



U.S. Department
of Transportation
Federal Railroad
Administration



DESIGN CONTROL PART 2



THOUGHTS

*“The woods are lovely, dark and deep,
but I have promises to keep, and miles
to go before I sleep . . . miles to go
before I sleep”*



Design level of reliability and safety means the level of reliability and safety built into the tank car and, therefore, inherent in its specification, design, and manufacture.

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TOPICS

- Objectives
- What is Design Control
- Design Control & M-1003
- Design Control & 49 CFR 179 / 180
- What Is Design Control
- Where Does Design Control Begin
- Case Studies



OBJECTIVE - WHAT THIS PRESENTATION IS !

“To teach design control principles for design level of reliability and safety, tank car qualification and maintenance programs, and managing fleet risk.”



OBJECTIVE - WHAT THIS PRESENTATION IS NOT !

“A discussion of financial matters”





WHAT IS DESIGN CONTROL?

- HM-216B (July 25, 2012);
- Transition from **TCF**-developed qualification and maintenance programs (QMP) to owner-developed / authorized programs;
- Transition from regulatory maximum qualification intervals to data-driven intervals;
- **Owner** QMPs incorporated into **TCF** QAPs.

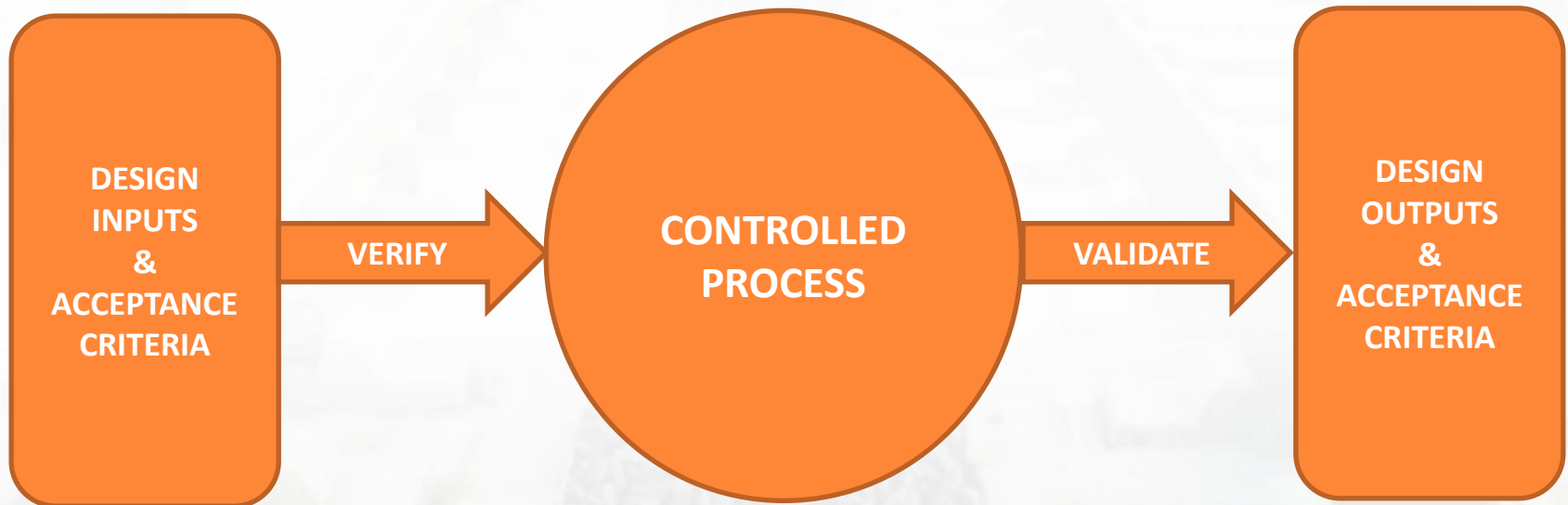


WHAT IS DESIGN CONTROL?

- Paper Must Match Paper;
- Paper Must Match Car;
- Car Must Match Paper.

