ESS RULES FOR CE MARKING

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1. INTRODUCTION

In numerous laboratories, facilities and installations in fields where the line between distinct areas of research and technology is blurred, the protective measures that have to be taken sometimes differ from the common practice measures. This is because the research buildings/equipment use new approaches that do not always allow the customary solutions to be implemented. Research facilities, especially large research centres, construct and operate buildings and equipment to be used for research purposes. The existing legislation governing equipment and product safety and workplace safety does not completely cater for the special requirements prevalent in research activities. In particular, the Machinery Directive[1] and corresponding AFS 2008:3[2], the provision with which the Machinery Directive is transposed into Swedish law, needs to provide more specific detail on this aspect.

This document aims to provide support for managerial staff on how to meet the legal requirements whilst also taking into account the conditions specific to research and development settings. At European Spallation Source ERIC (ESS) the Director General and the ESS Management Team have agreed on a strategy[3] to require CE-marking on all deliveries where there are applicable EU Directives, this has been done to secure that all deliveries follow European Law and are compliant with stated quality and safety requirements.

This Rule is subordinated to and in line with the ESS Policy for Safety, Health and Security[4] and the ESS Policy for Quality[5].

2. DEFINITIONS

Manufacturer/distributor

As defined by law, the managing directors or board members are the manufacturer/distributor of equipment designed for research purposes. Duties arising from this responsibility can be transferred in writing to reliable and competent persons. The legal requirements are set out in EU Directives and the provisions relating to it. The EU Directives stipulates safety requirements for products and equipment, which manufacturers/distributors of machinery, electrical equipment, pressure equipment and other equipment are obliged to be compliant. In accordance with the EU Machinery Directive, manufacturers and importers of machinery and equipment (including safety components) are responsible for conformity. A declaration of conformity *(Annex 1)* and a CE mark on the product or, in the case of partly completed machinery, a declaration of incorporation *(Annex 2)* serve as confirmation by the manufacturer that its machinery/equipment meets the requirements of the applicable EU directives. In certain cases, conformity has to be assessed by external bodies but usually the manufacturers issue the declarations themselves.

Operator

The managing directors or board members are deemed to be the operators of equipment designed for research purposes. Consequently, they are responsible by law for occupational health and safety. Duties arising from this responsibility can be transferred in writing to reliable persons who are competent in the specific field concerned.
The legal requirements are set out in the Work Environmental Act[6] this is regulated in Sweden thru SFS 1997:1160[7]. The Work Environmental Act stipulates requirements regarding the safe operation and periodic inspection of work equipment and devices requiring special monitoring.

On the market

According to the European Directives, a product has to comply with the CE requirements 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 European Economic Area (EEA) by the end user. In this context ESS is considered to be “on the market”.

Use

With regard to mechanical devices, the term “use” covers all of the activities shown in the *figure 1* below, arising in connection with the use of the mechanical device. It is clearly defined “intended use” is specified in the operating instructions.
The safe state of the mechanical device is required to be maintained during use. Damage can be identified in good time, enabling action to be decided on and carried out, by means of inspections. The risks involved in using the device are determined and assessed with the help of a user risk assessment, taking into account the specific operating methods, and necessary protective measures are then identified.

