



U.S. Department
of Transportation
Federal Railroad
Administration

RISK-BASED APPROACH TO QUALITY





LEARNING OBJECTIVES

- DOT Safety Policy;
- FRA Expectations;
- Regulatory Framework for Risk-Based Approach;
- Key Terms;
- Examples;
- Summary.



DOT SAFETY POLICY



POLICY STATEMENT ON SAFETY 2011

In carrying out our transportation mission, safety is our highest priority. Every life is precious, and we must strive to ensure the safety of every user of our transportation systems, as well as all who are affected by those systems. Injuries and loss of life are unacceptable in the efficient and effective transportation of goods and people, and we must take every practical action to prevent those tragedies from happening.

The American public has entrusted us with the responsibility of assuring the safety of our transportation systems. We will hold ourselves accountable, measure our performance, and continuously act to make our transportation systems safer. We expect no less from our transportation partners. Our guidance, oversight, and regulatory decisions will emphasize safety and be timely, fair, reasonable, and necessary. We can and should be a change agent by exemplifying and promoting a safety culture in which the values, actions, and behaviors of our employees reflect this priority.

Safety begins within our own Department, and the ability to carry out our statutory responsibilities is directly tied to the health and wellbeing of our workforce. The safety of our own employees is paramount. Each of our employees should be provided with a safe working environment, and know how to respond to emergencies and avoid unnecessary risks. We also expect supervisors and managers to provide our employees with an environment that promotes the open sharing of safety concerns, without fear of reprisal, as well as processes to assure those concerns are addressed. It is the responsibility of all DOT employees to conduct themselves in a way that does not pose unnecessary risks, or put themselves or others in danger.

Everyone within the Department is expected to exercise effective leadership in support of this policy, which shall be posted throughout the Department, clearly visible and accessible to all employees.

Ray LaHood



FRA EXPECTATIONS

- Paper Must Match Car!
- Car Must Match Paper!





REGULATORY FRAMEWORK

- Risk-Based Approach to Quality – *“A quality management approach that assigns activities and resources to the size of the risk i.e., the vital few vs. the trivial many”*;
- Risk – the product of the probability that harm will occur with the severity of the harm;



REGULATORY FRAMEWORK



ISO 13485 Risk-Based QMS for Medical Devices



REGULATORY FRAMEWORK

- *ISO 13485 Risk-Based QMS for Medical Devices:*
 - Selection and control of internal and external processes and suppliers;
 - Validation of computerized systems;
 - Product verification and validation;
 - Prevention of unwanted results;
 - FRA TCT bases inspections on risk assessment.



REGULATORY FRAMEWORK

- Facilities are more likely to be inspected if:
 - They perform tank-related activities;
 - They handle PIH/Hazmat commodities;
 - They have a large number of prior QAP inspection findings;
 - They have prior OTMA/NAR defects.



REGULATORY FRAMEWORK

- Implementing a Risk-Based Approach:
 - Identify risks associated with each process (public safety and regulatory);
 - Define measures to control risks;
 - Establish risk classes;
 - Adapt actions to risk classes;



KEY TERMS

- *Where Appropriate* – An element must be implemented unless quality would be affected by non-implementation;
- Reliability (FRA) - The quantified ability of an item to operate without failure over its design life or qualification interval;



KEY TERMS

- Reliability (AAR) – The quantified ability of an item or structure to operate for the specified period without failure over design life or until its next qualification;
- Design Level of Reliability and Safety (FRA) – The level of reliability/safety built into a *tank car* by its specification, design, and manufacture;



KEY TERMS

- Service Reliability Assessment-SRA (AAR) – Life-cycle analysis of an item based on systematically collected service data to verify railworthiness;
- Railworthy – The tank, service equipment, interior coatings/linings, safety systems, and components covered by Subpart F conform to the HMR and can perform their intended function without failure over its design life or qualification interval.



KEY TERMS

- Railworthy – The item must perform without failure over its design life or qualification interval;
- Regulatory maximum intervals may be used if verified with SRA.

