

# Audit Preparedness Checklist: DIY vs. Standardized STAT Kits

## 1. Expiration & Integrity Management

**Single-Point Expiration:** Does the kit have one external "Master Expiration" date visible for surveyors, or must staff open/inspect individual components?

---

*Risk: Failure to identify a single expired component during a CMS/Joint Commission walk-through results in an automatic Requirement for Improvement (RFI).*

**Tamper-Evident Sealing:** Is there a validated seal to prove the kit hasn't been "cannibalized" for parts?

---

*Risk: Using a partial kit in an emergency is a standard-of-care violation.*

## 2. Clinical Standardization

**Content Uniformity:** Are the contents identical across all units (ED, ICU, Med-Surg)?

---

*Risk: Surveyors may "cross-check" kits in different departments. Inconsistency suggests a lack of formalized clinical protocols.*

**IFU Accessibility:** Are the Instructions for Use (IFU) included for every device within the kit?

---

*Risk: Lack of immediate access to IFUs during a procedure is a common safety citation.*

## 3. Infection Control & Sterility

**Validated Packaging:** Is the kit container medical-grade and validated for the clinical environment?

---

*Risk: "Homemade" kits using non-validated bins or bags are magnets for Infection Control citations regarding dust accumulation and porous surfaces.*

**Assembly Environment:** Was the kit assembled in a controlled, sterile-adjacent environment?

---

*Risk: Manual assembly by staff in non-sterile breakrooms or nursing stations is a breach of aseptic secondary-packaging standards.*

## 4. Traceability & Recall Readiness

**Lot-Level Tracking:** Can the facility instantly locate a specific lot number in the event of an FDA Class I Recall?

---

*Risk: If a facility cannot prove they've removed a recalled component from their "homemade" kits, the liability falls 100% on the hospital, not the manufacturer.*

## The "Hidden Cost" Calculator

**Nursing Labor:** \$ \_\_\_\_\_ /hr x  
(Time spent re-stocking/checking DIY kits)

**Pharmacy Labor:** \$ \_\_\_\_\_ /hr x  
(Time spent auditing DIY expiration dates)

**Compliance Risk:** The average cost of a "Moderate" RFI (Request for Improvement) follow-up is estimated in the thousands when factoring in administrative time, corrective action plans, and re-surveys.