Introducing SAFETY in ORGANIZATIONS Lessons Learned

Day 1

Henrik Thane

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SAFETY INTEGRITY AB

2016-03-16

CV

Safety Integrity

Dr. Henrik Thane

- Senior Safety Assessor and Safety Manager, Safety Integrity AB
- Professor in Functional Safety, Mälardalen Real Time Research Center, MDH, 2012-
- Founded Safety Integrity AB in 2009
- Member of national standardization committees for IEC61508 and EN50128
- Product M Manager at ENEA, Responsible for all operating systems and tools
- CEO ZealCore, co-founded ZealCore 2001, acquired by ENEA 2008
- Associate Professor (Docent) at Mälardalen Real-Time Center until 2008
- Ph.D. from the Royal Institute of technology in Stockholm, 2000
- In addition to research I have during the last 15 years worked as an expert consultant for the industry and given numerous industrial courses on design and test of software in safety-critical computer based systems.

Safety Integrity AB

SOFTWARE SAFETY

We provide SERVICES, EDUCATION, DOCUMENTATION TEMPLATES

We are experts on the functional safety standards:
IEC61508 and it derivatives e.g., ISO26262, EN50128/9, EN62061, EN13849

We provide SERVICES as:

- Independent SAFETY ASSESSORS (ISA)
- SAFETY MANAGERS
- SAFETY MANAGEMENT STARTUP

We offer TRAINING in

- Safety Management courses for IEC61508, EN50128/9 and ISO26262, IEC62061, EN13849.

Inspection Body

INDEPENDENT SAFETY ASSESSOR

- Accredited TYPE A Inspection Body

QUALITY SYSTEM

- SS-EN17020:2012
  - Conformity assessment
  - Requirements for the operation of various types of bodies performing inspection

SWEDAC ACKREDITERING

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ISO/IEC 17020 (A)

OUR MARKET

All manufacturers of safety related products

- Customers:
  - ABB Robotics, Volvo Construction Equipment, Bombardier Transportation, Atlas Copco, Trafikverket, ABB Mining, Westermo, Arcticus Systems, Öresundsbron, etc.
- Products:
  - High speed trains (400km/h), Driverless trains, Autonomous vehicles/construction equipment, Industrial Robots, Mining Elevators (2 km ride), Operating systems/tool vendors, etc.

Position

- One of a few accredited inspection bodies in Sweden
- Most customers are based in Sweden. We have however had contracts for customers in South Korea, India, China, UK, Canada, and Italy.

Key in Functional Safety Standards

Independence

- Between doer and verifier
- Doer ← Verifier ← Validator ← Assessor

What is Assessment?

- *"Process of analysis to determine whether software,*
  - *which may include process, documentation, system, subsystem hardware and/or software components, meets the specified requirements and to form a judgment as to whether the software is fit for its intended purpose.*
  - *Safety assessment is focused on but not limited to the safety properties of a system"*

EN50128:2011

- *"Examination of a characteristic of an **item** or **element**"*

ISO26262-1:2011

Audit and Assessor?

Audit

- *"Examination of an Implemented process"*

ISO26262-1:2011

Assessor

- *"Entity that carries out an assessment"*

EN50128:2011

Assessment parts

Safety Planning
Project plan
Safety management plan
Verification plan
Validation plan
Change management plan
Documentation plan
Tools and COTS qualification plan
Assessment plan
All plans verification report

Safety Concept Phase
System Definition
Hazard Analysis
Hazard log
Safety Function Identification
Safety Function specification
Safety Function Validation Test Specification
Safety Concept verification report

Product development: System level HW/SW

Determine the required performance level
Safety Function design
Architecture selection (Single or Dual channel)
Evaluation of achieved PL report (MTTF, DC, CCF)
System integration test specification
Tools and COTS qualification report
System level verification report

Validation

System Integration Test Phase

System Integration Test Records

System Integration Test Report

Safety Function Validation Phase

Safety Function Validation Test Records

Safety Function Validation Test Report

Functional Safety Assessment

Assessment
Assessment report

After SOP: Deployment
Safety Manual
Release Notes
Deployment verification report

After SOP: Maintenance Phase

Impact analysis
Maintenance & Change records
Maintenance Validation Report
Assessment report (for every new release)

