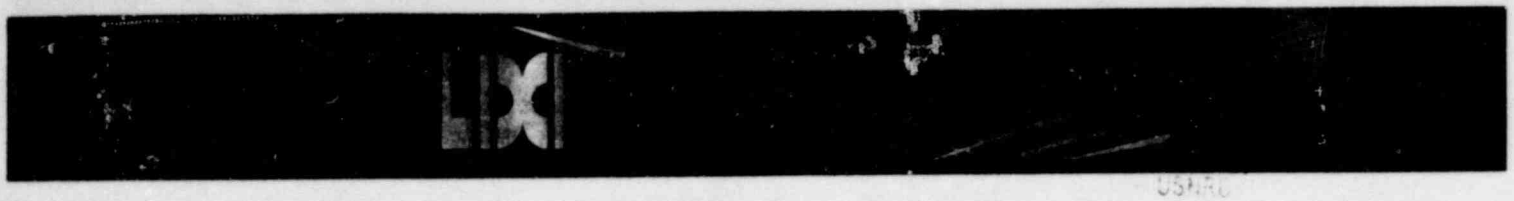

PROPOSED RULE PR-30,31,32 etal. (50 FR 30616) (95)

November 22, 1985

'85 DEC -2 A11:00

DOCKETING & SERVICE BRANCH

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555
Attn: Docketing and Service Branch

RE: Proposed Rule
Medical Use of Byproduct Material

Dear Secretary:

We have reviewed the proposed rule changes to part 35, and we wish to comment on four items:

1. General licenses
2. Regulatory Flexibility Certification
3. Subpart H
4. Suppliers 35.49

When formulating its statements on the above items, the NRC failed to consider how to handle new technological advancement of material use in medicine and the new trends in medical care. In the past, medical use licenses were issued primarily to large institutions. Because of the costs involved handling most radioactive devices or nuclear medicines, only large institutions could use this type of licensing in the past. However, the medical care industry is changing and so is the equipment available to it.

Today, items such as cost containment, Diagnostic Related Groups (DRG), Federal reimbursement programs and Insurance Programs (HMO and PPO) are shifting health care away from the hospitals and back to the doctor's office. In addition, new medical devices have been developed and existing devices have found new uses in the doctor's office.

The NRC regulation did not make allowances for these types of developments. We know because our company has spent the past four years developing guidelines with the NRC to allow for the licensing of doctors for these new devices. New developments in nuclear medicine usually comes from large teaching hospitals and in the past, only hospitals could afford to use these developments. Therefore, to say that only 9% of the general licenses are currently active or that there are 2,500 licenses of which only 300 are individual doctors ignores the fact that the future trends are toward the individual doctor obtaining licenses.

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The NRC only developed its "Policy and Guidance Directive FC 83-24; Licensing the Lixiscope and Bone Mineral Analyzer" on November 10, 1983. It has taken the past two years to orientate NRC and Agreement State personnel on the use of these guidelines. Each month more licenses are issued to individual doctors for lixiscopes and bone mineral analyzers. Within the next two years, the NRC will probably have 4,000 individual licensees as opposed to 2,200 institutional licensees.

The NRC's fee schedule does not recognize these conditions because category 7c is $580.00. This fee was based on the NRC's evaluation of what it costs to review a hospital's application. The same is true for the inspection fee of $480.00.

Subpart H as it is currently proposed includes only the lixiscope and the bone mineral analyzer. Since these two types of devices are certified for specific isotopes and maximum activity quantities, why must a licensee specify a maximum possession limit? If the purpose of the rule change is to streamline procedures and reduce unnecessary license review, then the NRC should limit possession to a definite number of millicuries per device possessed, with no limit on the number of devices. There would be no difference to health and safety if a doctor or hospital possessed one lixiscope or bone mineral analyzer or ten of each.

We are greatly concerned about the supplier of isotopes for these medical devices. If the supplier of the isotope is not the manufacturer of the device itself, the possibility for error is present. A case in point is the bone mineral analyzer. If the manufacturer of the analyzer is not the one who receives, checks and loads the isotopes into the source holders, then there is no assurance that isotope meets the design specifications of the equipment. An example of this is I-125. The manufacturer of the analyzer tells the customer to use I-125 in a certain size capsule from an isotope manufacturer. However, the analyzer manufacturer has no control over the quality or purity contents of the isotope. But the NRC has licensed isotope manufacturer to supply isotopes for the analyzers. Even though these manufacturers might be aware of some equipment specification, they are not specifically required to meet them.

We request that the NRC review these points and develop guidelines or license conditions to correct them.

Sincerely,

Lixi, Inc.

Robert J. Savini
Executive Vice President

RJS/ddb