CTA Product Safety Plan

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Version 1a

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1 Introduction

1.1 Purpose of this Product Safety Plan

This document defines the product safety program, strategies and methodologies to be adopted to undertake product safety management during the construction phase of the CTA Observatory, and how to fulfil the specified product safety requirements.

The product safety plan is a living document that must be revised at each project decision gate design review and adapted to the baseline definitions of the next project phase. The system product safety program comprises the:

- CTAO Product Safety Approach
- Product Safety program organization
- Product Safety analysis requirements and techniques
- Product Safety verification
- Operational/System safety
- Safety and concurrent engineering activities
- Project phase related product safety activities

1.2 Applicability

This Product Safety Plan is applicable for the entire Project life cycle from the start of the Preliminary Design Phase until the dismantling of the individual products.

This Product Safety Plan is applicable to all entities which supply a product to CTAO, in particular to In-Kind Contributor or similar.

The OSH Plan (Occupational Safety and Health) is beyond the scope of the present CTA Product Safety Plan.

The main strategy of an OSH Plan is the implementation of a **Preventive Safety Culture at the workplace.** A safe, healthy and conducive work environment leads to healthy, productive and innovative working environmental.

The OSH Plan will be developed and implemented by the CTAO - OSH Person. This person is named and authorized by the CTAO Director.

This CTA Product Safety Plan do not include the Construction Site safety. These OSH related aspects are the responsibility of the Construction Site Manager and the Construction Site Safety Engineer.

1.3 Applicable Documents

The following documents are applicable to the extent specified herein. If not explicitly stated otherwise, the latest issue of the document is valid.

AD	Document Title	Document Number
AD01	New legislative framework NLF	link
AD02	General Product Safety Directive 2001/95/EC	link
AD03	Electromagnetic Compatibility Directive 2014/30/EU	link
AD04	Low Voltage Directive 2014/35/EU	link
AD05	Machinery Directive 2006/42/EC	link
AD06	EN ISO 12100:2010 Safety of machinery - General principles for design – Risk assessment and risk reduction	

1.4 Acronyms and Abbreviations

Acronym / Abbreviation	Definition
AD	Applicable Document
AIV	Assembly, Integration and Verification
CTA	Cherenkov Telescope Array
CTAO	CTA Observatory
CM	Configuration Management
COTS	Commercial off-the-shelf, also component off-the-shelf
HQ	Headquarter
HTS	Hazard Tracking System
MAI(T)V	Manufacturing, Assembly, Integration, (Test), Verification
OHS-E	Occupational Health, Safety and Environment
PDR	Preliminary Design Review

PO	Project Office
Project	Project means all CTAO Facility System development, construction and scientific operation activities performed by CTAO and In-Kind Contributors
PSP	Project Safety Plan (this Document)
QA	Quality Assurance
RAMS	Reliability, Availability, Maintainability, Safety
SSO	Site safety officer

2 System Product Safety

2.1 Objectives

The objective of this Product Safety Plan is to ensure that all Product Safety risks associated with the delivery, assemble, operation and maintenance of CTA equipment are adequately identified, assessed, minimized, controlled and finally accepted through the implementation of this Product Safety Plan.

As mentioned in Section 1.2 (link), occupational safety and health aspects and construction site safety are excluded from the objectives of this plan.

2.2 CTA Product Safety Management Approach

CTAO as European Research Infrastructure has adopted the European product safety legislation as applicable legislation for the products produced und used at all CTA sites. That means, that all parts of products and products delivered to CTAO must - independently of the final place of use – fulfil the European product safety requirements applicable for products produced for the Extended Single Market in the European Economic Area EEA (link).

On this ground the CTA Contributors are obliged to apply European product safety legislations, which are transformed by the EU member states into national law.

