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November 4, 1985

Secretary of the Commission U.S. Nuclear Regulatory Commission Washington, DC 20555

Attention: Docketing and Service Branch

Dear Sir:

Medi-Physics, Inc., a manufacturer of radiopharmaceuticals, is responding to the Agency's advance notice of proposed rulemaking published in the Federal Register of June 7, 1985 which would impose financial responsibility requirements on NRC licensees for cleanup of accidental and unexpected releases of radioactive materials.

It is Medi-Physics' position that no requirement should be imposed on radiopharmaceutical manufacturers to demonstrate that they possess adequate financial means to pay for cleanup of accidental releases of radioactive materials. The following are our reasons:

- We are aware of no instance in the entire history of the radiopharmaceutical industry where the licensee manufacturer was unable to cleanup accidental releases of radioactive materials and where significant expenditures of State or Federal funds were required to assist in the cleanup effort.
- 2. Considering the nature of the radioactive materials involved, i.e. the small quantities and their short half lifes, the materials in most instances are decayed before any cleanup effort can be completed. Additionally, the small quantities of material are capable of being dispersed enough so that no cleanup is, in many instances, required. In short, these materials do not impose substantial dangers to the public even in the unlikely event there is an accident requiring cleanup.
- The cost of mandated financial coverage would result in increased overhead costs and such costs would in all likelihood be passed on to the purchasers of said products and ultimately the public.

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- 2 -In the event the Agency decides to ignore the foregoing comments and impose responsibility requirements on radiopharmaceutical manufacturers, these requirements should not be onerous. We believe a sliding scale requirement should be considered to match the financial requirements to the actual risks of various types and quantities of radioactive materials possessed. A criteria should be adopted based on the amount of activity involved, the product's half-life and quantities involved. Risk assessment must be handled on a case by case basis. We appreciate the opportunity to comment on this important proposed rulemaking and are hopeful that our comments above will be taken into consideration in the adoption of the proposed rule. Very truly yours) Lido L. Puccini Secretary LLP:1g cc: Mr. W. W. Rudley

Mr. T. J. Springer

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