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European Organisation
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ESO Safety

Safety Conformity Assessment Procedure

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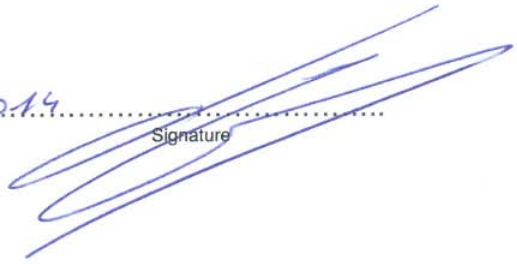
Approved by:	P. Geeraert ESO Safety Commission	28.05.2014 Date	 Signature

CHANGE RECORD

ISSUE	DATE	SECTION/PARA. AFFECTED	REASON/INITIATION DOCUMENTS/REMARKS
1	06.10.2006	All	New document
2	01.06.2012	All	Adapted to new standards Extensive streamlining and clean-up Supersedes issue 1
3	27.05.2014	Title page, Chapter 2; editorial 7.2.2.1, Appendix 5, 8.3 Table 1 3 4	Reflect new directorate structure Clarification of TCF and Safety File; Risk acceptance criteria added Updated Some clarification Updated

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1 Scope

This document defines the safety conformity demonstration process applicable to equipment or parts of equipment (components, sub-systems) developed and produced by the European Organisation for Astronomical Research in the Southern Hemisphere (ESO) internally and/or by external institutes/consortia and/or contractors for use at any ESO site. The document covers all project phases up to and including Preliminary Acceptance. For the definition of "equipment" see section 5.

2 Introduction

This Safety Conformity Assessment Procedure has been drawn up in cooperation with ESO Safety, and was released by ESO Management ESO-wide. It recognises ESO's need to invent, prototype and construct specialised equipment, in order to fulfil its scientific objectives. It reflects however ESO's requirement and duty to exclusively handle and operate such equipment and appliances that are safe to integrate, operate, maintain and decommission, and therefore to design, procure, construct and produce such items accordingly.

This document implements the ESO Safety Policy & Organisation and provides instruction, guidance and information on how to demonstrate that certain equipment is deemed safe.

3 General Requirements

Equipment that includes the European mark of conformity to New Approach directives (i.e. the CE Marking) shall be deemed safe under this procedure, provided its intended use conforms to the conditions foreseen for affixing the CE Marking. Non-European marking schemes establishing conformity with legal safety requirements (e.g. the UL Mark) can be recognised as compatible with these provisions on a case-by-case basis, provided their equivalence is established and documented for the equipment in question.

Where equipment suitable for the intended purpose can be procured commercially with such adequate proof and marking of conformity, this shall be done. Where this equipment cannot be commercially procured with its proof of conformity established, the manufacturer shall assess the conformity of that equipment or parts thereof (sub-systems, components).

ESO considers equipment or parts thereof as safe if it directly meets the essential requirements of European directives and/or regulations applying to this equipment, except in cases where ESO specifications or ESO standards exceed the requirements of the European directives or regulations.

ESO therefore requires the design, manufacture and testing of new equipment or upgrades or substantial modifications to existing equipment to be performed against European standards identified as "Harmonised Standards" by CEN, CENELEC and ETSI (referenced on the New Approach website http://www.newapproach.org), or similar standards considered equivalent by ESO, and documented as such. The same procedure shall be applied for equipment that is already certified as compliant but which will be used outside its intended use. In this case ESO shall assume the role of manufacturer of the equipment.

Owing to the cultural and scientific relevance of ESO equipment, it is permissible to combine the analysis of hazards towards humans or the environment with the analysis of hazards the equip-

ment may pose towards other equipment or itself, provided the nature of the risks is properly differentiated.

4 Applicable and Reference Documents

4.1 Applicable Documents

The following Applicable Documents (AD) of the exact issue form part of the present document to the extent specified herein.

AD Nr	Doc Nr	Doc Title	Issue
AD1	SAF-GAR-MAN-0002	Safety Manual Garching/Santiago	Latest
AD2	LPO-MAN-ESO-20100-0001	Safety Manual La Silla/Paranal Observatory	Latest
AD3	ESO-GEN-RM-002	ESO Risk Management Policy Chapter “Risk Management Procedure”	Latest

4.2 Reference Documents

The following Reference Documents (RD) contain useful information relevant to the subject of the present document, including some of the Directives most relevant for the design and construction of equipment for ESO. Note that this list shall not be considered as exhaustive. For a proper safety conformity assessment it is mandatory to follow the procedure laid down in this document.

