# AAR QAC QUALITY NEWSLETTER

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## HELP WITH 2.7 AND 2.8

*Submitted by Aaron Jakub – AAR MID Auditor*

Each year, a presentation is given at the Quality Assurance Conference outlining the elements that generate the most findings. Element 2.7, Document Control, and Element 2.8, Measuring and Testing Equipment, are usually at the top of the list.

As auditors we should apply the same attention equally to all elements being audited. If a requirement isn't being met or a procedure isn't being followed, it may present the program an opportunity for improvement. Most auditors tend to look at the same things within the specification and the facility's procedures. Auditors may request other documents referenced either within the initial procedure or within the facility's QA Manual. With the facility's defined procedures to address the specific requirements in MSRP Section J, the auditor can verify the process in the production or work area. Then, a sample of controlled documents currently in use is gathered. The same process is applied to measure and test equipment.

From the samples, the auditor records pertinent information and reviews with the facility representative. One of the most common findings in Document Control is a document in use in the shop or on the production floor that is obsolete (e.g., an earlier revision compared to the master list). Another common finding in Measure and Testing Equipment is information on the status indicator that does not match up with corresponding data in the master list.

Increasing sample size during internal audits can be an asset in finding problems in 2.7 and 2.8 prior to your official AAR audit. Each facility has its own collection of documents and measure and test equipment, so sample size will vary from location to location. Will increasing the sample size during facility internal audits reduce the amount of industry-wide findings year after year? Quite possibly. Would an increased sample size offer more opportunity to determine whether there is an issue? Arguably, yes. This maybe something to consider for your internal audits.

There are many software programs for tracking when certain items are in need of calibration, but a software program can only do so much. Here are a few things to consider:

- Who is filling out status indicators, a person that works in the facility or a subcontractor? Either is acceptable; however, if a subcontractor is recording pertinent information, be sure to check the data entries.
- Routine checks can have added benefit to the program by just looking at status indicators. It offers opportunity to verify that the indicator is still affixed, and is legible. It could offer an opportunity beyond normal required training to interact with the user about the importance of the status indicator, why it is there, and what needs to be done if it is missing or illegible.
- Does the user know specifically what to do if the calibrated item is damaged or lost?
- Does the procedure need revising, do you need to add or remove something from it?

While conducting an internal audit there are many opportunities for the auditor to go out to the floor or production areas and interact with personnel that use the controlled documents. This may help the auditor determine if there are any issues

that need to be addressed, as well as what personnel uses the documents, how they use them, and how they access them. While many programs are eliminating hard copies altogether, auditors still need to verify that the software is operational and revisions are being recorded and maintained. Auditors need to verify that the software in use is current.

Sometimes facility personnel will print off many copies of control documents for the week or month and have a stack near their desk or elsewhere for easy retrieval. This presents an opportunity for obsolete documents to be misused. As auditors, we do find documents in use on the shop or production floor that are obsolete or have been revised recently or in some circumstances, revised years ago. This can be the result of personnel not being aware that the facility has a document control procedure or its intended use. When conducting an internal audit, you could ask personnel what forms or instructions they use/ reference and how do they get them. Determine if all the documents they use are controlled and on their master list. Ask if "reference only" documents in use need to be classified as controlled. Determine if their answers are in line with the procedure, or does the procedure need to be revised.

Document Control and Measure and Testing Equipment generally garner findings in audits across our industry. Being aware of the items mentioned above may help your facility at the next audit.

## CALIBRATION VERSUS VERIFICATION

*Submitted by John Cross – Progress Rail*

Calibration versus verification and how to label measuring and test equipment (MTE) are areas where quality personnel sometimes gets confused. This typically has been occurring around torque wrenches, micrometers and calipers. Each facility had a log to record their checks and had marked the gages with stickers that state "Calibrate Prior to Use"; which is incorrect based on the actual process that was being completed on measurement equipment. Let's review the differences between the two and how measurement equipment should be handled when the equipment is required to be checked before use.

Calibration is defined as the action or process of calibrating an instrument or experimental readings. In the AAR M-1003 Section J manual, this is covered by clause 2.8.1: *The facility shall: establish and maintain documented procedures to control, calibrate, and maintain all measuring and testing equipment and devices used to verify quality and to monitor special processes*. This clause requires a facility to establish a documented calibration procedure for each style of measurement equipment, a process to establish frequency for the calibration process, and records of calibration to establish history of the measurement equipment. For example; an adjustable torque wrench would require calibration at a given interval throughout its adjustable range or a height gage would require calibration throughout its usable range.

