

have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.).

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

List of Subjects in 9 CFR Part 113

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 113 would be amended as follows:

PART 113—STANDARD REQUIREMENTS

1. The authority citation for part 113 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

2. In § 113.207, the section heading, the introductory text, the introductory text of paragraph (b), and paragraphs (b)(2), (b)(3), (b)(4), and (b)(5) would be revised to read as follows:

§ 113.207 Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus.

Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Each serial or subserial shall meet the requirements prescribed in this section and the general requirements prescribed in § 113.200, except those in § 113.200(d). Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

* * * * *

(b) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for

potency in accordance with the two-stage test provided in this paragraph. For each fraction contained in the product—Eastern type, Western type, or Venezuelan type—the serological interpretations required in this test shall be made independently. A serial or subserial found unsatisfactory for any of the fractions shall not be released.

(1) * * *

(2) Fourteen to 21 days after the second injection, serum samples from each vaccinate and each control shall be tested by a plaque reduction, serum neutralization test using Vero 76 cells.

(3) If the control serum samples show a titer of 1:4 or greater for any fraction, the test is inconclusive for that fraction and may be repeated: *Provided*, That, if four or more of the vaccinate serum samples show a titer of less than 1:40 for the Eastern type fraction, less than 1:40 for the Western type fraction, or less than 1:4 for the Venezuelan type fraction, the serial or subserial is unsatisfactory without further testing.

(4) If two or three of the vaccinate serum samples show a titer of less than 1:40 for the Eastern type fraction, less than 1:40 for the Western type fraction, or less than 1:4 for the Venezuelan type fraction, the second stage of the test may be used for the relevant fraction(s): *Provided*, That, if a fraction is found acceptable by the first stage of the test, the second stage need not be conducted for that fraction.

(5) If the second stage is used and four or more of the vaccinate serum samples show a titer of less than 1:40 for the Eastern type fraction or the Western type fraction, or less than 1:4 for the Venezuelan type fraction, the serial or subserial is unsatisfactory.

* * * * *

Done in Washington, DC, this 20th day of November 1996.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[Docket No. PRM-50-63]

Peter G. Crane, Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking filed by Mr. Peter G. Crane. The petition has been docketed by the Commission and has been assigned Docket No. PRM-50-63. The petitioner requests that the NRC amend its regulations concerning emergency planning to include a requirement that emergency planning protective actions include sheltering, evacuation, and the prophylactic use of potassium iodide, which prevents thyroid cancer after nuclear accidents. The request would amend one of the 16 planning standards in 10 CFR 50.47 by which licensee emergency plans are evaluated in order to assure that the option of using potassium iodide is included in emergency planning.

DATES: Submit comments by February 12, 1996. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except to those comments received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Attention: Docketing and Services Branch.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm on Federal workdays.

For a copy of the petition, write: Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. For information on submitting comments electronically, see "Electronic Access" under Supplementary Information.

FOR FURTHER INFORMATION CONTACT: Michael Jamgochian, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301-415-6534, or Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301-415-7163 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION: Electronic Access

Comments may be submitted electronically, in either ASCII text or WordPerfect format (version 5.1 or later), by calling the NRC Electronic Bulletin Board (BBS) on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or

directly via Internet. Background documents on this rulemaking also are available for downloading and viewing on the bulletin board.

If using a personal computer and modem, the NRC rulemaking subsystem on FedWorld can be accessed directly by dialing the toll-free number 800-303-9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using the ANSI or VT-100 terminal emulation, the NRC rulemaking subsystem can then be accessed by selecting the "rules menu" option from the "NRC main menu." Users will find the "FedWorld On-line User's Guides" particularly helpful. Many NRC subsystems and data bases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld also can be accessed by a direct-dial telephone number for the main FedWorld BBS, 703-321-3339, or by using Telnet via Internet: fedworld.gov. If using 703-321-3339 to contact FedWorld, the NRC subsystem will be accessed from the main FedWorld menu by selecting the "Regulatory, Government Administration and State Systems," then selecting "Regulatory Information Mall." At that point, a menu will be displayed that has an option "U.S. Nuclear Regulatory Commission" that will take you to the NRC on-line main menu. The NRC on-line area also can be accessed directly by typing "/go nrc" at a FedWorld command line. If you access NRC from FedWorld's main menu, you may return to FedWorld by selecting the "Return to FedWorld" option from the NRC on-line main menu. However, if you access NRC at FedWorld by using NRC's toll-free number, although you will not have access to the main FedWorld system, you will have full access to all NRC systems.