RD Nr	Reference	Short Title	Issue
RD1	ISO 12100	Safety of Machinery - General principles for design – Risk assessment and risk reduction	Latest
RD2	ISO/TR 14121-2	Safety of machinery -- Risk assessment -- Part 2: Practical guidance and examples of methods	Latest
RD3	89/391/EEC	Workplace Health and Safety Framework Directive	Latest
RD4	2014/34/EU	Directive on equipment and protective systems intended for use in potentially explosive atmospheres	Latest
RD5	95/16/EC	Directive on lifts	Latest
RD6	97/23/EC	Pressure Equipment Directive	Latest
RD7	2006/42/EC	Machinery Directive	Latest
RD7a	n/a	Guide to application of the Machinery Directive	Latest
RD8	2014/30/EU	EMC Directive	Latest
RD9	2014/35/EC	Low Voltage Directive	Latest
RD10	2014/29/EC	Simple Pressure Vessels Directive	Latest
RD11	305/2011	Construction Products Regulation	Latest
RD12	89/655/EEC	Council Directive concerning the minimum safety and health requirements for the use of work equipment by workers at work	Latest
RD13	2001/95/EC	General product safety	Latest

5 Definitions

ESO uses the following definitions in line with those given in the European Directives.

- Declaration of Conformity (DoC): With the Declaration of Conformity the manufacturer or his authorized representative declares that the equipment manufactured complies with the essential requirements of all relevant Directives. See section 7.2.2.3.
- Declaration of Incorporation (DoI): For equipment which is to be included in an assembly and which cannot function independently once assembled, the manufacturer is to draw up a Declaration of Incorporation. Such equipment must meet all relevant safety rules and regulations, as far as possible, and the manufacturer shall provide instructions for all safety measures to be taken during assembly. The DoI is only applicable for equipment, which meets the definition below. See section 7.2.2.3.
- Equipment: In this document, “equipment” means:
    - An assembly of linked parts or components joined together to form an individual product for a specific scientific application
    - An assembly of products as a system or a subsystem which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole
    - Interchangeable equipment modifying the function of a product for the purpose of being assembled with a product in so far as this equipment is not a spare part or a tool
    - Machines according to the definition in RD7 (Machinery Directive)
- Equipment/Product Limits: The limits of an equipment/a product include (for details see e.g. RD1):
    - Use limits: operating modes including maintenance and repair; intended use of the product including reasonably foreseeable misuse; training level of staff, etc.
    - Space limits: range of movement, space requirements for installation and maintenance, etc.
    - Time limits: foreseeable lifetime of the product, taking into account its intended use and/or its components.
- Harmonised Standards: These are European Standards, adopted by CEN, CENELEC or ETSI, following a mandate issued by the European Commission (EC) after consultation of the European Union (EU) Member States. The EC formally requests the European standardisation organisations to prepare Harmonised Standards in the form of European Standards (EN). They are developed using an open and transparent process, built on consensus between all interested parties.
- Manufacturer: For the purpose of this document a manufacturer is a legal entity responsible for designing, manufacturing, selling or modifying a product with a view to delivering it to ESO for operation or to operate it himself at an ESO site. ESO may be a manufacturer in this sense. Manufacturing includes all related activities, like design, production and test.
- Product Transfer to ESO: The product is considered to be transferred either when the physical hand-over including documentation and certification, or the officially documented transfer of ownership to ESO has taken place.
  If a product has been manufactured by ESO for its own use the product transfer is considered to take place when the equipment arrives at its designated place of use.
- Reasonably foreseeable misuse: Use of equipment in a way not intended by the designer, but which may result from readily predictable human behaviour.
- Residual Risk: Risk remaining after protective measures have been taken.

6 Responsibilities in the Assessment Process

6.1 ESO as Client

For equipment built to order, ESO shall define/communicate in the Technical Specifications/Purchase Order the “intended use”, the operational conditions, the environmental conditions as well as the site safety provisions (AD1, AD2) applicable at the place of usage and maintenance.

