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COMMON AEROSPACE PITFALLS

A Review of Commonly Misunderstood AS91XX Requirements

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INTRODUCTION

- Kim Wagner
  - Aerospace Program Manager at PJR
  - Certified Aerospace Auditor for AS9100, AS9110, and AS9120
  - With PJR for 10 Years
  - kwagner@pjr.com

OVERVIEW

- There are a few requirements within the AS9100/9110/9120 standards that some organizations seem to struggle with.
- Whether you are new to the Aerospace standards or have been maintaining a certified AQMS for a while now, we believe an in-depth review of these requirements and the misconceptions surrounding them will be helpful.
- In this webinar, we will tackle the following topics:
  - Value-added Process Measures
  - Supplier Performance Monitoring
  - Organizational Risk vs. Operational Risk
  - Control of Nonconforming Outputs Process Requirements
  - Corrective Action Process Requirements

VALUE-ADDED PROCESS MEASURES IN AS91XX

4.4.1 The organization shall establish, implement, maintain, and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

a. determine the inputs required and the outputs expected from these processes;

b. determine the sequence and interaction of these processes;

c. determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

d. determine the resources needed for these processes and ensure their availability;

e. assign the responsibilities and authorities for these processes;

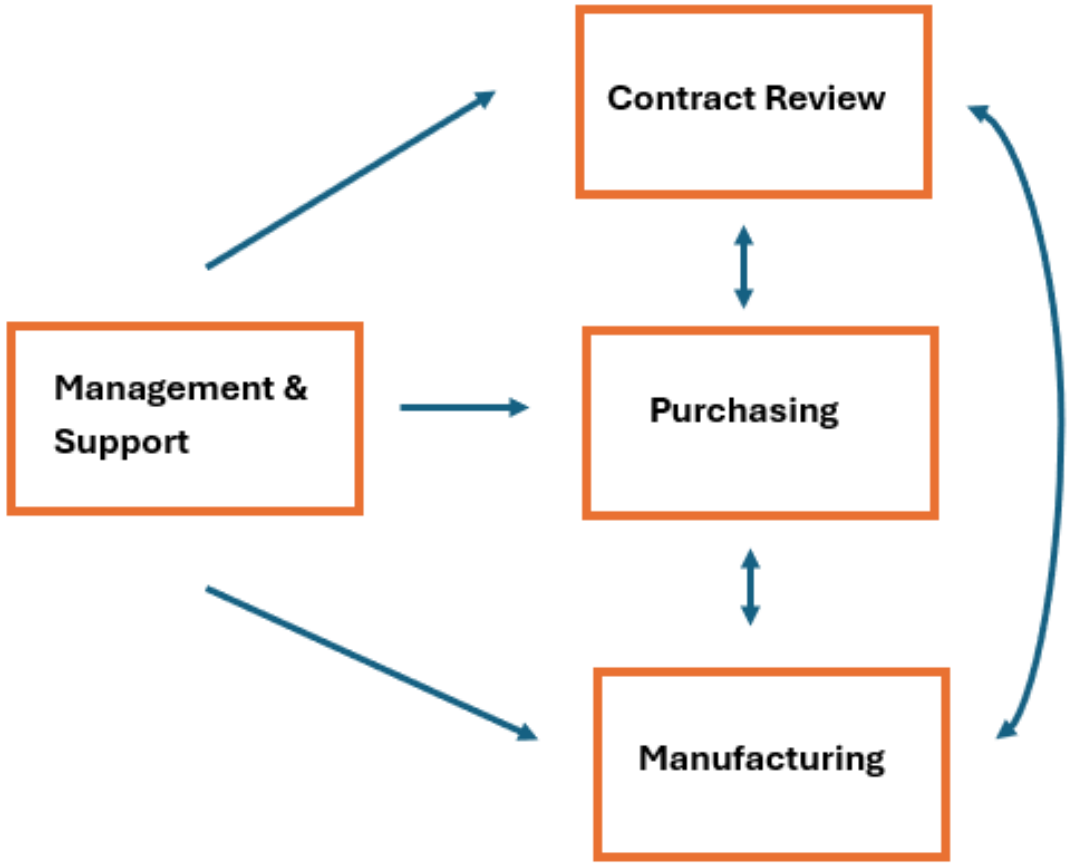
f. address the risks and opportunities as determined in accordance with the requirements of 6.1;

g. evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

h. improve the processes and the quality management system

VALUE-ADDED PROCESS MEASURES IN AS9IXX

- In sum, 4.4.1 requires that you determine the processes of your QMS and then:
  - Determine and apply the criteria and methods to measure the effectiveness of processes
  - Evaluate these processes and implement changes needed to ensure these process achieve their intended results



CLARIFICATION ON 4.4.1 C, G FROM IAQG

- The International Aerospace Quality Group (IAQG) maintains a Clarifications document on the 9100:2016 Series standards. It is a compiled list of questions and answers regarding specific clauses.
- It is a great source to utilize when you are unsure of the intent any clauses of the AS91XX standards.
- The document is available on the IAQG website. You can find a link to this here: https://iaqg.org/wp-content/uploads/2023/04/9100-2016-Series-Clarification-Table-2024-02-12.pdf
- They weighed in on clauses 4.4.1 c and g.

CLARIFICATION ON 4.4.1 C, G FROM IAQG

Question on 4.4.1c, g:

- Is it the intent of the standard that an organization can have just a top-level requirement(s) that is used to evaluate the effectiveness of the QMS and several individual processes without those processes having specific metrics? For example, OTD of product to the customer of 98% is the top-level metric and the metric used to evaluate the effectiveness of the purchasing process, contract review process, and the manufacturing process with no additional metrics. So, if they have met the OTD of 98%, then all processes are deemed as effective.

CLARIFICATION ON 4.4.1 C, G FROM IAQG

IAQG's Answer:

- No. 9100-series standards require the organization to determine if the identified processes are effective and achieving planned results (see clause 4.4.1c). Each process measure should evaluate the effectiveness of that process and be value added. This is the measure that would be included in Process Effectiveness Assessment Report (PEAR) as the key performance indicator for that process. The 9100-series standards does not mandate a certain number of process measures.

- Small organizations typically have fewer measures than larger organizations. These small organizations have increased visibility regarding process health due to their size. Regardless, this does not alleviate the need for determining if processes are effective and achieving planned results. The organization can have additional working level measures that may not flow up to top management or management review.

WHAT DOES THIS MEAN FOR YOUR AQMS?

- As the answer indicates, using a top-level objective as an overall measure for all processes is NOT appropriate and does not meet the intent of 4.4.1.
- As it says: "Each process measure should evaluate the effectiveness of that process and be value added."
- So, what are some examples of measures that are more value added and provide a more precise measure of effectiveness of these processes?

THE SUPPLY CHAIN MANAGEMENT HANDBOOK

- The IAQG has an online resource available called the Supply Chain Management Handbook (SCMH). It was developed by subject matter experts to assist organizations with understanding requirements and how to apply them. This is a great resource to have on hand!
- The SCMH section 7.11.2 includes examples of value-added Key Performance Indicators you can apply to your processes.
- Let's review a few of these examples for some common AQMS processes.

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CONTRACT REVIEW KPI EXAMPLES

Key Performance Indicator (KPI)	Description
Quote Turnaround Time	Measure of how many RFQs are answered with quotes sent to customer within a defined time frame (example: 3 days) vs total number of answered RFQs
Order Entry Errors	Measure of how many orders entered with errors vs how many total orders entered within a given time frame.
Quarterly Sales	Measure of overall sales made in the quarter vs a defined sales goal for that quarter
Sales Conversion Rate	Number of contracts awarded vs total number of contracts bid
Adherence to Program Gates	Measure of the number of program milestones successfully passed on time