If you contact FedWorld using Telnet, you will see the NRC area and menus, including the rules menu. Although you will be able to download documents and leave messages, you will not be able to write comments or upload files (comments). If you contact FedWorld using FTP, all files can be accessed and downloaded but uploading files is not allowed; you will only see a list of files without descriptions (normal gopher look). An index file listing all files within a subdirectory and descriptions of those files, is available. There is a 15-minute time limit for FTP access.

Although FedWorld also can be accessed through the Worldwide Web, like FTP, that mode only provides

access for downloading files and does not display the NRC Rules Menu.

For more information on NRC bulletin boards call Mr. Arthur Davis, Systems Integration and Development Branch, NRC, Washington, DC 20555, telephone (301) 415-5780; e-mail AXD3@nrc.gov.

Background

The NRC received a petition for rulemaking dated September 9, 1995, submitted by Mr. Peter G. Crane on his own behalf. The petition was docketed as PRM-50-63 on September 12, 1995. The petitioner requests that the NRC amend its regulations in 10 CFR Part 50 that govern emergency planning. Specifically, the petitioner is seeking to amend one of the 16 planning standards in 10 CFR 50.47 to include the use of potassium iodide (KI) as one action to be considered in emergency situations under licensee emergency plans.

Potassium Iodide

The petitioner discusses KI and its uses. Specifically, KI protects the thyroid gland, which is highly sensitive to radiation, from the radioactive iodine that would be released in extremely serious nuclear accidents. By saturating the gland with iodine in a harmless form, KI prevents any inhaled or ingested radioactive iodine from lodging in the thyroid gland, where it could lead to thyroid cancer or other illnesses. The drug itself has a long shelf life—at least five years—and causes negligible side effects.

The petitioner further states that, in addition to preventing deaths from thyroid cancer, KI prevents radiation-caused illnesses. The petitioner indicates that thyroid cancer, curable in 90-95 percent of cases, generally means surgery, radiation treatment, and a lifetime of medication and monitoring. The petitioner asserts that the changes in medication that go with periodic scans put many patients on a physiological and psychological rollercoaster. The petitioner states that hypothyroidism can cause permanent retardation in children and, if undiagnosed, can condemn adults to a lifetime of fatigue, weakness, and chills.

Three Mile Island

The petitioner discusses the U.S. policy with regard to KI before the Three Mile Island (TMI) accident. In December 1978, the Food and Drug Administration (FDA) announced that it had determined that potassium iodide was safe and effective for thyroid protection in nuclear accidents. The issue attracted little attention and the NRC and the Federal Government as a

whole took no public position on the drug.

Three months after the FDA announcement, on March 28, 1979, the TMI accident began to unfold. After two days of unsuccessful efforts to bring the reactor under control, it was still uncertain whether a major release of radioactivity could be averted. The petitioner states that Federal and State officials, searching for supplies of KI in case it should be needed, discovered that there was none to be had. A supply had to be manufactured, literally overnight. The petitioner indicates that at 3 am on Saturday, March 31, an FDA official arranged with the Mallinckrodt Chemical Company for the immediate production of 250,000 doses of KI. Without a written contract or a purchase order, the company began production and the first shipment of the drug arrived in Pennsylvania 24 hours later.

