

SOP: Controlled Substances Handling and Inventory Logging

This SOP describes the procedures for **controlled substances handling and inventory logging**, including secure storage, authorized access, accurate inventory tracking, regular audits, proper documentation, and compliance with legal and regulatory requirements to ensure the safe and accountable management of controlled substances.

1. Purpose

To outline standardized procedures for handling, storage, access, documentation, inventory logging, and auditing of controlled substances, ensuring full compliance with all applicable laws and regulations.

2. Scope

This SOP applies to all personnel involved in the receipt, storage, use, dispensation, and disposal of controlled substances within the facility.

3. Responsibilities

- **Controlled Substances Officer:** Oversee all controlled substances inventory and compliance.
- **Authorized Personnel:** Handle, log, and access controlled substances as per authorization.
- **Supervisors/Managers:** Ensure adherence to SOP and report discrepancies.

4. Secure Storage

- All controlled substances must be kept in a locked, secure storage cabinet or vault at all times except during authorized use.
- Access codes, keys, or other security measures must be restricted to authorized personnel only.
- Storage areas must be compliant with applicable DEA/local regulations.

5. Authorized Access

- Only personnel with documented authorization may access controlled substances.
- Maintain an up-to-date list of authorized personnel, reviewed quarterly.
- Visitors, trainees, or unauthorized personnel are strictly prohibited from unsupervised access.

6. Inventory Tracking and Documentation

- Log every receipt, dispensation, use, and disposal of controlled substances in the inventory log (electronic or paper-based).
- Record the following for each entry:
 - Date
 - Name and quantity of controlled substance
 - Lot/Batch number
 - Person responsible (signature/initials)
 - Purpose of use or transaction
 - Running balance
- Logs must be updated immediately after each transaction.
- Correct any errors with a single strikeout, initialed and dated. Never use correction fluid or erase data.

Date	Substance	Lot #	Quantity In	Quantity Out	Balance	User (Initials)	Purpose
2024-06-01	Morphine	9876	10 vials		10 vials	JDS	Initial Receipt
2024-06-03	Morphine	9876		2 vials	8 vials	ASB	Clinical Use

7. Auditing Procedures

- Conduct physical inventory audits at least quarterly and after any discrepancy or incident.
- Compare physical stock with inventory log; document and investigate discrepancies immediately.

8. Disposal of Controlled Substances

- Disposal must follow all regulatory guidelines (e.g., witnessed destruction, designated reverse distributor, proper documentation).
- Document disposal with date, quantity, method, and signatures of at least two authorized witnesses.

9. Documentation and Record Retention

- Retain all records, logs, and audit reports for the period required by law (typically 2-5 years).
- Store records in a secure and accessible location for potential inspections.

10. Compliance and Training

- All staff handling controlled substances must complete training on this SOP and applicable regulations.
- Periodic re-training and updates as required.

11. References

- DEA Controlled Substances Act
- State and local regulations
- Institutional policies

12. Revision History

Version	Date	Description	Author
1.0	2024-06-15	Initial release	Compliance Team