



excellence in dependable automation

The Evolution of European Safety Standards

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Standards Compliance – Europe versus US

- Ø European Professionals comply with Standards – Why?
 - è Standards have a long history and were used as trade barrier
 - è Standards are a protection against product liability
 - è Standards protect against personal liability and criminal law
 - è Rigid surveillance
 - è Mandatory Certification by Notified Body, if no harmonized application standard exists

- Ø US Professionals pay less attention to Standards – Why?
 - è Standards don't help in product liability cases
 - Standards may even hurt in product liability cases
 - è Employees are not sued for negligence – yet

Motivation for Safety

European Directives – National Laws

Personal Liability and Criminal Law

Enforcement by
compulsory accident insurance

Liability

Cost reduction by better Risk Assessment
Opportunities

Priority

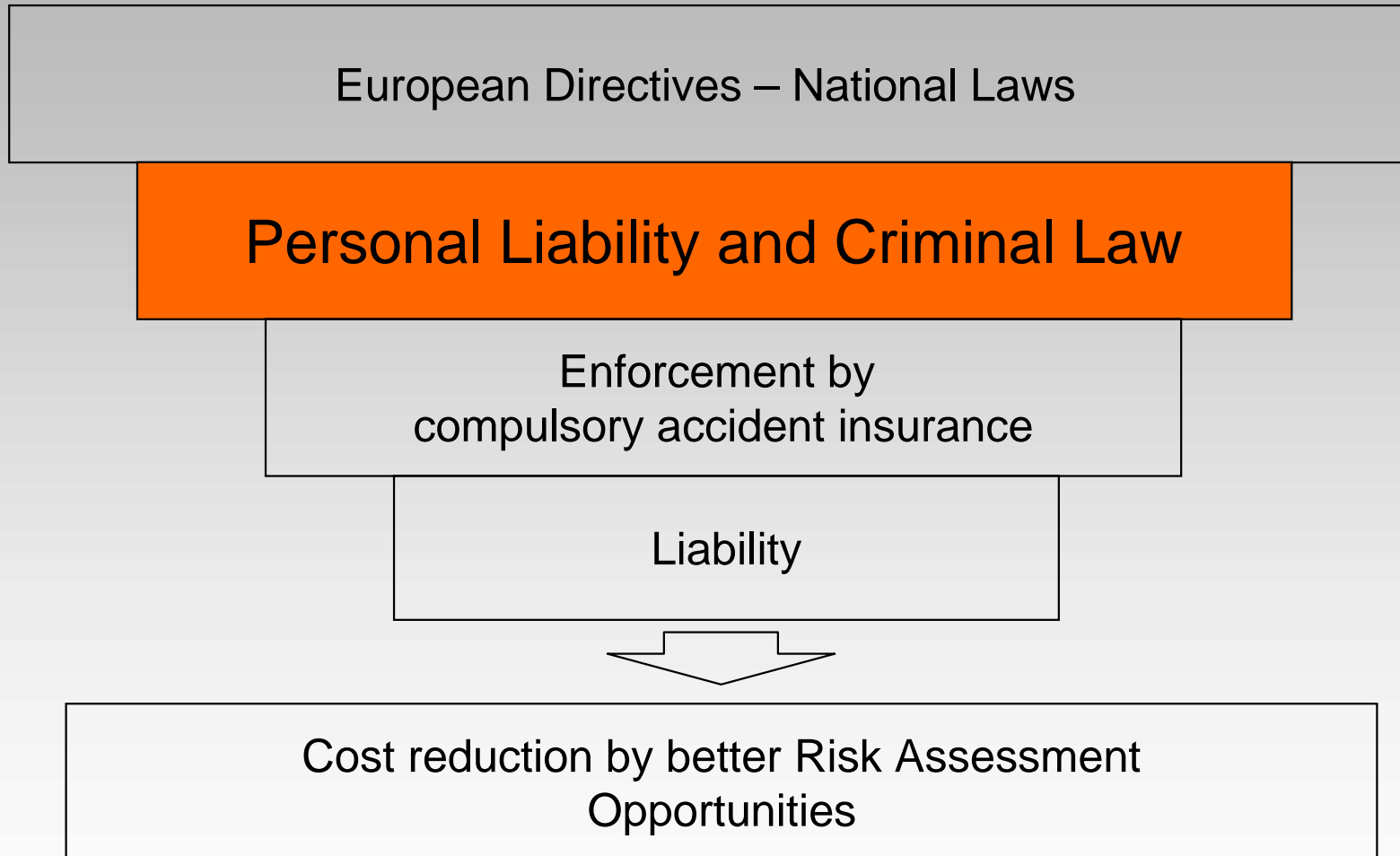
European Directive

Ø European Machine Directive - 98/37/EC

- è Applies to Machines and Machine Safety Devices
- è Includes a very comprehensive list of hazards
(Annex 1: Essential Health and Safety Requirements)
(1.2.1: Safety and reliability of control systems