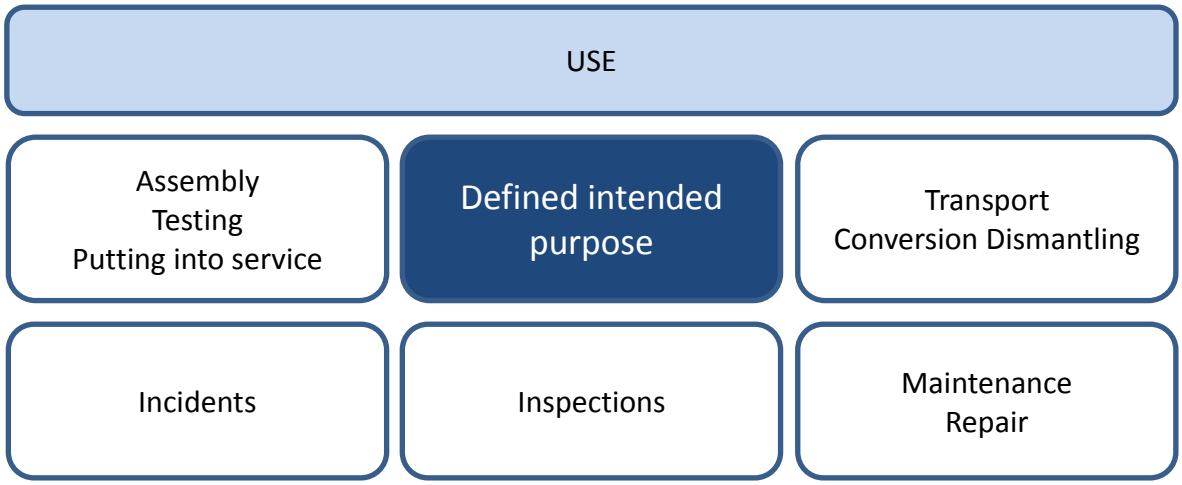

Figure 1. Definition of the term Use.

Manufacturer risk assessment

A risk assessment has to be carried out by the manufacturer of the equipment in line with EN ISO 12100[8] or equivalent. It comprises a risk analysis, risk evaluation and the resulting measures to reduce risk and identification of the residual risks. The residual risks are documented in the operating instructions. The manufacturer risk assessment only covers the risks posed by a piece of equipment. Any additional hazards due to interaction between the equipment and other factors during operation must be recorded in the operator's risk assessment.

User/operator risk assessment

The operator of the equipment is responsible for this assessment. It covers all hazards arising during use, the residual risks described in the instructions and any hazards arising from the work environment. The operator must also keep a record of the findings of the assessment, the measures the operator has identified as necessary and the results of activities to monitor compliance with the measures.

Notified bodies

A notified body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required. The European Commission publishes a list of such notified bodies. Notified bodies' role in the conformity assessment is either to approve and monitor the manufacturer's quality assurance system or to perform product testing.

Accredited bodies

As opposed to notified bodies, accredited bodies are accredited to conduct periodic inspections of equipment requiring special monitoring (including the inspections performed prior to the equipment being put into service for the first time or re-commissioning), in accordance with the EU Directives. This includes, for example, inspection of pressure equipment, which, due to the pressure-volume product, is no longer allowed to be inspected by in-house personnel. This is regulated nationally and in Sweden enforced thru AFS 2017:3[9].

Qualified person

In the Work Environment Act[6] the role of a "qualified person" is defined in this context. A qualified person is someone whose training, experience and recent professional activity give them the expertise necessary to inspect work equipment. The requirements for qualified persons are specified in detail in technical standards depending on the discipline they handle i.e. Pressure Directive etc. they cover general requirements for qualified persons plus additional qualifications required in work environments where there are explosion and/or pressure hazards. Where a device has to be inspected by a notified body, responsibility for correct inspection lies with the accredited organisation commissioned to perform the inspection work, i.e. the notified body.

The various areas of responsibility in the manufacturing process should be documented. A signature card of the kind illustrated in *Annex 3* can be used for this purpose. The tasks described in this section are not part of the duties to be performed by the safety specialist defined in the Work Environment Act[6]. If the safety specialist does perform one of the above-mentioned functions, it should by clearly defined in a job description and should be seen as distinct from his or her tasks as a safety specialist.

Temporary use

Temporary use in the laboratory means “not permanent “. The main factor to be considered here is the overall duration of the experiment. Generally speaking, “temporary” is taken to mean a period of no more than three years.

