MANAGEMENT

LINAC4 QUALITY ASSURANCE PLAN
AND PROJECT ORGANIZATION

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1. THE QUALITY MANAGEMENT SYSTEM

1.1 INTRODUCTION

The goal of the Linac4 project is to build a 160 MeV H⁻ linear accelerator replacing Linac2 as injector to the PS Booster (PSB) and to modify the PSB injection for the Linac4 beam. The beam brightness out of the PSB is expected to increase by a factor of 2, with a potential impact on LHC luminosity.

The success of a complex project as Linac4 relies, in a considerable part, on the specific competencies of its contributors and on the capability of the project management first and then of all the project engineers to successfully integrate those different competencies among them into a synergetic effort.

External institutes are expected to provide substantial contributions, in terms of knowhow and of important parts and equipments. These contributions should also be effectively integrated into the project and guarantee total compliance with the standards defined for the whole project.

Once the criteria for project quality are defined, quality must be planned, designed and built-in within the project’s processes.

The Quality Assurance Plan (QAP) provides the necessary information required to effectively manage project quality from project planning to delivery ¹.

The Linac4 Quality Assurance Plan has been largely derived from the LHC Quality Assurance Plan [1]. As much as possible of the well established LHC procedures has been retained for Linac4. Some procedures have been simplified for a project of a smaller scale and others have been adapted to the different environment. In particular, the design procedure has been adapted to include in the QAP the initial design phases. The Quality Assurance page of the Linac4 Web site (http://linac4.web.cern.ch/linac4/) contains a list of valid procedures and templates.

1.2 PURPOSE OF THE QUALITY ASSURANCE PLAN

The Linac4 QAP supports the Linac4 project in the achievement of its final objectives that are measurable and are summarized in the categories of Cost, Time, Scope and Quality, as they are defined in the Linac4 Risk Management Plan [2].

The QAP must empower all project contributors to take responsibility for the quality of their deliverables and of the processes leading to them.

The QAP must contribute preventing and solving problems by implementing effective work processes.

¹ Following a well established CERN convention, it has been decided to use the definition “Quality Assurance Plan (QAP)” for this document, even if modern project management literature prefers the terminology “Quality Management Plan (QMP)”. In our context the two denominations are synonyms.
It must foster the continuous improvement of working processes oriented to the achievement of quality, timeliness and cost-effectiveness.

The QAP must create the conditions for an effective control of changes within the project and the follow-up of all non-conformities.

It must promote the building up of a complete documentation for all phases of the project, from design to test and delivery, and allow the proper exploitation and maintenance of the accelerator during its lifetime.

1.3 SCOPE OF THE QUALITY ASSURANCE PLAN

The Linac4 Quality Assurance System applies to the whole project and more specifically to:

- The project infrastructure, including Civil Engineering, Cooling and Ventilation systems, Electrical distribution systems;
- The infrastructure related services like transport, survey, communications, access and system interlocks for personnel and machine protection;
- The Linac4 accelerator channel consisting of ion source, the chopper, RF accelerating structures, magnets, beam diagnostics, beam stoppers, dumps and collimators, vacuum system;
- The Linac4 accelerator ancillaries including power supplies, control system, RF low and high power electronics, beam instrumentation electronics;
- The Linac4 transfer line to the PS Booster including also the PS Booster injection system.

2. QUALITY POLICY

Quality is defined within the Linac4 accelerator project as the potential to provide an increased beam brightness for the LHC accelerator with respect to what can be obtained with Linac2 and to provide it reliably, i.e. with a fault rate low enough to be acceptable to the CERN Management and to the users, and safely, i.e. avoiding hazards to the CERN personnel and to the general public.

Responsibility for quality lies with management and each individual, section, group, department participating to the Linac4 project. In this respect everybody participating to the project is encouraged to communicate about areas that affect safety and quality.

To ensure that the quality objective is achieved, the Linac4 project team is committed to the achievement of high quality standards in all important aspects of the project realization: design and development of equipment and infrastructure, accelerator component fabrication and testing, machine commissioning.