Verification is defined as a process of establishing the truth, accuracy or validity of something. This would be the process of checking a torque wrench on a torque tester, a caliper with a gage block, etc…to ensure that it reads within the specified limits to the known value. This requirement is covered under AAR M-1003 Section J manual clause 2.8.2: *The facility shall: at prescribed intervals or prior to use, measuring and testing equipment shall be verified, calibrated, or adjusted utilizing certified equipment having a known valid relationship to nationally recognized standards*. The verification of the equipment at specified intervals ensures the measurement equipment is performing as it should be and limits the suspect product range, should an error be detected during the verification process. In the event of the calibration or verification activities resulting in a non-conforming reading all the product created and checked with the measurement equipment since the last known "good" check must be quarantined and the process for handling non-conforming material must take place to establish containment, rework, etc…. In addition, when a non-conforming value is found the calibration and verification frequencies should be reduced in time between checks until such a point where the confidence of the measurement equipment is established again.

To conclude, while the act of calibration and verification of measurement equipment on the surface might appear to be the same, the overall detail and requirements are different. When putting together an audit plan or a calibration program it is important to ensure both calibration and verification activities are occurring, and the results validate the frequencies established. A properly scheduled calibration and verification program helps reduce and/or eliminate errors based on the equipment being out of tolerance.

## GETTING INTIMATE WITH YOUR PROCEDURE

*Submitted by Aaron Jakub – AAR MID Auditor*

A procedure instructs how to properly execute a task. When a specific procedure is followed correctly, the result can be successfully and repeatedly duplicated. When certain situations occur, like a non-conformance or an incoming inspection, a procedure provides steps to follow to accomplish a repeatable, desired outcome or result. As auditors, a procedure is required in order to determine if the outcome has been accomplished by following the implemented steps. It is important for auditors to understand not only what you are doing, but more importantly, how you are doing things so we can verify that the instilled procedures are being followed.

When preparing for an audit, auditors look at the facility's Quality Assurance Manual first to see if it meets the requirements per the specification in MSRP Section J. The procedures in the QA Manual are what tells the auditor how your facility accomplishes a task. Each facility has its own way of doing certain things within a procedure to accomplish the desired outcome.

Auditors read procedures and focus on content. If the procedure says something will be done, then it needs to be done. If what is stated isn't being done, there is potential for a non-compliance. Conversely, if something is being done that isn't directed by a procedure, that also presents potential non-conformance. This is where getting intimate can really help a program.

When reviewing procedures or preparing for an audit, whether internal or external, get intimate with your procedures. Really dig into them — all of them — and analyze each one. As auditors, we have findings that directly relate to tasks performed that do not follow a published procedure. Sometimes we have findings where we determine that steps in a procedure are not being followed. Something to consider would be to go out to shop or production areas more frequently and talk with those directly involved, to observe what they know and how they perform work tasks. Generally, auditors read the procedure for the element they are auditing and familiarize themselves with what they should expect to see in the facility. To this end, auditors will have conversations with the key personnel involved.

Auditors will seek to learn if personnel are familiar with the procedure, if they've read it and understand it. Are they following the procedure, or is anything being done that isn't in the procedure? It is understood that situations change from time to time, and the internal audit could be an excellent opportunity to ensure instructed changes are reflected within the procedure. The internal audit can also verify that steps not in the written procedure have not been introduced.

Procedures should outline how to accomplish a task with little, if any deviation. If deviation is necessary, determine if the procedure allows for it. Getting intimate or having very close association with a procedure will let you look at the intricate and minute details within. This level of introspection helps personnel understand procedural importance, and will help determine if steps within the procedure are unnecessary or or are missing elements. It is important to determine if all steps in a process are necessary, comprehensive, and complete

Getting intimate with a procedure can be an effective evaluation tool and can go a long way in producing a quality product in an efficient, repeatable way.

## How does APQP work together with M-1003 to support customer satisfaction?

*Submitted by John Cross and Gary Studt – Progress Rail*

The AAR M-1003 quality standard is the *minimum requirement for companies offering the regulated activities for use in the North American rail industry. Advanced Product Quality Planning (APQP) in its simplest form is a structured approach to product and process design. This process uses a cross functional team to collaborate and develop both the product and process to manufacture the product to meet the needs of the customer. This process will ensure that the voice of the customer is integrated with the design and manufacture of the products to be delivered. APQP concentrates on early prevention throughout the processes to ensure all the risks are identified and corrected in a manner that protects the customer. APQP consists of several elements including: Design FMEA, Design Verification Plan and Report, Prototype Control Plan, Manufacturing Process Flow Chart, Process FMEA, Pre-Launch Control Plan, Operation Process Instructions, and Production Control Plan.