Laboratories

The term “laboratories in research facilities” is at ESS taken to mean not only laboratories in the narrow sense, but also other areas (buildings or sites) in which experiments are carried out. Such areas might be, for example, large-scale laboratories, buildings for experiments and the particle accelerator or sites used for fieldwork and outdoor experiments.

3. ORGANISATION

The Machinery Directive[1] does not specify which particular organisational measures should be taken to ensure that only machinery that meets the legal requirements is placed on the market. The employer is responsible for the conformity procedure. The employer or a person authorised by him/her signs the declaration of conformity. The declaration shall also specify the person responsible for the technical documentation.

4. LEGALLY COMPLIANT PROCUREMENT AND MANUFACTORING

The requirements for legal compliance are defined in the EU Directives and include a declaration of conformity/incorporation. Equipment specifically designed and built for research purposes and intended for temporary use (*see chapter 6)* in laboratories only is exempt from the Machinery Directive[1]*, see §60 below.*

> ***§ 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."

A documented agreement between the external provider and ESS needs to be signed if the delivery is deemed to be designed and constructed for temporary research use and therefor excluded in accordance to §60.

Equipment designed for research purposes is often subject to a lengthy, ongoing development process. Safe research activity in line with the health and safety and accident-prevention regulations must be guaranteed during that process but a declaration of conformity as required by the Machinery Directive[1] is not necessary during that process.

If equipment designed for research purposes, or parts thereof, has/have to be relocated as part of a joint experimental development project and ownership changes as a result, a declaration of conformity/incorporation is required. The principles laid out in *chapter 6* must be applied when procuring or manufacturing equipment designed for research purposes.

5. PROCUREMENT OF SCIENTIFIC EQUIPMENT FROM NON-EEA STATES

If equipment is purchased from outside the European Economic Area (EEA), the purchase contract should stipulate that the manufacturer must meet the EEA requirements and conduct the conformity procedure.

If this is not possible, the research institute, being the entity that places the equipment on the EEA market (i.e. the distributor), is responsible. It must provide evidence of conformity and produce the declaration of conformity (in other words, applying this rule document)

In case of equipment designed for research purposes that does not meet European Community directives and for which the conformity procedure cannot be conducted, the operator must observe the Swedish health and safety and accident-prevention regulations and guidelines, agreed in collaboration with ESS. The equipment must be inspected by a qualified person appointed by the operator or by an independent testing body before being put into service.

6. MANUFACTORING OF EQUIPMENT DESIGNED FOR RESEARCH PURPOSES

The steps below must be performed for equipment manufactured and designed for research purposes.

1. Classify the equipment:

    - Which EU Directive(s) applies?
    - Is CE marking necessary?
        - If yes: follow steps 2 – 7
        - If no: follow steps 2 – 6

2. Conduct the risk assessment (in accordance with EN ISO 12100[8], or equivalent).
3. Identify the standards to be applied and apply them (selection of materials, dimensioning, safety components, etc.).
4. Compile technical documentation *(see chapter 8)* which is handed over to ESS together with the delivery of the hardware.
5. If appropriate, bring in a notified body *(see chapter 2 and Annex IV of the Machinery Directive[1])*.
6. Draw up operating instructions (or assembly instructions in the case of partly completed machinery) and give them to the operator. The operating instructions must be written in a language acceptable to the operator and understandable for the users. At ESS the official project language is English(UK).
7. Produce declaration of conformity/incorporation and get it signed (employer) and affix the CE mark if required *(Annexes 1 and 2)*. When obtaining the signature, it is useful to conduct a formal check as well as the technical inspection *(Annex 4)*.

The person responsible for the manufacturing must ensure that this approach is adhered to. Responsibilities for the technical implementation of each design and manufacturing phase should be documented in writing. The conformity procedure described must also be adhered to in the case of an In-Kind collaboration agreement.

6.1. Flow chart

A flow chart that describes necessary steps/activities to be performed to be compliant with this approach is presented in *Figure 2*. For reasons not foreseen by this document it might be logic to perform the steps/activities in another order, therefore is the order described in the flow chart not mandatory as long as the final outcome comply with the intent of this rule document.

