Management Systems International, LLC
Powering Business Forward

Your Company Name

It was a pleasure to work with your Company [Date of Gap Analysis] by providing a Gap Analysis and regarding your interest to transition to ISO 9001: 2015. On behalf of Management Systems International, LLC (MSI), We are pleased to submit the results.

Since 1998, MSI comprehensively provides consulting, training and software on international standards to ***Power Business Forward.*** In true partnership with you, our expert consultants leverage years of experience with ISO 9001, 14001 and AS 9100 standards, advanced tools and highly effective procedures. We have amassed an impressive string of successes using our proven methodology. More than 60 organizations have adopted our SurePath™ approach and have been registered on the first attempt, for either ISO 9001, AS 9100 or ISO 14001 Standards; not one of our clients has ever been rejected. MSI has been present at all of our customers' audits which have allowed us the means to greatly improve our approach.

MSI's Vision is to innovatively develop and maintain management systems that deliver strategic and continuous improvements for all types of companies.

Your Company Name ISO 9001:2015 GAP Analysis Review Report

Report Generated by: MSI Consultant

Onsite: Date Intended to be onsite

Expected Completion: 5 days from date onsite

In advance an agenda is provided for how the Gap was to be performed.

Gap Analysis Introduction:

The changes from ISO 9001:2008 to ISO 9001:2015 include 6 new themes and updates to 13 existing clauses. Following is a list of the updated ISO 9001 requirement clauses and a detailed activity outline for the new ISO 9001:2015 themes.

Updated ISO 9001 Requirements:

5.1 Leadership and Commitment

6.3 Planning of Changes

7.1.5 Monitoring and Measuring Resources;

7.3 Awareness;

7.4 Communication

8.2 Determination of requirements for products and services

8.3 Design and Development of Products and Services

8.5.5 Control of Products and Service Provision

8.5.6 Control of Changes

8.6 Release of Products and Services

8.7 Control of nonconforming process output, products and services

9.3 Management Review

10.2 Nonconformity and corrective action

New Themes of ISO 9001:2015 include:

Business Planning and Strategic Direction

ISO Element	**Activity**
4.1; 4.2	Identification of internal and external issues and interested parties that are relevant to and/or support the strategic direction of the organization.
5.2.1	The strategic direction is utilized as an input to the Quality Policy, Quality Objectives, Risk management, and Management Review processes.
4.1; 4.2; 5.1.1; 9.3.2	Assessing and reviewing the quality management system in accordance with the strategic direction.
10.3	Changes to the quality management system in response to the above activities as necessary.

Process Risks

ISO Element	Activity
4.4.1; 6.1; 6.2; 6.3; 8.5.6	Risks to achieving process objectives are identified when establishing the quality management system and planning for changes.
8.1	Address the identified process risks.
6.1.2; 9.1.3; 9.3.2	Analyze the effectiveness of actions taken to address process risks.
10.2.1; 10.3	Updating the process risks after analysis and corrective action is evident.

Product and Service Risks

ISO Element	Activity
5.1.2, 6.1, 6.2, 8.1, 8.2.2, 8.2.3, 8.3.2	Have risks achieving product or service conformity bee: • Identified and considered as part of the planning for operational control • Identified and considered when determining and reviewing customer requirements • Identified and considered during design planning, including product or service complexity
8.1, 8.2.3.1, 8.3.3	Development and implementation of design and operational controls to address the identified product and service risks.
9.1.3, 9.3.2	Analyze the effectiveness of actions taken to address product or service risks
10.1	Determining and selecting opportunities for improvement on product and service.

Risk Associated with the control of externally provided product and services

ISO Element	Activity
6.1	Identify the risks associated with externally provided products, processes, or services (outsourced).
8.4.1, 8.4.2	Are the identified risks utilized as an input into: • The potential impact of externally provided product, process, or service • The type and extent of controls needed • The selection and evaluation of external providers • The degree of information provided to external providers

8.4.1, 9.3.2	Develop and apply defined criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers.
9.3.3	Modify the controls applied to external providers based upon the results of evaluation

Organizations Knowledge

ISO Element	**Activity**
7.1.6	Identify the knowledge specific to the organization that is gained through experience.
7.1.6	Establish a process to ensure that the knowledge is maintained and made available.
10	Review and improve processes based on experiences.

