**QUALITY MANUAL/PLAN**

**ORGANISATION/PROJECT/CONTRACT PACKAGE/ELEMENT OF WORK (TITLE)**

**Doc. No. XXX-XXXX-XXXXX, Revision XX, Day Month Year**

Prepared by: Name Job Position

Checked by: Name Job Position

Approved by: Name Job Position

Revision History

|  |  |  |
| --- | --- | --- |
| Revision | Date | Reason for Change |
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|  |  |  |
| A |  | First Draft for Review |

Note: All changes from the previous revision have a line to the left of the text.

Note: The [Name of Top Manager]’s approval satisfies acceptance of this Quality Plan within <PROJECT> Project and mandates its use for all activities within its scope.

Guidance Note:

All text colours have meaning as follows:

Black text Suggested text. Should be modified to meet situation.

Green italics Guidance

Red text Text that should be replaced or removed

*All text should be taken as suggestive. There is no mandate to use the words as written. They should be used as the basis for developing a document that suits the operation of the body it describes.*

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# Purpose

This Quality Plan defines the processes and practices to be adopted by <PROJECT> to provide assurance that all Works are managed in such a way that they are delivered to the standard required by the Contract/ISO 9001:2015 and that there is adequate evidence to provide assurance that that standard has been achieved.

This Quality Plan defines the policies, objectives and plans for completing all aspects of the Works that are under the responsibility of <PROJECT>.

This Quality Plan also contains a list of the current Procedures, Work Instructions, and other relevant documentation. Whilst every endeavour has been made to provide assurance that this list is correct and up to date at the time that this revision of the Plan was issued, readers are warned that deletions, insertions and text changes may have occurred since then.

This Quality Plan has been written to provide compliance to ISO 9001:2015, together with all relevant contractual requirements.

Guidance Note

Where this template is to be used to develop a Quality Manual, consideration should be given to mandating how arrangements will be made for project work, especially when it comes to control of parts and materials.

# Scope

This Quality Plan provides the processes and controls over, and is limited to, the following aspects of the Works:

* <Aspect One>
* <Aspect Two>
* <Add as required>

Guidance Note:

Note that the scope of the Quality Plan must take into account the results of the analysis of the context of the project. The scope must define the boundaries and applicability of the management system in all its facets and must cover all the issues raised, all the requirements of the relevant interested parties and the works to be delivered, both as delivered product and any services that may be provided during and after handover.

The scope must also be in line with the requirements of the Management System, which is, in itself, conformant with ISO 9001:2015. Where any part or parts of the Management System is not deemed to be appropriate, permission to deviate shall be obtained from the Manager of Quality and an appropriate statement with justification made in this clause of the Quality Plan. Any deviation must not affect the project’s ability to deliver products and/or services that conform to the requirements of the contract and enhance the Client’s satisfaction.

# Definitions

Guidance Note.

List any relevant definitions that are referenced in the document.

# Abbreviations

Guidance Note.

List all abbreviations that are used in the document. Abbreviations should be spelt out in full also where they first appear in the document or where there is a risk that the reader may have lost track after many pages of reading.

# Context

* 1. General Project Information

<INSERT TEXT>

Guidance Note:

This clause should provide a reasonably detailed description of the project, so as to begin to provide an understanding of the context of the works and the business environment in which it is being conducted.

* 1. Contractual Basis

The contractual basis upon which works are to be provided by <INSERT TEXT>

Guidance Note:

This clause should provide the number of the contract, the names of the contacting parties and reference to the Quality conditions. It is not necessary to list the Quality requirements in full, as contract changes could result in there being parallel development.

* 1. Interested parties

The following interested parties have been recognised:

Guidance Note:

Interested parties in this context are all those persons or organisations that may have some form of impact on the project. Typically, stakeholders could include, among others,

* Those responsible for managing risk
* Those evaluating effectiveness of risk management
* Those developing procedures
* Those operating procedures
* Those affected if risk materialises or who may present a risk themselves:
	+ Clients
	+ Supply Chain
	+ Neighbours (Site & Head Office
	+ Regulators
	1. Issues

The stakeholders listed above may present the following list of issues:

Guidance Note:

For each of the interested parties listed above, list the issues that each may present. Issues are not only problems that may affect time, cost and/or Quality, but must include beneficial effects. It may well be that two stakeholders present the same issue. This is normal. The risk of the issue materialising may be different. One way of analysing this is to use an Ishikawa (fishbone) diagram, with the interested parties as the headings and the various issues as the bones. There is a potential that the same issue may appear under more than one heading. The risks for each can be combined, if this is appropriate.

Typical issues could include:

|  |  |
| --- | --- |
| External FactorsCulturalSocialPoliticalLegalRegulatoryFinancialTechnologicalEconomicNaturalClimateLandscapeEnvironmentalCompetitiveKey DriversRelationshipsExternal StakeholdersCorporateOther GBUsClients past, present and futureRegulatory BodiesISO Guide 73:2009 Definition 3.3.1.1 | Internal FactorsGovernanceOrganisational StructureRoles and ResponsibilitiesAccountabilitiesPolicies and ObjectivesCapabilitiesResourcesKnowledgeCapital AvailabilityTime PeopleProcesses SystemsTechnologiesDelivery OfferingsInformation SystemsInformation FlowsInternal StakeholdersPerceptionsValuesRelationshipsCultureStandardsGuidelinesModels of ManagementForm and Context of Contractual RelationshipsEmployment ContractsInter-GBU AgreementsService Level AgreementsISO Guide 73 Definition 3.3.1.2 |

* 1. Risks

The following major risks have been recognised. Mitigation is provided in the Risk Management Plan, document number <INSERT DOCUMENT NUMBER>.

