1.0 Purpose

The purpose of this procedure is to specify the frequency in which an automated metal detector is inspected and calibrated on a production line in the Giles Repackaging facility. The procedure will identify who is responsible for the verification and calibration of the automated metal detector 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 outline the frequency and responsibility of verifications and calibrations needed to ensure the automated metal detector is performing properly.

3.0 Responsibility

Lead Operator – performs verification testing each shift using test chips provided by machine vendor
3rd Party Vendor – calibrates and certifies machine on an annual basis
Quality – retains annual calibration documents and weekly shift verification log

4.0 Safety Considerations

Observe all manufacturing safety requirements: Safety glasses and steel toed shoes.

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

Factory provided Test Chips: (visually inspect to verify metal bead is in one end of test chip before beginning verification test)

- 1.5 mm Ferrous Metal (Red)
- 2.5 mm Stainless Steel 316 (Blue)
- 2.0 mm Brass (Yellow)

6.0 Procedure

1. Turn Metal Detector power and conveyor on. Make sure air is on to kick off arm.
2. Place 1.5 mm Ferrous Metal [Red] test chip on top of filled pouch that has successfully passed through detector without being kicked off.
3. Place pouch and test chip on the in-feed conveyor.
4. Metal Detector should beep and kick pouch off into floor.
5. Verify that reject counter on touch screen increased by one.
6. Repeat steps 2 – 5 for each of the remaining chips (2.5 mm Stainless Steel 316 [Blue] and 2.0 mm Brass [Yellow])
7. If all chips cause a rejected pouch, then verification is successful and complete.

8. Record verification date and initial in *Weekly Shift Metal Detector Verification Log* (R17-PR-100-F066)
9. If one or more chips do not kick off, re-run samples a second time.
10. If chip(s) still do not kick off, contact Engineering for assistance.
11. Supervisor or Quality initials and dates after each shift of verification testing.

7.0 Reference Documents

Weekly Shift Metal Detector Inspection Log (R17-PR-100-F066)

8.0 Change Information

New Document