This Gap Analysis reviews all ISO 9001:2015 requirements to identify gaps in the established quality management system (QMS) and not just the new or updated clauses.

Your Company Name Background:

Your Company Name is a ……..owned small business that provides custom manufacturing of ……. Your company excels in ……, complex …….. Your Company has a xxxxx square feet of manufacturing space and an average employee tenure of xx years.

Certification Details:

ISO 9001:2008 certified by ……(your registrar Co name Registrar, Inc.

Last registration audit was date of last or certification audit

Registration scope: as stated on your current certificate

Operational Details:

Address-

Number of shifts-

Number of employees-

Overall:

# of whole requirements that are not being met. ## of requirements where portions of requirements are not being met. Some requirements to 2008 were not being met as shown below. Many recommendations were provided during the gap analysis.

Document Status:

Title	Doc #	Revision	Issue Date	Note/Comments
Quality Policy				
Quality Objectives				
Quality Assurance Manual				
Document Control				
Control of Records				
Internal Audit				
Control of Nonconforming Product Procedure				
Corrective and Preventive Action Procedure				
Customer Related Processes				
Purchasing Procedure				
Production				
Monitoring and Measurement				
ITAR				
Control of Monitoring and Measurement Devices				
Planning of Product realization				
Monitoring and Measurement of Process Procedure				
Design and Development				

ISO 9001:2015 Checklist:

Clause	ISO 9001:2015 Requirement	Comply	Comments / Evidence
4	**Context of the organization**		
4.1	**Understanding the organization and its context**		

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. The organization shall monitor and review information about these external and internal issues. *NOTE 1 Issues can include positive and negative factors or conditions for consideration.* *NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.* *NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.*		It is not evident that the following is being completed: Determine the external and internal issues that are: -relevant to the organizations purpose - relevant to the organizations strategic direction - affects the organizations ability to achieve intended result(s) of the quality management system (QMS) Monitor and review information about the external and internal issues Determine the strategic direction and determine the intended results of the QMS.
4.2 Understanding the needs and expectations of interested parties		
Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine: a) the interested parties that are relevant to the quality management system; b) the requirements of these interested parties that are relevant to the quality management system.		It is not evident that the following is being completed: Determine the interested parties their requirements, needs and expectations, that are relevant to the quality management system
4.3 Determining the scope of the quality management system		

The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider: a) the external and internal issues referred to in 4.1; b) the requirements of relevant interested parties referred to in 4.2; c) the products and services of the organization. The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system. The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system. Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.		It is not evident that the scope: The QMS Scope: - Determines the boundaries of the QMS - Demonstrate consideration to external and internal issued; requirements of relevant interested parties; and products and services of the organization when determining the scope. - State the types of products and services covered - States that all requirements of ISO 9001:2015 are applied to the QMS unless it is not applicable. - Provide justification for any requirement of ISO 9001:2015 determined as not applicable to the scope of the QMS Confirm that justified exclusions do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction. The scope is discussed at management review and stated in the manual, but not the extended required for 9001:2015. Determined exclusions are not stated in the scope. *** Note: the registrar certificate scope is different from this ISO 9001:2015 scope requirement.

4.4 Quality management system and its processes		
4.4.1 The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall: a) determine the inputs required and the outputs expected from these processes; b) determine the sequence and interaction of these processes; c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes; d) determine the resources needed for these processes and ensure their availability; e) assign the responsibilities and authorities for these processes; f) address the risks and opportunities as determined in accordance with the requirements of 6.1; g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results; h) improve the processes and the quality management system.		Process interaction chart is developed but: It includes design and development which is excluded and it does not include for outsourced processes. Process Flow Diagram does not include expected outputs nor key processes The resources are determined for the whole QMS, but not for the key processes. Risk and opportunities determination is new for 9001:2015 and not evident in current processes. The evaluation of processes and implementation of changes to ensure that processes achieve their intended results is not evident. Improvement of processes and the QMS are shown as discussed at the management review.