Effective performance reporting systems are used so to monitor the progress towards meeting the project goal, report observed quality problems and timely intervene.
The policies, processes and procedures involved in the Quality Management System are regularly reviewed in order to improve their effectiveness.

3. ORGANISATION

The basic requirement for the achievement of the Quality objectives of the project is to define an organisational structure that:

- Identifies precisely the responsibilities of each individual taking part in the project;
- Ensures that all equipment and procedures defined in the project have a well defined responsible person;
- Provides a structure for the definition of the interfaces between the individual teams taking part in the project.

These objectives are achieved by establishing:

- A Work Breakdown Structure (WBS);

3.1 WORK BREAKDOWN STRUCTURE

The Linac4 project is divided into Workpackages, corresponding to a homogeneous set of Linac4 activities. In order to give consistency with the CERN organisational structure, individual Workpackages always belong to a single CERN Group. This means that there are no Workpackages covered by more than one CERN Group, although a CERN Group can have more than one Linac4 Workpackage. The execution of the work defined in the Workpackage is under the responsibility of the CERN Group concerned. Each Workpackage is under the responsibility of a Workpackage Holder nominated by the Group Leader concerned. The Workpackage Holder coordinates the activities of his Workpackage and provides the interface between the project and the Group responsible for the Workpackage.

The Work Breakdown Structure of the project and the present list of the Workpackage Holders are given in EDMS document 908972.

Workpackages are subdivided into Workunits, each under the responsibility of a Project Engineer. The Workunits contain the project deliverables.

A detailed definition of the Workunits (responsible Project Engineer, deliverables, target dates, associated costs) has been provided by the Workpackage Holders for the Linac4 Earned Value Management (EVM), which is implemented into the CERN Administrative Planning Tool (APT).
3.2 MANAGEMENT AND COMMUNICATION STRUCTURE

The Project is under the responsibility of a Project Leader. The Project provides the basic specifications and coordinates the execution of the work. To achieve these goals, the Project Leader is supported by a “core team”, whose members are nominated by the Project Leader. The Linac4 core team includes the Deputy Project Leader(s), the Project Safety Officer, the Technical Coordinator, the Quality Manager, the persons in charge of commissioning of the different parts of the Linac4 project, and some of the Holders of large and critical Workpackages. The core team holds a weekly informal meeting and treats general subject concerning the overall coordination of the project.

A Technical Coordinator supports the Project Leader with the specific task of analysing the interfaces between Workpackages, with the goal of identifying possible overlaps or missing parts. He may directly lead activities meant at solving interface problems. The Technical Coordinator is also co-responsible for the implementation and the follow-up of the Quality Assurance Plan.

Communication within the project goes vertically across Workpackages through a series of regular topical meetings organised by the core team members. The goal of the topical meetings is to discuss problems and define solutions for topics at the interfaces between Workpackages. Communication on general issues and discussion on technical problems followed by decisions from the project management go into two regular bi-weekly meetings:

- The Linac4 Integration and Infrastructure Coordination meeting, devoted to problems concerning Civil engineering, infrastructure, integration, installation and general safety; and
- The Linac4 Beam Coordination Committee, devoted to problems having a direct impact on the Linac4 beam performance.

General project meetings are held 3-4 times per year, with the goal of informing all participants in the project of issues concerning schedule, budget, project organisation, etc.

The Linac4 management and communication structure is given in the EDMS document 908972.

3.3 SAFETY STRUCTURE AND RESPONSIBILITY

The Linac4 Safety Structure follows the general project structure and the CERN Safety rules. The Project Leader appoints a Project Safety Officer (PSO) who coordinates all safety issues concerning the project.

The safety responsibility for the work executed within the Linac4 Project lies with the Groups and the Departments that are responsible for the work, following the official CERN Safety chain. In this respect, the PSO is subject to the authority of the Departmental Safety Officers (DSO). The role of the PSO is to support the DSOs for all
safety aspects specifically related to the project. In particular and accordingly to the SAPOCO document, the PSO:

- verifies that all safety aspects are taken into consideration by the different Workpackages;
- controls safety aspects at the interface between the Workpackages, and
- provides a time perspective, taking into consideration safety problems that could appear during the whole lifetime of the infrastructure.

