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DOCKET NUMBER  
PROPOSED RULE PR 19+20  
(59FR5132)

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USNRC

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Mr. Samuel J. Chilk, Secretary  
United States Nuclear Regulatory Commission  
11555 Rockville Pike  
Rockville, MD 20852

OFFICE OF SECRETARY  
DOCKETING & SERVICE  
BRANCH



**MERCK**  
Research Laboratories

RE: Proposed Rule - Radiation Protection Requirements; Amended Definitions and Criteria  
RIN 3150-AE80-1

### BACKGROUND

Merck & Co., Inc. is a large international pharmaceutical company that operates a substantial research and development program at multiple sites. The use of radioisotopes is a critical component of any successful pharmaceutical research and development program, and Merck's program is no exception. To administer a safe and effective radiation safety program and our 10 CFR Part 33 license, Merck established a Health Physics Department. One of the many duties performed by this department is to provide radiation safety training in accordance with 10 CFR Part 19. The Health Physics Department provides radiation safety training to the researchers that handle radioactive material as well as any ancillary personnel that frequent our restricted areas. During 1992 and 1993, the Department provided radiation safety training to over 3,000 people at its two largest sites.

### ANALYSIS

The Proposed Rule for Radiation Protection Requirements; Amended Definitions and Criteria is intended to simplify the training requirements described in 10 CFR 19.12. Unfortunately, the proposed revision to 10 CFR 19.12 is more ambiguous than the existing regulation and will have grave impact on our program as well as other 10 CFR Part 33 licensees. The proposed revision to 10 CFR 19.12 will require that all individuals, who, in the course of employment in which the individuals' assigned duties involve the potential for exposure to radiation and/or radioactive material, receive training/instruction. Almost any employee on our plantsite may be walking down a hall (an unrestricted area) and pass a technician carrying an incoming package containing radioactive material or pushing a cart containing radioactive waste. That employee who passes the technician may receive a radiation exposure, however trivial. Under the proposed rule, that individual would require training/instruction. Conceivably, the Health Physics Department at Merck would be burdened with training an additional 10,000 employees. This additional training burden would not reduce the radiation exposure of one single individual.

The Commission's assessment of the impact of this proposed rule was also published in the Federal Register notice. Merck disagrees with the conclusion that "the conforming change to 10 CFR Part 19 is minor and will affect only a small number of licensees and will have a

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negligible impact. Although the training for an employee with potential for small exposures will not be extensive, identifying all those employees with potential to be exposed that require training and providing said employees with training is no small task. In addition, the tracking of individuals who have or have not had training and the associated recordkeeping will be a significant regulatory burden. This burden will not be offset by the reduced burden of not having to train a handful of members of the general public who currently frequent restricted areas.

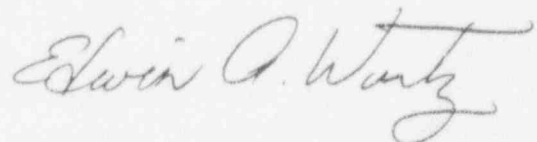
In the Federal Register notice, the Commission states that radiation doses received by individual workers at a rate greater than the public dose limit of 100 mrem in a year constitute a level of risk which requires training at least to a level which provides information on the risks of exposure and methods for reducing exposure in keeping with the ALARA principle. However, exposures less than 100 mrem in a year carry such minimal risk that the individuals involved do not require training. Merck agrees. Furthermore, we assert that any employee, whose assigned duties do not require working in a restricted area and who does not have the potential for exposure greater than 100 mrem per annum, should be treated like a member of the public. Since members of the public do not require instruction--even though they may potentially receive radiation exposure from a licensee--then employees who are not required to work in a restricted area and who have no potential to exceed the public dose limit should not be required to be trained.

In accordance with this reasoning, we suggest that the following change be made to the proposed rule:

"19.12(a) All individuals who in the course of employment in which the individuals' assigned duties involve either working in a restricted area or who have the potential for exposure to radiation and/or radioactive material such that their total effective dose equivalent is likely to exceed 0.1 rem in a year, shall be . . ."

I am sure that this comment will receive careful review and consideration before the final rule is promulgated. I would also welcome an opportunity to discuss this matter with a member of the NMSS staff. I can be reached at (215) 652-4890.

Sincerely



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