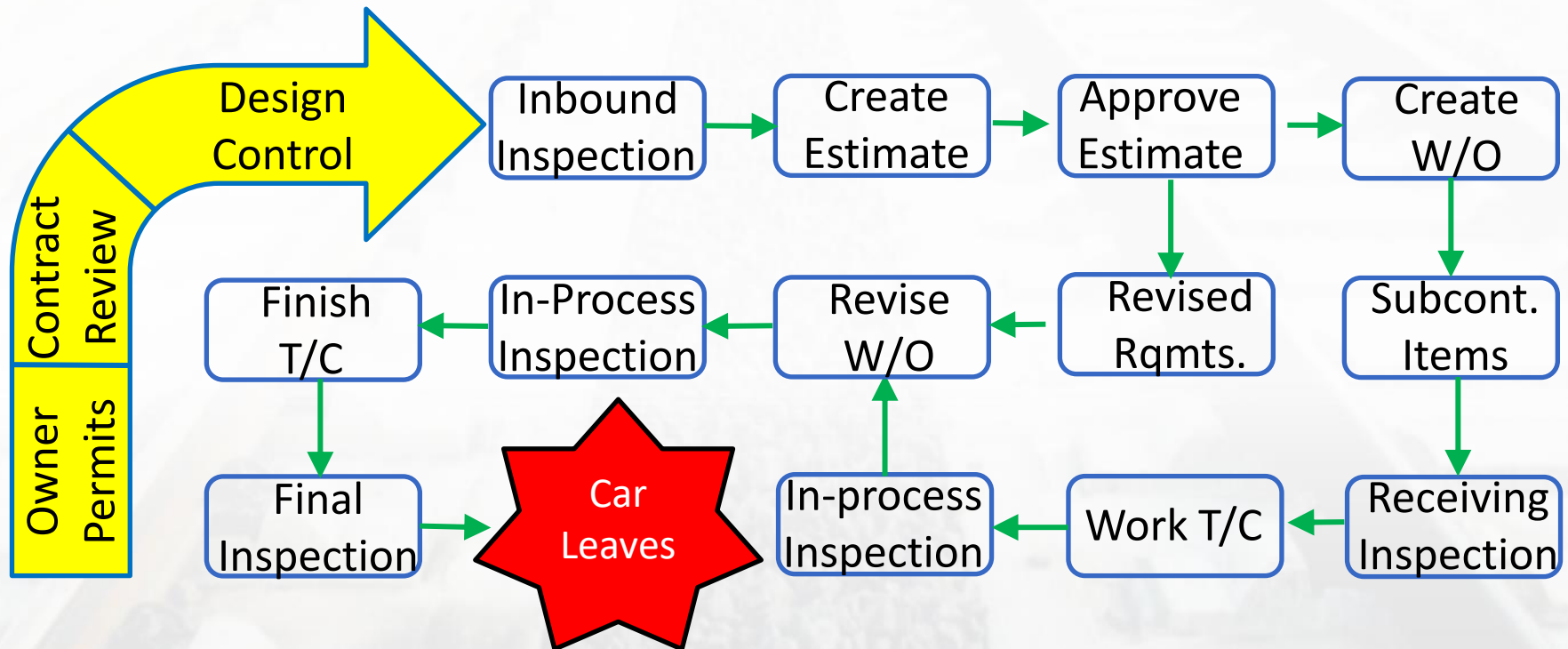


WHAT IS DESIGN CONTROL?





WHAT IS DESIGN CONTROL?





WHAT IS DESIGN CONTROL?

Design Inputs

- The first step toward the direction of creating and implementing the product in question.
- The main points of the design input process are to make sure that customer requirements are being met by the product as well as Federal regulations and AAR specifications. This step should be documented and recorded, ensuring that this information is correct and that the facility has applied the necessary controls to its design process to ensure that:
 - The results from the design process are clearly defined;
 - The design reviews take place in accordance with planned arrangements;
 - The design outputs meet the design inputs (verification);
 - The resulting products and services are fit for their intended use or specified application where this is known to the facility (validation).



WHAT IS DESIGN CONTROL?

Design Outputs

- Following the design input, the facility will create an actual definition of the product's design (output).
- Ideas for product design output documentation are: product drawings, written manufacturing / modification instructions, repair estimates, work orders, etc.

M-1003:2022 - Verification - Confirmation that an *activity*, condition, or control conforms to requirements specified in documents such as contracts, codes, standards, specifications, drawings, system function descriptions, and procedures.

ASQ - Verification: The act of confirming whether products and services conform to specific requirements.

M-1003:2022 - Validation – None

ASQ - Validation - The act of confirming whether a product or service meets the requirements for which it was intended.



WHAT IS DESIGN CONTROL?

- 2.1 Objective of QAP
- 2.2 Applicability and Scope
- 2.3 QAP and Manual Requirements
- 2.4 Management Responsibility
- 2.5 Production/Inspection/Test Planning
- 2.6 Corrective/Preventive Action
- 2.7 Document Control
- 2.8 Measuring/Test Equipment
- 2.9 Purchasing/Subcontracting
- 2.10 Incoming Inspection
- 2.11 In-Process Inspection
- 2.12 Final Inspection
- 2.13 Inspection Status
- 2.14 Identification/Traceability
- 2.15 Process Control
- 2.16 Preservation/Packaging/Shipping
- 2.17 Quality Records
- 2.18 Nonconformance Control
- 2.19 QAP Review/Manual Revision
- 2.20 Process Capability/Statistics
- 2.21 Internal QAP Audits
- 2.22 Training
- 2.23 Contract Review



WHAT IS DESIGN CONTROL?

