Docket Nos. 50-361 OL and 50-362 OL; referred to collectively as "San Onofre"), in which the challenged interpretation had been made, and remanded the matter to the Commission "for further consideration consistent with this opinion." 753 F.2d at 1150. In so ruling, the Court stated:

"[W]e impose no tight restraint on the NRC's regulatory authority. The Commission, on remand, may concentrate on the SONGS record; it may revisit the question, not now before us for review, of the scope of the section 50.47(b)(12) phrase 'contaminated injured individuals'; it may describe genuine 'arrangements' for medical services for dangerously exposed members of the general public; or it may pursue any other rational course." 753 F.2d at 1146 (emphasis added).

In this petition for rulemaking, Petitioner Southern California Edison Company (the "Petitioner") requests the Commission to accept the Court's invitation to revisit the question of the proper scope of the phrase in 10 C.F.R. § 50.47(b)(12) "contaminated injured individuals." Specifically, Petitioner requests that the Commission amend 10 C.F.R. § 50.47(b)(12) to expressly clarify that onsite and

offsite emergency response plans need only include medical arrangements for persons who are both contaminated with radioactive material and physically injured in some other manner which requires emergency medical treatment.

Petitioner submits that such a clarifying amendment is well-supported by the record in the operating license proceeding for San Onofre and is consistent with the studies leading to the adoption of 10 C.F.R. 50.47(b)(12). The San Onofre record demonstrates that persons suffering only from exposure to high levels of radiation would not require emergency medical services. As previously recognized by the Commission:

"The nature of radiation injury is that, while medical treatment may be eventually required in cases of extreme exposure, the patients are unlikely to need emergency medical care. The non-immediacy of the treatment required for radiation-exposed individuals provides onsite and offsite authorities with an additional period of time to arrange for the required medical service. Thus, any treatment required could be arranged for on an ad hoc basis." Southern California Edison Company, et al., (San Onofre Nuclear Generating Station, Units 2 and 3), CLI-83-10, 17 N.R.C. 528, 535-36 [Vol. I, pp. 160-61], quoted in Guard v. NRC, 753 F.2d at 1150.

Given the non-immediacy of the required treatment, such persons would be adequately identified and cared for on an ad hoc basis pursuant to (1) the existing requirements for relocation centers to register, monitor and decontaminate, as necessary, all persons in the plume exposure EPZ (10 C.F.R.

§ 50.47(b)(10); NUREG-0654 Planning Standard J), and (2) the existing accreditation requirements for hospitals, which assure sufficient facilities to provide treatment for onsite and offsite individuals suffering from excessive radiation exposure.

II.

PROPOSED AMENDMENT

10 C.F.R. § 50.47(b)(12) should be amended to read:

- (12) Arrangements are made for emergency medical services for persons who are both (i) contaminated with radioactive material and (ii) physically injured such that immediate treatment in a medical facility is required.

III.

PETITIONER'S INTEREST

Petitioner is one of the owners of the San Onofre Nuclear Generating Station, Units 2 and 3 ("SONGS 2 & 3") and is the licensed operator of SONGS 2 and 3.

The Court of Appeals decision in GUARD v. NRC has left undecided the planning standard to be applied pursuant to 10 C.F.R. 50.47(b)(12). Particularly, the class of people for whom advance arrangements for medical services are required is not clearly stated in 10 C.F.R. 50.47(b)(12) as presently worded. As a holder of an operating license subject to the Commission's regulations, Petitioner has an interest in having the meaning of 10 C.F.R. 50.47(b)(12) clarified. Moreover, Petitioner has an interest in the

establishment of standards for pre-arranged emergency medical services which are based upon a scientific and medical understanding of what is necessary and prudent to protect the public.

IV.

STATEMENT IN SUPPORT OF PETITION

a. Specific Issues Involved.

Petitioner believes that its petition raises one fundamental question:

Does the public safety require that emergency medical treatment be pre-arranged for severely irradiated persons who have not also suffered physical injury requiring immediate treatment in a medical facility?

b. Petitioner's View.

