



# **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.



#### **FRA EXPECTATIONS**

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





- 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**



Public Safety Risk Regulatory Risk



#### **ISO 13485 Risk-Based QMS for Medical Devices**

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- 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.



- 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.



- 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 <u>quantified</u> ability of an item to operate without failure over its design life or qualification interval;



#### **KEY TERMS**

- Reliability (AAR) The <u>quantified</u> 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) Lifecycle 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

OADT			
GAPT	2009	2019	
GAPT	2009	2019	
GAPT	2009	2014	
HCCPT	2009	2014	
GAPT	2009	2019	
GAPT	2009	2019	
	GAPT GAPT HCCPT GAPT GAPT	GAPT 2009   GAPT 2009   GAPT 2009   HCCPT 2009   GAPT 2009   GAPT 2009	

RUBBER LINED TANK PRESSURE TEST NOT REQUIRED

ABD	LUB
ABDW	NO
BLT-09-85 R	EBLT

PAINT CARBOLINE 876 SH GAPT-172 06 - 2009

APPLIED BY HCCPT LINING 2000B DATE APPLIED 2009



#### **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!



# **NOW FOR THE GOOD STUFF!**



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#### 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).



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#### APPLICATION FOR APPROVAL AND CERTIFICATE OF CONSTRUCTION

2 TYPE: construction

1 APPROVAL REQUESTED OF: Soc. Precedent
6 APPLICANT: ABC Took Cor Manufacturor
9 REPORTING MARKS AND CAR MUNRERS: LESS 0.02 - D22

3 647 NO.11 X090077 4 DATE: 12/10/2019 4 10 ROBER DATE: 12/10/2010 1 5 695 1000000 (0.0000) 7 TANK SPECIFICATION DCT-11/2010 0 STENDIED SPECIFICATION DCT-11/2010 10 X0000000 SPECIFIC 3000

11	initial Commonly	SET WOTES	12	Dons ty (L8 Per Gel an)	5.54
13	Full Whiter Capacity (Gallerin)	30200	14	Dome Capacity or Outage (Galiona)	per DOT 113.245(a) (1)
15	Material Type / Crede Heads	AAD CC 121. Gr. D	18.1	Tank Hoad Material Normal 200	Tes
15.2	Tarris Head Springs:	No.	18.3	Charsy Requirements	
16	Material Type and Grade Shall	340. CC 125, Gr. D	16.1	Tark Shel Material Normalized	Yes
16.2	Cherry Requirements		17	Material Thickness Heads (Inches)	2,5425
12	Koterial Tradeness Shell (Incres)	0.5675	19	Lining Type	Shre
20	Inside Dismeter - Center (Insher)	115.375	21	ina de Diameter - End Förge (Inchea)	219.075
22	Head Reclue, Main (Indhes # not 2:1)	2:1	23	Test Pressure (PS)	1.05
24	Insulation Type	CE-Ceneal Tiber	25	Insulation Trackness (menas)	3.5
26	Theme: Conducts ty (BTU - rate -files, -degree h)	9.253	27	Type of Safety Renar Devices	78.198
27.1	Number of Solely Rekel Decase	1	28	Pressure Relief Device Start-to-Discharge (PSI)	75
28	Pressure Relief Deade How Capacity (CFM Required)	2162	30	Pressure Relief Device Flow Capacity (CFM Actual)	20142
31	Terris Barrheos Anon (Sc #1)	1880	25	Underframe or Stud Sill Type	280050-280054 soda s101 Design
33	Center of Gravity Loacod (Indhee)	06.0	34	Estimated Light Weight (b)	20505
56	AAR Clearer to Diogram	e	36	Rel Loed Limit (b)	208050
37	Truck Depusity (Toris)	105	38	Have Shield Type	7 Full Chield
38.1	Head Shok Thokness (Incres)	0.7			

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		The Pollowing Prior Approvals Apply:			
	The Following Drawings Apply:	Drawing Kumbor	District	ing humber	Application/Cantilisato No
	General Antargoment	2-052-335039			
	Tank Arrangement	2-025-91110 SE 18-18			1
1	Reinforced Openings, including Calculations	2-026-2002* 50 1-0			X596363
2	Anchorage, Including Calculations	2-026-90025 SE 18-25			X200327
3	Fitings Arrangement	2-020-90240 58 1-2			
4	Manway Assembly	2-072-901578			X8973C8
ι.	Protective Housing	2-671-96033			8477337
5	venting, Loosing, and Discharge Valves	SSE PAUE 2			
7	Pressure Rel of Devices	FORD #S75015			P5B 1950/1
8	Heater Systems (itt.)	3037			
19	Gauging Dovices	2-030-90097 58 3			X197101
50	Estion Outlet Valvo	2-014-90362 5B 18+2A			
51	Repairs				
52	Manway Dover	2-021-90133			X19/371
53	Calculations	P=01R=90005			X16/395
4	Tank Oxalification Drawing	2-63-860010			V16F365
				and the DOT Relineed SIGNATURE: Service TITLE: ABC Relining	balany App lanca filanda tuk Unan mening
APPR	ROVAL - AAR Tank Car Committee				
			Date Approved 01/32/2020	Secreth Dorsey	
APPR	ROVAL COMMENTS:			(signature) on be	fall of the Tark Car Committee



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#### EXAMPLE #1





#### EXAMPLE #1





#### **DOT 117R100W** QUALIFIED DUE STATION 2023 TANK QUALIFICATION TICM 2013 THICKNESS TEST 2013 2023 TICM SERVICE EQUIPMENT 2013 2023 TMMX 2017 2027 75 PSI TIJA PP NONE LINING: TIJA 88.B.2 INSPECTION 2013 2023 TMMX STUB SILL INSPECTION TMMX 2013 2023

LINING - INTERNATIONAL 2900LV APPLIED - TXXV 05 - 2013







#### EXAMPLE #2

49 CFR Part180.509(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.



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Note: Owners may use regulatory maximum intervals <u>ONLY IF</u> 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)
Н	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
К	Service equipment (including pressure relief device)	See § 180.509(k)



#### SUMMARY

	IA IUU	10-1	
		M Losh	
	STATION	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	2014	2023
88.B.2 INSPECTION	TETX	2014	2024
STUB SILL INSPECTION	TETX	2014	2024

VS.



	and the second second	STATION	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 INSPE	CTION	GAPT	2009	2019
STUB SILL IN	ISPECTION	GAPT	2009	2019
STUB SILL IN	ISPECTION	GAPT	2009 PAINT	2019

BLT-09-85 RE

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.

#### Paper Must Match Car! Car Must Match Paper!



#### THOUGHTS???