2.24 Design Control

2.24.1 The *facility* shall establish and maintain documented procedures to control and verify the design and development planning of the product to ensure that the specified requirements are met. *Where product design, redesign, or modifications are not usually performed, the design procedures must address how adherence to existing design criteria is maintained. The facility must define the procedure when a design change is required.*

2.24.2 The *facility* shall prepare plans for each design and development activity. The plans shall include the review, verification, and **validation** requirements that are appropriate to each design and development activity.

The plans shall describe or reference these activities and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated as the design evolves.



WHAT IS DESIGN CONTROL?

2.24.3 The *facility* shall define organizational and technical interfaces between different groups who contribute to the design process and shall document, transmit, and regularly review the necessary information. The *facility* shall manage the interfaces between the different groups to ensure effective communication and clear assignment of responsibility.

2.24.4 The *facility* shall identify and document design and development input requirements relating to the product, including applicable statutory and regulatory requirements, functional and performance requirements, and, where applicable, information derived from previous similar designs and other requirements essential for design and development. The *facility* also shall review their selection for adequacy.

Incomplete, ambiguous, or conflicting requirements shall be resolved with those responsible for imposing these requirements. Design input shall take into consideration the results of any contract review activities. Planning output shall be updated, as appropriate, as the design and development activity progresses.



WHAT IS DESIGN CONTROL?

2.24.5 The *facility* shall document the design and development output and express it in terms that can be verified against design and development input requirements and **validated** (see paragraph 2.24.9). Design and development output shall do the following:

2.24.5.1 Meet the design and development input requirements.

2.24.5.2 Contain, or refer to, acceptance criteria.

2.24.5.3 **Identify those *characteristics* of the design that are crucial to the safe and proper functioning of the product (e.g., operating, storage, handling, maintenance, and disposal requirements).**

2.24.5.4 **Provide appropriate information for purchasing, production, and servicing provision.**

2.24.6 **The *facility* shall review design and development output documents before their release.**



WHAT IS DESIGN CONTROL?

2.24.7 At appropriate stages of design process, formal reviews of the design and development results shall be planned and conducted to evaluate the ability of the results to meet design and development input requirements. The review shall identify any problems and shall propose appropriate resolution actions. Participants at each design review shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of such reviews shall be maintained and necessary actions shall be documented.

2.24.8 At appropriate stages of the design process, verification shall be performed to ensure that the design and development output meets the design and development input requirements. The design and development verification measures and any necessary actions shall be recorded and any actions taken shall be documented.



WHAT IS DESIGN CONTROL?

2.24.9 The *facility* shall perform design and development **validation** to ensure that product conforms to defined user needs and / or requirements and to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. In this regard, the *facility* shall:

2.24.9.1 Complete validation prior to the delivery or implementation of the product, wherever practicable.

2.24.9.2 Maintain records of the results of validation and any necessary actions.

2.24.10 All design and development changes and modifications shall be identified, documented, reviewed, verified, and validated as appropriate and then approved by authorized personnel.

2.24.10.1 The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

2.24.10.2 The *facility* shall maintain records of the review of changes and any necessary actions.



WHAT IS DESIGN CONTROL?

179.7(b) – The **TCF QAP** must have:

- (1) Statement of authority and responsibility for those persons in charge of QAP;
- (2) Organization chart showing relationship between managers, engineers, purchasing, production, inspection, testing, QC personnel;
- (3) Procedures ensuring latest applicable drawings, design calculations, specifications, instructions are used in manufacture, inspection, testing, repair;
- (4) Procedures ensuring production items are properly identified / documented;
- (5) Description of manufacturing, inspection, test, repair, QMP, acceptance criteria, to identify the characteristics / elements to inspect / examine / test at each point;
- (6) Procedures to monitor / control process / product characteristics;
- (7) Nonconformance correction procedures;
- (8) Provisions indicating M-1002 apply;
- (9) NDT personnel qualification requirements;



WHAT IS DESIGN CONTROL?

- (10) Procedures for evaluating inspection / test techniques used, including the accessibility / reliability / sensitivity of the inspection / test technique and minimum detectable crack length;
- (11) Procedures for periodic calibration / measurement of inspection / test equipment;
- (12) A system for the maintenance of quality records and the interpretation of results;
- (d) A system to ensure only qualified NDT personnel perform the NDT method;
- (e) Employee training on the QAP / QMP.



WHAT IS DESIGN CONTROL?

180.5XX – The **TCF** must have:

- (1) **Owner** / 3rd party QMP;
- (2) **Owner** OK before starting work;
- (3) The means to detect any non-conformity;
- (4) The means to perform and evaluate work per the **Owner** QMP;
- (4) The means to provide the **Owner** QMP documents / data to workers;
- (5) The means to train workers on the **Owner** QMP documents / data;
- (6) The means to report all work performed to the **Owner**;
- (7) The means to report all observed damage, deterioration, failed components / non-compliant parts to the **Owner**;
- (8) The means to report all inspection / test results to the **Owner**;
- (9) The means to leak test service equipment / closures installed, re-installed or replaced except closures removed for loading / unloading;
- (10) The means to reliably detect structural defects of the type / size required by the **Owner** QMP.



