

No. 92-144
Tel. 301/504-2240

FOR IMMEDIATE RELEASE
(Friday, October 2, 1992)

NRC ELIMINATES CERTAIN RECORDKEEPING REQUIREMENTS
FOR RADIOPHARMACEUTICALS

The Nuclear Regulatory Commission is amending its regulations to eliminate certain recordkeeping requirements related to the preparation and use of radiopharmaceuticals.

The requirements are associated with departures from manufacturer's instructions approved by the Food and Drug Administration (FDA). Specifically, the revisions to Parts 30 and 35 of the Commission's regulations eliminate recordkeeping requirements related to the justification for each departure, a precise description of each departure, and the number of departures.

On August 23, 1990, the NRC issued an interim final rule granting, in part, a petition from the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM). The ACNP and SNM had asked the NRC to amend its regulations to allow (1) departures from the manufacturer's instructions for preparing diagnostic radiopharmaceuticals and (2) the use of radiopharmaceuticals for therapeutic indications and methods of administration not included in the FDA-approved package insert containing the approved manufacturer's instructions.

The interim final rule allowed departures from the manufacturer's instructions for preparing diagnostic radiopharmaceuticals using generators and reagent kits for which the FDA has approved a New Drug Application. It also included recordkeeping requirements for the specific nature of the departure, a brief statement of the reasons for the departure and the number of departures. The interim final rule is effective through August 23, 1993.

After examining the documentation collected to date and consulting the FDA staff, the NRC decided that these information collection requirements are no longer necessary. Both the NRC and the Food and Drug Administration staffs agree that the major trends in departures that might be identified by the recordkeeping requirements are already clear; collection of

additional data would not be expected to reveal any significant new information and is therefore unnecessary.

A proposed rule on this subject was published in the Federal Register for comment on June 11, 1992. No substantive changes have been made as a result of the comments received.

The final rule eliminating these requirements is effective immediately upon publication of the Federal Register notice on October 2, 1992.

#