###### (Company)

**QUALITY MANAGEMENT SYSTEMS**

Revision 3

Issued 1/4/2017

Conforms to ISO:9001 2015 Standards

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1. **Revision History and Approval**

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| --- | --- | --- | --- |
| **Rev.** | **Nature of changes** | **Approval** | **Date** |
| 0 | Original release. | Management | 1/4/2017 |
| 1 | Updated ISO process map | Management | 3/14/2017 |
| 2 | Removed maintenance from process list, added Engineering | Management | 4/19/2017 |
| 3 | Changed engineering to Quality | Management | 6/23/2017 |
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1. **Welcome to (Company), INC**

(Company) Inc is a manufacturer of tungsten products based in Laramie, Wyoming. Our modern, state-of-the-art facility featuring advanced environmental control, metallurgical technology and quality control, ensures that our materials meet the most critical standards. We are committed to promoting an understanding of our customers’ needs and expectations, together with a culture of integrity and commitment to continuous improvement.

1. **About The (Company) Quality Manual**

This manual is prepared for the purpose of defining the company’s interpretations of the ISO 9001:2015/AS9100D international standard, as well as to demonstrate how the company complies with that standard.

This manual is not aligned with the clause numbering scheme of ISO 9001/AS9100D; instead, Appendix B provides a cross-reference table that shows where, in the manual, each ISO 9001/AS9100D requirement is addressed.

This manual presents “Notes” which are used to define how (Company) has tailored its management system to suit its purposes. These are intended to clarify implementation approaches and interpretations for concepts which are not otherwise clearly defined in ISO 9001:2015. *Notes appear in italics, with gray background.*

Where subordinate or supporting documentation is reference in this manual, these are indicated by ***bold italics***.

1. **Terms and Definitions**

(Company) adopts the following terms and definitions within its Quality Management System. Where no definition is provided, the company typically adopts the definitions provided in ***ISO 9000: Quality Management – Fundamentals and Vocabulary***. In some cases, specific procedures or documentation may provide a different definition to be used in the context of that document; in such cases, the definition will supersede those provided for in this Quality Manual or ISO 9000.

**General Terminology**

**(Company)** – (Company), Inc

**Document** – written information used to describe how an activity is done.

**Record** – captured evidence of an activity having been done.

**SOP** – standard operating procedure

**Risk-Based Thinking Terminology**

**Risk** – Negative effect of uncertainty

**Opportunity** – Positive effect of uncertainty

**Uncertainty** - A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)

**Nonconforming Product Terminology**

**Rework:** Efforts to bring nonconforming product into conformance through additional operations that *do not* alter the original design of the product.

**Repair:** Efforts to bring nonconforming product into conformance through additional operations that alter the original design of the product; this may be through the addition of material no specified in the original design, or through altering pre-existing design features.

**Scrap**: The discard of nonconforming product in lieu of rework or repair.

1. **The Scope and Context of the (Company) QMS**

**4.1 Determining Our Strategic Direction**

(Company) has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This involves:

* Understanding our core products, and scope of management system (see 4.2 below).
* Identifying “interested parties” (stakeholders) who receive our products, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are identified in the document ***Context of the Organization.***
* Understanding internal and external issues that are of concern to (Company) and its interested parties; also identified in the document ***Context of the Organization***. Many such issues are identified through an analysis of risks facing either (Company) or the interested parties. Such issues are monitored and updated as appropriate, and discussed as part of management reviews.

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.

**4.2 Scope of the Management System**

***4.2.1 Scope Statement***

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products, (Company) has determined the scope of the management system as follows:

**(Company), Inc located in Laramie, WY, producing tungsten balls, tungsten cubes, tungsten penetrators and tungsten machining blanks**

***4.2.2 Facilities Within the Scope***

Laramie, WY only

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

1665 Venture Drive

Laramie, WY 82070

Phone: (307) 314-2808

Web: <http://www.tungstenheavypowder.com/laramie/>

***4.2.3 Permissible Exclusions***

The following clauses of ISO 9001/AS9100D were determined to be not applicable to (Company).

* Design & Development

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.

|  |
| --- |
| 6170 Cornerstone Court East, Suite 310 San Diego, CA 92121 |

***4.2.4 Scope of the Quality Management Systems***

This manual is prepared for the purpose of defining the company’s interpretations of the ISO 9001:2015/AS9100D international standard, as well as to demonstrate how the company complies with that standard.

