TABLET MACHINE STOPPED

Purpose: To prevent recurrence, not place blame.

Report Date: 10-16-2014
Start Date: 10-13-2014
Report Number: n/a

I. Problem Definition

What: Tablet Machine Stopped
When: Tuesday 0930, 14OCT14 (latest stoppage), problems started at the beginning of a batch
Where: Tablet Compression Machine #1
Significance: Reduced production throughput, overtime to meet weekly goals
Safety: n/a
Environment: n/a
Revenue: n/a - will work overtime to meeting production goals
Cost: Saturday shift of overtime, one operator, $500 per week, 50 weeks/year, $25,000/year/machine; $75,000/year for all three machines
Frequency: Intermittent problem that has gone on for 10 years on all three tablet compression machines

II. Report Summary

The tablet compression machines have a history of short production stoppages caused by the "low powder feed hopper level" alarm. The operators have
accepted this problem as a random occurrence that cannot be corrected. Some batches run better than others, but no one understood why. A team was brought
together after the latest occurrence. The team analyzed the causal relationships and have identified a number of cost effective and easy to implement solutions.
Solutions will address a failure to understand how to install the powder level sensor and what could cause the sensor to be installed incorrectly.
Reference #1 provides a process flow diagram for the tablet compression process.
The attached RealityChart explains the causal relationships and identified the root causes.

III. Solutions

Causes	Solutions	Solution Owner	Due Date
Low powder level alarm limit reached	Alarm if the valve remained stopped for more than x minutes while tablets are being produced	Jim Northrup	11-13-2014
Operators not trained on installation procedure	Add instructions to SOP	Mayo Smith	10-30-2014
Operators not trained on installation procedure	Add training requirement for operator training	Mayo Smith	10-30-2014
Operators not trained on installation procedure	Add functional failure/ cause by information to the troubleshooting guide	Al Kaline	10-30-2014
Operators not trained on installation procedure	Obtain the installation procedure from the manufacturer	Jim Northrup	10-23-2014

IV. Team Members

Name	Email	Member Info
Dan DeGrendel	Ddegrendal@somewhere.com	Facilitator
Mickey Stanley	mstanley@somewhere.com	Operator
Mayo Smith	msmith@somewhere.com	Production Manager
Jim Northrup	jnorthup@somewhere.com	Instrumentation Technician
Al Kaline	akaline@somewhere.com	Reliability Engineer