WHAT IS DESIGN CONTROL?

180.5XX – The **Owner** must:

- (1) Develop or contract 3rd party QMP;
- (2) Give **TCF** permission to use QMP;
- (3) Ensure **TCF** inspects, tests, evaluates each item per QMP;
- (4) Collect and analyze inspection / test results, define failure;
- (5) Set reliability goals based on (4);
- (6) Set interval-based reliability goals, commodities and risk;
- (7) Qualify acquired AIP cars;
- (8) Collect / analyze nonconformance reports to improve QMP, validate intervals, improve safety;
- (9) Ensure **TCF** marks each car per 180.515 and M-1002 Appendix C;
- (10) Ensure **TCF** prepares documents per 180.515, sends to the **Owner**;
- (11) Make documents available to FRA upon request.



WHERE DOES DESIGN CONTROL BEGIN?



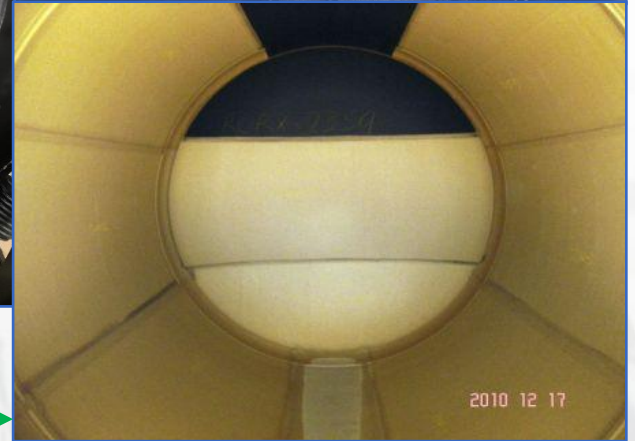


WHERE DOES DESIGN CONTROL BEGIN?





WHERE DOES DESIGN CONTROL BEGIN?





WHERE DOES DESIGN CONTROL BEGIN?

- The **Tank Car Owner MAY OR MAY NOT** be the Service Equipment and / or Interior Coating / Lining **Owner**;
- **TCF** Must Obtain Tank Car, Service Equipment and / or Interior Coating / Lining **Owner** Permission **BEFORE** Performing Work Affecting Alteration, Conversion, Repair, or Qualification and Maintenance of the **Owner's** equipment;
- **TCF** Must Use Written Instructions (Procedures) Furnished by the **Owner** or **Owner's WRITTEN CONFIRMATION** to Use 3rd Party Procedures;
- **2.9.2.3** The title, number, and issue of the quality standard to be used;
- **2.9.3** The **TCF** shall review and approve purchasing documents for adequacy of the specified requirements prior to release.



WHERE DOES DESIGN CONTROL BEGIN?



APPENDIX E13.0 BOTTOM OUTLET VALVE AND NOZZLE ARRANGEMENTS.

13.1 A nozzle, or a nozzle with an auxiliary valve, must have a breakage groove or *breakage groove equivalent (bge)* that meets 49 CFR 179.200-17(a)(7).

13.2 The relative strength of the primary valve connection to the tank and the nozzle breakage groove or bge must comply with the following:

13.2.1 The strength of the breakage groove, or bge, must not exceed 60% of the primary valve-to-universal flange or valve to universal flange bolting material or tensile strength, and the minimum primary valve-to-nozzle connection bolting material yield strength.



WHERE DOES DESIGN CONTROL BEGIN?



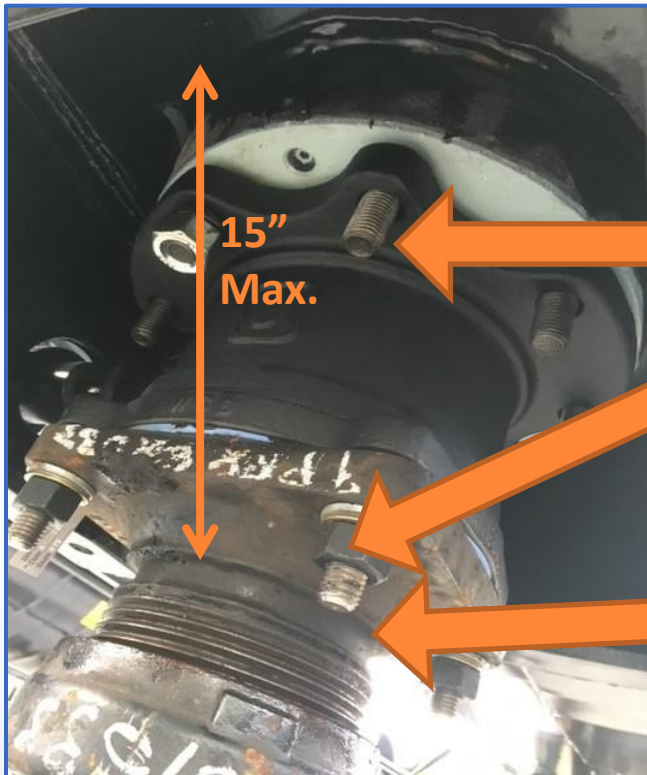
13.2.1 The strength of the breakage groove, or bge, must not exceed 60% of the primary valve-to-universal flange or valve to universal flange bolting material or tensile strength, and the minimum primary valve-to-nozzle connection bolting material yield strength.

