

21 NCAC 46 .2705 LABELING REQUIREMENTS OF RADIOPHARMACEUTICALS

(a) In addition to other labeling requirements of the Board for non-radioactive drugs described in this Chapter, the container of a radiopharmaceutical shall also be labeled with:

- (1) The standard radiation symbol;
- (2) The words "CAUTION - RADIOACTIVE MATERIALS";
- (3) The radionuclide of the radiopharmaceutical contained therein;
- (4) The chemical form of the radiopharmaceutical contained therein;
- (5) The amount of radioactivity of the radiopharmaceutical contained therein and the date and time of the calibration of that radioactivity;
- (6) The date and time of the expiration of the radiopharmaceutical contained therein;
- (7) If the radiopharmaceutical is a liquid, the volume;
- (8) If the radiopharmaceutical is a solid, the number of capsules or weight contained therein;
- (9) If the radiopharmaceutical is a gas, the number of ampules, vials, or syringes contained therein;
- (10) The name, address and telephone number of the nuclear pharmacy dispensing the radiopharmaceutical;
- (11) The prescription or lot number; and
- (12) The name of the pharmaceutical.

(b) No radiopharmaceutical may be dispensed unless a tamper-evident seal is applied and a label is affixed to the delivery container of each dose bearing the following information:

- (1) The standard radiation symbol.
- (2) The words "Caution - Radioactive Material."
- (3) The radionuclide and chemical form.
- (4) The volume if in liquid form.
- (5) The requested activity and the calibration date and time.
- (6) The prescription number.
- (7) Labels for radiolabeled blood components and therapeutic dosages must always contain the patient's name at the time of dispensing.

Where the patient's name is not available at the time of dispensing for diagnostic dosing, a 72-hour exemption is allowed to obtain the name of the patient. No later than 72 hours after dispensing the radiopharmaceutical, the patient's name must be associated with the prescription in a readily retrievable manner and must be retained for a period of three years.

- (8) The name and address of the nuclear pharmacy.
- (9) The name of the end authorized user, must also be a prescriber.
- (10) The lot number of the preparation.

History Note: Authority G.S. 90-85.6; 90-85.34;

Eff. January 1, 2005;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.