**AAR M-1003 section 2.1.1 states "At a minimum, the facility's Quality Assurance Program must include the 24 required elements specified in this chapter."*

**DFMEA (Design Failure Mode and Effects Analysis)** is a structured approach that ensures potential product failure modes and their associated causes have been considered and addressed during product design. This process allows for early identification of the ways the design can fail, how often it could fail, and the severity of the failure. Numerical values are given for each of these 3 factors and then multiplied to produce a Risk Priority Number (RPN). This DFMEA RPN process allows the team to sort the failure modes, identify those that have the highest risk to the customer and take action to address them early in the design concept phase. This will allow the design to be completed in such a way that is most efficient at reducing cost and risk to the customer, while initiating a consistent and effective process flow to production, and by designing a more reliable product for the end users.

**Design Verification Plan & Report (DVP&R)** is used to effectively organize, describe, document, and report the results of a design analysis and product testing. DVP&R is a simple tool that documents the plan that will be used to confirm that the product, system or component meets its design specification and performance requirements. Where the DFMEA records what is to be tested the DVP&R records the process of how to test the failure modes. The DVP&R also records the criteria for the test and captures the results to allow them to be easily reported. The DVP&R is used to easily present a clear picture to the stakeholders that can be easily understood. DVP&R is also beneficial during a quality investigation throughout the life cycle of the product.

**Prototype control plans** are applicable during the early phases of design and development. This control plan is list of all descriptions of dimensional measurements, material types, and performance tests happening during the development of the prototype. The use of the prototype control plan stops at the end of the prototype phase. After the prototype phase the pre-launch control plan will be used.

**Manufacturing process flow chart** is a detailed sequential list of all the process steps that a product or process must go thru in order to completely meet all the intended requirements. The manufacturing process flow chart is to help better understand the process visually. This allows the stakeholders to study the process more easily and effectively. The flow allows for improved communication among all those that come into contact with the process from the planning phases thru the final production phase.

## Have a Question?

Submit your M-1003 request for clarification or interpretation by emailing QA@aar.com.

## Have an Idea for an Article?

Please submit your drafts to Bob Wolbert at bwolbert@progressrail.com or Annette Miller at armiller@progressrail.com.

**PFMEA (Process Failure Mode and Effects Analysis)** is a systemic approach to identify all the possible causes of a failure for every input within a process. The PFMEA allows you to understand your process in detail. It will highlight the risks and develops the counter measures necessary to control the risks. The PFMEA is utilized as a living document that is updated with changes or additions as the process evolves through continuous improvement. The PFMEA is something that can also be cross-referenced to other like products that may go thru a similar process. The PFMEA process should be conducted when you modify an existing process, introduce new technology to a process or relocate a process.

**Pre-launch control plan** builds off the prototype control plan. The pre-launch control plan has more detailed features with more process steps, and more testing that may be required prior to production startup. The pre-launch control play is from the process of material receipt to delivery with increased samples or increased frequency of inspection to ensure that the process is in control. The use of the pre-launch control is for a period of time or quantity of parts that are specified by the customer, or until the production control plan has been fully validated.

**Operation process instructions** are the documented instructions that the production employees follow to assure they comply with the control plan, engineering requirements, and customer requirements. The operation process instructions are written to match each of the process steps listed in the process flow chart. These instructions have the most detail. They are additional instructions to the design engineering requirements. They add all the small details to be followed for the production process to produce products meeting the requirements. The operation process instructions may also include instructions that control how to maintain the process and or machinery.

**Production control plan** contains a comprehensive listing of the product and process specific characteristics, process controls, measurement methods and tests that are to be performed during regular production runs. The production control plan is put into the process after the pre-launch requirements have all been met, and the production process has been proven to be stable and in control. The production control plan typically require a reduced inspection sample size or frequency from that of the pre-launch control plan.

The APQP tools have a structured approach to control every design input, customer input, and process input. These additional controls and details within the process improves the robustness of the quality management system while serving to drive down customer dissatisfaction by reducing the risk of making and shipping products that will not meet their needs.

## VIEWS AND INTERPRETATIONS

*(Interpretations in this section are official and subject to audit for compliance. Items below will generally be included in the revisions to the M1003 specification or Appendix C containing other interpretations not readily consistent with incorporation into the M1003 specification. )*

From time to time questions arise about the M-1003 specification and certain sections regarding applicability and intent. Let us look at Section 2.5 Production, Inspection, and Test Plan and specifically an excerpt from 2.5.2.

The excerpt's highlighted text below is one such example resulting in questions regarding intent. By specifying "…all criteria from incoming inspection (element 2.10) through packaging and shipping (element 2.16) are addressed." is sometimes interpreted as excluding the other Critical to Quality (CTQ) elements such as 2.9 Purchasing / Subcontracting; 2.23 Contract Review and 2.24 Design Control.

**Each facility,** must demonstrate compliance to all 24 elements of the M-1003 Specification. This requirement is clearly stated in the excerpt below from 2.1.