4.4.2 To the extent necessary, the organization shall: a) maintain documented information to support the operation of its processes; b) retain documented information to have confidence that the processes are being carried out as planned.		ISO folder exists to support 9001:2008
5 Leadership; 5.1 Leadership and commitment; 5.1.1 General		
Top management shall demonstrate leadership and commitment with respect to the quality management system by: taking accountability for the effectiveness of the quality management system; b) 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; c) ensuring the integration of the quality management system requirements into the organization's business processes; d) promoting the use of the process approach and risk-based thinking; e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. *NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core*		The strategic direction is a new requirement for ISO 9001:2015 and is not yet developed. Therefore, confirmation that quality policy and quality objectives are compatible with the context and strategic direction is not evident. The current QMS is integrated into the business processes. Promoting the use of the process approach and risk based thinking is not evident. The management review demonstrates the resources needed for the QMS, their availability, and cross training is identified. Communicates the importance of the quality policy and objectives. Management review, weekly meetings, and monthly company meetings ensures the QMS achieves its intended results; supports personnel to contribute to the effectiveness of the QMS; promoted improvement; and supports other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. and weekly meetings

to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.		
5.1.2 Customer focus		
Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met; b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; c) the focus on enhancing customer satisfaction is maintained.		Vice president of operations and vice president of engineering is involved in quoting. ITAR 100% customer satisfaction Returns are a means of measuring customer score cards. The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are not yet determined and addressed.
5.2 Policy		
5.2.1 Developing the quality policy		
Top management shall establish, implement and maintain a quality policy that: a) is appropriate to the purpose and context of the organization and supports its strategic direction; b) provides a framework for setting quality objectives; c) includes a commitment to satisfy applicable requirements; d) includes a commitment to continual improvement of the quality management system.		The Quality Policy provides a framework for quality objectives such as late shipments, customer returns and internal rejects. The Quality Policy does not include a commitment to satisfy applicable requirements or to continually improve the QMS. Not evident that the quality policy is appropriate to the purpose and context of the organization and supports its strategic direction, and these are yet to be developed, cannot confirm that the quality policy is appropriate to these.
5.2.2 Communicating the quality policy		

The quality policy shall: a) be available and be maintained as documented information; b) be communicated, understood and applied within the organization; c) be available to relevant interested parties, as appropriate.		The Quality Policy is not maintained ad documented information as it does not have documented control. It is communicated, understood, applied and available electronically and posted on the website.
5.3 Organizational roles, responsibilities and authorities		
Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. Top management shall assign the responsibility and authority for: a) ensuring that the quality management system conforms to the requirements of this International Standard; b) ensuring that the processes are delivering their intended outputs; c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management; d) ensuring the promotion of customer focus throughout the organization; e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.		The responsibilities and authorities for quality assurance and quality control are listed in procedures. Training is conducted by…... Management Review, Weekly meetings, and Monthly Company meetings are used to report on the performance of the QMS and opportunities for improvement to top management, promote customer focus throughout the organization; and ensures the integrity of the QMS when changes are planned and implemented. The responsibilities and authorities to ensure that the processes are delivering their intended outputs are not evident.
6 Planning		
6.1 Actions to address risks and opportunities		

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement.		

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;
b) how to:
   1) integrate and implement the actions into its quality management system processes (see 4.4);
   2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

6.2 Quality objectives and planning to achieve them		
6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system needed for the quality management system. The quality objectives shall: a) be consistent with the quality policy; b) be measurable; c) take into account applicable requirements; d) be relevant to conformity of products and services and to enhancement of customer satisfaction; e) be monitored; f) be communicated; g) be updated as appropriate. The organization shall maintain documented information on the quality objectives.		Yearly data already exists, but improvement is needed for trending and adding in the past 6 months data.