The person named as ESO’s technical responsible in the contract shall have the overall safety responsibility for the contract and shall be the official single contact point at ESO with respect to any safety related aspects.

6.2 Manufacturer

The ESO internal and external equipment manufacturer is responsible to fulfil the requirements documented in the Statement of Work and the Technical Specifications. The manufacturer shall demonstrate conformity with the applicable safety requirements when transferring the responsibility for the technical equipment to ESO or before the technical equipment is used on ESO sites. The demonstration of conformity shall be documented by preparing a Declaration of Conformity or Declaration of Incorporation dependent on the constraints specified in the Statement of Work.

6.3 Assembler/Integrator/Installer

For machinery which is to be included in an assembly and which cannot function independently once assembled, the Assembler/Integrator/Installer is responsible for taking all measures necessary to ensure that the assembled system complies with the essential safety requirements at the moment of first use at ESO or at the acceptance of the product by ESO. This includes taking into account the safety related intentions of the designer.

The compliance of the assembled system must be documented in a Declaration of Conformity on the basis of the Declarations of Incorporation of the constitutive parts of the assembly.

7 The Process of Conformity Assessment

This chapter describes the conformity assessment procedure to be executed to obtain and demonstrate conformity with the relevant essential safety requirements.

Safety of equipment needs to be systematically developed throughout the whole project. To ensure a smooth safety compliance process, especially if several contractors are working at the sub-system level, it is recommended that subsystems be analysed for safety compliance at an early stage. This supports the mandatory compliance process for the whole system. Finally, the preparation of a Declaration of Conformity or, respectively, a Declaration of Incorporation shall complete the conformity assessment process.

Optionally, if requested by ESO, a Safety Mark on the equipment may close the whole process.

The following fundamental tasks shall be performed to demonstrate that the equipment to be put into service is in conformity with the applicable safety requirements. Completion of these tasks shall be checked during the appropriate project reviews.

1. Identification of essential safety requirements:
    a. Preparation of the Preliminary Hazard List (PHL);
    b. Preparation of the Preliminary Hazard Analysis (PHA);
    c. Preparation of a List of Relevant Provisions (i.e. the list of applicable EC Directives, Harmonised Standards, ESO safety requirements) resulting from the PHL and PHA;
2. Performance of a Conformity Assessment Cycle:
    a. Preparation of the detailed Hazard Analysis (HA);
    b. Preparation of Documentation (Safety Compliance Report and Safety File);
    c. Preparation of a Declaration of Conformity/Declaration of Incorporation;
3. Conformity Marking (if requested).

The following table defines the required tasks depending on the various project phases.

Task			Project phase			
Task nr.	**Title**	**Section**	**Phase A**	**Preliminary Design**	**Detailed Design**	**MAIT**
1	Identification of essential safety requirements	7.1				
1.a	Preparation of Preliminary Hazard List (PHL)	7.1.1	X	CX	CX	CX
1.b	Preparation of Preliminary Hazard Analysis (PHA)	7.1.2	N/A	X	N/A	N/A
1.c	Preparation of the List of Relevant Provisions	7.1.3	N/A	X	CX	CX
2	Performing a Conformity Assessment Cycle	7.2				
2.a	Preparation of Hazard Analysis (HA)	7.2.1	N/A	N/A	X	CX
2.b	Preparation of the Safety Compliance Report and Safety File	7.2.2.1 7.2.2.2	N/A	N/A	N/A	X
2.c	Preparation of Declaration of Conformity/ Incorporation	7.2.2.3	N/A	N/A	N/A	X
3	Conformity Marking	7.3	N/A	N/A	N/A	RC

X: Applicable; proper release of documentation required
CX: Applicable to changes of design or equipment
N/A: Not Applicable
RC: only if explicitly required by the contract

Table 1: Tasks and documentation vs. project phases

7.1 Identification of Essential Safety Requirements

The required analysis to be performed is dependent on the progress of a project and comprises the sequential execution of three main activities:

1. Identification of the hazards that may be inherent in the product concept and compilation in a PHL.
2. Performance of a PHA to identify safety critical areas and provision of an initial hazard assessment of the hazards as well as the definition of required hazard control and follow-up actions.
3. Based on the PHL and PHA all applicable Safety Rules and Regulations, which reduce the risk, shall be identified by preparing a List of Relevant Provisions.

