IKON#14
EU conformity

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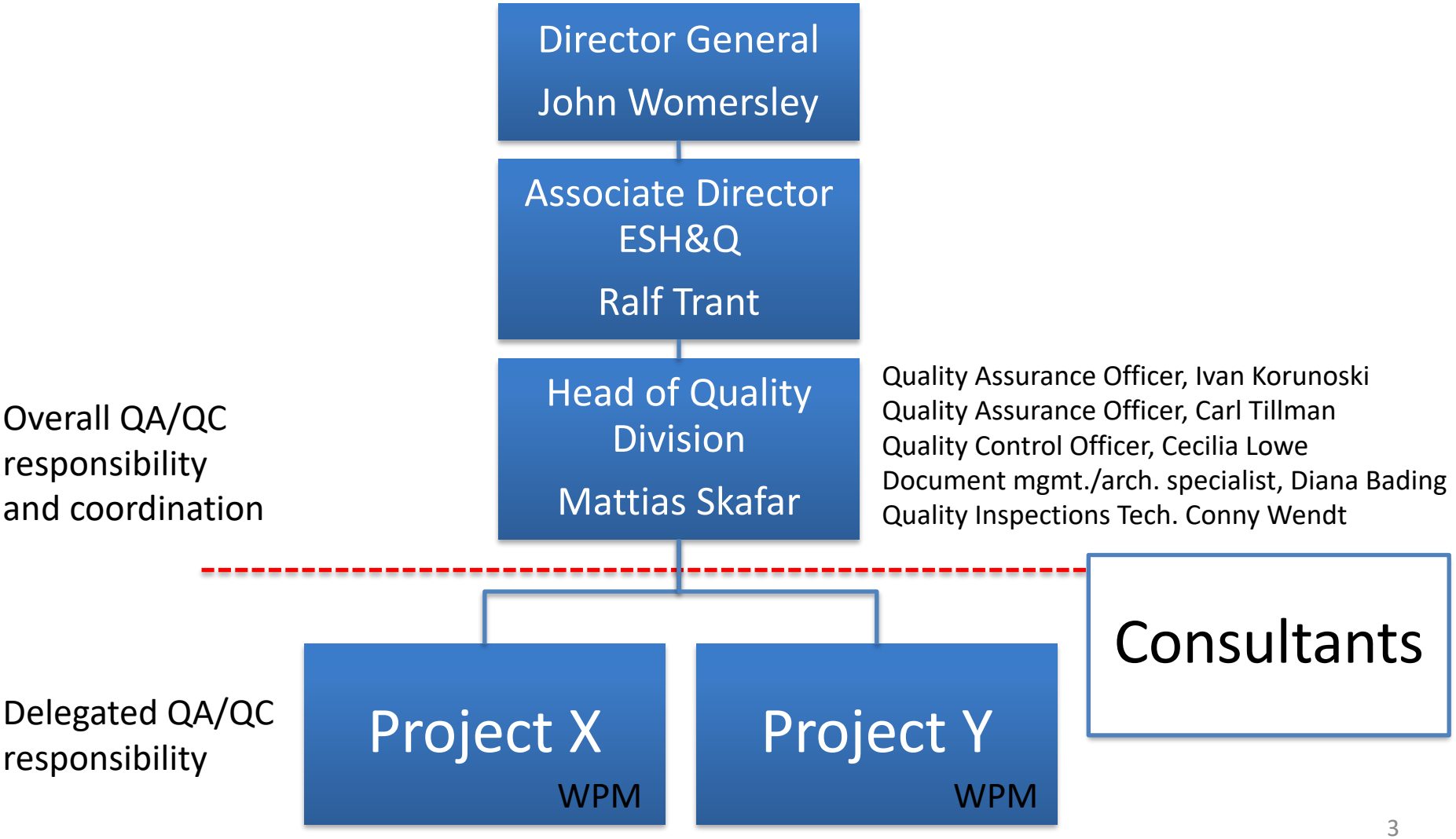
Agenda

