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PROPOSED RULE 40
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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

RE: 67 FR 55175-9, August 28, 2002
10 CFR Part 40 Amendment
Transfers of Certain Source Materials by
Specific Licensees

Attn: Rulemakings and Adjudications Staff

The following comments are submitted on behalf of the Sierra Club, Waste Committee, Nuclear Waste Working Group. We urge the Commission to adopt these recommendations in concert with those of other non-governmental organizations, such as the Nuclear Information and Resource Service and portions of the critique provided by Alliance for Nuclear Accountability.

Comments on Supplementary Information:

The purpose of this proposed rule is stated by NRC to be to require NRC approval for transfers of low-concentration source materials (<0.05 percent by weight) containing uranium and thorium from persons licensed to possess such materials to persons exempt from licensing, in order to ensure protection of public health and safety. The staff admits that this exemption, adopted some forty years ago, was selected not on the basis of protection of human health and safety, but rather in order for certain concentrations of source material to be allowed to be utilized in commercial activities, without regard for the decommissioning and disposal standards and regulations that do not apply to general licensees.

Resultant doses, according to NRC calculations could exceed the agency's 100 mrem/year maximum permissible dose limit. Therefore, it appears that the actual result of this proposed rule will be to relax or abolish regulatory controls in a manner that will increase some dose levels to members of the public -- absent any demonstrable benefit to them from the higher doses. A fundamental basis of radiation regulation is to assure that any additive dose to naturally occurring levels provides a benefit greater than or commensurate with the added risk incurred by the recipient, and that the recipient has a choice to accept or reject the additional exposure.

In a large portion of the United States, the annual dose received from naturally occurring background radiation sources -- prior to the development of military and commercial uses of nuclear energy -- was reported to be approximately 80-100 millirem per year. This regulation, allowing doses that could exceed the NRC's own maximum permissible dose limit, if promulgated, would permit licensees to more than double the dose to individual members of the public, regardless of their age and conditions of health, and without regard for the many other sources of potential radiation exposures to which they may be subjected from naturally occurring, exempted, unregulated, and insufficiently stringent regulated sources. The NRC must not permit either specific or general licensees to violate that basic, if overly lax, standard.

The NRC should not limit its proposed approval regulations at Part 40.51 to only specific licenses and licensees. The regulations must be applicable to all licenses and licensees, to both specific and general licenses. The staff's claim that exclusion of general licenses and licensees from the rule is justified because general licensees handle "more limited quantities of material" is without foundation or merit.

Moreover, since the EPA's maximum annual exposure standard for members of the public is 25 mrem, the NRC clearly must not permit a dose limit fourfold greater than that level -- a level that is already additive by approximately one-quarter to the doses that are received in much of the United States from

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naturally-occurring background radiation, exclusive of indoor radon. Exclusions of uranium and thorium “that [are] essentially at the natural background levels of the surrounding area,” apart from the dose attributable to indoor radon, is not shown to be justified. Uranium and its decay product alpha particle emitters are particularly harmful when received as internal doses, due to their substantially higher relative biological effectiveness and often long hazardous life. Alpha emitters definitely should not be exempted from regulatory control.

We note that the higher “average background dose level” of 300-plus mrem/yr, which is often cited by the nuclear industry and its regulators as resultant from “naturally occurring radon gas should instead be considered to be “technologically enhanced” radon, due the fact that indoor radon doses result from building construction that is designed to minimize indoor heating and cooling energy losses. Any significant increases in “background” radiation levels may be the result of the combination of routine operational releases, accidental ones, and sources consisting, increasingly, of exempted, deregulated, and released radioactive materials and wastes that are allowed to be recycled into various unregulated products and uses. Actions by regulatory agencies that in any way increase dose levels for members of the public are unacceptable to that affected public and should be prohibited by regulators in the interest of public health and safety.

The Commission’s interest in bringing under regulatory control “chemical mixtures, compounds, solutions, or alloys” for source material that is less than 0.05 percent by weight is commendable, but appears to be outweighed by allowance of the 100 mrem/yr dose limit in its effectiveness for protecting public health and safety. In fact, any standard set that will permit, as will this one, the exposure to numerous additive doses from multiple exposure sources is unacceptable to the public. These regulations are directed in large part to the general licensees who are not otherwise bound by the 0.05% weight concentration limits and refer also to the wide variety of uses and users under Part 40.13.

Furthermore, Sections 11a, 61, and 62 of the Atomic Energy Act, as Amended, give discretion to the Commission to define source materials other than those named in the law. This means that members of the public may encounter various and numerous materials exempted from regulatory control under the provisions of this proposed rule – with each such encounter contributing some additive amount of exposure to the recipient. The annual total cumulative doses to that individual will not be calculated and thus may remain undetected at levels that could markedly exceed the EPA’s 25 mrem limit and even the NRC’s annual 100 mrem limit. Although the NRC offers the possibility (but no guarantee) that it will take into account factors such as unlicensed facility occupational exposures, recipient informed consent, dose duration, prior similar dose sources, and appropriate regulations, there is no certainty for an affected member of the public that the dose assessments will be complete, reliable, and accurate.

