



NYSERDA New York State Energy Research and Development Authority

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September 26, 1996

Joseph DelMedico
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

DOCKET NUMBER
PROPOSED RULE PR 20
(61 FR 3334)

(99)

Dear Mr. DelMedico:

As the inter-agency coordinator for New York's Agreement State Program with the U.S. NRC, the New York State Energy Research and Development Authority submits the following comments for consideration relative to the draft final rule on Unauthorized Use of Radioactive Material. These comments reflect the views of the New York State Departments of Health and Labor and the New York City Department of Health which license the receipt, possession and use of Atomic Energy Act radioactive materials pursuant to New York State's regulatory Agreement with NRC.

Despite the overwhelming negative response to the proposed rule (81 of the 85 who commented opposed the rule including eight Agreement States), NRC intends to proceed with its adoption. Intentional misuse of materials is not a common occurrence. Rather, it appears that this rule is a reaction to two recent well-publicized incidents at the Massachusetts Institute of Technology and National Institute of Health since NRC admits that it discovered only 8 such incidents in a search of its entire Nuclear Materials Events database. At the recent Agreement States Meeting, the States were unanimously opposed to the rule and argued strongly that if adopted by NRC it should not be made a matter of compatibility for Agreement States.

The New York Agreement Program agencies identified above concur with the position taken by the other Agreement States. The experience of these regulatory agencies suggest this rule is not needed and may be potentially counterproductive. Enclosed for your further consideration are specific comments provided by these agencies.

New York would appreciate NRC's serious consideration of its comments on this matter. If you have any questions on the State's position, please do not hesitate to contact us.

Sincerely,

John P. Spath
Director
Radioactive Waste Policy and
Nuclear Coordination

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Att.

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cc: R. Aldrich-DOL
S. Gavitt-NYSDOH
G. Miskin-NYCDOH

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Rule

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STATE OF NEW YORK
DEPARTMENT OF HEALTH

Office of Public Health

11 University Place

Albany, New York 12203-3399

Barbara A. DeBuono, M.D., M.P.H.
Commissioner

Karen Schimke
Executive Deputy Commissioner

September 20, 1996

Joseph DelMedico
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Draft final rule on unauthorized use of radioactive materials

Dear Mr. DelMedico:

The Department concurs with the views expressed by other Agreement States and the Organization of Agreement States opposing the adoption of this rule. While the Department is concerned about unauthorized use of radioactive materials, the proposed rule does nothing to further protect the public health and safety and only adds another layer of regulation and cost to licensees and regulatory agencies. We are not aware of a single incident (in NYS) where this rule would have prevented an unnecessary exposure or prevented further unauthorized use of radioactive materials.

The draft rule cannot be justified in terms of providing a tangible benefit for the substantial cost it would impose. Additionally, the rule is not consistent with the NRC's recently released Strategic Assessment and Rebaselining Initiative Stakeholder Involvement Process Paper where on page DSI-12-2 it is stated that the NRC as well as Congress have issued directives to use risk-based and cost-benefit criteria in developing regulations. Further, the Department would not be able to justify adoption of this rule based on New York's regulatory process established by the Governor's Office of Regulatory Reform.

If I may be of assistance, please contact this office at (518) 458-6485, FAX: (518) 458-6434, E-mail: smg03@health.state.ny.us

Sincerely,

Stephen M. Gavitt, Chief
Radioactive Materials Section
Bureau of Environmental Radiation
Protection

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STATE OF NEW YORK
DEPARTMENT OF LABOR
DIVISION OF SAFETY AND HEALTH
Radiological Health Unit
Building #12, Room 457
State Office Building Campus
Albany, NY 12240

February 23, 1996

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attn: Docketing and Service Branch

Dear Sirs:

Please accept the following comments from the New York State Department of Labor on the proposed amendment of 10 CFR Part 20, RIN: 3150-AF44, "Reporting Requirements for Unauthorized Use of Licensee Radioactive Material".