This manual does not strictly follow the numbering structure of ISO 9001. Instead, Appendix B presents a cross reference between the sections of this manual and the clauses of ISO 9001:2015/AS9100D.

This manual presents “Notes” which are used to define how [Short Client Name] has tailored its management system to suit its purposes. These are intended to clarify implementation approaches and interpretations for concepts which are not otherwise clearly defined in ISO 9001:2015/AS9100D. *Notes appear in italics, with gray background.*

Where subordinate or supporting documentation is reference in this manual, these are indicated by ***bold italics***.

1. **Quality Policy**

The Quality Policy of (Company) is as follows:

**(Company) is committed to making the world safer by providing products that meet our customer’s expectations for quality, delivery and cost through the use of continuous improvement and employee engagement.**

1. **Management System Processes**

**6.1 Process Identification**

(Company) 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 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 (Company):

* Purchasing
* Production
* Quality
* Shipping
* Support
* Sales and Order Entry

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*** 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

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.*

**6.2 Process Controls & Objectives**

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.

*Note: some processes have multiple objectives and multiple metrics. This is determined by the nature of the process, it’s impact on products, and associated risks.*

*Note: Whereas ISO 9001 discusses process measurements and “quality objectives” as separate concepts, (Company) combines them; i.e., quality objectives are used to control the processes. Additional objectives for products may be assigned, but these will also be used to measure process effectiveness.*

Throughout the year, metrics data is measured and gathered by process owners or other assigned managers, in order to present the data to the Management Team. The data is then analyzed by the Management Team in order that the Management Team 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 minutes of Management Review, per section 8.8.

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.

**6.3 Outsourced 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***.

The type and extent of control to be applied to the outsourced process take into consideration:

1. the potential impact of the outsourced process on the company’s capability to provide product that conforms to requirements,
2. the degree to which the control for the process is shared,
3. the capability of achieving the necessary control through the purchasing contract requirements.
4. **Documentation & Records**

**7.1 General**

The management system documentation includes both documents and records.

*Note: the ISO 9001:2015 standard uses the term “documented information”; (Company) does not use this term, but instead relies on the terms “document” and “record” to avoid confusion. In this context, the terms are defined per section 3.0 above. Documents and records undergo different controls as defined herein.*

The extent of the management system documentation has been developed based on the following:

1. The size of (Company)
2. Complexity and interaction of the processes
3. Risks and opportunities
4. Competence of personnel

**7.2 Control of Documents**

Documents required for the management system are controlled in accordance with procedure ***Control of Documents***. The purpose of document control is to ensure that staff have access to the latest, approved information, and to restrict the use of obsolete information.

All documented procedures are established, documented, implemented and maintained.

**7.3 Control of Records**

A documented procedure ***Control of Records*** has been established to define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. This procedure also defines the methods for controlling records that are created by and/or retained by suppliers.

These controls are applicable to those records which provide evidence of conformance to requirements; this may be evidence of product requirements, contractual requirements, procedural requirements, or statutory/regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system.

1. **Management & Leadership**

**8.1 Management Leadership and Commitment**

Management Team of (Company) provides evidence of its leadership and commitment to the development and implementation of the management system and continually improving its effectiveness by:

1. taking accountability of the effectiveness of the management system;
2. ensuring that the ***Quality Policy*** and quality objectives are established for the management system and are compatible with the strategic direction and the context of the organization;
3. ensuring that the quality policy is communicated, understood and applied within the organization;
4. ensuring the integration of the management system requirements into the organization’s other business processes, as deemed appropriate (see note);
5. promoting awareness of the process approach;
6. ensuring that the resources needed for the management system are available;
7. communicating the importance of effective quality management and of conforming to the management system requirements;
8. ensuring that the management system achieves its intended results;
9. engaging, directing and supporting persons to contribute to the effectiveness of the management system;
10. promoting continual improvement;
11. supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

*Note: “business processes” such as accounting, employee benefits management and legal activities are out of scope of the QMS.*

**8.2 Customer Focus**

Management Team of (Company) adopts a customer-first approach which ensures that customer needs and expectations are determined, converted into requirements and are met with the aim of enhancing customer satisfaction.

This is accomplished by assuring:

1. customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
2. the risks and opportunities that can affect conformity of products and the ability to enhance customer satisfaction are determined and addressed;
3. the focus on enhancing customer satisfaction is maintained.