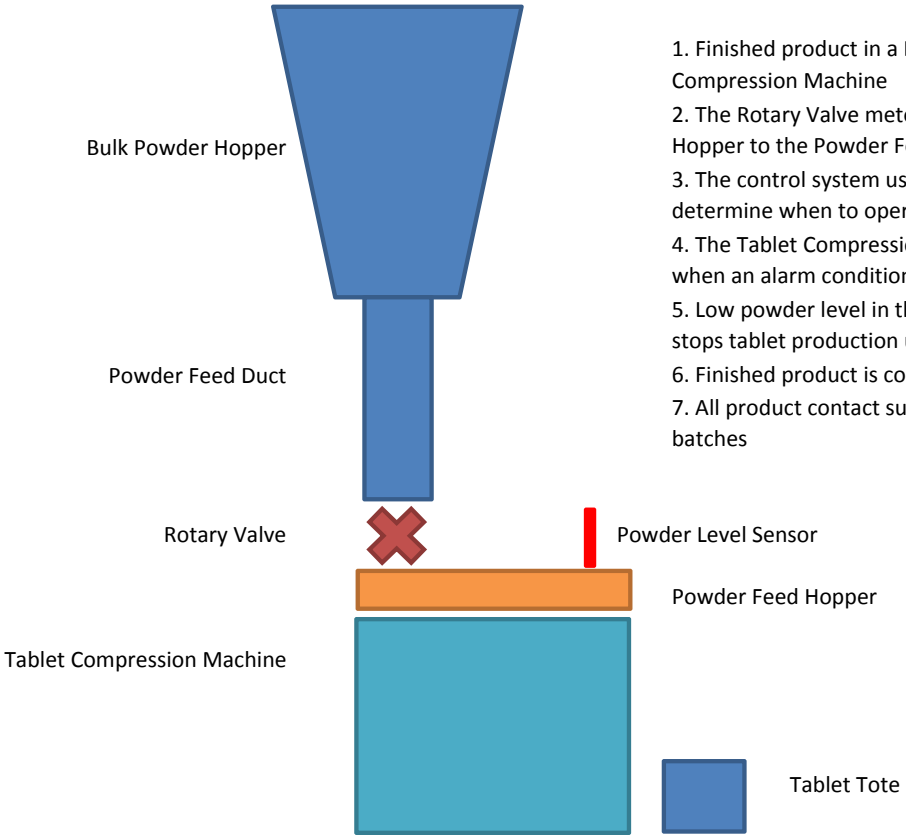
V. Notes

1. Realitychart Status: The Realitychart is in draft form and the Incident Report has not been finalized.
2. Rules Check Status: Missing Causes Resolved.
3. Rules Check Status: Conjunctions Resolved.
4. See Reference 1, Tablet Compression Machine Process Flow Diagram, for a general explanation of the process.

VI. References

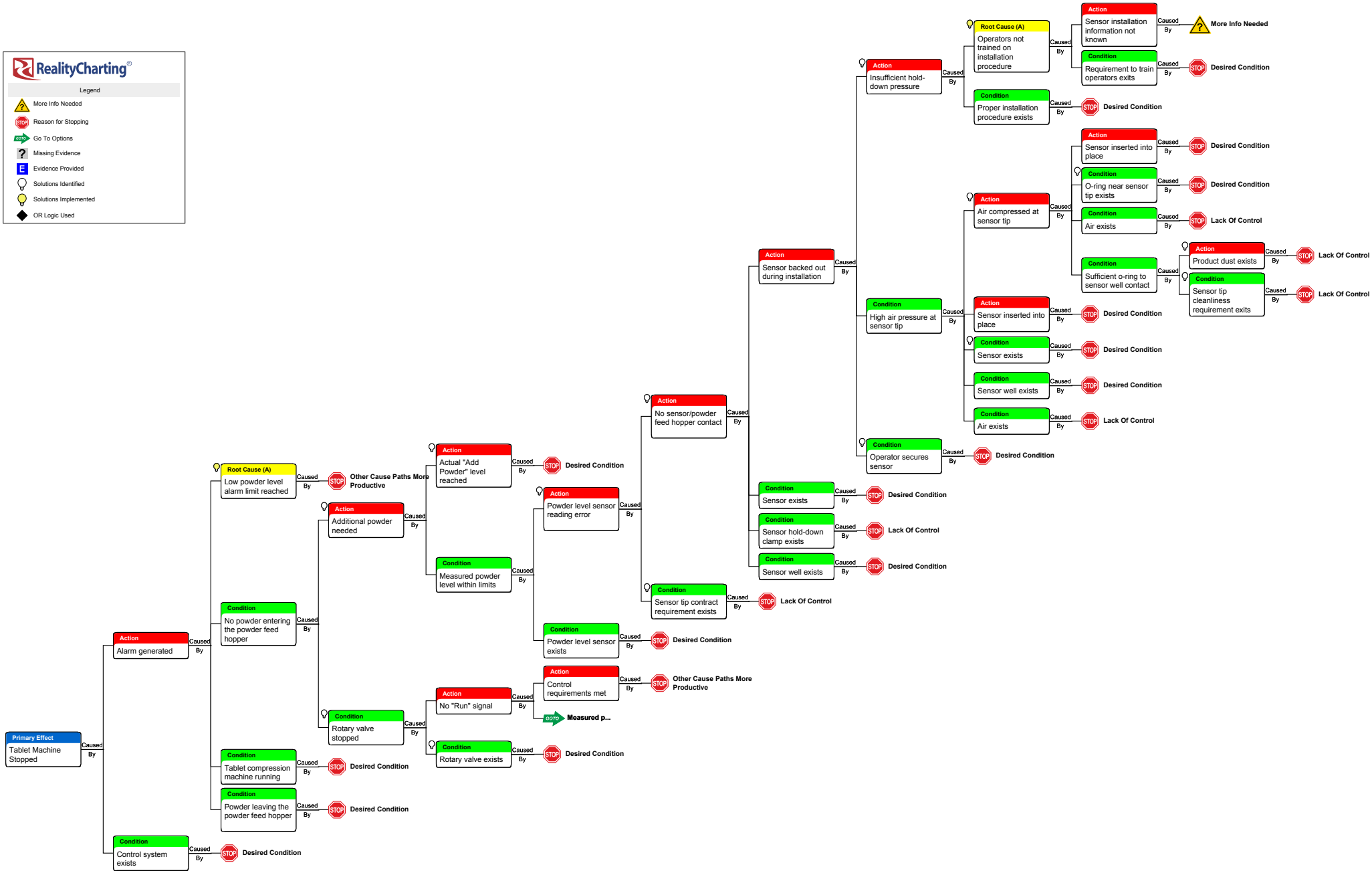
1. Tablet Compression Machine Process Flow Diagram