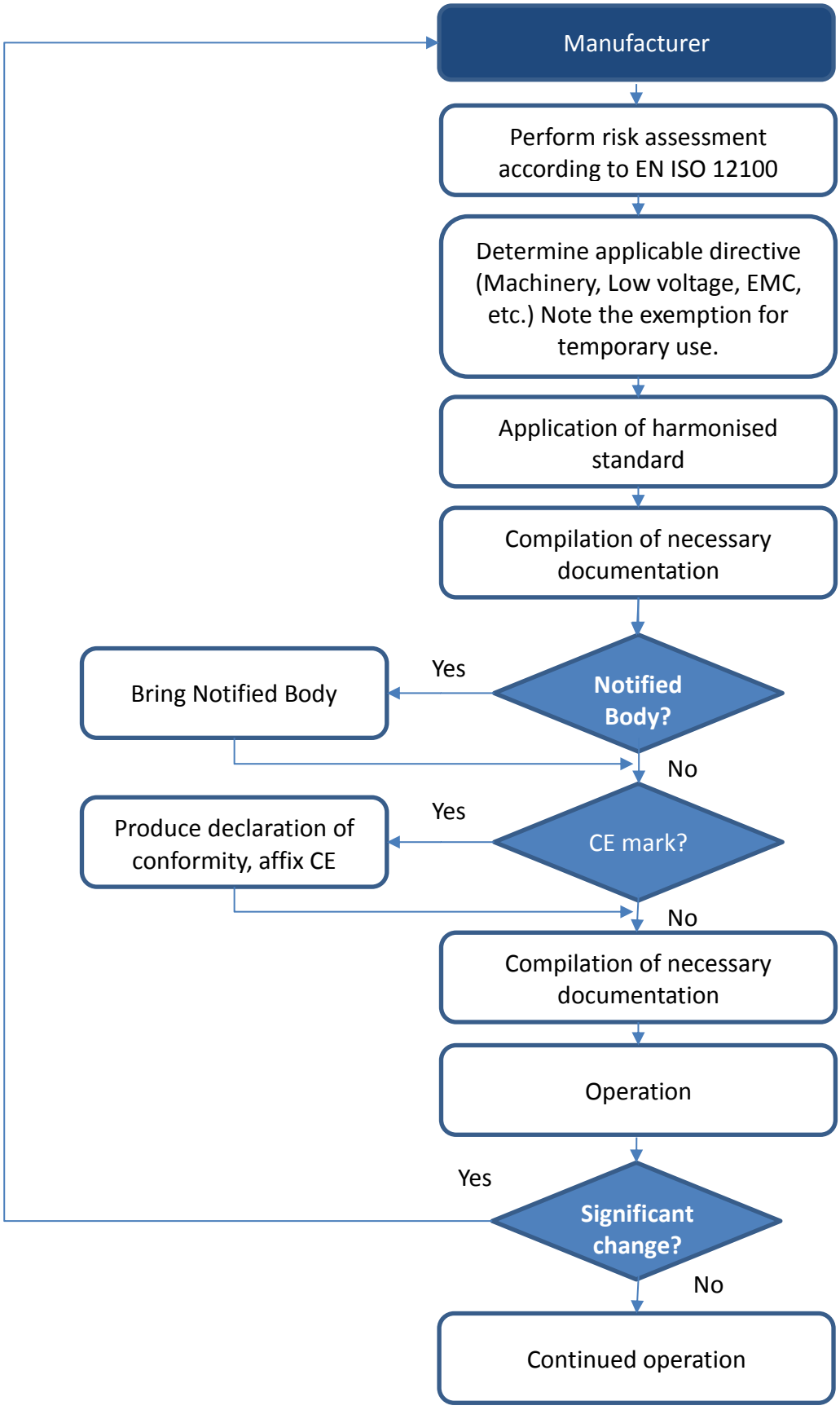

Figure 2. Flow chart, Manufacturing equipment for research purposes.