Guidance Note:

It is important only to mention the top few major risks. Otherwise, the plan will become unwieldy. In any case, the Risk Management Plan will contain all the risks, together with the manner in which they were arrived. At this stage, it is probably advisable to consider preparing a failure mode and effect analysis (FMEA). This can list the interested parties, the issues they present and the risks that each of these issues may have on the successful completion of the works. The risks can be allocated a probability of occurrence, a potential for damage or enhancement and a probability that the risk will not be discovered. The risks can then be ranged by importance and suitable treatment defined in the Risk Management Plan. Importantly, the organisation can decide how risk-tolerant it is, so that it can decide which risks it wishes to treat as part of the Quality Management System for the Project.

Typically, treatments can include:

* Avoid (Do something else)
* Remove source
* Change the likelihood
* Change the consequences
* Share the risk (Collaborative Working?)
* Retain by decision and manage (This then forms the basis for developing procedures, etc.)
* Take the risk away

The Risk Management Plan, as defined in ISO 9001:2015, requires that it

* Contains criteria for successful management of the risks
* Gives assurance that the QMS can achieve its intended goal
* Prevents or reduces undesired effects
* Achieves continual improvement
	1. Other Quality Inputs

Guidance Note.

List any of the following that might be relevant to the document, whether or not direct reference is made in the text:

* Any documents that have provided background information
* Any documents that are contractual and thereby have relevance
* Any documents, which, if changed during the lifetime of the plan, may require changes to the plan or vice-versa
* Any requirements for confirming that consistency between any of the document types listed above and the plan during the lifetime of the plan.

# <PROJECT> Quality Policy Statement

<PROJECT> is committed to meeting its Customer’s expectations by efficiently delivering all requirements right first time. <PROJECT> believes that a commitment to quality is essential for its own and its Client’s long-term success and undertakes that the Quality Management System will provide assurance that the project will provide a safe and efficient <railway/motorway/airport/other> to schedule and budget.

To do this, the project shall implement, maintain and control an efficient and effective Quality Management System in compliance with the requirements of the contract and with ISO 9001:2015, under the umbrella of the certification to this standard maintained by <PROJECT >.

All services that are supplied by the project shall comply with all professional and legislative standards and requirements and shall be provided by staff known to have the correct competencies to undertake the tasks allotted to them.

<PROJECT> shall set technical standards for Quality and define robust processes for all its activities. <PROJECT> shall provide regular monitoring and assessment of the Quality of its work. The results of these measures shall be documented and reviewed as part of the regular review of the Quality System and shall be used as the basis for improving its working practices.

<PROJECT> shall establish and maintain an appropriate level of communication with the Client to so that it can provide satisfaction with respect to the Quality of its service. The Quality management system shall enable the Project to respond to client expectations. Customer feedback, together with analysis of audits and other measures, shall be utilised to drive improvements in the quality system.

This policy will be cascaded to all <PROJECT> staff to so that they understand their part in the successful delivery of the Works.

Guidance Note:

The policy statement must demonstrate the Top Management’s commitment to using the Quality Management System as the only way in which the project/organisation will operate, noting that Top Management has now to fulfil a much more practical involvement with the development and management of the Quality Management System. For this reason, the whole Quality Management System, and especially the policy and objectives, must be practical, related to the delivery of the works and meet all the relevant contractual and regulatory requirements.

Clearly, a policy in a Quality Manual will require significant change from the wording above.

The statement must inform staff and relevant interested parties where the policy statement may be found, other than in this Quality Plan. Examples include the web site(s), the intranet and notice boards.

# Quality Objectives

*Guidance Note*

*The objectives must be relevant to the Works, reflect the requirements of the Client as expressed in the contract, marketing information or otherwise, provide opportunities for improvement, i.e., contain stretch targets, and be measurable, so that they may form the basis for the Project’s Key Process Indicators. Where applicable, lower level, measurable targets may be defined additionally to assist in achievement of the objectives. The objectives must be directly related to the Quality Policy Statement, so that meeting them provides evidence that staff are following the policy.*

Examples:

* To define and maintain a management system for <PROJECT> that provides assurance that the delivered Works meet the requirements of the Contact and the <PROJECT> Quality Objectives.
* To monitor processes for conformance to the Quality aspects of the Contract and the <PROJECT> Quality Management System.
* To advise and strengthen staff at all levels in the execution of the Works during all phases, including design, mobilisation, construction and certification
* To provide assurance that designs are complete and constructible prior to work starting, that they reflect the needs for the Works as expressed in the contract and that there is adequate evidence to support the assurances given.

# Description of the Quality Management System

* 1. Conformance with Standards for Quality

The <PROJECT> Quality Management System has been designed to fulfil the requirements of ISO 9001:2015.

 Guidance Note

The requirement to conform to ISO 9001 or any other Quality Management Standard needs to be confirmed, especially for joint ventures and secondments.

* 1. Documented Systems

The Quality Plan forms one of two management documents that control the delivery process. The other is the Project Execution Plan that defines the approach that the project as a whole takes towards executing the Works, including the structure of the programme and the processes by which it will be delivered.

