Quality Plan

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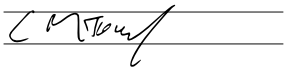
2.1	2015-10-26	Complete re-write post i-CDR. Does not yet fully deal with software. Some placeholders remain for future work. Released for comment but should be considered approved for use – hence no checker yet.	Open	Editor: C.M. Townsley Checker: _____ Approver: 

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1 Quality System

The CTA Construction Project Quality System consists of a set of quality plans, methods or procedures, standards, tools and resources developed and specifically chosen for meeting the CTA Quality Objectives and is applicable to the design, production, and assembly of the CTA Observatory. (For operations and maintenance, another quality system will be developed and implemented in the CTA observatory.)

The CTA construction project quality system consists of:

- Quality Objectives
- Quality Policy and Management Commitment
- Quality Plans
- Test Plans
- Test Equipment and Test Facilities
- Standards
- Documented Procedures and Work Instructions
- Control Plans and Inspection Plans
- Quality Agreements with Suppliers
- Audits of Suppliers' Quality Systems
- Surveys of the CTA Work-Packages' Quality Systems
- Quality Records
- Non-Conformance Management

Quality standards and procedures associated with the top level quality plan of the CTA construction project may be found in the appendices of this document.

1.1 Quality Objectives

The Quality Objectives of the CTA construction project are to build and deliver a defect free, reliable observatory that fulfils all requirements and specifications in order to be operated efficiently with a high quality of service and availability, and capable of delivering reliable data to the scientific community. The CTA construction project quality system is designed to meet the objectives in a cost effective manner by substantially reducing defects, errors and repair costs.

The CTA quality objectives are:

- Support the design of products for meeting all requirements.

- Support the production processes for keeping them under control and capable of producing parts that fully meet the specifications.
- Support the procurement processes for obtaining products from external suppliers that are free of defects and which meet all the specifications.
- Prevent non-conforming parts arriving at the observatory site.
- Resolve and minimize quality problems, guiding the improvement process for eradicating the cause of non-conforming products.
- Keep control and maintain quality of project documentation.

1.2 Quality Policy and Management Commitment

The collective CTA Project Management undertakes to construct and deliver the CTA observatory, meeting all stakeholders' requirements and quality objectives through full support and commitment in terms of resources (manpower, training, facilities, and equipment), motivation and implication of the personnel in implementing the quality system and through appropriate quality agreements with the external suppliers. They also undertake to support and foster the continual improvement of all processes during the construction and later during the operation of the observatory.

1.3 Management of the Quality System

The quality activities of each work-package or in-kind contributor are managed by its Quality Representative with the technical support and supervision of the CTA Quality Officer.

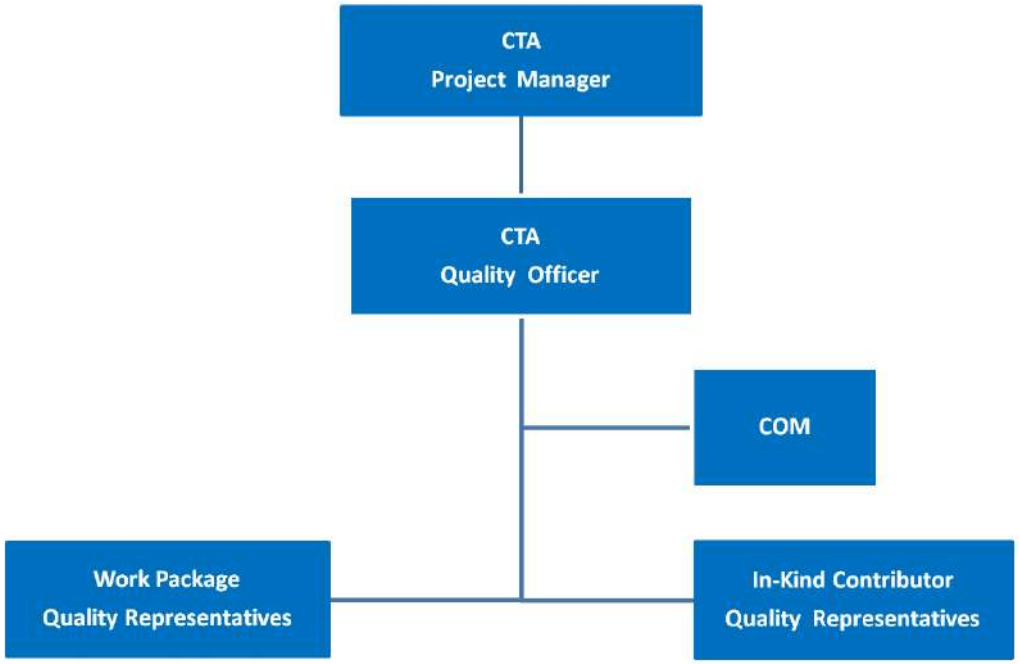

Figure 1.1 – CTA quality organization structure. Until in-kind contribution contracts are established it is not defined exactly the distribution of responsibility for quality between in-kind providers and work-packages. In the text 'work-packages' means both 'work-packages' and 'in-kind contributor' interchangeably until the situation is fully established. This diagram covers all possibilities. COM performs Quality Assurance and Quality Control on behalf of the CTA Project Office and is delegated to do so by the Project Manager and quality officer.

The tasks and responsibilities for developing, implementing and maintaining the CTA quality system and for meeting the CTA quality objectives are:

The collective CTA project management, consisting of the Project Board, Project Committee and their members:

- Fully supports the quality policy and objectives described in the present document.
- Communicates the quality policy and objectives to all members of the CTA project.
- Provides the necessary resources in terms of budget, training, qualified personnel, facilities and equipment in order to achieve the quality objectives of the project.
- Motivates and involves all the personnel for implementing the CTA quality system.
- Makes decisions including the request of deviations and waivers (approving or rejecting them.)

The Quality Officer:

- Defines this CTA quality system.
- Prepares the top level quality plan (contained in this document) and creates and implements specific documented procedures for project office quality activities.
- Provides support to the work-packages for developing and implementing their own quality plans.
- Assesses whether the test plans and control plans of the work-packages are appropriate for achieving the quality objectives.
- Assesses the test reports of the work-packages.
- Assesses and carries out surveys of the quality system implemented by the work-packages.
- Concludes quality agreements with external suppliers of the project office.
- Checks that the project documentation is controlled and satisfies quality standards.
- Defines Key Performance Indexes (KPI) and collects quality data from the work-packages for measuring the progress and achievement of the quality goals.
- Assesses the impact that deviations, waivers and changes can have on quality.

The Quality Representative of each work-package and of each in-kind contributor:

- Develops and implements their own quality plan.
- Creates specific documented procedures for quality activities.
- Takes part in the definition of functional and critical characteristics of the products of their work-package.
- Assesses the work-package test plans and test reports.
- Prepares and implements control plans.
- Makes quality agreements with external suppliers.
- Implements incoming inspections for external products arriving to the work-packages' (or to the in-kind contributors') production facilities.
- Carries out supplier quality audits.
- Carries out internal quality audits.
- Participates in validation and acceptance events.

- Ensures that there is an adequate process for dealing with nonconforming products. Launches nonconformity reports, manages the process for solving and closing them and promotes a continuous improvement process to prevent that the same or similar nonconformity occurs again.
- Keeps records of the quality data.
- Keeps control of the internal documentation.
- Assures that the CTA project office receives the required documentation.

1.4 Auditing the CTA Quality System

The work-package quality representative should audit the work-package's quality system periodically and make sure that it is in place and it is being applied. The CTA quality officer will carry out periodic surveys of the work-package's quality systems in order to check performance and promote corrective actions when necessary. For this purpose, the quality officer should have access to all production and test facilities subject to suitable prior notification.

1.5 Resources

The correct implementation of the quality system will require in many cases specific equipment, work environments and training of personnel. If the production is outsourced, the work-package quality representative should check that these resources are considered and described in the supplier's quality plan.