**8.3 Quality Policy**

Management Team has developed the ***Quality Policy***, defined in section 5.0 above, that governs day-to-day operations to ensure quality.

The ***Quality Policy*** is released as a standalone document as well, and is communicated and implemented throughout the organization.

**8.4 Organizational Roles Responsibilities & Authorities**

Management Team has assigned responsibilities and authorities for all relevant roles in the company. These are communicated through the combination of the ***Organizational Chart*** and all management.

The Management Team accepts responsibility and authority for:

1. ensuring that the management system conforms to applicable standards;
2. ensuring that the processes are delivering their intended outputs;
3. reporting on the performance of the management system;
4. providing opportunities for improvement for the management system;
5. ensuring the promotion of customer focus throughout the organization;
6. ensuring that the integrity of the management system is maintained when changes are planned and implemented.

**8.5 Internal Communication**

Management Team of (Company) ensures internal communication takes place regarding the effectiveness of the management system. Internal communication methods include:

1. use of corrective and preventive action processes to report nonconformities or suggestions for improvement
2. use of the results of analysis of data
3. meetings (periodic, scheduled and/or unscheduled) to discuss aspects of the QMS
4. use of the results of the internal audit process
5. regular company meetings with all employees
6. internal emails
7. (Company)’s “open door” policy which allows any employee access to all managers for discussions on improving the quality system

**8.6 Change Management**

When (Company) determines the need for changes to the management system or its processes, these changes planned, implemented, and then verified for effectiveness; see the document ***Change Management.***

Documents are changed in accordance with procedure ***Control of Documents***.

**8.7 Risks and Opportunities**

*Note: (Company) deviates slightly from the approach towards risk and opportunity presented in ISO 9001. Instead, (Company) views “uncertainty” as neutral, but defines “risk” as a negative effect of uncertainty, and “opportunity” as a positive effect of uncertainty. (Company) has elected to manage risks and opportunities separately, except where they may overlap. Formal risk management may not be utilized in all instances; instead, the level of risk assessment, analysis, treatment and recordkeeping will be performed to the level deemed appropriate for each circumstance or application.*

(Company) considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system; likewise, these are considered relative to all products. Risks and opportunities are identified as part of the “Context of the Organization Exercise” defined in ***Context of the Organization,*** as well as throughout all other activities of the QMS.

Risks and opportunities are managed in accordance with the document ***Risk Management***. This procedure defines how risks are managed in order to minimize their likelihood and impact, and how opportunities are managed to improve their likelihood and benefit.

**8.8 Management Review**

The Management Team reviews the management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement, and the need for changes to the management system, including the ***Quality Policy*** and quality objectives.

Management review frequency, agenda (inputs), outputs, required members, actions taken and other review requirements are defined in the documented procedure ***Management Review.***

Records from management reviews are maintained.

1. **Resources**

**9.1 Provision of Resources**

(Company) determines and provides the resources needed:

1. to implement and maintain the management system and continually improve its effectiveness
2. to enhance customer satisfaction by meeting customer requirements

Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs related to supplier expectations.

Resources and resource allocation are assessed during management reviews.

**9.2 Human Resources**

Senior management ensures that it provides sufficient staffing for the effective operation of the management system, as well its identified processes.

Staff members performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience. The documented procedure ***Training Procedures*** defines these activities in detail.

Training and subsequent communication ensure that staff are aware of:

1. the quality policy;
2. relevant quality objectives;
3. their contribution to the effectiveness of the management system, including the benefits of improved performance;
4. the implications of not conforming with the management system requirements.

*Note: the management system does not include other aspects of Human Resources management, such as payroll, benefits, insurance, labor relations or disciplinary actions.*

**9.3 Infrastructure**

(Company) determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

1. buildings, workspace and associated facilities;
2. process equipment, hardware and software;
3. supporting services such as transport;
4. information and communication technology.

Equipment is validated per the procedure ***Equipment Validation*** and maintained per the procedure ***Preventive Maintenance.***

Where equipment is used for critical measurement activities, such as inspection and testing, these shall be subject to control and either calibration or verification; see the procedure ***Calibration.***

*Note: Calibration and measurement traceability is not employed for all measurement devices. Instead, (Company) determines which devices will be subject to calibration based on its processes, products and services, or in order to comply with specifications or requirements. These decisions are also based on the importance of a measurement, and considerations of risk.*

**9.4 Work Environment**

(Company) provides a clean, safe and well-lit working environment. The Management of (Company) manages the work environment needed to achieve conformity to product requirements. Specific environmental requirements for products are determined during quality planning and are documented in subordinate procedures, work instructions, or job documentation. Where special work environments have been implemented, these shall also be maintained per 9.3 above.