Moreover, the applicability of the proposed rule to transfer of contaminated materials and to their *in situ* abandonment under the NRC’s Part 20, Subpart E, License Termination Rule is now altered by the EPA’s relinquishing its dual regulatory authority to the NRC, without guaranteed opportunity even for consultation concerning the disposition of radioactively contaminated materials and wastes, under the NRC/EPA MOU signed in October 2002.

This proposed rule also opens wide the door to deregulation and release/recycle/reuse of radioactively contaminated materials and wastes for essentially any purposes the market may determine. And the Commission should in all circumstances prohibit, by plain language in the rule, intentional dilution of contaminated materials for the purpose of facilitating their disposal. Disposal must not be included with exempted activities under 10 CFR 40.13(a).

With respect to transfer for direct disposal, the NRC's narrative states that request for transfer would normally be approved if the dose to a member of the general public "is unlikely to exceed 0.25 mSv/yr (25 mrem/yr). No definition of "unlikely" is provided, nor is there an explanation or definition of the "unique circumstances" under which a dose to a member of the public would be allowed to be exposed to a dose greater than the NRC's 100 mrem/yr limit.

Even more troubling is the language stating that "such dose limits" for transfers of material for purposes such as recycle or "indirect disposal" "may not be appropriate" and that "Lower dose limits *may need to be considered.*" (Emphasis added) This wording is an empty promise; it carries no weight in the realm of regulatory requirements to protect the public health and safety or the quality of the environment. The Commission should not indulge in such misleading statements. The Commission should also cease the case-by-case approvals it has used in order to accommodate industry requests for decisions that lead to exemptions and deregulations by the recipient licensees.

In response to the Commission's request for comment, as for intentional and unintentional dilution of licensed source materials, the Commission should outright prohibit that method used by the nuclear industry to reduce concentrations in order to transfer contaminated materials to licensees that are not required to dispose of them in regulated facilities and that are allowed to exempt such materials from regulation and release them for recycle or unregulated disposition. We suggest that it should be a regulated duty of the holder of a specific license to prevent inadvertent dilutions, such as are described in the Supplementary Information; to report them if they occur; and to pay penalties imposed by the regulator. Intentional dilution, we emphasize, should not be condoned or authorized by the Commission, either prior to or post occurrence.

At 10 CFR part 40.13(a), the Commission must not expand its existing list of exempted activities to include disposal. Nor should exemption from regulated disposal of materials or mixtures of material containing under 0.05 percent by weight derived from licensed material, be allowed under 40.13(a), nor via "reevaluation" under 10 CFR 40.42, nor 10 CFR 20, Subpart E. Each one of these seemingly endless deregulations and exemptions from regulatory control will carry the potential to become an additive and cumulative portion of the total annual doses that are received by uninformed members of the public, and each carries the potential to be a causative part of a cumulative dose to that recipient, which, in concert with all other "slightly radioactive" doses to that individual, results in life-shortening disease to the recipient or genetic injury to subsequent generations.

Agreement State Compatibility:

Because individual states, whether Agreement States or not, have varying sources and amounts of both radiological and other hazardous materials from which the state is required by Constitution and/or law to protect the well-being of its population, it should be left to the judgment of each state to determine if its circumstances warrant regulations more restrictive than those of federal agencies in order to be adequately protective of its people. Certain compatibilities are, of course sensible, such as basic definitions of terms, but the ability for a state to exceed the levels of protection provided by a federal regulator should not be prevented by claims of federal preemption.

Voluntary Consensus Standards:

The final sentence of this section, concerning "establishment of a standard" appears to fail the requirement above for Plain Language. A sentence with clear meaning would be helpful.

Finding of No Significant Environmental Impact (FONSI): Availability:

It is astonishing that the Commission states that a full Environmental Impact Statement is not required for this action that the agency itself confesses may result in radiation doses to members of the public -- doses that are potentially *in excess of the agency's own maximum permissible dose limit of 100 mrem/yr.* (Emphasis added) We are informed by other commenting organizations that, contrary to statements in this notice, an Environmental Assessment claimed by the agency was not in fact performed and that health, safety and environmental impacts were not properly taken into consideration in issuance of a FONSI. This charge and the narrative comments on this matter submitted by the organizations Heart of American Northwest and Alliance for Nuclear Accountability to Chairman Richard Meserve are deeply troubling. The NRC staff must explain its alleged falsification and must now produce a full EIS and describe in detail the bases for the staff's stated conclusion that there would be no environmental or health impacts from promulgation of this proposed rule. In this instance a heavy burden of proof lies with the agency.