1.5.1 Human Resources

Each work-package and in-kind contributor should nominate a quality representative with appropriate skills to setup and administer the quality system and, if necessary, be trained to obtain them. The quality representatives will coordinate and supervise the quality activities in the team and will be the contact person for quality related issues.

1.5.2 Training

Personnel should be properly trained for implementing the quality system and for working with the quality tools, test facilities and measuring equipment.

1.5.3 Materials

The personnel involved in item development are responsible for defining the specifications of the materials that will be used for meeting the project requirements. The quality representative will assure that the materials used in the product meet these specifications, for example by means of material certificates.

1.5.4 Work Environment

When an item requires a special work environment or facility for its production/assembly or test (for example, clean rooms, protection against electrostatic discharge, controlled room temperature, humidity, illumination, etc.), the quality plans will describe the specifications and parameters of such work environment and the equipment that is needed (air conditioning, air filters, lamps, etc.).

1.5.5 Test Equipment and Measuring Instruments

The necessary resources should be provided in terms of facilities and equipment for carrying out test plans, control plans, inspections, etc. It is the responsibility of each work-package, in-kind contributor and supplier, to guarantee that any tool, instrument or equipment used for measuring or testing the product is calibrated and in good working condition.

1.5.6 COM Test Facilities

Parts of the COM work-package on behalf of the project office designs, builds and operates a set of facilities for evaluating and testing mirrors (Mirror Test Facilities) and cameras (Camera Test Facilities) to ensure that the main performance, stability, and other requirements are met. The remit of the COM work-package may be expanded in the future to cover components/activities such as drive systems and finite element analysis, it will also almost certainly be more tightly integrated with the work of the project office.

These parts of COM are involved in all phases of the project:

- During the pre-construction phase, to evaluate and test technology, providing feedback for design improvement against the requirements.
- During the pre-production phase, testing that the designs meet the requirements.
- During the production phase, carrying out routine tests, in order to prevent nonconforming items arriving at the observatory site.

For further information on these test facilities and procedures consult the relevant Technical Design Report(s).

2 Quality Plan

2.1 Introduction and Scope

The CTA construction project quality plan describes the general quality requirements, activities, methods and required resources applicable to all CTA project work-packages, in-kind contributors and external suppliers in order to meet the quality objectives. It applies to all phases of the project.

Based on this quality plan, each work-package and in-kind contributor is responsible for creating and implementing their own quality plan according to its internal organization, products, processes, and phase of the CTA project in which they are involved. Each quality plan should describe how quality is managed within its constituent organization and how the required activities will be carried out, either in the quality plan itself or by reference to appropriate documented procedures or other documents. These quality plans and referenced documents must be made available to the CTA project office.

These specific quality plans should include the following:

1. All aspects contemplated in this CTA construction project quality plan or, in special cases, well-founded reasons for excluding certain aspects of the present document.
2. Responsibilities and authorities of the persons involved in the design and production of the contributed item during the different project phases.
3. Allocation of resources, manpower, training, equipment, etc. necessary for quality related activities.
4. Quality assurance activities for the product design.
5. Quality assurance and quality control activities for production, construction and commissioning.
6. Sequence of events, key dates and hold points.
7. Methods of document control (e.g. revision and issue control, storage system, approval procedures, etc.).
8. List of quality records to be retained.
9. Reference to the documented change control procedure.
10. Quality requirements for procurement which should be negotiated and agreed with the suppliers.
11. Necessary testing, controls, inspections and audits for each phase of the project.
12. Method of identification and traceability of items.
13. Internal control procedure of nonconforming items.

The necessary support and guidelines for creating and carrying out the quality plans will be provided by the CTA project office, in some cases this may include parts of quality plans and procedures which may be copied from this document if appropriate.

2.1.1 Special Characteristics

The term *Special Characteristic* is an important term used for quality control and is explained here since it is mentioned in many sections of this document. Special characteristics are particularly important product characteristics or process parameters which require additional measures in order to assure their compliance. They should be clearly identified in the technical drawings, the Control Plan (see section 4.8.1) and the Work Instructions.

Special characteristics are of two categories:

- Significant Characteristics: which can affect fit, function, performance or subsequent processing (identified with a diamond/rhombus symbol or with 'SC')

Figure 2.1 – Significant Characteristic symbol

- Critical Characteristics: which can affect safety or compliance with government regulations (identified with an inverted triangle inside a circle or with 'CC')

Figure 2.2 – Critical Characteristic symbol

One type of special characteristic is an inspection dimension consisting of a measurable dimension (often relevant for assembly interfaces) which shall be handled with special attention by the quality assurance team and controlled during production. Inspection dimensions should be defined and clearly identified (i.e. 'ballooned') in the technical drawings, using for example the guidelines of the norm DIN 406.

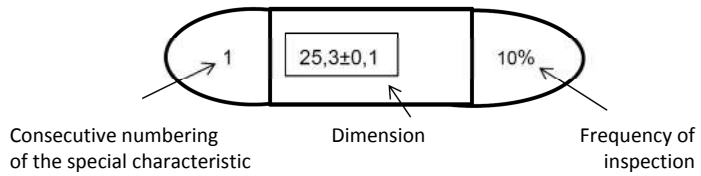

Figure 2.3 – Inspection balloon

In this example, the dimension 25.3 (including measurement units) of this special characteristic identified with the number 1 should be checked in 10% of the production.

Other special characteristics could be for example the water tightness of an electrical device that will be exposed to the rain; the minimum allowed glass thickness of a mirror or, in the case of a characteristic related to the production process, the cleanliness of a mirror surface before coating it.

Most special characteristics arise from the corresponding product FMEA (Failure Mode and Effects Analysis) and PFMEA (Process Failure Mode and Effects Analysis). The systematic control and inspection of these characteristics reduces the risks found in the FMEAs.

2.2 Control of Documents

The quality officer and each quality representative will audit regularly that:

- The CTA project documents are controlled.
- Only the last approved version is available to the members of the CTA project.
- The document references, histories and approval status are correct and consistent.
- The documents are stored in the right place.

The relevant standards are described in the appendices of this document.

All documents must be kept for at least the duration of the project but are likely to be kept for the lifetime of the observatory if decided so at project close-out.

2.3 Control of Quality Records

The following quality data must be recorded and stored by the quality representatives of the work-packages and of the in-kind contributors and a resume should be sent regularly to the CTA project office:

- Calibration data of equipment used for measuring and testing critical characteristics (once per year).
- Nonconformity reports and corrective action plans (ongoing).
- Test plans (once and when it has been modified).
- Test results in form of a Test Report (once per validation of the product design and when the design has changed).
- Control plans (once and when it has changed).
- Control and inspection results during and after production (once per delivery).
- Data obtained from internal quality audits and the corresponding outcomes and action plans (once per audit).

(The items listed above are described in the present document.)

The following quality data will be recorded and stored by the quality representatives of the work-packages; the in-kind contributors and by their respective suppliers. This data will not be sent to the CTA project office, however its existence and correct analysis should be audited regularly (once every 6 months) by the quality officer or, in the case of suppliers, by the quality representative (once every 3 months):

- Raw Data obtained from tests, controls and inspections.
- Traveller Sheets (for traceability purposes) with serial numbers of the components, batch number of materials used, date of production and name of the person who carried out the work at each step of production.

- Register of the expiry dates of those materials and chemicals used in production that need to be strictly observed (epoxies glues for example often have a short life time and for that reason, the date when the bottle seal has been removed must be recorded).

2.4 Quality Assurance for the Pre-Construction Phase

The following sections describe the tools and activities to assure that the product design meets the requirements. It is the role of the quality members to ensure that the activities take place.

2.4.1 Failure Mode, Effects and Criticality Analysis

During the detailed design phase, developers and the quality representative should assess the risks affecting the products by means of Failure Mode, Effects and Criticality Analysis and should carry out as many loops of design improvement and FMECA analysis as necessary, in order to solve or minimize eventual criticalities.