This Quality Plan defines the internal processes that will be used to provide assurance that the <PROJECT> Project Execution Plan is being properly and correctly implemented and that suitable evidence is provided on a timely basis in support of delivery to the Client.

The <PROJECT> Quality Management System consists of a tiered system of documentation that has been implemented across the whole of the project. It consists of the following:

* This Quality Manual
* The Procedures
* Specific work instructions, where these are essential to provide additional information to enable implementation of a particular procedure.

The <PROJECT> Quality Manual and Procedures are mandated for all activities within the project. They are prepared for general use and are available on the electronic document management system.

This Quality Plan also defines the means by which assurance of adequate conformance to process and workmanship standards is provided.

The most up-to-date list of Quality Management System documentation is to be found in the electronic documentation management system.

Guidance Note

The need to provide a Project Execution Plan and a Project Quality Plan is a moot point. Clearly, project documents will not be required for an organisation developing a Quality Manual and the text must be adapted to suit. Also in the precedence of documents below.

* 1. Precedence of Documentation

In case of differences between documents, the following precedence is assumed:

* The Contract
* The Project Execution Plan
* This Quality Plan and its supporting procedures
* The Work Instructions.
	1. Management of this Quality Plan

This Quality Plan is reviewed at least once each year. It is also reviewed following a significant change in procedures, processes or organisation, whether generated internally or as a result of external influence.

Any changes are reviewed and approved by the persons who reviewed and approved the previous revision, unless organisational changes make this impossible.

# Management Responsibilities

* 1. Organisation Chart

Guidance Note:

Insert a copy of the organization chart for the project/contract package/element of work, showing the interfaces and interactions between the team members. Reporting lines should be shown.

* 1. Authority, Accountability and Responsibility

Guidance Note:

For each member of the team with responsibility for delivering all or part of the Works, in hierarchical order beginning with the most senior, define the following:

* Authority: what level of authority does this person have within the project? What are the boundaries to that authority? For the Quality Manager at least, this should include authority to stop the job, where there is a real and present risk that the Works could be delivered incorrectly to contract, especially where future Works may conceal what has been done.
* Accountability: Who is the person’s supervisor to whom s/he is accountable for delivering his/her part of the Works to Quality, cost and schedule?
* Responsibility: For what part of the Works is this person responsible for delivery to Quality, cost and schedule?

This clause should provide details for:

* All those individuals who plan, implement, execute, control and monitor the Quality Management System
* All those individuals responsible for scheduling the Works to so that it is delivered to time and cost
* All those individuals responsible for communicating the Client’s requirements as expressed in the contract to others
* All those individuals responsible for resolving issues that may arise across boundaries between one group and another, internally within the project and externally
* All those individuals responsible for audit, surveillance and other monitoring activities, for reviewing the results of monitoring and for defining and monitoring corrective and preventive action. This may include authorizing exemptions from the Quality plan, although care needs to be taken to confirm that no contractual requirement is waived unintentionally in the process.
* All those individuals responsible for authorizing change to the Quality plan or any of its supporting procedures, work instructions or other documentation that together form the documented Quality Management System.
* The presence of a Management Representative, normally the Quality Manager, who has the responsibility for ensuring that the processes are established, implemented and maintained, for reporting on the status of the management system to Top Management at specified intervals, including suggesting improvement actions and ensuring that the Client’s requirements are known across the Project, especially those related to the standard of work and other Quality matters. Part of the reporting mechanism is the use of formal management review, see later.

 Note that ISO 9001:2015 does not specifically require that a Management Representative be appointed. However, there is a need for a member of the team to undertake these responsibilities, who, for the sake of this plan, is called the Management Representative. Note also that there is a requirement for Top Management to confirm that these activities take place.

* Setting suitable communication processes, both between the project and the Client and within the Project itself, so that all may be kept informed.

ISO 9001:2015 places particular emphasis on the part that Top Management play in the Quality Management System. This means that Top Management has to provide evidence of personally:

* *taking accountability for the effectiveness of the quality management system;*
* *ensuring that the quality policy and quality objectives are established for the quality management*
* *system and are compatible with the context and strategic direction of the organization;*
* *ensuring the integration of the quality management system requirements into the organization’s business processes;*
* *promoting the use of the process approach and risk-based thinking;*
* *ensuring that the resources needed for the quality management system are available;*
* *communicating the importance of effective quality management and of conforming to the quality management system requirements;*
* *ensuring that the Quality Management System achieves its intended results;*
* *engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;*
* *promoting improvement;*
* *supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.*
* *demonstrating leadership and commitment with relation to customer focus particularly in relation to regulations, conformity of product and service and the focus on customer satisfaction.*

These should be reflected in the description of the Top Management’s responsibilities as defined in this Quality Plan/Manual, noting that delegation is permitted as long as the accountability remains.

Top management also must demonstrate that they have defined the roles of their staff for conformance of the Quality Management System, which includes providing assurance that staff follow the requirements of the Quality Management System, reporting on the performance of the Quality Management System and ensuring that the Quality Management System is sufficiently robust to withstand change without reduction is customer satisfaction with the works.

