

# Mallinckrodt, Inc.

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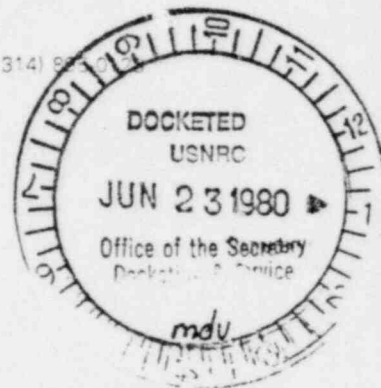
DOCKET NUMBER

PROPOSED RULE

PR-20 (63)

(45 FR 18023)

Secretary of Commission  
U. S. Nuclear Regulatory Commission  
Washington, D.C. 20555  
ATTN: Docketing and Service Branch



Re: Doc. 80-8381  
45 FR 18023 (March 20, 1980)

Dear Secretary:

These comments to the Advanced Notice of Proposed Rulemaking ("ANPR") on 10 CFR Part 20 are submitted on behalf of Mallinckrodt, Inc., P.O. Box 5840, St. Louis, Missouri 63134. Mallinckrodt has an interest in this proposal as a member of the industry manufacturing radiopharmaceuticals from short lived isotopes.

## Meaningful Proposed Rulemaking Will Require Defining a Number of New Terms.

The ANPR uses a number of new terms previously undefined in 10 CFR. For example, item a3 uses the phrase "selected for the appropriate circumstances". Item b4 uses a term "annual limits of intake (ALI)". Item b6 uses "provisions for emergency exposures", and b5 uses "provisions for planned special exposure and over-exposure situations". Item c2 brings in an undefined term called the "special population groups". Later on the proposal calls for provisions to limit "collective" doses. Meaningful proposed rulemaking will require all terms like these to be defined.

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Acknowledged by card. 6/23/80. m.d.v.

ALARA Numbers Must Be Reasonable

According to the ANPR, NRC through its subsequent rulemaking procedures will establish actual numbers as ALARA guidelines, taking social and economic factors into account. In developing these numbers, it is most important for NRC to pay close attention to the general scientific capabilities of the persons engaged in the activity to be covered by the new guidelines. Unless these capabilities are taken into account, it is possible the use of ALARA could subject all licensees to unreasonable standards. In the one case in which the NRC has tried to establish an ALARA level for a group of licensees, that is nuclear medicine departments in hospitals, their original level was ridiculously low and failed to recognize abnormal operational problems that will arise in the best operated organizations.

Technical Bases for Numerical Limits Should be Both Readily  
Identifiable and Scientifically Reasonable

The ANPR indicates technical bases for numerical limits are to be readily identifiable in the rulemaking it plans to undertake. These bases should also be scientifically reasonable and limits arising therefrom should only be established after the economic and social factors have been taken into account. Thus, these bases should be bottomed on good scientific evidence that actual health and environmental benefits will result from limits which are established. Limits should not be set solely for the sake of establishing limits, but instead must be designed to provide a well defined and documented benefit which NRC wishes to achieve.

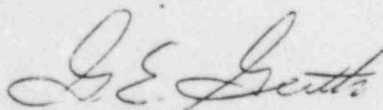
A Cost/Benefit Analysis Should be Conducted  
on Proposed Regulations

Before proposing any new regulations to Part 20 Mallinckrodt urges NRC to carefully consider the social benefits it expects to be derived from each of the regulations. In addition, NRC should assess the costs which are likely to be incurred as a result of implementing new regulations. In some instances, it is quite possible regulatory requirements could vary depending upon the particular radioisotopes involved. Thus, while more stringent regulations might cover long lived isotopes, less stringent regulations might also apply to short lived isotopes.

Furthermore, additional reporting requirements should be initiated only if a well defined benefit is to be derived. Costs for preparing and filing reports is already quite high and should not be increased unless a substantial benefit is expected.

Thank you for the opportunity to comment on this Advance Notice Proposed Rulemaking. We will provide you additional comments as new regulations are proposed.

Sincerely yours,



G. E. Gerth  
Manager, Plant Services

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