2.4.2 Tests for Validating the Design

Each product design needs to be verified, which means to make sure that it meets all specifications of Level C and I (interface specifications) and hence all CTA requirements. For this purpose a series of tests will be developed, described and formally approved in form of test plans during the pre-construction phase by the work-package teams.

The Test Plan describes the requirements and characteristics to be tested, the tolerances, the applied method, the necessary test equipment, the necessary personnel skills and the pass fail/criteria.

The Test Plan should take into account the verification methods associated with the specifications. When applicable, the test plans should include accelerated life testing and accelerated degradation testing for verifying the Reliability, Availability Maintainability and Safety (RAMS) requirements.

The project will decide which requirements need this full treatment at various gateway reviews (such as the pre-production and (mass) production readiness reviews).

Test Plan Preparation

The personnel involved in the technical development assisted by the quality representative will prepare test plans for those requirements that can be verified at this stage. (It might not be possible to verify a few requirements on a sub-system or component but only later on a complete telescope or complete array and will require their corresponding test plan in a later stage of the project).

Test Readiness Review

The project office systems engineers, the work-package manager and the quality representative will review that the test plans are appropriate for proving that the requirements are fulfilled and also that they are consistent with the proposed verification methods. The outcome of this review should be the formal approval of the test plans.

Test Equipment

Following the approval of the test plans, the work-package developers will then choose the equipment and tools necessary for carrying out the test plan, procure them or design and build them. When the test equipment and tools are ready, they shall be calibrated, reviewed and formally accepted by the work-package quality representative and the work-package leader.

Testing

The tests will take place during the pre-construction phase and the pre-production phase and also at a later stage of the project whenever a change is made in the product design.

Test Reports for the Validation of the Design

The test results will be summarized in the corresponding test reports for further assessment by the work-package manager, the quality representative and the CTA project office. If a requirement is not met, the product should be re-designed and tested again. In special cases when a re-design is not feasible, it might be necessary to change the requirement. When the outcome of this assessment is favourable, the design can be validated, which means that the design is formally accepted and frozen.

Any change in the product design from here on needs to follow the Change Control procedure.

2.4.3 Control of Changes

When considered necessary and after a careful investigation, a change request of design or of the requirements can be initiated. The procedure is described elsewhere.

2.4.4 Documentation for the Pre-Construction phase

The documentation related to quality that should be prepared in the pre-construction phase is following:

- Quality Plan
- FMECA
- Test Plan
- Test Report and assessment outcome (approval and freeze of design or rejection and action plan)
- Eventual change request for changing a requirement

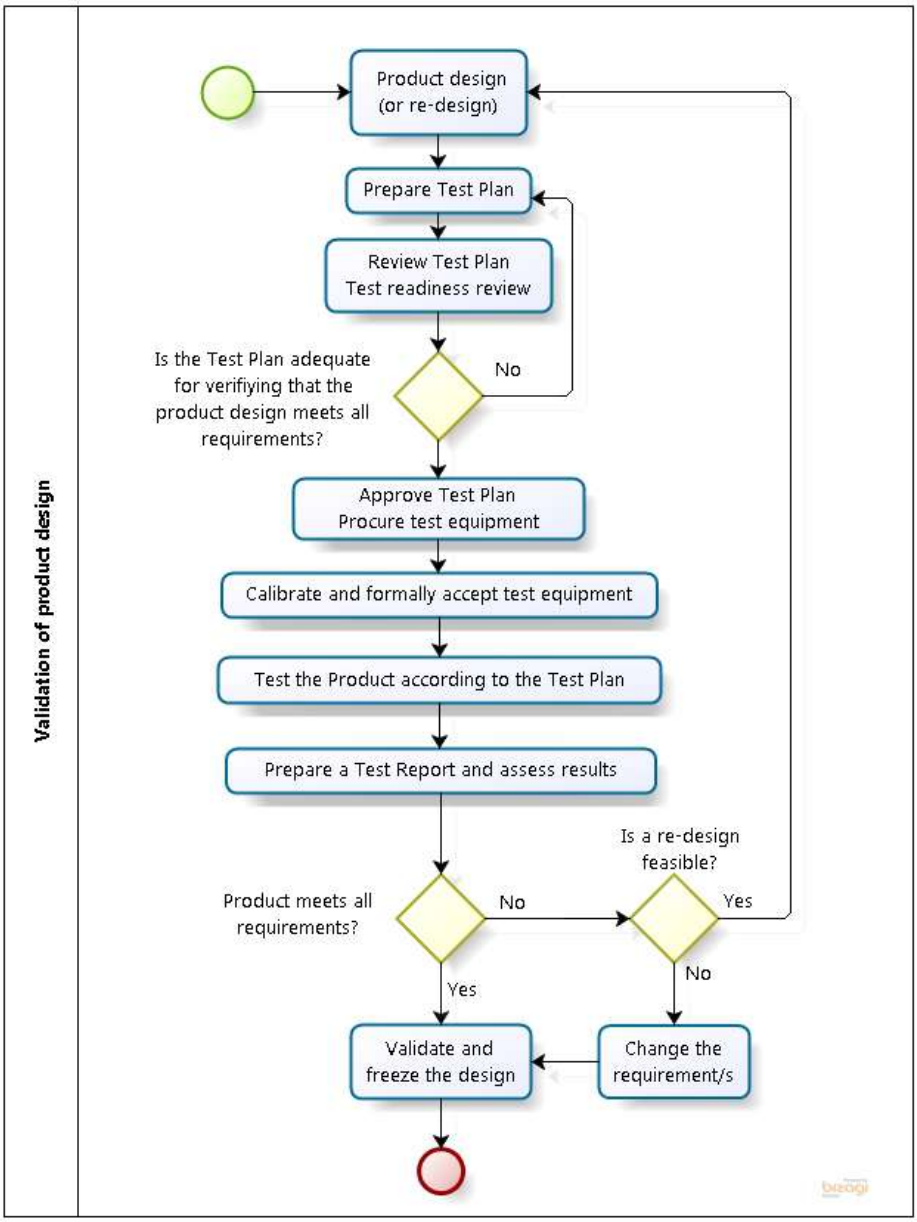

Figure 2.4 – Process of product design validation

2.5 Quality Assurance for Construction

During the construction phase, which consists of the pre-production and the production phases, the goal of the quality activities is to deliver products to the various CTA locations that are free of defects. For achieving this, it is necessary to procure defect free raw materials and components, to have stable production processes, adequate controls along the production chain and trained personnel for operating the processes.

The quality of externally produced products will be assured through incoming inspections and by means of quality agreements with each supplier.

A production layout, work flow and process FMEA should be created during the pre-production phase. This allows the definition of the controls that are necessary at each step of the production and to document them in form of control plans.

Before starting production, a (Mass) Production Readiness Review should take place for making sure that the criticalities have been solved, the inspections and control plans are in place and the production process is capable of producing the required quality and quantity on schedule.

2.5.1 Control Plans

Each item to be manufactured by a work-package, in-kind contributor or supplier should have its corresponding control plan, describing for each special characteristic and other characteristics considered relevant, where in the production process they are controlled, how often, by whom, with which equipment or instrument and the pass fail/criteria. Control plans may also be useful for parts of the prototyping where many items are required.

For procured products, the need of a control plan implemented by the supplier should be specified in the contract.

The input data for creating a control plan is obtained in the following chronological sequence:

1. Design FMEA from which the special characteristics are obtained.
2. Production layout and process flow diagram (with numbered production steps).
3. Process FMEA (PFMEA) and resulting special characteristics.

The control plan is usually a spreadsheet prepared for a specific production process. Control plans must be kept updated and will be audited by the quality representative/officer.

Production Process Flow Diagram

The production team of the work-package or of the supplier should prepare a flow diagram of the production process in which all steps are described and numbered.

