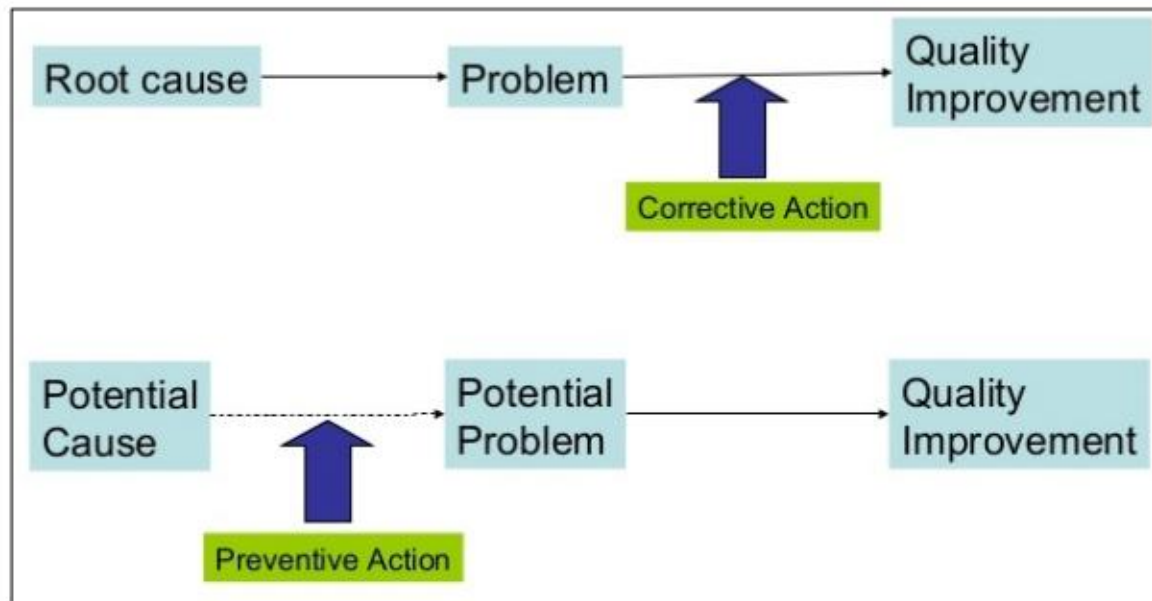


# CAPA-Corrective and Preventive Action

## Principles



### Corrective Action

- Identify problem
- Document & assign
- Contain & remediate
- Track

### Problem Solving

#### Root Cause Analysis

- Identify possible causes
- Collect & analyze data
- Determine actual cause(s)
- Identify solutions
- Implement solutions
- Evaluate results