In particular, the PSO is responsible, together with the Project Leader, for compiling and keeping up to date the Project Safety File, which contains an overview of all safety issues in the project with reference to all relevant documents.

The local safety coordination during the Linac4 installation and commissioning phase will be provided by the Territorial Safety Officers (TSO) appointed by the DSOs, following proposals by the Project. The TSOs know the project infrastructure and have the authority to intervene for matters concerning safety.

The Linac4 Safety structure is given in Fig. 1.

3.4 QUALITY MANAGEMENT ORGANISATION

Being established that the responsibility for quality implementation and compliance is shared among all personnel, CERN staff and external contributors, participating to the Linac4 project, a Quality Management Team (QMT) is specifically created to follow up
all quality related aspects of the project and put under the responsibility of the Linac4 Quality Manager.

The QMT is formed by the Project Leader, by the Technical Coordinator and by the Quality Manager (QM) plus additional members appointed by the Project Leader.

The QMT is responsible for monitoring the implementation of quality management throughout the project and supports all levels of project management. It must ensure compliance with the policies reflected in this QAP and the related standards and procedures throughout all project phases.

More in details, the responsibilities of the QMT can be summarized as follows:

- Maintain awareness of the importance of quality within the project;
- Provide management with the visibility of the processes used in project development;
- Notify the appropriate manager in a timely manner about existing or potential quality-related problems;
- Develop and implement a quality program to ensure the project’s processes and deliverables meet requirements;
- Make recommendations regarding policies, methodology, processes, procedures, and standards;
- Develop supplemental quality management procedures and standards, as needed;
- Administer a quality-focused problem management process, including monitoring and reporting on the problem resolution process;
- Conduct reviews on delivered project documentation;
- Conduct project process audits;
- Brief project personnel on quality procedures, and baseline procedure, as requested;
- Assist the appropriate manager in planning and, if necessary, interpreting requirements and applying guidance and associated standards and procedures;
- Provide project staff with orientation in quality management responsibilities and processes.

The QM supports the Linac4 Project Management Team in defining and overseeing implementation of the Quality Management program. Responsibilities in this role include:

- Develop and maintain the project QAP;
- Ensure the QAP addresses the quality goals and priorities of the project and satisfies all organization requirements;
• Ensure the QAP is put under the management control and made available to all affected groups and individuals;

• Establish processes and procedures to perform Quality Management activities;

• Report findings to Linac4 project and identify corrective actions related to the deliverable and process verifications.

The QM reports to the Linac4 project management.

Collaborating Institutes contributing to the Linac4 project must follow and apply the QAP. They will provide the requested documentation concerning the activities related to their deliverables to the QMT, which will use them in the frame of the Quality Assurance and Control through the CERN coordinator of the collaboration.

3.5 PROCESSES

The Core Competencies and their associated sub-processes constitute the set of organizational processes in the Linac4 project. The Core competencies represent the main processes and are highlighted by a coloured background in the picture. Fig. 2 summarizes their interactions:

![Process flow chart for a generic project with main procedures. Safety activities permeate all processes from design to commissioning and operation.](image)

Design Engineering, represented by each project engineer responsible for a Work package or for a Workunit inside a work package, develops the device/system specification by discussing the requirements with the project management (Project Leader + Core Team) and by producing a Workpackage Description document;
• After a Design Review, the Workpackage Description is approved and the detailed design can be started. The result of the detailed design work is represented by an Engineering or Technical specification; in the case that any change is needed to the Engineering or Technical Specification after its approval, the project engineer in charge is required to produce a Engineer Change Request (ECR). If needed, the Workpackage holder may start a design review process, with the aim of changing the Engineering Specification;

• Design Engineering, the Specification Committee, Purchasing, Manufacturing and Quality Assurance collaborate in the selection of the suppliers for major devices/systems;

• Design Engineering with Fabrication and Testing optimize the design and fabrication process, with the support of Quality Control and Metrology, to desired performance and can decide the production of a pre-series before launching the final line;

• Quality Assurance works across the board to assure integrity of processes and performs audits, supports metrology, helps coordinating incoming, in-process and final inspections and testing. It supervises the control of documents and of records;

• The Installation and Commissioning teams need to report directly to the Linac4 project management, where the implications for budget and planning are being considered in the perspective of the Linac4 set to operation. Reviews agreed with the Linac4 project management team are organized to assure the achievement of the Linac4 project objective;

• The Safety team is transverse across all processes and sub-processes to ensure that the safety policy is applied and that Safety criteria are considered and put into practice during all phases of the project, thus allowing the respect of safety rules also during the accelerator exploitation after the project completion.