Human factors are considered to the extent that they directly impact on the quality of manufactured products.

*Note: Social, psychological and safety aspects of the work environment are managed through activities outside of the scope of the management system. Only work environment aspects which can directly affect process efficiency or product and service quality are managed through the management system.*

**9.5 Organizational Knowledge**

(Company) also determines the knowledge necessary for the operation of its processes and to achieve conformity of all products. This may include knowledge and information obtained from:

1. internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;
2. external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

This knowledge shall be maintained, and made available to the extent necessary.

When addressing changing needs and trends, (Company) shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.

1. **Operation**

**10.1 Operational Planning and Control**

(Company) plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the management system. Such planning considers the information related to the context of the organization (see section 4.0 above), current resources and capabilities, as well as product requirements.

Changes to operational processes are done in accordance with the document ***Change Management***.

**10.2 Customer-Related Activities**

During the intake of new business (Company) captures:

1. requirements specified by the customer, including the requirements for delivery and post-delivery activities;
2. requirements not stated by the customer but necessary for specified or intended use, where known
3. statutory and regulatory requirements related to all products;
4. any additional requirements determined by (Company).

Once requirements are captured, (Company) reviews the requirements prior to its commitment to supply the its products. This review ensures that:

1. all product requirements are defined,
2. contract or order requirements differing from those previously expressed are resolved,
3. the organization has the ability to meet the defined requirements, and/or the claims for the products it offers, and
4. risks have been identified and considered.

These activities are defined in greater detail in the procedure ***Order Entry.***

**10.3 Customer Communication**

(Company) has implemented effective communication with customers in relation to:

1. providing information relating to all products;
2. handling enquiries, contracts or orders, including changes;
3. obtaining customer feedback relating to products, including customer complaints;
4. handling or controlling customer property;
5. establishing specific requirements for contingency actions, when relevant.

**10.4 Design and Development**

(Company) manufactures parts to customer specification only. The customer is sole proprietary of the design. (Company) customer provides all the characteristics and specifications of each manufactured part. (Company) does not participate in Design and Development.

**10.5 Purchasing**

(Company) ensures that purchased products or services conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased products or services is dependent on the effect on subsequent and final products.

(Company) evaluates and selects suppliers based on their ability to supply product and service in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established.

Purchases are made via the release of formal purchase orders and/or contracts which clearly describe what is being purchased. Received products or services are then verified against requirements to ensure satisfaction of requirements. Suppliers who do not provide conforming products or services may be requested to conduct formal corrective action.

These activities are further defined in the documents ***Purchasing*** and ***Receiving***.

**10.6 Provision of (Company) products**

***10.6.1 Control of Provision of Products***

To control its provision of products, (Company) considers, as applicable, the following:

1. the availability of documents or records that define the characteristics of products as well as the results to be achieved;
2. the availability and use of suitable monitoring and measuring resources;
3. the implementation of monitoring and measurement activities;
4. the use of suitable infrastructure and environment;
5. the appointment of competent persons, including any required qualifications;
6. the implementation of actions to prevent human error;
7. the implementation of release, delivery and post-delivery activities.

(Company) utilizes some “special processes” where the result of the process cannot be verified by subsequent monitoring or measurement. The special processes in use and the methods of validation of each are defined in the document ***Special Process.***

***10.6.2 Identification and Traceability***

Where appropriate, (Company) identifies its products or other critical process outputs by suitable means. Such identification includes the status of products with respect to monitoring and measurement requirements. Unless otherwise indicated as nonconforming, pending inspection or disposition, or some other similar identifier, all products shall be considered conforming and suitable for use.

If unique traceability is required by contract, regulatory, or other established requirement, (Company) controls and records the unique identification of the product.

The documented procedure ***Identification & Traceability*** defines these methods in detail.

***10.6.3 Property Belonging to Third Parties***

(Company) exercises care with customer or supplier property while it is under the organization’s control or being used by the organization. Upon receipt, such property is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer or supplier and records maintained.

For customer intellectual property, including customer furnished data used for design, production and / or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage or inappropriate use.

This activity is defined in greater detail in the document ***Customer Property.***

***10.6.4 Storage***

(Company) preserves conformity of product or other process outputs during internal processing and delivery. This preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

The documented procedure ***Preservation*** defines the methods for preservation of product.