Software
V-model.
See Figure 2

Hardware
V-model.
See Figure 3

ISO 13849

Assessment parts

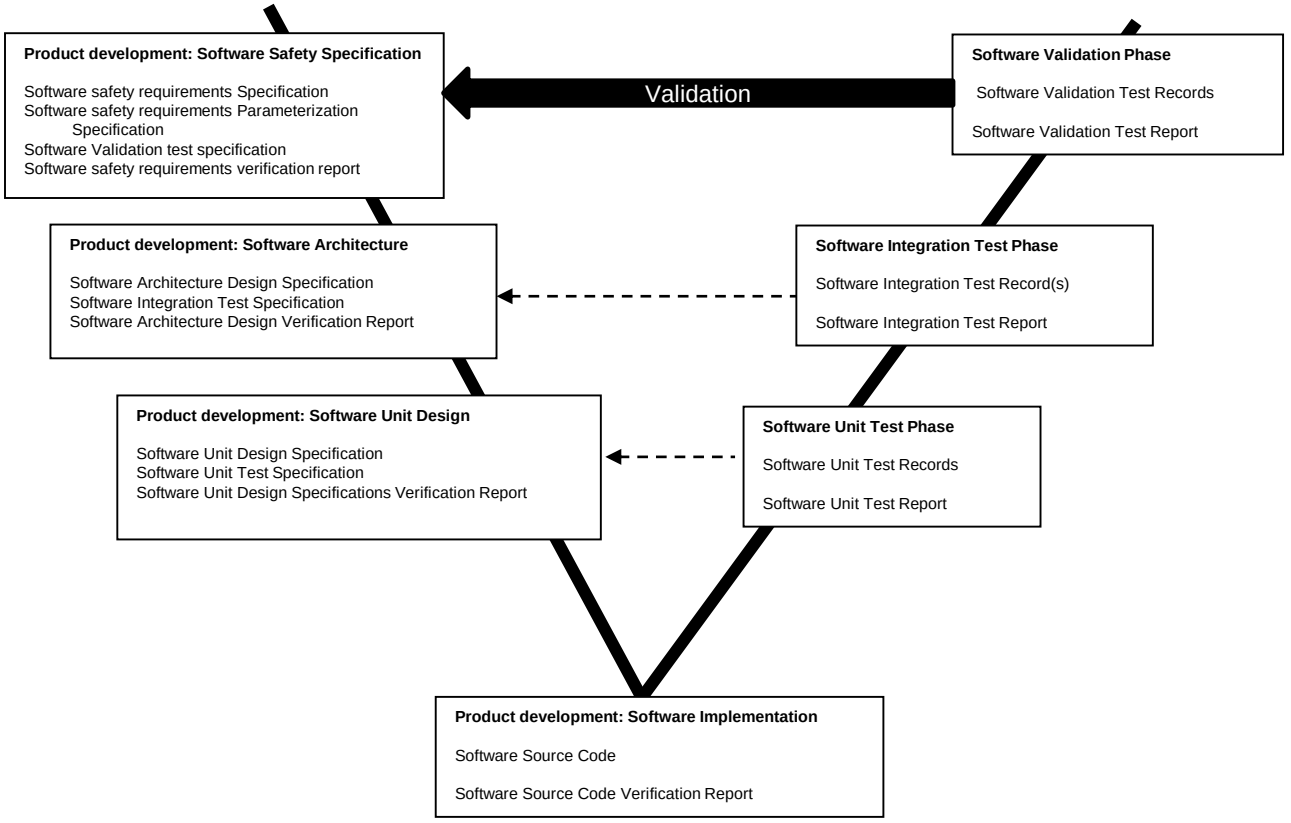


Figure 2

ISO 13849

I have assessed many projects…
and
performed hundreds of assessments

Safety Integrity

Recent Projects

- **Safety Assessor, V300 Zefiro High speed train (400km/h), Bombardier Transportation Italy, 2011-2015**
- **Safety Assessor Articus Systems, ISO26262 ASIL D certification of Real-Time Operating System. 2012-2015**
- **Safety Assessor, TCMS C30, Bombardier Transportation Sweden, 2014-**
- **Safety Assessor**/mentor**, Pentronic AB, IEC61508, 2014-**
- **Safety Assessor**/mentor**, Atlas Copco Rock Drills, EN13849, 2013-2014**
- Safety Manager, Mining Rock Drill Protection System, Etteplan, Atlas Copco Rock Drills, 2013
- Safety Assessor, Öresund Bridge, upgrade of Computer control and SCADA system for Tunnel safety and supervision, EN50129/EN50128, 2013
- Safety Manager ABB Robotics, Safety Controller, EN13849, 2012-
- Managing the update of the entire life cycle process for Volvo Construction Equipment towards ISO26262 compliance, 2011- 2012
- Safety Manager ABB Mining, regarding IEC62061, 2011-
- Safety Manager Volvo CE, project CEA2+, NEAT, RFT, regarding ISO26262, 2011-2012
- Safety Process Mentor for Leine & Linde regarding EN62061/EN-ISO138491, 2011
- Safety Process Mentor for Data Respons, and Westermo regarding EN50129 and EN50128, 2010-2012
- Safety Assessor Volvo CE, Process and tools, regarding IEC61508, 2010
- Safety Assessor, Regina SJ, intercity train project, Bombardier, 2010-
- Safety Assessor, Zefiro China, High speed train (400km/h), Bombardier Transportation, 2009-2013
- Safety Assessor, Delhi Metro project (DM2), Bombardier Transportation. 2009 -2010
- Safety Assessor, London underground project (SSL), Bombardier Transportation. 2008 -2011
- Senior expert/consultant/mentor on a number of safety critical applications, within Transportation/Vehicles, and Industrial automation 1995-2011.