.... **errors in logic shall not lead to dangerous situations**)
- è Mandatory Certification by Notified Body if no harmonized application standard exists

Ø Enforcement defined by the EU Directive

- è Personal responsibility of the CEO of the vendor company
CEO must sign the Declaration of Conformity
confirming the safety of the machine / device



Criminal Law – Responsibilities

§ 13 Labour Protection Law (ArbSchG)

(1) Responsible for the fulfillment of the obligations are not only the employer

...

5. other assigned persons in the context of their functions and authority.

Cable car accident in Austrian Alps, Kaprun, 11.11.2000; a fan heater ignited hydraulic oil,

155 people were killed by the fire in the tunnel

Design engineers, Assessors and Department Leaders are now in **Court: “Professional negligence - causing of a blast”**, not Senior Management

Personal Liability and Criminal Law

Criminal law and personal liability apply, if **Gross Negligence** must be assumed.

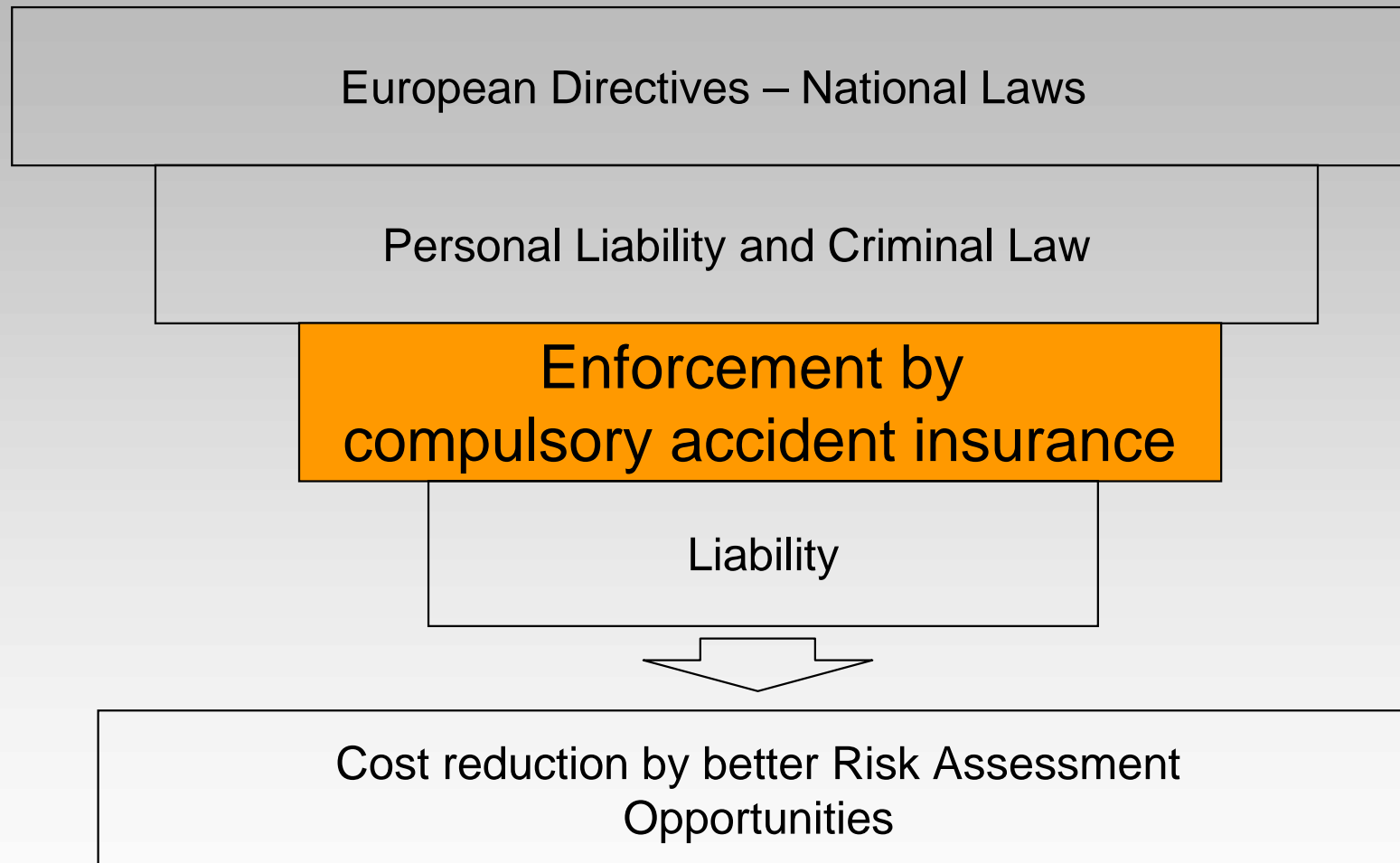
Negligence: Ignore the necessary attention (unconscious or conscious), to which one is obligated according to personal knowledge and abilities. This includes violation of duties to exercise diligence.