3.5.1 CRITERIA AND METHODS

The criteria and the metrics adopted by each device/system to allow assessing that its quality objective is achieved are indicated in the respective Technical or Engineering Specification document and they represent the guideline to effectively manage the Linac4 project processes and sub-processes.

It is the responsibility of the project engineer in charge to define the criteria and the metrics adopted for his device/system and make them explicit in the Technical or Engineering Specification document.

4. DOCUMENTATION REQUIREMENTS

The Linac4 Quality Management System (QMS) includes a wide range of documents that are produced throughout the project extent. This documentation has the form of procedures, work instructions, records and templates.
All the documentation is created and kept in electronic form within the project EDMS structure. A master list of the complete set of procedures, work instructions, forms and templates is summarized in a hub document where an electronic link is provided to the current version of the concerned document.

It might be the case that a procedure or template, which has not yet been made available by the QMT, is urgently required by a work package holder. In this case, it is the responsibility of the work package holder to contact the QMT to express this need and the responsibility of the QM to release such document with an urgent procedure.

4.1 CONTROL OF DOCUMENTS

EDMS is the tool that has been chosen to store and maintain the Linac4 documentation. Each document is uniquely identified within the EDMS structure by its title and by the EDMS number.

The Linac4 project tree structure distinguishes between Baseline documentation and Working documentation.

The Baseline documentation includes all documents shown in Figure 5 and in particular:
- Work package description;
- Technical specification;
- Engineering specification;
- Interface specification;
- Engineering change request (ECR);
- Certificate of conformity;
- Non-conformity report;
- Assembly and alignment procedures;
- Safety procedures;
- Audit reports;
- Engineering drawings, which are stored in CDD;
- Manufacturing, test and measurement records, which are stored in EDMS by means of the MTF interface.

The Working documentation comprises:
- Minutes of meetings;
- Fabrication intermediate reports;
- Metrology reports;
- Intermediate procedures;
• Procedures still in preparation;
• User manuals and instructions.

The decision if a document belongs to the Baseline or to the Working documentation is left to the Project Leader, who may delegate it to the QMT.

In the case of documents belonging to the project baseline, Quality Assurance documents and templates, a document identification code is also assigned by the Quality Management Team.

It is the Quality Management Team’s responsibility to control the document and assign the document identification code when dealing with baseline documents (that must be stored in the Linac4 Baseline EDMS area) or templates. The Quality Management Team also maintains the documentation system in collaboration with the EDMS team.

If the document is not part of the project baseline, each project engineer and/or person in charge of a work package is in charge of the documentation that he produces. He is responsible for defining and applying the required approval procedure.

Externally received documents are controlled by the concerned project engineer and integrated into the project documentation system. A formal approval procedure is required for the document publication under the responsibility of the project engineer and of the person in charge of the work package concerned.

Revision control of documents is performed by the person who has the document’s responsibility. If dealing with a document that is in the project baseline, he must produce an Engineering Change Request whenever the document needs substantial changes and in particular when the modifications have an impact on other Workpackages and/or on the budget and schedule. He has the responsibility to define, with the support of the Technical Coordinator, the persons required to check and approve the document, and to control that the approval procedure is followed before the release of the document.

4.2 CONTROL OF RECORDS

All quality records are stored under electronic form. They are identified by their title and EDMS number. The maintenance of quality records is the responsibility of each project engineer or work package manager. Each record must clearly indicate who is responsible for it and the status of the record (online, obsolete, obsolete but retained).