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PURCHASING KPI EXAMPLES

Key Performance Indicator (KPI)	Description
Purchase Order Launch Performance	The number of purchase orders sent on time (in line with business needs and supplier contractual lead-times) vs. total number of purchase orders
Purchase Order Acknowledgement Rate	The number of purchase orders acknowledged by the Supplier within the required due date vs. total number of purchase orders sent
Supply Chain Performance	The measure of overall on-quality and on-time performance of the supply base.
Supplier Capacity Rating	The measure of the supplier's capacity versus the capacity required by the product/program fulfillment as planned by customer
Receiving Inspection Acceptance Rate	The number of received materials/services that pass receiving inspection without incident vs. total number of received materials/services

MANUFACTURING KPI EXAMPLES

Key Performance Indicator (KPI)	Description
Scrap Rate	The number of items that were scrapped divided by the number of items produced during time period.
Item Escape Rate from internal processes to internal customer	The number of items produced and identified by internal customers that were not compliant vs the total number of items produced during time period.
First Pass Yield	Rate of on-quality deliverables produced by process divided by the number of deliverables going into that process over a time period. Only good units with no rework/scrap counted.
Inventory Accuracy	Measure of the accuracy of inventory by taking an actual count of items in stock compared to what is recorded in database
Labor Efficiency	The ratio between the amount of time planned for completing certain activities and the action time taken to complete those activities.
On-time Manufacturing	Number of items completed on time in the given time period vs number of items planned to be completed in that time period

SUMMARY

- Establishing strong, value-added process measures will allow you to have higher level of visibility on the health of your processes.
- If you do miss a KPI target, you can zero in on the specific cause of the underperformance and take corrective action. This leads to continual improvement of each process and in turn, of your overall QMS.

SUPPLIER PERFORMANCE MONITORING IN AS9IXX

8.4.1.1 The organization shall:

a. define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;

b. maintain a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);

c. periodically review external provider performance including process, product and service conformity, and on-time delivery performance;

d. define the necessary actions to take when dealing with external providers that do not meet requirements;

e. define the requirements for controlling documented information created by and/or retained by external providers.

SUPPLIER PERFORMANCE MONITORING IN AS9IXX

- 8.4.1.1 c states that you are required to periodically review your suppliers' performance, including their on-time delivery and quality performance.
- However, there has been some confusion on WHICH suppliers need to be reviewed.
- And of how often?

CLARIFICATION ON 8.4.1.1C FROM IAQG

- Question on 8.4.1.1: "If the organization wishes to apply a risk management approach to suppliers indicating varying levels of rigor for evaluation, approval, and re-evaluation dependent upon the effect on product conformity… is that acceptable?
- Answer: Clause 8.4.1.1c requires a periodic review of external provider performance, including conformity and on-time delivery. So, it is required that every supplier that affects product, process, and service conformity have a periodic review of this information. The organization can review this information at various frequencies depending upon risk, but the information is still required to be reviewed.
- Without a periodic review of quality and OTD how would an organization apply a risk management approach?

SUMMARY

- It is up to you as an organization to determine the frequency for this supplier performance review.
- You can have varying frequencies for different supplier “tiers.”
- But all suppliers that affect product/service quality MUST be periodically reviewed.

ORGANIZATIONAL RISK VS. OPERATIONAL RISK

- In the AS9100:2016 and AS9110:2016 standards, there are two clauses dedicated to risk management: 6.1 and 8.1.1. (8.1.1 is not applicable to AS9120:2016).
- These clauses require your organization to manage different kinds of risks: Organizational Risks (6.1) and Operational Risks (8.1.1).
- These sometimes can be confused for one another.
- Let's take a closer look at each of these clauses and analyze some examples of risk management!

6.1 REQUIREMENT

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.

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.

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

NOTE 1: Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2: Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

6.1 REQUIREMENT

- TC-176 Interpretation - ISO/TS 9002 - 6.1.1 - The intent of this subclause is to ensure that when planning the quality management system processes, the organization determines its risks and opportunities and plans actions to address them. Its purpose is to prevent nonconformities, including nonconforming outputs, and to determine opportunities that might enhance customer satisfaction or achieve an organization's quality objectives.

- When determining the risks and opportunities for the quality management system, the external and internal issues (see ISO 9001:2015, 4.1) as well as relevant interested parties' requirements (see ISO 9001:2015, 4.2) should be considered. Examples of the risks that the quality management system will not achieve its objectives include the failure of processes, products and services to meet their requirements, or the organization not achieving customer satisfaction.

