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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

SEP 15 1987

MEMORANDUM FOR: Bruce S. Mallett, Ph.D., Chief
Nuclear Materials Safety and Safeguards Branch
Division of Radiation Safety and Safeguards, RIII

FROM: Vandy L. Miller, Chief
Medical, Academic, and Commercial Use Safety Branch
Division of Industrial and Medical Nuclear Safety, NMSS

SUBJECT: LABELING OF IN VITRO DIAGNOSTIC TEST KITS PURSUANT TO 10 CFR 32.71(c)

This is in reference to the August 18, 1987 memorandum from Evelyn Matson of your staff to Michael Lamastra of my staff. The issues raised in the memorandum have also been discussed by Ms. Matson with Bruce Carrico and Patricia Vacca of my staff.

We believe that the phrase "prepackaged unit" as it is used in 10 CFR 32.71 is intended to mean the vial, bottle, test tube, or other final source container, and is not intended to refer to the box or other outer packaging that contains the kit components. This interpretation is reasonable because it would ensure that a person handling a final source container that had been separated from the outer packaging would still be alerted to the presence of radioactive material and to the identity, chemical form and quantity of the radionuclide, and would be reminded that the material is "Not for Internal or External Use in Humans or Animals."

Although we believe that there are many cases where the labeling required by 10 CFR 32.71(c) can be placed on the final source container, we also recognize that there may be special situations in which all of the labeling required by the regulation cannot be placed on the final source container (such as in the case of a very small vial). These latter situations may be considered for exemptions pursuant to 10 CFR 30.11. Applicants desiring an exemption should explain why the label on the final source container cannot contain all of the

information required by 10 CFR 32.71(c) and how and where they propose to provide the required information. Applicants should be encouraged to use final source container labels that contain as much of the information required by 10 CFR 32.71(c) as possible. Applicants for renewals of licenses issued pursuant to 10 CFR 32.71 that have a stock of existing labels may request authorization to use the existing labels for a reasonable period of time until new labels that fulfill the requirements of 10 CFR 32.71(c) can be printed.

Exemptions from the requirements of 10 CFR 32.71(c) should be coordinated with Headquarters in accordance with Policy and Guidance Directive FC 84-12, Revision 2, dated November 12, 1986.

We appreciate your bringing this matter to our attention and, by copy of this memorandum, are notifying the other Regions and the Agreement States of our views. If you have any questions on this matter, please contact Michael Lamastra (FTS 427-4093).

Vandy L. Miller, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
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cc w/copy of memo dtd 8/18/87:
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