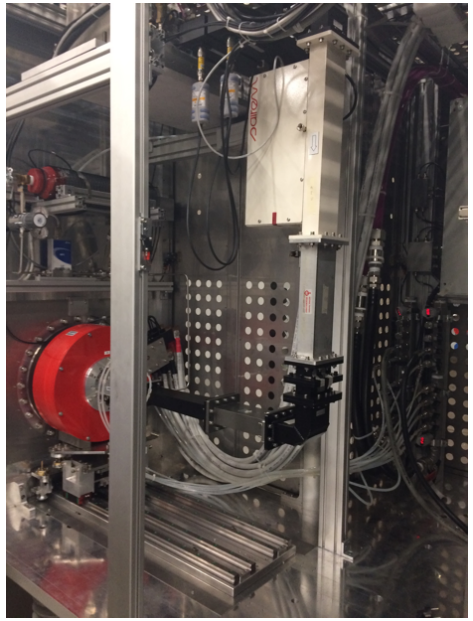
- ESS Strategy for Compliance to European Directives
  - Compliance Approach
  - Examples of potentially applicable Directives
  - Document Management
- Example/discussion
  - Fundamental questions
  - Risk assessment (template)
  - Installation/operation manual (template)
  - Declaration of conformity (template)

Organisation



ESS Strategy for CE Marking

- Approved by DG and ESS Management Team
- The Strategy (ESS-0103087) applies to:
  - Internal deliverables
  - Commercial contracts
  - In-Kind Contributions
- CE marking is mandatory.
  - when there is an applicable European Directive.
- The delivery shall include:
  - Risk assessment (ISO 12100)
  - Technical File, drawings, wiring diagram, P&ID, etc.
  - Operational Manual, in English
  - Declaration of Conformity



Ion Source INFN - LNS

CE marking Rule + 4 templates

Extract from Strategy doc.

- In order to support European Spallation Source ERICS's (ESS) vision, mission and core values, especially our commitment to excellence, all deliverables to ESS must comply with applicable European safety, quality and other directives, and we therefore require that they are CE marked accordingly.

- In exceptional cases, where the provider can present solid justification, CE marking can be exempted. However in any such cases, the mandatory risk assessment, technical file and related operational manual still need to be provided with the delivery.

- Any exemption shall be agreed between the two parties in writing and be approved by ESS. If no such agreement is present then CE marking is required.

Machinery Directive 2006/42/EC Exclusion:

Article 1.2(h) machinery specially designed and constructed for research purposes for temporary use in laboratories;

§ 60 Machinery for research purposes[10]

- *"The exclusion set out in Article 1 (2) (h) was introduced since it was not considered reasonable to submit to the requirements of the Machinery Directive[1] laboratory equipment specially designed and constructed for the needs of particular research projects.*

- *Consequently, the exclusion does not apply to machinery permanently installed in laboratories that may be used for general research purposes or to machinery installed in laboratories for purposes other than research such as, for example, for testing purposes.*

- *The exclusion only applies to equipment designed and constructed for temporary research use, that is to say, equipment that will cease to be used when the research projects for which it was designed and constructed have been completed."*

What does CE marking mean?

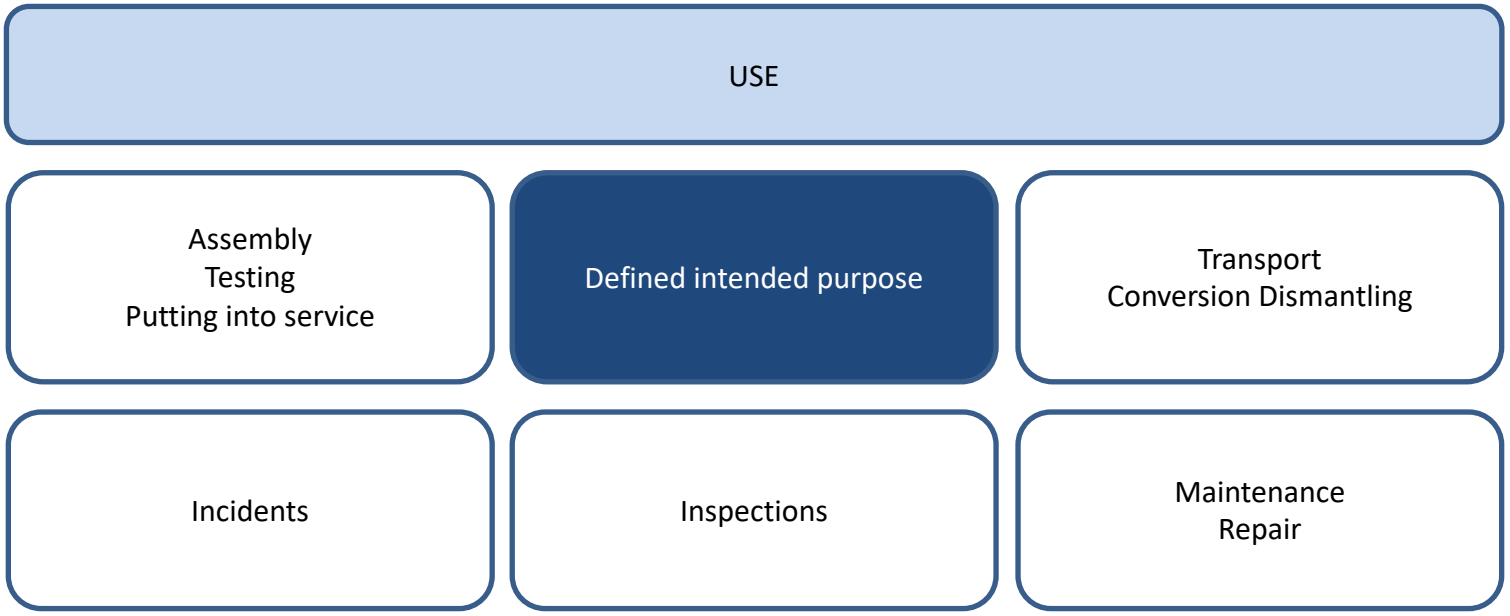
- The CE mark is a mandatory conformity marking for certain products placed **on the market** within the European Economic Area (EEA) since 1985. Sweden was adopting to the EU Directives in 1994.
- CE marking signifies that the product conforms with all EU Directives or EU regulations that **apply** to it.
    - Machine Directive, 2006/42/EC
    - Pressure Equipment Directive, 2014/68/EU
    - Low Voltage Directive, 2014/35/EU
    - EMC 2014/30/EU
    - ATEX Directive 2014/34/EU
- The **manufacturer** of CE marked goods has to verify that the product complies with all applicable EU requirements, such as safety, health and environmental protection.