NON FLAMMABLE LIQUIDS ONLY
DOT 111A100-W5

| | STATION STENCIL | QUALIFIED | DUE |
|----------------------|-----------------|-----------|------|
| TANK QUALIFICATION | GAPT | 2009 | 2019 |
| THICKNESS TEST | GAPT | 2009 | 2019 |
| SERVICE EQUIPMENT | GAPT | 2009 | 2014 |
| PRD: VENT 165 PSI | | | |
| LINING: | HCCPT | 2009 | 2014 |
| 88.B.2 INSPECTION | GAPT | 2009 | 2019 |
| STUB SILL INSPECTION | GAPT | 2009 | 2019 |

RUBBER LINED TANK
PRESSURE TEST NOT REQUIRED

PAINT
CARBOLINE 876 SH
GAPT-172 06 - 2009

APPLIED BY HCCPT
LINING 2000B
DATE APPLIED 2009

ABD
ABDW

LUB
NO

BLT-09-85 REBLT- -



KEY TERMS

- Verification (AAR) – Confirmation that an *activity (item)*, condition, or control conforms to requirements specified in documents such as contracts, codes, standards, drawings, specifications, system function descriptions, and procedures.

Ensuring the design includes all requirements.

Paper Must Match Car!



KEY TERMS

- Validation (ASQ) – Confirmation, using objective evidence, that the requirements which define an intended use or application have been met. The design meets customer and regulatory requirements over its design life or qualification interval.

Car Must Match Paper!



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NOW FOR THE GOOD STUFF!





EXAMPLE #1

- M-1002 Chapter 1.3.6.5 (AAR) - In addition to individual valve and/or closure approval requirements, the *fittings arrangement* on the tank car also requires approval.



EXAMPLE #1

- M-1002 Chapter 1.3.6.5 (AAR) - The fittings arrangement drawing is listed on the CoC (AAR 4-2) and is approved as part of the *tank car* design.

