GUIDANCE FOR USING QMSCAPA REPORTS USED IN THE MANAGEMENT REVIEW PROCESSES OF AS9100D & ISO 9001:2015

Quality Management Systems

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1. Management Review Requirements

This ABCI guidance document refers to the following AS9100D & ISO 9001:2015 Quality Management Systems — Requirements, beginning with Clause 9 Performance evaluation, 9.3 Management Review.

9.3.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization.

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

a. the status of actions from previous management reviews;
b. changes in external and internal issues that are relevant to the quality management system;
c. information on the performance and effectiveness of the quality management system, including trends in:

1) customer satisfaction and feedback from relevant interested parties;
2) the extent to which quality objectives have been met;
3) process performance and conformity of products and services;
4) nonconformities and corrective actions;
5) monitoring and measurement results;
6) audit results;
7) the performance of external providers;
8) *on-time delivery performance (AS9100D)*

d. the adequacy of resources;
e. the effectiveness of actions taken to address risks and opportunities (see 6.1);
f. opportunities for improvement.

2. Statistical Process Control (SPC)

Statistical Process Control (SPC) is a method used in QMSCAPA software, among other Quality Management Systems, to monitor and control a process through statistical analysis. Here are some basic SPC tools and techniques found in QMSCAPA:

2.1 Control Charts: These charts help monitor process performance over time and identify variations. They distinguish between common cause variation (inherent to the process) and special cause variation (due to external factors).

2.1.1 Pareto Charts: These charts identify and prioritize the most significant factors in a process, helping to focus improvement efforts on the most impactful areas.

2.1.2 Histograms: These are bar charts that show the distribution of data, helping to understand the variation within a process.

2.1.3 Scatter Diagrams: These diagrams show the relationship between two variables, helping to identify correlations and potential causes of variation.

3. Standard Deviations

3.1 The identification of standard deviations is critical when using Statistical Process Controls (SPC) and analysis. Standard deviation is a key measure of variability or dispersion in a dataset. It indicates how much the individual data points deviate from the mean (average) of the dataset.

3.2 In the QMSCAPA SPC tools, understanding standard deviation is crucial for several reasons:

3.2.1 Setting Control Limits: Control charts, a fundamental tool in SPC, use standard deviations to establish control limits. These limits (typically set at ±3 standard deviations from the mean) help identify when a process is "out of control" or exhibiting unusual variation.

3.2.2 Assessing Process Stability: By monitoring standard deviations over time, you can determine if a process is stable or if its variability is changing. An increase in standard deviation may indicate a problem with the process.

3.2.3 Calculating Process Capability: Process key performance indices (KPI) rely on standard deviation to assess whether a process can consistently meet specifications. These indices compare the process's variability (as measured by standard deviation) to the specification limits.

3.2.4 Making Data-Driven Decisions: Standard deviation provides valuable information for making informed decisions about process adjustments, improvements, and problem-solving. It helps distinguish between common cause variation (inherent in the process) and special cause variation (due to specific factors).

3.3 In summary, standard deviation is essential in SPC for understanding process variability, setting control limits, assessing process capability, and making data-driven decisions to improve and maintain process stability.

3.4 By using these tools, organizations can detect issues early, improve process stability, and enhance overall quality.

4. QMSCAPA Cause and Effect Tools and Techniques

4.1 The QMSCAPA Fault-Tree Diagrams help identify, and separate potential causes of a problem, organizing them into weighted categories for easier analysis.

4.2 Five Why tool and technique is a powerful tool for identifying the root cause of a problem by repeatedly asking "why" until the underlying issue is uncovered.

4.3 Importance of the Five Whys:

4.3.1 Simplicity: The method is straightforward and easy to implement without requiring complex tools or extensive training.

4.3.2 Focus on Root Cause: By digging deeper with each "why," it helps avoid superficial solutions and addresses the core issue.

4.3.3 Encourages Critical Thinking: It promotes a deeper understanding of the problem and encourages analytical thinking.

4.3.4 Prevents Recurrence: Identifying and addressing the root cause helps prevent the problem from recurring in the future.

4.3.5 Versatility: It can be applied to various types of problems across different industries and disciplines.

4.4 Value of the Five Whys

4.4.1 Cost-Effective: It doesn't require significant resources, making it an economical approach to problem-solving.

4.4.2 Engages Teams: It fosters collaboration and collective problem-solving, as team members contribute to identifying the root cause.

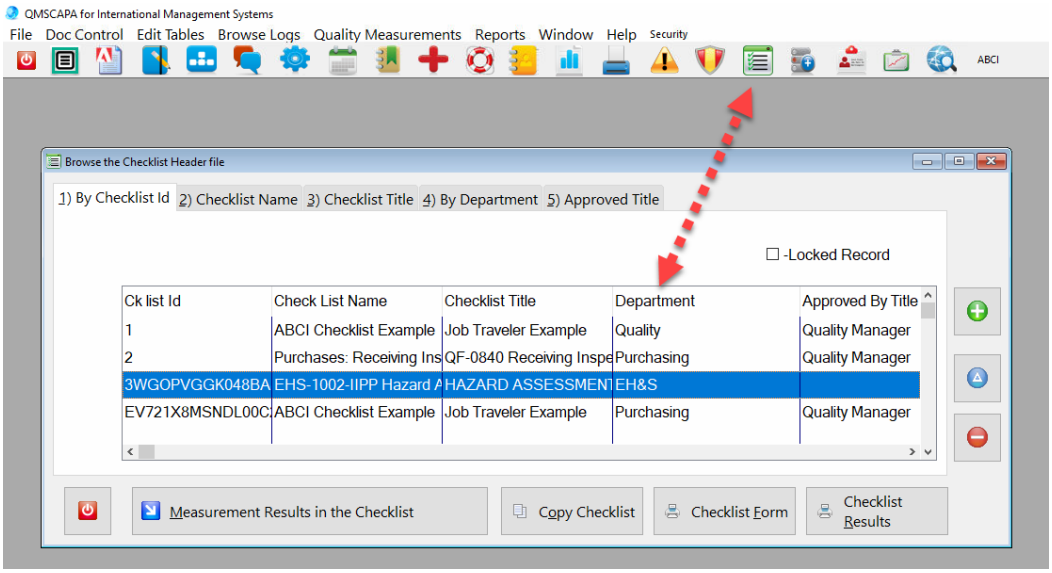
4.4.3 Improves Processes: By addressing the root cause, it leads to more effective and sustainable process improvements.

4.4.4 Enhances Learning: It provides valuable insights and learning opportunities, helping teams understand the underlying issues better.

4.4.5 Supports Continuous Improvement: It aligns with continuous improvement methodologies like Lean and Six Sigma, promoting a culture of ongoing enhancement.

5. QMSCAPA Check List/Sheets

5.1 These are simple forms used to collect and analyze data, often used for tracking defects or occurrences.



6. Alert, Incidents, Messages and Nonconformance Report (AIMNCR)

6.1 AS9100D & ISO 9001:2015, Clause 8.7

6.2 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

6.3 The organization's nonconformity control process shall be maintained as documented information including the provisions for:

6.4 defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving people making these decisions;

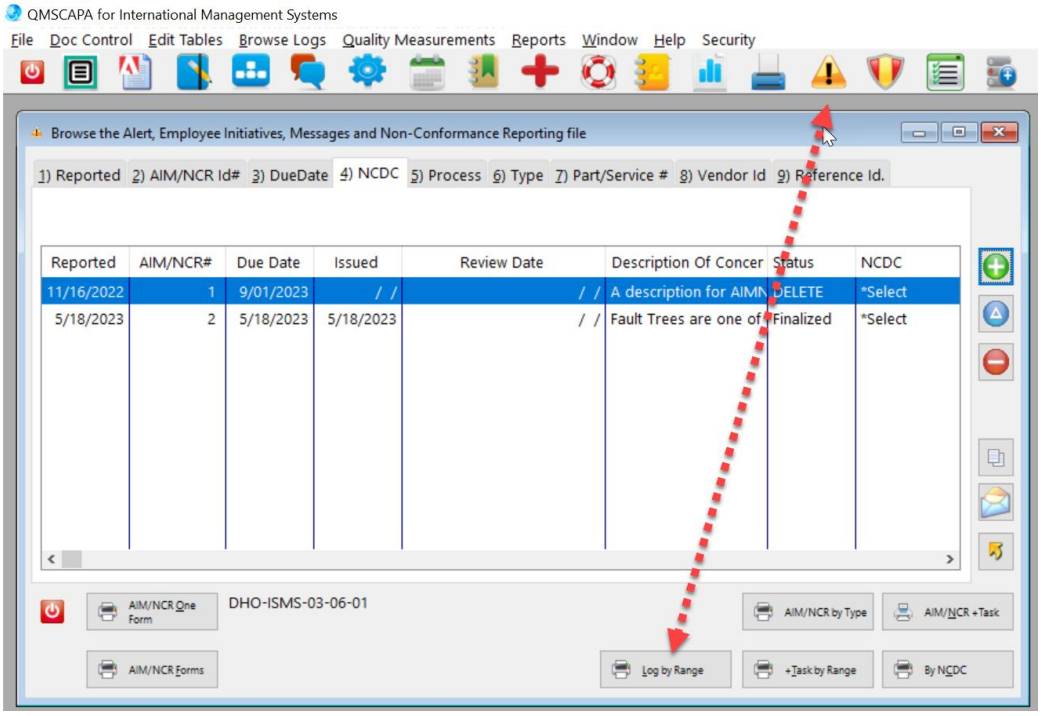
6.5 taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;

6.6 timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;

6.7 defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).