The use of the Hazard Analysis template provided by ESO is strongly recommended.

7.1.1 Preliminary Hazard List

The purpose of the PHL is to compile a list of potential hazards early enough in the project life cycle to enable the contractor and ESO to identify any hazardous areas, either for Members of Personnel, for the environment or for equipment or Third Parties.

It is strongly recommended to use the methodology and systematic exemplified in ISO 12100 (RD1) and ISO/TR 14121-2 (RD2).

The PHL shall provide the following elements:

- A system description (including intended use and reasonably foreseeable misuse, operator qualification, etc.);
- An overview of the life-cycle phases, operational modes and functional states;
- A matrix of hazardous element in the various operational modes and functional states.

These hazardous elements shall comprise:

- Hazards as described e.g. in RD1 and RD2 or any other suitable standard;
- Hazardous components (e.g. electrical systems, cooling fluids including cryogenics, toxic substances, hazardous construction materials, pressure systems and other energy sources);
- Safety related interface considerations between the various elements of the system (e.g. material compatibilities, electromagnetic interference, inadvertent activation, fire ignition and propagation, hardware and software controls);
- Environmental constraints, including transport, maintenance, handling and operating environments (e.g. drop, shock, vibration, extreme temperatures, noise, exposure to toxic substances, health hazards, fire, electrostatic discharge, electromagnetic environmental effects, ionizing and non-ionizing radiation including laser radiation).

7.1.2 Preliminary Hazard Analysis

The purpose of the PHA is to

1. Assess the risk involved in each hazard and hazardous element identified in the PHL;
2. Identify risk elimination or reduction measures to arrive at a tolerable residual risk.

In the first step the manufacturer (as defined in section 5) shall determine the initial risks relevant to a particular concept or system. Hence, work on the PHA should commence in the preliminary design phase of a project so that safety considerations are included already in trade-off studies and design alternatives. Based on the best available data, including mishap data from similar systems and other lessons learned, hazards associated with the equipment in question shall be

evaluated for their impact and likelihood following the scales and criteria listed in section 8/ (Appendix 1) throughout the life cycle of the equipment.

In the second step the manufacturer (as defined in section 5) shall consider safety provisions and design alternatives necessary to eliminate hazards or to reduce their associated risk score to an acceptable level as defined in section 8.3.

The PHA shall consider at least the following elements for the evaluation of hazards and the mitigation of associated risks:

1. PHL;
2. Operating, test, maintenance and emergency procedures (e.g. human factors, engineering, human error analysis of operator functions, tasks and requirements; the effect of factors such as equipment layout, potential exposure to toxic materials, effects of noise or radiation on human performance, combination of independently insignificant hazard factors into significant multi-factorial hazards);
3. Facilities, support equipment (e.g. provisions for storage, assembly, check-out, testing of hazardous systems and assemblies which may include toxic, flammable, corrosive or cryogenic fluids; radiation or noise emitters; electrical power sources) and training (e.g. training and certification pertaining to safety operations and maintenance);
4. Safety-related equipment, safeguards, and possible alternative approaches (e.g. interlocks, system redundancy, hardware or software fail-safe design considerations, subsystem protection, fire suppression systems, protective equipment for personnel, industrial ventilation and noise or radiation barriers).

PHL and PHA may be combined in a single document.

7.1.3 List of Relevant Provisions

For each identified hazard, the applicable safety rules and regulations shall be compiled in a List of Relevant Provisions in a view to document the adequate measures to mitigate the corresponding risks. This list shall contain the following information:

7.1.3.1 Identification of ESO Safety Requirements

The definition of the equipment's "intended use" including the operational, environmental and maintenance conditions applicable at the place of usage and maintenance shall be taken from ESO Technical Specification and the Statement of Work. In addition, any special safety requirements and safety instructions applicable at the ESO destination site shall be identified.

7.1.3.2 Identification of applicable EC Directives

The applicable EC Directives shall be selected from the list "Directives & Standards" published by the three European Standards Organisations (CEN, CENELEC, ETSI) together with both the EC and EFTA on the New Approach Website referenced above. There, the linked "Standards activities" provide more information on the products covered by the individual Directive.

