



# Standard Operating Procedure (SOP) for ABC

KK-1208-25

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Prepared for  
Information Mapping Interview

## Standard Operating Procedure: KK-1208-25

Title of SOP	Document Name	Date	Page. No
ABC	KK-1208-25-ABC-SOP	07/06/2021	1

## Table of Contents

---

<b>Overview .....</b>	<b>2</b>
Introduction .....	2
Contents .....	2
<b>Standard Operating Procedure: KK-1208-25 .....</b>	<b>3</b>
Purpose .....	3
Scope .....	3
Responsibility .....	3
Accountability .....	3
Constraint .....	3
Procedure .....	3
<b>Procurement of the Resource .....</b>	<b>4</b>
Required Operators .....	4
Tools .....	4
Dress code of operators .....	4
<b>Pre-setup for a coating run .....</b>	<b>5</b>
Pre-Setup .....	5
Batch Document .....	5
Release Liners .....	5
Validation of Batch Documents .....	5
Preparation of pump and slot die setup .....	6
Coater Startup and Shutdown Procedure .....	6
<b>Cleaning and verification .....</b>	<b>7</b>
Cleaning of Slot Die .....	7
Cleaning of Zenith Pump .....	7
Cleaning of Pump Trunions and all Swagelok fittings .....	7
Cleaning of Contact Surfaces and Tools .....	7
Verification .....	8

**Standard Operating Procedure: KK-1208-25**

Title of SOP	Document Name	Date	Page. No
ABC	KK-1208-25-ABC-SOP	07/06/2021	2

**KK-1208-25-ABC-SOP****Overview**

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**Introduction**

This document has required procedures and responsibilities related to machine and material preparation prior to a coating run and to cleanup after a coating run.

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**Contents**

Topic	See Page
Standard Operating Procedure KK-1208-25	3
Procurement of Resource	4
Pre-setup for a coating run	5
Cleaning and Verification	7

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**Standard Operating Procedure: KK-1208-25**

Title of SOP	Document Name	Date	Page. No
ABC	KK-1208-25-ABC-SOP	07/06/2021	3

**Standard Operating Procedure: KK-1208-25**

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**Purpose** The purpose of this SOP (Standard Operating Procedure) is to document the required procedures and responsibilities related to machine and material preparation prior to a coating run and to cleanup after a coating run.

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**Scope** This SOP (Standard Operating Procedure) provides procedures and responsibilities related to machine and material preparation prior to a coating run and to cleanup after a coating run for the operator.

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**Responsibility** Operators

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**Accountability** Production Supervisor

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**Constraint** This document does not provide detailed information regarding how to operate the C/D/L, as this is covered in detail by the Operator Instructions (document KK-1208-03).

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**Procedure** Procedures and responsibilities related to machine and material preparation prior to a coating run and to cleanup after a coating run are discussed in these stages:

1. Procurement of Resource
2. Pre-setup for a coating run
3. Cleaning & verification

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**Standard Operating Procedure: KK-1208-25**

Title of SOP	Document Name	Date	Page. No
ABC	KK-1208-25-ABC-SOP	07/06/2021	4

## Procurement of the Resource

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**Required Operators**

A minimum of two Operators will be required for C/D/L (Coater) Start Up and for completion of a Production batch. Three Operators may be necessary when Operators are inexperienced. Coating should be continued through lunch, in which case one operator would remain in the Coating room and one operator will take a lunch break.

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**Tools**

In the coating room during production, only required process tools are allowed. Required tools include the following:

Tool Name	Specifications
Allen wrenches	1/8", 5/32", 3/16", 7/32", and 1/4"
Open end/box wrenches	9/16", 3/4", 13/16", 7/8"
SS rulers/straight edge	6" and 12"
Straight and Phillips screw driver	-
3 pairs of industrial steel scissors	-
Black bold marking pens	-
Razor knives	-

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**Dress code of operators**

Dress code for Operators in the Coating room:

- Lab Coats must be worn that extend down to the knee.
  - Long pants must be worn (no skirts or shorts).
  - Hair nets must be worn.
  - Beard covers must be worn by anyone with facial hair.
  - Socks must be worn.
  - Shoe covers must be worn unless dedicated shoes (that never leave the clean environment) are available.
  - No rings or watches shall be worn, and no wallets or cell phones will be allowed.
  - Surgical gloves should be worn when there is a chance of exposure to the coating liquid.
  - Surgical gloves should be discarded before leaving the coating room.
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## Standard Operating Procedure: KK-1208-25

Title of SOP	Document Name	Date	Page. No
ABC	KK-1208-25-ABC-SOP	07/06/2021	5

### Pre-setup for a coating run

#### Pre-Setup

In this stage we discuss how Machine and material preparations performed prior to a coating run.

Operator has to perform these steps:

- Validation of Batch document
- Preparation of pump sand slot die setup
- Coater Startup and Shutdown Procedure

#### Batch Document

Batch document includes a list of all materials required for the batch and provides clear instructions for how the Operator should determine which side of the web coating should be applied to.