6.2.2 When planning how to achieve its quality objectives, the organization shall determine: a) what will be done; b) what resources will be required; c) who will be responsible; d) when it will be completed; e) how the results will be evaluated.		
6.3 Planning of changes		
When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4). The organization shall consider: a) the purpose of the changes and their potential consequences; b) the integrity of the quality management system; c) the availability of resources; d) the allocation or reallocation of responsibilities and authorities.		Few changes have occurred recently. On the document master list, it is recommended to add a column for training. Management Review considered the changes to 9001:2015 for the availability of resources and allocation of responsibilities and authorities. It was not evident that the purpose of the changes and their potential consequences or the integrity of the QMS are considered.
7 Support		
7.1 Resources		

7.1.1 General		
The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. The organization shall consider: a) the capabilities of, and constraints on, existing internal resources; b) what needs to be obtained from external providers?		During Management Review the organization determines and provides resources needed for the QMS. It is not evident that consideration has been given for the capabilities of and contracts on existing internal resources not what needs to be obtained from external providers.
7.1.2 People		
The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.		
7.1.3 Infrastructure		

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. *NOTE Infrastructure can include:* a) *buildings and associated utilities;* b) *equipment, including hardware and software;* c) *transportation resources;* d) *information and communication technology.*		
7.1.4 Environment for the operation of processes		
The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. *NOTE A suitable environment can be a combination of human and physical factors, such as:* a) *social (e.g. non-discriminatory, calm, non-confrontational);* b) *psychological (e.g. stress-reducing, burnout prevention, emotionally protective);* c) *physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).* *These factors can differ substantially depending on the products and services provided.*		
7.1.5 Monitoring and measuring resources		
7.1.5.1 General		

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.		
7.1.5.2 Measurement Traceability		
When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information; b) identified in order to determine their status; c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.		
7.1.6 Organizational knowledge		

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.		Power points exist regarding products and services, but the organization knowledge requirement for 9001:2015 is not fully developed.
7.2 Competence		
The organization shall: a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system; b) ensure that these persons are competent on the basis of appropriate education, training, or experience; c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; d) retain appropriate documented information as evidence of competence. *NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re- assignment of currently employed persons; or the hiring or contracting of competent persons.*		Job descriptions exist. It is recommended to review the job descriptions for improvements

7.3 Awareness		
The organization shall ensure that persons doing work under the organization's control are aware of: a) the quality policy; b) relevant quality objectives; c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance; d) the implications of not conforming with the quality management system requirements.		This is in process. It is suggested to add content in existing procedures.
7.4 Communication		

The organization shall determine the internal and external communications relevant to the quality management system, including: a) on what it will communicate; b) when to communicate; c) with whom to communicate; d) how to communicate; e) who communicates.		There are weekly meetings with some notes, but the determination of this internal and external communication relevant to the QMS is not evident.
7.5 Documented information		
7.5.1 General		

The organization's quality management system shall include: documented information required by this International Standard; documented information determined by the organization as being necessary for the effectiveness of the quality management system. *NOTE The extent of documented information for a quality management system can differ from one organization to another due to:* *— the size of organization and its type of activities, processes, products and services;* *— the complexity of processes and their interactions;* *— the competence of persons.*		Updates needed to meet ISO 9001:2015 new requirements.
7.5.2 Creating and updating		
When creating and updating documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number); b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic); c) review and approval for suitability and adequacy.		
7.5.3 Control of documented information		

7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;
b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

a) distribution, access, retrieval and use;
b) storage and preservation, including preservation of legibility;
c) control of changes (e.g. version control);
d) retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by: a) determining the requirements for the products and services; b) establishing criteria for: 1) the processes; 2) the acceptance of products and services; c) determining the resources needed to achieve conformity to the product and service requirements; d) implementing control of the processes in accordance with the criteria; e) determining and keeping documented information to the extent necessary: 1) to have confidence that the processes have been carried out as planned; 2) to demonstrate the conformity of products and services to their requirements. *NOTE "Keeping" implies both the maintaining and the retaining of documented information. The output of this planning shall be suitable for the organization's operations.* *The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.* *The organization shall ensure that outsourced processes are controlled (see 8.4).*		
8.2 Requirements for products and services		
8.2.1 Customer communication		