The consequences for the Project are:

- All parts or the final products that will be delivered to any CTAO site must comply with the EU product safety legislation.
- Each In-Kind Contributor and other suppliers are responsible for the compliance with the European product safety legislation applicable for their produced products.
- The EU product safety legislation including the safety assessment processes must be applied by all suppliers during all project phases.
- The EU Safety Conformity Assessment Procedure must be followed from the beginning of the Preliminary Design Phase throughout all project phases until final delivery and acceptance by CTAO.

2.3 CTA Product Safety Organisation

This section of the PSP describes the organizational context, both technical and managerial, and the tasks and responsibilities of the responsible actors.

2.3.1 Organisation Chart tree of accountability

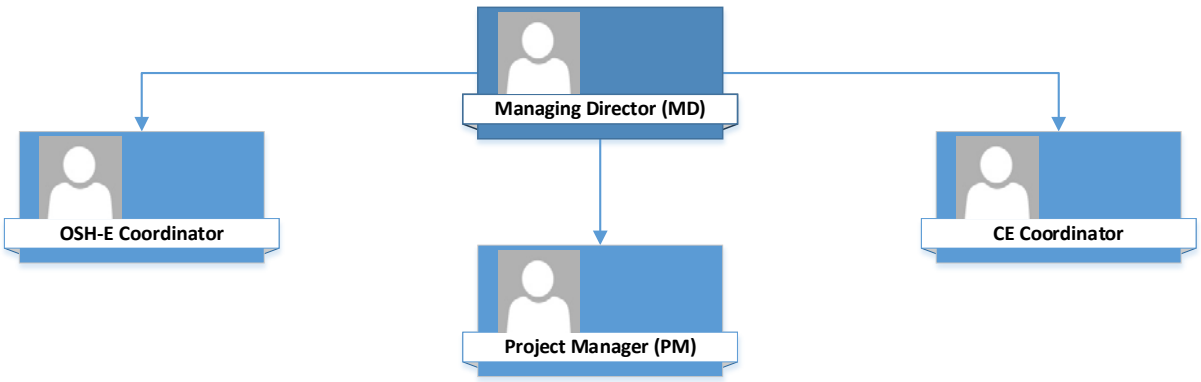

Figure 1 CTA tree of accountability

2.3.2 Product Safety Task and Responsibility

2.3.3 Managing Director

The general responsibility of the CTA Product Safety lies with the CTAO Managing Director. He is responsible for implementation of all safety activities required by the applicable laws. He delegates the CTA Product Safety work to the CTAO CE Coordinator and monitors their correct execution.

CE compliance (link) is a corporate task. The managing director is responsible for the suitable organization. It's not enough to simply designate an employee as the "CE Coordinator for this task", The person responsible for "CE" also has to have the corresponding technical knowledge, the necessary experience and, what is very important, the corresponding competencies and certificates to fulfil this position, as the declaration of conformity is a legal act.

The CE Coordinator is a part of "compliance management" in the company.

2.3.4 CTA CE Coordinator

The CTA CE Coordinator acts during the entire construction phase.

2.3.4.1 General tasks and responsibilities:

The CTA CE Coordinator shall have the organizational authority and independency to:

1. establish and maintain this Product Safety Plan,
2. manage all product safety assurance aspects of the CTA System (including software) during the Construction Phase
3. coordinate the product safety related interfaces:
    a) with the relevant In-Kind Contributors
    b) with ESO (South Site)
    c) with IAC (North Site)
    d) with DESY, Zeuthen (SDMC Site)
    e) with all Site Managers

In particular, the CTAO CE Coordinator is responsible for:

- Preparation of this Product Safety Plan
- Monitor and control the correct execution of the Product Safety Plan at the Project Office and all In-Kind Contributors
- Convening and chairing product safety related meetings
- Defining applicable product safety requirements, standards and tools
- Providing initial system product safety program training, including CE Conformity Assessment, to the CTA staff and the In-Kind Contributors involved in safety activities.