Non compliant safety process

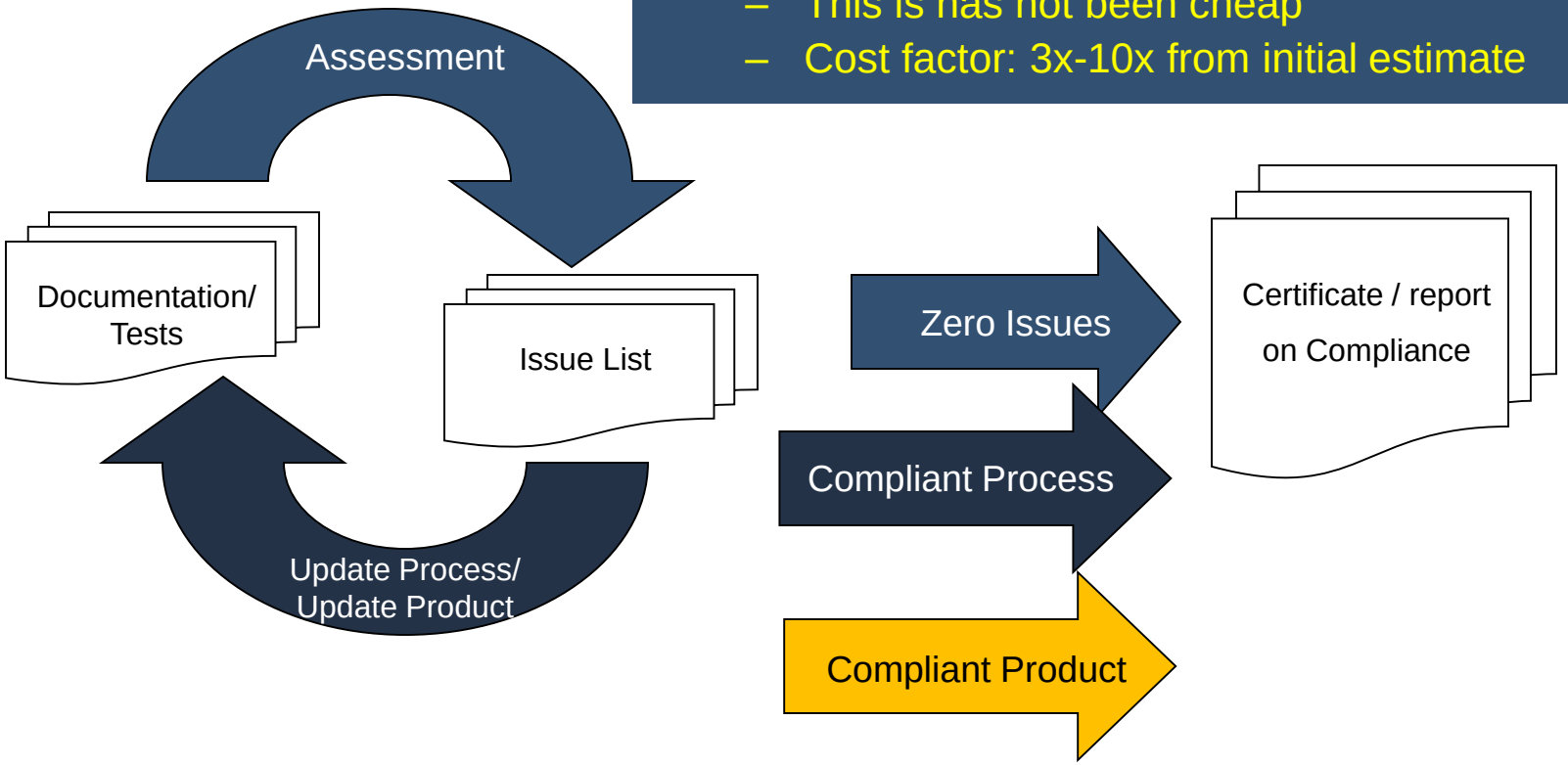
Experience

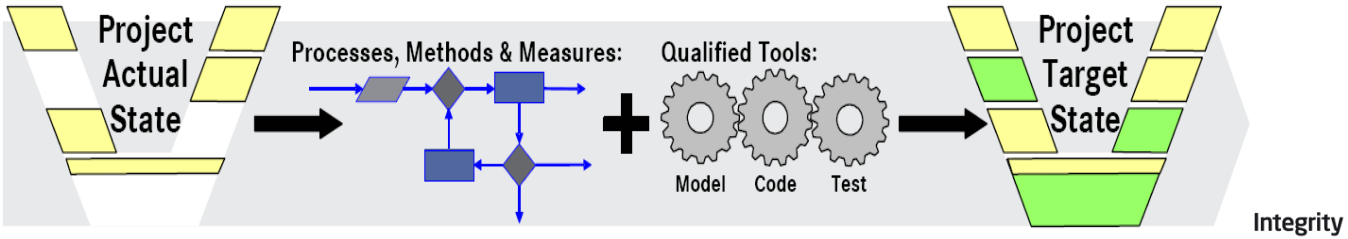
No project has had a streamlined organization and Development/Lifecycle Process for complying with the required safety standard.

Compliance has been fulfilled through:

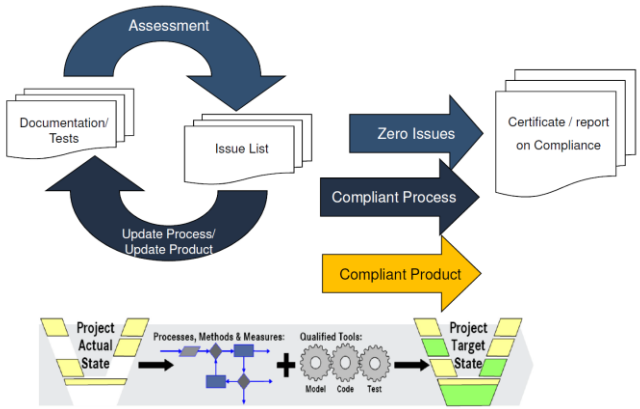
- Repetitive assessments/gap analysis
- Corrective actions, i.e., changed process and updated documentation