6.2. Components and Subassemblies

Where experiments use unusual/one-of a kind components/subassemblies, the following distinctions must be made.

6.2.1. Testing Devices

Testing devices (e.g. motorised specimen holders), are produced as prototypes or in small quantities. Examples of such devices could be support devices, assemblies or modified series produced parts that are used in a pre-experimental set-up. The question of whether certification is required has to be decided on a case-by-case basis i.e. considering temporary use, *see chapter 2.*

6.2.2. Add-on parts

Components of the shelf (COTS) or add-on parts, are series-produced parts (pumps, drives, power packs, etc.) purchased from an industrial manufacturer including add-on parts that are clearly definable as machinery. They always require CE certification. Add-on parts also include laboratory and workshop equipment, such as machine tools, appliances and measuring instruments.
Please take note of the following with regard to “equipment specifically designed and built for research purposes and intended for temporary use, *see chapter 4*.

7. COMMON LEGISLATION AND PROVISIONS

7.1. Machinery Directive, 2006/42/EC[1] (Swedish implementing provision, AFS 2008:3[2])

The Machinery Directive 2006/42/EC is a European Union directive concerning machinery and parts of machinery. Its main intent is to ensure a common safety level in machinery placed on the market or put in service in all member states and to ensure freedom of movement within the European Union by stating that "member states shall not prohibit, restrict or impede the placing on the market and/or putting into service in their territory of machinery which complies with the Directive".

The directive applies to machinery as well as interchangeable equipment, safety components, lifting accessories, chains/ropes/webbing, removable mechanical transmission devices and partly completed machinery.

7.2. Electro Magnetic Compatibility Directive, 2014/30/EU[11]

Though declarations of conformity and CE marks are not required for fixed installations due to their special nature, the installations do have to meet the protection requirements. This is normally the case if the individual components are CE-certified and have been assembled in accordance with good electrical engineering practice. If the individual components are intended to be incorporated into affixed installation and are not commercially available, placed on the market, they do not have to be CE-certified. However, there must be instructions and precautions in place to ensure that the equipment can be operated in accordance with the EMC law when the component has

been incorporated. European Union Member States shall take all appropriate measures to only put equipment on the market or into service if it complies with this Directive when properly installed, maintained and used for its intended purpose.

7.3. Low Voltage Directive 2014/35/EU[12] (Swedish implementing provision ELSÄK-FS 2016:1[13])

The Low Voltage Directive applies to electrical equipment placed on the market and used with a rated voltage: between 50 and 1,000 V in the case of an alternating current, and between 75 and 1,500 V for a direct current. The above-mentioned voltage ranges refer to the rated input and output voltage of the equipment. The voltages inside may be higher than the rated voltage. The definition of “placed on the market” means any supply of electrical equipment for distribution, consumption or use on the European Union market in the course of a commercial activity, whether in return for payment or free of charge.

7.4. Pressure Equipment Directive 2014/68/EU[14] (Swedish implementing provision AFS 2016:1[15])

The Pressure Equipment Directive applies unconditionally to equipment designed for research purposes.

The Directive shall be applied to all design, manufacture and conformity assessment of pressure equipment and assemblies with the maximum allowable pressure greater than 0,5 bar gauge. It also sets the administrative procedures requirements for the "conformity assessment" of pressure equipment, for the free placing on the European market without local legislative barriers.

The content of the necessary documentation for the Directives mentioned above is presented in *chapter 8.*

7.5. Further legislation and ordinances that can be applicable

- Simple Pressure Vessels Directive 2014/29/EU[16], (Swedish implementing provision AFS 2016:2[17])
- ATEX, Explosion Protection Directive 2014/34/EU[18], (Swedish implementing provision AFS 2016:4[19] and ELSÄK-FS 2016:2[20])
- Medical Devices Directive 93/42/EEC[21]
- etc.