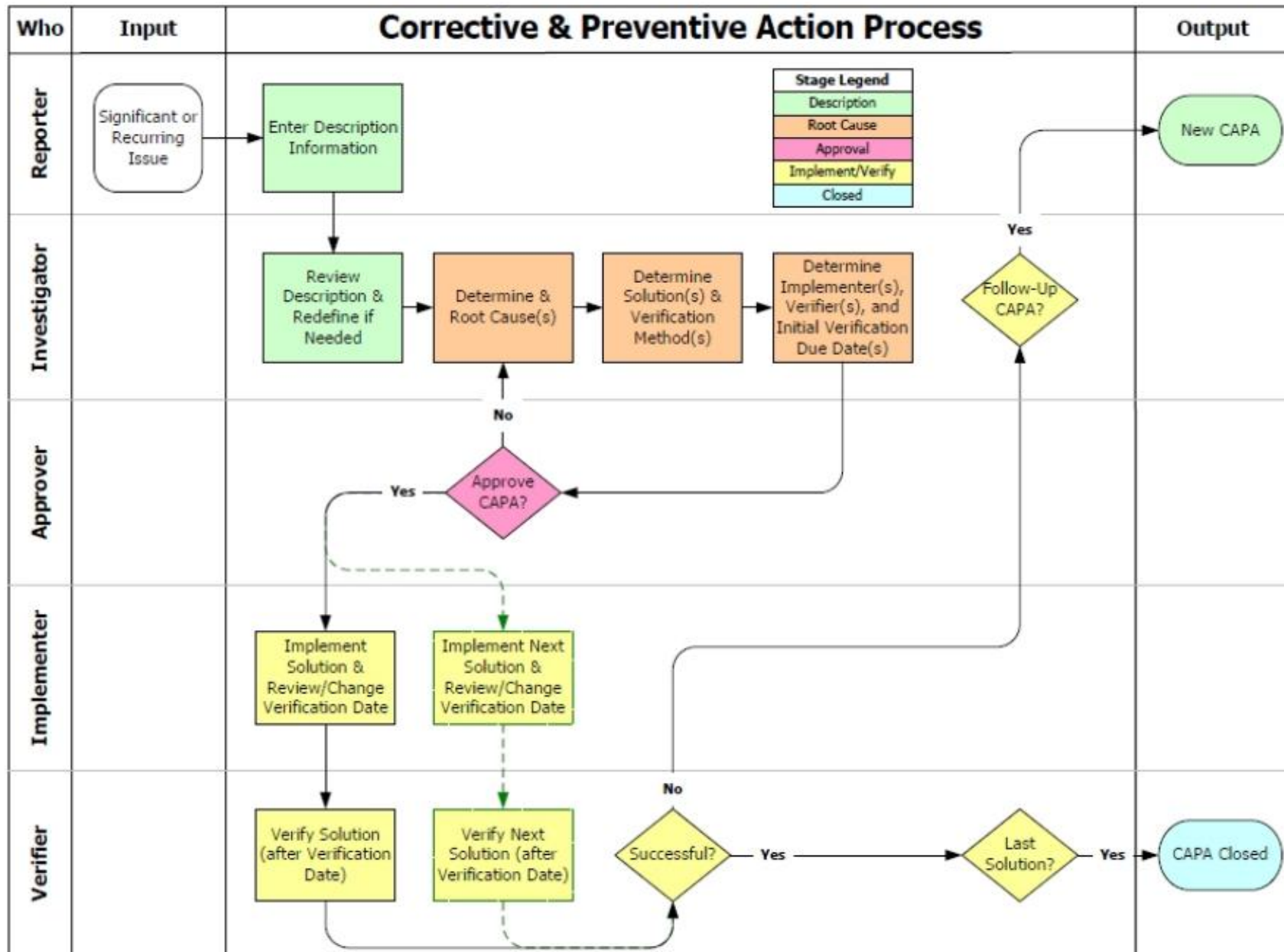
### Correct = Repair



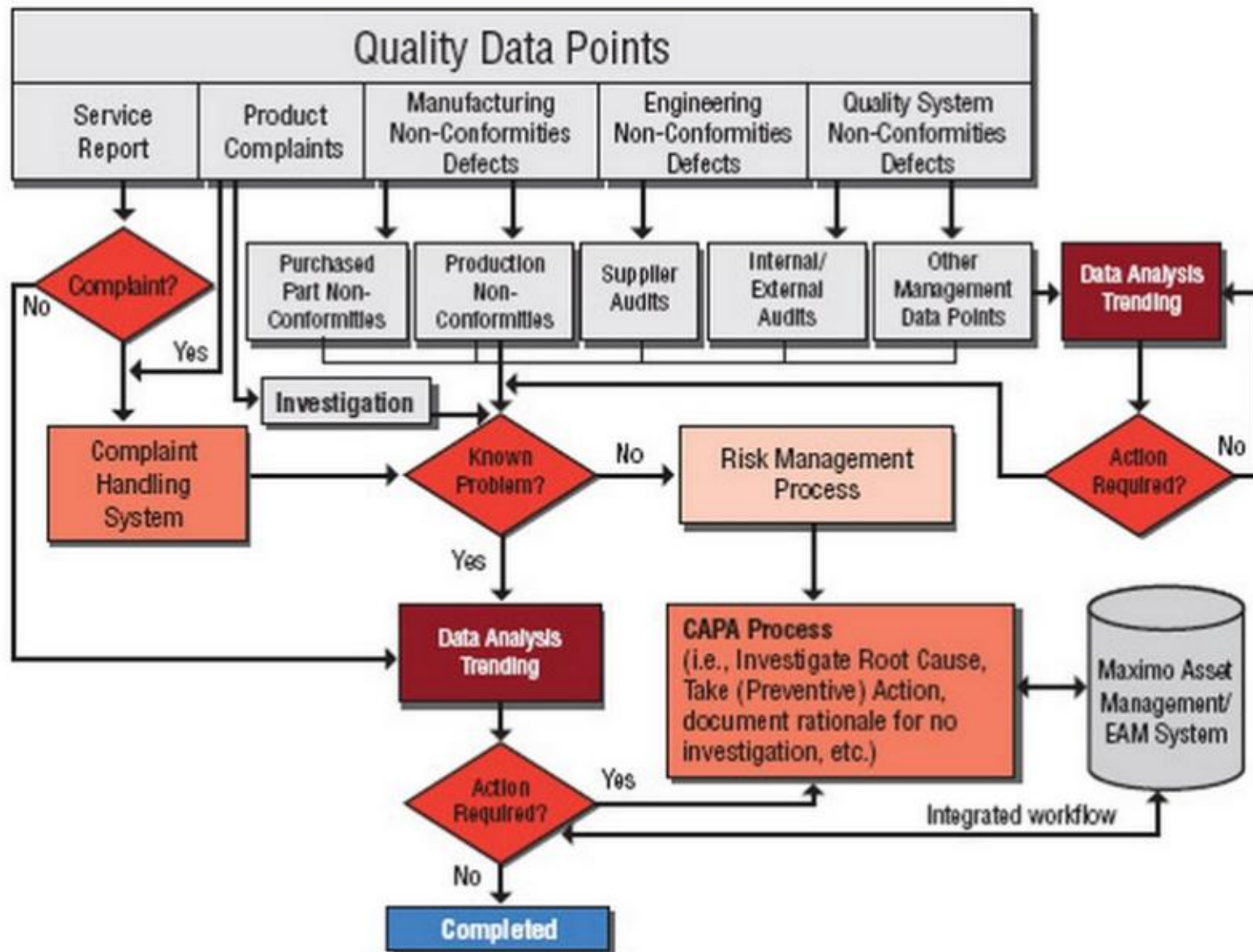
### Prevent = Maintain



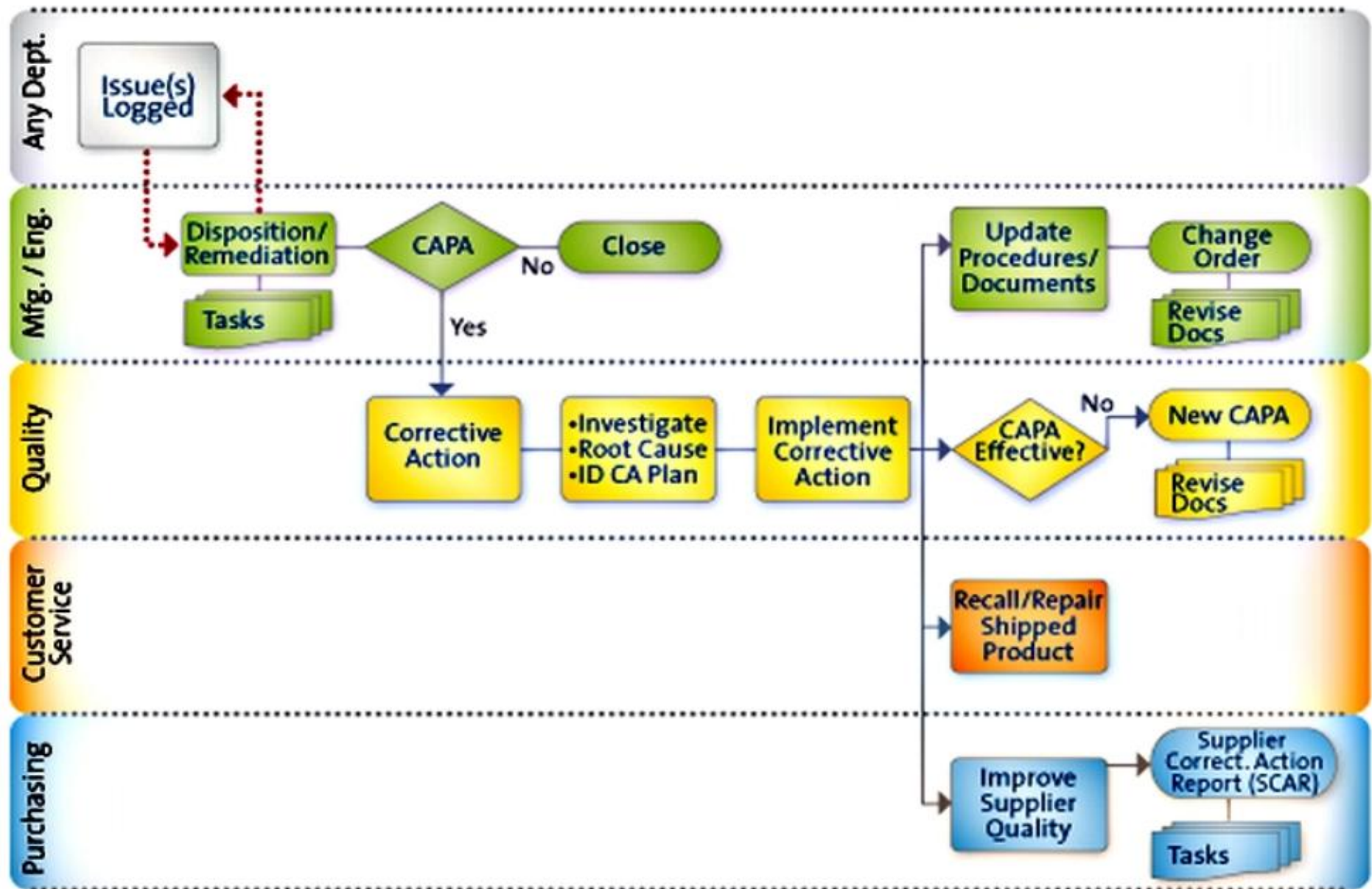
# CAPA Process Flow



# CAPA Process Flow



# CAPA Process Flow



# CAPA Tools

Measure	Analyze	Improve	Control																																																																																															
<p>(1) Describe the Problem</p> <table border="1"> <tr> <td></td> <td style="color: green;">IS</td> <td style="color: red;">IS NOT</td> </tr> <tr> <td>What</td> <td></td> <td></td> </tr> <tr> <td>Where</td> <td></td> <td></td> </tr> <tr> <td>When</td> <td></td> <td></td> </tr> <tr> <td>Extent</td> <td></td> <td></td> </tr> </table> <p>(2) Measure Magnitude of Problem</p> <p>(3) Determine When Problem Started</p>		IS	IS NOT	What			Where			When			Extent			<p>(4) Identify Potential Causes</p> <p>(5) Analyze Existing