On the market…

- According to the CE directives, a product has to comply with the EU Directives and have a CE-marking from the moment it is:
  - placed on the Community market for the first time;
  - put into service(use) in the Community market for the first time.
- Placing on the market is the initial action of making a product available for the first time, either for **payment** or **free of charge**.
- Putting into service(use) takes place at the moment of first use within the EEA by the end user.

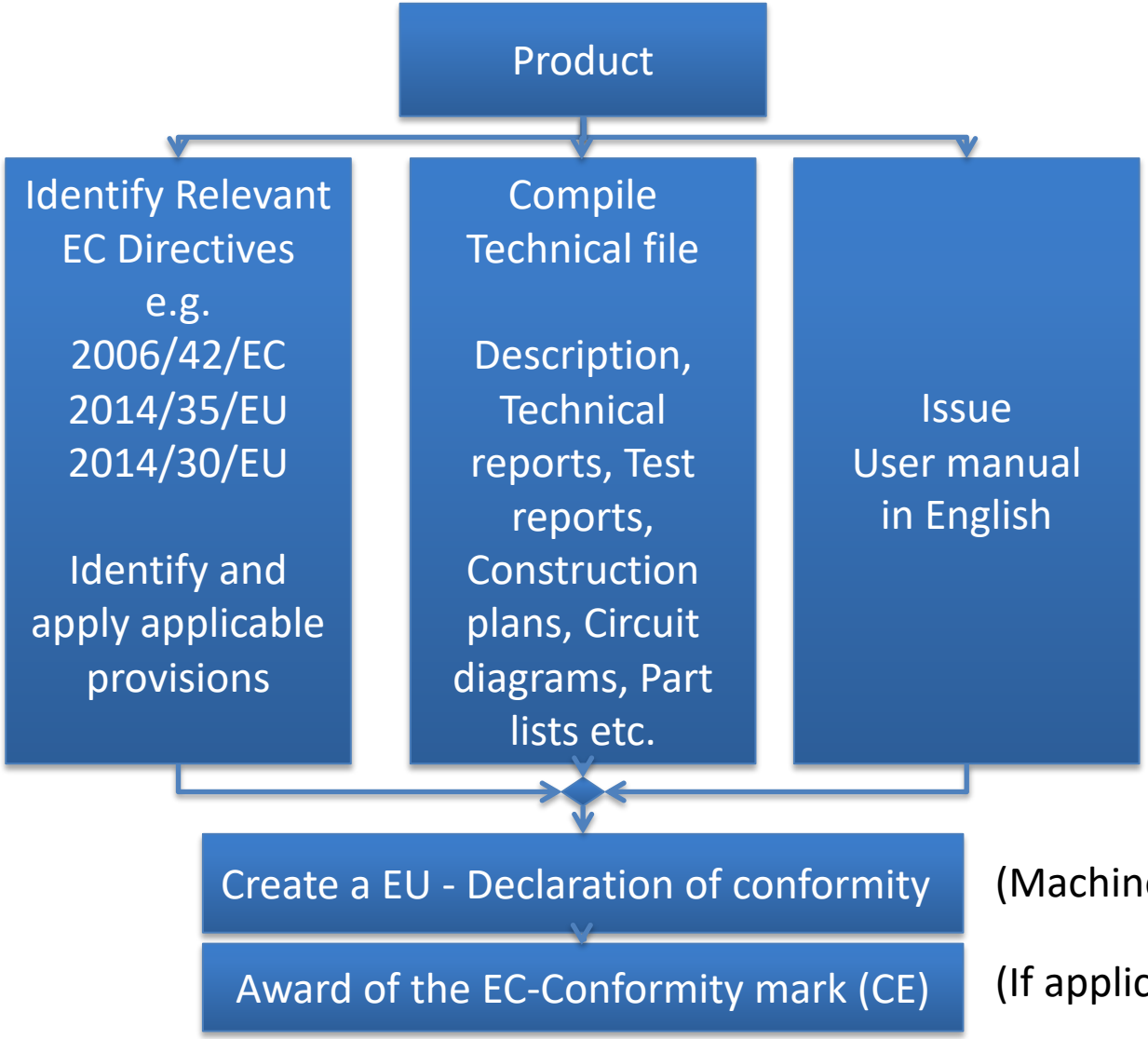
Put into service - USE

With regard to mechanical devices, the term „use” covers all of the activities shown in the diagram below, arising in connection with the use of the mechanical device.



Its clearly defined intended use is specified in the operating instructions or manual.

Workflow



(Machine or part of a machine)

(If applicable)

Declaration of Conformity – DoC (Declaration for Incorporation)

- Contributions needs to be delivered with a DoC
- Verifying that applicable directives and requirements have been applied by the supplier/IKC.
  - This will ease the integration process and secure that the **Manufacturer** of a deliverable have taken their responsibility for the delivery in terms of:
    - Essential safety and health requirements, always Annex 1 in Directive.
    - Quality requirements, as stated in Technical annex
    - Technical requirements , as stated in Technical annex
    - Compliance to European legislation/directives
- Applies for commercial and In-Kind deliveries

Why document management?

- ESS has several internal and external stakeholders requiring us to have our Management system and facility documentation structured and retrievable.
  - ESS organization itself
  - Swedish Radiation Authority - SSM
  - Swedish work environmental authority
  - Insurance company
- This to be able to show:
  - how the facility is built
  - how safety analysis and measures have been applied
  - how requirements have been met