6.8 Record all nonconforming issues from January 1, 2025, through December 31, 2025 and going forward to maintain AS9100D & ISO 9001:2015 Certification.

6.9 Print the AIMNCR Log by Date Range Report.



7. Corrective Action & Preventive Action (CAPA Log)

7.1 AS9100D & ISO 9001:2015, Clause 10.2.2

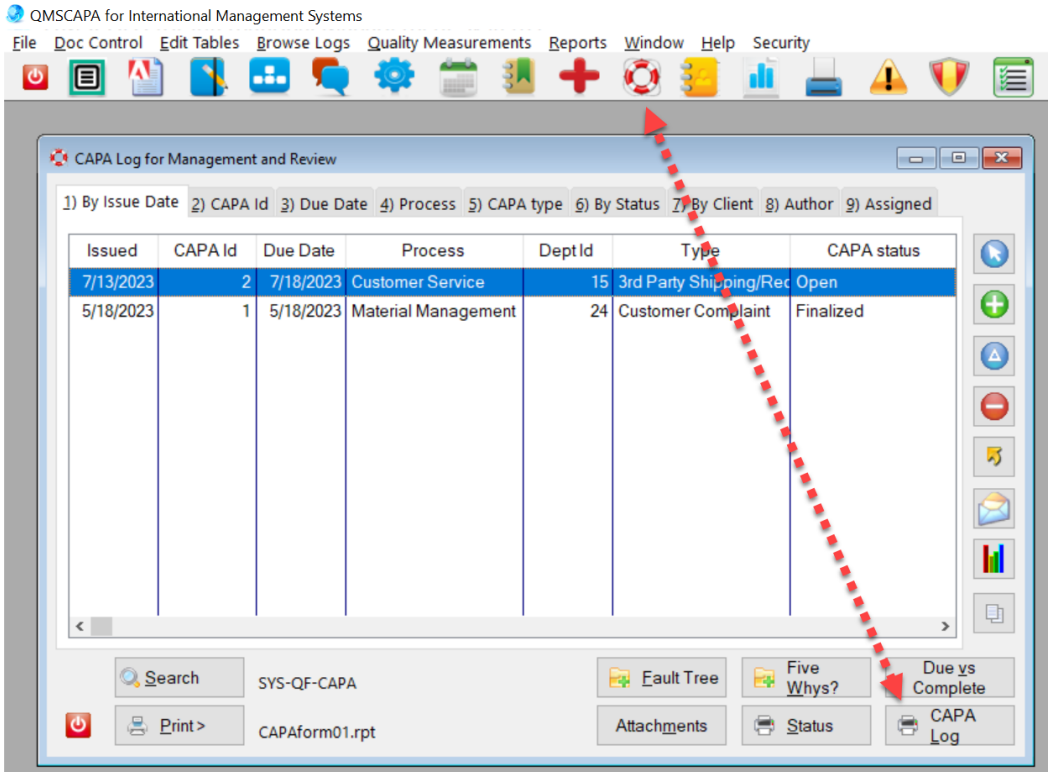
7.2 The Organization shall retain documented information as evidence of:

a. the nature of the nonconformities and any subsequent actions taken;

b. the results of any corrective action.

7.3 Record all Corrective Actions from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

7.4 Print the CAPA Log by Date Range Report.



8. Customer Contract Review (Order Log)

8.1 AS9100D & ISO 9001:2015, Clause 8.2.3.1

8.2 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to the customer, to include:

a. requirements specified by the customer, including the requirements for delivery and post-delivery activities;
b. requirements not stated by the customer, but necessary for the specified or intended use, when known;
c. requirements specified by the organization;
d. statutory and regulatory requirements applicable to the products and services;
e. contract or order requirements differing from those previously expressed.

8.3 This review shall be coordinated with applicable functions of the organization.

8.4 If upon review the organization determines that some customer requirements cannot be met or can only partially be met, the organization shall negotiate a mutually acceptable requirement with the customer.

8.5 The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

8.6 The customer requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

8.7 NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

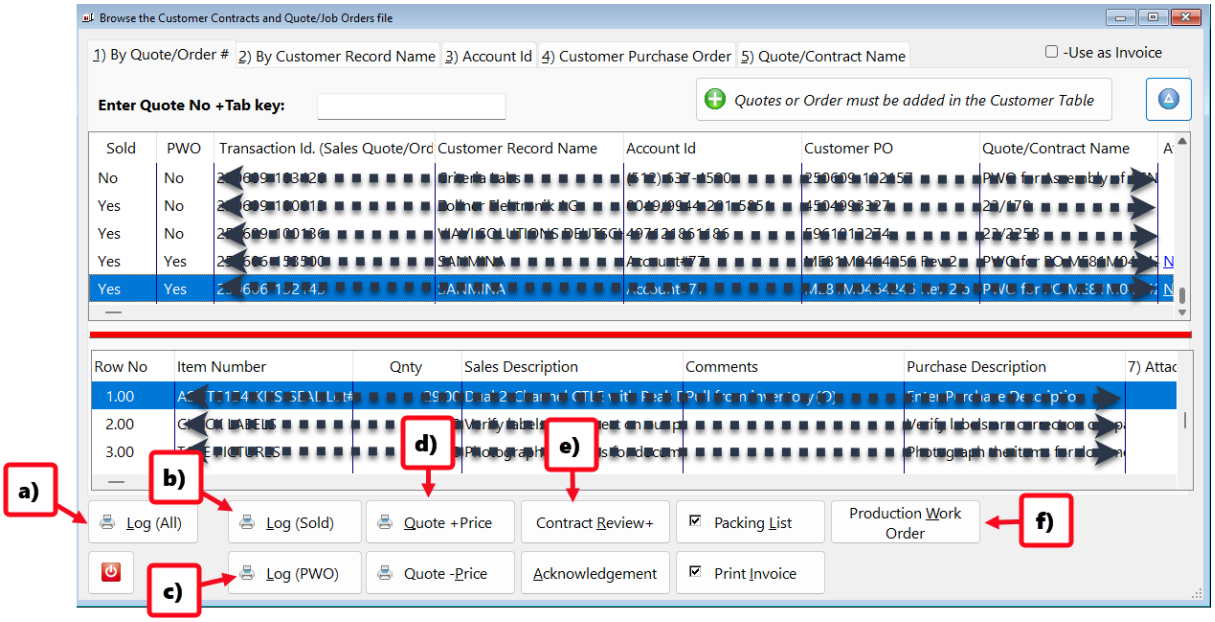
8.8 Clause 8.2.3.2 The organization shall retain documented information, as applicable:

a. on the results of the review;
b. on any new requirements for the products and services.

8.9 Record all Corrective Actions from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

8.10 Select Browse Logs from TEXT MENU > Sales Quotes and Contract Review

8.11 Select to print the Order Log (All) by Range Report.



a) Print Log (All);
b) Print Log (Sold);
c) Print Log (PWO) production work-order;
d) Print as Quote/Order with prices or without prices;
e) Print as Contract Review;
f) Print as PWO.