If the maximum nozzle bolting material tensile strength is used, the nozzle connection strength may be equal to the minimum calculated valve-to-universal flange bolting material yield strength.



WHERE DOES DESIGN CONTROL BEGIN?

49 CFR 179.200-17(a)(7) On cars without continuous center sills, the breakage groove or its equivalent must be no more than 15 inches below the tank shell.



15"
Max.

Primary valve to universal flange bolting material.

Nozzle bolting material - bge

Nozzle material breakage groove equivalent (bge).



WHERE DOES DESIGN CONTROL BEGIN?

- Ensure **Owner** is Identified and Authorizes **TCF** to Perform the Work;
- Ensure **Owner** QMP is Identified, Distributed, Understood, and Controlled;
- Ensure **TCF** / Suppliers / Subcontractors can meet Customer and TCF Contract Requirements and Revisions Thereto, including Servicing Requirements;
- Ensure **TCF** Contract Documents / Purchase Orders include Applicable FRA / AAR / Customer Requirements;
- Ensure **TCF** / Suppliers / Subcontractors Document Contract Reviews and Revisions Thereto;
- Ensure **TCF** / Suppliers / Subcontractors Have Processes for Reviewing / Implementing Contract Revisions Including Effective Dates.



WHERE DOES DESIGN CONTROL BEGIN?

- Purchase Orders / Spec. Sheets / Data Sheets for New Tank Cars;
- New / Revised Certificates of Construction;
- **Owner** Authorization To Use Qualification and Maintenance Program / Perform Work;
- Purchase Orders for Tank Car Components;
- Purchase Orders for Service Equipment;
- Purchase Orders for Subcontractor Services.