***10.6.5 Post-Delivery Activities***

As applicable, (Company) conducts the following activities which are considered “post-delivery activities”:

* Customer survey

Post-delivery activities are conducted in compliance with the management system defined herein.

***10.6.6 Process Change Control***

(Company) reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

Process change management is defined in the document ***Change Management.***

***10.6.7 Measurement and Release of Products***

Acceptance criteria for products are defined in appropriate subordinate documentation. Reviews, inspections and tests are conducted at appropriate stages to verify that the product requirements have been met. This is done before products are released or delivered.

Each process utilizes different methods for measuring and releasing of products. These methods are defined in ***Production Management.***

***10.6.8 Control of Nonconforming Outputs***

(Company) ensures that all products or other process outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The controls for such nonconformances are defined in ***Control of NCP.***

1. **Improvement**

**11.1 General**

(Company) uses the management system to improve its processes, products and services. Such improvements aim to address the needs and expectations of customers as well as other interested parties, to the extent possible.

Improvement shall be driven by an analysis of data related to:

The results of analysis shall be used to evaluate:

1. conformity of products;
2. the degree of customer satisfaction;
3. the performance and effectiveness of the management system;
4. the effectiveness of planning;
5. the effectiveness of actions taken to address risks and opportunities;
6. the performance of external providers;
7. other improvements to the management system.

**11.2 Customer Satisfaction**

As one of the measurements of the performance of the management system, (Company) monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information include:

* recording customer complaints
* product rejections or returns
* repeat orders for product
* changing volume of orders for product
* trends in on-time delivery
* obtain customer scorecards from certain customers
* submittal of customer satisfaction surveys

The corrective and preventive action system shall be used to develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

**11.3 Internal Audit**

(Company) conducts internal audits at planned intervals to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of ISO 9001, and to management system requirements. Audits also seek to ensure that the management system has been effectively implemented and is maintained.

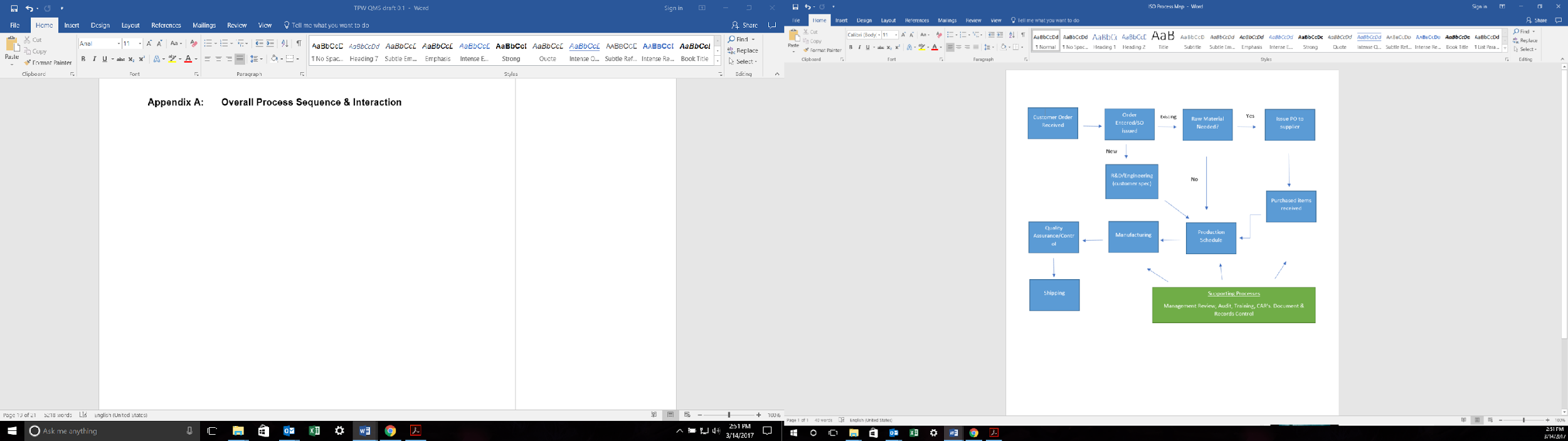
These activities are defined in the document ***Internal Auditing.***

**11.4 Corrective and Preventive Action**

(Company) takes corrective action to eliminate the cause of nonconformity in order to prevent *recurrence*. Likewise, the company takes preventive action to eliminate the causes of potential nonconformities in order to prevent their *occurrence*.