# Management Review

Management review is a formal examination of the Quality Management System operated by the Project. It relies on analysis of:

* 1. the status of actions from previous management reviews;
	2. changes in external and internal issues that are relevant to the quality management system;
	3. information on the performance and effectiveness of the quality management system, including trends in:
		1. customer satisfaction and feedback from relevant interested parties;
		2. the extent to which quality objectives have been met;
		3. process performance and conformity of products and services;
		4. nonconformities and corrective actions;
		5. monitoring and measurement results;
		6. audit results;
		7. the performance of external providers;
	4. the adequacy of resources;
	5. the effectiveness of actions taken to address risks and opportunities (see 6.1);
	6. opportunities for improvement.

Guidance Note:

The list above is taken from the mandatory inputs to Management Review as stated in ISO 9001:2015, clause 9.3.2 and should be used in its entirety at corporate level. Quality Managers should provide such data as they can to assist Corporate Quality to fulfil its function in delivering a robust Management Review. See Guidance Note below.

Management Review is normally undertaken at a Corporate level and not within a project. A project or other subsidiary organisation provides information into the review.

The (Corporate/Functional) Quality Manager prepares a report describing the performance of the Quality Management System against each of the topics listed above, which is presented to Senior Management on the Project for discussion at the project’s management review meeting.

The output of the review forms part of the formal records of the Project/Organisation and contains at least:

* Actions to improve the effectiveness of the Quality management system
* Actions to correct issues found in the Quality management system
* Actions related to issues with the constructed Works
* Any need for changes to the Quality Management System for the project
* Resources needs to complete the actions that have been specified satisfactorily within the stated timeframe.

Guidance Note:

The list above contains the mandatory outputs from Management Review as stated in ISO 9001:2015, clause 9.3.3 and should be used in its entirety at corporate level.

The (Corporate/Functional) Quality Manager submits a copy of the report and the minutes of the review that include as a minimum the output topics listed above to the Manager of Quality for incorporation into the <PROJECT> Management Review report.

Guidance Note:

There is no requirement in the standard for each project to hold a management review. There is a requirement for <PROJECT> to hold one at periods defined in the Corporate Quality Manual. Documented Information that will provide evidence from the project must be submitted to the Manager of Quality in good time for preparation to be completed. There is a case for the project to consider how it has performed over the previous period, so as to be able to provide the data that is needed into the Management Review in a timely manner.

# Control of Documented Information

Guidance Note

The standard now lumps documents and records into one category of “documented Information”.

This clause should define details of how documented information will be identified. Identification provides a means for ensuring that each document at each revision status is clearly marked to provide sufficient information to make sure that the pertinent revision of each document is available at the place(s) where work is taking place and to confirm that any out-of-date or incorrect documents can be easily identified and removed. The format and media must be defined for each type of documented information, for example, the language of the document, the format to be used for design data, such as BIM and CAD and the pace where the documented information will be stored, such as the processes related to the electronic document and record management system

The clause should also identify who has authority to review and approve documents.

It is recognized that this could introduce a significant amount of detail into the Quality Plan that may bog the reader down. Authors are advised to make reference to a separate procedure on document control, rather than trying to cram it all into the Quality Plan.

The Quality Plan should list, or refer to a list, of all records that need to be generated. These records should reflect the list of deliverable documentation required by the Client as stated in the contract. This clause should not cover the processes to be employed for creating the assurance evidence: that may be found later in this Quality Plan template. A separate procedure for the control of records may be employed, again to avoid too many words. A summary may be provided in that case. Matters to be considered include:

* *The list of deliverable documentation*
* *The manner in which the retained information (records) will be held. Where an Electronic Document Management System is used to control documents, the manner in which documents are to be entered, defined and retrieved, together with any limitations of access, must be defined.*
* *The contractual, statutory and regulatory requirements, both in terms of the records to be retained and the manner in which they are to be kept*
* *The media used to store the records (hard and/or soft copy) and the precautions to be taken to make certain that they will remain legible and retrievable. Note that the introduction of a new Electronic Document Management System, or even an upgrade, may render stored documents illegible.*
* *Any requirements for ensuring that the records are protected from electronic or human intrusion*
* *The arrangements that have been made to deliver records during and at the close of the Works, including the format of the records (hard and/or soft copy) and the way they will be physically provided to the Client or other person nominated in the contract*
* *The language for all records*
* *The timing and manner of disposal of records which are no longer required. Retention times for documented information that has to be retained by <PROJECT> .*
* *Controls over the receipt of documented information of external origin, such as Client and sub-contractor documentation, national and international standards and working documents provided by other parts of <PROJECT>.*
* *Controls over changes to documented information.*
* *Resources*

Where appropriate, a list of the relevant documentation can be included as an appendix to the Quality Plan. However, as this is likely to change regularly during the course of the project, it may be better to make reference to an external register or Lost of Documents.

# Resources

Guidance Note

The standard requires the organisation to consider the capabilities and constraints on existing internal resources and what needs to be obtained from external providers.

* 1. Provision of People

Guidance Note:

This clause should define the numbers of persons required to successfully complete the Works, together with the level of qualification by education, experience and/or training needed for each of the positions listed. This should include both manual and non-manual staff.

Organisations have to decide on the level and form of competence required for each task that is to be undertaken, confirm that members of staff undertaking the work have achieved that level of competence and that there are records available to provide evidence of such. Where there are shortfalls, the organisation must provide training or other means to resolve them.

Staff must also be made aware of the Quality Policy and objectives, how their work contributes to the effectiveness of the Quality Management System (that includes the effectiveness of the work that they are undertaking) and the implications of not conforming to the requirements of the Quality Management System.

