

Standard Operating Procedure for the Safe and Compliant Use of Precision Extraction Solutions C-15 Centrifuge Extractor

Objective:

The primary objective of this Standard Operating Procedure ("SOP") is to establish comprehensive guidelines that ensure the safe, compliant, and precise operation of the Precision Extraction Solutions C-15 Centrifuge Extractor ("C-15") in accordance with [STATE] law and cGMP guidelines. This SOP aims to mitigate risks, enhance operating efficiency, and uphold a consistent standard of performance for all personnel involved in the operation of the C-15 within [COMPANY]. This document further seeks to promote a culture of responsible equipment handling, reduce the likelihood of accidents or injuries, and facilitate optimal functionality and longevity of the equipment.

I. Introduction

A. Purpose

The purpose of this SOP is to establish comprehensive guidelines and protocols for the safe, efficient, and compliant operation of the C-15. This document aims to ensure that all personnel involved in the operation of the C-15 are fully informed and trained on the necessary procedures to mitigate risks, uphold safety standards, and adhere to regulatory requirements.

B. Scope

This SOP applies to all authorized personnel responsible for operating the C-15.

II. Equipment Overview

A. Model Information

The C-15 features multifunction jacketed housing supporting either liquid coolant or vacuum insulation. Simplified material loading and unloading makes the C-15 a very user-friendly, single operator solution. The C-15's complete system package includes tanks and pumps. Its welded parts are manufactured out of 304L, 316, and 2205 sanitary stainless steel.

B. Functionality

The key functions and features of the C-15 includes:

- Dimensions (approx.) 46" L x 28" W x 52" H
- Weight (approx.) 1,050 lb.
- Interior Finish Spec 32 Ra or Better
- Basket Size 50L (Ø18" X 12")
- Variable Frequency Drive 0-1800 RPM (828 Gs)

- Max Flood Volume 2.5 FT3 (72 Liters)
- HMI Size 7" Panelview 7 Plus
- 24 VDC with Ethernet
- Sanitary
- Connection Specs
- 1" Feed
- 1" Effluent Outlet
- 1" Lid (Qty 2)

III. Safety Precautions and Protocols

A. Personal Protective Equipment ("PPE")

Employees must wear the following PPE before conducting any extraction activities:

- Safety Glasses
- Gloves
- Lab Coat
- Half-face respirator, as applicable

B. Safety Protocols

To ensure safe operation of the C-15, employees will conduct all extraction activities within a Class 1, Division 2 ("C1D2") extraction booth.

Prior to conducting any extraction activities, employees must abide by [COMPANY] policy and cGMP guidelines including:

- Personal Hygiene:
 - Maintain good personal hygiene practices, including regular handwashing and use of sanitizers. Employees must also maintain proper grooming, including clean and appropriate clothing to prevent the introduction of contaminants.
- Hand Hygiene:
 - Practice thorough handwashing before entering the extraction area. [COMPANY] will provide hand sanitizers in areas where handwashing facilities are not readily available.
- Protective Clothing:
 - Wear appropriate protective clothing, as dictated in the PPE list above.
 - Protective clothing must be clean, in good condition, and used only within designated areas.
- Jewelry and Accessories:
 - Limit or prohibit the wearing of jewelry, watches, or accessories in extraction areas to prevent the risk of contamination.
- Illness Reporting:
 - Promptly report any illness or health condition that could compromise product safety or quality.
- Training and Education:
 - All employees must be adequately trained on the correct usage of the C-15 prior to operating this equipment. Only employees that have received proper training AND have signed the Compliant and Safe C-15 Usage Agreement may operate this equipment.

- Refer to [COMPANY]'s comprehensive Hygiene Practice SOP for a complete overview of the mandated hygiene practices, including handwashing techniques, proper use of PPE, and awareness of hygiene-related risks.
- Facility Access Controls:
 - Only authorized employees may enter the extraction area. To enforce this, [COMPANY] may use barriers, security measures, and hygiene checks at entry points to prevent unauthorized access and maintain hygiene standards.

C. Operational Environment

Ensure that all lights are working in the C1D1 Extraction booth to ensure that the extraction booth is properly lit.

Ensure the workspace is clean and free of clutter to avoid accidents.

D. Emergency Procedures

Familiarize yourself with the location of emergency exits, first aid kits, and fire extinguishers.

In case of an emergency, immediately shut down the equipment and follow the established emergency protocols.

IV. Operating Procedures

A. Pre-Operation Checks

Verify that the C-15 is clean and free from any residual materials from previous use.

Check that all components, including the lid and safety interlocks, are in good condition.

Ensure the C-15 is properly grounded before operation.

B. Loading and Unloading

Carefully load the materials into the C-15 according to the specified capacity.

Ensure that the load is evenly distributed to prevent imbalance during operation.

Follow the manufacturer's guidelines for loading and unloading.

C. Start-Up and Shutdown Procedures

Follow the specified start-up sequence outlined in the user manual.

Monitor the equipment during operation and be prepared to shut it down immediately if any issues arise.

Follow the manufacturer's guidelines for the proper shutdown procedure.

V. Maintenance and Cleaning

A. Regular Maintenance

Perform routine maintenance tasks as specified in the user manual.

Schedule regular inspections to identify and address any wear and tear.

B. Cleaning Procedures

Clean the C-15 after each use using recommended cleaning agents.

Follow the cleaning instructions provided by Precision Extraction Solutions.

VI. Record Keeping

A. Usage Log

Maintain a usage log that includes details such as date, time, operator name, and any observations during operation.

B. Maintenance Records

Document all maintenance activities, including dates, tasks performed, and any replacement parts.

VIII. Review and Revision

A. Regular Review

Periodically review this SOP to ensure its continued effectiveness.

Revise the SOP as needed to incorporate any updates or changes in procedures.

IX. Approval

This SOP has been reviewed and approved by:

[Name]

[Position]

[Date]