

(61FR58346)

DOCKETED
USNRC

February 7, 1997

(4)
ACNP

John Hoyle, Secretary
Nuclear Regulatory Commission
Washington, DC 20555-0001

'97 FEB -7 AM 1:32

Attention: Docketing and Service Branch
OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

Re: Fed. Reg. 61(221), 14 Nov. 96, pp. 58346-58353:
Specific Domestic Licenses of Broad Scope for
Byproduct Material, ANPR.

American
College of
Nuclear
Physicians

California
Chapter

Dorothy Duffy Price
Executive Director

Box 31
Los Altos, CA 94023

TEL (415) 949-1341
FAX (415) 949-1341

Dear Sir:

The California Chapter of the American College of Nuclear Physicians wishes to comment on the proposed changes to 10 CFR Part 33 regarding licenses of broad scope, as published in the Federal Register on November 14, 1996.

The Nuclear Regulatory Commission (NRC) states that it wishes "to clarify the regulatory and health and safety basis of current licensing practices and to provide licensees with the flexibility to make certain types of changes to their radiation safety programs.". It further states that the proposed changes are "supported by two recent events of a similar nature, involving phosphorus-32 (P-32) internal contamination of individuals at large biomedical research facilities.". These two well publicized incidents at NIH and MIT were terrorist type acts that can not be prevented by a change or clarification of regulations. Indeed, the NRC never states how their proposed rule changes would prevent such terrorist type incidents, and considerable discussion supporting this point took place at the May '96 CRCPD meeting in Albuquerque which was well attended by NRC staff and management.

The NRC's statement that the proposed new rules would result in "the development of a standard license condition for broad scope licensees that is functionally equivalent to 10 CFR 50.59 for nuclear power reactor licensees" is a demonstration of a flawed perspective. The proposed changes would not merely be an example of diminishing returns, but we believe it would actually be counter-productive.

There are always additional problems in administering a radiation safety program at renowned universities and research laboratories. This is especially true when there is a proliferation of new regulations. It is extremely difficult to convince a Noble Prize winner or other famous clinical and basic researchers to change the way they do science or stop and write new policies and procedures merely to adhere to a new regulation by the NRC, when these researchers can give you very cogent arguments showing that the operation of their laboratories do not represent a hazard to laboratory personnel or to the public. Most

DS10

February 7, 1997
John Hoyle, Secretary
Page -2-

of these researchers are aware of the NAS/IOM Report condemning the overregulation of byproduct material by the NRC. New regulations that will not prevent terrorist acts, such as the P-32 incidents, will not improve radiation safety. Such regulations will be resented and make the RSO's job more difficult.

This is best demonstrated in the NRC's own words: "Generally, the current program governing the regulation of specific licenses of broad scope for byproduct material has worked well to provide for public health and safety from these licensed activities." NRC goes on to state that there were only 38 events in a 4 year period that resulted in some type of enforcement action. Even though these events did not apparently imperil the public health, the NRC is concerned that such events "could potentially result in doses to the public from radioactive material." The NRC jumps from what didn't happen to what "could potentially" happen and then jumps to a proposal to equate certain aspects of a broad scope license to a license for a nuclear power plant. If the NRC is so concerned with "could potentially", it should decrease its regulation of Medicine and Pharmacy and focus its efforts on power reactors, where "could potentially" represents a true nightmare.

The NRC clarification of 10 CFR Part 33 is also not needed. Speaking of the current regulations, the NRC says, "In practice, Part 33 reduces the administrative burden for both licensees and the Commission without reducing safety standards.". It goes on to acknowledge that a broad license is only issued to "large-scale activities with licensed material under oversight by persons with extensive training and experience in radiation safety.". It also states that these broad licensed programs "do not require the same degree of regulatory oversight" as other types of licensees, i.e., broad licensed programs have the greatest expertise and require the least amount of clarification. Therefore, there is certainly no compelling reason to promulgate new regulations that will require everyone to revise or develop new written policies and procedures, which will not be paid for under existing clinical, research, or other funding mechanisms.

The NRC points out that it has utilized a regulatory guide to clarify certain regulations. This approach should be used to change the definition of "ministerial change" or to otherwise increase the flexibility of broad licensed programs. The Regulatory Guide could also be used to consolidate the three types of broad licenses. A regulatory guide, however, should not be used to impose new requirements or regulations that increase the burden on licensees. Otherwise, it is de facto regulation without honoring the requirements of the Administrative Procedures Act. A regulatory guide should give guidance that

February 7, 1997
John Hoyer, Secretary
Page -3-

permits the desired flexibility. We see no need for a further definition of the requirements and duties of the RSO and RSC. The NRC already requires local management to make a written statement of delegation of power to the RSO for the operation of the radiation safety program.

The "master materials license" that has been utilized for the armed services has "worked well" according to the NRC. There is no need to codify this masters materials program until there is more experience in evaluating and regulating such new programs.

In summary, the California Chapter, American College of Nuclear Physicians sees no valid reason for the proposed changes to 10 CFR Part 33 and urges that they not be adopted. In addition, this whole concept is in direct opposition to the recommendations of the NAS-IOM, whose opinion was sought by NRC. The costs for this study, \$1.25 million, were borne by NRC medical licensees who wish to see the NAS-IOM advice implemented.

Sincerely,

Marvin B. Cohen

Marvin B. Cohen, M.D.
President, ACNP-California Chapter
Professor of Medicine
and Radiological Sciences, UCLA
*Chief, Nuclear Medicine Service
VA Medical Center, Sepulveda, CA

*Dr. Cohen's opinions are his and those of the ACNP and are not necessarily those of the Department of Veterans Affairs.

cc: Chairman Shirley Ann Jackson
Commissioner Greta J. Dicus
Commissioner Nils J. Diaz
Commissioner Kenneth C. Rodgers
Commissioner Edward McGaffigan
Hugh Thompson, Jr., Deputy EDO
Edward Jordan, Deputy EDO

MBC:sfd