



QAD Adaptive Applications

User Requirements Specifications
QAD EQMS Applications
Inspection & SPC

70-3463-2025

QAD EQMS 2025

March 2025

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Inspection & SPC User Requirements Specification Change Summary

The following table summarizes significant differences between this document and previous versions.

Date/Version	Description	Reference	Changed By
JULY 2020/v2020	Initial upload	--	RQT
NOV 2020/v2020.1	Updated versioning; Added a General section.	p. 7	RQT
MAR 2021/v2021	Updated versioning.	--	RQT
AUG 2021/v2021.1	Updated versioning; Updated Inspection Plans; Updated Inspection Events.	p. 6, p. 6	RQT
MAR 2022/v2022	Updated versioning.	--	RQT
SEPT 2022/v2022.1	Updated versioning; Updated the General section	p. 7	RQT
MAR 2023/v2023	Updated versioning; Updated the General section	p. 7	RQT
MAR 2024/v2024	Updated versioning; Updated the Inspection Events section; Updated the General section	p. 6, p. 7	RQT
SEPT 2024/v2024.1	Updated versioning; Updated the Inspection Plans section; Updated the Inspection Events section; Updated the General section	p. 6, p. 6, p. 7	RQT
MAR 2025/v2025	Updated versioning; Updated the Inspection Events section; Updated the General section	p. 6, p. 7	RQT

Confidentiality

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QAD Inc.

100 Innovation Place

Santa Barbara, CA 93108

Phone: + 1 (805) 566-6100

<http://www.qad.com>

Purpose

This requirements specification includes the documentation of the EQMS Applications business requirements for the EQMS Inspection & SPC Module version 2025.

This document was used as the basis for the configuration of the Inspection & SPC Module and shall be used in the definition of testing criteria for operational qualification.

Scope

The scope of this document is to define the EQMS Applications business requirements for the Inspection & SPC Module version 2025.

Inspection & SPC

Facilitates real time inspection checks and sampling typically triggered by integration with enterprise systems and based on the control inspection methodologies prescribed by the APQP application. Inspection deviations escalate issues to NCR, SCAR, and CAPA activities.

Inspection Plans

1. The system shall have the ability to create inspection plans for driving inspections where manufacturing documents are not utilized (added in 2019).
2. The system shall protect ITAR Inspection Plan information from non-ITAR persons' view (added in 2021.1).
3. The system shall provide the ability to embed videos in Inspection Plans (added in 2024.1).

Inspection Events

1. The system shall have the ability to capture product and/or process specification measurements for a specific date/time, inspector, and item combination.
2. The system shall have the ability to capture one or more samples for a given product or process specification.
3. The system shall have the ability to capture specification measurements of either numeric, logical (pass/fail, go/no-go), date, or text.
4. The system shall have the ability to define an inspection type and one or more inspection stations for the purposes of limiting what product or process specifications are part of an inspection event.
5. The system shall have the ability to document the lot and/or serial number along with the batch or lot size for the inspection event.
6. The system shall pull the product and/or process specifications from the official documentation set control plan for the purposes of conducting per current official documentation.
7. The system shall have the ability to view the specification details including any special classification identifier associated with a specification while conducting an inspection.
8. The system shall have the ability to view controlled documents while conducting an inspection.
9. The system shall have the ability to identify the gauge used to complete the inspection of a specification and capture the current calibration status of the gauge.
10. The system shall have the ability to define the samples for the numeric, logical, or text data types based on the defined controls including fixed sample size, AQL tables, or manually set sample sizes.
11. The system shall have the ability to automatically determine the overall result of the inspection event.
12. The system shall have the ability to automatically generate a non-conformance if an inspection fails.
13. The system shall have the ability to configure direct feeds for automated collection from smart gauges and other data sources using USB or serial ports.
14. The system shall have the ability to include an inspection approval prior to completion based on inspection type.

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15. The system shall have the ability to do skip lot receiving inspection (added in 2018.1).
 16. The system shall protect ITAR Inspection Event information from non-ITAR persons' view (added in 2021.1).
 17. The system shall add the ability to control, upon an inspection failure, whether an Incident Investigation OR a Non-conformance is created. Set at the site level (added in 2024).
 18. The system shall provide the ability to embed videos in Inspection Events (added in 2024.1).
 19. The system shall provide a Certificate of Analysis report for an inspection event (added in v2025).

Statistical Process Control (SPC)

1. The system shall have the ability to display an SPC chart for each inspected specification.
2. The system shall have the ability to automatically calculate and display the mean, upper control limit, and lower control limit.
3. The system shall have the ability to dynamically adjust the number of data points and subgroup size of the SPC chart.
4. The system shall have the ability to display the specification upper limit and lower limit on the SPC chart.
5. The system shall have the ability to display the following SPC charts: Run, X-Bar & R, X-Bar & S, Histogram, and X-Bar & MR.
6. The system shall have the ability to display the following attribute charts (P-Chart and NP-Chart).
7. The system shall have the ability to display Cpk and Ppk on the X-Bar & R chart.

Metrics

None defined.

Reports

1. The system shall have the ability to export the data, including each sample, for analysis using external SPC tools.

General

1. The system shall support Coordinated Universal Time (UTC), which adjusts Date/Time fields to represent the Date/Time in the current user's timezone (added in 2020.1).
2. The system shall have a global search feature to search for records within the system that have the search term in applicable fields and within files linked to File fields (added in 2020.1).
3. The system shall have the ability to create URLs to other systems in the Navigation menu (added in 2020.1).
4. The system shall provide audit trail reports for all records (added in 2022.1).
5. The system shall have an option to disable the ability to approve a record without opening it (added in 2022.1).

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6. The system shall allow checklist responses to have the same score among different responses—e.g. to allow all wrong answers to have a zero value (added in 2023).
 7. The system shall allow users to easily move to the next detailed record based on the search screen initiating the detailed screen view (added in 2023).
 8. The system shall provide a web-based report designing tool (added in 2023).
 9. The system shall provide an option to limit users to be able to only view records associated with the sites specified in their employee record (added in 2023).
 10. The system shall have an option to see the prior rejection comments during a re-approval of a record (added in 2023).
 11. The system shall provide the ability to report on the security configured for each process including customer extensions/changes to security setup (added in 2024).
 12. The system shall allow the user to cancel the generation of a report (added in 2024).
 13. The system shall provide the ability to open multiple EQMS windows in the same browser tab (added in 2024).
 14. The system shall provide the ability to embed video in key areas (added in 2024.1).
 15. The system shall provide the ability to support arrays of images in key areas (added in 2024.1).
 16. The system shall provide (for critical workflow processes) a visual indicator of the progress of a record through its life-cycle (added in v2025).
 17. The system shall provide a mechanism to socialize a record with others including @mentions that notify those individuals mentioned (added in v2025).