###### [FULL CLIENT NAME ALL CAPS]

**[Quality Manual Doc Title]**

Revision [Rev Number]

[Date of Issue]

Conforms to ISO 9001:2015

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1. Revision History and Approval

|  |  |  |  |
| --- | --- | --- | --- |
| **Rev.** | **Nature of changes** | **Approval** | **Date** |
| [Rev Number] | Original release. | [Quality Manual Approver Name] | [Date of Issue] |
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|  |  |  |  |
|  |  |  |  |

1. Welcome to [Full Client Name Reg Caps]

Add welcome language here. This is the first thing a reader will see, so it’s a good idea to add basic information about the company. If the intended audience includes customers, you can add marketing language here, too.

Adding some photos of the facility or staff is a nice touch here, as well.

1. Quality Policy

[Senior Management Team Name] has developed the following Quality Policy which governs day-to-day operations to ensure quality. The Quality Policy is communicated and implemented throughout the organization.

The Quality Policy of [Short Client Name] is as follows:

**Add Quality Policy here.**

1. Context of the [Short Client Name] Organization

[Short Client Name] has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This requires understanding internal and external issues that are of concern to [Short Client Name] and its interested parties; the interested parties are identified per the document ***[Context of the Org Proc. Title].***

Such issues are monitored and updated as appropriate, and discussed as part of management reviews.

The issues determined above are identified through an analysis of risks facing [Short Client Name] and its interested parties. “Interested parties” are those stakeholders who receive our [Products or Services Plur.], or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are identified per the document ***[Context of the Org Proc. Title].***

This information is then used by senior management to determine the company’s strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

1. Scope of the [Short Client Name] Quality Management System

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products and services, [Short Client Name] has determined the scope of the management system as follows:

**Add scope statement here. The scope statement must include a description of your products and/or services. This is what will appear on any resulting ISO 9001 certificate; you may consult with your certification body for assistance.**

(If more than one site)

The quality system applies to all processes, activities, and employees of the following locations within the company:

|  |  |
| --- | --- |
| [Street Address]  [City] [STATEABBREV] [Zip]  [Phone] | Site 2 Address |
| Site 3 Address | Site 4 Address |

(If single site)

The quality system applies to all processes, activities and employees within the company. The facility is located at:

[Street Address]

[City] [STATEABBREV] [Zip]

Phone: [Phone]

Fax: [Fax]

Web: [Website]

(If exclusions)

The following clauses of ISO 9001 were determined to be not applicable to [Short Client Name].

* List clause exclusions and rationale for each here.

(If no exclusions)

The company claims no exclusions from the ISO 9001 standard.

(Optional: site exclusion table)

The following sites are excluded from the company quality system at this time; in the future, these may be incorporated into the company QMS, and this manual will be updated accordingly.

|  |  |
| --- | --- |
| Site 1 Address | Site 2 Address |
| Site 3 Address | Site 4 Address |

1. QMS Processes

[Short Client Name] has adopted a process approach for its management system. By identifying the top-level processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming [Products or Services Plur.] discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes.

*Note: not all activities are considered “processes” – the term “process” in this context indicates the activity has been elevated to a higher level of control and management oversight.* *The controls indicated herein are applicable only to the top-level processes identified.*

The following top-level processes have been identified for [Short Client Name]:

* List processes here
* List processes here

Each process may be supported by other activities, such as tasks or sub-processes. Monitoring and control of top level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Each top-level process has a ***[Process Definition Doc Title]*** document which defines:

* applicable inputs and outputs
* process owner(s)
* applicable responsibilities and authorities
* applicable risks and opportunities
* critical and supporting resources
* criteria and methods employed to ensure the effectiveness of the process
* quality objectives related to that process

The sequence of interaction of these processes is illustrated in Appendix A.

*Note: Appendix A represents the typical sequence of processes, and may be altered depending on customer or regulatory requirements at the job or contract level, as needed.*

Additional QMS documented procedures have been developed to support the QMS and its processes; these are listed in Appendix B. This list only provides some top-level procedures, and may not reflect the entirety of all QMS documentation.

Each process has at least one objective established for it; this is a statement of the intent of the process. Each objective is then supported by at least one “metric” or key performance indicator (KPI) which is then measured to determine the process’ ability to meet the quality objective.

Throughout the year, metrics data is measured and gathered by process owners or other assigned managers, in order to present the data to [Senior Management Team Name]. The data is then analyzed by [Senior Management Team Name] in order that [Senior Management Team Name] may set goals and make adjustments for the purposes of long-term continual improvement.

The specific quality objectives for each process are defined in the applicable ***[Process Definition Doc Title]***.

Metrics, along with current standings and goals for each objective, are recorded in records of management review.

When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes.

Any process performed by a third party is considered an “outsourced process” and must be controlled, as well. The company’s outsourced processes, and the control methods implemented for each, are defined in ***[Outsourced Processes Title]***.

Appendix A: Overall Process Sequence & Interaction

Add diagram of sequence flow here.

Appendix B: Subordinate QMS Procedures

* [Calibration Proc. Title]
* [Change Mgmt Doc Title]
* [Context of the Org Proc. Title]
* [Control of Documents Proc. Title]
* [Control of NCP Proc. Title]
* [Control of Nonconforming Service Proc Title]
* [Control of Records Proc. Title]
* [Corrective Preventive Action Proc. Title]
* [Customer Property Proc. Title]
* [Design Procedure Doc Title]
* [Equipment Validation Proc. Title]
* [Identification & Traceability Proc. Title]
* [Internal Auditing Proc. Title]
* [Management Review Proc. Title]
* [Outsourced Processes Title]
* [Preservation Proc. Title]
* [Preventive Maintenance Proc. Title]
* [Purchasing Proc. Title]
* [Quoting and Orders Doc Title]
* [Receiving Proc. Title]
* [Risk Management Proc. Title]
* [Special Process Doc Title]
* [Training Proc. Title]