Details of all relevant training required to complete the Works should be listed. This will include, for example, craft training on new or different construction techniques and equipment, access and other permits needed to undertake the Works and general Quality awareness, including providing an understanding of this Quality Plan and its supporting procedures and work instructions. Motivational and team development should also be considered. All training should be evaluated after a period of time to confirm that it was effective. Any improvements to the training should be noted.

* 1. Infrastructure and Work Environment

*Guidance Note:*

*Controls over the work environment should be detailed here, especially where there is a risk that the work environment may have a direct effect on the Quality of the completed Works. This might include provision of cooling air in hot climates, protection of materials in frozen conditions, controls over the use of paint, adhesives and other similar materials in low temperatures. The provisions of this clause are not intended to replace any conditions that are more correctly found in the Health and Safety Plan. The requirement should cover all forms of infrastructure where work is to be undertaken, including buildings, equipment, transport and information/communication technology. This latter could, for example, consider the use of tablet computers in the field.*

*The concern for Quality is in the deliverable Works (primarily), although consideration should be given to the conditions under which the staff will be expected to work, for example, working outdoors in hot climates. This should cover social, psychological and physical conditions under which staff may be required to work.*

* 1. Organisational Knowledge

Guidance Note:

Organisational knowledge covers all that information which a member of staff needs to know in order to complete his or her tasks correctly and could include technical information, procedural documents and briefings. The knowledge must be readily retrievable by the person concerned. The member of staff must be aware of any changes to that knowledge that might affect their ability to perform their tasks. Organisational knowledge can be derived internally, including from lessons learned and knowledge from experience, and externally, such as that from customers/external providers, attending conferences and academia.

# Communication

* 1. General

Guidance Note:

The organisation must determine on what it will communicate, to whom, when and how it will communicate and, importantly, who will communicate. This latter is particularly important when communicating on subjects of a delicate or sensitive nature, such as when approaches are made by the press or other public bodies.

* 1. Customer Communication

*Guidance Note:*

*The plan should state who has is to act as the prime channel of communication with the customer, as well as defining who in each department is to liaise with whom on the Client side, where this is appropriate. This will include providing information about products or services, handing enquiries and orders/contracts, dealing with customer’s property and establishing requirements for contingency actions. The means of communication should be stated, for example, when formal letters are to be used, what records are to be retained of meetings with Clients and how informal approaches are to be handled.*

*The process of handling all forms of feedback, including complaints, from the Client should be documented.*

# Delivery Process *(Operation)*

*Guidance Note:*

*Throughout this part of the Quality Plan, reference can, and should, be made to the Project Execution Plan, the relevant procedures and the work instructions that support the processes. The Quality Plan is designed to describe the main principles, leaving the working details to the lower level documentation. The plan also acts as a directory into the other management system documentation.*

Details of the overall process to be used to deliver the project should be given with only sufficient detail to permit the reader to understand how the Works are to be designed, constructed and assured. Further details appear in the clauses below.

* 1. GATES Process – (if used)

The GATES process is a staged approach to releasing work at each for each significant step in the process. At each GATE, evidence is provided and its Quality checked to provide assurance that the risk to successful completion is reduced to as low a level as is reasonably practicable. Release is only authorized by a nominated member of the <Project>’s Senior Management Team, normally the Project Manager, after confirmation by third parties, including Quality and Document Control, that all relevant documents are in place and correct, that there is adequate finance available to complete and that the delivery team are in a fit condition to successfully complete the Works to Quality, cost and time.

Guidance Note

Where a GATES process is not used, the Plan/Manual must define the controls to be applied.

* 1. Planning for Design and Construction

Guidance Note:

This section should describe the controls that are placed by Project Controls (or equivalent team) over scheduling and budget. Typically, this should include what is to be designed and constructed, when it is to be designed and constructed, possibly relating this to the GATES process, the required verification, validation and design review and the records that will be needed to assure that the constructed Works are in conformance with the requirements of the Contract. It should define the controls that are to be placed over the management of the project schedule.

ISO 9001:2015 also asks for the following to be documented in addition to those aspects that are listed elsewhere in this plan:

* The internal and external resources needed,
* The criteria for processes and product/service
* The controls over the interfaces, especially during the design phases,
* The level of involvement by customers and other interested parties,
* The level of control that is imposed by customers and other interested parties,
* The documented information that will be generated to provide evidence of assurance of conformance to the contract and any other relevant requirements, such as those required by legislation or statutory instrument.

# Requirements Capture

Guidance Note:

A reference should be made to the output of the requirements capture exercise that was used to confirm that the Project has a full understanding of the Works that are to be delivered. The clause should also explain the process whereby each person with a responsibility to deliver against the requirements knows and understands their part in the task before they commit to start. Where appropriate, a summary of the requirements may be included in the Quality Plan with the reference.

Requirements include all statutory and regulatory requirements and any established internally for the successful completion of the works, as well as those that have been stipulated by the Client/Customer. Any alterations to the requirements must be resolved.

Part of the process of requirements capture is to confirm that each specific part of the Works is reviewed prior to, during and at the close of the job to provide assurance that all requirements have been successfully met. To this end, the criteria for acceptance should be defined against the requirements as part of the capture process.

A formal review of the requirements should be undertaken to provide assurance that all the requirements have been clearly defined and documented, that any issues or potential misunderstandings about exactly what the requirements are has been resolved and that the Project has the capability to successfully complete the Works to schedule, budget and standard. The output of this review forms part of the formal records of the Project. The process for confirming with the Client/Customer that the requirements have been fully understood and accepted by both sides should be defined.

