

(381)

Department of Health Services

DOCKETED
USMRCDOCKET NUMBER
PROPOSED RULE **PR** 20, 32 + 35
(63FR43516)

'98 SEP -2 P2:30

FaxOFFICE OF
RULE
ADJUDICATION**To:** Cathy Haney**From:**John Hickman, Chief Medical
Licensing, State of Ca.**Fax:** 301-415-5369**Pages:** 1**Phone:** [Click here and type phone number]**Date:** 08/25/98**Re:** Part 35 revisions**CC:****Date:** Tuesday, August 25, 1998**e-mail** jhickma1@rhm.dhs.ca.gov☐ **Please Reply****please identify e-mail address**

• Comments: I was hoping to talk with you at the San Francisco meeting but was not able to be at the right place at the right time.

I am concerned with the item of supervision. We have a policy that declares the authorized user as the responsible person for the prescription, administration, analytical process, and interpretation of results and patient information. This can be a major problem with physicians who wish to only interpret the results.

An additional problem that we face is the presence of the supervisor. We require the physical presence for the oral administration of therapeutic radiopharmaceuticals. The other administrations can be covered by "general supervision". The area of general supervision is loose and not defined.

In reviewing the proposed 35, I find the section on supervision to be confusing. I can appreciate the written directive as being a part of the supervision but the signature and date are important to making the determination that supervision was present. From my understanding, the licensee is the supervisor. If the licensee is the supervisor then are authorized users also supervisors or are they to be supervised by the licensee. Is the licensee the applicant?

The issue of "telesupervision" should be addressed. Many authorized users find that with present technology that they can stay in their office 100 miles from the treatment site and believe that they supervise the procedure. We do not agree. The emerging technologies will present us with challenges and the regulations should be focused on the future as much as possible to accommodate the reasonable but to assure protection of public health and continuing radiation safety.

9809040358 980825
PDR PR
20 63FR43516 PDR

DS10