> **2.1 Objective of Quality Assurance Program**
>
> **2.1.1** The Quality Assurance Program must be established and maintained by the facility for the purpose of ensuring that the activities conform with all applicable standards, specifications, rules, codes, statutes, regulations, contractual requirements, and adopted recommended practices. At a minimum, the facility's Quality Assurance Program must include the 24 required elements specified in this chapter.

Additional clarification is provided in appendix C for element 2.5 regarding tank car facilities below.

> **5.0 PRODUCTION INSPECTION AND TEST PLAN (REFERENCE PARAGRAPH 2.5 IN THE SPECIFICATION)**
>
> For tank car facilities, the Production Inspection and Test Plan is not to be limited to the 'tank,' but needs to address those specific work procedures/component parts encompassed in the scope of the program.

## CALENDAR OF EVENTS AND IMPORTANT LINKS

The Association of American Railroads (AAR) Quality Assurance Committee (QAC) has cancelled all face to face AAR M-1003 Quality Assurance Training classes. The QAC has rescheduled the Basic Auditor and Root Cause Analysis Training classes in a Webinar-based training format. The M-1003 Advanced Auditor Training classes will be offered in 2021.

Cancelled Classes:

| 2020 AAR M-1003 Quality Assurance Training Schedule | | | |
|---|---|---|---|
| **Course** | **Date** | **Location** | Update |
| Basic Auditor Training Class | September 22-24 | Nashville, TN | Cancelled |
| | September 22-24 | Guadalajara, MX | Cancelled |
| | November 10-12 | New Orleans, LA | Cancelled |
| Advanced Audtior Training Class | Sept. 29-Oct. 1 | Jacksonville, FL | Cancelled |
| | October 13-15 | Colton, CA | Cancelled |
| | November 17-19 | Greenville, SC | Cancelled |
| Root Cause & Corrective Action Class | October 20-21 | Orlando, FL | Cancelled |
| AAR Quality Auditor and Industry Conference | January 26-28, 2021 | Fort Worth, TX | TBD |

New Webinar-based Classes:

| Revised 2020 AAR M-1003 Quality Assurance Training Schedule | | |
|---|---|---|
| **Course** | **Date** | **Location** |
| Basic Auditor Training Class | September 22-23 | Online Webinar |
| | November 3-4 | Online Webinar |
| Root Cause & Corrective Action Class | August 18-19 | Online Webinar |
| | October 20-21 | Online Webinar |

Interested parties are encouraged to enroll promptly as classes have limits and tend to fill quickly and acceptance is based on a first-come first-serve basis. Root Cause Analysis training class materials have also been revised and improved.

Registation links can be found on our website at: https://aar.com/standards/QA_training.html

## Important Links

**Registry of M-1003 Certified Companies**

**M-1003 Frequently Asked Questions**

**AAR M-1003 Certification on-line Application**

**AAR M1003, Section J Specification for Quality Assurance**

**AAR Training Schedule**

**AAR Circulars**

**MSRP Publication Current Revision Status**

**AAR Online Material Nonconformance Reporting System (Chapter 7)**

**Railway Supply Institute**

**RSI QAC & Previous Newsletters**

**RSI Tank Car Resource Center**

**The AAR QA Newsletter is provided through the efforts of AAR Quality Assurance Committee members in an effort to provide information that is important to our industry in support of improving the quality of products and services provided. You can support this process by submitting your questions and ideas for improvement to QA@aar.com.**

### The following are the AAR QAC team members:

**Don Guillen**
Manager, Quality Assurance Committee
Transportation Technology Center, Inc.

**Mark Rusovick**
Engineer, Quality Assurance
Transportation Technology Center, Inc.

**BNSF Railway (Chair)** - Michael Anderson, Compliance Manager

**Amtrak (Vice-Chair)** - Tony Parolsi, Director, Quality Management

**Canadian Pacific Railroad** - Gordana Halvadzija, Manager, Quality Assurance

**Central Maine & Quebec Railway** - Chad Mowery, Vice President of Operations

**CSX Transportation** - Randall Norman, Manager, Mechanical Car Engineering

**Greenbrier** - Adrian Morgan, Director Quality Engineering & Warranty Admin.

**New Orleans and Gulf Coast Railroad** - Tracy Ulm, Chief Mechanical Officer

**Norfolk Southern Corporation** - Brad Brenneman, Quality Assurance Supervisor

**Pan Am Railways** - Wakine Lucas, Director of Quality Assurance & Mechanical Training

**Progress Rail Services** - Bob Wolbert, Vice President of Quality

**Standard Steel, LLC** - Mark Lumadue, Director of Quality Assurance

**TTX Company** – Kevin Gentry, Assistant Manager, Quality Assurance

**Union Pacific Railroad** - Sanjay Varma, Director-Supplier Quality

**Union Tank Car Company** - Jason Riggs, VP, Quality & Regulatory Compliance

**Watco Companies, LCC** - Alan Keneipp, Vice President Mechanical Training & Comp