7/24/79

Note to: Accession Unit
Room 050
Phillips Building

From: Deborah A. Bozik, RHSB/SHSS/OSD

Please place the attached document in the PDR using the following file and file points:

| PDR File (Select one and enter number) | | Additional Info (Enter if appropriate) | |
|---|---|---|---|
| Proposed Rule (PR) | 44FR24570 | ACRS Minutes No. | |
| Reg. Guide | | Relates to Proposed Rule (PR) | |
| Petition (PRM) | 31-3 | Relates to Reg. Guide | |
| Effective Rule (RM) | | Relates to Petition (PRM) | |
| ANSI | | Relates to Effective Rule (RM) | |
| IAEA | | Federal Register Notice | |
| | | SD Task No. | RH904-3 |
| | | NUREG Report | |
| | | Contract No. | |

Subject: VALUE-IMPACT STATEMENT for the proposed rule to add veterinarians to the in vitro general license in §31.11 of 10 CFR Part 31

cc:
Central Files

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VALUE/IMPACT STATEMENT

I. THE PROPOSED ACTION

A. Description

Presently, the NRC does not authorize veterinarians to obtain a general license in Part 31 to use byproduct material for *in vitro* (outside the body) clinical or laboratory testing. However, physicians use byproduct material under a general license for the same type of tests as the veterinarians. A general license is useful for the regulation of a large number of identical or similar uses under circumstances in which the safety of the use is not highly dependent upon the competence of the user or when it is practical to identify a class of users who may be assumed to have the necessary qualifications. Veterinarians have similar training to physicians in the areas of diagnostic radiology and radiation biology. General licensees in § 31.11 can possess iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75 and Mock Iodine-125 (a combination of iodine-129 and americium-241). The licensee is allowed to possess a total of 200 microcuries of the shorter-lived radionuclides (I-125, I-131, Fe-59 and Se-75) and the extact amount of each particular isotope is detailed in the general license. Therefore, this small quantity of radioactive material which the veterinarian would use and the similarity of that use to a physician's use suggest that the licensing for a veterinarian should be the same as that for a physician.

B. Need for the Proposed Action

The proposed rule change would fulfill a need expressed by veterinarians to use byproduct material for in vitro clinical or laboratory testing. Currently, there are approximately 25 veterinarians under specific license. However, if this proposed change is adopted, it would be possible to expect at least 10 new applications per year. There is also a need for NRC to determine why veterinarians are specifically licensed when they are doing tests similar to physicians who are generally licensed.

C. Value/Impact of the Proposed Action

1. NRC Operations

The adoption of this amendment to 10 CFR 31.11 would result in a definite value to the NRC licensing process. The general license would be broadened to include veterinarians with those already authorized to use byproduct material for in vitro clinical and laboratory testing. Presently, no such alternative exists for veterinarians. They have been operating under specific licenses under Part 30, in which they must file an application form along with a fee of $110. The general license would require neither an application form nor a fee. There would be a savings to each veterinarian of $110 while the NRC would save a similar amount in paperwork by not having to process the applications and fees. The veterinarian would only have to fill out a registration certificate which involves no cost. As specific licensees,

the veterinarians are inspected by NRC every three or four years and these inspections are on a low priority basis. As general licensees, there would be no routine inspections. General licensees are only inspected if an emergency would occur. However, the Office Inspection and Enforcement plans to initiate a program whereby general licensees would be inspected on a more routine basis.

2. Other Government Agencies, Industry, Public

This amendment does not affect other government agencies or the public. There would be no adverse health effects either to the veterinarians or the public. The conforming amendment to § 32.71 of 10 CFR Part 32 will permit industry to manufacture and distribute byproduct material for in vitro clinical or laboratory testing to veterinarians who possess the general license.

D. Decision on the Proposed Action

Authorization should be given to veterinarians to be included in the general license for use of byproduct material for in vitro clinical or laboratory testing.

II. PROCEDURAL APPROACH AND POSSIBLE ALTERNATIVES

The best SD procedure that can be used to promulgate the proposed action is the regulation.

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The only possible alternative is to not amend the present rule [i.e., maintain the status quo]. However, no simple grounds exist for denial of the petition since there are minimal radiation hazards and there is a need for a new regulation.

## IV. STATUTORY CONSIDERATIONS

### A. NRC Authority

This regulatory action derives its statutory authority from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

### B. Need for NEPA Assessment

Under § 51.5(a)(10) of 10 CFR Part 51, the proposed action is not a major action and does not require an environmental impact statement because the environmental impact of the action would be insignificant and nonsubstantive and is exempt under § 51.5(d)(3) of 10 CFR Part 51.

## IV. SUMMARY AND CONCLUSIONS

An amendment to the general license in § 31.11 of 10 CFR Part 31 should be approved in order that veterinarians will be among the groups authorized to use byproduct material for in vitro clinical and laboratory testing.