#### Release Liners

Release Liners (Mylar, Polyester) typically have a Silicone coating on one side that allows the coated products to peel off easily for the end user (patient). Typically, the coating will be applied to this "Release Side".

To determine Release Side, the Operator uses a bold black marking pen to scribble on both sides of the release liner, the marking pen will not write on the Release Side, where as it writes very clearly on the non-release side

#### Validation of Batch Documents

Steps followed in Validation of Batch document are:

Step	Action
1	On entering the coating room for a production run, both operators will review batch documents, make sure that all C/D/L parameters are set according to the batch documents provided by the production supervisor.
2	Both operators will verify that the materials and process to determine which side (In or Out) of the Web Release liner are correct and clear then both operators will sign the batch documents so that both operators assume responsibility for the accuracy of all information.
3	If there are any discrepancies, the operators will not proceed with the batch, and the discrepancies will be reported to the production supervisor immediately.

**Note:** The explanation above is based on our experience with typical products and typical materials.

*Continued on next page*

**Standard Operating Procedure: KK-1208-25**

Title of SOP	Document Name	Date	Page. No
ABC	KK-1208-25-ABC-SOP	07/06/2021	6

**Pre-setup for a coating run, continued****Preparation of pump and slot die setup**

Preparation of pump and slot die setup are:

1. The Mixing room personnel and a "Spill" team will make all plumbing connections to the Zenith Delivery pumps. They also deliver the slurry mixing vessels to the Coating room
2. They will stay in the Coating room (prepared as a "spill" team) until the Operators have wetted the plumbing loop and Zenith Delivery pumps safely.
3. the Coater Operators will mount and adjust the Slot Die and Zenith Delivery pumps onto the Coater.

**Operator role**

Role of the Coater Operators is to mount and adjust the Slot Die and Zenith Delivery pumps onto the Coater.

**Note:**

The Operators are NOT responsible for bringing the "Slurry" (coating liquid) from the mixing room into the Coating room.

**Coater Startup and Shutdown Procedure**

ABC establish procedures for

1. Starting the C/D/L, heating up the dryer, threading web, priming the plumbing from the mixing vessel to the Pump and from the Pump to the Slot Die, and finally, beginning coating.
2. Shutting down the C/D/L and leaving it in a state so that it can easily be restarted for the next batch.
3. For taking samples, and for periodically recording actual process values to verify that, no important process values have deviated from the setpoints listed on the batch documents provided by the Production Supervisor.

After preliminary trials have been performed to establish exactly how ABC will be operating the machine, it will probably be helpful to write a more concise startup procedure.

Procedures for starting, operating, and shutting down the C/D/L are covered in detail by the Operator Instructions (document KK-1208-03). The Operator Instructions provide detailed information covering different options, modes, and scenarios.

**Standard Operating Procedure: KK-1208-25**

Title of SOP	Document Name	Date	Page. No
ABC	KK-1208-25-ABC-SOP	07/06/2021	7

## Cleaning and verification

**Cleaning of Slot Die**

Process of cleaning slot Die:

Stage	Description
1	The Slot Die Top Jaw and the Slot Die Shim should be removed for cleaning and the Slot Die Bottom Jaw will be left in place.
2	The Slot Die Top Jaw, Shim and Slot Die Bottom Jaw should be cleaned separately by using an appropriate cleaning solution (solvent, alcohol, water, ...) for the coating liquid that was used
3	During this process, the Slot Die Top Jaw should be inspected for scratches or dings on the lips and on the mating surfaces. If necessary, have it refinished / reground.

**Warning:**

1. Don't touch the slot die with any metal objects when swapping / cleaning, which creates scratches and dings
2. Don't touch the top jaw with the bottom jaw and vice versa.

**Cleaning of Zenith Pump**

Zenith Pump should be removed. Disassembling, cleaning, and re-assembling of a zenith pump is explained in the B-Series Gear Pumps Installation, Care and Maintenance Guide.  
The Pump should be inspected for any signs of wear or damage.

**Cleaning of Pump Trunions and all Swagelok fittings**

Pump Trunions and all Swagelok fittings should be cleaned using an appropriate cleaning solution (solvent, alcohol, water, ...) for the coating liquid that was used

**Cleaning of Contact Surfaces and Tools**

Any Rolls, machine areas or components, and tools that have come in contact should be cleaned using an appropriate cleaning solution (solvent, alcohol, water, ...) for the coating liquid that was used.

Pay more attention to the following product contact parts:

1. The area underneath the Slot Die.
2. All Rolls that form the web path from the Primary Unwind to the Rewind (including the Idler Rolls in the Dryer).
3. All tools that have been used.
4. Determine and inspect All of the obvious places that might come into contact with the coating liquid have been cleaned, all other machine surfaces should be wiped and cleaned as well.

*Continued on next page*



**Standard Operating Procedure: KK-1208-25**

Title of SOP	Document Name	Date	Page. No
ABC	KK-1208-25-ABC-SOP	07/06/2021	8

**Cleaning and verification, continued**

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**Verification**

A properly trained person (other than the operators) should perform a "wipe test" in several different locations to verify that cleaning has been done properly. After it has been verified that cleaning has been done properly, the C/D/L will be ready for the next batch.