2.3.4.2 Access:

The CTA CE Coordinator

1. has the right of access to all safety-related data relevant to Project product safety
2. has unimpeded access to any management level without organizational constraint on any aspect of Project product safety

2.3.4.3 Authority:

The CTA CE Coordinator hall have the authority to:

1. reject any project document, or to stop any project activity on any CTAO site that does not conform to CE approved product safety requirements or procedures,
2. interrupt hazardous operations on any CTAO site when it becomes clear by the CTAO CE Coordinator that the operation or the product does not conform to the agreed measures defined in the corresponding hazard report and derived approved hazard procedure.

2.3.5 Safety Management Interfaces

As integral part of the CTAO Management Organization the CTAO CE Coordinator interfaces directly with all PO members and the related project management disciplines, ensuring that the contractual provision and schedule planning for the definition and phasing of product safety activities are met.

The CTAO CE Coordinator interfaces directly with the In-Kind Contributors, the relevant staff at ESO, IAC and DESY and the CTA Site Managers regarding all product safety related matters.

The CTAO CE Coordinator will keep the CTA Managing Director and CTA Project Manager appropriately informed about the subjects of his contacts with the In-Kind Contributors.

2.3.6 Safety Audits

In order to guarantee the CE product safety audits may be performed by the CTAO CE Coordinator at the contributor’s site. Safety audits are reviews to verify CE compliance to the described CTA System Product Safety Management Approach and specified product safety requirements when necessary to overcome failures or existing product safety problems.

2.4 Constraints and Requirements placed on Product Safety

This section lists the “external” product safety related constraints, and requirements placed on the Projects and the entire system

2.4.1 Product / Equipment / System Safety

The EU Product Safety Legislation formulated in the various EU Directives, e.g. the EU Directive 2001/95/EC on general product safety, is applicable throughout the entire project.

2.4.2 Safety Analysis Requirements and Techniques

The European Commission outlines on their Web Page “CE Marking”, http://ec.europa.eu/growth/single-market/ce-marking/manufacturers/index_en.htm, the principles product manufacturers have to follow for “ensuring that products placed on the extended Single Market of the EEA are safe”.

These principles apply to all individual CTA products and for all CTA Subsystems CTA-North, CTA-South, the Headquarter, SDMC and to the complete CTA System.

2.4.3 Safety Analysis Requirements

The safety analysis requirements are defined in the applicable EU Directives, e.g. Machinery Directive 2006/42/EC.

Note: Not only the individual telescopes and other similar products are covered by the Machinery Directive, also the entire Telescope Arrays of CTA-North and CTA-South are considered as a machine.

2.4.4 Safety Analysis Techniques

If the applicable EU Directives do not specify different processes, the analysis techniques defined in the standard DIN EN ISO 12100 and Guideline ISO/TR 14121-2” shall be used for the preparation of the safety assessment documents.

2.5 Product Safety Verification

For all product safety verifications traceability shall be provided by means of implementation and execution of the following subsections:

2.5.1 Safety Status Review

The status of the hazard control and risk reduction activities shall be reviewed at Project progress meetings and the project phase related design reviews (PDR, CDR, etc.) for compliance with decisions taken and achievement of intended results.

2.5.2 Safety Verification Methods

A systematic safety verification approach shall be implemented on all CTA system and subsystems levels. This approach shall start from the beginning of the preliminary design phase and shall continue through all project phases. As a minimum, the activities of the following two subsections plus those verification activities required by the national safety legislation shall be included.

2.5.3 Safety Compliance Assessments

The following table describes the safety compliance assessment activities to be performed during the individual project phases.