Gross Negligence: Ignore the necessary attention to a severe degree including thoughtless action, do not consider simple, more obvious and elementary rules. Violation of elementary duties to exercise diligence.

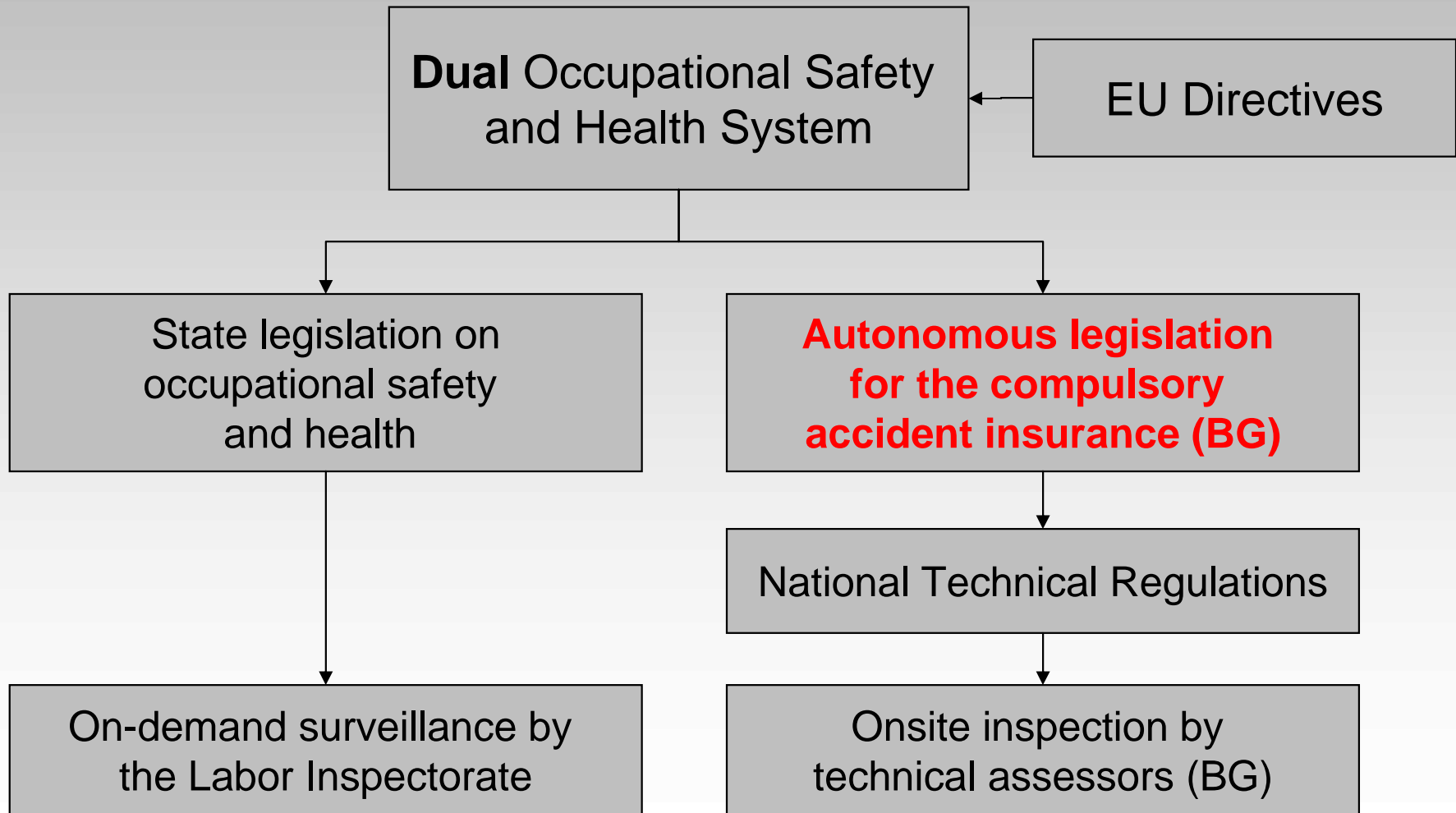


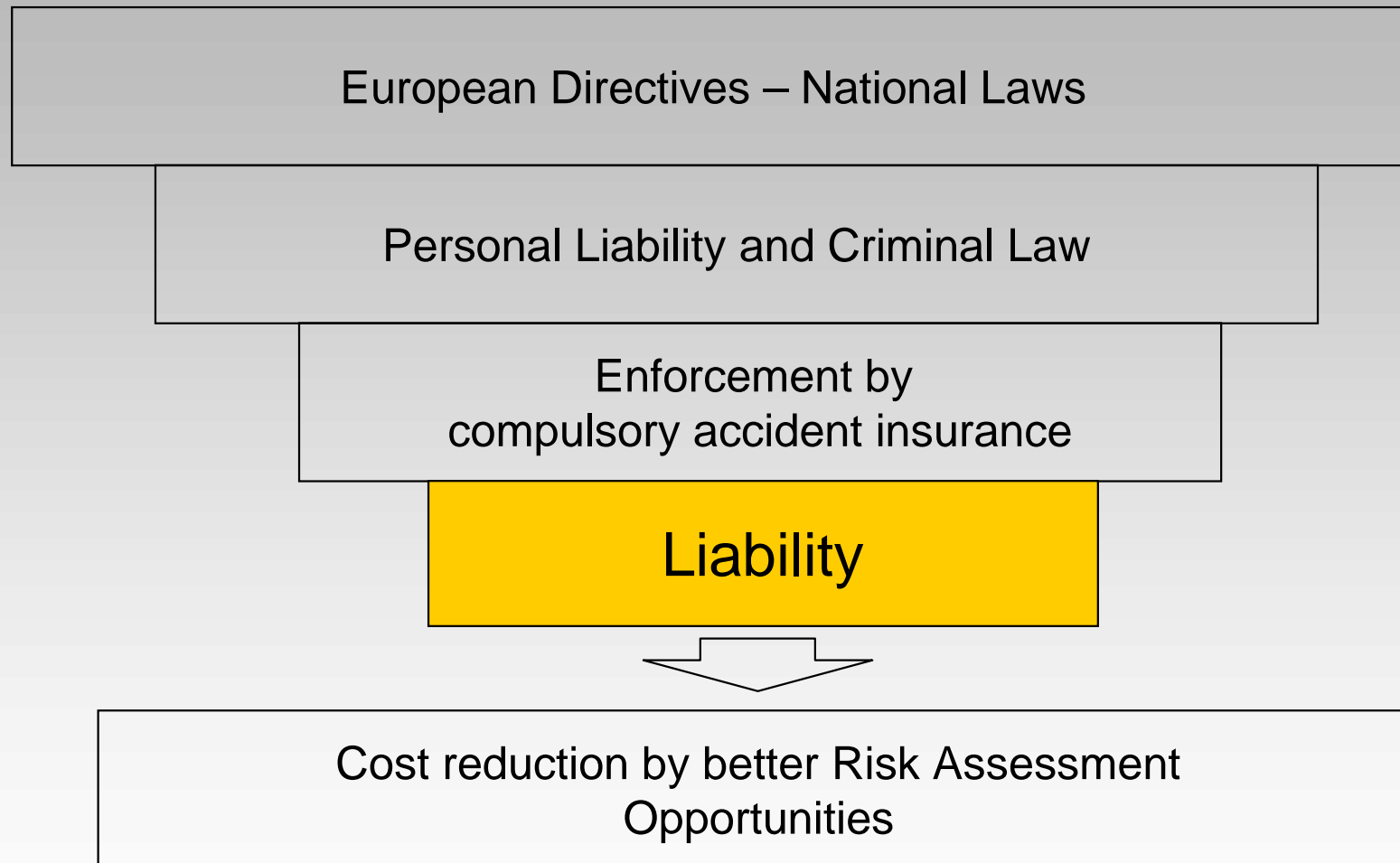
Basic Obligations

- Basic Obligations in Industrial Safety
 - determine, which regulations are to be applied
 - determine the hazards
 - check for less risky solutions
 - determine preventive measures
(covering employees, uninvolved persons, environment)
 - select, train and instruct personnel
 - provide for necessary resources