The petitioner also discusses that after the accident, President Carter appointed John Kemeny to head a commission to investigate the accident. The Kemeny Commission report, issued in October 1979, was strongly critical of the failure to stockpile KI. Among the Kemeny Commission's major recommendations was that an adequate supply of the radiation protective agent, potassium iodide for human use, should be available regionally for distribution to the general population and workers affected by a radiological emergency. The report also explained that different types of accidents might require different kinds of emergency response, particularly that in some accident situations, evacuation may not be the emergency planning measure of choice.

Potassium Iodide Policy

The petitioner states that Federal agencies initially supported the Kemeny Commission recommendation. In NUREG-0632, "NRC Views and Analysis of the Recommendations of the President's Commission on the Accident at TMI," issued in November 1979, the NRC agreed with the findings of the Commission and planned to require nuclear power plant licensees to have adequate supplies of KI available for nuclear power plant workers and the general public as part of a State emergency response plan.

According to the petitioner, the three agencies most concerned, the FDA, NRC, and Federal Emergency Management Agency (FEMA), all favored the stockpiling KI for the next several years. The petitioner states that the Atomic Industrial Forum, a nuclear industry trade association, declared itself against the stockpiling of KI in May 1982.

The petitioner indicates that the NRC staff was strongly in favor of KI stockpiling as late as September 27, 1982, when the staff issued a memorandum to the Commissioners proposing that the NRC agree with a draft interagency policy statement supporting KI stockpiling. The petitioner further states that on October 15, 1982, less than three weeks after sending the draft policy statement to the Commission for approval, the staff sent a supplementary paper withdrawing the memorandum of September 27. The later memorandum informed the Commissioners that NRC's Office of Nuclear Regulatory Research could, by January 1, 1983, produce a paper showing that KI was significantly less cost beneficial than previously assumed. The staff proposed sending this document to the FDA and FEMA with the recommendation not to stockpile and distribute KI.

The petitioner indicates that the NRC staff briefed the Commissioners on the staff's proposal to take a strong position against KI in November 1983. A policy statement was later issued that disposed of, once and for all, the Kemeny Commission's recommendation in favor of stockpiling KI. According to the petitioner, only a year later, the Chernobyl accident would give tangible proof of the value of the drug in radiological emergencies.

Effects of Chernobyl

The petitioner states that during the Chernobyl accident of 1986, the damaged reactor spewed radioactive iodine over a wide area of what was then the Soviet Union and Poland. The petitioner further states that in Russia and the Ukraine, and also in Belarus, where the distribution of KI was inadequate and untimely, they are now experiencing extraordinarily high levels of childhood thyroid cancer; however, in Poland, where KI was administered to 97 percent of the nation's children, there has been no similar increase in thyroid cancer. The petitioner believes that Poland is a proof-positive example of the benefits of a well-prepared KI program.

The petitioner describes the U.S. Government spending to study radiation-caused thyroid cancer in Ukraine and Belarus. Announcing a \$15 million 15-year program that will follow 70,000 children in Ukraine, the Department of Energy (DOE) declared in a press release that the studies provide a unique opportunity to understand the thyroid cancer risk of exposure to radioiodine. The DOE press release explained: "The release of radioiodine is likely to figure prominently in any

nuclear power plant disaster and knowledge of its carcinogen potency is inadequate, especially in children." In addition, the petitioner further states that the U.S. Government has spent generously to bring Ukrainian doctors to the United States for training in thyroid surgery because mishandled operations can result in damaged nerves and larynxes, and children rendered permanently mute.

The petitioner discusses post-Chernobyl developments on KI policy. He states that the Chernobyl accident demonstrated that KI worked and that countries that failed to stockpile and distribute it are finding themselves with serious public health problems.

Potassium Iodide Reconsidered

In June 1989, the NRC reconsidered the KI issue after the petitioner filed a differing professional opinion urging a change in policy. On November 27, 1989, the American Thyroid Association wrote to the NRC Commission urging KI stockpiling on a nationwide basis, and in 1990, the NRC announced that it was reconsidering the existing Federal policy. In April 1992, a contractor, under the sponsorship of the NRC Office of Nuclear Regulatory Research, issued a report that included a revised cost-benefit analysis of the use of KI. The petitioner describes the report as concluding that stockpiling continued not to be cost-effective, but that the difference between costs and benefits was narrower than had been calculated by the NRC staff in the early 1980s. Then the petitioner indicates that, in December 1993, an industry trade group, the Nuclear Management and Resources Council, sent a report entitled, "Review of Federal Policy on Use of Potassium Iodide," to the Commission arguing against any change in current KI policy.