# Design

* 1. General

Guidance Note:

For each project or part of a project, a Design Management Plan should be prepared in conformance with ISO 9001:2015 Clause 8.3. For brevity, the requirements for this document are not replicated here. The Quality Plan should make reference to the Design Management Plan and give an outline of its provisions.

The plan should not duplicate the information that is in the Design Management Plan to avoid parallel development. Where there is no Design Management Plan, the Quality Plan must contain all the details required by ISO 9001:2015, clause 8.3.

Where design is not part of the contract, a statement stating this should be added to the Quality Plan to prevent misunderstanding.

The Quality Plan should list, or refer to a list, of all the relevant codes, standards, specifications, Quality characteristics and regulatory requirements that will be used as criteria for determining whether or not the design of the Works has been delivered in accordance with the contract.

Processes for reviewing, verifying and validating the design should be given.

* Verification is a process for ensuring that the documented design meets the criteria stated in the contract before any construction takes place.
* Validation is needed where a new material, process or product, of which the Project has no experience, is to be used, to confirm that the material, process or product will perform to specification.
* A design review is a wide ranging examination of all aspects of the design.

The Quality Plan should list the assurance evidence that is to be delivered at the various GATES, including design check certificates, trial and test records created during the development cycle and minutes of verification, validation and review, as appropriate.

* 1. Design Change

Guidance Note

Design changes occur at several points in the design and construction cycles. The Quality Plan should define the processes for:

* Recording and undertaking changes found during the design cycle
* Informing design sub-contractors of the need for changes
* Receiving and undertaking changes found to be necessary during construction

Details that should be provided include:

* How requests for change are to be controlled
* Who can initiate a change request
* The arrangements for raising Field Design Change Notes and Field Design Change Requests, emphasizing the controls to prevent misuse.
* The process for reviewing change
* Who is authorized to authorize change
* Any requirements for undertaking further design review, verification and/or validation of the changes design
* The process for recording changes to the configuration status of the Works, as appropriate
* How the changes will be implemented
* How the changes affect any testing and/or inspection activities, including any changes to baseline documents used as the criteria for success.
* How change is to be accepted by the customer or other interested parties, in particular in the way that the results of the requirements capture will need to be reviewed and amended.

# Provision of Parts and Materials

Guidance Note:

The term “Parts and Materials” must be taken to include all products and services that are to be delivered to the Client/Customer. It should also include all product or services that will be used during the construction process, such as that used for temporary works. The arrangements for the procurement of common off-the-shelf parts and materials, such as nails for use in formwork, from a local supplier, should also be defined. Plant on purchase or hire should also be included.

* *The Quality Plan should describe the parts and materials that are to be used in the Works. Any special characteristics of the parts and materials that may affect the Quality of the completed Works should be described. This could include:*
* *Markings and other identification*
* *Specific standards and/or specifications to be met by parts and materials*
* *Handling, storage and other preservation requirements, including, where appropriate, safety requirements. This includes processes for controlling limited life items, hot items, cold items, sharp items, heavy items and items that could deteriorate unless handled correctly.*
* *Requirements for identification and traceability. This should include the status of the conformity of product, especially where measurements have been taken to prove acceptability, a unique identification that will allow it to be traced as the works progress and, where applicable, a record of traceability back through the supply chain to an appropriate point.*
* *A list of actions to be taken prior to delivery to confirm that specified materials meet the required standard prior to dispatch from factory. This will include the need for factory inspections and acceptance tests, as deemed necessary. Note that the process for such tests will be defined later in the Quality Plan under Inspection and Test.*
* *Checks to undertaken on specific materials on arrival at the receive dock to confirm that they are correct to specification/standard. Where appropriate, examples of incoming assurance evidence can be provided to assist inspectors in their checks.*

# Externally Provided Processes, Products and Services

Guidance Note:

The Quality Plan should establish the critical characteristics of products and services that are being provided by external organisations, either directly or by reference. This should include the procurement of materials and parts, together with any services that may be used, be it for incorporation into the works, direct delivery to the Customer or for use in support of the project. The plan should document the actions that need to be taken during:

* *Specification as part of the ordering process*
* *Procurement*
* *Receipt, including inspection and test records from the Supplier*

The organisation must consider the potential impact of externally provided product or services on its ability to meet its own commitments. The Quality Plan should define what arrangements have been made to mitigate any risk from this.

The plan should explain how these characteristics are to be communicated to the Suppliers and what evidence the Suppliers will have to produce to assure the Quality of the procured items. This may include provisions for audit as part of the tender process or during manufacture, presence for factory acceptance or other Quality Control activities at the Suppliers’ premises and other forms of approval that the procured items meet the requirements of the contract or purchase order.

Where a subcontractor is employed, the Quality plan must explain how the subcontractor is to remain under the project’s Quality Management System, the controls to be applied, including how effectiveness of the controls applied by the subcontractor will be monitored. The organisation must confirm that the external provider is competent to undertake the work, approving products, services, methods and processes used during delivery, equipment to be used and arrangements for release, including the <PROJECT>’s role as part of the factory/site acceptance process, where applicable. The Quality Plan must define how documented information regarding the performance of external providers will be retained.