The staff argues that there are no health or environmental impacts associated with this proposed rule from the continued transfers of low concentration source materials from specific licensees to exempt persons by virtue of, in future, merely having to apply for NRC approval. The statement that "some transfers to exempt persons *may not be approved*" and that the change in 40.13(a) is merely for clarification, and therefore there would be no impact on human health or the environment is specious indeed. (Emphasis added)

As for the statement that "the NRC welcomes public participation," the signing of the NRC/EPA Memorandum of Understanding in early October *prior to any public meeting* -- much less formal hearings or written public and state comments -- gives the lie to the seriousness of the agency's concern for the public participation that NRC says it desires. (Emphasis added)

Regulatory Analysis and Regulatory Flexibility Certification:

Any regulatory analysis of the cost impacts of the proposed rule must take into account and assess the potential costs of what are currently considered by the regulated industry and its regulator to be externalities that may be ignored. These externalities would include but not be limited to the health impacts for those who may in any manner be exposed to increased levels of radiation exposure in consequence of the exemption. Similarly, the Commission must take into account environmental impacts resultant from the NRC's allowed transfers and exemptions of low concentration source materials, taken in concert with other sources of radiation damage and in combination with other hazardous materials that synergistically and adversely affect the components of the biosystem. These exposures and damages to people and environment have real world costs and must, finally, be accounted for.

10 CFR Part 40: Domestic Licensing of Source Material:

By the wording of the changes in Part 40 that would expand exemptions, releases, and higher radiation exposures from radioactive materials transfers from a specific licensee to a person exempt from regulator control for low concentrations of source materials less than 0.05 % by weight, the nuclear Regulatory Commission intends to allow further exemptions and releases from regulatory control, higher radiation exposures for members of the public, and loss of control over certain radioactive materials with a radioactive half-life of four and one-half billion years, and a hazardous life potentially twenty or more times longer than the half-life -- beyond human imagination. If only one person per million were to

experience cancer and premature death from the NRC's exemption and/or release of these materials among populations who will be born and live out their lives in the world of the 4.5 billion-year future during only the first half-life of alpha-emitting uranium, the premature death toll resulting from the NRC staff's and commissioners' decision in this matter will be enormous. We can find no information in the proposed rule that takes into account such an impact on human health and lifespan. The proposed rule fails to provide evidence of any beneficial gains for either individuals or populations from these further relaxations of regulatory control, at the very time when fundamental microbiological research programs are reporting confirmations of adverse low-level radiation health impacts at the cellular and molecular levels of investigation. The sole prospective "benefit" from the rule might be an unspecified but likely small cost gain for the specific license holder. But no valid justification for the proposed changes has been demonstrated by the staff. The proposed rule should be withdrawn.

Summary:

1. The NRC is to be commended for at least indicating a concern for improvement of public health and safety. However, this proposed rule does not appear to accomplish that goal. The draft rule should therefore be withdrawn. Instead, measures to disallow exemptions from regulations should be formulated and promulgated to increase protection of public health from exposures to ionizing radiation.
2. All actions that may result in higher radiation doses from all sources to which members of the public are exposed are contrary to the public interest and to the Commission's statutory mandate to protect health and safety.
3. The current NRC maximum permissible individual radiation exposure limit of 100 mrem/year is unacceptably high. It is an unacceptable level for members of the public. There is no conservatism at this dose level. The regulatory stance of the agency must be to assure that it is reduced and never permitted to be exceeded.
4. In view of the recognition and acceptance by the National Academy of Science and National Research Council linear no-threshold hypothesis (as stated in BEIR V, 1990), adoption by NRC of any dose level that allows exemption, deregulation, and release for recycle and reuse is a violation of the Commission's responsibility to protect public health and safety, is both arbitrary and capricious and contrary to law.
5. A full EIS that includes a cost/benefit analysis that incorporates all economic, health, societal, and environmental costs to the public that have traditionally been omitted is necessary and should be undertaken for all NRC proposed regulations that relate to exposures of members of the public to ionizing radiation that is additive to naturally occurring background and cumulative.
6. All radiation protection standards and their applications should be grounded in the recognition of the sensitivities of members of the population other than Standard Man; and should incorporate consideration of the multiplicity of sources of exposure now loosed into the biosphere, all adverse health impacts in addition to lifetime risk of fatal cancers and gross genetic defects in the first few succeeding generations, and should account for synergistic interrelationships between and among the full range of contaminants to which the radiation recipient is exposed.
7. The Commission is in need of adopting the Precautionary Principle as a basis for all rulemaking.

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