9. Customer Feedback Log

9.1 AS9100D & ISO 9001:2015, Clause 8.2.1 Customer Communication

9.2 Communication with customers shall include:

9.3 providing information relating to products and services;

9.4 handling enquiries, contracts, or orders, including changes;

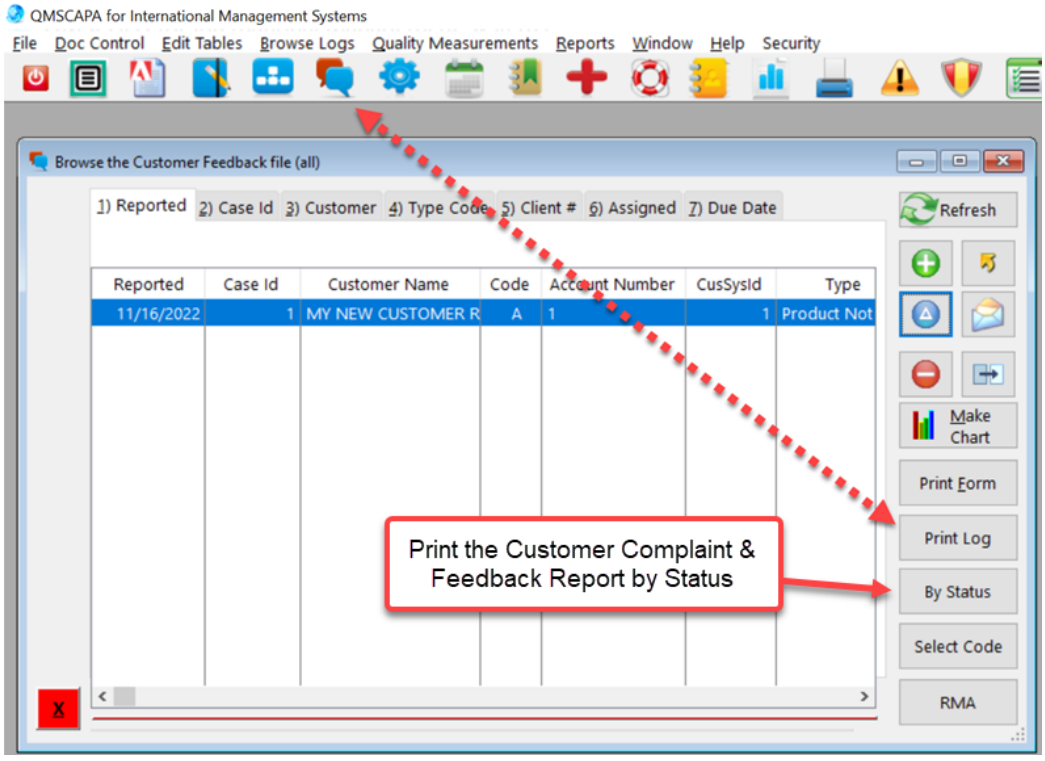
9.5 obtaining customer feedback relating to products and services, including customer complaints;

9.6 handling or controlling customer property;

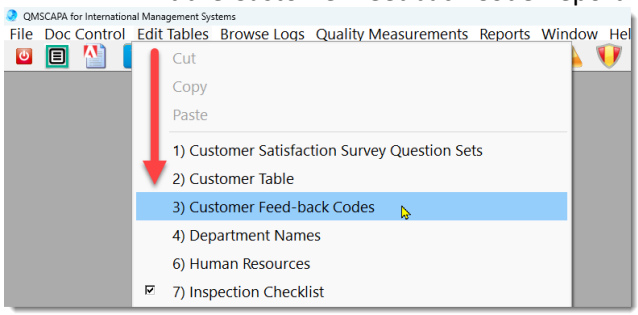
9.7 establishing specific requirements for contingency actions, when relevant.

9.8 Record all Customer Feedback from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

9.9 Print the Customer Feedback Log Report.



- Print the Customer Feedback Code Report



10. Customer Satisfaction Survey Results

10.1 AS9100D & ISO 9001:2015, Clause 9.1.2 Customer Satisfaction

10.2 The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring, and reviewing this information.

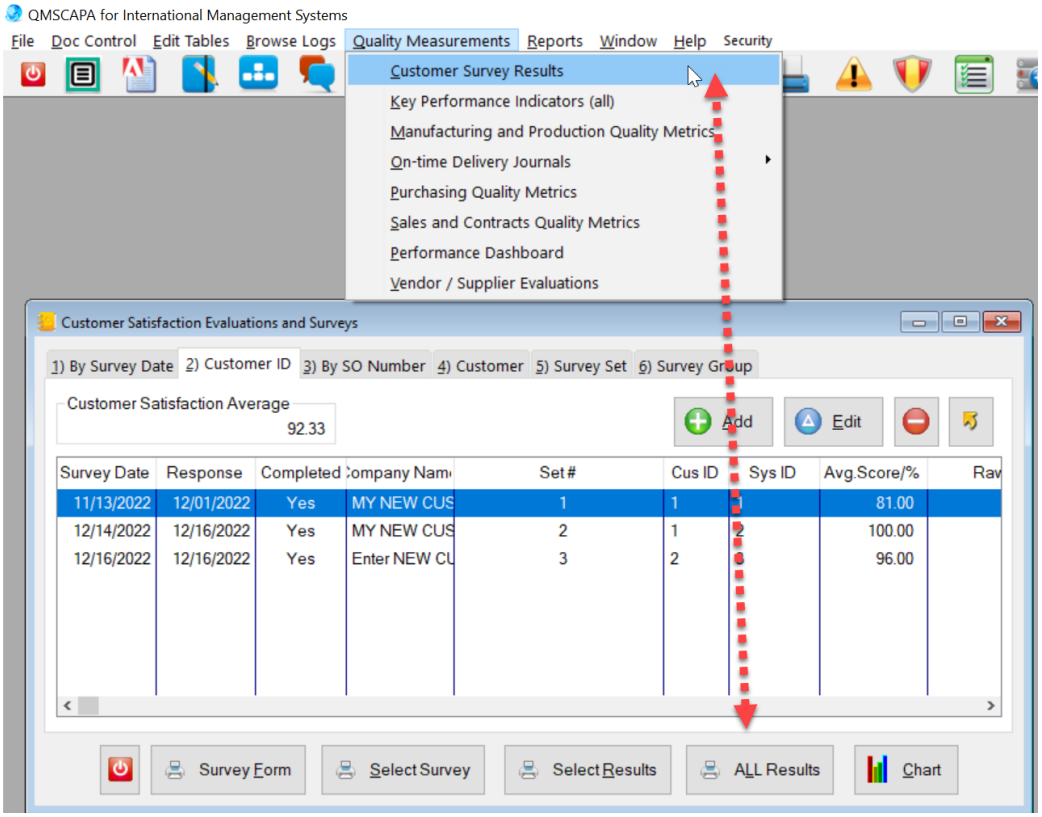
10.3 NOTE: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims, and dealer reports.

10.4 Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests.

10.5 The organization shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

10.6 Record all Customer Satisfaction Evaluations and Surveys from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

10.7 Print the Customer Survey Results Report.



11. Document Control Index

11.1 AS9100D & ISO 9001:2015, Clause 7.5.3 Control of Documented Information

11.2 (7.5.3.1) Documented information required by the quality management system and by this International Standard shall be controlled to ensure:

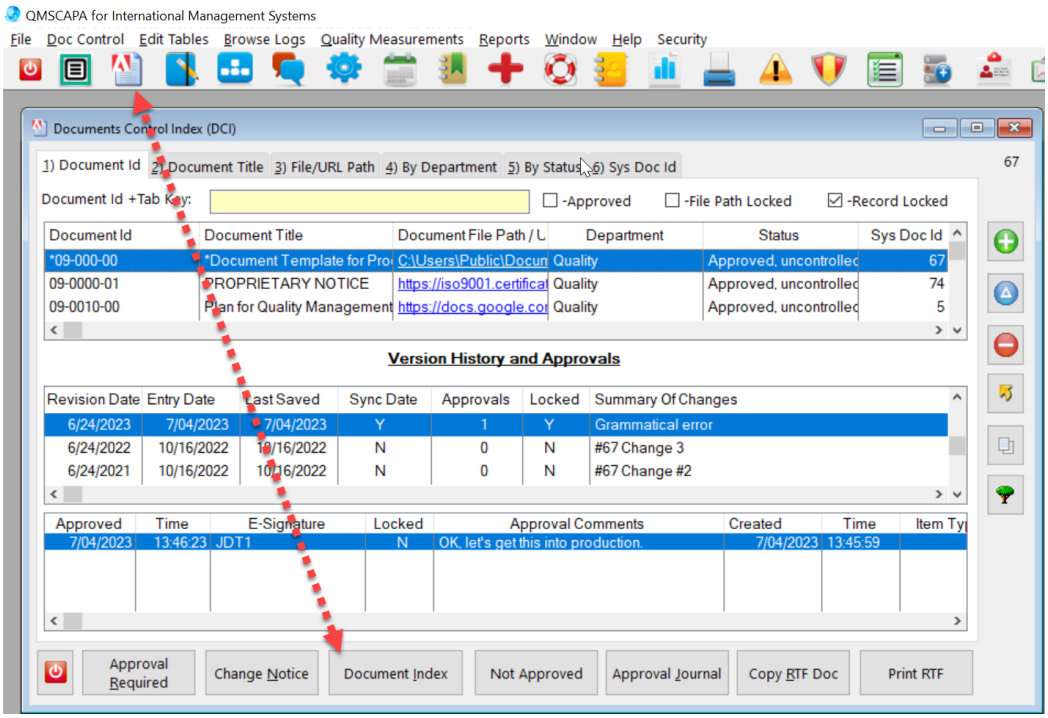
a. it is available and suitable for use, where and when it is needed;
b. it is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).