Tablet Compression Machine Flow Diagram



General Notes

1. Finished product in a Bulk Powder Hopper is staged above a Tablet Compression Machine
2. The Rotary Valve meters the flow of bulk powder from the Bulk Powder Hopper to the Powder Feed Hopper
3. The control system uses the Powder Level Sensor as an input parameter to determine when to operate the Rotary Valve
4. The Tablet Compression Machine temporarily stops producing tablets when an alarm condition exists
5. Low powder level in the Powder Feed Hopper will generate an alarm that stops tablet production until the alarm is cleared
6. Finished product is collected in the Tablet Tote
7. All product contact surfaces are disassembled and cleaned between batches


RealityCharting
Legend
More Info Needed
Reason for Stopping
Go To Options
Missing Evidence
Evidence Provided
Solutions Identified
Solutions Implemented
OR Logic Used
Primary Effect
Tablet Machine Stopped
Caused By
Action
Alarm generated
Condition
Control system exists
Desired Condition
Root Cause (A)
Low powder level alarm limit reached
Other Cause Paths More Productive
Condition
No powder entering the powder feed hopper
Action
Additional powder needed
Action
Actual "Add Powder" level reached
Condition
Measured powder level within limits
Action
Powder level sensor reading error
Action
No sensor/powder feed hopper contact
Action
Sensor backed out during installation
Action
Insufficient hold-down pressure
Root Cause (A)
Operators not trained on installation procedure
Action
Sensor installation information not known
More Info Needed
Condition
Requirement to train operators exits
Desired Condition
Condition
Proper installation procedure exists
Desired Condition
Condition
High air pressure at sensor tip
Action
Air compressed at sensor tip
Action
Sensor inserted into place
Desired Condition
Condition
O-ring near sensor tip exists
Desired Condition
Condition
Air exists
Lack Of Control
Condition
Sufficient o-ring to sensor well contact
Action
Product dust exists
Lack Of Control
Condition
Sensor tip cleanliness requirement exits
Lack Of Control
Action
Sensor inserted into place
Desired Condition
Condition
Sensor exists
Desired Condition
Condition
Sensor well exists
Desired Condition
Condition
Air exists
Lack Of Control
Condition
Operator secures sensor
Desired Condition
Condition
Sensor exists
Desired Condition
Condition
Sensor hold-down clamp exists
Lack Of Control
Condition
Sensor well exists
Desired Condition
Condition
Sensor tip contract requirement exists
Lack Of Control
Condition
Powder level sensor exists
Desired Condition
Action
Control requirements met
Other Cause Paths More Productive
GOTO
Measured p...
Action
No "Run" signal
Condition
Rotary valve stopped
Condition
Rotary valve exists
Desired Condition
Condition
Tablet compression machine running
Desired Condition
Condition
Powder leaving the powder feed hopper
Desired Condition