Essential requirements set up by EC Directives may overlap or complement each other, depending on the nature of the equipment and the hazards covered by these Directives. RD3-RD10 provide a non-exhaustive list of the most applicable Directives.

7.1.3.3 Identification of applicable Standards

More detailed technical specifications for equipment meeting the “essential requirements” set out in the EC Directives are laid down in “Harmonised Standards”.

The Harmonised Standards associated with the EC Directive(s) applicable for the equipment in question shall be selected from the New Approach website referenced above. Harmonised Standards are available as national standards from the national standards bodies in the EU member states in the corresponding languages.

Where no ESO specific provisions or Harmonised Standards exist, national standards of ESO host states or ESO member states may be used.

For equipment conforming to safety legislation other than the one stated above, ESO reserves the right to decide on a case-by-case basis. The manufacturer of the equipment in question must demonstrate in writing that the applied safety requirements are equivalent to the ones mentioned above.

7.2 The Conformity Assessment Cycle

7.2.1 Hazard Analysis

The HA is the continuation of the PHA and associated mitigation effort performed on the preliminary design.

The purpose of the HA is to demonstrate that the design satisfies contractual safety requirements, insofar as all identified hazards and risks associated with the design of the equipment are adequately mitigated.

The manufacturer shall perform a HA concerning all components and subsystems including software whose performance, performance degradation, functional failure or inadvertent functioning could result in a hazard. The HA must be documented in writing and shall consider the hazards already identified and evaluated in the PHA plus any additional hazards created or discovered during the detailed design phase.

7.2.2 The Conformity Statement Procedure

Before drawing up the declaration of conformity a Technical Construction File (TCF) shall be prepared by the manufacturer, as required notably by the Machinery Directive.

7.2.2.1 The Technical Construction File

All conformity assessment results (assessment reports, test reports, declarations, certificates, etc.) shall be collected in the TCF together with, notably, full as-built documentation to be able to demonstrate conformity with the declared requirements in accordance with all applicable EC Directives.

In this stage of the process the TCF information need not permanently exist as a single file, but the manufacturer must be able to assemble it within a reasonable time. To this effect the manufacturer shall prepare, at the latest at Preliminary Acceptance, a “Safety Compliance Report” that substantiates the Declaration of Conformity/Declaration of Incorporation (DoC/DoI; see section 7.2.2.3) and references the documents demonstrating conformity. See also Appendix 5.

Any change in the supporting documentation, which affects the validity of the DoC/DoI shall be documented.

If the equipment consists of several subsystems, the identification process shall be performed at system and subsystem levels and down to individual product level, as required. Consequently, the above-mentioned documents shall be prepared at the system, subsystem and if required, any individual product level.

7.2.2.2 The Safety File

For the commissioning of equipment destined for the ESO observatories the manufacturer shall collect all safety relevant information referring to installation, commissioning and operation from the TCF and make this sub-set of documents available as a single source called Safety File. See Appendix 5.

The Safety File shall contain the following documents:

1. Declaration of Conformity/Incorporation;
2. Safety Compliance Report;
3. The Integration and Commissioning Plan(s);
4. Operating and maintenance manuals of the equipment;
5. Hazard analysis;
6. Any other documents related directly to the safety of the equipment;
7. Any relevant observatory instructions (for example: general and location-specific emergency procedures, lock-out/tag-out procedures, crane instructions, handling of liquid nitrogen, etc.) that are relevant to the installation, commissioning and operation of the equipment.

The manufacturer shall provide items 1-6 of the preceding list. ESO shall provide item 7.

7.2.2.3 The Declaration of Conformity/Declaration of Incorporation

The manufacturer shall, as part of the conformity assessment procedure, draw up the DoC. With this document, the manufacturer confirms in a legally valid form that the product he has produced conforms to all applicable essential safety requirements and is manufactured in compliance with the applicable Harmonised and other relevant Standards.

The form and contents of the DoC/DoI are defined in the applicable EC Directive(s). Where several Directives apply to a product, the manufacturer may merge all the declarations into a single document. In this case the DoC shall include the List of Applicable Directives, a List of Applicable Harmonised Standards and a listing of all other relevant standards, which have been chosen where no EU legislation was available.