11.3 (7.5.3.2) For the control of documented information, the organization shall address the following activities, as applicable:

a. distribution, access, retrieval, and use;
b. storage and preservation, including preservation of legibility;
c. control of changes (e.g., version control);
d. retention and disposition;
e. prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

11.4 Record all Controlled Documents from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

11.5 Print the Document Control Index Report.



12. Key-Performance-Indicators (General Process KPI Log)

12.1 AS9100D & ISO 9001:2015, Clause 9.1 Monitoring, Measurement, Analysis, and Evaluation

12.2 (9.1.1) General

12.3 The organization shall determine:

c. what needs to be monitored and measured;

d. the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results;

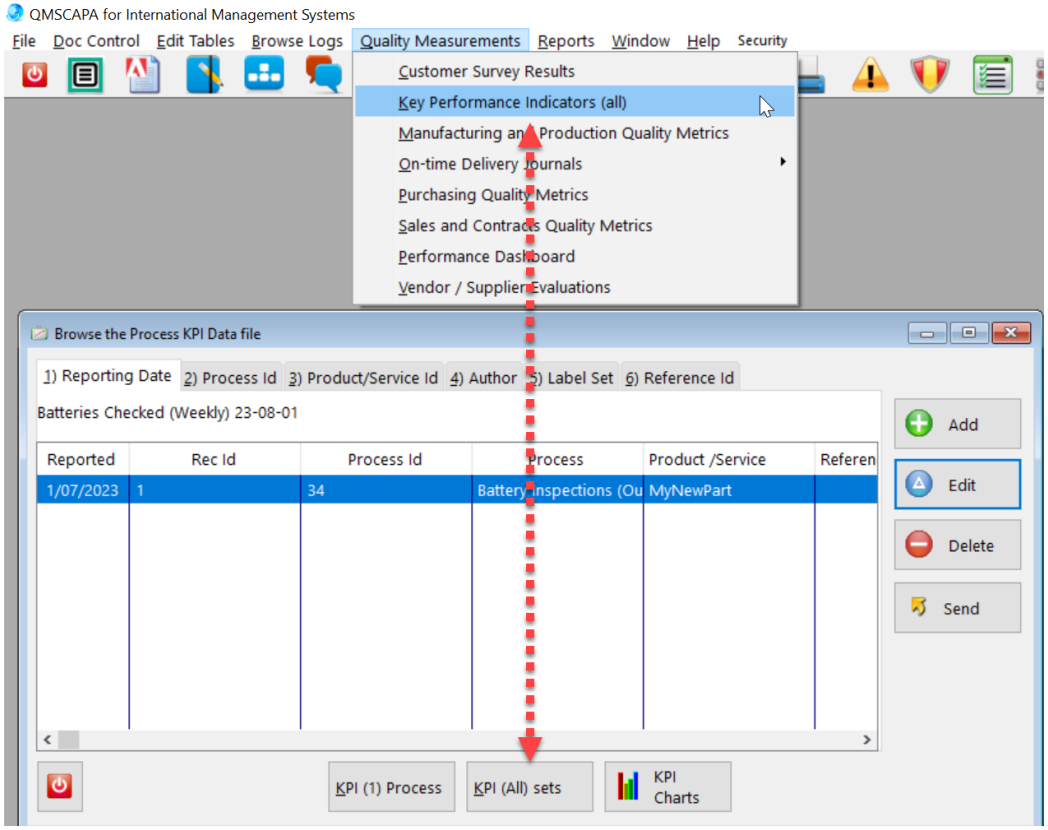
e. when the monitoring and measuring shall be performed;

f. when the results from monitoring and measurement shall be analyzed and evaluated. The organization shall evaluate the performance and the effectiveness of the quality management system.

12.4 Use the QMSCAPA Process KPI Log to record the monitoring of processes that are not considered as primary Quality Objectives.

12.5 Record all Process KPIs from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

12.6 Print the Process KPI Log (All) by a Date Range.



13. Monitoring and Measuring Resources

13.1 AS9100D & ISO 9001:2015, Clause 7.1.5.1

13.2 The organization shall ensure that the resources provided:

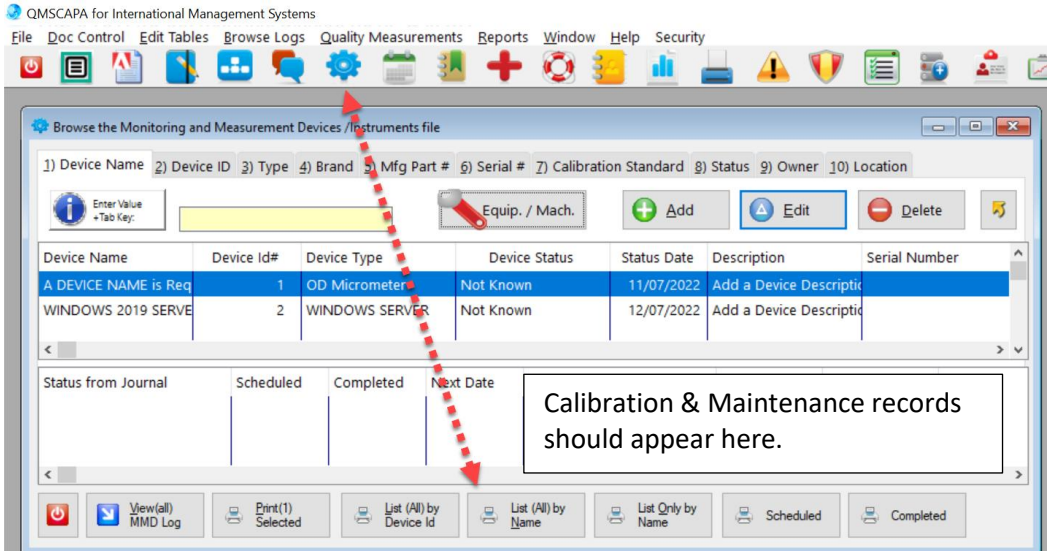
13.3 are suitable for the specific type of monitoring and measurement activities being undertaken;

13.4 are maintained to ensure their continuing fitness for their purpose.

13.5 The organization shall retain appropriate documented information as evidence of fitness for the purpose of the monitoring and measurement resources.

13.6 Record all Monitoring and Measuring Resources (calibration and maintenance) from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

13.7 Print the Monitoring and Measuring Devices List Report. Each Device should have a calibration and, or maintenance record (see Status from Journal).



14. Manufacturing or Production Quality Metrics (Quality Objective Product Acceptance)

14.1 AS9100D & ISO 9001:2015, Clause 6.2 Quality Objectives and Planning to Achieve Them

14.2 6.2.1 The organization shall establish quality objectives at relevant functions, levels, and processes needed for the quality management system.

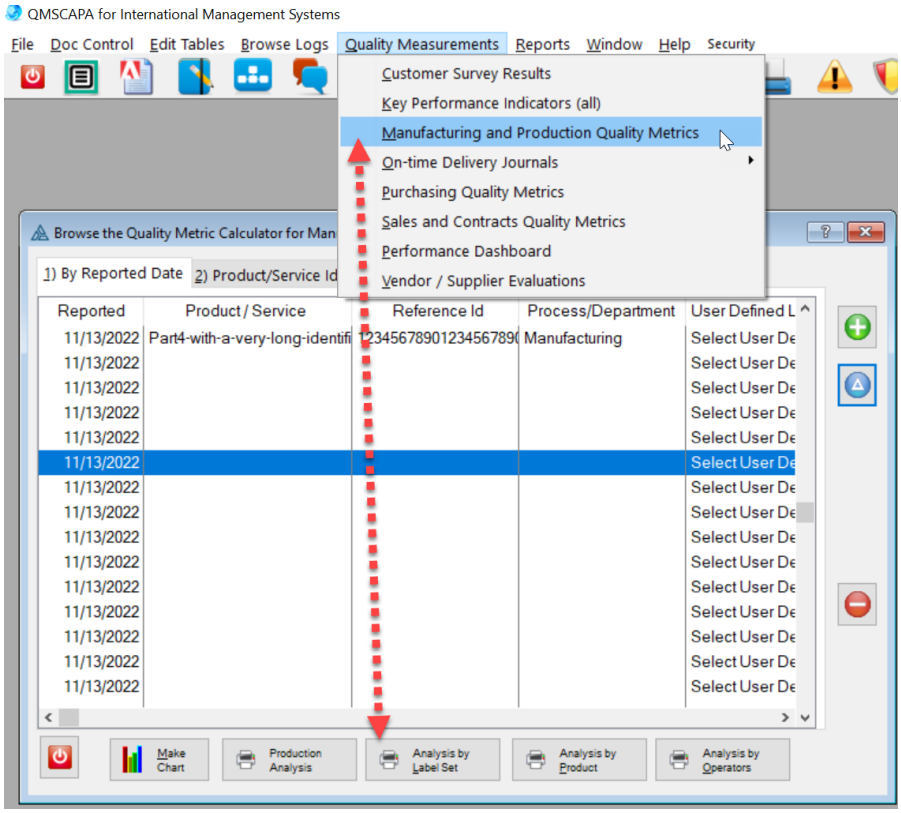
14.3 The quality objectives shall:

a. be consistent with the quality policy;
b. be measurable;
c. take into account applicable requirements;
d. be relevant to conformity of products and services and to enhancement of customer satisfaction;
e. be monitored;
f. be communicated;
g. be updated, as appropriate.

