

6800.8550 LABELING OF RADIOPHARMACEUTICALS.

Subpart 1. **Immediate container of bulk radiopharmaceutical product.** Each compounded container must bear a label containing the following information:

- A. standard radiation symbol with words "Caution - Radioactive Material";
- B. radiopharmaceutical name or its abbreviation; and
- C. radiopharmaceutical lot number.

Subp. 2. **Outer container of bulk radiopharmaceutical product.** Each individual prepared dose must bear a label containing the following information:

- A. standard radiation symbol with words "Caution - Radioactive Material";
- B. radiopharmaceutical name or its abbreviation;
- C. amount of radioactivity;
- D. calibration date and time;
- E. expiration date and time;
- F. volume - if liquid, weight - if solid, number of vials or ampoules - if gas, number of capsules - if capsules;
- G. added substances, such as stabilizers and preservatives;
- H. radiopharmaceutical lot number;
- I. name, address, and telephone number of nuclear pharmacy, if it is to be transferred for commercial distribution; and
- J. initials of preparing nuclear pharmacist, if it is to be transferred for commercial distribution.

Subp. 3. **Immediate container of each radiopharmaceutical dispensed.** Each individual prepared dose must bear a label containing the:

- A. standard radiation symbol with words "Caution - Radioactive Material";
- B. radiopharmaceutical name or its abbreviation;
- C. radiopharmaceutical prescription or lot number; and
- D. patient name.

Subp. 4. **Outer container of each radiopharmaceutical dispensed.** Each individual prepared dose must bear a label containing the:

- A. standard radiation symbol with words "Caution - Radioactive Material";
- B. radiopharmaceutical name or its abbreviation;

- C. amount of radioactivity;
- D. calibration date and time;
- E. expiration date and time;
- F. volume - if liquid, or weight - if solid, and number of vials or ampoules - if gas;
- G. added substances, such as stabilizers and preservatives;
- H. radiopharmaceutical prescription or lot number;
- I. name, address, and telephone number of nuclear pharmacy;
- J. patient name; and
- K. initials of dispensing nuclear pharmacist.

Statutory Authority: *MS s 151.06*

History: *36 SR 237*

Published Electronically: *September 21, 2011*