  - how we intend to archive and plan for long term preservation of facility documentation
- This will give us the means to:
  - Install,
  - Operate,
  - Maintain,
  - Repair and update

} the facility in a safe and cost effective way.

Facility documentation

ESS definition on high-level (extract from ESS-0068713):

1. System Requirement Specification
2. Concept of Operation Description
3. System Architecture Description
4. System Detailed Design Descriptions
5. Non-Conformity Reports
6. Verification Report
7. Validation Report

Minimum requirement from SSM (req. 6-21 as identified in ESS-0121507):

- The term technical facility documentation refers to relevant drawings of the facility, its building structures, systems, components, and devices, as well as documentation showing how these have been manufactured, installed, and checked.
- Where applicable, information on any changes made to the facility should also be included in the documentation.
- The technical facility documentation should also include relevant process and flow charts, as well as the investigations and analyses that form the basis of safety analysis reports.

Documentation custody

- The manufacturer of machinery or his authorised representative shall keep the original EU declaration of conformity for a period of at least **10 years** from the last date of manufacture of the machinery.
- The manufacturer of partly completed machinery or his authorised representative shall keep the original declaration of incorporation for a period of at least **10 years** from the last date of manufacture of the partly completed machinery.

Liability

- Product Safety Act (2001/95/EC)
  - Manufacturer or entity putting product on the Market is liable for the safety of the product for 10 years from the date the product is made available to users.
- This means that everything slowly but surely will become ESS responsibility.
- Consequently, ESS needs the Technical doc.
- After these 10 years have passed National legislation regulating USE of the equipment applies.