14.4 The organization shall maintain documented information on the quality objectives.

14.5 Record all Customer Feedback from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

14.6 Print the Production Analysis Log, and, or Analysis by Label Set



15. On-time Delivery Log (Recommended) or Batch Log Records)

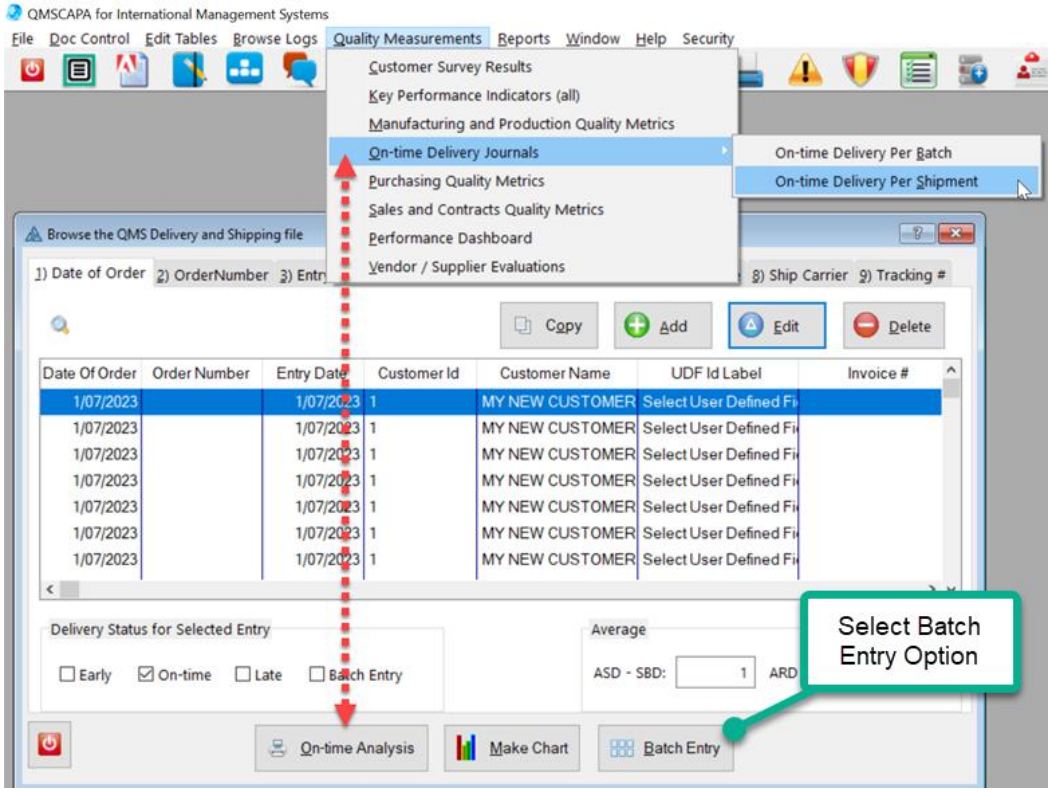
15.1 AS9100D & ISO 9001:2015, Clause 8.1 Operational Planning and Control

15.2 The organization shall plan, implement, and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in clause 6, by:

c. determining the resources needed to achieve conformity to the product and service requirements and *to meet on-time delivery of products and services*;

15.3 Record all On-time Delivery by Customer and Order from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

15.4 Print the On-time Delivery Journal by a date range.



16. Planning Actions to Address Risks and Opportunities

16.1 AS9100D & ISO 9001:2015, Clause 6.1 Actions to Address Risks and Opportunities

16.2 (6.1.1) When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a. give assurance that the quality management system can achieve its intended result(s);
b. enhance desirable effects;
c. prevent, or reduce, undesired effects;
d. achieve improvement.

16.3 (6.1.2) The organization shall plan:

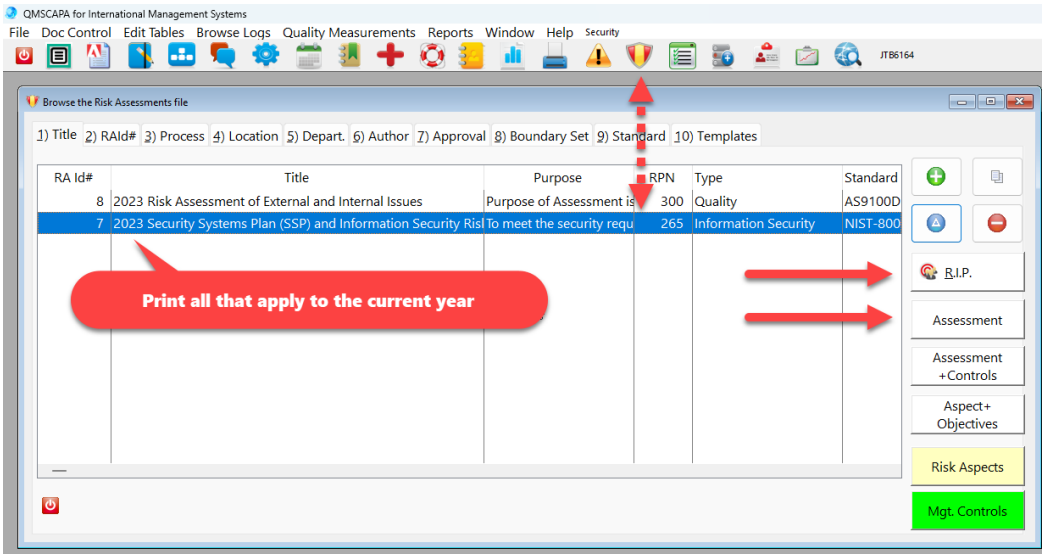
a. actions to address these risks and opportunities;
b. how to:

1. integrate and implement the actions into its quality management system processes (see 4.4);
2. evaluate the effectiveness of these actions.

16.4 Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

16.5 Record all Customer Feedback from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

16.6 Print the Risk Assessment Report, and, or the Risk Assessment +Controls Report for the current Management Review period and share this information with your team.



17. Purchasing Quality Metrics (Supplier/Vendor KPI report)

17.1 AS9100D & ISO 9001:2015, Clause 8.4 Control of Externally Provided Processes, Products, and Services

17.2 8.4.1 The organization shall ensure that externally provided processes, products, and services conform to requirements.

17.3 The organization shall determine the controls to be applied to externally provided processes, products, and services when:

a. products and services from external providers are intended for incorporation into the organization's own products and services;

b. products and services are provided directly to the customer(s) by external providers on behalf of the organization;

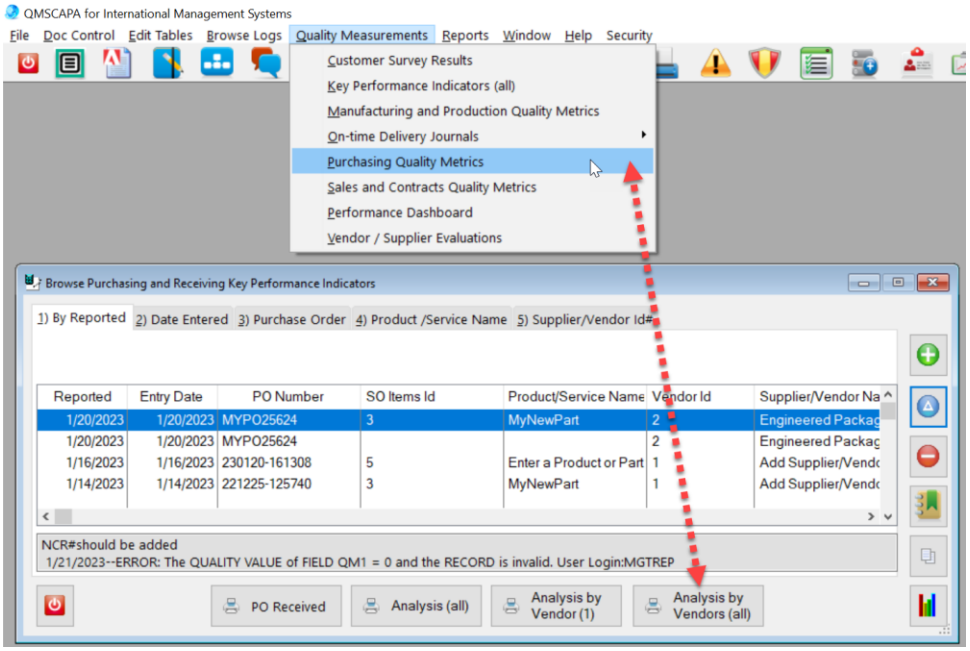
c. a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

17.4 The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and reevaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.