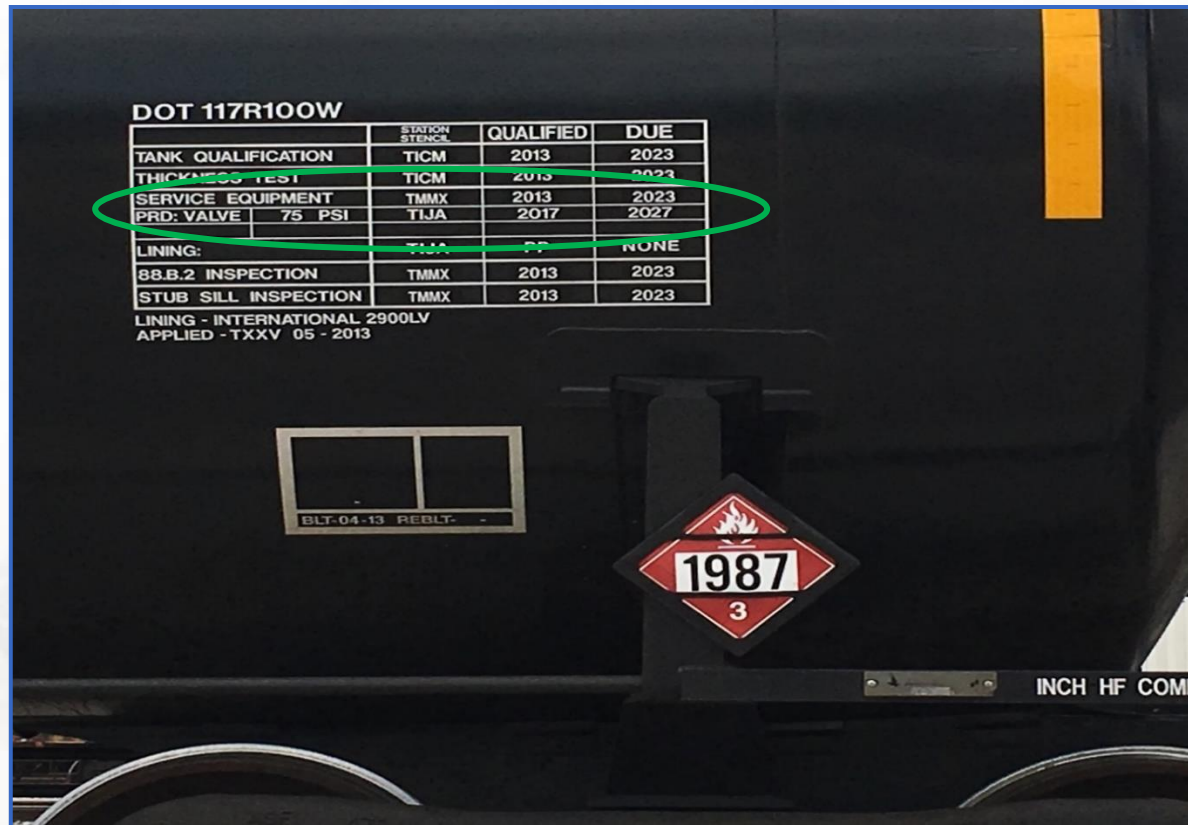


EXAMPLE #1

- M-1002 Chapter 1.3.6.5 (AAR) - If the fittings arrangement is altered, the alteration must be approved. The alteration of the fittings arrangement must be submitted using the AAR 4-2 and approved drawing(s).