CE – Steering documents

- ESS has issued a steering document describing the general approach:
  - ESS Rules for CE Marking
    - ESS-0127031
- Supported by four templates:
  - EU Declaration of Conformity (machine)
    - ESS-0145024
  - EU Declaration of Incorporation of partly completed machines
    - ESS-0145023
  - Signature card for EU Declaration of Conformity
    - ESS-0145020
  - Checklist for formal assessment of the EU conformity procedure
    - ESS-0145018

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Example

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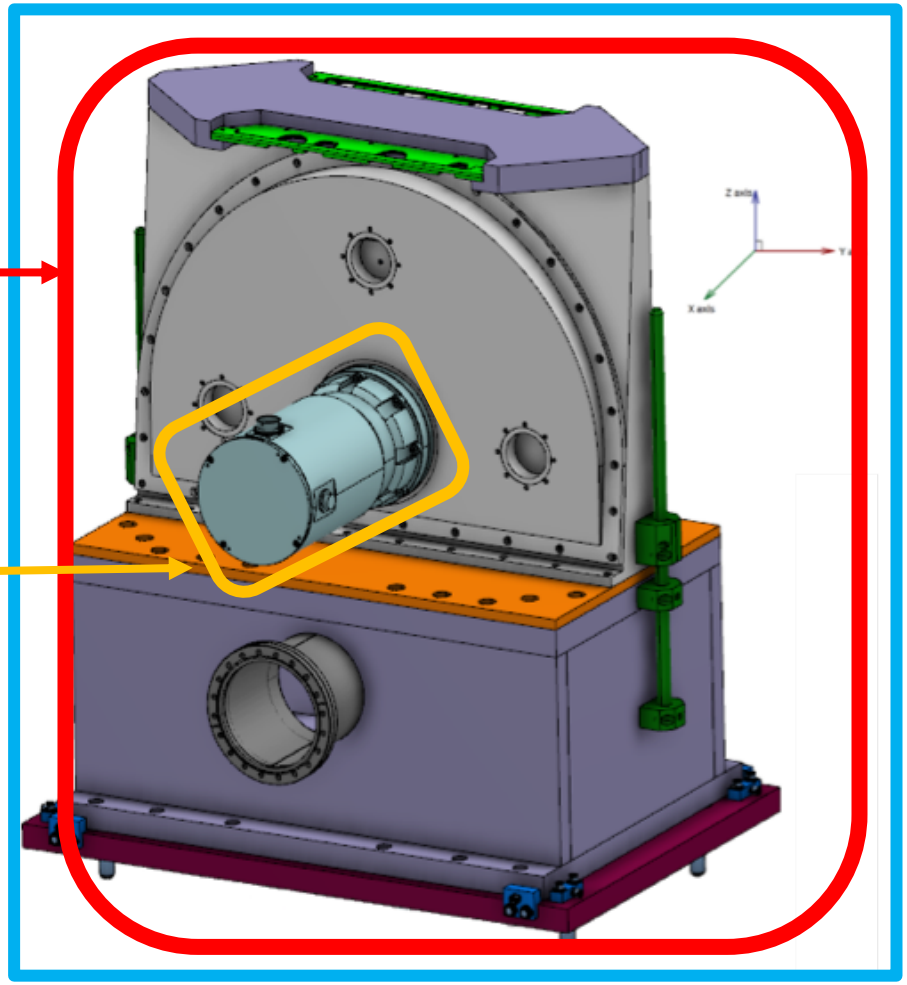
Example – Chopper unit