17.5 The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

17.6 Record all Purchasing Quality metrics from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

17.7 Print the Purchasing Analysis Report by Vendors (all), and, or Purchase Analysis Report (all) .



18. Purchasing Processes Forms and Logs

18.1 Use the Purchasing Processes module to record:

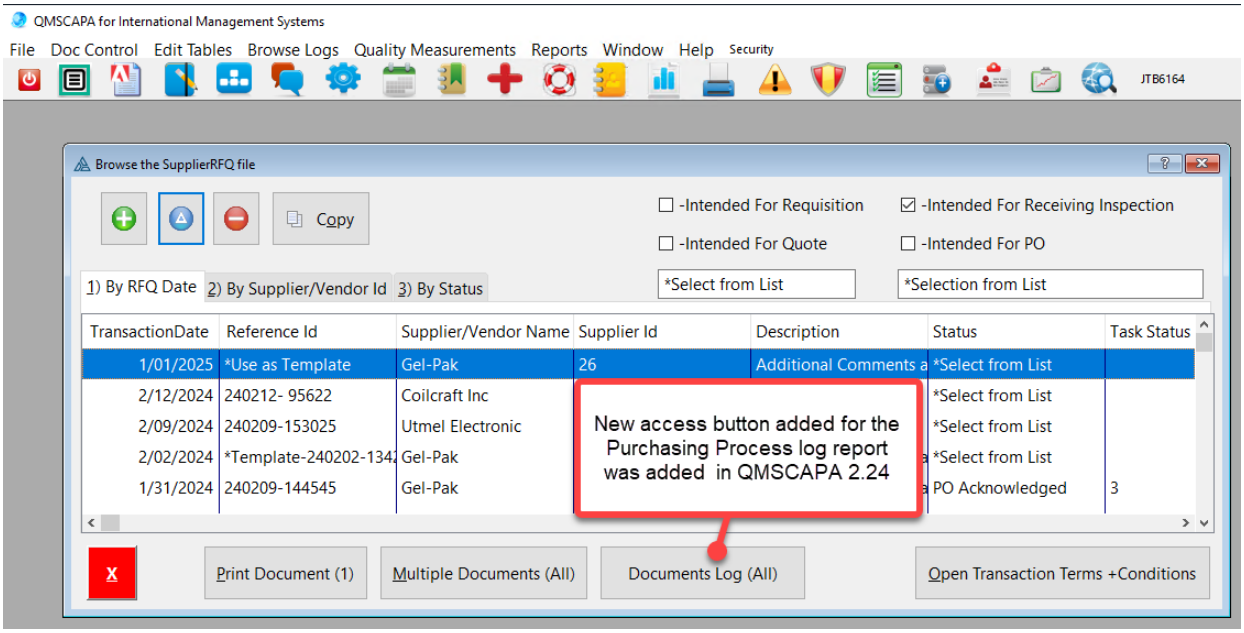
18.2 Credit Card Purchases with Suppliers

18.3 Request for Quotes sent to Suppliers

18.4 Request for POs sent to internal Accounting Department/Teams

18.5 Send a Purchase Order to a Supplier

18.6 Send a Receiving Inspection Form to Inbound Shipping Department/Teams.



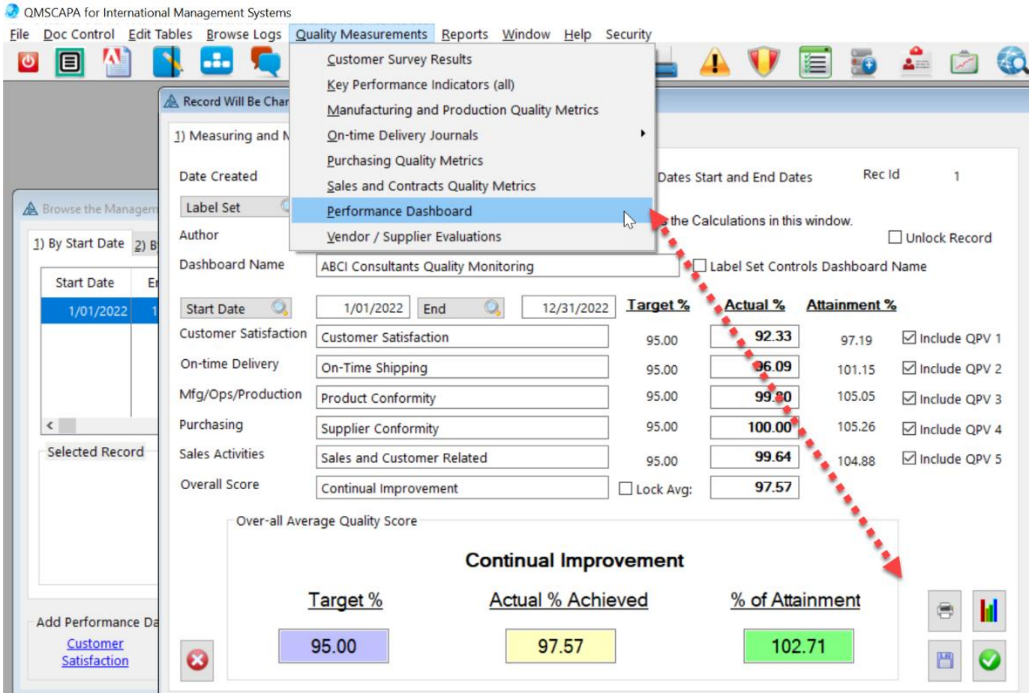
19. Quality Performance Dashboard (Includes continual improvement trend)

19.1 AS9100D & ISO 9001:2015, Clause 6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

a. what will be done;
b. what resources will be required;
c. who will be responsible;
d. when it will be completed;
e. how the results will be evaluated.

19.2 Record all Quality Measurements from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

19.3 Print the Performance Dashboard with the Date Range for the current Management Review period and share this information with your team.



20. Records Control Index (RCI)

20.1 AS9100D & ISO 9001:2015, Clause 8.5.2 Identification and Traceability

20.2 The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

20.3 The organization shall maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

20.4 The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

20.5 When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish controls for the media.

20.6 The organization shall control the unique identification of the outputs when traceability is a requirement and shall retain the documented information necessary to enable traceability.

20.7 NOTE: Traceability requirements can include:

f. the identification to be maintained throughout the product life;

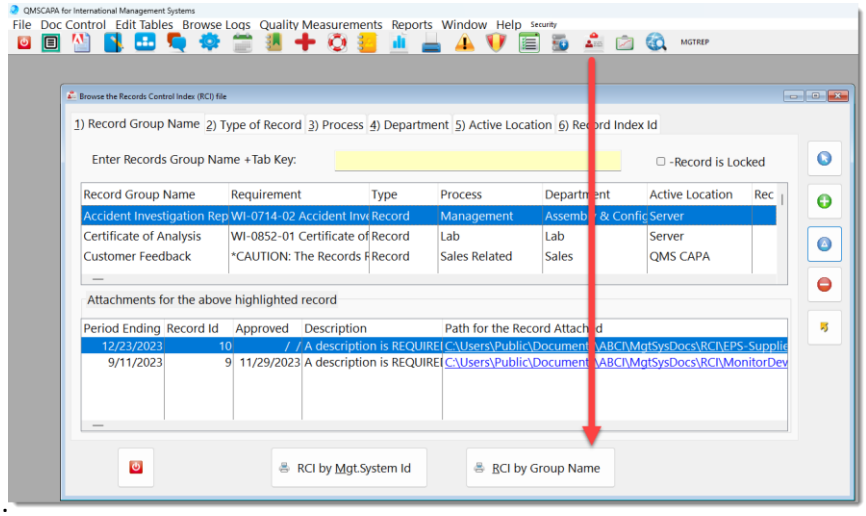
a. the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch to the destination (e.g., delivery, scrap);

b. for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;

c. for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.