EXAMPLES OF 6.1.1 RISKS

- Aging workforce with multiple retirements approaching – 6.1
- Effects of tariffs in certain industries on material costs – 6.1
- Cyber Security risks, such as phishing, ransomware, malware, etc. – 6.1
- Risks associated with extreme weather events, such as forest fires, hurricanes, earthquakes, etc., depending on region - 6.1

RISK MANAGEMENT TOOLS

- There are many tools and methodologies that an organization can adopt to help manage risks and identify opportunities included:
  - Learning from the Past (Lessons Learned)
  - PEST (Political, Economic, Social, Technological)
  - PESTLE (Political, Economic, Social, Technological, Legal, Environmental)
  - SWOT (Strengths, Weaknesses, Opportunities, Threats)
  - FMEA (Failure Modes and Effects Analysis)
  - BCM (Business Continuity Management)

8.1.1 REQUIREMENT

8.1.1 Operational Risk Management

The organization shall plan, implement, and control a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to the organization and the products and services:

a. assignment of responsibilities for operational risk management;

b. definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);

c. identification, assessment, and communication of risks throughout operations;

d. identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

e. acceptance of risks remaining after implementation of mitigating actions.

NOTE 1: While clause 6.1 addresses the risks and opportunities when planning for the quality management system of the organization, the scope of this clause (8.1.1) is limited to the risks associated to the operational processes needed for the provision of products and services (clause 8).

NOTE 2: Within the aviation, space, and defense industry, risk is generally expressed in terms of the likelihood of occurrence and the severity of the consequences.

EXAMPLES

- Customer's PO identifies a delivery date that will be challenging to meet with current workload – 8.1.1
- Customer requires use of a vendor you have previously had issues with - 8.1.1
- New customer RFQ for a large component that takes up more facility space than usual - 8.1.1
- Customer contract flows down requirements that your organization has not yet implemented, such as specific requirements for a counterfeit parts prevention program or CMMC - 8.1.1

SUMMARY

- As shown, the standard differentiates between the risks associated with planning for your QMS (organizational risks in 6.1) and risks specifically associated with the provision of products/services (operational risks in 8.1.1).
- Having effective methods in place to identify and mitigate both types of risks will allow your system to reduce undesired effects and better achieve its intended results.

CONTROL OF NONCONFORMING OUTPUTS AND CORRECTIVE ACTION

- In 9100:2016-Series standards, there are two required "procedures" or processes that need to be defined and maintained as documented information:
  - Control of Nonconforming Outputs Process (Clause 8.7)
  - Nonconformity and Corrective Action Process (Clause 10.2)
- These processes do go hand-in-hand. It is acceptable to include the requirements for both in a single procedure or document. However, you must ensure that the procedure addresses all aspects of both 8.7 and 10.2.
- Let's take a closer look at these clauses and what they require.

8.7 - CONTROL OF NONCONFORMING OUTPUTS

- The intent of this clause is to prevent the unintended delivery or use of nonconforming outputs (at all stages of production and service provision).
- There are different ways to deal with nonconforming outputs.
- When further action is needed, the requirements for corrective action should be applied, which is when clause 10.2 steps in.

8.7 - CONTROL OF NONCONFORMING OUTPUTS

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

NOTE: The term “nonconforming outputs” includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

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

- ***defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;***
- ***taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;***
- ***timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;***
- ***defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).***

NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.

The organization shall deal with nonconforming outputs in one or more of the following ways:

a. correction;

b. segregation, containment, return, or suspension of provision of products and services;

c. informing the customer;

d. obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:

− after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;

− after authorization by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 The organization shall retain documented information that:

a. describes the nonconformity;

b. describes the actions taken;

c. describes any concessions obtained;

d. identifies the authority deciding the action in respect of the nonconformity.

WHAT DOCUMENTATION IS REQUIRED?