Data</p> <p>(6) Construct List of Verified Facts</p> <table border="1"> <thead> <tr> <th colspan="2">FACTS</th> </tr> </thead> <tbody> <tr> <td>(1) All Machines</td> <td></td> </tr> <tr> <td>(2) Second Shift</td> <td></td> </tr> <tr> <td>(3) Certain Codes</td> <td></td> </tr> <tr> <td>(4) Started 8/22</td> <td></td> </tr> <tr> <td>(5) Steadily Worse</td> <td></td> </tr> <tr> <td>(6) All Operators</td> <td></td> </tr> </tbody> </table> <p>(7) Compare Causes to Facts</p> <table border="1"> <thead> <tr> <th></th> <th>Fact 1</th> <th>Fact 2</th> <th>Fact 3</th> <th>Fact 4</th> <th>Fact 5</th> </tr> </thead> <tbody> <tr> <td>Cause 1</td> <td>O</td> <td>X</td> <td>X</td> <td>O</td> <td>A</td> </tr> <tr> <td>Cause 2</td> <td>X</td> <td>O</td> <td>A</td> <td>A</td> <td>O</td> </tr> <tr> <td>Cause 3</td> <td>O</td> <td>O</td> <td>A</td> <td>A</td> <td>O</td> </tr> <tr> <td>Cause 4</td> <td>X</td> <td>A</td> <td>X</td> <td>O</td> <td>O</td> </tr> <tr> <td>Cause 5</td> <td>O</td> <td>O</td> <td>O</td> <td>O</td> <td>X</td> </tr> </tbody> </table> <p>(8) Collect Additional Data Until Root Cause Identified</p>	FACTS		(1) All Machines		(2) Second Shift		(3) Certain Codes		(4) Started 8/22		(5) Steadily Worse		(6) All Operators			Fact 1	Fact 2	Fact 3	Fact 4	Fact 5	Cause 1	O	X	X	O	A	Cause 2	X	O	A	A	O	Cause 3	O	O	A	A	O	Cause 4	X	A	X	O	O	Cause 5	O	O	O	O	X	<p>(9) Determine Best Solution</p> <p>(10) Pilot Solution</p> <p>(11) Verify Solution Works</p>	<p>(12) Implement Solution</p> <p style="text-align: center;"><b>Control Plan</b></p> <table border="1"> <thead> <tr> <th>Item</th> <th>Function</th> <th>Performance</th> <th>Measure</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Item	Function	Performance	Measure	Control																									
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