The petitioner states that in March 1994, the NRC staff declared its support for KI stockpiling. However, the NRC staff proposal for a change in policy was blocked when the Commissioners voted 2 to 2 in May 1994. Under NRC procedures, a tie vote on a proposal means that it fails.

Additional Support

The petitioner describes a September 1994 FEMA publication proposing a "Federal Radiological Emergency Response Plan" that envisions the use of KI during radiological emergencies. According to the petitioner, this implies that the authors of the plan recognize the drug's usefulness. Under the plan, the NRC would be the lead Federal agency during emergencies at nuclear power plants and would advise State

and local governments (based on advice received from an interagency panel); the States and localities would then administer the KI, if necessary.

The petitioner also indicates that in 1994, the Board of Governors of the International Atomic Energy Agency, with U.S. Government support, adopted new "International Basic Safety Standards." These standards represent the consensus of the world's experts on radiation safety. With regard to emergency planning, they provide, among other things: "Intervention levels of immediate protective actions, including sheltering, evacuation, and iodine prophylaxis, shall be specified in emergency plans * * *" thus the international radiation protection, like the Kemeny Commission in 1979 and the short-lived draft Federal policy statement of 1982, recognize that effective preparedness for radiological emergencies meant having three items to consider.

Discussion of the Petition

The NRC is soliciting public comment on Mr. Cranes's petition, which requests the changes to the regulations in 10 CFR part 50.

The petitioner has submitted this petition for rulemaking because he believes the NRC should implement the recommendation of the President's Commission on the Accident at Three Mile Island, known as the Kemeny Commission, that the United States maintain the option of using the drug potassium iodide for thyroid protection during nuclear accidents. The petitioner requests that the Commission definitively review and decide on the issue rather than simply have the NRC staff decide not to propose it to the Commission.

The petitioner states that evacuation is not necessarily the protective measure of choice in every emergency, and even when it is the preferred option, it is not always feasible. The Kemeny Commission report explained that different types of accidents, and the particular circumstances presented, may call for different protective measure. The petitioner believes maintaining a KI option ensures that responsible authorities have an additional type of protection at their disposal.

The petitioner indicates that NRC has made it clear that a finding of adequate emergency planning does not translate into a guarantee that the entire affected public can be evacuated necessarily, but that evacuation is generally feasible. The petitioner believes that sometimes, either by choice or necessity, authorities may be sheltering people or telling them to remain indoors rather than

evacuating them. The petitioner believes that it may be desirable to administer KI any time people are sheltered or told to stay indoors, when evacuation routes take people through areas of radiological contamination and when there is a large airborne release high in the atmosphere.

The petitioner believes that the decision on stockpiling KI should turn on whether, given the enormous consequences of being without it in a major accident, the drug is a prudent measure; not on whether it will necessarily pay for itself over time. The petitioner further believes that KI represents a kind of catastrophic-coverage insurance policy, offering protection for events which, while they occur only rarely, have such enormous consequences that it is sensible to take special precautions.

The petitioner states that the estimates of KI's cost-effectiveness depend on estimates that are no more than informed guesses about the probability of severe accidents. The NRC's cost-benefit analysis of the early 1980's was based on the assumption that a severe accident with a major release of radioactivity could occur in this country only once every thousand years.

The petitioner believes that if it were really true that serious accident with a release of radioactivity were so unlikely, there would be good reason not only to reject stockpiling of KI but also to dispense with all the rest of emergency planning. The petitioner also states that if KI is not cost-effective, then the rest of nuclear emergency planning is probably not cost-effective either. If serious accidents are really possible only every one or two thousand years, it is unlikely that any element of current nuclear emergency planning could be found cost-effective.