Provision should be made to cascade the Project’s Quality Management System to Suppliers and Sub-Contractors right down the supply chain. A word of caution: it is unreasonable to expect a supplier of commercial off-the-shelf items, such as hardware, to submit a full set of Quality documented information. An element of discretion should be built into the Quality plan to avoid over-loading suppliers unnecessarily, especially as this will add cost for no benefit to the project.

Reference can be made to a Procurement Manual or other equivalent control documents.

# Construction

Guidance Note:

Persons setting up and operating construction sites should be aware of, and work in accordance with, the Construction (Design and Management) Regulations 2015, together with any internal construction management documentation.

* 1. Construction Start-Up

Guidance Note:

A statement needs to be made to reinforce the mandate that work cannot start on site until all the relevant information is available. This is normally assured with a successful completion of the relevant GATE. Typically, assurance should be given that:

* *There is adequate information about what has to be constructed so that no mistakes can be made. This should include a definition of what is to be constructed, the relevant technical information and a set of criteria that have to be achieved. There should also be a description of the actions to be taken when human error does occur.*
* *Sufficient numbers of competent persons to complete the works to the standard required.*
* *An appropriate environment and infrastructure. This should explain how the environment and infrastructure described above will be implemented for each element of the works*
* *All relevant procedures and work instructions are available, clear and understood by all*
* *All equipment needed to complete the Works satisfactorily is available, operational and within its maintenance period. Inspection, test and measuring equipment is to be within its calibration period.*
* *Suitable monitoring and measurement is in place. This includes ensuring that all site files are in place and that there is adequate stationery to collect the assurance evidence as it is produced.*
* *Where the output of a process cannot be validated after the Works have been completed, for example, some forms of welding where assurance is confirmed primarily through the skill of the welder, criteria for review and approval of the process, approval of specific equipment and use of specific procedures shall be mandated. The records to be kept should be specified.*
* *The arrangements for release of the finished works should be defined.*
	1. In-Process Control

Guidance Note:

Each Project will have its own views on how the day-to-day construction activities are to be controlled. The only guidance that can be given is for the Project to carefully consider the delivery process and then describe both it and the controls that they intend to employ, to meet the requirements of the contract and the Works to be delivered. Where appropriate, a list of the relevant documentation can be included as an appendix to the Quality Plan. However, as this is likely to change regularly during the course of the project, it may be better to make reference to an external register or List of Documents.

The means whereby product is preserved at all stages of the works must be defined. This will include forms of storage that are suitable for parts and materials, including those that have limited life, are electrostatically sensitive and/or have limits to their temperature range. Controls over handling and usage of such items must also be defined, as appropriate to the works.

* 1. Control of Non-Conforming Product

Guidance Note:

The Quality Plan must identify the arrangements that are to be put in place to confirm that outputs that do not conform to their requirements are identified and controlled. This must prevent nonconforming items from unintended use or delivery. This may include marking them, labelling them or moving them to a specified quarantine zone. The critical word is “unintended”. The Quality Plan should define the processes used, together with the ways in which non-conforming items are dispositioned.

 Actions could include:

* *Repair*
* *Rework*
* *Use as is*
* *Offer a Concession to the Client*

The Quality Plan must define, or refer to, the arrangements for recording nonconformity, including what the non-conformance was, what action was taken by whom, any concessions that were raised and the person with authority to release the item following correction.

Where repair or rework is used, the Quality Plan should define what action is to be taken to confirm that the item is in conformance after the repair or rework has been completed.

The Quality Plan should explain how data regarding non-conforming product will be collected, analysed for trends and reported to senior management.

* 1. Client Property

Guidance Note:

Where the Project is holding property belonging to the Client, the Quality Plan should define the precautions that will be taken above normal conditions so that the Project exercises its Duty of Care over the items. Typically, Client property will include items that have been purchased directly by the Client, stored by the Project and then taken out to site for integration into the Works. The arrangements for dealing with Client/Customer property following loss or damage must also be defined.

* 1. Temporary Works

Guidance Note:

The section should define the controls that are to be placed over the design, construction, maintenance and demolition of temporary works. In cases where an assessment has determined that there is a potential risk in the temporary works or where the temporary works are complex, Projects should carefully consider employing the same design and construction processes as they would use for permanent works, including providing suitable assurance evidence of safe and correct construction. The Temporary Works Coordinator should be named.

# Assurance

* 1. Assurance Evidence

Guidance Note:

Assurance evidence will be based around Inspection and Test Plans and certification of completion.

Details of how inspection and test plans are to be created, approved, completed progressively on site and filed should be given. This should also include details of the supporting information that might be required. Details of how this evidence is collated and approved prior to submission to the Gate review should be given. Where stage completion is anticipated, the rules governing what evidence is to be provided, together with the process for providing assurance to the Client should be defined. This will also be needed for final delivery to the Client.

* 1. Release of Completed Works

Guidance Note:

The Quality Plan should be specific about how the completed works will be released to the Client/Customer. It must mandate that release cannot take place until such time as all arrangements have been completed and acceptance has been confirmed. The arrangements must include documented information that is to be provided in support of release, together with the name of the person or persons who are permitted to make that release.

*Where appropriate, reference may be made to the Project Assurance Plan.*

# Monitoring and Measurement

* 1. General

Guidance Note

This clause should provide outline processes for the identification, collection and analysis of Key Process Indicators (KPIs). The key is to identify in the subsequent clauses a small number of meaningful KPIs that can be used to provide management information for the control and improvement of the processes and product.