The DoI must include in addition a statement that the equipment must not be put into service until the equipment into which it is to be incorporated has been declared in conformity with the applicable provisions.

The manufacturer shall keep the TCF and the DoC/DoI for at least ten years after Product Transfer to ESO. For equipment built by ESO they shall be kept during the entire useful lifetime of the equipment. ESO shall archive the original declarations together with the contractual documentation. In addition, electronic copies shall be archived with the technical documents.

7.3 ESO Acceptance Procedure and Conformity Marking

In those cases referred to in the introduction, where equipment required for ESO's scientific activities is not commercially available, ESO does not normally ask its contractors to affix the CE Conformity Mark to equipment produced under ESO contract, although all other activities and measures requested by European Directives applicable to the equipment in question must be performed. If ESO requires affixing the CE mark then this shall be clearly stated in the contract.

In cases, where it would not be considered appropriate to follow the spirit of the New Approach, the essential requirements of European Directives and/or Harmonized Standards, the contractor shall propose a suitable safety and conformity approach in a detailed product-specific safety concept. He shall apply to ESO for prior approval of this concept. This specific safety concept shall follow or exceed the minimum safety and health requirements and levels of protection laid down in RD11 (Council Directive concerning the minimum safety and health requirements for the use of work equipment by workers at work), RD12 (general product safety) and RD7 (machinery).

In all cases ESO specific safety and health requirements as laid down in applicable policies, manuals and procedures shall be applied.

8 APPENDIX 1: Risk Assessment

In application of section "Risk Assessment" of AD3, the following scales for Impact (I) and Likelihood (L) shall be used for the risk assessment of ESO equipment.

8.1 Impact scale

Impact I	Scale	Impact criteria
1	Very low	Less than minor injuries, less than minor occupational illness, irritation, no loss of work days
2	Low	Minor injury, minor occupational illness
3	Medium	Severe injury, severe occupational illness, in particular with irreversible consequences
4	High	(Potential) fatality

If an impact scale is applied to **physical damage** to equipment (e.g. an astronomical instrument), then a similar scale should be used:

Impact I	Scale	Project criteria	Operational criteria
1	Very low	Negligible	Equipment is less than one day out of operation
2	Low	Marginal	Equipment can be repaired by ESO staff, and/or Equipment is up to one week out of operation
3	Medium	Critical	Equipment can be repaired but support from the supplier/industry is necessary, and/or Equipment is up to four weeks out of operation
4	High	Catastrophic	Equipment cannot be recovered at a reasonable cost, and/or Equipment is more than four weeks out of operation

Note that this table refers to loss of operations due to physical equipment damage, not due to failure per se. It does not define the reliability acceptance scale.

8.2 Likelihood scale

Likelihood L	Probability of occurrence	Workplace approximation	Probabilistic approximation in equipment (annual)
1	Low/Rare	E.g. Significantly less frequent than every 100 careers, but cannot be excluded	<10^-5
2	Medium/possible	E.g. Likely to occur once in 10 careers	10^-5 – 10^-4
3	High/likely	E.g. Likely to occur every 5 years	10^-4 – 10^-3
4	Very high/frequent	E.g. Likely to occur half-yearly or more often	>10^-3

8.3 Risk score

The risk score (S) associated with a hazard is the product of the impact (I) and the likelihood (L) of the hazard.

Risk Score (S)		Impact (I)			
		High	Medium	Low	Very low
Likelihood (L)		4	3	2	1
Very high / frequent	4	16	12	8	4
High / likely	3	12	9	6	3
Medium / possible	2	8	6	4	2
Low / Rare	1	4	3	2	1

Risk scores S are:

High:	S ≥ 8 or if I = 4 or L = 4
Medium:	8 > S > 2
Low:	S ≤ 2

Projects may deviate from this matrix if this is justified in their Project Management Plan.

A “High” risk score is considered as unacceptable.

A “Medium” risk score should be reduced to “Low” by introducing inherently safe design measures or, if this is not possible, by safeguarding, i.e. by implementing complementary protective measures, or, if this is not possible, by information for use (see RD1). For a Medium risk score the written acceptance by ESO Is required.

A “Low” risk score is considered as acceptable without further action.