Communication with customers shall include: a) providing information relating to products and services; b) handling enquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant.		
8.2.2 Determining the requirements related to products and services		
When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including: 1) any applicable statutory and regulatory requirements; 2) those considered necessary by the organization; b) the organization can meet the claims for the products and services it offers.		
8.2.3 Review of requirements related to products and services		

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities; b) requirements not stated by the customer, but necessary for the specified or intended use, when known; c) requirements specified by the organization; d) statutory and regulatory requirements applicable to the products and services; e) contract or order requirements differing from those previously expressed.		
8.2.4 Changes to requirements for products and services		
The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.		
8.3 Design and development of products and services		
8.3.1 General		
The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.		

8.3.2 Design and development planning

In determining the stages and controls for design and development, the organization shall consider: the nature, duration and complexity of the design and development activities; b) the required process stages, including applicable design and development reviews; c) the required design and development verification and validation activities; d) the responsibilities and authorities involved in the design and development process; e) the internal and external resource needs for the design and development of products and services; f) the need to control interfaces between persons involved in the design and development process; g) the need for involvement of customers and users in the design and development process; h) the requirements for subsequent provision of products and services; i) the level of control expected for the design and development process by customers and other relevant interested parties; j) the documented information needed to demonstrate that design and development requirements have been met.		

8.3.3 Design and development inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider: a) functional and performance requirements; b) information derived from previous similar design and development activities; c) statutory and regulatory requirements; d) standards or codes of practice that the organization has committed to implement; e) potential consequences of failure due to the nature of the products and services. Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. The organization shall retain documented information on design and development inputs.		
8.3.4 Design and development controls		
The organization shall apply controls to the design and development process to ensure that: the results to be achieved are defined; b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements; c) verification activities are conducted to ensure that the design and development outputs meet the input requirements; d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use; e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities; f) documented information of these activities is retained.		

8.3.5 Design and development outputs		
The organization shall ensure that design and development outputs meet the input requirements; a) are adequate for the subsequent processes for the provision of products and services; b) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria; c) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision. The organization shall retain documented information on design and development outputs.		
8.3.6 Design and development changes		

The organization shall identify, review and control changes made during, or after, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The organization shall retain documented information on: a) design and development changes; b) the results of reviews; c) the authorization of the changes; d) the actions taken to prevent adverse impacts.		
8.4 Control of externally provided processes, products and services		
8.4.1 General		

The organization shall ensure that externally provided processes, products and services conform to requirements. The organization shall determine the controls to be applied to externally provided processes, products and services when: a) products and services from external providers are intended for incorporation into the organization's own products and services; b) products and services are provided directly to the customer(s) by external providers on behalf of the organization; c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization. The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re- evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.		C of C Levels and flowed down requirements The review by quality assurance of the purchase order is not evident as stated in the procedure. The process of determining and applying criteria for the initial evaluation/selection of suppliers is not in place. Procedure no record of due diligence. Risk management criteria stated in the procedure

8.4.2 Type and extent of control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. The organization shall: a) ensure that externally provided processes remain within the control of its quality management system; b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output; c) take into consideration: 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements; 2) the effectiveness of the controls applied by the external provider; d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.		

8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider. The organization shall communicate to external providers its requirements for: a) the processes, products and services to be provided; b) the approval of: 1) products and services; 2) methods, processes and equipment; 3) the release of products and services; competence, including any required qualification of persons; d) the external providers' interactions with the organization; e) control and monitoring of the external providers' performance to be applied by the organization; f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.		

8.5 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities.		