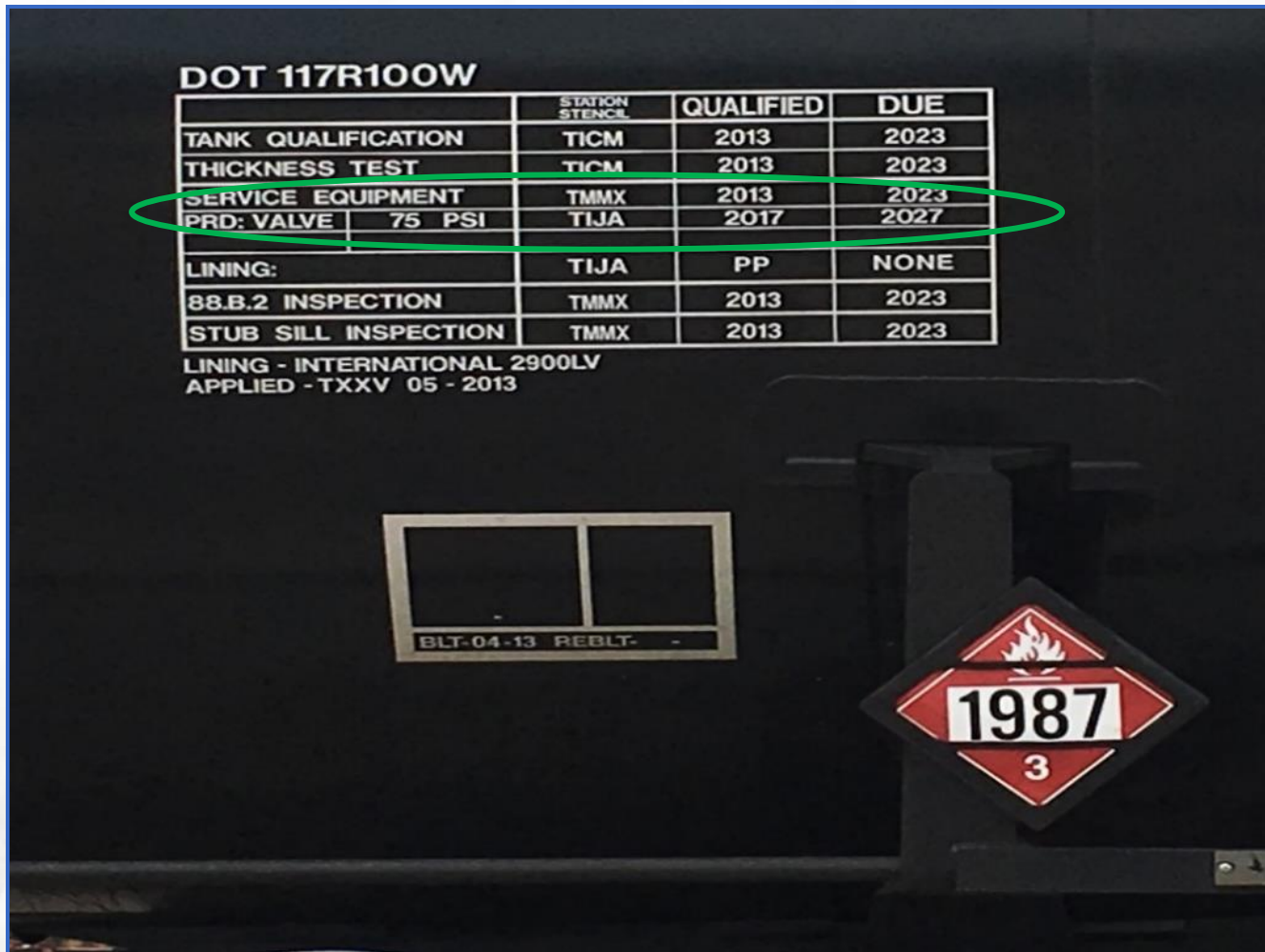
EXAMPLE #1





EXAMPLE #1





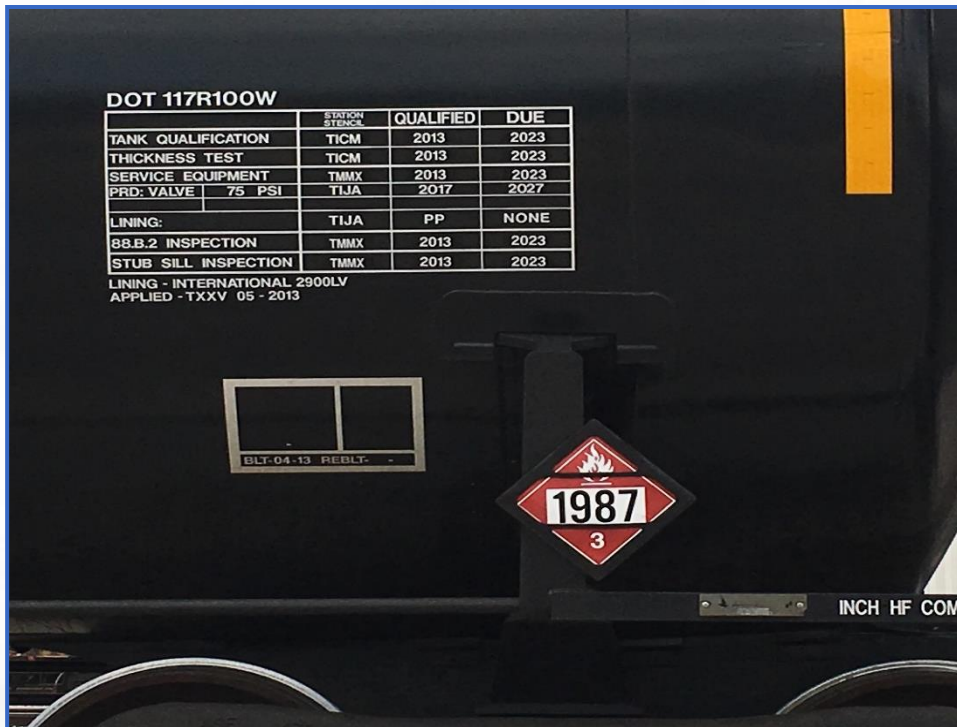


EXAMPLE #2

49 CFR Part 180.509(1)(e)(iii) - The tank shell butt welds within 60.96 cm (2 feet) of the bottom longitudinal centerline, unless the tank car owner can determine by analysis (e.g., finite element analysis, damage-tolerance analysis, or service reliability assessment) that the structure will not develop defects that reduce the design level of reliability and safety or fail within its operational life or prior to the next required inspection.