Separately, the Quality Plan should define the arrangements for ensuring that valid and reliable results are obtained when measuring product.

Overall, the Quality Plan should define what monitoring and measurement is to take place. The methods for monitoring, measurement, analysis, evaluation and reporting should be determined, with records of the outcomes being retained. The standard has a list of items that are to be analysed and evaluated. In particular, the performance and effectiveness of the Quality Management System must be evaluated.

* 1. Process Monitoring

Guidance Note:

The Project should establish KPIs around the processes to provide early warning of processes that look as though they may be going out of control. The Quality Plan should list the main process KPIs and explain how they will be collected, analysed for trends and reported to senior management.

* 1. Conformity of Product.

Guidance Note:

The Project should determine what measurements it is likely to take during the course of the Works. It needs to determine whether it will be taking the measurements itself or relying on others, typically sub-contractors, to do that for them. The measurements to be taken should relate back to the criteria for acceptability that were defined during the requirements capture. This will provide evidence to confirm that the delivered product or service has met its objectives. Any measurement should take into account the uncertainty of measurement of the instrument being used.

Processes should be defined for:

* *Procurement of appropriate inspection, test and measuring equipment*
* *Rules for use of the equipment, including prevention of damage during storage, handling or transport*
* *Rules to prevent calibration being invalidated*
* *Rules concerning recalibration*
* *Rules concerning actions where equipment is found to be unfit for use, for example, because it has been damaged or found out of calibration when returned to the calibration laboratory, including potentially revalidating any readings taken with the faulty equipment*
* *Confirmation that any software used in test does provide valid evidence of conformity.*

The Quality Plan should require that all inspection, measuring and test equipment that does not belong directly to the project, but that is used to make measurement, is controlled as if in the ownership of the Project.

Results from inspections and tests of product should be used to determine the levels of Quality for product at the various stages of construction, including:

* *Off-Site (Factory Acceptance)*
* *Receipt*
* *In-process, including Site Acceptance*
* *Post-process*
* *Delivery*

*The Quality Plan should list the main product KPIs and explain how they will be collected, analysed for trends and reported to senior management*.

* 1. Customer Satisfaction

Guidance Note:

KPIs relating to the Project’s understanding of the level of satisfaction that the Client has with the Works and the way in which they are being provided should be defined, together with the techniques used for collecting and analysing them. The methods by which Customer satisfaction should be defined, including the use of surveys.

* 1. Internal Audit

Guidance Note:

The Quality Plan should detail the way in which it intends to conduct audits of both its internal management system and those of their sub-contractors, as required. Audits are required to confirm that the documented management system has been properly implemented and maintained. Reference may be made to a separate procedure for auditing. Typically, the following topics should be included:

* *An audit programme, based on the status, importance and risk inherent in the areas to be audited*
* *Criteria, scope, frequency and methods of audit for each of the audits or in general, as appropriate*
* *The selection of auditors to provide assurance that they are competent to audit, based on relevant training, education and experience. The audit procedure should require that all auditors have attended either an external or internal auditor training course provided by the Quality Function or an external provider.*
* *The recording and retention of the records or audit*
* *Details of how audits will be followed up to confirm that any corrective or preventive actions have been successfully completed*
* *Details of how the results will be analysed for trends in non-conformance and reported to senior management.*

# Data Analysis and Improvement

* 1. General

Guidance Note:

The Quality Plan should explain how data gathered from monitoring and measuring activities described above is analysed for trends to provide the information that senior management can use to provide proper control is retained over the Project. This clause should explain how the information is to be presented and the schedule for presentation.

The data that has been monitored and analysed, together with information from corrective and preventive action should be used to identify opportunities for improvements. These may be in the form of starting points for Six Sigma Process Improvement Projects (PIPs) or may be of a “Just Do IT” nature. The Quality Plan should describe the processes for dealing with corrective actions and corrective actions, as well as for initialising improvement actions.

* 1. Nonconformity

Guidance Note

Nonconformity can arise from audits, complaints from interested parties and product. The Quality Plan should define the arrangements for recording and controlling nonconformity and dealing with the consequences, noting that these may have an effect on the interested party who complained.

The arrangements should cover reviewing and analysing the nonconformity, undertaking root cause analysis and determining if further similar nonconformities could occur. Any action that is needed should address the root cause and prevent recurrence. The arrangements should define how risks and/or opportunities arising from the nonconformity are to be analysed and leveraged, as well as placing them into the risk register. The process for introducing change to the Quality Management System as a result of the analysis should be defined.

The Quality Plan should define how the nature and root cause of the nonconformity are to be formally documented as project records, together with the results of the corrective and preventive actions taken, successful or otherwise.

* 1. Continual Improvement

Guidance Note:

The Quality Plan should define the arrangements for using the data that has been generated to meet needs or opportunities related to the Quality Management System (or, more importantly, the way the business is being managed).. Inputs to this can include:

* *Lessons Learned*
* *Analysis of product non-conformance*
* *Analysis of process non-conformance*
* *Analysis of Key Performance Indicators*
* *Analysis of complaints, especially of those from interested parties*
* *Output from Management Review*

The arrangements should also define who is to undertake the analysis and how they are to make any perceived changes to the Quality Management System.

**APPENDICES**

The appendices shall be listed in this section.

Guidance Note:

Where appropriate, the List of Documents should form one or more of the Appendices.

Appendix 1

Appendix 2