 - control and inspect the implementation of the defined measures
- Documentation
 - document the results of all safety-related activities



National Regulation





Contract & Product Liability

- ∅ Vendor friendly national Product Liability Law being replaced by Consumer friendly European Product Liability regulations.

Burden of proof for fault freeness is with the vendor

- ∅ Enforcement is weak.
Fines and compensations are very low.

High speed train accident in Eschede, Germany, 3.6.98,
101 fatalities, 105 injured

Volunteer compensation by Deutsche Bahn:

15,315.-- Euro per fatality – 23M Euro total

Court confirmed it as more than legally required.

Lawyers try to start a liability court case in the US.



Opportunity by Evolution of Standards

Standard Type	80s – today	90s – today	Today
Descriptive (Design) Principles to achieve safety	EN/IEC 60204 BIA Handbook TÜV Handbook	EN 954-1 DIN V VDE 0801	IEC 61508 IEC 62061 Draft EN 954-1
Test standard How to demonstrate safety by testing		EN 954-1 IEC 61131-2 EN 61496	
Performance based (semi-quantitative) What are related safety properties		EN 292	IEC 61508 IEC 62061 Draft EN 954-1

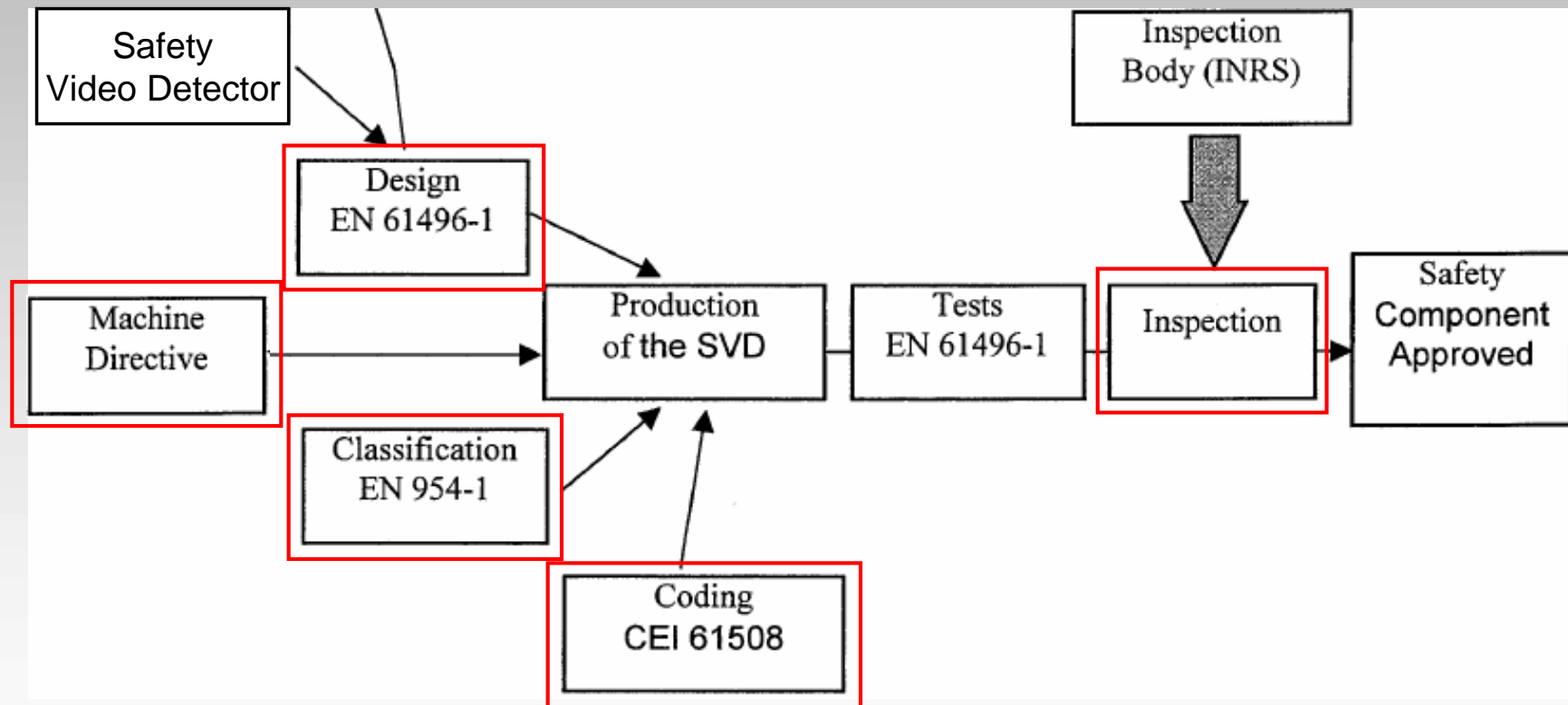
Where do Standards go?