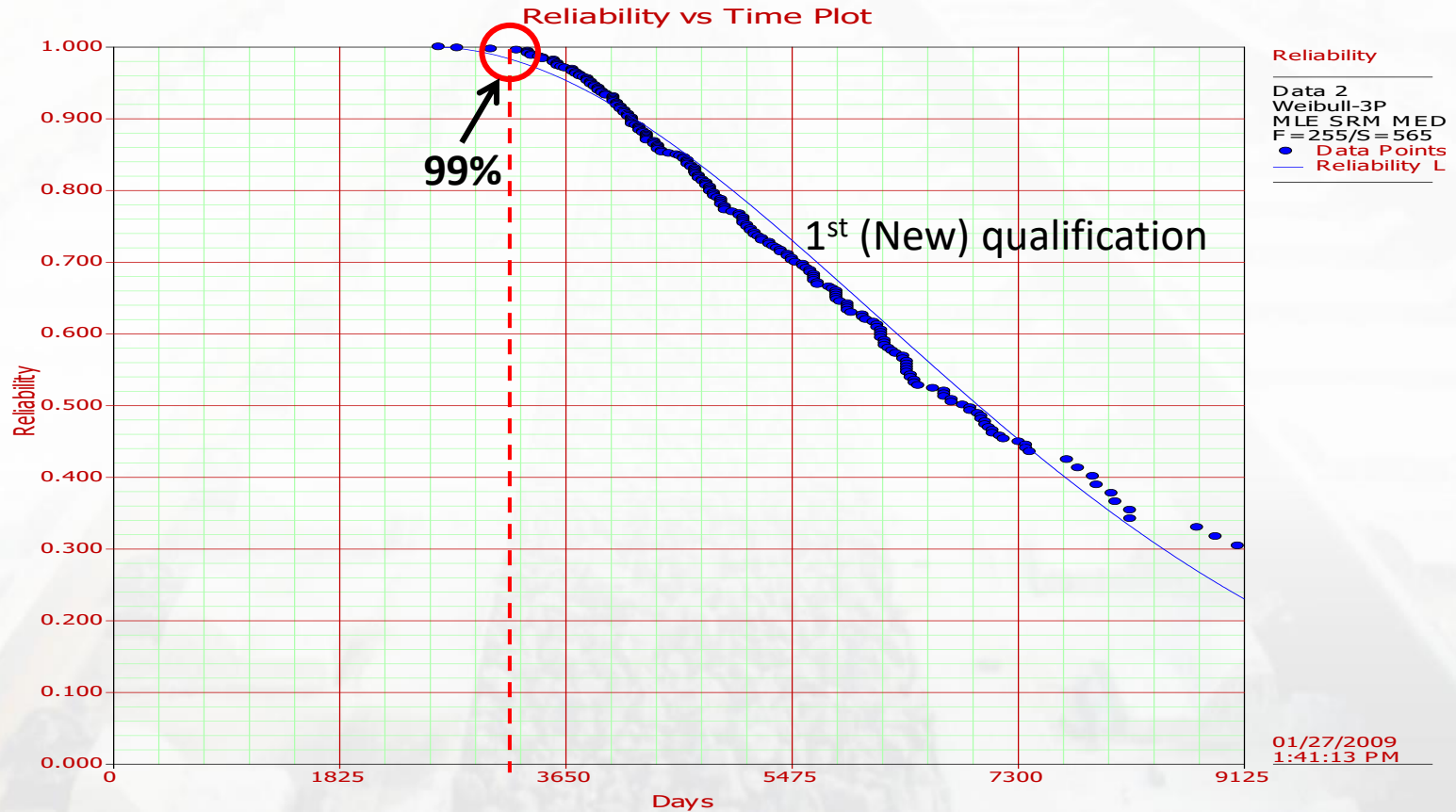


EXAMPLE #2





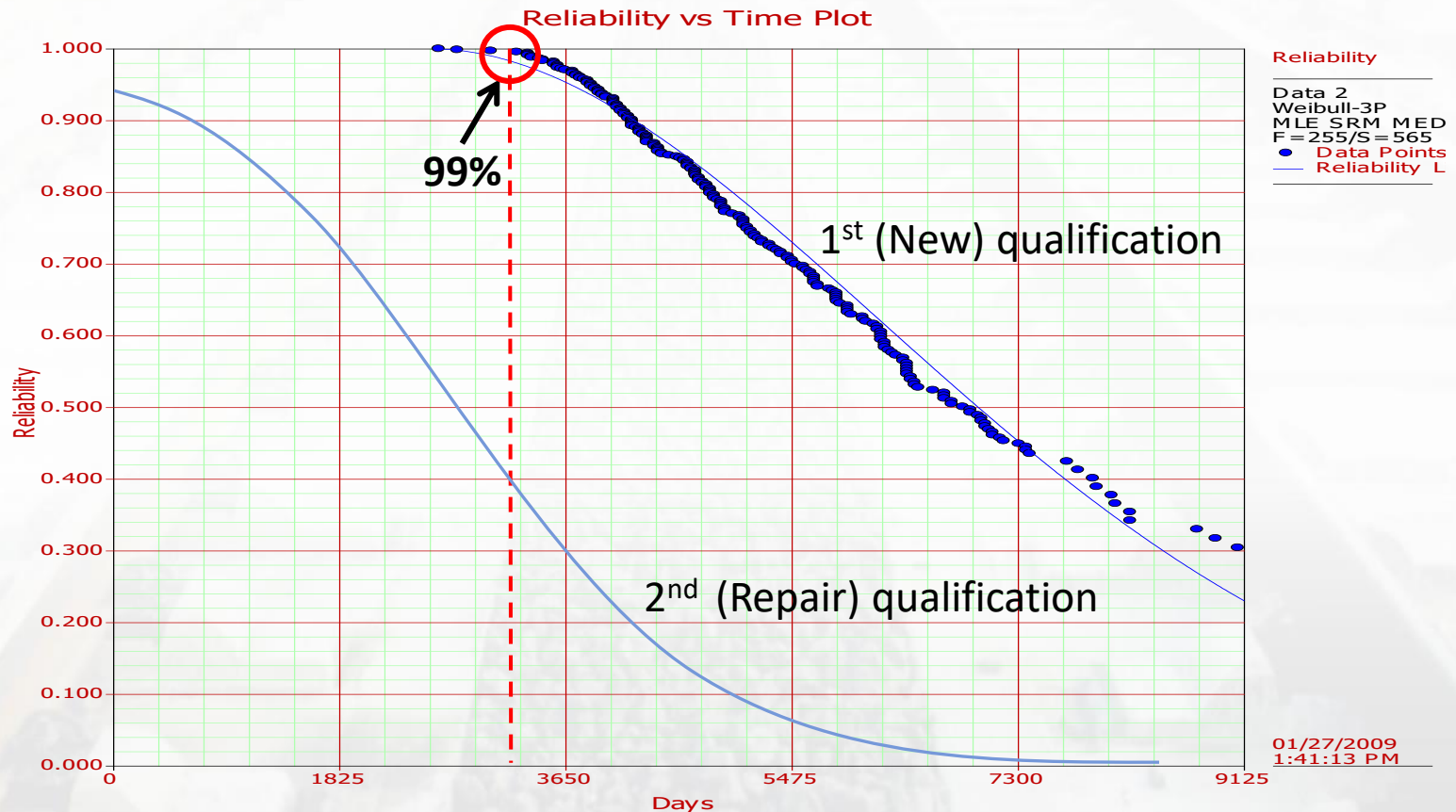
EXAMPLE #2



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EXAMPLE #2



$\beta=1.8885, \eta=5336.4158, \gamma=2584.0000$



EXAMPLE #2

Note: Owners may use regulatory maximum intervals **ONLY IF** validated by SRA!

FREQUENCY OF QUALIFICATION INSPECTION AND TESTS

| Section 180.509(*) | Description | Maximum Interval |
|--------------------|-------------------------------------------------------------------------------------------------------------|------------------|
| D | Visual inspection | 10 years |
| E | Structural integrity inspection | 10 years |
| F | Thickness test | See § 180.509(f) |
| H | Safety systems | 10 years |
| I | Internal coating or lining (for materials corrosive or reactive to the tank) (See definitions at § 180.503) | See § 180.509(i) |
| J | Leakage pressure test | After reassembly |
| K | Service equipment (including pressure relief device) | See § 180.509(k) |



SUMMARY

DOT 111A 100 W-1

| | STATION STENCIL | QUALIFIED | DUE |
|----------------------|-----------------|-----------|------|
| TANK QUALIFICATION | TETX | 2014 | 2024 |
| TANK THICKNESS TEST | TETX | 2014 | 2024 |
| SERVICE EQUIPMENT | TETX | 2014 | 2024 |
| PRD: VALVE A 75 PSI | UTC 135 | 2013 | 2023 |
| PRD: VALVE B 75 PSI | UTC 135 | 2011 | 2023 |
| 88.B.2 INSPECTION | TETX | 2014 | 2024 |
| STUB SILL INSPECTION | TETX | 2014 | 2024 |

BLT 5-78 RTC

VS.



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DATE APPLIED 2009

ABD
ABDW

LUB
NO

BLT-09-85 REBLT-

VS.





SUMMARY

Federal regulations require that marking a tank car as qualified and railworthy means the tank car meets all FRA regulations, AAR specifications, and owner acceptance criteria according to documented procedures.

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THOUGHTS???