Petitioner contends that public safety does not necessitate the pre-arrangement of emergency medical treatment for severely irradiated persons who have not also suffered physical injury requiring immediate treatment in a medical facility. Specifically, Petitioner contends that scientific and medical studies, as well as evidence developed in hearings with respect to the licensing of SONGS 2 & 3, support the following conclusions:

(1) Time is not of the essence in treatment of excessive radiation and, therefore, persons suffering from irradiation do not require emergency treatment.

(2) The number of persons who potentially could be so severely irradiated as to require non-emergency

hospitalization is far less than existing hospitals are capable of treating. The nature of radiation injury is such that transport to facilities anywhere in the United States would not increase the danger to such persons.

(3) Petitioner's views are consistent with the studies upon which 10 C.F.R. 50.47(b)(12) was based.

c. Facts In Support of Petitioner's View.

In support of this petition for rulemaking, Petitioner is submitting to the Commission four volumes of documents,^{1/} a brief summary of which is as follows:

SONGS Record Volume I (pages 1-435): This volume is the Joint Appendix submitted to the United States Court of Appeals for the District of Columbia (Docket No. 84-1091; GUARD v. United States Nuclear Regulatory Commission, 753 F.2d 1144 (1985)).

SONGS Record Volume II (pages 436-543): This volume consists of selected testimony dealing with the necessity for arrangements for medical services for injured contaminated individuals pursuant to 10 C.F.R. 50.47(b)(12) from the extensive hearing record in the SONGS 2 & 3

^{1/} Bracketed citations in this petition refer to the cited documents as bound and paginated in the four SONGS Record volumes submitted with the petition. Citation is also made to cited documents as officially printed. Transcript references ("tr.") refer to the transcript from the hearing record developed in Southern California Edison Co. (San Onofre Nuclear Generating Station, Units 2 & 3), LBP-82-39, 15 NRC 1163 (1982).

Operating License Proceeding. (Southern California Edison Co. (San Onofre Nuclear Generating Station, Units 2 & 3), LBP-82-39, 15 NRC 1163 (1982) (NRC Docket Nos. 50-361 OL and 50-362 OL).

SONGS Record Volume III (pages 544-964): This volume consists of certain exhibits entered in the above-cited operating license proceeding.

SONGS Record Volume IV (pages 965-1364): This volume consists of excerpts from present emergency response plans of various California agencies and governments which are relevant to SONGS 2 & 3 as well as letters of agreement which are part of the SONGS 2 & 3 Emergency Plan.

The record in San Onofre provides ample evidence of the fact that persons experiencing excessive doses of radiation (such as might be received from a nuclear power plant accident) do not need immediate emergency medical attention. The conclusiveness of the evidence is reflected in the Licensing Board's Initial Decision of May 14, 1982 (15 NRC 1163) [vol. I, p. 1] and the Appeal Board's Decision (ALAB-680) of July 16, 1982 (16 NRC 127) [vol. I, p. 131].

The Licensing Board specifically found:

"4. Time is not of the essence in decontamination or treatment of excessive radiation. Treatment of a traumatic injury always takes precedence. Persons can be decontaminated at home or at any facilities where showers are available. (Linnemann, Tr. 7084, 7087 [Vol. II, pp. 440, 443], Hauck, Tr. 7121-22, 7798 [Vol. II, pp. 468-69, 477])

5. In excessive exposure cases, there is an uninterrupted clinical course which evolves over days and weeks. The gradual evolution of the injury allows for time in which to bring the results of tests and expertise to bear. (Linnemann, Tr. 7102-03, 10,843-44 [Vol. II, pp. 455-56, 535-36])" 15 NRC 1163, 1245 [Vol. I, p. 83].

The Appeal Board agreed with the Licensing Board's assessment of the time requirements for emergency medical treatment and concluded:

"People who suffer radiation injury, on the other hand, are unlikely to need emergency treatment." 16 NRC 127, 137 [Vol I, p. 141].

The medical basis for distinguishing the treatment of persons suffering only from irradiation was summarized by the Appeal Board as follows:

"Contaminated injured" is a distinct category encompassing potential patients whose traumatic (i.e., physical) injuries are complicated by radioactive contamination. As Dr. Roger E. Linnemann explained:

A patient who has been exposed to radiation does not, in turn, give off radiation any more than a burn[ed] patient gives off heat. There has been damage and . . . the clinical course unfolds over a period of time.