- This is has not been cheap
- Cost factor: 3x-10x from initial estimate





Example of costly convergence



Rev	Date	Authors	Comments	Open Process Issues	Closed Process Issues %	Partially Closed Process Issues %	Open Product Issues (3.8)	Rate
1st draft	2011-11-20	Dr. Henrik Thane	Assessment plan preparation	390	0%	0%		
Audit 1	2011-12-07	Dr. Henrik Thane	Audit regarding safety management & Plans	366	(24) 6%	(22) 5.6%		6%
Audit 2	2012-04-25	Dr. Henrik Thane	Backlog plans	347	(43) 11%	(24) 6%		5%
Audit 3	2012-06-14	Dr. Henrik Thane	Backlog plans, Lifecycle documentation product integrity checklist added	343	(47) 12%	(27) 7%	46	1%
Audit 4	2012-09-26	Dr. Henrik Thane	Backlog plans	325	(65) 17%	(31)8%	46	5%
Audit 5	2012-11-23	Dr. Henrik Thane	Backlog and requirements	307	(83) 21%	(39)10%	46	4%
Audit 6	2013-02-22	Dr. Henrik Thane	Backlog and requirements	292	(98) 25%	(42)11%	46	4%
Audit 7	2013-04-26	Dr. Henrik Thane	Backlog and requirements	278	(113) 29%	(46)12%	46	4%
Audit 8	2013-06-13	Dr. Henrik Thane	Backlog and requirements	254	(137) 35%	(46)12%	46	9%
Audit 8b	2013-06-16	Dr. Henrik Thane	Backlog and requirements + missing arguments	243	(148) 38%	(40)10%	46	
Audit 9	2013-09-26	Dr. Henrik Thane	Backlog and requirements	231	(158) 41%	(41)11%	46	3%
Audit 10	2013-12-03	Dr. Henrik Thane	Backlog and test	213	(177) 45%	(32)8%	46	4%
Audit 11	2014-03-17	Dr. Henrik Thane	Backlog and parameterization	184	(206) 53%	(32)8%	46	8%
Audit 12	2014-04-29	Dr. Henrik Thane	Backlog	168	(224) 57%	(29)7%	46	4%
Audit 13	2014-05-28	Dr. Henrik Thane	Backlog + deployment	134	(256) 66%	(22)6%	46	9%
Audit 14	2014-06-26	Dr. Henrik Thane	Backlog	113	(277) 71%	(23)6%	46	5%
Audit 15	2014-08-22	Dr. Henrik Thane	Backlog	102	(288) 74%	(23)6%	46	3%

Observed Manufacturer Challenges

- Separated processes and organizations
  - One for development
  - One for safety management
    - Similar to HW development and SW development processes and organizations

Observed Manufacturer Challenges

- Fragile (one-off mentality)
  - After first release change management is not harmonized
  - Development documentation and artifacts diverge from safety documentation
- Safety anxiety
  - Organization change takes time
  - Safety culture implementation takes time
  - Harmonized safety and development process takes time

Lessons learned

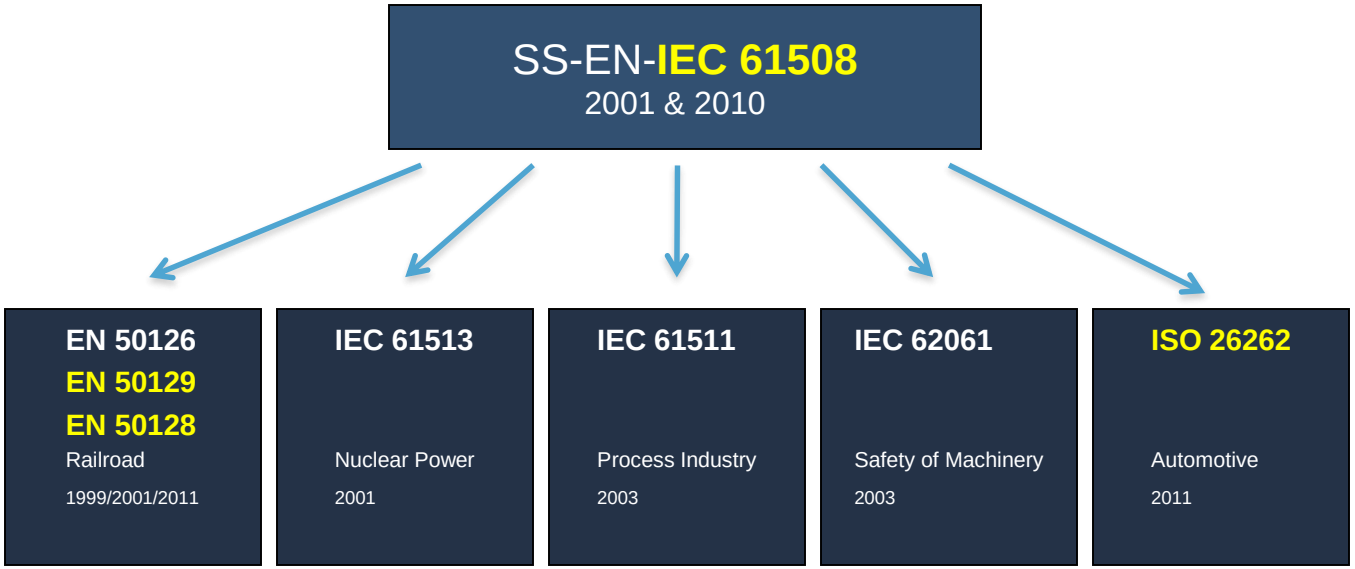
- Reuse is very important
  - Reuse documentation from previous projects
    - Plans, templates, verification checklists, etc.
    - Preferable have a certified safety management system
      - That can be instantiated for every new project
    - Continuous improvement
- Continuous Training
  - Role centric training
    - Project Manager, Safety Manager, Requirements Manager
    - Architect, Implementer,
    - Test manager, Verification manager
    - Validator
    - Assessor
    - Configuration Manager
  - Mentors (with experience from previous projects)
  - New people who are introduced late in a project often think the process is over ambitions and require way too much work. They need to be trained and mentored.