8.5.2 Identification and traceability		
The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.		
8.5.3 Property belonging to customers or external providers		
The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred. *NOTE A customer's or external provider's property can include material, components, tools and equipment, premises, intellectual property and personal data.*		

8.5.4 Preservation		
The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. *NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.*		
8.5.5 Post-delivery activities		

The organization shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the organization shall consider: a) statutory and regulatory requirements; b) the potential undesired consequences associated with its products and services; c) the nature, use and intended lifetime of its products and services; d) customer requirements; e) customer feedback. *NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.*		
8.5.6 Control of changes		
The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.		

8.6 Release of products and services		
The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. The organization shall retain documented information on the release of products and services. The documented information shall include: a) evidence of conformity with the acceptance criteria; b) traceability to the person(s) authorizing the release.		
8.7 Control of nonconforming outputs		

8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. The organization shall deal with nonconforming outputs in one or more of the following ways: a) correction; b) segregation, containment, return or suspension of provision of products and services; c) informing the customer; d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are corrected. **8.7.2** The organization shall retain documented information that: a) describes the nonconformity; b) describes the actions taken; c) describes any concessions obtained; d) identifies the authority deciding the action in respect of the nonconformity.		

9 Performance evaluation		
9.1 Monitoring, measurement, analysis and evaluation		
9.1.1 General		
The organization shall determine: a) what needs to be monitored and measured; b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results; c) when the monitoring and measuring shall be performed; d) when the results from monitoring and measurement shall be analyzed and evaluated. The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results.		
9.1.2 Customer satisfaction		

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information. *NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.*		
9.1.3 Analysis and evaluation		

The organization shall analyses and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate: a) conformity of products and services; b) the degree of customer satisfaction; c) the performance and effectiveness of the quality management system; d) if planning has been implemented effectively; e) the effectiveness of actions taken to address risks and opportunities; f) the performance of external providers; g) the need for improvements to the quality management system. *NOTE Methods to analyses data can include statistical techniques.*		

9.2 Internal audit		
9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system: a) conforms to: 1) the organization's own requirements for its quality management system; 2) the requirements of this International Standard; b) is effectively implemented and maintained. **9.2.2** The organization shall: a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits; b) define the audit criteria and scope for each audit; c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process; d) ensure that the results of the audits are reported to relevant management; e) take appropriate correction and corrective actions without undue delay; f) retain documented information as evidence of the implementation of the audit programme and the audit results.		The internal audit program is established and the records are available. Internal audit schedule 2016 for 1X in the year. It would at least be expected that the key processes are audited more than 1x per year. Consideration of the importance and frequency is not evident on the internal audit schedule. 2 auditors, but it is not evident that they are objective and impartial of the audit process. More auditors should be trained Audit results
9.3 Management review		
9.3.1 General		

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.		Management Review 7/26/2017 does not address the following: -Conclusion if the QMS is suitable, adequate, and effective. -Confirmation that the QMS is in alignment with the strategic direction of the organization
9.3.2 Management review inputs		
The management review shall be planned and carried out taking into consideration: a) the status of actions from previous management reviews; b) changes in external and internal issues that are relevant to the quality management system; c) 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; d) the adequacy of resources; e) the effectiveness of actions taken to address risks and opportunities (see 6.1); f) opportunities for improvement.		
9.3.3 Management review outputs		

The outputs of the management review shall include decisions and actions related to: a) opportunities for improvement; b) any need for changes to the quality management system; c) resource needs. The organization shall retain documented information as evidence of the results of management reviews.		
10 Improvement		
10.1 General		

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include: a) improving products and services to meet requirements as well as to address future needs and expectations; b) correcting, preventing or reducing undesired effects; c) improving the performance and effectiveness of the quality management system. *NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.*		
10.2 Nonconformity and corrective action		