CASE STUDY - #1 - DTA

AAR Form 4-2 Certificate of Construction Chicago Tank Car Company

Order Date: November 4, 2010

Tank / Head Material: AAR TC-128

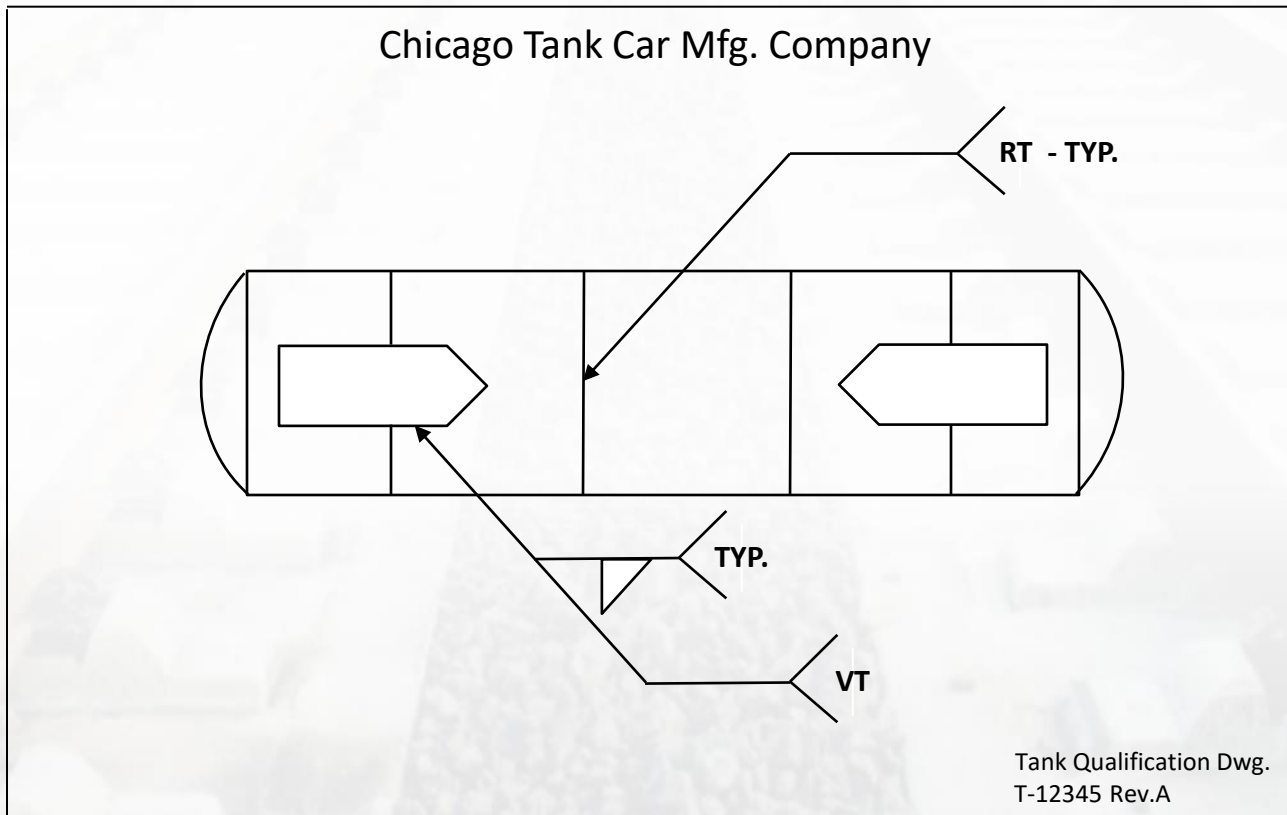
Qualification Drawing T-12345

Const. Spec. DOT105A500W
Sten. Spec. DOT105J500W

I.M. Needy
V.P. Sales & Marketing
Authorized Representative

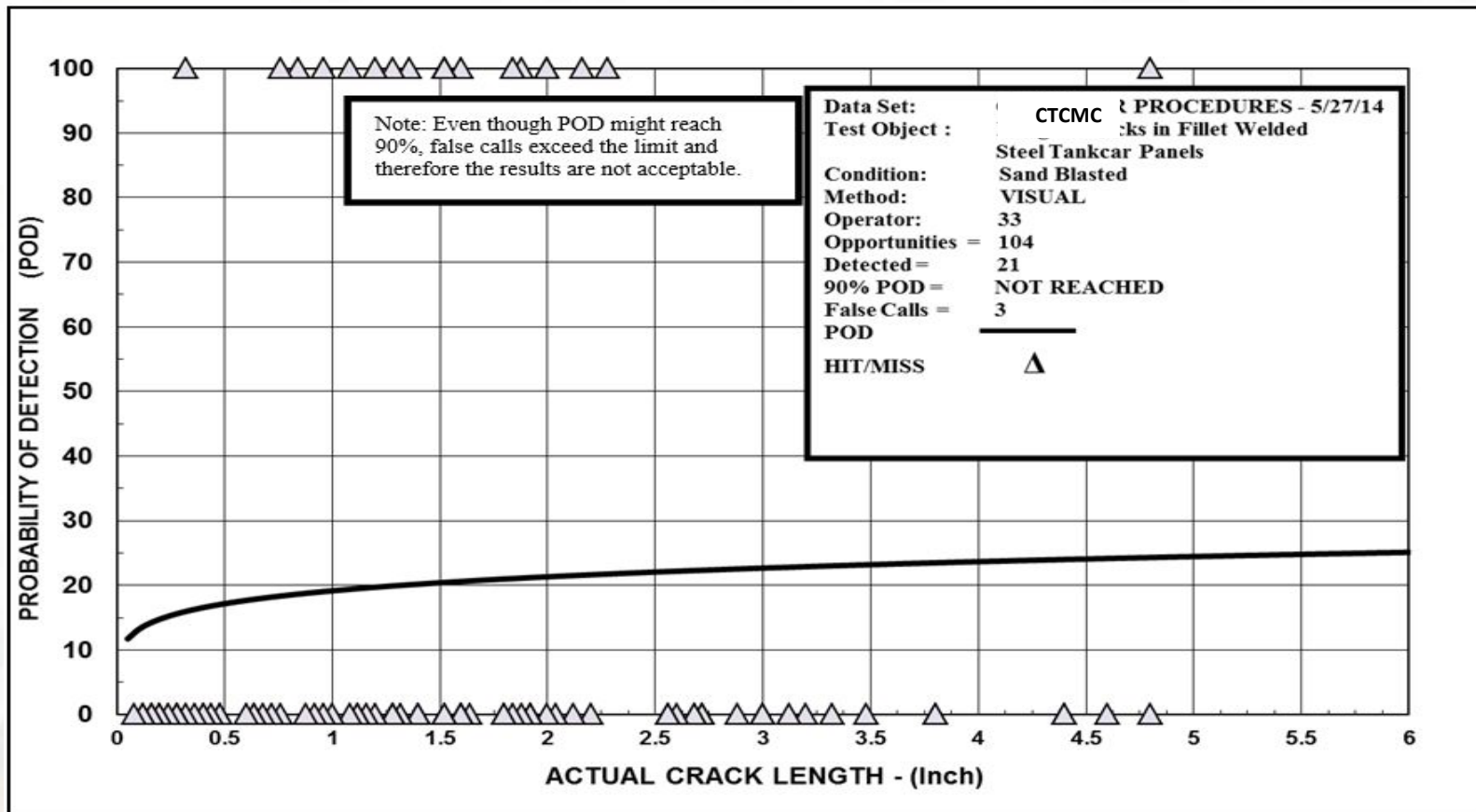


CASE STUDY - #1 - DTA





CASE STUDY - #1 - DTA





CASE STUDY - #2 - NOZZLE

Chicago Tank Car Leasing Company Purchase Order

P.O. No.1 01-28-2020

To: Ajax Tank Car Service Equipment Company

1 – 1pc. HP Manway Nozzle per drawing A-12345.

