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NCR CLASSIFICATIONS

1. Major Nonconformance:

- The absence of, or systemic breakdown of, the Process Control and/or Quality Management system.
- Any non-conformance where the effect impacts or has the potential to impact the integrity of the product.

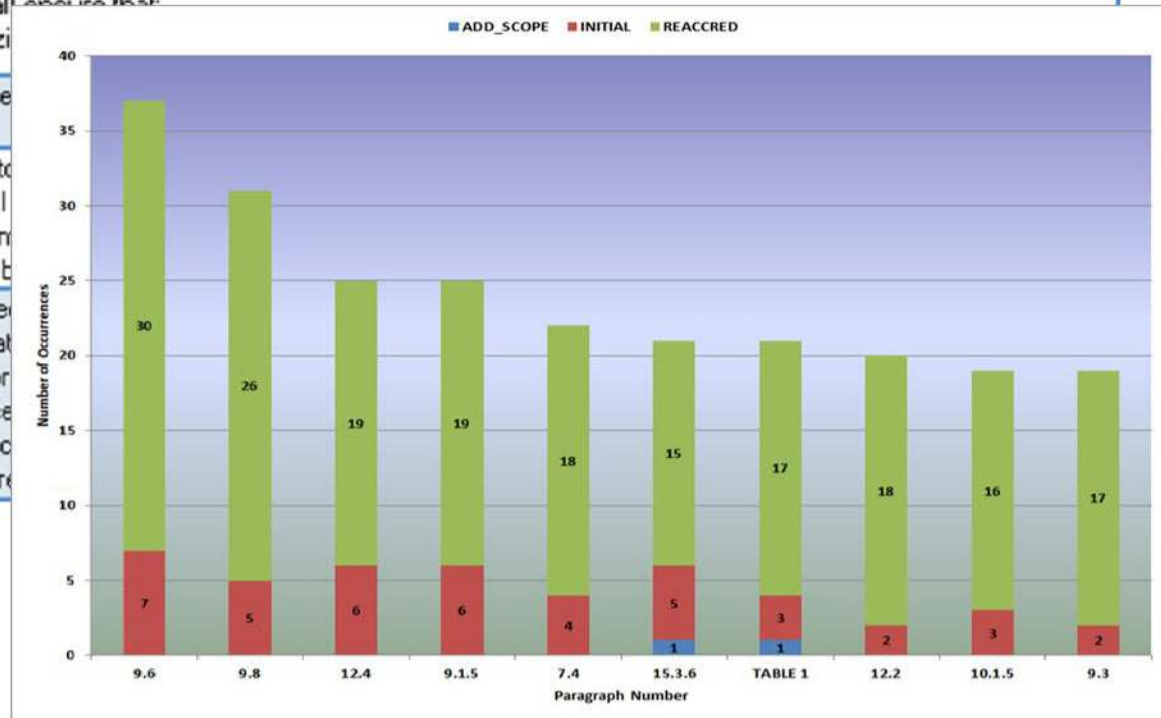
2. Minor Nonconformance:

- A non-systemic lapse in conformance to the Process Control and/or Quality Management system.

MTL Top 10 NCR Paragraph References

AC7006 – Overall Findings

Top NCR	Paragraph Ref	Text
1	5.10.2.1-e.	Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so: e. identification of the method used;
2	4.9.1-e	The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that: e. the responsibility for authorizing
3	5.10.2.1-i.	Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:
4	5.2.2	The management of the laboratory shall ensure that the laboratory personnel. The laboratory shall ensure that the training program and the training actions taken shall be
5	5.5.2	Equipment and its software used for testing and shall comply with specifications established for key quantities or parameters. Before being placed into service, the equipment shall be checked and/or calibrated before



RESPONDING TO NON-CONFORMANCES

- Immediate Corrective Action Taken (Containment Actions)
- Root Cause of Nonconformance
- Impact of all Identified Causes and the Root Cause
- Action Taken to Prevent Recurrence
- Objective Evidence is required on ALL findings
- Effectivity Date