9 APPENDIX 2: Abbreviations and Acronyms

This document employs several abbreviations and acronyms to refer concisely to an item, after it has been introduced. The following list is aimed to help the reader in recalling the extended meaning of each short expression:

CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation
ETSI	European Telecommunications Standards Institute
DoC	Declaration of Conformity
DoI	Declaration of Incorporation
EC	European Commission
EFTA	European Free Trade Association
EN	European Standard
EU	European Union
ESO	European Southern Observatory
HA	Hazard Analysis
MAIT	Manufacture/Assembly/Integration and Test
PAE	Preliminary Acceptance Europe
PHA	Preliminary Hazard Analysis
PHL	Preliminary Hazard List
TCF	Technical Construction File

10 APPENDIX 3: Sample Declaration of Conformity

EC Declaration of Conformity for XXX (Directive YYYY/ZZ/EC)

The manufacturer
[name, full address]
hereby declares that the equipment

[name of equipment, description of function, model, type, serial number]

- Complies with the essential requirements of the above mentioned Directive
- Complies with the requirements of further Directives, namely
  - Directive 1
  - Directive 2
  - …
- The following harmonised standards have been applied:
  - ENxx
  - ENyy
  - …
- The following other technical specifications or standards have been applied [voluntary]:
  - Standard 1
  - Standard 2
  - …
- The following person is authorised to compile the Technical Construction File:
  - [name, address]
- The following notified body
  [name, address]
  has been involved with regard to the
  - [e.g. EC-type examination no. xx] and/or
  - [e.g. approval of yyy]

[Location, date]

[identity of the person empowered to draw up the declaration]

[signature]

11 APPENDIX 4: Sample Declaration of Incorporation of Partly Completed Equipment

EC Declaration of Incorporation of Partly Completed Equipment for XXX (Machinery Directive 2006/42/EC)

The manufacturer
[name, full address]
hereby declares that the partly completed equipment

[name of equipment, description of function, model, type, serial number]

- Complies with the following essential requirements of the above mentioned Directive:
  - requirement 1
  - requirement 2
  - …
- Complies with the requirements of further Directives, namely
  - Directive 1
  - Directive 2
  - …
- The following harmonised standards have been applied [optional]:
  - …
- The following other technical specifications and/or standards have been applied [optional]:
  - …

The relevant technical documentation (construction file, including the assembly instructions) has been compiled in accordance with part B of Annex VII of the Machinery Directive.

Upon ESO's written agreement, we will transmit relevant information in response to a reasoned request by the appropriate national authorities in electronic form.

The machinery is incomplete and must not be put into service until the machinery into which it is to be incorporated has been declared in conformity with the provisions of the Directive.

The following person is authorised to compile the relevant technical documentation:
- [name, address in the EU]

[Location, date]

[identity of the person empowered to draw up the declaration]

[signature]

12 APPENDIX 5: Technical Construction File and Safety File

The contents of the TCF are the responsibility of the manufacturer. The TCF should however typically contain the following elements:

- Manufacturer and product identification
  - Name and address of manufacturer
  - Name and function of the employee authorised to assemble the TCF
  - Name of the product
  - Type designation of the product
- Product description
  - Design drawings relevant for safety
  - Design description
  - Parts lists/Bill of materials
  - Photographs
  - Etc.
- List of relevant provisions
  - List of applicable EU Directives
  - List of norms and standards used for the conformity assessment
- Analyses and test reports
  - Design calculations
  - Evaluation reports indicating which evaluations were performed, which methods and equipment used, their results and the acceptance criteria
  - Test reports indicating which tests were performed, which methods and equipment used, their results and the acceptance criteria
  - Hazard analysis (**Safety File**)
  - Safety Compliance Report describing the measures taken to reduce or eliminate hazards. This report may be integrated in the Hazard Analysis, e.g. adding a column with the relevant information and reference to the hazards table. (**Safety File**)
  - Declaration(s) of Conformity/Incorporation (whichever is applicable) (**Safety File**)
- Manuals and plans (whichever are applicable)
  - User manual
  - Operating manual (**Safety File**)
  - Maintenance manual (**Safety File**)
  - Integration plan (**Safety File**)
  - Commissioning plan (**Safety File**)

The Safety File as defined in section 7.2.2.2 is a subset of the TCF. Its elements that are deliverables of the manufacturer are marked with “Safety File” in the list above.

End of document