8. DOCUMENTATION REQUIREMENTS FOR RELEVANT EU DIRECTIVES

Content of documentation as per Machinery Directive	Content of documentation as per Low Voltage Directive	Content of documentation as per Pressure Equipment Directive*
1. Declaration of Conformity	1. Declaration of Conformity	1. Declaration of Conformity
2. Signature card, see annex 3	2. Signature card, see annex 3	2. Signature card, see annex 3
3. Description of function	3. Instructions 3.1 General description of the equipment. 3.2 Assembly. 3.3 Installation. 3.4 Operation. 3.5 Breakdown. 3.6 Decommissioning. 3.7 Disposal.	3. Description of function
4. List of standards applied	4. Technical documentation 4.1 Drawings. 4.2 Descriptions. 4.3 Standards. 4.4 Result of design calculations. 4.5 Result of examinations and test reports. 4.6 Technical documentation for purchased parts. 4.6.1 Declarations of Conformity. 4.6.2 Declarations of incorporation and assembly instructions.	4. List of standards applied
5. Risk assessment 5.1 Description of method applied (ISO 12100**). 5.2 List of essential health and safety requirements. 5.3 Description of the protective measures performed. 5.4 Description of residual risks.	5. -	5. Hazard analysis 5.1 List of hazards. 5.2 Assessment of hazards. 5.3 Protective measures. 5.4 Residual risks.
6. Instructions 6.1 General description of the equipment 6.2 Assembly. 6.3 Installation. 6.4 Operation and Maintenance. 6.5 Breakdown.	6. -	6. Operation instructions 6.1 Mounting including assembly of different pieces of pressure equipment. 6.2 Putting into service. 6.3 Use. 6.4 Maintenance, including check lists.

6.6 Decommissioning. 6.7 Disposal.		6.5 Technical details. If appropriate, indications of misuse.
7. -	7. -	7. Technical documentation (depending on module) 7.1General description of the pressure equipment 7.2 Conceptual design and manufacturing drawings and drawings of components, subassemblies and circuit diagrams. 7.3 Descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment 7.4 Description of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in article 5 have not been applied. 7.5 Results of design calculations made, examinations carried out, etc. 7.6 Test reports
* Minimum requirements, for **safety SSC´s** additional requirements are mandatory. Consult ESS Quality Division for clarification if needed. ** Recommended.		

Figure 3. Comparison of document requirements for common EU Directives.

9. GLOSSARY

Term	Definition
AFS	Arbetsmiljöverkets Författnings Samling, Swedish Work authority's provision
COTS	Components Of The Shelf
EEA	European Economic Area
ESH	Environment, Safety and Health
ESS	European Spallation Source ERIC
EU	European Union
SFS	Svensk Författningssamling, Swedish code of statutes
SSC	System, Structure or Component
Q	Quality Division

10.ANNEXES

Annex 1: ESS-0145024, EU Declaration of Conformity, template
Annex 2: ESS-0145023, EU Declaration of Incorporation, template
Annex 3: ESS-0145020, Signature card for EU Declarations of Conformity, template
Annex 4: ESS-0145018, Checklist for formal assessment of the EU conformity procedure

11.REFERENCES

[1] 2006/42/EC, Machinery Directive
[2] AFS 2008:3, Swedish Work authority's provision
[3] ESS-0103087, ESS Strategy for CE marking
[4] ESS-0019190, ESS Policy for Safety, Health and Security
[5] ESS-0000126, ESS Policy for Quality
[6] Work Environment Act, National work environment legislation
[7] SFS 1997:1160, Swedish Work Environment Act
[8] EN ISO 12100, Safety of Machinery – General principles for design – Risk assessment and risk reduction
[9] AFS 2017:3, Swedish Work authority's provision for Use and control of Pressurised devices. See ESS-0177972 for an unofficial ESS English translation
[10] Guide to application of the Machinery Directive 2006/42/EC
[11] 2014/30/EU, Electro Magnetic Compatibility Directive
[12] 2014/35/EU, Low Voltage Directive
[13] ELSÄK-FS 2016:1, The Swedish National Electrical Safety Board's regulations on Electrical equipment.
[14] 2014/68/EU, Pressure Equipment Directive
[15] AFS 2016:1, Swedish Work authority's provision for Pressure Equipment
[16] 2014/29/EU, Simple Pressure Vessels Directive