- There needs to be a procedure (or other means of maintained documented information) that defines your provisions for:
  - defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
  - taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;
  - timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
  - defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).
- You also must keep records that describe the nonconforming outputs, actions taken to address them, any concessions obtained from customers or relevant authorities, and who authorized the action to be taken.

CLARIFICATION ON 8.7 FROM IAQG

- Question: Our organization makes parts from foam, plastics and fiberglass and as such it is impossible to permanently mark the scrap (scrap is normally the excess material from die cutting, water jet cutting or routing). We had special bins made that had "Scrap/Trash" on the sides. These bins are emptied into a trash compactor as they fill up. Is putting this type material in a marked bin adequate or does each piece require marking?
- Answer: The intent of this requirement is to ensure no defective product re-enters the value stream, which is the purpose of having the requirement to physically render nonconforming product unusable. It is important to remember that clause 8.7 is for product that does not conform to product requirements. Therefore, if the materials are conforming and there is material excess from die cutting, water jet cutting or routing operations (or other splitting operations for distributors); your excess material does not fall within the scope of scrap control in this clause. If your product is nonconforming to product requirements that is when the scrap provisions of clause 8.7 would be applicable. Once that material is dispositioned as scrap, it would need to be marked or positively controlled until it could be rendered unusable.

10.2 – CORRECTIVE ACTION

- The intent of this clause is to ensure your organization manages nonconformities and implements corrective actions appropriately.
- When a nonconformity occurs (**including those arising from identified nonconforming outputs**, from complaints, problems arising from external providers, audit results, etc.), the organization must take action to investigate what has gone wrong, correct it, and avoid similar issues from recurring.

10.2 – NONCONFORMITY AND CORRECTIVE ACTION

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

a. react to the nonconformity and, as applicable:

1. take action to control and correct it;
2. deal with the consequences;

b. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1. reviewing and analyzing the nonconformity;
2. determining the causes of the nonconformity, ***including, as applicable, those related to human factors***;
3. determining if similar nonconformities exist, or could potentially occur;

c. implement any action needed;

d. review the effectiveness of any corrective action taken;

e. update risks and opportunities determined during planning, if necessary;

f. make changes to the quality management system, if necessary***;***

g. flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;

h. take specific actions when timely and effective corrective actions are not achieved.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

The organization shall maintain documented information that defines the nonconformity and corrective action management processes.

10.2.2 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.

WHAT DOCUMENTATION IS REQUIRED?

- Your organization needs to define your process for nonconformity and corrective action, addressing all items of 10.2.1. This must be maintained as documented information. Typically, this in the form of a procedure, but it doesn't necessarily have to be.
- You must also keep records as evidence of the:
  - "nature of nonconformities" – What was the nonconforming condition?
  - "any subsequent actions taken" – This includes Correction, Containment, Root cause analysis, and Corrective Action.
  - "the results of any corrective action" – Were the corrective actions effective? Ineffective? How did you determine this? Is additional action needed? Were risks updated?
- This means that all 10.2.1 a through h needs to be recorded in some way. We typically see this captured on a corrective action form.

CLARIFICATION ON 10.2 FROM IAQG

- Question: “Some are interpreting this requirement that we are required to determine causes for EVERY nonconformity we encounter, no matter how insignificant. 9100:2009 allowed us to define our requirements on when we would determine causes in our procedure. Realistically I don't believe that any organization has the resources to determine causes for every nonconformity.”
- Answer: Clause 10.2.1.b starts with "evaluate the need for action..." so the first action is to determine if there is a need for action. If so, then the following actions in clause 10.2.1.b would be required including root cause analysis and corrective action. The organization establishes criteria for when taking corrective actions are appropriate to the effects of the nonconformities encountered. It is not wise to expend significant resources for isolated low-cost nonconformities.
- So, when your organization encounters a nonconformity, you correct it, THEN you determine based your defined process if further action is needed. At that point, you would follow the actions in 10.2 b through h.

CLARIFICATION ON 10.2 FROM IAQG

- Question on 10.2.1.b.2: “Is it acceptable to just list “human factor” as the cause as stated in this requirement?
- Answer: No. The intent of adding “those related to human factors” is to consider human factors in the causal analysis and not stop at “human factor” or workmanship.