Process FMEA (PFMEA)

The production team will prepare a Process FMEA (PFMEA) which analyses the steps of the production process in order to identify and evaluate the potential failures that can occur and prioritise the action items for alleviating the risk. The PFMEA shall undergo as many analysis loops as necessary until the risks are solved or minimized by means of a re-design of the production process and additional controls and error proof methods (Poka Yoke). The PFMEA should be reviewed and signed by the work-package systems engineer and, in case of external production, by the supplier as well.

Identification of Special Characteristics

The product developers and the quality representative will identify, define and document the special characteristics of the product and of the production process based on the design FMEA and PFMEA analysis. Special characteristics should be clearly identified in the technical drawings, the control plan and the work instructions.

Preparation of the Control Plan

The quality representative from the work-package, from the in-kind contributor or in case of purchased parts, from the supplier), will assist in the preparation of control plans according to the production flow and FMEAs results.

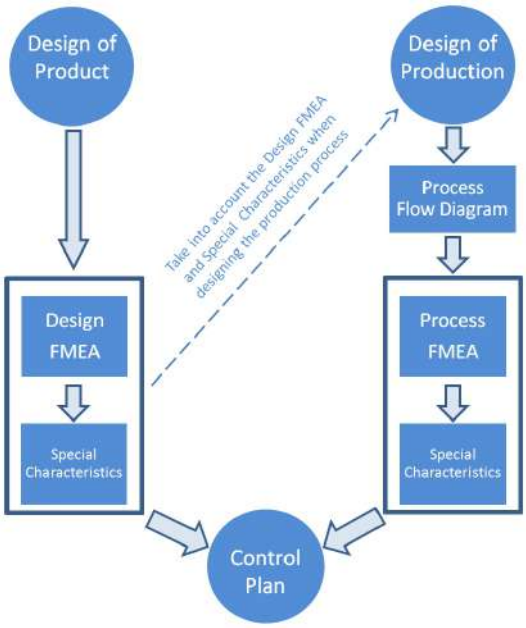

Figure 2.5 – Sequence for preparing a control plan

The control plans should be approved in all cases (for internally and for externally produced parts) by the work-package quality representative.

For procured products, the need of a control plan should be included as a requirement in the procurement contract and the quality representative of the work-package should check that the supplier has implemented it properly.

The figure below shows an example of a control plan spreadsheet – it is possible to also create a database for the same purpose. In each section of the sheet the following data should be filled in:

Section 1: Control Plan Information Table.

This section is self-explanatory and includes information of the part number, drawing number, supplier or contributor, contact information, approval dates, etc.

Section 2: Process

- The first column lists only those production steps in which a control or inspection activity takes place. These steps are listed in the same order in which the manufacturing process takes place and should match the numbering in the process flow diagram and PFMEA.
- The second column should contain a clear description of the process step.
- The third column lists the equipment, tool or machine needed to complete the process step.

Section 3: Quality Characteristics of Product and Process

- The first column is a unique identifying number for the characteristic being inspected or controlled.
- If the characteristic is measured on the product itself, the second column is filled in with the description, otherwise it is left blank.
- If the characteristic belongs to a process (i.e. temperature parameters of a machine), the third column is filled in with the description, otherwise it is left blank.
- If the characteristic is a special characteristic, it is noted in the fourth column with the corresponding symbol or acronym SC (Significant Characteristic) or CC (Critical Characteristic).

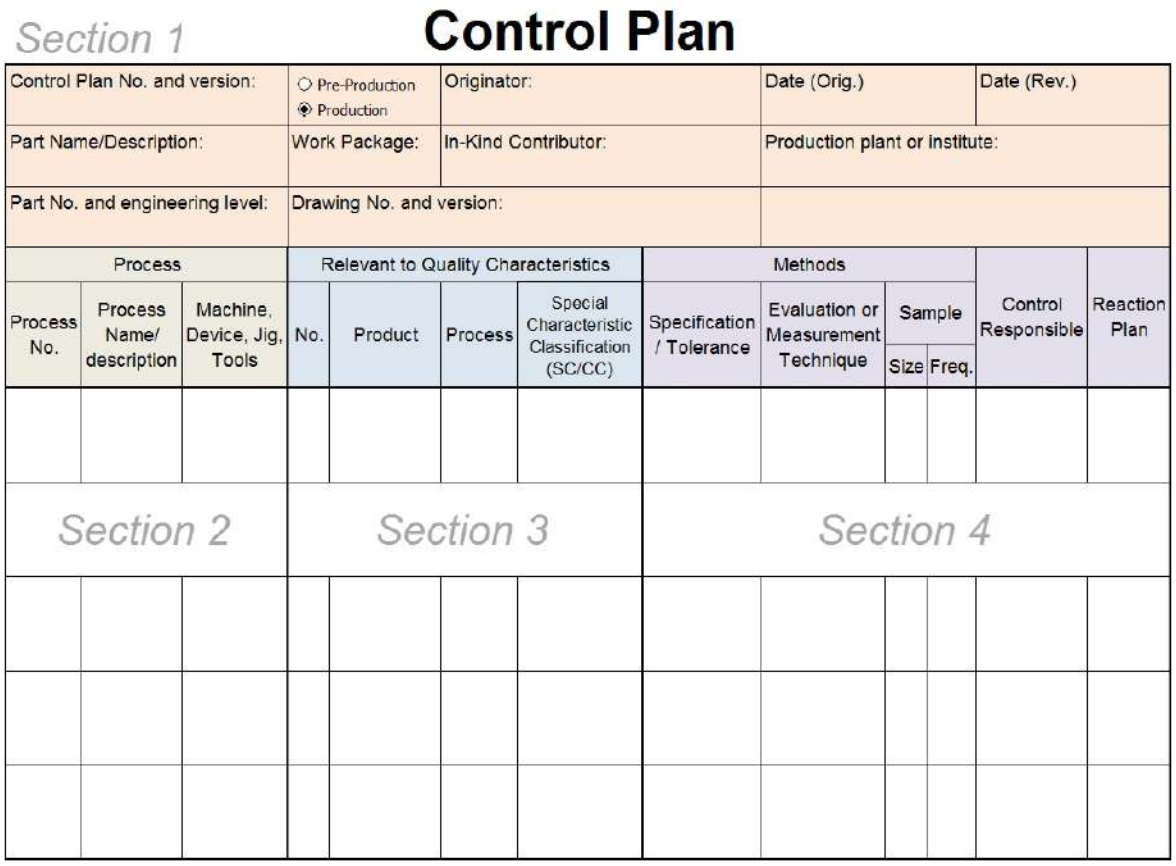

Figure 2.6 – Control plan example.

Section 4: Control Methods

- The first column lists the specification and tolerance for each characteristic.
- The second column describes the measurement method to collect the data (scale, caliper, go/no-go gauge, etc.
- The third column describes the sampling plan. How many samples are drawn at what frequency.
- The fourth column shows the responsible in charge of making the controls. It can be the person working in the production, the quality responsible, the production manager, etc.
- The Reaction Plan column shows the reference number to a reaction plan flow-chart that tells what to do in the event of an out-of-control or out-of-spec. condition. Reaction plans may be somewhat generic for families of processes with similar criticality.

Control Charts

The Control Chart is a tool that helps to monitor if a manufacturing process is under control, which means that variations are due to common causes (usual, historical, quantifiable variations) or if on the contrary it is not under control and shows variations due to special causes (unusual, not previously observed, non-quantifiable variation).

A control chart is useful for monitoring processes with a high number of produced parts in which it is possible to collect enough historical data for an adequate statistical analysis. Therefore the use of control charts could be considered for large production number items such as mirrors an detector modules.

A simplified control chart shows the nominal value of the characteristic and its upper and lower control limit. The measured values of a specific product or process characteristic are introduced in the chart periodically during the production process, allowing a real time detection of any process shift and to know if it is due to a special or a common cause. Values beyond the upper and lower control limits (typically at 3 standard errors from the centre line) are considered statistically unlikely and therefore due to a special cause. (More information regarding control charts can be found for example in the ISO Norm 7870.)