- Ø IEC before EN – pre-developed by interest groups
Examples: Safety Fieldbus, IEC 61131-X Functional Safety of PLC
- Ø End-Users request Functional Safety standards
(in process industry in particular, IEC 61508, draft IEC 61511, ISA S84.01)
- Ø Generic, performance-based and complex (IEC 61508)
 - è Semi-quantitative
 - è Functional safety management oriented
 - è Application standards refer to these standards
- Ø Also Machine safety device vendors follow IEC 61508
 - è Marketing – distinguisher
 - è EN 954-1 doesn't yet specify requirement for complex, software-based safety devices

Functional Safety Standards

- ∅ Also Machine safety device vendors follow IEC 61508
 - è Marketing – distinguisher
 - è Withdrawal of the German computer safety standard DIN V VDE 0801 in 08.2004
 - è EN 954-1 doesn't yet specify requirement for complex, software-based safety devices
 - è Upcoming standards, draft EN 954-1, draft IEC 62061 take over the principles of IEC 61508

Where do Standards go?



Source: Gérard Ghibaudo
Safety Video Detector, secured camera detection system
and method for mechanical system control

Construction Industrielles de la Méditerranée – CNIM
France

Opportunity for Cost Reduction

ü Thorough Risk Assessment

- ü Semi-quantitative approaches introduced by IEC 61508/61511 avoid over-engineering and under-engineering (LOPA and calibrated Risk graph)
- ü Successful in process industry (e.g. SHELL, DOW Chemical)
 - ü Shell Global Solutions cut up to 20% from the cost of implementing safety systems. Extensive investigation showed that about 65% of safety functions are over-engineered while 10% are actually under-engineered and represent a weak link in the overall integrity management of the facility. Only 25% didn't require changes.
- ü Machinery industry still considers it as a burden
Consequence: Require Cat. 4 to be on the safe side
- Ü Strong request for services by safety equipment vendors**

Opportunities by New Technology

- ü Increase productivity by electronic safety devices
 - ü Timed Operation at presses
replace two-hand control by Light Curtains
- ü Increase flexibility by electronic safety devices
 - ü Replace safety mats and mechanical safe guards by Light Curtains and Laser Scanners
 - ü Replace mechanical safe guards by Vision Based Safety Devices (HONDA study, test houses: TÜV IT, INRS, BIA)

Opportunities by Reduced Time to Market

ü Situation

- ü Harmonized standards require no certification by Notified Body
- ü Harmonized standards do not yet sufficiently address new computer technology
- ü End-users require certainty for use of complex systems

ü Answer: IEC 61508

- ü World-wide acceptance is rapidly growing
Quantifies safety, enhances software development processes
draft EN 954-1, draft IEC 62061 follow
- ü State of the Art, open for tailoring, not allied to a Directive

- ü Vendors choose more pragmatic approaches,
e.g. Safety Case supported by Safety Service companies

