

Mandatory Element: 2.5 Production, Inspection, & Test Planning

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- What is the requirement per MSRP Section-J?
 - What does it mean?
- How do you audit this element?
 - What to ask for?
 - What to look for?
 - How does this relate to other elements in the audit?
- What is not required for this Element



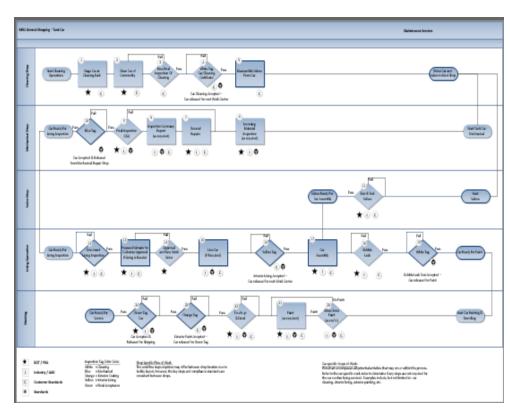
Requirements per MSRP Section-J

- 2.5.1 The facility shall:
 - 2.5.1.1 Plan the requirements for production.
 - 2.5.1.2 Plan the requirements for inspection and testing.
 - 2.5.1.3 Develop an inspection and test plan in accordance with paragraph 2.5.2.
 - 2.5.1.4 Update the plan to reflect inspection and test revision.
- 2.5.2 The inspection and test plan may be of any format to suit the facility's QAP. This includes flow charts, as long as all criteria from incoming inspection (element 2.10) through packaging and shipping (element 2.16) are addressed. It shall, however, do at least the following:
 - 2.5.2.1 Indicate each inspection and test point and its relative location in the processing cycle, including incoming inspection, preservation of items, packaging, and site inspection and testing.
 - 2.5.2.2 Identify or make reference to the characteristics to be inspected, examined, and tested at each point and specify acceptance criteria to be used. The production, inspection and test plan is not required to list every potential document used.
 - 2.5.2.3 Identify inspection and test points where measurement and test records are maintained so that assessments required by paragraph 2.8.6 can be met.
 - 2.5.2.4 Indicate mandatory hold points that require witnessing or verification of selected characteristics and that beyond which the work shall not proceed.
 - 2.5.2.5 Define or refer to sampling plans and statistical process control, including the criteria for selection, if proposed, and indicate where they will be used.
 - 2.5.2.6 Define or refer to how verification of compliance to process procedures will be accomplished and documented.
 - 2.5.2.7 When required, specify where lots or batches will be used.
 - 2.5.2.8 Indicate where subcontractor services will be employed.



In a nutshell, what is Production, Inspection, and Test Planning?

- A Production Plan is a document that outlines the manufacturing procedures of a product. It includes the methods, production flow, and materials.
- An Inspection and test Plan is a document that outlines the inspection and testing procedures used to ensure the quality of the product. This plan also includes hold points to ensure the quality of the product is progressing as it should.
- These plans could be assembled into <u>one document or</u> <u>multiple smaller documents</u> depending on the size and variables within the production cycle and the size and capability of the facility.



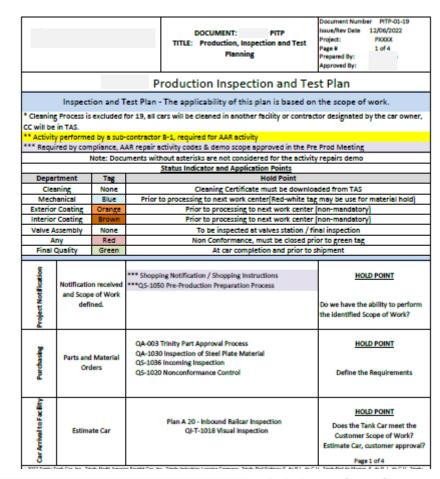


Pre-Audit

- This one element will encompass activities from Incoming Inspection through Shipping (Elements 2.10 – 2.16)
 - You can audit those elements before or after this element; either way, you choose, they
 complement each other, and you will have all the necessary data to close the loop on the
 facility's PIT Plan.
 - Mandatory Element or not, I find the best method to audit is to request the PIT Plan before the audit.
 - Either way, you can arrange and map out your audit before arriving and request procedures, acceptance criteria, calibration records, etc, to be printed out and ready at the opening meeting.
 - Even better if you have never visited a facility before.
 - This will give you a high-level overview of the activities and layout of the facility before going to the GEMBA and digging deeper.