The feasibility of using control charts will be analysed case by case by the work-packages together with the CTA quality officer.

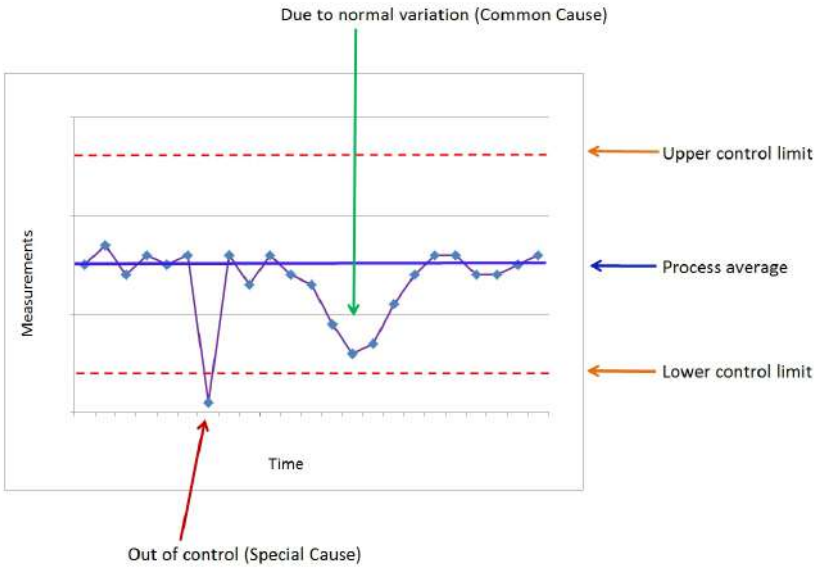

Figure 2.7 – Control Chart

2.5.2 Deviations and Waivers

In some cases it might be necessary and perhaps feasible to supply a nonconforming product. In such cases, a request for waiver or a request for deviation must be issued by the supplier in order to collect the authorisation of the customer. The supplier is either an external supplier of the work-package or it can be the work-package/in-kind contributor itself when supplying to the observatory. The customer is then the work-package/in-kind contributor or the observatory respectively.

Deviation

A Deviation occurs when the product does not meet the requirements or specifications before it has been produced (for example a failure in the design has been detected), or when there is known evidence in advance that it will not meet the requirements once produced (when the production process has a known problem) but for some reason the production must continue (for example due to schedule constrains).

Waiver

A request for waiver is a request for authorization to accept an item which, during manufacture or after final inspection, is found to depart from specified requirements but nevertheless is considered suitable for use as it is or after being reworked by an approved method.

Exclusion: a waiver or deviation cannot be requested for a critical characteristic that departs from the required value because it would contravene by definition the term ”critical”. Products whose critical

characteristics are nonconforming should never be approved nor delivered to the observatory.

2.5.3 Incoming Inspections

Upon arrival of externally produced parts to the assembly/production facility of a supplier, work-package, in-kind contributor or to the CTA observatory site, an incoming inspection must always be carried out. The quality representative will create an incoming inspection check list describing how to carry out the inspection, the characteristics to be controlled, the sampling frequency, the pass/fail criteria, the necessary tools, the person who carries out the inspection and how to proceed when the product shows a nonconformity (see Section 2.7).

The checklist should be filled in for each incoming inspection and forwarded to the head of production for revision and acceptance of the batch or the product before storing it in the warehouse or bringing it to the production line. The data of each incoming inspection is part of the quality records and must be kept until the final decommissioning of the observatory for traceability purposes. When the number of pieces is high and an incoming inspection of all parts is not feasible, the quality representative may choose a sampling method (for example ISO 3951).

Examples of aspects to be checked during an incoming inspection are:

- The packaging meets the requirements and is not damaged (including shock and tilt indicators).
- Product looks ok at a first glance (no loose parts, dents, cracks, etc.).
- The product corresponds to the type, model and characteristics that had been ordered.
- The product is marked with the corresponding identification (reference, engineering level, serial number).
- The quantity of pieces, batch number and serial numbers match with the packing list and with the purchase order.
- The required documentation is attached to the delivery (packing list, as build configuration, level of engineering, handling and safety instructions, etc.).
- A measurement or test of special characteristics carried out on a sample(s) is satisfactory.

In case any of the inspected parameters shows a nonconformity, the entire batch must be put immediately in quarantine and clearly labelled to prevent that it arrives to the assembly/production line. The next step is to launch a nonconformity report describing the problem and to inform the work-package leader in order to decide if the lot can be accepted after a full inspection of all parts, can be reworked or if it must be rejected and sent back to the supplier.

2.5.4 Product Identification

Product identification is fundamental for proper control of the system configuration and for future maintenance activities and product upgrades. All parts and components produced or purchased must be clearly identified with a product number, serial number and engineering level. This information must be engraved or placed in such a way that it cannot be removed or deleted accidentally. The product identification data shall be recorded and stored in a document together with a brief description of the changes made in each new engineering level (product history). Electronic components with firmware and Printed Circuit Boards (PCBs) must have a sticker indicating the firmware version and engineering level. When the firmware is modified (upgraded or downgraded), the sticker must be replaced by a new one with the corresponding version. The firmware should be password protected in order to avoid accidental or unauthorised changes.

2.5.5 Packaging

The quality representative will prepare a specific test plan for verifying that the packaging of especially delicate parts is adequate for the transport conditions. For critical and costly products, the use of shock and tilt indicators as well as humidity and temperature sensors could be taken into consideration, especially when a verification of the integrity of the product upon arrival to the site is technically not feasible or very complex. In such cases, it is necessary to define a threshold of humidity, temperature or shocks/accelerations and to design an appropriate packaging. Items (for example electronic components) which can be damaged by condensed water that may appear inside the packaging during transport due to big temperature and pressure changes should be protected additionally (humidity absorbers, waterproof sealing, etc.)

In case of procured products which are shipped directly to the site, the quality representative should inform the supplier about the transport and environmental conditions and should supervise that the packaging requirements are met. The packaging design should be tested by the product developers and approved by the work-package manager.

2.5.6 Process Capability Study

For complex production processes and high number of produced parts with strict delivery schedule, it may be important to verify that the production process is capable of producing the ordered quantity with the required quality. The study consists of auditing the production under standard conditions, counting how many pieces are produced in a period of time (perhaps one day or one shift) and taking some samples for verifying in detail that all requirements are met. Not only the total number of produced parts is important for extrapolating if the order can be delivered on schedule but also the amount of parts that are defect and the type of defects, since this shows if the process is reliable and hence if the quality requirements can be met consistently. If for example a process produces many defect parts (e.g. more than 1%), then a mandatory 100 % inspection is necessary. This could be considered for mirrors, actuators and other high-volume parts.

2.5.7 Documentation for the Construction Phase

The documentation related to quality that should be prepared in the construction phase is following:

- Production layout and process flow diagram
- Process FMEA
- Control plan (and control charts if applicable)
- Process capability study in specific cases (high amount, high complexity, tight schedule)
- Checklists for incoming inspections
- Product history describing the changes made on each new engineering level
- Test plan for checking the packaging of very delicate products
- Eventual request of deviation/waiver

2.6 Procurement

The work-packages are responsible not only for the quality of their own products but also for the quality of the products procured by them. Therefore the work-packages need to make sure that the quality systems of their suppliers are appropriate and that they are in place during the duration of the contract for preventing that the supplier delivers defect material or components.

Each work-package or in-kind contributor should define criteria for evaluating and selecting the external suppliers from a quality point of view. For example a request for information can be sent to the supplier in order to collect data regarding their quality system, quality certifications, awards, quality tools, level of expertise in similar products or technologies, offered warranty conditions and after-sale service, availability of spare parts in the long term, etc.