Records coming from subcontractors or external collaborators are put under the responsibility of the project engineer or work package manager in charge of the supplying, who must formally approve them. They must be in the form of product specification, certificates of compliance, qualification test data or analysis data.

Quality records are a key source of information in the Quality Assurance process to be used during internal/external audits and project reviews.
A special kind of records is represented by fabrication drawings that, whenever concerning parts of equipment that are meant to be part of the Linac4 accelerator, transfer line or infrastructure, must follow an approval process lead by the project engineer or work package manager directly concerned.

5. PRODUCT REALIZATION

This part of the QAP describes the methods employed and the responsibilities for the planning and application of processes and sub-processes required to achieve the realization of the goals of the Linac4 project.

The project leader and the management team are responsible for publishing, at the beginning of the project and then regularly after management reviews, the project general planning and the yearly objectives that will serve as guidelines to the single Workpackages.

Each project engineer and work package holder must provide a planning for his deliverables that is compatible with the objectives of the project general planning.

5.1 DESIGN AND DEVELOPMENT

All deliverables required for the successful realization of the Linac4 project are included in a Linac4 work package.

The realization of such deliverables is assigned to the project engineer in charge by the work package holder or by the department to which that project/service has been ascribed.

The responsibility for this deliverable, together with the delivery date, is clearly reported in the Linac4 hardware database, which is created and maintained under the responsibility of the Work Package Holder and submitted to the approval of the Linac4 project leader.

The different phases of the design process, from conceptual design to the start of fabrication are summarised in Fig. 3 together with an example of the documents required at each stage of the process.
Fig. 3: Flow diagram representing the steps of the design process and showing some of the template documents to be used.
5.1.1 DESIGN INPUT

The Project provides a Conceptual Design [3] and successively a Technical Design Report (TDR) [4], prepared with the contribution of the Groups involved in the project, which are the basis for the definition of the detailed design. Updates from the TDR are communicated by the Project to the Workpackage Holders.

Starting from the available documentation and in close contact with the Project and with their Group, the Workpackage Holder prepares the Workpackage Description document. All elements required by the design of a project/service are found in this document, in the form of a functional specification. Further details may be produced during technical meetings and validated during a L4BCC or Linac4 Integration Committee meeting, thus completing the functional specification.

The functional specification is usually based on a specification sheet, detailing the main parameters required for the project execution.

5.1.2 DESIGN OUTPUT

The Design and Development process output consists of an Engineering and/or Technical Specification document and, if it is the case, fabrication drawings.

The Engineering/Technical Specification document and the fabrication drawings must have followed a formal approval process and have received the final approval by the concerned work package holder and by the Linac4 project leader. The validation is intended to demonstrate that the product or service meet the requirements for specified application or intended use.

The Engineering/Technical Specification document must indicate explicitly what the acceptance criteria are and the metrics used for the conformity test at delivery.

5.1.3 DESIGN REVIEW

Any project/service must have passed at least one project review before coming to the final approval. The review is typically performed at a project meeting where the Workpackage Description document is presented and discussed. If further project reviews are needed, they can be in the form of a specific review meeting organized by the Workpackage Holder or a formal presentation to a L4BCC or Linac4 Integration Committee session. A requisite is that minutes of the meeting are taken with conclusions. The minutes are stored in the project EDMS area and are part of the project quality records.

Project reviews can be organized, depending on the project complexity, also during the project realization, in order to check the project progress or decide on a possible change in the specification.

5.1.4 DESIGN CHANGE

Any changes to project drawings and/or to the Engineering/Technical Specification document must be documented and the new version of the drawings and of the Specification document must be formally approved before coming into force.
For this purpose the Project Engineer or the Workpackage Holder creates an Engineering Change Request (ECR) that must be approved by the Linac4 project leader to become effective.

A new version of the project drawings concerned by the change and/or of the Technical Specification is created, with explicit indication of the change made, while the old version is declared obsolete.

5.2 PURCHASING AND CONTRACTING

The CERN purchasing rules are defined by the CERN Finance Committee and must be followed by all Linac4 procurements. A compendium of all CERN purchasing rules presently valid is available from the Finance and Procurement Department [5].