[17] AFS 2016:2, Swedish Work authority's provision for Simple Pressure Vessels
[18] 2014/34/EU, Explosion Protection Directive (ATEX)
[19] AFS 2016:4, Swedish Work authority's provision for Equipment in potentially explosive environments
[20] ELSÄK-FS 2016:2 The Swedish National Electrical Safety Board's regulations on Electrical equipment in potentially explosive environments
[21] 93/42/EEC, Medical Devices Directive

12.DOCUMENT REVISION HISTORY

Revision	Reason for and description of change	Author	Date
1	First issue	Mattias Skafar	2017-11-01

Annex 1. ESS-0145024, EU Declaration of Conformity

EUROPEAN SPALLATION SOURCE

Document Type	Document Template
Document Number	ESS-0145024
Date	Nov 14, 2017
Revision	2
State	Released
Confidentiality Level	Internal
Page	1 (1)

EU DECLARATION OF CONFORMITY

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 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
Comment:	
The following standards were applied:	
The person appointed to manage the technical file is (name and address):	
Position:	☐ External supplier (In-kind / Supplier)
	☐ ESS Authorised person
Name, date & signature:	

Annex 2. ESS-0145023, EU Declaration of Incorporation

EUROPEAN SPALLATION SOURCE

Document Type	Document Template
Document Number	ESS-0145023
Date	Nov 14, 2017
Revision	2
State	Released
Confidentiality Level	Internal
Page	1 (1)

EU DECLARATION OF INCORPORATION
IN ACCORDANCE WITH ANEX II, 1B OF THE MACHINERY DIRECTIVE 2006/42/EC

Manufacturer/authorised representative	
Description of the machinery:	
Denomination/make:	
Type:	
Serial number:	
Year of manufacture:	
We hereby declare that the following essential requirements of Machinery Directive 2006/42/EC have been met:	
Comments:	
Important notice: The partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provision of this directive, where appropriate.	
The person appointed to manage the technical file is (name and address):	
Position:	☐ External supplier (In-kind / Supplier)
	☐ ESS Authorised person
Name, date & signature:	

Annex 3. ESS-0145020, Signature card for EU Declarations of Conformity

EUROPEAN SPALLATION SOURCE

Document Type	Document Template
Document Number	ESS-0145020
Date	Sep 21, 2017
Revision	2
State	Released
Confidentiality Level	Internal
Page	1 (1)

SIGNATURE CARD FOR EU DECLARATIONS OF CONFORMITY

Please sign the appropriate box to confirm that you are responsible for and have fully completed the task concerned for:						
Machine/ equipment:						
Type:						
Serial number:						
Year of construction:						
Task	**Required?**		**Name**	**Position**	**Date**	**Signature**
	Yes	**No**				
Selections of directives to be applied	☐	☐				
Risk evaluation (risk assessment/ safety strategy), selection of and conformity with standards						
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 of the line management responsibility)	☐	☐				

Annex 4. ESS-0145018, Checklist for formal assessment of the EU conformity procedure

EUROPEAN SPALLATION SOURCE

Document Type	Document Template
Document Number	ESS-0145018
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Revision	2
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Confidentiality Level	Internal
Page	1 (2)

CHECKLIST FOR FORMAL ASSESSMENT OF THE EU CONFORMITY PROCEDURE

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	☐	☐	☐

Annex 4. Page 2.

	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:			