Lessons learned

- When the deadline approaches
  - Often all ambitious safety goals are washed out
  - All kinds of shortcuts are sought.
  - Extremely important to keep to the process then and that there are sufficient resources.

- Regard the safety standards with respect but not fear. They are there to help.

Functional Safety Standards



- Embedded Systems Safety
  - IEC 61508 (2001) and (2010 2nd ed.)
- Industry specific
  - Software for Machines
    - ISO13849-1
    - ISO 62061
  - Transportation
    - EN 50128 – railway software
    - ISO 26262 – Automotive/Trucks/Construction Equip.

- Industry specific
  - Aerospace and aviation
    - DO-178B, Aviation, USA
    - NASA-STD-8719-13, NASA, USA
    - ESA PSS-05-0, Space, European
  - Military
    - MIL-STD-882D, DoD, USA
    - 00-55/00-56, MoD, UK
    - MIL-STD-498, DoD, USA

Functional Safety Challenges

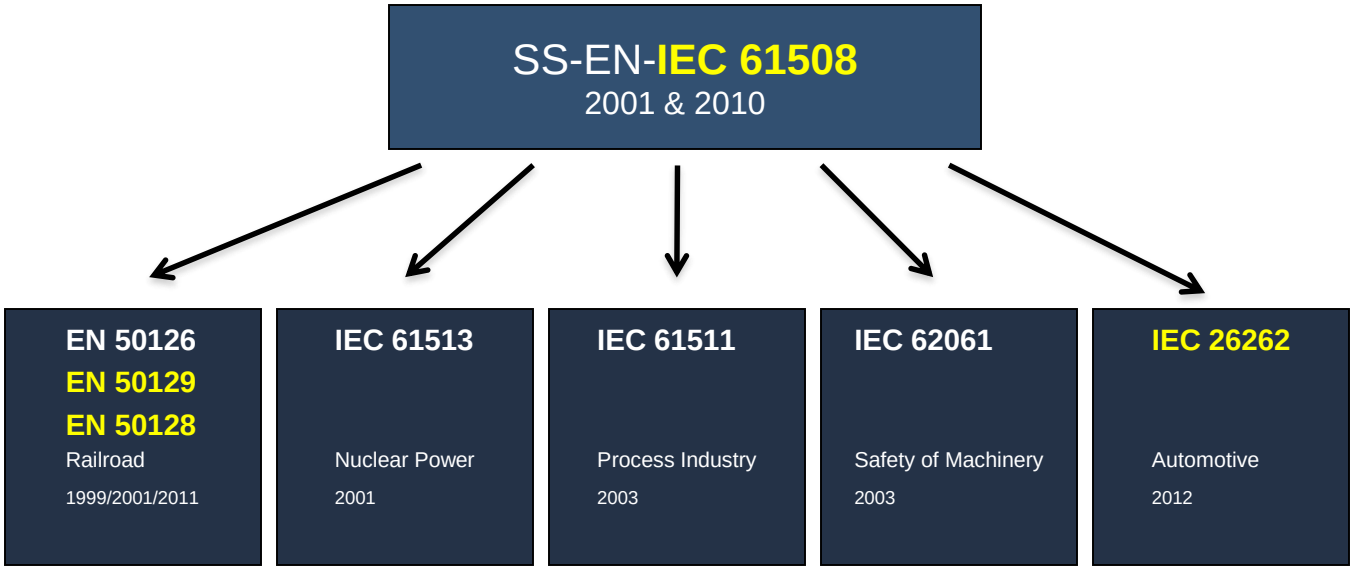
Current situation

- It is about a 10 year turn-around time for new functional safety standards

Functional Safety Challenges

- **High complexity**
  - The complexity of computer controlled systems increase exponentially
  - Current standards do not deal with high complexity systems
- **Multiple concerns: Safety and security jointly**
  - More and more systems are connected to the Internet: IoT, Cars, Trains, …
  - Functional safety deals with dangerous faults stemming from the system itself
  - Security deals with intentional sabotage of systems, this is not covered by current functional safety standards to any extent.
- **Multiple domains**
  - Need to be able to deal with many functional safety standards concurrently in a cost efficient manner
    - For example OEMs who target Automotive, Construction Equipment, and railway at the same time
    - Tool vendors, who want to certify their tools for many different safety standards in order to increase customer value and market share

