

4731.4528 REPORT AND NOTIFICATION FOR AN ELUATE EXCEEDING PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND STRONTIUM-85 CONCENTRATIONS.

Subpart 1. **Telephone notification.** The licensee must notify, by telephone, the commissioner and the distributor of the generator, within seven days after discovery, that an eluate exceeded the permissible concentration listed in part 4731.4435, item A, at the time of generator elution. The telephone report to the commissioner must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

Subp. 2. **Written report.** The licensee must submit a written report to the commissioner within 30 days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; the probable cause and an assessment of failure in the licensee's equipment, procedures, or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subpart 1.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *46 SR 791*

Published Electronically: *May 26, 2022*