



DRP INFORMATION NOTICE
IN-02-02

TO: North Carolina Medical Use Licensees

FROM: J. Marion Eaddy III, Health Physicist 

DATE: Monday 06 May 2002

IN RE: **Measurement of alpha and/or beta-emitting radiopharmaceuticals prior to patient administration**

Agency regulations require that radiopharmaceutical doses be measured in a dose calibrator prior to the administration of the dose to a patient. The dose calibrator serves to measure (1) the activity of the eluant (2), the activity of Molybdenum 99 in the eluant and (3) the patient dose. The requirement for a dose calibrator was made in an effort to (A) ensure reproducibility in the preparation of individual patient doses from eluant, (B) prevent excessive amounts of molybdenum from being administered to a patient and (C) protect the patient from receiving either a dose too low for clinical benefit or one that is too high and potentially causes patient harm.

However, dose calibrators are designed around measurement of photon-emitting radionuclides, not beta-emitters. Special calibration factors and/or shields are needed in order to ensure that the beta-emitter can be measured with some degree of accuracy. Nuclear pharmacies are equipped with dose calibrators which have been calibrated for measurement of beta-emitting radiopharmaceuticals. These devices are examined during agency inspections of the nuclear pharmacy to verify their calibrations.

In an effort to address this area, the agency is issuing this information notice. The notice grants medical use licensees relief from conducting direct measurements of radiopharmaceuticals tagged with either alpha- or beta-emitting radionuclides. In granting this exemption, the following conditions MUST be met:

- a. the licensee orders the material in "unit dose" form only;
- b. the license obtains the radiopharmaceutical from either the manufacturer or an entity licensed pursuant to 10 CFR 32.72 or equivalent Agreement State Regulations; and,
- c. the licensee will decay correct from the distributor/manufacturer's calculated activity and record this activity as the administered dose.

This exemption **DOES NOT** relieve the licensee from any of the following:

1. direct measurements for PHOTON-EMITTING radiopharmaceuticals;
2. direct measurements of doses drawn from "bulk" vials obtained from the manufacturer; or
3. direct measurement of the dose (activity) drawn (eluted) from a "generator;"

Additionally, all medical use licensees must develop a policy to address this exemption. The policies/procedures should be developed and made available to agency representatives during your next inspection. Modifications to the licensee's quality management program should be made accordingly and a copy sent to the agency per 15A NCAC 11 .0356.

Amendments to existing licenses are NOT required at this time. A standard condition is being developed and that condition will be placed on your license the next time it is amended or at the time of renewal, whichever comes first.

If you have any questions concerning this notice, please contact me directly.