2 – Complete all forms and send to CTCLC.

I.M. Needy
V.P. Sales & Marketing
Authorized Representative





CASE STUDY - #2 - NOZZLE

Chicago Tank Car Leasing Company Purchase Order

P.O. No.2 01-28-2020

To: Alpha NDT Labs

1 – NDT Testing Services by Personnel Qualified to SNT-TC-1A
and Tank Qualification Dwg. T-12345.

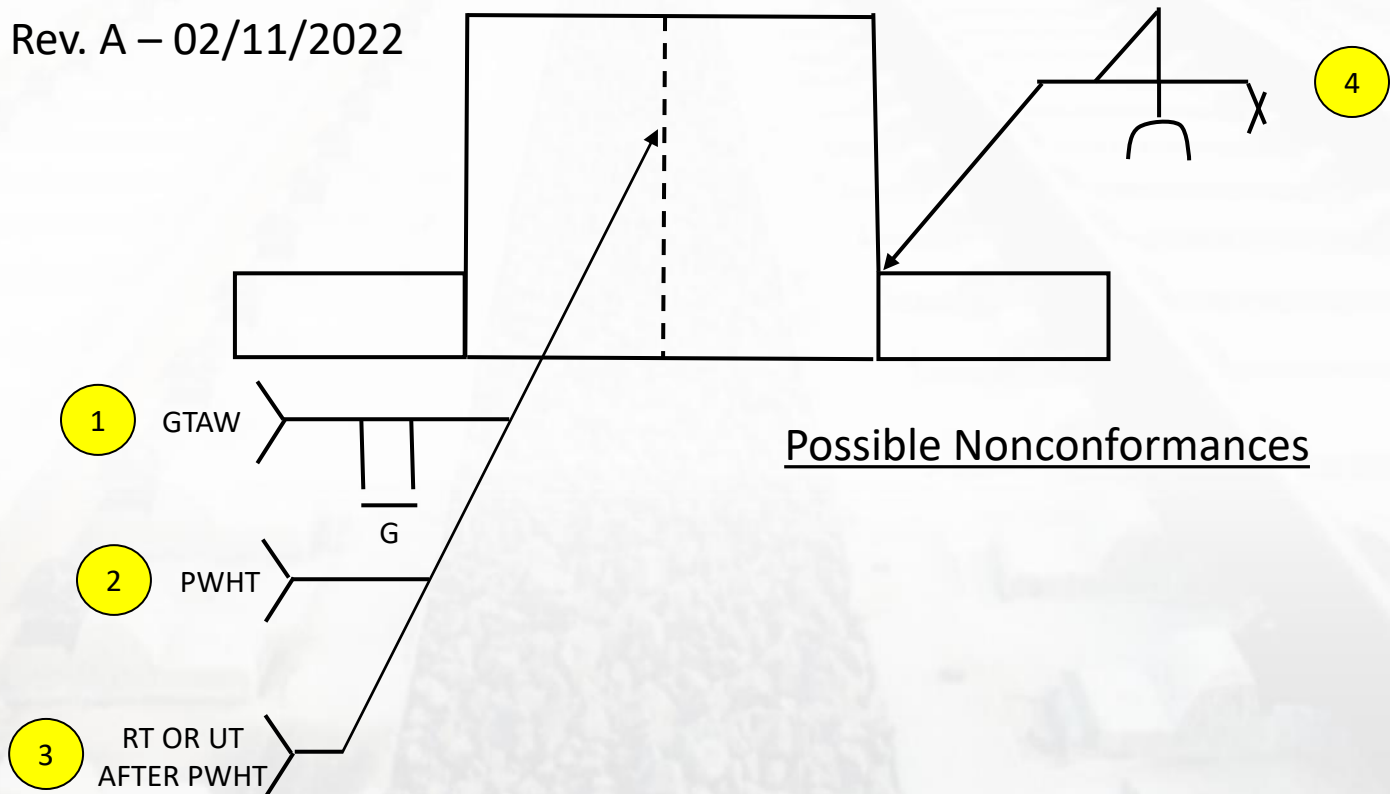
I.M. Needy
V.P. Sales & Marketing
Authorized Representative





