

Non-conformance:

Based on objective evidence, the absence of, or a significant failure to implement and/or maintain conformance to requirements of the applicable standard. Such issues may raise significant doubt as to the capability of the management system to achieve its intended outputs.

Action required: This category of findings requires the auditor to issue a formal NCR; to receive and approve proposed correction and corrective action plans; and formally verify the effective implementation of planned activities.

- **Minor nonconformance**

A minor nonconformance is a failure to conform to an ISO 9001:2015 requirement that is a single observed lapse or isolated incident. A minor nonconformance is unlikely to result in a failure of the QMS.

Examples of minor nonconformance include a single unauthorized change to a document, a missing training record or an instrument that's incorrectly calibrated.

- **Major nonconformance**

A major nonconformance is a total breakdown of the QMS or one of its processes, evidence of a significant failure in the QMS or the failure to address a key ISO 9001 requirement. A major nonconformance could threaten an organization's ability to assure controlled processes, achieve its goals or protect its customers.

Examples of major nonconformances include a pattern of unauthorized document changes, critical purchases made from unapproved suppliers or untested products being shipped.

Observation:

Area of the system for which the client is required to investigate potential nonconformity.

Action required: Lack of client attention to such issues implies that a preventive action system is not working effectively and could result in an NCR being raised at a later date.

Opportunity for Improvement:

A documented statement, which may identify areas for improvement however shall not make specific recommendation(s).

Action required: Client may develop and implement solutions in order to add value to operations and management systems.