The petitioner believes that cost-benefit analysis is a technique that should be applied with good sense, especially where public health measures are concerned. According to the petitioner, the cost-benefit analysis of KI proceeded from the assumption that there was no difference in desirability between prevention of radiation-caused thyroid disease and cure; thus the only factor to be considered in evaluating KI was the difference in cost. The petitioner also believes that the U.S. Government determined that instead of spending money to prevent radiation-caused thyroid disease, society should spend its money treating the disease if and when it occurs.

The petitioner believes that the existing policy on KI was defective from the start because it was based, in part, on inaccurate information provided to

the NRC Commissioners. He states that the information provided to the NRC Commissioners seriously understated the significance of radiation-caused thyroid disease and thereby understated to an equal degree the value of KI.

The petitioner also believes that it was not clear that the Commission had any idea of the real nature of post-accident thyroid disease at the time they adopted an anti-KI position.

The petitioner states that existing policy purports to leave the judgment on stockpiling KI to the States; however this policy also ensures that the States do not have an adequate basis for making informed decisions. He believes that the Federal Government, and NRC in particular, has failed to provide the States with sound technical advice on the subject. The petitioner also believes that without accurate and current information on KI—including the Chernobyl experience and the consensus of international experts—States cannot make an informed judgment.

The petitioner mentions a letter to the Commissioners from Senators Simpson and Lieberman sent in April 1994. This letter stated that the Federal Government has a moral responsibility to provide the public with complete and accurate information regarding the risks from Federally-licensed activities and ways in which those risks may be reduced. The petitioner also mentions FEMA's Federal Emergency Response Plan of September 1994. The plan provides that, in an emergency at a nuclear power plant, an interagency advisory team will provide guidance on KI to the NRC, and the NRC will provide advice to State and local governments on measures that they should take to avoid or reduce exposure to the public, including sheltering, evacuation, and prophylactic use of iodine.

The petitioner believes that no State or local official or member of the public could imagine that in a real emergency, there would be no iodine to administer. The petitioner raises the question: If KI stockpiling is not worthwhile, why is administration of the drug one of the protective measures identified in the plan? He also questions that if KI is worthwhile, as the plan implies, then why isn't something being done to make sure that it is available?

The petitioner believes that the Federal Government should either change the 1985 policy and make the use of KI a viable option in a real emergency, or it should explain why the United States has decided that KI will not be an option.

The Petitioner's Proposed Amendment

The petitioner requests that 10 CFR Part 50 be amended to include language taken from FEMA's Federal Radiological Emergency Response Plan of September 1994 and recommends the following revision to the regulations:

The petitioner proposes that § 50.47 be amended by revising paragraph (10) to read as follows:

§ 50.47 Emergency plans.

(a) * * *

(10) A range of protective actions, including sheltering, evacuation, and prophylactic use of iodine, have been developed for the plume exposure pathway EPZ [emergency planning zone] for emergency workers and the public. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

* * * * *

The petitioner believes that if this change is adopted, the plan will become an accurate description of emergency preparedness for radiological emergencies; the recommendation of the Kemeny Commission will at last be implemented; and the United States will be in compliance with the International Basic Safety Standards.

The petitioner suggests that the NRC, either on its own or jointly with other agencies, issue a policy statement declaring that KI stockpiling is a sensible and prudent measure that is necessary to ensure that the drug will be available in the event of a major accident. The petitioner believes that this statement would clarify that KI can be used in conjunction with evacuation and sheltering to maximize protection to the public.

The petitioner also believes that the policy statement would state the willingness of the NRC to provide a stockpile of the drug to States and localities upon request, and would support the Kemeny Commission's recommendation for the creation of regional stockpiles of the drug as a backup for emergencies.

Dated at Rockville, Maryland, this 20th day of November, 1995.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 95-28832 Filed 11-24-95; 8:45 am]

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