20.8 Record where all documented records are stored from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

20.9 Print the Records Control Index Report by Group Name for the current Management Review period and share this information with your team



21. Relevant Interested Parties of the Quality Management Systems

21.1 AS9100D & ISO 9001:2015, Clause 4.2 Understanding the Needs and Expectations of Interested Parties

21.2 Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

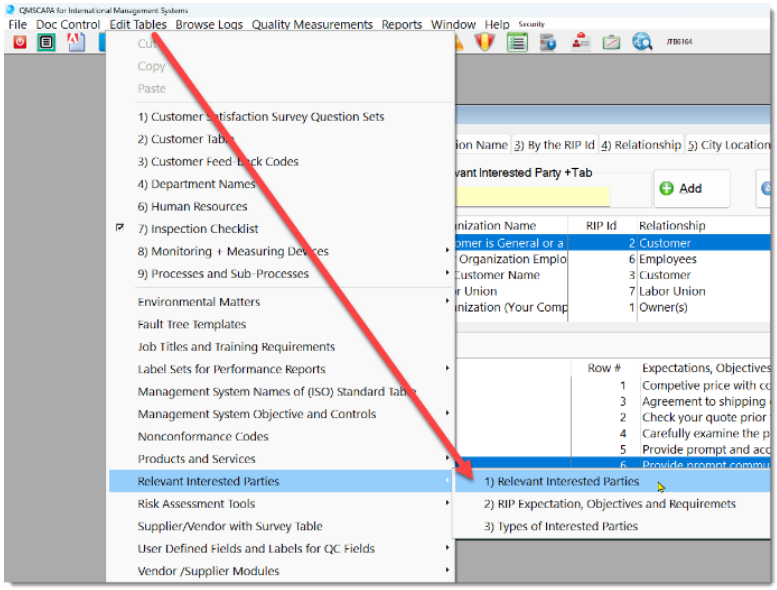
21.3 the interested parties that are relevant to the quality management system;

21.4 the requirements of these interested parties that are relevant to the quality management system.

21.5 The organization shall monitor and review information about these interested parties and their relevant requirements.

21.6 Record all Customer Feedback from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

21.7 Print the Relevant Interested Party Report.



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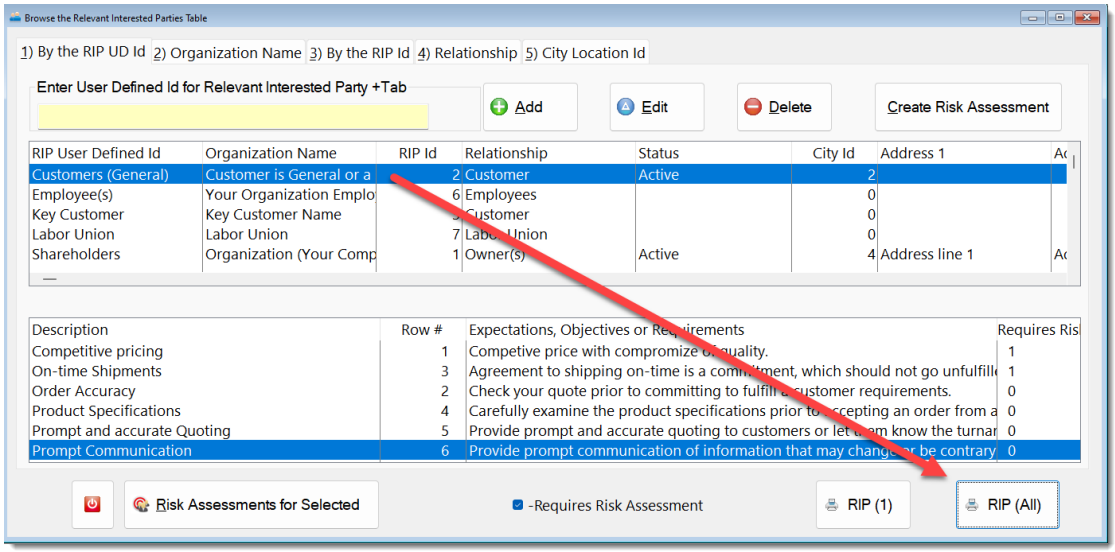
21.8 Table of Interested Parties which are relevant to the Quality Management Systems.



23. Inspection of Sales Quoting and Contract Review (Sales Process KPI report)

23.1 AS9100D & ISO 9001:2015, Clause 8.2.3 Review of the Requirements for Products and Services

23.2 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. *The organization shall conduct a review before committing to supply products and services to the customer, to include:*

a. requirements specified by the customer, including the requirements for delivery and post-delivery activities; b. requirements not stated by the customer, but necessary for the specified or intended use, when known; c. requirements specified by the organization; d. statutory and regulatory requirements applicable to the products and services; e. contract or order requirements differing from those previously expressed.

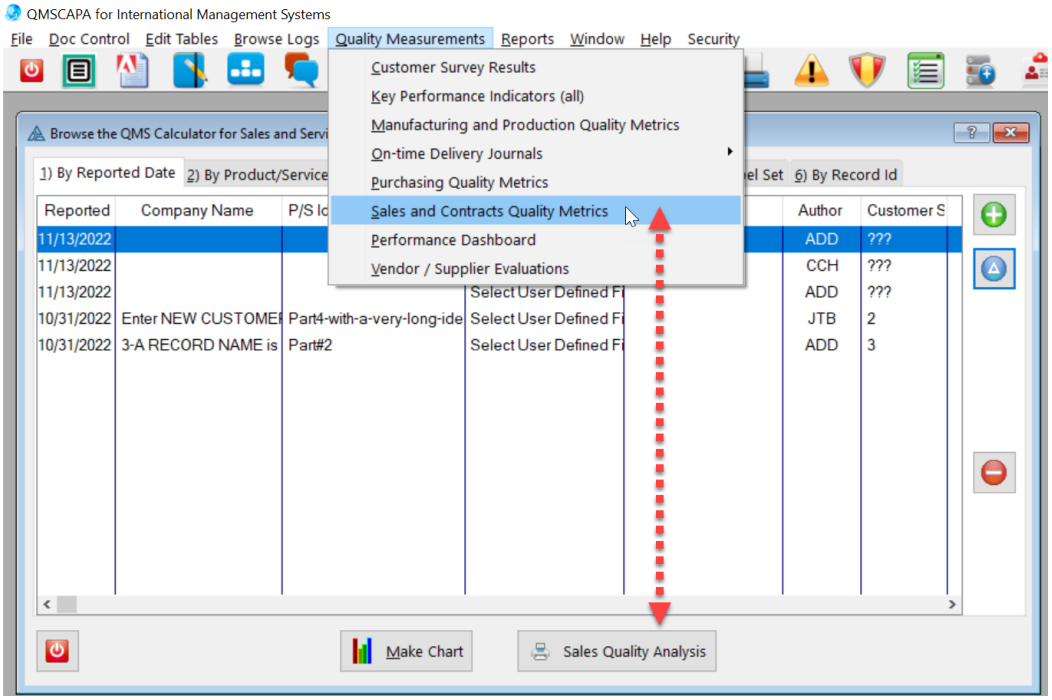
23.3 This review shall be coordinated with applicable functions of the organization.

23.4 The customer requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

23.5 Record all Sales Contract Reviews from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

23.6 Print the Sales Quality Analysis Report for the current Management Review period.



24. Supplier/Vendor Approval Report

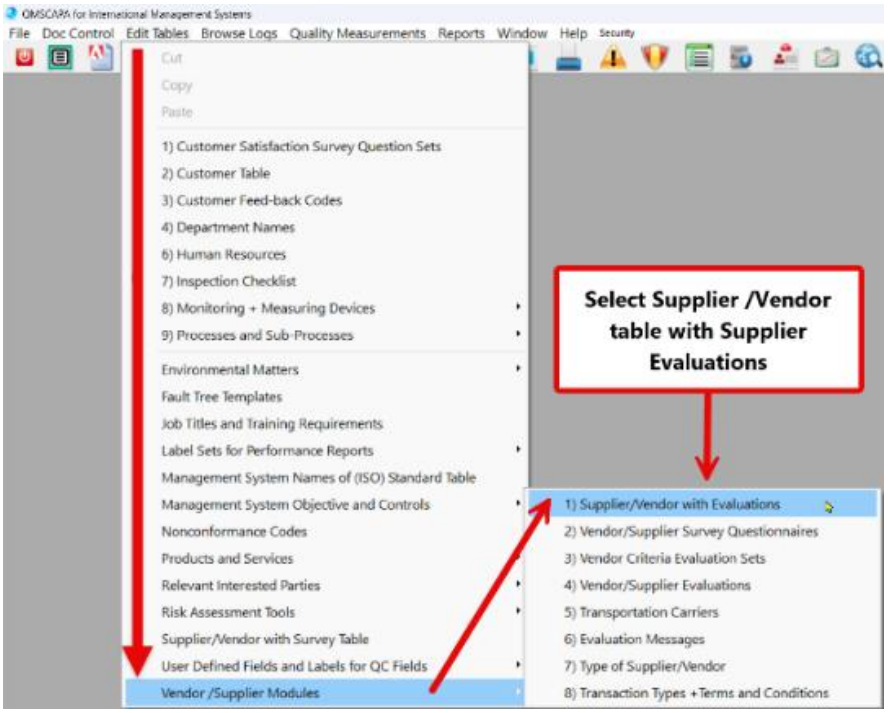
24.1 AS9100D & ISO 9001:2015, Clause 8.4.3 Information for External Providers

