

Detection Potential (D) for the Validation of the Process Design

Detection Controls rated according to the Detection Method Maturity and Opportunity for Detection.

D	Ability to Detect	Detection Method Maturity	Opportunity for Detection
10	Very low	No testing or inspection method has been established or is known.	The failure mode will not or cannot be detected.
9		It is unlikely that the testing or inspection method will detect the failure mode.	Failure Mode is not easily detected through random or sporadic audits.
8	Low	Test or inspection method has not been proven to be effective and reliable (e.g. plant has little or no experience with method, gauge R&R results marginal on comparable process or this application, etc.).	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that should detect the failure mode or failure cause.
7			Machine-based detection (automated or semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as coordinate measuring machine that should detect failure mode or failure cause.
6	Moderate	Test or inspection method has been proven to be effective and reliable (e.g. plant has experience with method, gauge R&R results are acceptable on comparable process or this application, etc.).	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that will detect the failure mode or failure cause (including product sample checks).
5			Machine-based detection (semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as coordinate measuring machine that will detect failure mode or failure cause (including product sample checks).
4	High	System has been proven to be effective and reliable (e.g. plant has experience with method on identical process or this application), gauge R&R results are acceptable, etc.	Machine-based automated detection method that will detect the failure mode downstream , prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.
3			Machine-based automated detection method that will detect the failure mode in-station , prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.
2		Detection method has been proven to be effective and reliable (e.g. plant has experience with method, error-proofing verifications, etc.)	Machine-based detection method that will detect the cause and prevent the failure mode (discrepant part) from being produced.
1	Very high	Failure mode cannot be physically produced as-designed or processed, or detection method proven to always detect the failure mode or failure cause.	