CASE STUDY - #2 - NOZZLE

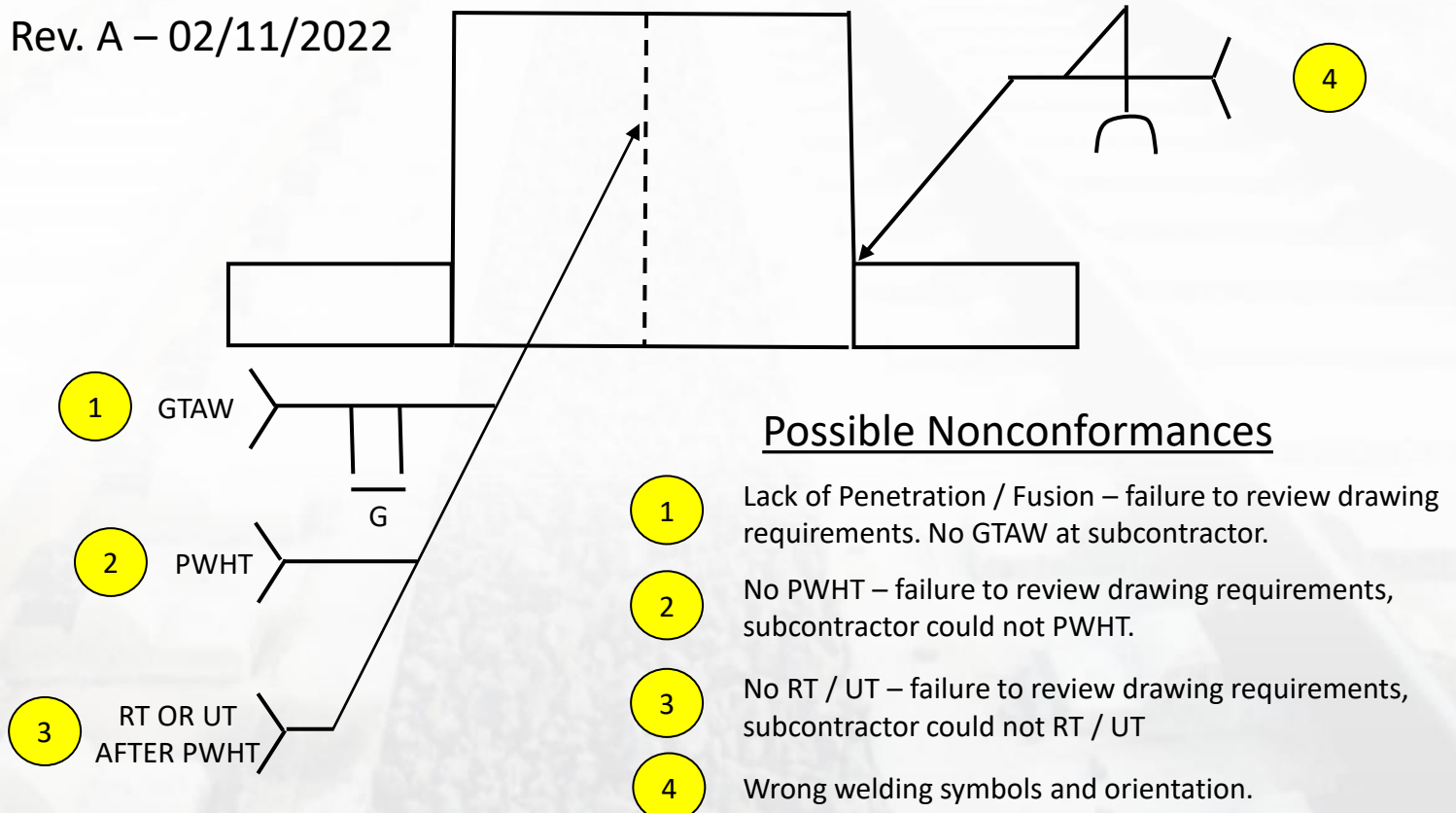
Dwg. 1234 Rev. A – 02/11/2022





CASE STUDY - #2 - NOZZLE

Dwg. 1234 Rev. A – 02/11/2022





CASE STUDY - #2 - NOZZLE

- Tank Component Ships to Facility
Out of Compliance At
Great Risk !



CASE STUDY - #3 – LEAK TEST

Chicago Tank Car Leasing Company Leak Test Procedure #30

Issue Date: November 4, 2016

Test Pressure: 50 psi.

Soak Time: 1 minute \pm 30 seconds

Dwell Time: 5 minutes

Leak Detect Solution: Super Duper Snooper

Approved: I.M. Needy
V.P. Sales & Marketing
Authorized Representative



CASE STUDY - #3 – LEAK TEST

Ajax Tank Car Repair Company Leak Test Procedure #300

Issue Date: June 6, 2004

Test Pressure: 30 psi.

Soak Time: 5 minutes

Dwell Time: 1 minute \pm 30 seconds

Leak Detect Solution: Olympic Magic Dragon Solution

Approved: John Nova
V.P. Production
Ajax Tank Car Repair Co.



CASE STUDY - #4 - GASKET





U.S. Department
of Transportation
Federal Railroad
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QUESTIONS ???