These activities are done through the use of the formal Corrective Action (CAR Form Abbreviation) system, and are defined in the document ***Corrective/Preventive Action.***

**Appendix A: Overall Process Sequence & Interaction**



**Appendix B: ISO 9001:2015 Cross Reference**

|  |  |
| --- | --- |
| **ISO 9001:2015 Clause** | **Section in Manual** |
| 4.0 Context of the Organization (all) |  |
| 4.1 Understanding the Organization & Its Context | 4.1 Determining Our Strategic Direction |
| 4.2 Understanding the needs & expectations of interested parties | 4.1 Determining Our Strategic Direction |
| 4.3 Determining the scope of the QMS | 4.2 Scope of the Management System |
| 4.4 Management system and its processes | 6.0 Management System Processes |
| 5.0 Leadership |  |
| 5.1 Leadership & Commitment | 8.1 Management Leadership and Commitment |
| 5.1.1 General | 8.1 Management Leadership and Commitment |
| 5.1.2 Customer focus | 8.2 Customer Focus |
| 5.2 Policy | 50 Quality Policy  8.3 Quality Policy |
| 5.3 Organizational Roles Responsibilities and Authorities | 5.4 Organizational Roles and Responsibilities and Authorities |
| 6.0 Planning |  |
| 6.1 Actions to address risks and opportunities | 8.7 Risks and Opportunities |
| 6.2 Quality objectives and planning to achieve them | 6.2 Process Controls & Objectives |
| 6.3 Planning of changes | 8.6 Change Management |
| 7.0 Support |  |
| 7.1 Resources |  |
| 7.1.1 General | 9.1 Provision of Resources |
| 7.1.2 People | 9.2 Human Resources |
| 7.1.3 Infrastructure | 9.3 Infrastructure |
| 7.1.4 Environment for the operation of processes | 9.4 Work Environment |
| 7.1.5 Monitoring and measuring resources | 9.3 Infrastructure |
| 7.1.6 Organizational knowledge | 9.5 Organizational Knowledge |
| 7.2 Competence | 9.2 Human Resources |
| 7.3 Awareness | 9.2 Human Resources |
| 7.4 Communication | 8.5 Internal Communication |
| 7.5 Documented information | 7.0 Documentation & Records |
| 8.0 Operation |  |
| 8.1 Operational planning and control | 10.1 Operational Planning and Control |
| 8.2 Requirements for products and services |  |
| 8.2.1 Customer communication | 10.3 Customer Communication |
| 8.2.2 Determining the requirements related to products & services | 10.2 Customer Related Activities |
| 8.2.3 Review of requirements related to products & services | 10.2 Customer Related Activities |
| 8.2.4 Changes to requirements for products and services | 10.2 Customer Related Activities |
| 8.3 Design and development of products and services | 10.4 Design and Development |
| 8.4 Control of externally provided processes, products & services | 10.5 Purchasing |
| 8.5 Production and service provision |  |
| 8.5.1 Control of production and service provision | 10.6.1 Control of Provision of Products |
| 8.5.2 Identification and traceability | 10.6.2 Identification and Traceability |
| 8.5.3 Property belonging to customers or external providers | 10.6.3 Property Belonging to Third Parties |
| 8.5.4 Preservation | 10.6.4 Preservation |
| 8.5.5 Post-delivery activities | 10.6.5 Post-Delivery Activities |
| 8.5.6 Control of changes | 10.6.6 Process Change Control |
| 8.6 Release of products and services | 10.6.7 Measurement and Release of Products |
| 8.7 Control of nonconforming outputs | 10.6.8 Control of Nonconforming Outputs |
| 9.0 Performance evaluation |  |
| 9.1 Monitoring, measurement, analysis and evaluation |  |
| 9.1.1 General | 11.1 Improvement: General |
| 9.1.2 Customer satisfaction | 11.2 Customer Satisfaction |
| 9.1.3 Analysis and evaluation | 11.1 Improvement: General |
| 9.2 Internal audit | 11.3 Internal Audit |
| 9.3 Management review | 8.8 Management Review |
| 10.0 Improvement |  |
| 10.1 General | 11.1 Improvement: General |
| 10.2 Nonconformity and corrective action | 11.4 Corrective and Preventive Action |
| 10.3 Continual improvement | 11.1 Improvement: General |