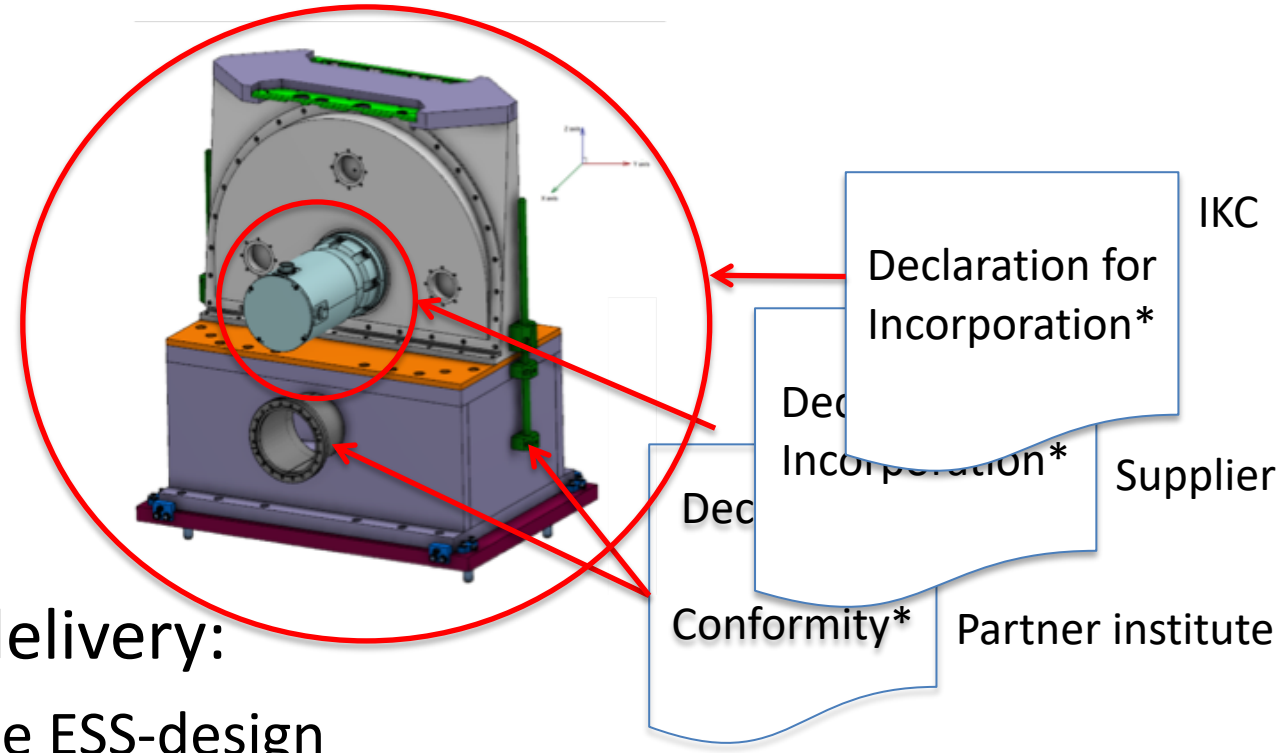
Installed chopper unit

Supplied Chopper unit

Subcontracted Chopper spindle



Example – Chopper unit



- Type of delivery:
  - In house ESS-design
  - In-kind Contributions
  - External provider(supplier)
  - COTS(Components Of The Shelf), CE marked

* Declaration for Incorporation for part of machine (to be incorporated) or Declaration of Conformity for a complete machine

Divide in Logical packages

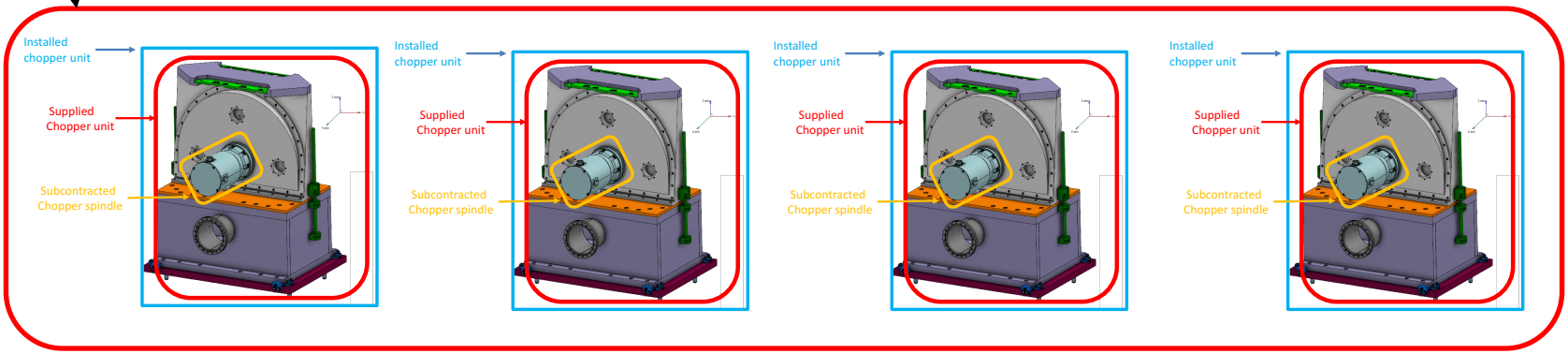
ESS level

Declaration of Conformity

* Declaration of Conformity for part of machine (to be incorporated) or a complete machine

Installed chopper system

IKC A*	IKC B*	IKC C*	IKC D*
Declaration for Incorporation	Declaration for Incorporation	Declaration of Conformity	Declaration of Conformity



Fundamental questions…

- Powered by non human(animal) effort?, MD
- Moving parts?, MD
- Safety component?, MD/ATEX/LVD
- Lifting accessories?, MD
- Explosive atmosphere?, ATEX/LVD
- Potentially explosive atmosphere?, ATEX/LVD
- Emitting electromagnetic disturbances? EMC
- Voltage between 50 and 1000V AC, 75 and 1500 DC? LVD
- Pressure greater than PS 0,5 bar?, PED

