

## ATTACHMENT A RADIOACTIVE DRUG DISTRIBUTORS

1. Indicate type of operation:
- A. Registered or licensed with U.S. Food and Drug Administration as a drug manufacturer .....
  - B. Registered or licensed with State Agency as a drug manufacturer .....
2. Periodically reviews work of supervised individuals preparing drugs, and records kept to reflect work. [License condition (L/C)] .....  Y  N

Basis for Findings:

3. Radioactive drugs are measured (assayed) by direct measurement or combination of measurement and calculation before commercial distribution [10 CFR 32.72(c)] .....  Y  N

Basis for Findings:

4. Instrumentation Used to Measure Radioactivity of Drugs
- A. List type of equipment used to assay alpha and beta particles.
  - B. Procedures for instrument use developed and implemented [10 CFR 32.72(c)] .....  Y  N
  - C. Calibration tests performed before initial use, periodically, and following repair for accuracy, linearity, and geometry dependence, as appropriate for use of the instrument [10 CFR 32.72(c)(1); L/C] .....  Y  N
  - D. Adjustment to instrumentation made when necessary [10 CFR 32.72(c)(1); L/C] .....  Y  N

- E. Instruments are checked for constancy and proper operation at the beginning of each day of use [10 CFR 32.72(c)(2); L/C] .....  Y  N

Basis for Findings:

- 5. Transport radiation shield (on transfers for distribution) labeled with radiation symbol, "CAUTION [or DANGER], RADIOACTIVE MATERIAL," name, and quantity at specified date and time<sup>1</sup> [10 CFR 32.72(a)(4)(I); L/C] .....  Y  N
- 6. Syringes, vials, or other containers labeled with radiation symbol, "CAUTION [or DANGER], RADIOACTIVE MATERIAL," and an identifier to correlate with the information on the transport radiation shield label [10 CFR 32.72(a)(4)(ii); L/C] .....  Y  N

Basis for Findings:

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<sup>1</sup> The time may be omitted for drugs with a half-life greater than 100 days.