



Ohio Administrative Code Rule 4729:5-6-04 Record keeping.

Effective: February 1, 2022

(A) In addition to the applicable record keeping requirements of division 4729:5 of the Administrative Code, a terminal distributor shall maintain records in compliance with USP <825> for all activities involved in repackaging, preparing, preparing with minor deviations, compounding, or dispensing radiopharmaceuticals.

(B) In addition to the requirements set forth in paragraph (A) of this rule, there shall be positive identification of the authorized nuclear pharmacist conducting the final check of the radiopharmaceutical.

(C) All records maintained in accordance with this rule shall be readily retrievable and uniformly maintained for at least three years.

(1) Except as provided in paragraph (C)(2) of this rule, all records maintained in accordance with this chapter shall be kept on-site.

(2) A pharmacy located in this state intending to maintain records at a location other than the location licensed by the state board of pharmacy shall send a request in a manner determined by the board. The board will provide written or electronic notification to the outpatient pharmacy documenting the approval or denial of the request. A copy of the board's approval shall be maintained at the licensed location. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(D) All records maintained pursuant to this chapter may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

(1) Complies with the requirements of this rule;



- (2) All paper records maintained electronically shall be scanned in full color via technology designed to capture all information in the paper record in one form and reproduce it in an electronic medium presentable and usable to an end user;
 - (3) Contains security features, such as unique user names and passwords, to prevent unauthorized access to the records; and
 - (4) Contains daily back-up functionality to protect against record loss.
- (E) All records required in accordance with this chapter shall be maintained under appropriate supervision and control to restrict unauthorized access.