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable: 1) act to control and correct it; 2) deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: 1) reviewing and analyzing the nonconformity; 2) determining the causes of the nonconformity; 3) determining if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered. **10.2.2** The organization shall retain documented information as evidence of: a) the nature of the nonconformities and any subsequent actions taken; b) the results of any corrective action.		Nonconformities go to quality assurance. Reject log, but it does not have a column to indicate if a corrective action is needed and the number of cause is only on reject yearly. If a corrective action is initiated the nonconformity is reviewed and analyzed. It is not evident that the following is being conducted: React to the nonconformity to deal with the consequences; Evaluate the need for action to eliminate the cause(s) of the nonconformity; Determine if similar nonconformities exist, or could potentially occur; Review the effectiveness of any corrective action taken; If necessary, update risks and opportunities determined during planning; Documented information is not retained as to the results of any corrective action.
10.3 Continual improvement		

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.		Cross Training New inspection equipment

Documented Information Evidence/ Record Requirements

ISO 9001:2015 Clause	Type or name of Record	Evidence Yes/No	Evidence Observed	Notes/ Comments
4.3	The scope of the organization's quality management system			
4.4.2	Documented information to support the operations of its processes			
4.4.2	Documented information to demonstrate confidence that the processes are being planned?			
5.2.2	The Quality Policy			
6.2.1	The Quality Objectives			
7.1.5.1	Evidence of fitness for purpose of the monitoring and measurement resources			
7.1.5.2	The basis used for calibration or verification			

7.2	Evidence of competence			
7.5.3.2	External origin documented information			
8.1	Documented information to have confidence that the processes have been carried out as planned			
8.1	Documented information to demonstrate the conformity of products and services to their requirements			
8.2.3.2	Documented information on the results of the review of the requirements for products and services			
8.2.3.2	Documented information on any new requirements for the products and services			
8.2.4	Amendments to documented information when the requirements for services are changed			
8.3.2	Documented information needed to demonstrate the design and development requirements have been met.			
8.3.3	Design and Development inputs			
8.3.4	Design and Development controls			

8.3.5	Design and Development outputs			
8.3.6	Design and Development changes			
8.3.6	Design and Development review results			
8.4.1	External providers: - Determine and apply criteria for evaluation, selection, performance monitoring and re-evaluation of their ability to provide processes, products and services in accordance with requirements. - Necessary actions arising from the evaluations			
8.5.1	Documented information that defines the characteristics of the products to be produced, the services to be provided or the activities to be performed.			
8.5.1	Documented information that defines the results to be achieved for the control of production and service provisions.			
8.5.2	Traceability: - Control the unique identification of outputs when traceability is			

	required and retain documented information necessary to enable traceability			
8.5.3	Documented information reporting to the customer or external provider when property is lost, damaged, or otherwise found to be unsuitable for use and documented information on what has occurred.			
8.5.6	Description of the results of the review of the person(s) authorizing the change for production or service provision, and any necessary actions arising from the review.			
8.6	The release of products and services including: - Evidence of conformity with the acceptance criteria - Traceability to the person(s) authorizing the release			
8.7.2	Control of nonconforming outputs documented information that: - Describes the nonconformity - Describes the actions taken - Describes any concessions obtained			

	- Identifies the authority deciding the action in respect of the nonconformity			
9.1.1	Evidence of the monitoring, measuring, analysis and evaluation results.			
9.2.2	Implementation of the audit program and audit results			
9.3.3	The results of management review			
10.2.2	The nature of the nonconformities and any subsequent actions taken			
10.2.2	The results of corrective action			

GAP ANALYSIS RESULTS

Your Company Name's Quality Management System is effectively implements to meet the ISO 9001:2008 requirements. The production management and job planning is well established, clearly understood, and effectively implemented. This is assist in the transition as 23 clauses above are being met for ISO 9001:2015.

There are xx clauses above that are not being met, which will require most of the new processes, training, and implementation. Then xx clauses have been identified as partially being met with the current QMS. It is recommended to review the in-part requirements closely to ensure all the gaps are closed for each clause.

We wish you success in your transition to ISO 9001:2015. https://msi-international.com/iso/information-request/ Call today for how to start and guidance.

Auditor Signature: _____

Report Submitted for Final Review on (date): _____