Project Phase					
Task nr.	**Activity Title**	**Preliminary Design**	**Final Design**	**MAIV[1]**	**Operation**
1	Identification of essential safety requirements				
1.a	Preparation of Preliminary Hazard List (PHL)	X	CX	CX	CX
1.b	Preparation of Preliminary Hazard Analysis (PHA)	X	N/A	N/A	N/A
1.c	Preparation of the List of Relevant Provisions	X	CX	CX	CX
2	Performing a Conformity Assessment Cycle				
2.a	Preparation of Hazard Analysis (HA)	N/A	X	CX	CX
2.b	Preparation of the Technical File	N/A	X	X	X
2.c	Preparation of Declaration of Conformity/ Incorporation	X	X	X	X
3	Conformity Marking	X	X	X	X

Table 1 Safety Compliance Assessment Activities

X: Applicable; CX: applicable to changes.

[1]MAIV: Manufacturing, Assembly, Integration and Verification include activities at the supplier as well as at the observatory sites

2.5.4 Safety Compliance Assessments

At the beginning of the individual project phases and in the absence of the subsystem safety compliance assessment results the preparation of the system safety compliance assessments will start on the assumption that all subsystems completely fulfil all essential safety requirements defined in the relevant EU Directive. The system safety compliance assessments will be revised as soon as the results of subsystem safety compliance assessments become available during the individual project phases.

2.5.5 Subsystem Safety Compliance Assessments

The In-Kind Contributors are responsible for the execution of the tasks on product level. The resulting documents defined by the EU directives and the associated harmonized standards are part of the product design review documentation and the preparation effort shall be reported in the standard progress reports and progress meetings. The results of the product activities shall be provided during the individual project phases early enough to enable their incorporation into the system level activities.

2.5.6 Product Safety Inspections and Tests

Product Safety critical functions shall be inspected and tested by the contributor during the MAIV phase and the subsequent project phases.

Inspections and tests which are considered as necessary in order to meet safety requirements of the system shall be identified and included in

1. the MAIV verification procedures,
2. the installation and commissioning plans and procedures,
3. the operation manuals and procedures.

2.5.7 Declaration of conformity

The Declaration of conformity shall be done in accordance with the Machinery Directive 2006/42/EC, EMC Directive 2014/30/EC and LVD Directive 2014/35/EU and other applicable EU Directives.

Definition:

The EC declaration of conformity is a legal act and is the written statement and a single declaration drawn up by the manufacturer to demonstrate the fulfilment of the essential EU safety requirements relating to a product bearing the CE marking he has manufactured.

3 Product Safety and Project Engineering Activities

This section outlines the concurrent product safety and project engineering activities in continuous support of the Project design and development and MAIV processes.

3.1 Preliminary Design Phase

Safety analysis and risk reduction activities shall support a continued and more detailed safety optimization of the system design and operations and the identification of technical safety requirements and their applicability.

In addition to the safety compliance assessment activities on system and subsystem level, the CTAO CE Coordinator as well as the In-Kind Contributor shall

1. review the CTA system product safety requirements of the CTA technical specifications, and – if necessary - formulate precise safety related performance requirements in a specific safety performance requirement specification document. This document shall be included in the Design Configuration Baselines (DCB).
2. prepare a product safety report summarizing the status of the safety activities and highlighting safety matters needing special attention during the following project phase,
3. prepare the safety related input for the
    (a) Requirement Specifications
    (b) Configuration Baseline established following the PDR
    (c) PDR documentation
    (d) Verification Plan
    (e) Safety activity planning for the following project phases
4. participate in CCB and other project meetings as required.

3.2 Review the CTA system product safety requirements of ESO Loaned and Furnished Property

The equipment loaned from ESO or provided by ESO for use in the Project as part of the installation activities shall conform to the product safety requirements and principles of the ESO Technical Specification and this product safety plan. ESO is responsible for performing the necessary safety compliance assessments for the ESO equipment, and for demonstrating the safety compliance to CTA during the hand over process.

3.3 COTS and Third Party Produced Items

Commercial-of-the-shelf (COTS) items and items produced by third parties shall comply with the EU Product Safety Legislation.

