Title: Metal Detection					
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Introduction
This document provides guidance in the installation, use and maintenance of metal detectors in Pharmaceutical and Animal Health solid oral dosage form drug products and medical devices that by design do not contain metal components.

1. **Definitions** ï the following terms apply specifically to metal detection as used in this guidance.
Rotonoid ï double acting electrical solenoid valve that is electrically controlled in two directions (e.g., open and closed) with no spring return.

2. Site quality teamôs decision on whether routine metal detection operations are required for products at their Site should be based on, and not limited to, the following factors:

- Product history of metal contamination incidents (e.g., equipment failures, equipment metal-to-metal contact causing contamination, raw materials with metal contaminants);

- Assessment of manufacturing and/or packaging processes involved in terms of possible metal contamination

- Effectiveness of the metal prevention systems and processes used at the site; and

- Commitments to Regulatory Authorities.

3. Action Levels for the total number of units (e.g., tablets, capsules, bottles) isolated by the metal detector should be developed by the quality team based on and not limited to:

- Historical data on the number of units contaminated with metal according to product and/or manufacturing or packaging process step;

- Investigation reports [e.g., Deviation Reports] including any documented product recovery from contaminated units; and

- Applicable quantitative results indicating that preventive measures have reduced metal contamination in manufacturing and/or packaging process steps. Such preventive measures include and are not limited to:
    - Installation of rare earth magnets at raw material charging stations;
    - Raw material process improvements by the vendor that reduced contamination; and
    - Manufacturing or packaging equipment set-up improvements that reduced contamination resulting from equipment wear.

not limited to:

- Reject gate reaction time, if reject gates are present;
- Length of time reject gate stays open;
- Throughput process speed; and
- Sensitivity settings.

11. Metal Detector IQ should include, and is not limited to, verification and documentation that:

- Metal detector is installed according to specifications;
- Utilities (e.g., electrical, air supply) are identified and the direction of flow indicated when necessary; and
- Routine preventive maintenance measures are established.

12. Metal Detector OQ should include, and is not limited to:

- Alarm tests;
- Test for radio frequency interference;
- Challenge metal detectors used in manufacturing operations with discs/cylinders containing spherical 0.5mm ferrous, 0.5mm non-ferrous, and 0.8mm stainless steel metal;
- Challenge metal detectors used in packaging operations with discs/cylinders containing spherical 1.0mm ferrous, 1.0mm non-ferrous, and 1.5mm stainless steel metal;
- The above challenge tests should be performed with the manufacturing or packaging process performing at its maximum validated throughput rate;
- Sensitivity settings for each product or group of products with the same product signal noise are established;
- Reject gate reaction and delay time for each product or group of products with the same product signal noise is established; and
- Length of time that reject gate stays open is established.

13. The Metal Detector Sensitivity Settings should be verified and documented by a qualified operator during the set-up operation.

14. Metal Detection Equipment Set-Up and Operating Parameters for each product or process combination should include, and are not limited to:

- Clean and dust-free environment during set-up;
- Correct sensitivity settings for each product or product group;
- The reject gate reaction and delay time, when a reject gate is used;
- Length of time reject gate stays open;
- Throughput speed; and
- Correct chute and chute alignment for aperture size.

15. In-Line Metal Detector Challenges should be conducted with the process equipment running. Each challenge should consist of three passes of the challenge disc/cylinder through the aperture. Such in-process challenge tests should be performed and documented, at a minimum, as follows:

- Lot/batch start-up;
- After re-starting equipment (e.g., after breaks, shift changes, or downtime exceeding two hours); and
- At the end of a batch/lot.