SIDE NOTE ON HUMAN FACTORS

- 10.2.1 b, 2 requires says you must evaluate the need for action to eliminate the cause(s) of the nonconformity by "determining the causes of the nonconformity, including, as applicable, those related to human factors;"
- The "Dirty Dozen" Human Factors include the following:
  - Lack of Communication
  - Complacency
  - Lack of Knowledge
  - Distractions
  - Lack of Teamwork
  - Fatigue
  - Lack of Resources
  - Pressure
  - Lack of Assertiveness
  - Stress
  - Lack of Awareness
  - Norms

CLARIFICATION ON 10.2 FROM IAQG

- Question: Clause 10.2.1.e requires organizations to “update risks and opportunities determine during planning, if necessary.” Does this need to be performed for every corrective action?
- Answer: The organization determines when to update risk and opportunities based upon corrective actions. This is the risk feedback loop where a possible escape from the risk process has occurred and the organization determines if inclusion to risk and opportunity planning is required.

WHAT IS THE DIFFERENCE?

- Let's look at an example.
- A machinist accidentally drops a part (PN 1234) while transporting finished parts to Quality Control (QC) for inspection. QC determines that the part is damaged and no longer conforming. The part is tagged with a red Nonconforming tag and placed in a bin for nonconforming parts. QC then fills out a form for the nonconforming part, documenting the issue and authorizing rework to be completed by the machinist to bring the part back into conformance. The specific person who authorized this signs their initials on the form. No concessions were needed. The QC personnel who signed is listed in the Control of Nonconforming Outputs procedure as someone who has been approved to disposition NC parts.
- This is an example of the Control of Nonconforming Outputs process in action in compliance with 8.7.

WHAT IS THE DIFFERENCE?

- Now, let's say this same organization requires all nonconforming output forms to be submitted to the Quality Manager (QM). The QM then reviews the forms to determine if additional action is needed. The QM tracks these NCs to see if there are any trends. The QM sees that in the last few months, there have been a several issues with parts being dropped. Due to this, he determines that corrective action is necessary and initiates a Corrective Action form.
- What information needs to be recorded on that form?

WHAT IS THE DIFFERENCE?

- Statement of Nonconformity: The process for transporting parts to QC for inspection is not currently effective.
- Objective Evidence: Machinist dropped PN 1234 when bringing the part to QC.
- Containment: Not needed.
- Correction: The dropped nonconforming part (PN 1234) was reworked and brought back into conformance.
- Root cause: The process of transporting parts by hand is not effective due to the susceptibility of human error. This can be addressed by utilizing carts, but personnel are not currently trained to use carts. This is due to the work instruction not requiring the use of carts
- Corrective action: Purchased carts for the purpose of transporting parts. Applicable employees underwent training on the new process for transporting parts to QC and back. Training records attached. The work instruction has also been revised to include clause stating that parts must be transported via cart. Revised work instruction attached.
- Verification of Effectiveness: Implemented the cart system on 10/1/24. On 10/31, no recurrences of dropped parts have been reported or observed. Interviewed employees reported that the process is effective. Corrective action has been verified and is closed.
- Update Risks?: Not needed at this time.

WHAT IS THE DIFFERENCE?

- The prior slide is an example of the Corrective Action process in action in compliance with 10.2.
- In this example, a nonconforming output was input for the CA process. Inputs can also come from customer complaints, audit findings, employee-identified problems, external provider issues, performance data, etc.

SUMMARY

- The Control of Nonconforming Outputs process and the Corrective Action process are related, but it is important that each process is fully realized in your AQMS.
- As discussed, both 8.7 and 10.2 require a procedure (or other means of documented information). You can utilize a single document to address both clauses if you'd like, but you must ensure that all aspects of 8.7 and 10.2 are defined and documented.
- A robust Control of Nonconforming Outputs process and Corrective Action process will lead to a continually improving and effective AQMS.

Any questions?

If you have any additional questions, please feel free to reach out to PJR's Aerospace Program Manager, Kim Wagner, at kwagner@pjr.com!