In addition to the standard purchasing rules, the sLHC Specification Committee will check the consistency of the proposed purchase with respect to technical characteristics, delivery schedule and cost for all procurements exceeding the amount of 200000 CHF.

The Technical Specification document that is presented to the sLHC Specification Committee must have previously followed a formal approval procedure receiving the approval by the Linac4 Project Leader.

Collaborating Institutes must follow the same rules when the invoices are charged to CERN. In case of in-kind contributions from Member or Non-Member States, purchasing rules specific to the supplying Institute will be followed, but the Linac4 Project must give its prior agreement for the technical content and performances of the supply.

In the case of complex in-kind contributions from external institutes, source inspection is preferred with on-site qualification test for preliminary acceptance. The order document must clearly state when this procedure applies.

Final acceptance will be given after final test at CERN premises. Acceptance is documented by the approval signature of the project engineer on the acceptance test document, which becomes part of the project quality records.

5.3 IDENTIFICATION AND TRACEABILITY

The layout components of the Linac4 accelerator are identified following the Quality Assurance document L4-PM-QA-0002 [6], which takes into account special requirements for Linac4.

In addition, the physical elements or parts of the Linac4 are identified according to the CERN equipment identification scheme described in document LHC-PM-QA-208.00 [7]. This provides a unique and non ambiguous identification of any physical equipment on the CERN domain that is used to trace this piece of equipment throughout its entire lifecycle. The Linac4 part identification will have the form PXABCDE123-FGxxxxxx where:
- PX is the two character prefix indicating that the PS complex coding scheme is applied;
- ABCDE is a five character long equipment code to classify the equipment design;
- 123 is a 3 digit sequential number to identify the design variant of the equipment;
- FG are two characters to identify the supplier or the production site;
- xxxxxxx is the serial number of the each manufactured part.

This scheme is in line with the LHC part identification rules described in LHC-PM-QA-206.00 [8] which has been adopted for the PS complex as recalled in PS-C-QA-0001 [9]. It must also be used to prepare barcode stickers to label each individual part of the Linac4 machine. To be clear with the terminology, PXABCDE123-FGxxxxxx is the “part identifier” assigned to a physical piece of equipment while PXABCDE123 is often referred as the “part number” to identify the design of this piece of equipment. The identification rules to be followed for designs and drawings are also described in PS-C-QA-0001 [9].

Traceability must apply systematically to all equipment installed in the Linac4 tunnel to comply with the safety rules regarding the management of potentially radioactive material. The Linac4 project adopts the Manufacturing and Testing Folder (MTF) as the tool for following up the realization, installation and maintenance of buildings, all hardware equipment and components related to the project. For this purpose all parts must be properly identified following the above mentioned scheme that is compatible with MTF.

Traceability is not required for the ancillary equipment that is installed outside of the Linac4 tunnel, but it is however recommended whenever the equipment is a complex assembly, with variations in design and/or performances relative to the production period or to the supplier. The implementation of MTF for the Linac4 project covers all premises allocated to the project and thus allows for that traceability.

It is the responsibility of the project engineer, supported by the Quality Management Team, to assign the proper identifier to the machine part.

The responsibility for the control of identifiers is with the Quality Management Team, supported by the EDMS team.

For critical components, like accelerating structures, it is recommended that traceability is assured for raw materials at each step of the component manufacturing.

Traceability must also be assured for CERN components provided to external suppliers for being integrated into the final supply.

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2 The prefix HC, referring to the LHC catalog, might appear when the equipment was originally designed for the LHC or when the equipment group has decided to standardize their equipment identification within the entire accelerator complex.
Equipment coming from external collaborations must be traceable if so stated in the agreement document detailing the deliverables of the collaboration. It is the responsibility of the CERN Project Engineer to provide the external collaborators with the necessary identifiers for the parts concerned. When raw materials are supplied by the external collaborators, material certificates must be produced detailing initial characteristics and data from the manufacturing process.

5.3.1 INSPECTION AND TEST STATUS

When Linac4 components and equipments are received at CERN, the project engineer in charge takes care of the initial inspection and testing.

Inspection and test report is signed by the project engineer in charge and stored into EDMS system, by means of the MTF.