1. formulate precise safety related performance requirements in a specific safety performance requirement specification document. This document shall be included in the Design Configuration Baselines (PCB).
2. prepare a product safety report summarizing the status of the safety activities and highlighting safety matters needing special attention during the following project phase,
3. prepare the safety related input for the
    a. Requirement Specifications
    b. Configuration Baseline established following the PDR
    c. PDR documentation
    d. Verification Plan
    e. Safety activity planning for the following project phases
4. participate in CCB and other project meetings as required.

3.4 Final Design Phase

Product Safety analysis and risk reduction activities shall support the detailed design. These safety activities shall also support operational safety optimization, safety requirements implementation evaluation, risk reduction verification, and hazard and risk acceptance.

Analysis of operations shall also support the identification of emergency and contingency response planning and training requirements, and the development of corresponding procedures.

In addition to the product safety compliance assessment activities on system and Product level, the CTAO CE Coordinator as well as the In-Kind Contributor shall

1. prepare a safety report summarizing the status of the product safety activities and highlighting safety matters needing special attention during the following project phase
2. prepare the safety related input for
    (a) MAIV documentation, in particular for safety related inspections and test, e.g. inspection and test plans and procedures, safety related handling procedures
    (b) user and maintenance manuals,
    (c) integration handling, transport, shipping, installation and commissioning documentation
    (d) Design Configuration Baseline established following the CDR
    (e) CDR documentation
    (f) Safety activity planning for the following project phases
3. participate in CCB and other project meetings as required.

3.5 MAIV Phase

Safety analysis and risk reduction activities shall support the manufacturing, integration, and test/verification activities.

In addition to the product safety compliance assessment activities on system and subsystem / product level the CTAO CE Coordinator as well as the In-Kind Contributor shall

1. prepare a product safety report summarizing the status of the safety activities and highlighting safety matters needing special attention during the following project phase
2. prepare the safety related input for
    (a) user and maintenance manuals
    (b) user and maintenance handbook
    (c) transport, shipping, installation and commissioning documentation
    (d) Product Configuration Baseline established following the internal product acceptance
    (e) Preliminary acceptance documentation
    (f) Safety activity planning for the following project phases
3. participate in CCB and other project meetings as required
4. preform safety training for users and maintenance staff
5. participate in MAIV safety inspections and tests
6. participate in preliminary acceptance related activities
7. preparation of the CE Compliance Assessment document

3.6 Transport and Shipping

In addition to the product safety compliance assessment activities, the CTAO CE Coordinator as well as the In-Kind Contributor shall have the right to

1. monitor the safety related transport and shipping activities, whereby the transport safety responsibility remains with the contributors.
2. participate in CCB and other project meetings as required.
3. participate in Paranal / ORM Observatory incoming inspections.

3.7 Installation and Commissioning Phase

Safety analysis shall evaluate design and operational changes for impact on product safety, assuring that safety margins are maintained and that operations are conducted within accepted risk.

The analysis shall also support the evaluation of operational anomalies for impact on product safety, and the continued evaluation of risk trends.

In addition to the product safety compliance assessment activities on system and subsystem level the CTAO CE Coordinator shall

1. organize in cooperation with the site safety officer In-Kind Contributor staff training in observatory safety regulations
2. perform safety related inspections and tests
3. monitor the safety related reintegration and installation activities
4. perform safety training for users and maintenance staff
5. participate in CCB and other project meetings as required

3.8 Final Acceptance

Final acceptance of any deliverable is performed at the CTA site and documented by an acceptance certificate issued by CTAO.

By signing the acceptance certificate, CTAO confirms that the deliverable complies with the contractually specified requirements.

The CE Conformity Declaration is an essential legal document for the acceptance act.

3.9 Operation Phase

During the Construction Phase the operational product safety procedures and processes will be defined by the Project Office in cooperation with the Operation Department and the CTAO CE Coordinator. The execution of these procedures and processes is the responsibility of the Operation Department.