DEPARTMENT OF HEALTH SERVICES
RADIOLOGIC HEALTH BRANCH
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October 19, 1999

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OSP

Deputy Director
Office of State Programs
U.S. NRC
Mailstop 03C10
Washington, D.C. 20555

Dear Deputy Director:

REVIEW OF AGREEMENT STATE REGULATIONS

As requested in the Office of State Programs (OSP) Procedure SA-201, *Review of State Regulations*, the enclosed final regulations (R-12-98) are submitted for your review. The regulation text was approved by the California Office of Administrative Law and becomes effective on November 12, 1999.

One minor change to the proposed regulations has been made since rour previous review of the proposed regulations. Enclosed is the final text with the previous text in strike-out and the final text underlined (§30210.2(a)(2)(B)). The final text more closely parallels the equivalent federal regulation.

The regulation establishes compatibility with the amendment of 10 C.F.R. sec. 32.72(a)(4) as noted in the Federal Register, volume 60, page 322, published on January 4, 1995. We believe that the differences noted in a review of California's final regulations and the NRC's regulations are not significant. This is based on Appendix B of OSP Procedure SA-201.

If you have any questions regarding the proposed regulations, please contact me or David Wheeler, Senior Health Physicist at (916) 324-3609.

Sincerely,

Deborah Bellegiuni for

Edgar D. Bailey, Chief
Radiologic Health Branch

enclosure

cc: Dave Wheeler, Senior Health Physicist
Radiologic Health Branch
P.O. Box 942732 MS 178
Sacramento, CA 94234-7320

TITLE 17. PUBLIC HEALTH

DIVISION 1. DEPARTMENT OF HEALTH SERVICES

CHAPTER 5. SANITATION

SUBCHAPTER 4. RADIATION

GROUP 2. LICENSING OF RADIOACTIVE MATERIALS

ARTICLE 5. TRANSFER OF MATERIAL

§ 30210.2. Labeling Requirements for the Manufacture, Preparation or Transfer for Commercial Distribution of Drugs Containing Radioactive Material for Human Use as Authorized by a Specific License.

(a) A person applying for a specific license to manufacture, prepare or transfer for commercial distribution radioactive drugs for human use shall satisfy the following labeling requirements:

(1) A label shall be affixed to each transport radiation shield of a radioactive drug to be transferred for commercial distribution. The label shall include:

(A) The radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL";

(B) The name of the radioactive drug or its abbreviation; and

(C) The quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

(2) A label shall be affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include:

(A) The radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL", and

(B) An identifier that ensures that the syringe, vial, or other container ~~shall~~ can be correlated with the information on the transport radiation shield label.

Note: Authority cited: Sections 100275 and 115000, Health and Safety Code.
Reference: Sections 114965, 114970, 115060, 115165 and 115235, Health and Safety Code.