- 2.5.1. The facility shall:
 - Plan the production, inspection, and testing requirements, including 2.5.2 criteria, and keep it current.
 - Does the facility have documentation regarding their PIT Plan, and are they keeping it current?
 - Remember, this is a hierarchy document laying out the process, material flow, and inspection plan. It will differ from company to company and possibly between facilities of like companies depending on the product/service provided.
 - This can vary by facility for a product in a manufacturing cycle, a service in a repair shop, or even a service provided by a distribution center.

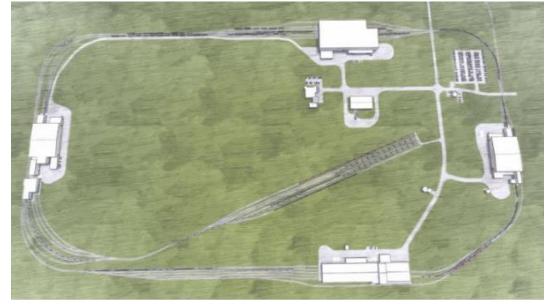




Auditing

 2.5.2.1, 2.5.2.3, 2.5.2.4 Indicate where measurement and test records are maintained, and each inspection and test point, mandatory hold points, and their relative location in the processing cycle, including incoming inspection, preservation of items, packaging, and site inspection and testing.

- This is to create a safety net to prevent defective products from going past this point. This also works to track a defect back to its origin.
- The same is true for measurement and test equipment. If a torque wrench fails calibration, you know where it was located and can trace back to which activity it was for and which cars.
- Does the Plan identify Inspection and Hold Points?
 - Do these Hold Points make sense to their relative location in the process cycle?



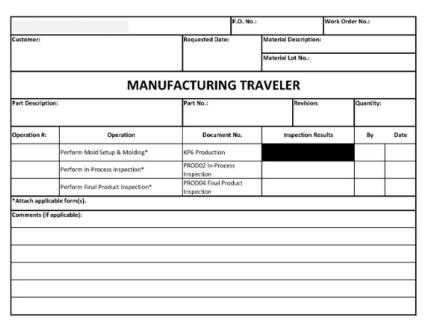
- 2.5.2.2 Identify or make reference to the characteristics to be inspected, examined, and tested at each point and specify acceptance criteria to be used.
 - For example, which NDT Method is to be used here?
 - What are the criteria for using Ultrasonics Testing (UT) on this welded plate?
 - Who can perform this method?
 - What are the acceptance criteria to pass this UT Inspection?



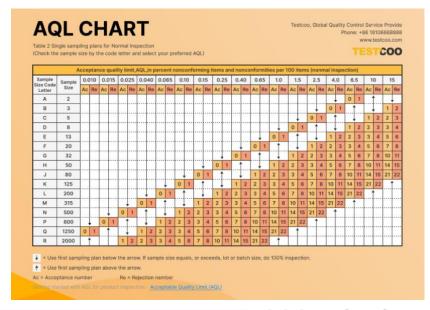
- 2.5.2.5 Define or refer to sampling plans and statistical process control, including the criteria for selection, if proposed, and indicate where they will be used.
 - Identify where in the process SPC is being used.
 - Which methods are being used, and what are the acceptance criteria for each method?
 - Defects per Unit Production
 - Scrap Rates Scrap/Waste
 - Gage R&R Calibration
 - Executive Dashboard



- 2.5.2.6 Define or refer to how verification of compliance to process procedures will be accomplished and documented.
 - Sign-off sheets/Travelers
 - Inspection Reports



- 2.5.2.7 When required, specify where lots or batches will be used.
 - Inspection is based on sample size
 - Is the sample size adequate, and is it used consistently throughout the facility



- 2.5.2.8 Indicate where subcontractor services will be employed.
 - Where and for what process
 - NDT, Internal Quality Audits
 - Heat Treatment Services



Almost Finished

- After your review, go to the Shop Floor and compare what you just went through.
 - Is the process flow the same?
 - Are the Hold Points correct?
 - Remember Element 2.5.1.4 Update the plan to reflect inspection and test revision.
 - Is the PIT Plan up to date with current processes and layout?



What is not required for this Element

– Per the 2nd sentence in 2.5.2.2, The production, inspection, and test plan is not required to list every potential document used.

- A complete listing of all documents and activities
- A thorough review of each process per Elements covered throughout this scope
 - This is covered within Elements 2.10 2.16