The U.S. Nuclear Regulatory Commission is proposing to require that licensees notify them without twenty-four hours of discovering that licensed radioactive material was used for a purpose not authorized in the license, when such use caused or could have caused a radiation exposure to an individual, and such unauthorized use is believed to be intentional.

Proposal of the rule appears to be motivated by two recent incidents in which personnel at large institutions (broad licenses) incurred internal contamination through misuse of radioactive materials, resulting in small radiation doses to those personnel.

These incidents became known to the U.S. Nuclear Regulatory Commission even though there is currently no special reporting requirement for them, apparently during routine inspections by NRC staff. Since broad licensees are inspected every year, and since the review of incidents such as contamination events (particularly an internal contamination incident) is an important part of such inspections, the maximum period of time that could elapse before NRC became aware of such an incident without the proposed reporting requirement, is one year.

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The stated reasons for imposing the twenty-four hour reporting requirement are:

1. "to ensure that the NRC is made aware of any intentional or allegedly intentional activities for a purpose not authorized by the applicable license or regulations in order to take the necessary follow-up actions or to conduct investigations in a timely manner; and
2. "The NRC needs to have prompt assurance that the licensee is taking the appropriate actions to assess the consequences of the situation and to take the necessary steps to reduce any likelihood that further exposures would occur"

These reasons are disturbing because the functions described are clearly the responsibilities of licensees. Neither NRC nor the Agreement States will issue a radioactive materials license to a facility unless it presents an organized and effective radiation protection program, to be conducted by qualified radiation safety professionals who act for, and are responsible to, the facility's top management. The radiation protection program must be adequate to ensure the safe use of the materials authorized in the license. In the case of broad licensees, the authorized radioactive materials are frequently of a type and quantity that could be extremely hazardous if not properly controlled. If NRC doubts the ability or intent of its licensees to take necessary follow-up actions, conduct investigations in a timely manner, take appropriate actions to assess the consequences of a situation and to take necessary steps to reduce the likelihood of further exposures it should refuse to grant the license in the first place, or revoke it when this becomes evident.

Since NRC has presented no information on how effectively the two institutions in question (NRC licensees) handled these incidents, we are unable to judge what additional benefit a twenty-four hour notification to NRC would have produced in these instances. However, we must also consider the possibility that it might have had a negative impact. Licensee radiation safety staff would have had additional burdens of responding to questions from the regulatory agency while trying to assess exposures, decontaminate affected areas and conduct an investigation. There would also almost certainly have been regulatory staff dispatched to the site to conduct their own investigation, further complicating matters and heightening the concern of exposed individuals. The latter aspect should receive particular consideration since these are not incidents involving radiation exposures of a magnitude that would otherwise be reportable.

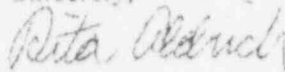
There are already a large number of reporting requirements in NRC and Agreement State regulations, ranging from radiation exposures and releases exceeding regulatory limits to "unplanned" fires and explosions in licensed facilities. Any additional reporting requirements should be based on a clear need for the regulatory agency to take immediate action to protect health, safety or property; not for the agency to perform functions that every licensee should be prepared and qualified to undertake, whether a licensee is dealing with an "intentional" or unintentional incident.

We are also at a loss to understand why an "intentional" misuse of licensed materials should be a matter of immediate reportability, while an incident of similar or even greater hazard would not be reportable if it were due to misunderstanding, lack of knowledge or

incompetence. However, we are assuming here that NRC is using the word "intentional" to mean that an individual who knows exactly what is authorized in a license, deliberately and knowingly acts otherwise. Since the word is not defined in the proposed rule, this will probably create pressure on licensees to report any use of radioactive materials not explicitly authorized in a license, regardless of intent or the potential to cause exposure. The resulting over-reporting would be a common result of vague and poorly conceived regulatory requirements, such as the proposed rule.

As an Agreement State agency, we have experienced no need for such a reporting requirement and do not intend to adopt one.

Sincerely,



Rita Aldrich
Principal Radiophysicist

RA/fdh