Summary: Safety Assessment

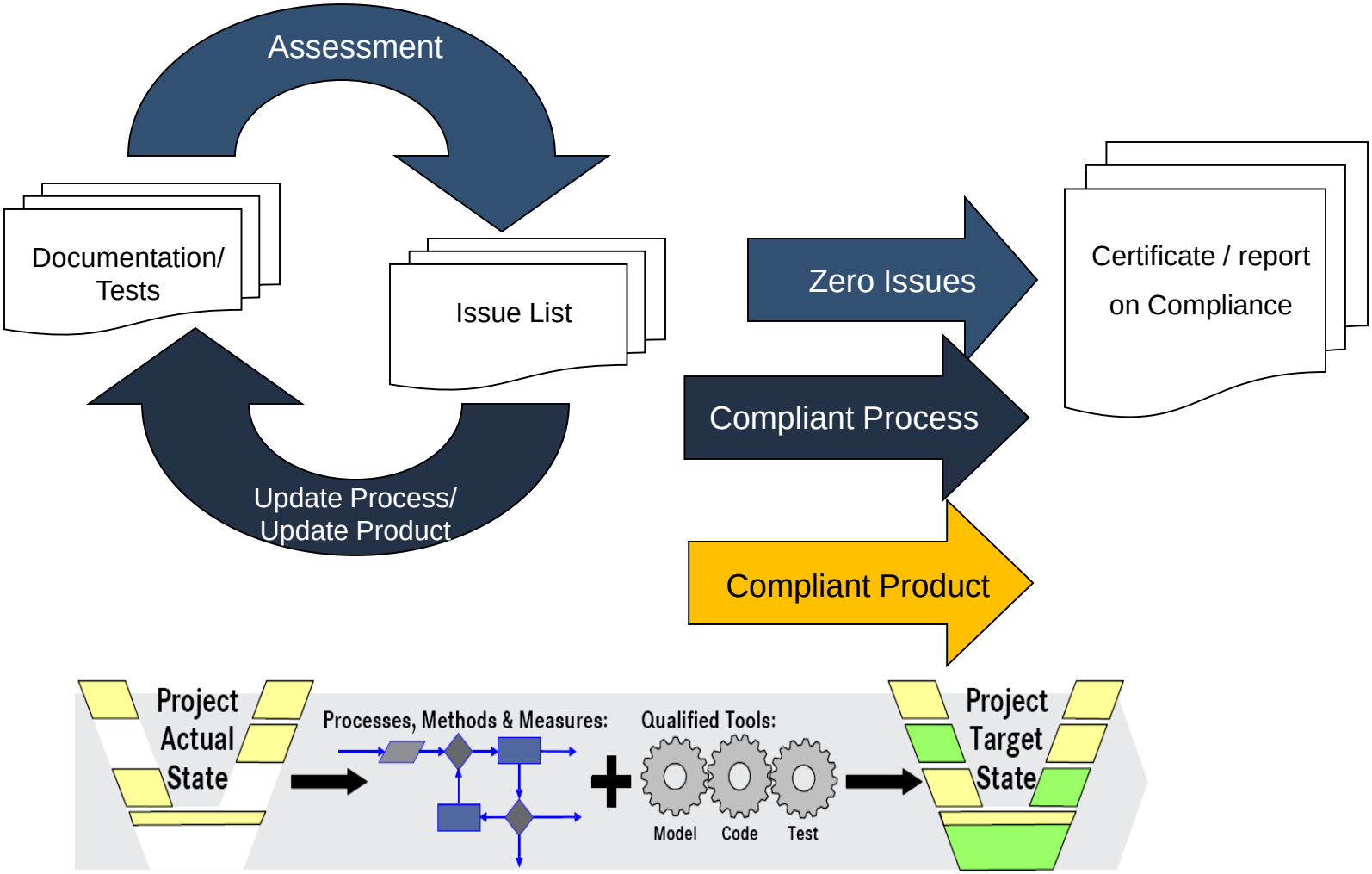


Compliance by fulfillment of all Product and Process Requirements:

- Plans & Process
- Requirements
- Verification for each phase
  - Static (reviews)
  - Dynamic (tests)
- Independence
  - Between doer and verifier
  - Doer – Verifier – Validator -Assessor

- Reports for each phase
- Change management