MD – Machine Directive, LVD – Low Voltage Directive, PED - Pressure Equipment Directive, ATEX – **AT**mosphères **Ex**plosibles Directive

Risk assessment - Approach

- Define Intended use, limits and boundaries
- Hazard identification
  - Multidisciplinary group, mechanical, electrical, fire.
- Risk assessment
  - EN ISO 12100 (recommended)
  - ISO/TR 14121-2 (recommended)
- Method description
  - FMEA, HAZOP, FTA etc.
- Risk reduction
  - by design measures
  - by containment, protective measures
  - by information, administrative measures
- Declaration
  - Declaration of Conformity (machine)
  - Declaration for incorporation (part of machine)

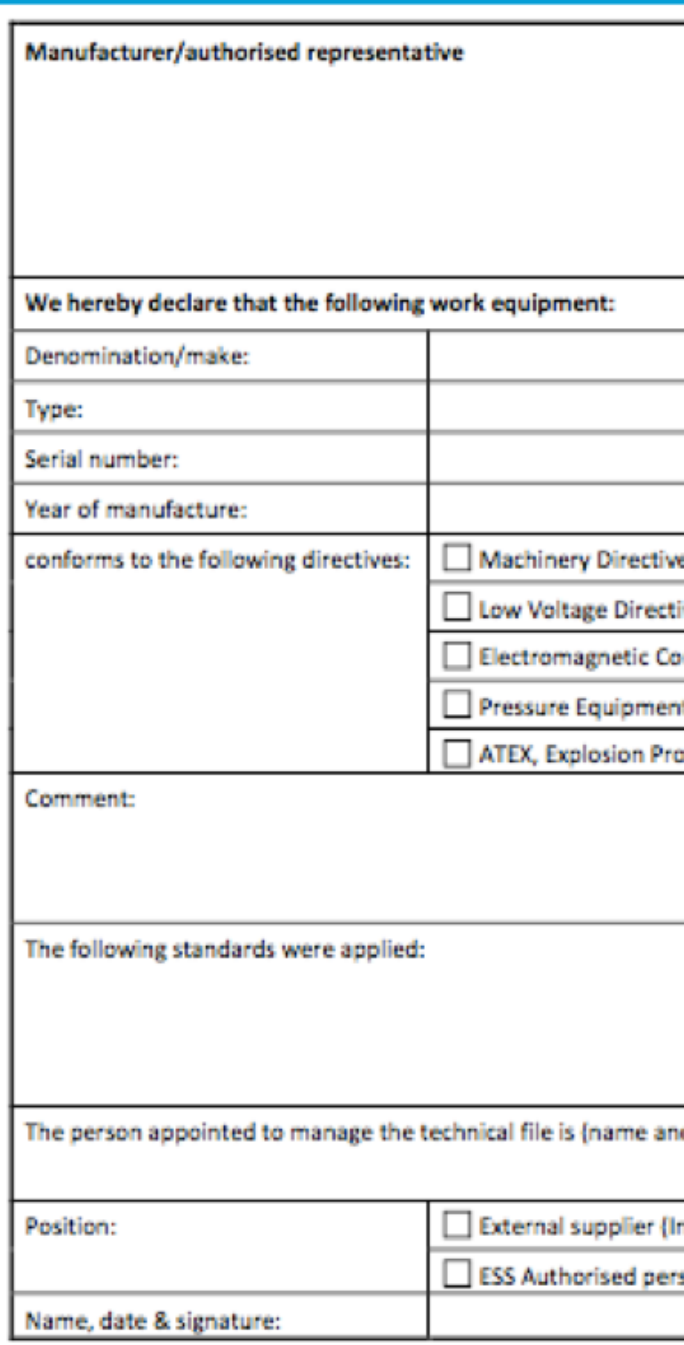
Essential Safety and health requirements

Extract from MD Annex 1

- Designed to handle intended use
- Ergonomics
- Control systems
- Stopping
- Assembly
- Power loss
- Stability
- Moving parts
- Guards
- Electrical, temperature, vibration risks
- Fire, explosion
- Emissions
- Radiation
- Warning of residual risks
- Instructions

Declaration of Conformity ESS-0145024

- External Provider
- Identity of product
- Applied Directives
- Used standards
- Person responsible for tech. file
- Signature