MTF is the tool that is chosen for performing the follow-up of manufacturing and test activities in the linac4 project. This is because of its ability to associate documents with equipment and its capability of producing reports, also in written form, of equipment characteristics and test results.

Manufacturing procedures, certification of raw materials, testing procedures and test result record sheets are considered as quality-related documents and as such must be identified using the same coding as for the design file. All records pertaining to a specific item must also bear the item identifier.

An inspection test tag is issued by the project engineer following the result of the inspection and tests performed; copy of the tag is transmitted to the Quality Management team, whose intervention may be required in the case the equipment acceptance is put in stand-by.

Non-conformal products must be segregated and a non-conformance report is issued. Corrective actions are indicated in the non-conformance report.

5.4 FABRICATION AND TESTING PROCESS CONTROL

Fabrication and testing is carried out according to the quality plan.

The manufacturing and testing processes are controlled by the individual departments and groups which are involved and responsible for the different fabrication and testing steps and are coordinated in their actions by the project engineer in charge.

A procedure dealing with the control of all stages of the fabrication and testing process is in preparation and will be made available on the Linac4 Quality Assurance web site.

Specific procedures may be issued by departments and groups to meet specific requirements of some fabrication and testing steps. These procedures are all part of this manual.
5.4.1 PRESERVATION OF PRODUCT

The preservation of equipment and devices after they have been accepted remains under the responsibility of the project engineer. In the case that long term storage is required before final installation in the Linac4, the project engineer takes care that the device is properly packaged in such way that re-testing is not required before installation.

In the case of equipment delivered by external suppliers, including international collaborations, the supplier is responsible for the correct packaging and for the safe delivery of the equipment concerned, including the stipulation of the necessary assurance coverage, bearing the related cost at its charge except if a different agreement has been stipulated by writing between CERN and the party concerned.

5.5 CONTROL OF MONITORING AND MEASUREMENT DEVICES

CERN requires that the equipment used to perform testing to decide acceptance or rejection of equipment and devices that are part of Linac4 have a valid calibration certificate.

The same requirement applies to all external suppliers and international collaborators. The required accuracy or precision of the measurement equipment is established by the project engineer in agreement with the third party when this is the case.

CERN may request that the acceptance of supplied equipment is performed at third party premises by means of instrumentation provided by the Linac4 project and under the supervision of the project engineer, who takes responsibility for the final acceptance of the equipment concerned.

5.6 INSPECTION MEASUREMENT AND TESTING

The Linac4 project requires that measurements related to acceptance and acceptance criteria of equipment are established and specified. Those measurements are performed to verify conformance to specified requirements.

Such measurements are left to the responsibility of the project engineer and must be established by considering, but not limited to, the following aspects:

- The conformance to specified requirements of deliverables, including components, and of equipment provided by external suppliers;
- The definition of several measurement points in the production process, when required, from raw material to equipment completion;
- Which characteristics are to be measured at each point, the definition of acceptance criteria, if required, at each point and the documentation that needs to be produced;
- Equipment and tools required, including requirements for instrument calibration;
- When the equipment is provided by external suppliers, establish hold points in the production process when formal approval is required by the project engineer to go beyond;

- Qualification of:
  o Material
  o Product
  o Process
  o People or
  o The Quality Management System

- Outputs of the measurement process, like inspection and test reports, approved check lists, conformance certificates.

5.7 CONTROL OF NONCONFORMING PRODUCT

It is the Linac4 project policy that all non-conforming equipment produced by external suppliers (contractors and collaborating institutes), by CERN departments and groups are segregated so to prevent their installation in the accelerator.

All people involved in the design, fabrication and testing processes have the obligation to report any suspected non-conformance to the project engineer in charge of the equipment, who will then report in writing the suspected non-conformity to the Quality Manager or to a member of the QMT.

If equipment fails a test and can be reworked, it is then retested and reinspected. When it cannot be reworked, it must be segregated.

When non-conformity is confirmed, it is the project engineer’s responsibility to write and sign the non-conformance report and send it to the QMT, who will keep trace of it in a log document under electronic form.