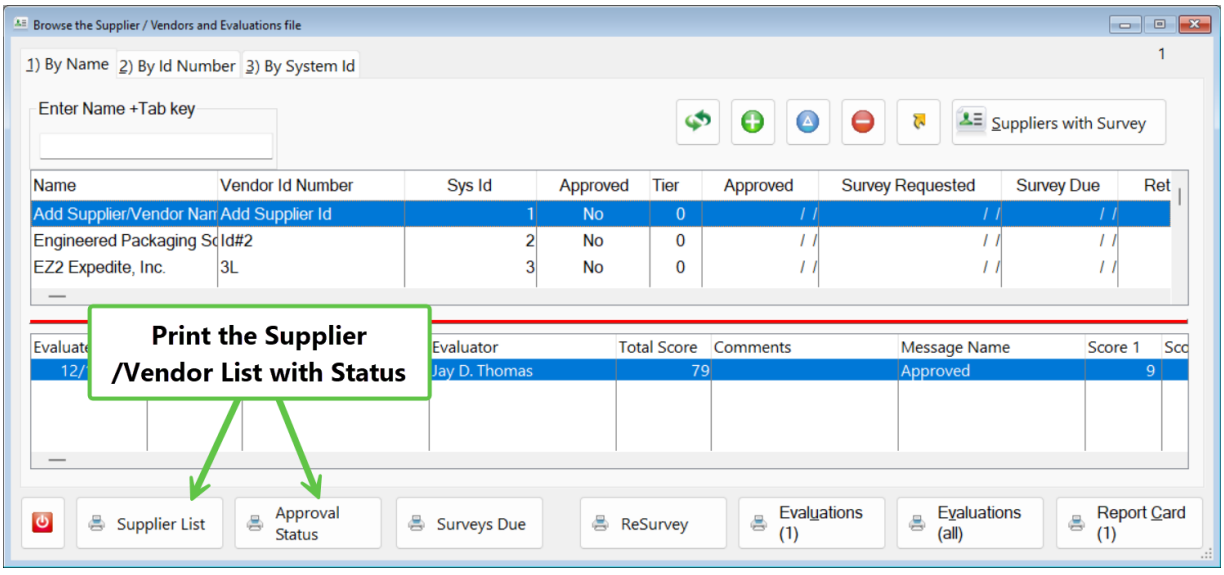
24.2 The organization shall ensure the adequacy of requirements prior to their communication to the external provider. The organization shall communicate to external providers its requirements for:

a. the processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions); … truncated text.
b. the approval of products and services, methods, processes, and equipment; the release of products and services;
c. competence, including any required qualification of persons;
d. the external providers' interactions with the organization;
e. control and monitoring of the external providers' performance to be applied by the organization;
f. verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises;
g. design and development control;
h. special requirements, critical items, or key characteristics;
i. test, inspection, and verification (including production process verification);
j. the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;
k. the need to implement a quality management system; use customer-designated or approved external providers, including process sources (e.g., special processes); … truncated text.
l. the right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;
m. ensuring that persons are aware of their contribution to product or service conformity; their contribution to product safety; the importance of ethical behavior.

24.3 Record all Suppliers/Vendors by their status (approved, conditional, not approved) from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

24.4 Print the Supplier /Vendor List Report and, or Supplier List by Status Report for the current Management Review period.

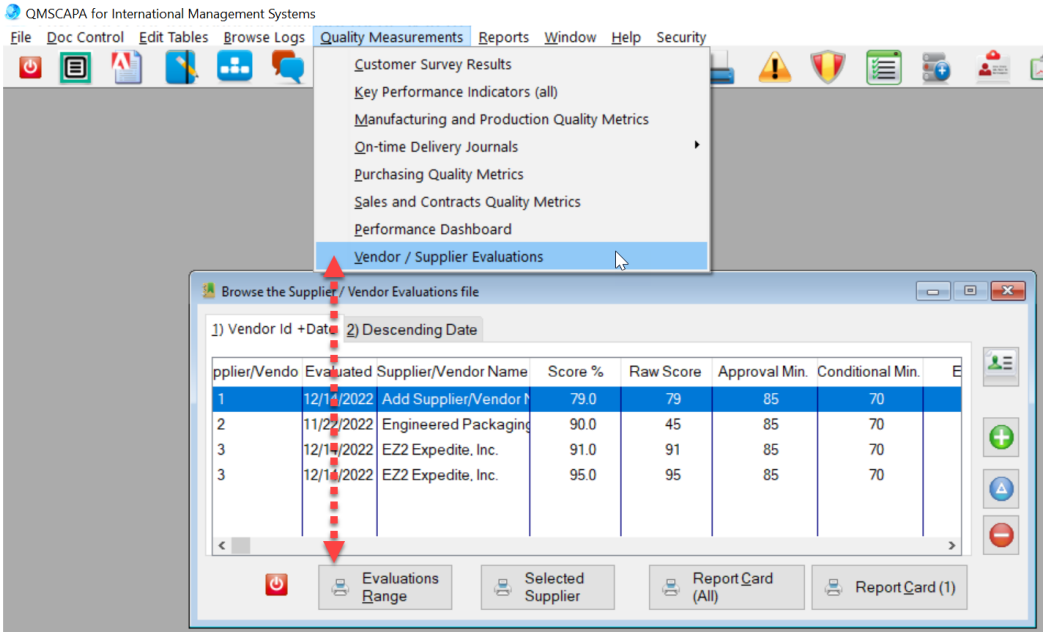




25. Supplier/Vendor Evaluation Report (Assigned to TJM)

25.1 Record all Suppliers/Vendors by their status (approved, conditional, not approved) from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

25.2 Print the Supplier/Vendor Evaluation Reportand, or Supplier List by Status Report for the current Management Review period.



26. Training Scheduled and Completed Report

26.1 AS9100D & ISO 9001:2015, Clause 7.2 Competence

26.2 The organization shall:

n. determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

o. ensure that these persons are competent on the basis of appropriate education, training, or experience;

p. where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

q. retain appropriate documented information as evidence of competence.

26.3 Clause 7.3 Awareness

26.4 The organization shall ensure that persons doing work under the organization's control are aware of:

a. the quality policy;

b. relevant quality objectives;

c. their contribution to the effectiveness of the quality management system, including the benefits of improved performance;

d. the implications of not conforming with the quality management system requirements;

e. relevant quality management system documented information and changes thereto;

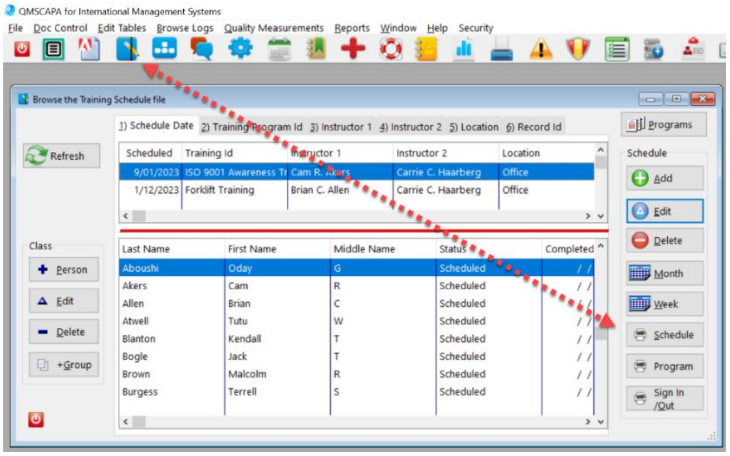
f. their contribution to product or service conformity;

g. their contribution to product safety;

h. the importance of ethical behavior.

26.5 Record all Competence and Awareness Training scheduled and completed from January 1, 2025, through December 31, 2025, and going forward to maintain AS9100D Certification.

26.6 Print the Competence and Awareness Training Scheduled and Completed Report for the current Management Review period.



27. Index of Referenced Documents Created in QMSCAPA

#End-of-Document