2.6.1 Special Characteristics of Purchased Products

The product development team and the quality representative will identify the special characteristics of the purchased products that are relevant for them (for example for interfaces) and will communicate them to the supplier. The supplier should include also other special characteristics according to its experience. Although the supplier might want to keep its own special characteristics confidential as part of their intellectual property, they should at least confirm that they are being controlled.

2.6.2 Quality Agreement with Suppliers

A quality agreement between the work-package and the external suppliers should be included in all procurement contracts except perhaps for commercial products of the shelf (COTS).

The quality agreement establishes:

- The quality requirements that the work-package manager needs to communicate to the supplier.
- The need of a supplier's quality plan and control plan.
- The tests, inspection and controls before, during and after production which the supplier has to implement.
- The list of special characteristics to be controlled by the supplier, including method and frequency.
- The calibration documentation, showing the status of test equipment used for controlling critical characteristics.
- The file format which should be used for exchanging technical drawings between the work-package and the supplier (e.g. IGES).
- The warranty conditions.
- The procedure for solving nonconformities.
- The packaging requirements.
- The requirements for product identification, marking and labelling
- A signed Capability Commitment, where the supplier confirms to be capable of meeting all requirements and of supplying the requested quantity and quality on schedule.
- The documentation which the supplier must attach to each delivery, for example:
  - As-built configuration with product number, revision index, production date and serial numbers of components and sub-components.
  - Test results, inspection logs.
  - Material certificates.
- Other supplier documentation: maintenance manual, spare parts lists, RAMS data, operation manuals, transport and handling instructions.

2.6.3 Material Certificate

A material certificate proves that the quality and properties of the material correspond to the specifications. It can either just confirm the compliance with an international norm or it can contain the results of a chemical analysis and/or physical test made by a certified laboratory together with a statement that the required specifications are met.

The CTA work-packages should request the suppliers to attach a material certificate to each delivered batch of critical or relevant parts (for example for the steel of the telescope structure, special fixation screws, concrete of telescope foundations, etc.)

In most cases, the material certificate should have no extra cost for the work-packages because the supplier obtains it systematically with each lot of raw material it purchases. The supplier just forwards a copy corresponding to raw material it used for the produced parts to the work-package quality representative.

In some cases in which there is a special concern, lack of confidence or high risk, it might be convenient that the work-package makes or contracts an independent analysis of the material on its own.

2.6.4 Audit of Suppliers

Before signing the purchase contract, the work-package an in-kind contributor quality representative should audit the supplier's quality system and production facilities (if this was not done before, during the suppliers selection process), in order to verify that the quality requirements can be fulfilled. This audit can be carried out together with CTA quality officer if desired and should take no longer than half a day or, for very critical parts, perhaps one day. During the duration of the contract, the quality representative will continue auditing the supplier's quality system and production facilities periodically in order to verify that the quality agreements are being fulfilled and the quality system continues in place. The supplier should be audited also when a major change in the production process is made and when a production line is moved to a different location. It is important that the work-packages reserve the right to carry out these audits at the supplier's facilities and that this is clearly stated in the procurement contract.

2.6.5 Documentation for Procurement

The documentation related to quality that the supplier should prepare is:

- Production layout and process flow diagram
- Process FMEA
- Control plan (and control charts if applicable)
- Process capability study only for special products (high amount, high complexity, schedule relevant)
- Check lists for incoming inspection
- Check lists for final inspection before delivery
- Material certificates
- Product history describing the changes associated to each new engineering level
- Test plan for checking the packaging of products that require special conditions.
- Request of deviation/waiver (if a non-conforming product needs to be delivered)

The documentation related to quality assurance in the procurement process that the work-package or in-kind contributor should prepare is following:

- Quality agreement with suppliers
- Audit of suppliers (audit questionnaire and audit report)

2.7 Management of Nonconformities

A nonconformity is defined as a failure to meet the requirements and may be detected in the product itself or in the process used for its realization. It can be detected in internal or external audits, tests, incoming inspections, during production, after production or even through customer complaints.

For reporting and solving nonconformities with external suppliers and among the work-packages and the observatory, a nonconformity procedure should be implemented. This nonconformity procedure is applicable to all approved parts, software, services, systems, subsystems and infrastructure of the CTA project but not to prototypes since they are not in-kind contributions to the observatory.

The objective of the procedure is to respond to the unintended delivery of nonconforming products and to prevent undesired consequences. Furthermore, the causes of all nonconformities should be investigated and a Corrective Action Plan implemented, in order to avoid whenever possible a repeat of the same nonconformity.

This procedure should be mandatory for all suppliers (internal and external) and therefore should be included as a requirement in all procurement contracts.

The term ‘Customer’ is applied here not only to the final customer (the observatory or the scientist), but also to each person or group in the process of added value within the project work-flow who receives an item for transforming it into another item or receives a service. Therefore, each member in the chain acts as a customer and in most cases also as a supplier.

2.7.1 Responsibilities Related to Nonconformities

It is the responsibility of any person involved in the CTA project who detects any service, process or product that does not meet the requirements, to report the problem immediately to its team members and to the supplier of the affected service, process or product. It is the responsibility of the coordinator/manager of the working group or of the supplier who originated the nonconformity to ensure that the causes are investigated and solved in a satisfactory manner.

2.7.2 Procedure for Handling Nonconformities

The following process model shows the steps for creating, solving and closing nonconformities within the CTA project. Nonconformities originated by external suppliers should in principle be handled in a similar way, however some suppliers may prefer to use their own NC procedures and therefore the process can vary slightly, depending on specific agreements that have been made with them. Refer to Figures 2.8 and 2.9.

Containment Plan

The coordinator communicates the nonconformity to the team involved in the production of the affected product and nominates an Action Committee to plan and implement an action plan consisting of Containment and Corrective Actions. These actions are written down in the NCR including the names of the responsible of each task, the due dates and the final fate of the noconforming product. The NCR is then stored with the status ‘Action Plan’. In order to allow a fast response, the Containment Action plan should be written and implemented within 24 hours and a detailed Corrective Action plan within five working days from detection of the NC. The coordinator of the working group is responsible for

implementing the plans in the defined schedule.

The containment action plan will include (to the extent that is possible in each case) the following steps:

1. Within the first 48 hours after receiving of the NCR the coordinator should locate, identify and quarantine all nonconforming products and those that could be potentially affected by the same problem, based on the traceability logs, production travellers and delivery documentation. Locating the NC products means to find out if they are in their own production line, in the warehouse, in transit to the customer, in the customer's warehouse or even built in the final product.
2. All quarantined products will be clearly identified with a red label and NCR number and must be checked 100% before using them. The schedule for checking them is determined by the production needs and is independent of the action plans in the NCR.
3. When procured products are nonconforming, the coordinator shall communicate the nonconformity to the supplier by means of an NCR and request a list of affected and potentially affected batches. This list shall be delivered by the supplier within the next 24 hours. From now on the supplier must check 100% of all products before delivering them until the cause has been identified and eradicated. If the non-conforming procured products are already affecting final products produced and delivered by the work-package, the coordinator of the work-package should communicate the problem to its customers and send them a list of affected and suspicious batches that should be quarantined. The coordinator might also provide additional information (photos, defect samples, special test instructions) for helping the customer to identify the affected products.

Corrective Action Plan

The corrective action plan (applicable also to suppliers) includes following steps:

1. The coordinator (or supplier) will set up a team to investigate the causes of the nonconformity and design a solution to eradicate the problem.
2. If it is decided that in the meantime that the production can continue, an inspection of 100% of produced parts should be implemented.
3. The team implements the solution and checks its efficacy for example by inspecting the first 50 produced parts.

