1.0 Purpose

The purpose of this procedure is to ensure line clearances occur between runs as outlined in 21 CFR 211.130.

2.0 Scope

This procedure applies to every line on the production floor.

3.0 Responsibility

Line Operators, Supervisors and/or Quality Unit are responsible for this procedure

4.0 Safety Considerations

Safety glasses and steel toed shoes are required.

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

N/A

6.0 Procedure

This procedure is to be performed each time a line changes over to a different product.

1. Left over materials must be counted, recorded on the changeover sheet and removed to storage.
2. All trash must be removed from the line and emptied.
3. Packing and stacking areas must be cleared of all corrugated, pouches or cartons.
4. If using dry additives, the feeder box must be emptied and cleaned.
5. If a fragrance barrel is used it needs to be removed from the line. The machine and all utensils used for scented product must be cleaned.
6. If changing from scented salt to USP salt, the machine and line components must be thoroughly cleaned before a swab test can be completed. Testing will be conducted as outlined in the *Residual Fragrance Test using TLC (R12-PR-100-015)* procedure.

7. Once line is free of materials from production run, fill in the Line Clearance section of the changeover form. Completed paperwork must be returned to Supervisor.

7.0 Reference Documents

Residual Fragrance Test using TLC (R12-PR-100-015)

8.0 Change Information

Revised Purpose, Procedure, reference document name & changed owner.