A copy of the non-conformance report is attached to the equipment during segregation.

Any corrective action taken is previously agreed between the Project Engineer and the Quality Manager, reported on the non-conformance report and finally validated by the project engineer and by the Linac4 Project Leader before it is implemented. Corrective actions are also traced in the non-conformity log.

Corrective actions include also preventive actions to avoid that the same non-conformance occurs in the future.

5.8 INTERNAL AUDIT

The Linac4 Project Leader or the CERN Management may decide to perform an internal or external audit, respectively, on Quality Assurance related topics.
In the case of an internal audit, it is the responsibility of the Quality Manager to schedule and organize the audit. He takes also care of preparing a checklist prior to the audit, as a guide line for the auditors, in order to assure that all wanted sections are covered during the audit.

In the case of an external audit, the Quality Manager assists the auditors in the preparation of the audit sessions.

The output of internal audit sessions is represented by audit reports, prepared by the team of auditors and issued by the QMT. The reports include action and corrective action items that are proposed to the Linac4 project management to improve effectiveness of the quality management system. It may also include possible comments from the audited team.

Audit reports are submitted to the “Control of records” policy and kept in the EDMS system. Copies of the audit report are distributed to the Linac4 project management and the people directly concerned by the results of the audit, whom are asked, for example, to implement actions or corrective actions.

6. SAFETY

The objective of safety assurance policy is to ensure that all safety risks associated with the design, development, production, operations and disposal or recycling of Linac4 equipment and activities are adequately identified, assessed, minimised, controlled and finally accepted through the application of the CERN safety rules and regulations.

The Linac4 Project safety policy is:

- To ensure that the Linac4 Project systems and activities will not cause a hazard to, in order of priority:
  - Human life,
  - The environment,
  - CERN installations and private property.

- To determine and evaluate the safety risks associated with the Project activities,
- To minimise safety risks by appropriate preventive measures and in a cost-effective manner,
- To ensure adequate verification of safety control measures.

The Linac4 Project safety policy is implemented to ensure that:

- Safety is designed into the Linac4 systems and components,
- Safety requirements are met,
- Hazards are identified and eliminated or, where this is not possible, minimised, ranked, and controlled in accordance with the Project objectives.
The reference document for all Safety issues concerning the Linac4 Project is the Linac4 Safety file [10].

6.1 GENERAL SAFETY

The CERN Director General defines the general CERN policy in matter of safety with the advice of the Safety Policy Committee, SAPOCO. The basic document in this matter is referenced as SAPOCO/42 (Rev. February 2003) [11], which stipulates:

- Everybody is responsible for the safety of the work he is performing,
- Each supervisor is responsible for the safety of his team,
- Nobody can discharge himself from his responsibility in matter of safety, and shall make himself and his subordinates aware of safety rules pertaining to his activities,
- CERN must supply the staff with all of what is necessary for ensuring safety for the assigned tasks.

The Linac4 Project must comply with this reference document. In particular, the Project will use the internal safety organisation, which is described in the relevant Departmental Safety Plans, and the Safety Commission will control all safety aspects of the project.

A Project Safety Officer (PSO) has been appointed to follow all aspects of safety related to the realization, installation, commissioning and operation of Linac4. He provides the liaison with the Departmental Safety Officers (DSO) which are responsible for Safety for work performed for Linac4 by their Department. In particular, the PSO supports the DSOs by considering possible safety issues appearing at the interface between Workpackages and by providing an overall view on safety issues during the entire lifecycle of the Linac4 installations. He also assists the commissioning team to carry out the individual and collective commissioning of Linac4 equipment in a safe manner.

Collaborating Institutes outside CERN can follow their own national safety rules in performing their tasks but have to prove that the end product they deliver for the Linac4 Project fulfils CERN requirements in matter of safety.

As for Quality Assurance, safety must be included in all stages of product fabrication, from early design to final installation, operation and even removal from the machine.

Safety requirements and procedures valid during the installation phase are defined in the “Work and Safety Coordination Plan for Installation of Linac4” [12]. In particular, all external firms working in the Linac4 site will have to comply with the rules defined in this document.
7. REFERENCES