This means that we do have time to react and time to plan.

* * *

[T]he problem arises if the person is injured and contaminated. This requires special facilities at a hospital. It requires special facilities because we would rather not admit those persons to our normal emergency room because contamination is

loose. It can fall on the floor . . . in the emergency rooms, where people move in and out quite quickly, and the first thing you know you could cause contamination in the hallways of the hospital. . . . [T]herefore we have designed facilities where a patient can be treated for his traumatic injury while you control the contamination.

Tr. 7719-21 [Vol. II, pp. 466-68]. See also Tr. 7082-84, 7727-29, 7745-48 [Vol II, pp. 438-40; Vol. I, pp. 363-69]. Dr. Linnemann further explained that because the clinical course of radiation injury unfolds over time and 'is seldom, if ever, life threatening[,] . . . in all cases [treatment of] the traumatic injury takes precedence.' Tr. 7721 [Vol. II, p. 468]." 16 NRC 127, 137 [Vol. I, p. 141].

Thus, there is a significant medical distinction between the class of persons who are both contaminated and severely injured and those who are only irradiated.

As there are more than sufficient numbers of properly prepared hospitals to handle persons who suffer only from severe irradiation, recognition of this distinction in an amendment of 10 C.F.R. 50.47(b)(12) will in no way compromise the treatment and care of the general public.^{2/}

^{2/} With respect to the treatment of contamination, 10 C.F.R. § 50.47(b)(10) and Planning Standard J.12 of NUREG-0654 requires the designation of relocation centers capable of registering, monitoring and decontaminating all persons within the plume exposure emergency planning zone ("plume EPZ"). See, e.g., Incident Response Plan for San Onofre Nuclear Generating Station, County of Orange, Interjurisdictional Procedure No. 12 (Decontamination) [Vol. IV, p. 1164].

In any accident, the number of persons receiving severe radiation doses and requiring hospitalization would be relatively small. In San Onofre, for example, the Licensing Board assumed that, in the event of such a low-probability accident, there might be as many as 1000 persons who would receive doses requiring hospitalization. 15 NRC at 1200 n. 30 [Vol. I, p. 38]. Cf. Rood Tr. 10,339-41 [Vol. II, pp. 512-14]. Uncontroverted evidence in the record demonstrated, however, that those 1000 persons could be accommodated by existing medical facilities. Dr. Ehling, Health Officer for the County of Orange, testified that hospital facilities exist within and beyond the plume EPZ to handle as many as 2000 persons if necessary and as many as 31,000 persons could be treated on an area-wide, southern California basis. Tr. 9917, 9991-9993 [Vol. I, pp. 371, 373-5].

The record in San Onofre concerns nuclear power plants in close proximity to a major metropolitan area and is, therefore, a reasonable basis upon which to establish whether sufficient local and regional hospital facilities are likely to exist to treat persons that may require hospitalization following an accident at any nuclear power plant.

Even if, however, local and regional hospitals could not handle all severely irradiated persons, any hospital which meets the requirements of the "Joint

Commission on Accreditations for Hospitals" would be able to provide the necessary medical services. In order to be accredited a hospital must have facilities capable of treating persons accidentally exposed or contaminated by radiation. Emergency departments of hospitals having nuclear medicine departments must be capable of handling radiological emergencies. Emergency department services must be related to:

"[the] emergency management of individuals [] who have actual or suspected exposure to radiation [or] who are radioactively contaminated. [] Such action may include radioactivity monitoring and measurement; designation and any required preparation of space for evaluation of the patient, including, as required, discontinuation of the air circulation system to prevent the spread of contamination; decontamination of the patient through an appropriate cleansing mechanism; and containment, labeling and disposition of contaminated materials." Accreditation Manual for Hospitals 1982, Joint Commission on Accreditation for Hospitals, pp. 29-30 [Vol. I, pp. 431-32].

As radiation exposure, no matter how severe, does not require immediate treatment, there would be time to transfer severely irradiated persons to hospitals throughout the nation if necessary. Dr. Ehling, Tr. 9992-92 [Vol. II, pp. 493-94]; cf. Dr. Linnemann, Tr. 7106 [Vol. II, p. 459].