Manufacturer/authorised representative	
We hereby declare that the following work equipment:	
Denomination/make:	
Type:	
Serial number:	
Year of manufacture:	
conforms to the following directives:	☐ Machinery Directive
	☐ Low Voltage Directi
	☐ Electromagnetic Co
	☐ Pressure Equipmen
	☐ ATEX, Explosion Pro
Comment:	
The following standards were applied:	
The person appointed to manage the technical file is (name an	
Position:	☐ External supplier (I
	☐ ESS Authorised pers
Name, date & signature:	

Declaration for Incorporation ESS-0145023

- External Provider
- Identity of product
- Specify what essential req. of Machine Dir. have been met
- Important notice
- Person responsible for tech. file
- Signature

Manufacturer/authorised representative:	
Description of the machinery:	
Denomination/make:	
Type:	
Serial number:	
Year of manufacture:	
We hereby declare that the following essential requireme met:	
Comments:	
Important notice: The partly completed machinery must not be put into serv incorporated has been declared in conformity with the pr	
The person appointed to manage the technical file is (nam	
Position:	☐ External suppli
	☐ ESS Authorised
Name (in block letters)	
Date & signature:	

Signature card for EU Declaration of conformity, ESS-0145020

- Identity
- Responsible to select Directives
- Risk assessment/discipline
- Notified Body Y/N
- Monitoring by WP
- Monitoring by Line Manager

Please sign the appropriate box to confirm that you are respon completed the task concerned for:				
Machine/ equipment:				
Type:				
Serial number:				
Year of construction:				
Task	**Required?**		**Name**	**Posi**
	Yes	**No**		
Selections of directives to be applied	☐	☐		
Risk evaluation (risk assessment/ safety strategy), selection of and co				
For the mechanical design	☐	☐		
For the mechanical production	☐	☐		
For the electrical engineering	☐	☐		
For the controls	☐	☐		
For the pneumatics	☐	☐		
For the hydraulics	☐	☐		
Production of documentation	☐	☐		
Inclusion of notified body (Annex IV of the Machinery Directive, Pressure Equipment Directive, etc.)	☐	☐		
Monitoring and objective assessment of the procedure by the coordinator responsible in the organisational unit (Documentation of project responsibility)	☐	☐		
Monitoring and formal assessment of the procedure by the line manager of the coordinator in the organisational unit (Documentation	☐	☐		

Checklist for formal assessment of the procedure, ESS-0145018

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- Applied Directives
- Technical file
- Risk assessment
- Instructions
- Signature

	Yes	No	N/A
Circuit diagrams	☐	☐	☐
Standards	☐	☐	☐
Required inspections for installation and operation	☐	☐	☐
The CE procedure has been conducted in accordance with the directive(s). A CE mark will be affixed.	☐	☐	
Comments:			
Position:	☐ External supplier (In-kind / Supplier)		
	☐ ESS Authorised person		
Name, date & signature:			

Applicable directives	**Yes**	**No**	
Machinery Directive 2006/42/EC	☐	☐	
Low Voltage Directive 2014/35/EU	☐	☐	
Electromagnetic Compatibility Directive 2014/30/EU	☐	☐	
Pressure Equipment Directive 2014/68/EU	☐	☐	
ATEX, Explosion Protection Directive 2014/34/EU	☐	☐	
	☐	☐	
Technical work equipment, experiments, machinery, safety components, etc.	**Yes**	**No**	**N/A**
Ready for use	☐	☐	☐
Still being developed	☐	☐	☐
Is used in research centre	☐	☐	☐
Is used outside research centre	☐	☐	☐
Might be provided to third parties	☐	☐	☐
Might be sold to third parties	☐	☐	☐
Risk assessment	**Yes**	**No**	**N/A**
Risk analysis has been produced	☐	☐	☐
Risk has been evaluated	☐	☐	☐
Protective measures have been described and implemented	☐	☐	☐
Residual risk after mitigation	☐	☐	Ref. doc.:
Instructions	**Yes**	**No**	**N/A**
Assembly	☐	☐	☐
Installation	☐	☐	☐
Operation and Maintenance	☐	☐	☐
Breakdown	☐	☐	☐
Decommissioning	☐	☐	☐
Disposal	☐	☐	☐
Drawings	☐	☐	☐

Supporting documents cont.

- Risk assessment -template
- User Manual - template

Support – Provided by ESS

- ESS – Consultant, in Lund
  - Available for consultation, risk assessment etc.
- Expert panel
  - Discipline experts Electrical, Mechanical, ATEX, EMC etc.
  - Will be composed in Lund by ESS staff and relevant consultants
  - Chaired by Quality Division
- Steering Documents, templates and checklists

Bulk of work still resides with the IKC

Thank you for your time!

and now...

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