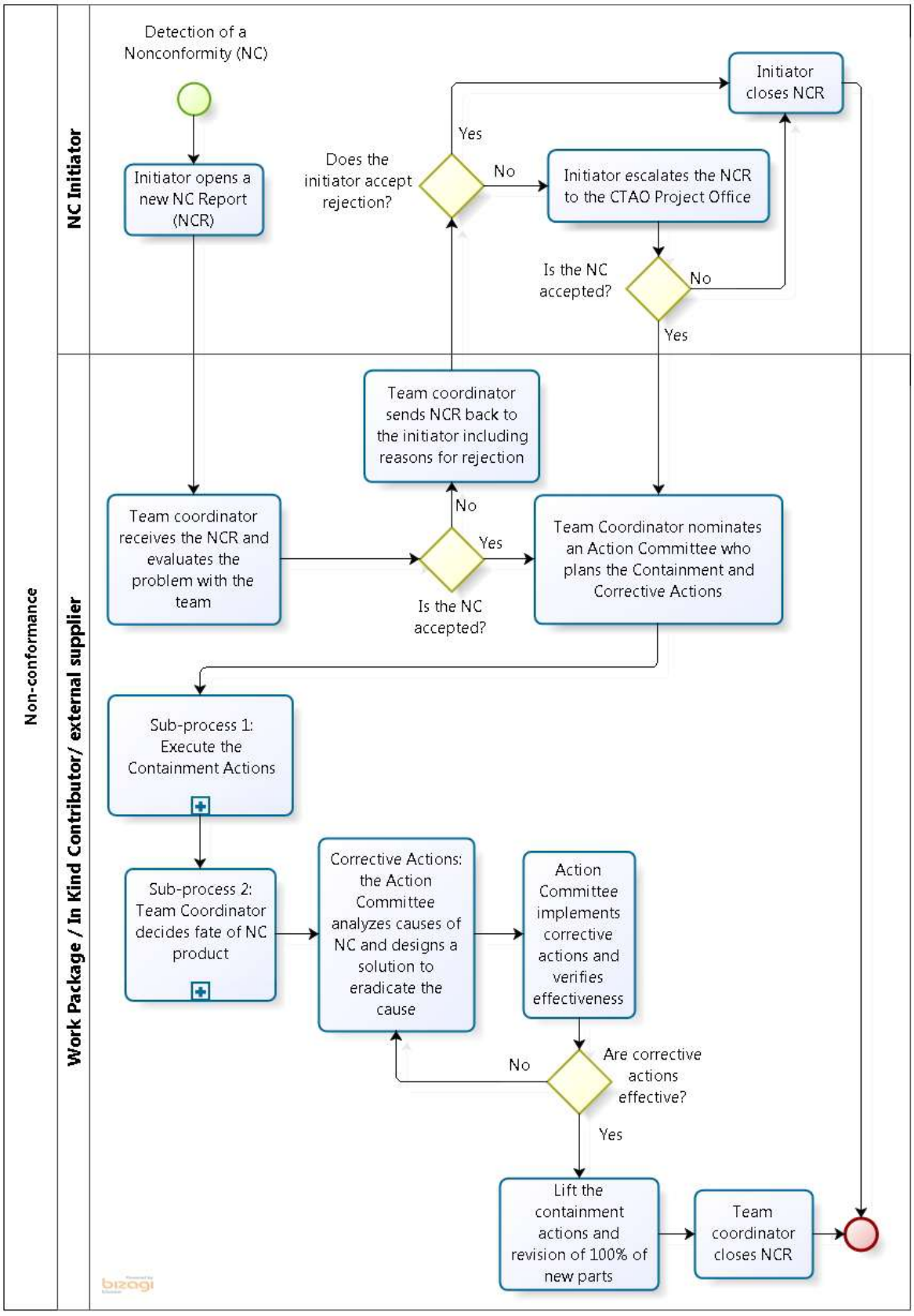

Figure 2.8 – Nonconformance process model.

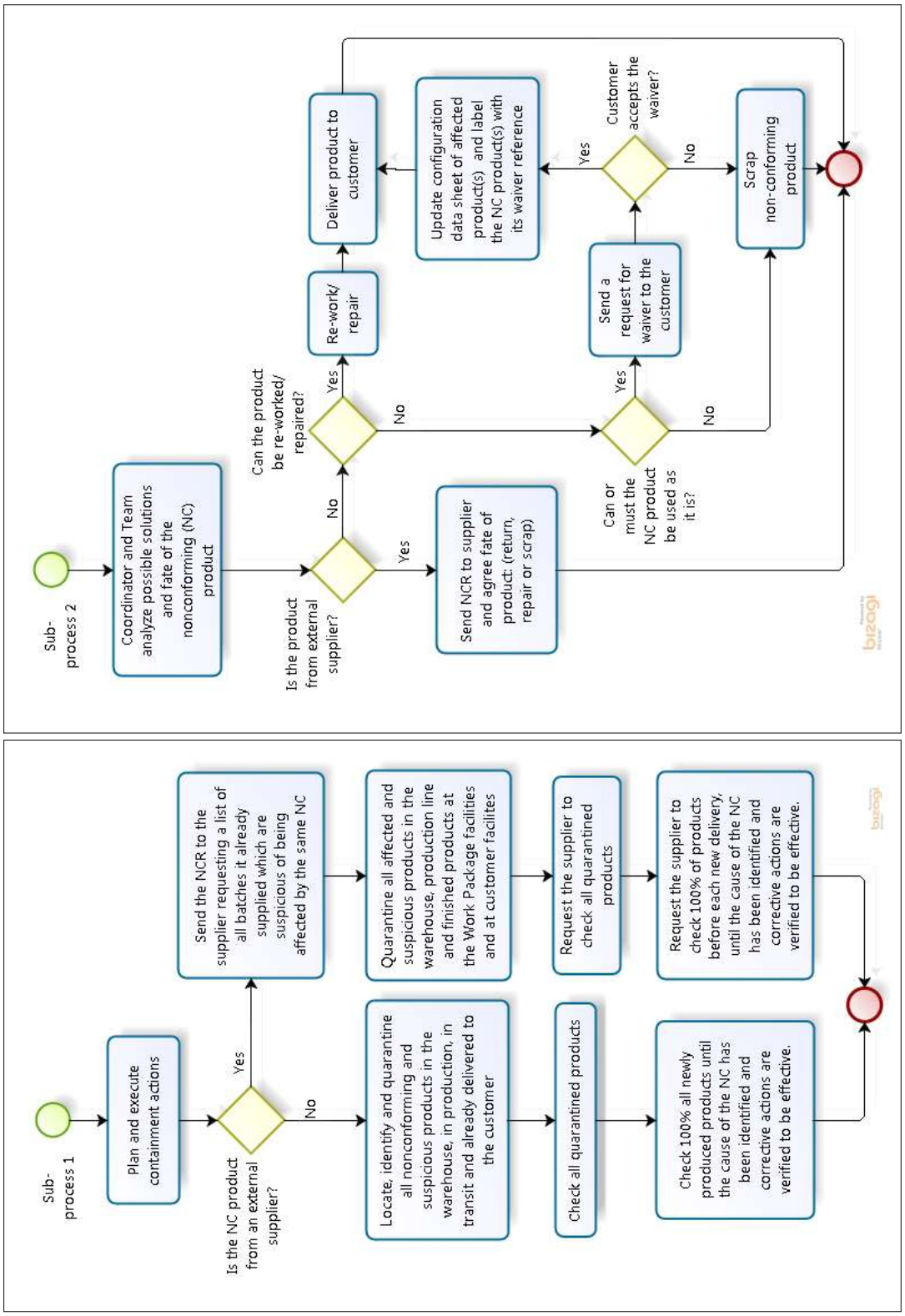

Figure 2.9 – (Left) Containment action process model. (Right) Fate process model.

A Quality Standards for Documentation

All documents produced by the CTA project office and all documents delivered to the CTA project office by the teams must follow the standards described in this appendix. They are not obligatory for internal documentation within the work-packages that will never be seen by the project office but are advised – in which case, an alternative system must be documented via their quality plan.

Attention is drawn especially to the section below titled ‘Version and Approval Control’.