- A complete documentation trail
- Assessment

Important to integrate safety process & development process



THANK YOU!

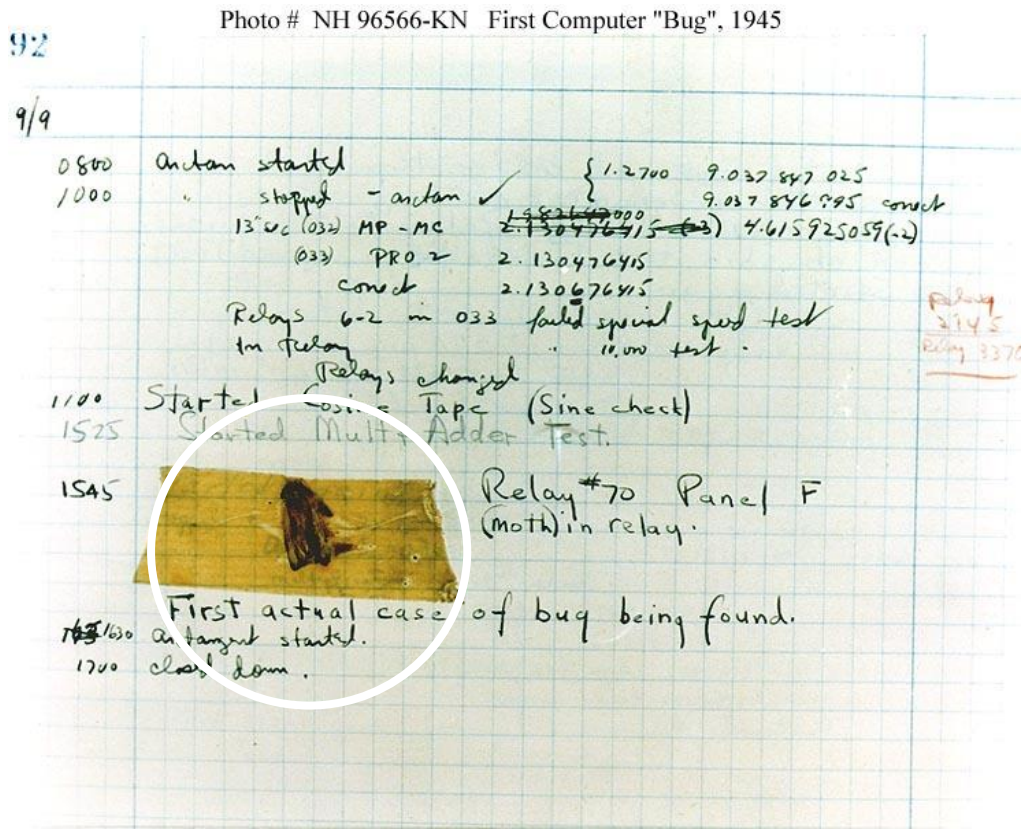


Figure 1. Allegedly the first computer bug - found by Grace Hopper's Team in 1945. Exhibited at the Museum History of American Technology/Smithsonian

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