OpsAuditHub opsaudithub.com	DOC ID: **SAF-0174**	REVISION: **Rev 2.4 (2026)**
	STANDARD: **CDC Vaccine Storage and Handling Toolkit / FDA 21 CFR Part 211 / USP 1079**	AUDIT FREQUENCY: **Daily Pre-Shift and Monthly Compliance Audit**

Medical Refrigeration Temperature Log Safety Audit Checklist

Operational Scope: Establishes a mandatory protocol for monitoring medical refrigerator and freezer temperatures to prevent vaccine and pharmaceutical spoilage. Mitigates the risk of biological hazard exposure and ensures full regulatory compliance with cold chain integrity standards.

MANDATORY PPE:	Nitrile Examination Gloves (ASTM D6319), Lab Coat or Protective Medical Scrub, Closed-Toe Slip-Resistant Footwear, Safety Glasses with Side Shields (ANSI Z87.1)
PREREQUISITES:	Verify calibration status of the primary and secondary continuous temperature monitoring devices. | Ensure backup emergency power source (UPS/Generator) is verified and operational for all cold storage units.

DAILY TEMPERATURE LOGGING & DEVICE CALIBRATION

#	COMPONENT / ITEM	VERIFICATION CRITERIA & ACCEPTANCE STANDARD	SEVERITY	STATUS
1	**Refrigerator Ambient Storage Temperature**	Internal storage temperature must read consistently between 2°C and 8°C (36°F to 46°F) verified via calibrated digital data logger.	**Critical (Immediate Out of Service)**	[ ] PASS [ ] FAIL [ ] N/A
2	**Freezer Ambient Storage Temperature**	Ultra-low or standard medical freezer temperature must remain between -50°C and -15°C (-58°F to +5°F) depending on storage class.	**Critical (Immediate Out of Service)**	[ ] PASS [ ] FAIL [ ] N/A
3	**Min/Max Temperature Log Sheet Verification**	Current, minimum, and maximum temperatures are recorded manually or digitally twice daily; no excursions noted outside acceptable range without documented corrective action.	**Warning**	[ ] PASS [ ] FAIL [ ] N/A
4	**Temperature Probe Placement**	Buffered probe is placed centrally in the unit, away from walls, evaporator coils, and doors to reflect true product temperature.	**Standard**	[ ] PASS [ ] FAIL [ ] N/A

UNIT INTEGRITY, POWER & ENVIRONMENTAL SAFETY

#	COMPONENT / ITEM	VERIFICATION CRITERIA & ACCEPTANCE STANDARD	SEVERITY	STATUS
5	**Door Seals and Gasket Integrity**	Magnetic door gaskets create a tight, uniform seal around the perimeter with no visible cracks, tears, or frost accumulation indicative of air leaks.	**Warning**	[ ] PASS [ ] FAIL [ ] N/A
6	**Dedicated Power Supply & Circuit Lock**	Refrigeration unit is plugged directly into a dedicated wall outlet (no daisy-chained extension cords or multi-plug strips) equipped with a safety plug guard.	**Critical (Immediate Out of Service)**	[ ] PASS [ ] FAIL [ ] N/A
7	**Internal Air Circulation & Loading**	Inventory is stored at least 2 inches away from interior walls and floor vents to ensure unobstructed forced-air circulation.	**Standard**	[ ] PASS [ ] FAIL [ ] N/A
8	**Alarm System and Battery Backup**	Audible and remote temperature excursion alarms function properly; test alarm button confirms signal transmission to facility monitoring system.	**Critical (Immediate Out of Service)**	[ ] PASS [ ] FAIL [ ] N/A

EMERGENCY PROTOCOLS & EXCURSION MANAGEMENT

#	COMPONENT / ITEM	VERIFICATION CRITERIA & ACCEPTANCE STANDARD	SEVERITY	STATUS
9	**Emergency Backup Storage Plan**	A validated backup storage facility or qualified transport cooler with conditioned phase-change materials is readily accessible on-site.	**Warning**	[ ] PASS [ ] FAIL [ ] N/A
10	**Excursion Corrective Action Log**	Clear written SOP and documentation forms are posted near the unit for logging temperature excursions, quarantining affected stock, and notifying clinical leads.	**Standard**	[ ] PASS [ ] FAIL [ ] N/A

Certified Medical Equipment Technician / Lead Nurse Signature: _____	**Date / Time:** _____	**Badge / Cert #:** _____
Clinical Facility Safety Officer / Operations Manager Sign-off: _____	**Review Date:** _____	**Audit Status:** [ ] Approved [ ] Rectify

COMPLIANCE NOTICE: This document must be archived for a minimum of 36 months in accordance with healthcare regulatory compliance and vaccine management guidelines.

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