Style and Template

Documents should copy the style of the present document (this Quality Plan document). In the majority of cases this implies use of the specially written CTA Latex class. The class file may be found on the CTA project/quality extranet site and may be updated from time-to-time. If absolutely necessary, unless instructed otherwise by the project office, other software may be used (such as Microsoft Word), however a standard template for this does not (yet) exist. In these cases teams may produce their own but it must be identical in style to the Latex-produced documents.

An option within the Latex class is in development for shorter or ‘working’ documents. The option will combine the first two pages of ‘front matter’ onto the first page. Until this is available teams should use the current style.

Documents received from external consultants (for example architects, engineers and reviewers) may retain the originators’ style but must have CTA-style cover pages pre-pended to them. For completeness of page numbering the received document should be inserted into the CTA latex file using the ‘pdfpages’ package.

Font sizes, headings and line spacing etc are not described here since they are automatically defined in the Latex template. No attempt should be made to defeat these settings.

These style standards are directly applicable to ‘normal’ A4 textual documents. Excel sheets, drawings and other formats do not currently follow any particular style but should still contain all the factual information described below in a consistent manner.

Document Title Information

This consists of three parts:

- ‘CTA Construction Project’ should appear automatically in the left-hand footer according to the template. If this is not the case (for example if ‘CTAO gGmbH’ appears) then you are either using an incorrect template or an incorrect option in the style.
- The main title should be reasonably short and concise. If it spreads over two lines this should not be too long and the line spacing should be equal to that between the first line and the horizontal bar above.
- The left-hand footer should include a ‘short title’ below ‘CTA Construction Project’. This can be a cut-down version of the full title to enable it to fit in the footer of every page and to enable a

less wordy reference to the document (for example ‘MST TDR’ instead of ‘Medium-Size Telescope Technical Design Report’).

Document Reference and Version

The document reference, version and date should appear in the right-hand footer.

Document Reference This consists of three strictly defined ‘fields’; the first two derived from the CTA Product Breakdown Structure (PBS). Explained here by example:

MAN-QA/110405

1. The first field is the acronym of the top-level project work-package/product under which the document has been produced (level 1 of the PBS). In this example ‘MAN’ denotes the Project Management work-package. At the time of writing other possibilities are OBS, INFRA, ACTL, DATA, SST-1M, SST-2M ASTRI, SST-2M GCT, MST, LST, SCT, SYS.
2. All documents in CTA exist in branch number 0 (‘DOC’) of level 2 of the PBS, so the second field of the document reference is an acronym from level 3 of the PBS. (The level 2 acronym ‘DOC’ is unnecessary as it would appear in all references.) In this case ‘QA’ indicates quality assurance documentation. There are too many other possibilities to list but other examples include TDR, PLANS, V&V – reference should be made to the PBS.

   Note 1: This second field of the document reference is strictly defined by the PBS - editors should not guess.

   Note 2: This second field *does not* reference technical parts of the PBS: for example MST-MECH/151022 is not a valid document reference. Instead the PBS field for ‘detailed design documentation’ should be used instead.
3. The third part of the reference is the date on which the document was first produced in the form YYMMDD. If by chance more than one document is produced on the same day with the same acronyms and date then a, b, c,... should be appended.

The document reference is not changed if the document is updated in the future - this includes not changing the date field. In this way the document reference will remain the same and unique through all updates of the document.

This form of document reference allows every document to have a unique reference to ease searches together with sufficient ‘human readable’ information to discover the document in a file system. In future it may be necessary to add extra acronym depth but the system is flexible enough to allow this if it becomes necessary.

If teams want to use their own document referencing system *in addition to* the standard CTA system described above, they may do so and enter it in the line below the ‘official’ CTA reference in the footer. However no provision is (yet) made for this in the CTA latex template and it is not supported.

Document Version Number Under Latex this automatically updates the same field in the ‘This Version:’ box. Significant version changes should be incremented by a full integer. For internal or small changes increment by a single decimal.

Document Date (of current version) This is automatically filled when compiled under Latex, it changes every compilation and there is no need to do anything.

Document Properties

Description of the tables on page 2. It is not strictly necessary to enter internal (unreleased) changes in the table but the decimal version number should be incremented every time you show the document to another individual.

This Version: Enter information for the present version of the document only. 'Ver.' and 'Created' are automatically entered and should be identical to the information in the document footer.

Add a brief Comment for the current document such as changes from a previous version or caveats to document use. If the document is subject to full change control (such as the Technical Design Reports) there should be a reference to an appendix with full details of changes from the previous version and their justification.

Enter the groups to whom you believe the document should be distributed.

The roles under 'Corresponding...' are described below and should be strictly applied.

Editor Ideally this is the name of the single individual tasked with compiling the information in the document. If absolutely necessary (but not preferred) you may refer to an appendix with a full author list. The name should be entered using the template.

Checker This individual is responsible for checking *in full detail* every fact in the document and carries as much responsibility for the document as the editor. It should be signed using an electronic signature. The checker must not be the same person as Editor.

Approver The approver is ultimately accountable for the contents of the document. This should be a single individual but they are responsible for ensuring that the relevant persons have been consulted in the document's development. It should be signed using an electronic signature. The approver may be the same individual as either Editor or Checker (but not both). The approver is not obliged to read the document in full but is accountable for assuring the competency of the Editor and Checker; is responsible for the principles contained in the document and is accountable for its contents.

All documents released by the CTA project office must be approved by the project manager (the project manager will consult the project committee or project board when relevant guided by the project rules on escalation). Documents delivered to the project office or used elsewhere in the project must be approved by the relevant work-package leader.

Keywords: Enter a few useful keywords. (When filing in sharepoint these should be copied into the dialogue box to assist searching.)

Version History: Transfer all old information here. If the previous version consisted of an author list reference then replace the Editor reference with 'Various'.

Grammar, Spelling, Punctuation and Writing and Graphics Style

Documents should be clearly written in 'British' English according to the Oxford English Dictionary. Headings should have important words capitalized but only up to three of four words long. If titles are longer than this only capitalize the first word. Glossary terms used in the text should only be capitalized on first use – avoid capitals wherever possible.

Avoid paragraphs with only a single sentence – such as this one.

The use of a glossary and reference section at the end of the document is encouraged in the CTA Latex style. Avoid repeating obvious glossary entries and conflicting with the CTA Basic Definitions.

Tables should be produced in Microsoft Excel and imported as pdf extracts. The style should be as used in the technical design reports, the template is available on the project extranet.

Quality Assessment Criteria

1. Is the document style correct and neatly applied? Is the title evenly spaced? Are the font sizes and headers etc correct throughout the document?
2. Does the footer state 'CTA Construction Project'?
3. Does the footer contain a short title, reference, version number and date? Are they correct and correctly formed?

4. Is the version information correctly entered in the ‘This Version:’ table? If more than one Editor is there a correct reference
5. Is there a signature for Editor, Checker and Approver?
6. Is the keywords box populated with useful words?
7. Is the version history complete?
8. Is the document written in clear English with correct spelling, punctuation and grammar?

B Procedure for Document Storage

Procedure for uploading and control of documents in sharepoint.

This will be produced in a future version of this document.

C Standards for Information Control

Explanation of the status and control of information not contained in documents. For example emails, slides and meeting notes.

This will be produced in a future version of this document.

D Procedures for Project Reviews

Procedures to follow to carry out project reviews, both internal and external.

This will be produced in a future version of this document.

Glossary

COM	Common Technology Evaluation, Testing and Calibration work-package
COTS	Commercial products Of The Shelf
CTA	Cherenkov Telescope Array
CTAO	Cherenkov Telescope Array Observatory
DVD	Design Verification Document
FMEA	Failure Mode and Effects Analysis
FMECA	Failure Mode, Effects and Criticality Analysis
NC	Non-Conformity
NCR	Nonconformity Report
PBS	Product Breakdown Structure
PFMEA	Process Failure Mode and Effects Analysis
RAMS	Reliability, Availability Maintainability and Safety