The studies leading to adoption of 10 C.F.R. 50.47(b)(12) and NUREG-0654 are not inconsistent with the amendment of 10 C.F.R. 50.47(b)(12) proposed by Petitioner.

In December, 1978 the "Planning Basis for the 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 ("NUREG-0396") was issued. The document was the product of a Task Force of Nuclear Regulatory Commission and Environmental Protection Agency personnel. NUREG-0396 is significant in that it states the technical basis for subsequent emergency planning requirements and establishes a concept of emergency planning that considers a broad spectrum of accidents ranging from design basis accidents to "Class 9 Accidents," i.e., those exceeding design basis.

In describing the planning basis for the concept of Emergency Planning Zones (EPZs), NUREG-0396 stated:

"The EPZ guidance does not change the requirements for emergency planning, it only sets bounds on the planning problem. The Task Force does not recommend that massive emergency preparedness programs be established around all nuclear power stations. The following examples are given to further clarify the Task Force guidance on EPZs:

No special local decontamination provisions for the general public (e.g., blankets, changes of clothing, food, special showers)

No stockpiles of anti-contamination equipment for the general public

No construction of specially equipped fallout shelters

No special radiological medical provisions for the general public

No new construction of special facilities for emergency use

No special stockpiles of emergency animal feed

No special decontamination equipment for property and equipment

No participation by the general public in test exercises of emergency plans.

Some capabilities in these areas, of course, already exist under the general emergency plans of Federal and State agencies." NUREG-0396, pp. 14-15.

These provisions suggest that pre-arrangements for clinical facilities to immediately treat members of the general public suffering only from irradiation was not deemed necessary by the task force which developed NUREG-0396.

By Nuclear Regulatory Commission Policy Statement dated October 18, 1979, "Planning Basis for Emergency Response to Nuclear Power Reactor Accident," 44 Fed. Reg. 61123, (October 23, 1979) the Commission concurred in and endorsed the guidance set forth in NUREG-0396. The Commission specifically endorsed the concept of considering a spectrum of design basis and core-melt accidents in developing emergency planning guidance and directed the NRC Staff to incorporate the planning basis of NUREG-0396 into the NRC's subsequent regulations and guidance on emergency planning. 44 Fed. Reg. 61123, (Oct. 23, 1979).

Pursuant to the Commission's direction, reliance on the planning basis of NUREG-0396 is specifically acknowledged in NUREG-0654 in the discussion of "Planning Basis as follows:

"NUREG-0396 . . . provides a planning basis for offsite emergency preparedness efforts considered necessary and prudent for large power reactor facilities. The NRC's policy statement of October 23, 1979 (44 FR 61123), directs the NRC staff to incorporate the guidance in the report into emergency preparedness documents. Additionally, the guidance in [NUREG-0396] is now reflected in the NRC Final Rule on Emergency Planning. FEMA has also concluded that the guidance in NUREG-0396 should be used as the planning basis for emergency preparedness around nuclear power facilities." NUREG-0654, pp. 5-6 (emphasis added) [Vol. I, pp. 398-99].

The discussion of NUREG-0396 in NUREG-0654 establishes that the Commission intended the parameters of emergency preparedness, including offsite medical planning, to be determined in conformity with NUREG-0396. This intention is confirmed by the Commission's reference to NUREG-0654 in its emergency planning regulations as providing the criteria for determining compliance with the standards set forth in its emergency planning regulations, including the provision on medical services arrangements. 10 C.F.R. 50.47(b)(12) and 50.47(b) n. 1.

V

CONCLUSION

In the absence of alternative action by the Commission, this rulemaking is required to respond to the mandate of the Court of Appeals in GUARD v. NRC.

A rulemaking establishing clearly that 40 C.F.R. 50.47(b)(12) applies only to persons both traumatically injured and contaminated with radioactive material is warranted by the facts that (1) time is not of the essence in treatment of excessive radiation and (2) sufficient facilities exist in the form of accredited hospitals to adequately treat persons suffering from severe irradiation. These facts are well-established. Petitioner's proposed amendment would properly implement the findings dictated by current scientific and medical evidence and current hospital accreditation regulations.

Dated: March 29, 1985.

Respectfully submitted,

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