

DEPARTMENT: Pharmacy

PROCEDURE: PS-190

SUBJECT: Sterile Products: Expiration Dates

PURPOSE: Expiration dates for sterile products shall be assigned according to this policy.

RESPONSIBILITY: Pharmacy

PROCEDURE:

1) ADJUSTMENT OF EXPIRATION DATES

- a. A pharmacist may adjust expiration dates based on current literature and professional judgment.

2) EXPIRATION DATES FOR COMPOUNDED STERILE PRODUCTS

- a. Expiration dates shall be assigned to all compounded sterile products. The assigned expiration date shall not extend beyond the stability period established by the manufacturer or listed in a current, authoritative reference. A pharmacist shall determine if the products are usable after this date.
- b. Single and Multi-dose Containers:
 - i. **Multi-Dose:** Beyond-use date 28 days, unless specified otherwise by the manufacturer, for closure sealed multiple-dose containers after initial opening or entry.
 - ii. **Single Dose:** Beyond-use time of 6 hours, unless specified otherwise by the manufacturer, for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry.

- 3) Beyond-use time of 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air.