1.0 Purpose:

The purpose of this procedure is to outline a metal contamination prevention program that should achieve an acceptable level of control. This procedure will describe a three-tiered approach along with engineering and procedural controls needed to stay compliant with 21 CFR sections 211.67(a) and 211.84(d)(5) as well as FDA's *Compliance Program Guidance Manual* 7356.002 "controls to prevent contamination".

2.0 Scope:

This procedure will cover preventative measures for avoiding metal contamination in the sites facility's through the application of in-process controls to remove the presence of metal particles and monitoring controls to verify the continued effectiveness of the in-process controls.

The in-process controls shall be in place at all times during normal operation and monitoring of the controls shall occur at intervals specified within this document.

3.0 Responsibility:

It is the Production Unit's responsibility to monitor and ensure that all controls are in place any time product is being produced.

The Quality Unit is responsible for verifying that the controls are in place during daily floor audits.

4.0 Safety Considerations:

Appropriate PPE should be worn at all times. This includes but is not limited to steel-toed shoes and safety glasses.

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:

- Compact Force Gauge CFG+ 200N

6.0 Procedure

There is a zero tolerance for product with metal contamination. In order to achieve this, a three-tiered process has been established. The process includes prevention, removal, and detection.

Prevention –

Design:
A failure mode and effects analysis (FEMA) was conducted during set up of the processes that make up the company's systems in order to prevent contamination (ie. small bolts are avoided, bearings have spacers when possible, etc.).

Maintenance:
A preventative maintenance program is in place for all equipment in the facility to eliminate or significantly reduce the risk of any contamination from machinery.

Process System:
The process is a closed system where possible to reduce the risk of any foreign contaminates. Any areas that are exposed to atmospheric conditions are protected by means of locking covers and shields.

Removal-

Filtration:
Filtration is used for the Brine and Mother Liquor to prevent solid contaminants of any type:

1. The Filter Press filters the Brine at 5 micron progressing to sub-micron levels to remove metal contaminates if any from the raw materials.
2. A sock filter is used for the Mother Liquor that is fed to the Crystallizers. This sock has a pore size of 100 microns.
3. The sock is cleaned and inspected on weekly clean days. This is documented on the *Weekly Clean Day Log (P12-FM-100-017)*

Screens:
Screens are used at various points in the system to stop contaminants in the system:

1. A screen and rejecter combination is in place after the Dryer/Cooler to remove anything over 0.25 inches in size. This rejecter removes nuts, bolts, and other large pieces that could get into the system after the Crystallizer/ Centrifuge system.
2. 0.25" screen's in the hopper chutes protect the system from the Dryer/Cooler to the salt collection hoppers.
3. All screens are visually inspected at least once per shift and cleaned of any debris (i.e. bolts, nuts, salt clumps, etc.). Any debris are retained and brought to the attention of the quality department.

4. The Quality department also visually inspects the screens and records their findings on the *Manufacturing Process Quality Audit (P14-QA-100-F090).*

Magnets:
Large rare-earth magnets are used at strategic locations to remove any ferrous particulates that make it all the way to the place of final package.

1. Bolt-on magnets are in place on top of the hopper screens to remove any particulates that may have been picked up in the salt screws.
2. Screen magnets are located below each salt hopper to remove any particulates that could be found in the hoppers.
3. On each clean day the magnets are removed and cleaned, this is documented on the *Weekly Clean Day Log (P12-FM-100-017)*.

Grates and Hopper Covers:
All hoppers at the repackaging facility are equipped with grates and hopper covers to prevent environmental contaminates and contaminates that may fall in during salt loading.

Detection –

Magnets:
In-line magnets are used as both a means of removal and a means of detection.

1. All in-line magnets will be checked by production daily for any excess build-up (residue retained on the magnets in excess of 1/8" from the surface of the magnet).
2. The Quality Department will examine the bolt-on magnets during the *Manufacturing Process Quality Audit (P14-QA-100-F090)* and check for any build-up and record their findings.
3. If any build-up is found, the magnets will be cleaned thoroughly and the recently produced product will be visually inspected for metal particulates and process will be evaluated to determine the source of the particulates.
4. All magnets will be checked bi-annually with a calibrated force gauge to ensure their strength is within conformance (> 15.0N). Results will be recorded on *Magnet Strength Test (Q15-PR-100-F027).* If magnets do not fall within specifications they will be replaced.
   (Note: The magnet strength limit of 15.0N was established as 75% of the baseline results from the installed magnets.)

Visual Inspection:
Normal human vision can detect particulates in the range of 40-50um in size. Which is an acceptance limit clarified by the FDA in 2002.

1. A statistically-based product inspection will be conducted by the Quality Department daily by inspecting finished product samples from multiple time-points throughout active production hours. These inspections will be recorded on the *Daily SCR Quality Audit (P12-QA-100-F077)*.
2. If any non-conformances are found, an in depth audit will be performed to determine the products affected and process will be evaluated to determine the source of the particulates all affected product will be quarantined.

7.0 Reference Documents

Weekly Clean Day Log (P12-FM-100-017)
Manufacturing Process Quality Audit (P14-QA-100-F090)
Daily SCR Quality Audit (P12-QA-100-F077)
Magnet Strength Test (Q15-PR-100-F027)

8.0 Change Information

New Document