



Ohio Administrative Code

Rule 3701:1-58-105 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

Effective: August 15, 2021

(A) The licensee shall notify by telephone the department at 614-644-2727 and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in paragraph (A) of rule 3701:1-58-35 of the Administrative Code at the time of generator elution. The telephone report to the department 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.

(B) By an appropriate method listed in rule 3701:1-40-04 of the Administrative Code, the licensee shall submit a written report to the department within thirty calendar 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; and 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 paragraph (A) of this rule.
