

JANUARY 15, 2021



# QUALITY SYSTEM MANUAL

REV A

# Approvals

|                                    |               |  |
|------------------------------------|---------------|--|
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**Notice:**

The Quality System Manual is a controlled document. It is controlled in electronic format. If a hard copy version is utilized, it is considered a reference tool.

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| <u>Date</u>             | <u>Description of Change</u>  |
|-------------------------|---|
| <i>January 15, 2021</i> | Created for Management Review and Approval from Top Management using the ISO9001:2015 & AS9120 Rev B Standard |
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## **0.1. Introduction**

### **A. General**

The purpose of this quality manual is to document Next Level Manufacturing quality management system (QMS), in accordance with the ISO9001:2015 & AS9120 Rev B criteria.

This manual is our primary reference document for all quality-related activities and is used to communicate our commitment to quality and the effectiveness of our QMS. It also provides a framework for our QMS to be audited.

The potential benefits to Next Level Manufacturing implementing a quality management system based on the ISO2009:2015 standard.

- a) The ability to consistently provide products and services that meet customer and applicable Statutory and regulatory requirements;
- b) Facilitating opportunities to enhance customer satisfaction.
- c) Addressing risks and opportunities associated with its context and objectives.
- d) The ability to demonstrate conformity to specified quality management system requirements.

The ISO9001:2015 & AS9120 Rev B Standard employs the following process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

The process approach enables Next Level Manufacturing to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed and those opportunities for improvement are determined and acted on.

Next Level Manufacturing enables the process approach of Risk-based thinking. Next Level Manufacturing has determined the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise.

### **B. Company Background / Capabilities**

Next Level Manufacturing was created to streamline the supply chain for custom engineered components. NLM provides cost efficient and quality driven components to our OEM clients. We investigate and research our clients' needs so we can tailor those individual needs with the right Manufacturing partner.

Next Level Manufacturing is a supplier and procurement provider for CNC Turning, CNC Milling, Acrylic Fabrication, Plastic Injection Molding, Metal Fabrication as well as Custom Gaskets and Seals. We are strategically aligned with some of the best Manufacturing partners that are strictly based in the United States of America. We specialize in precision product Manufacturing and sourcing solutions geared to increase profitability for our clients. Our team of vetted manufacturers provide an extensive array of services that has provided the highest level of quality along with saving our clients on their bottom line.

NLM provides better Manufacturing solutions because of our proven history, experience, and knowledge of the Manufacturing sector. The strategic relationships we have developed over 20 plus years of providing Manufacturing solutions lends us an edge over our competition. NLM has developed the right strategic partnerships with the right manufacturers, the right material suppliers, and the right distributors to deliver Next Level Manufacturing solutions while providing our clients Total Cost Reduction on their designs.

Next Level Manufacturing has the expertise to work in over 65 different materials including but not limited to the following Steel ( Carbon, Alloy, Stainless), Aluminum, Brass, G10, PEEK, Ultem, Glass Filled Nylon, Delrin, ABS, Torlon, KEL-F, Teflon, Acrylic, Polycarbonate and many others

### C. Types of Products

Next Level Manufacturing provides a diverse range of products and services to meet our customer specifications for the following industries including but not limited to.

- Fluid Handling
- Aerospace
- Food processing
- Automotive
- Lighting
- Medical
- Chemical
- Petroleum

### D. Scope of Quality Management System

Next Level's clients are diverse coming from multiple industries. Industries include but not limited to fluid handling, aerospace, food processing, lighting and medical. Our clients require that their parts are made right the first time on time. Our experienced personnel are committed to providing complex quality components delivered to our customers on time".

The scope and intent of our QMS is to define and communicate our commitment to continually enhance customer satisfaction through:

- effective process improvements to all systems of the business;
- to assure conformity to our customer's and applicable statutory and regulatory requirements;
- provide policies, procedures developed and implemented with the primary focus to assure the continual compliance of the requirements of the International Standard ISO 9001:2015 & AS9120 Rev B

Next Level Manufacturing's scope of Registration is **"The supply of precision engineered components"**.

#### **Not applicable to the Next Level Manufacturing QMS**

(8.3) - Design and Development of Products and Services.

#### **Justification:**

Next Level Manufacturing does not perform design activities therefore the fulfillment to the requirements of this Clause is not applicable to our QMS.

(7.1.5.2) Measurement traceability

#### **Justification:**

Next Level Manufacturing is a 3<sup>rd</sup> party Distributor of manufactured products and relies on documentation and test reports from suppliers. (i.e., but not limited to First Article Report, In-Process Inspection Reports, CofC, Raw Material Test Reports)

### E. Mission Statement / Quality Policy

Next Level Manufacturing is dedicated to the distribution of quality products that meet and exceed the expectations of our diverse customer base. Our clients in fluid handling, aerospace, food processing, lighting, medical, and distribution industries require that their parts are made right the first time and on time. Our experienced personnel are committed to meeting all these requirements. Quality is the cornerstone of our company culture.

- On time
- To print
- Every time
- Continuous improvement

## 0.2 Quality management principles.

Next Level Manufacturing quality management system is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for Next Level Manufacturing Corporation, some examples of benefits associated with the principle and examples of typical actions to improve our performance when applying the principle.

The quality management principles are as follows:

- A. Customer focus.
- B. Leadership.
- C. Engagement of people.
- D. Process approach.
- E. Improvement.
- F. Evidence-based decision-making.
- G. Relationship management.

## 0.3 Process approach

### 0.3.1 General

Next Level Manufacturing uses a process approach when developing, implementing, and improving the effectiveness of the quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in section 4.4 of this manual

The understanding and managing of interrelated processes as a system-contributing factor Next Level Manufacturing's effectiveness and efficiency in achieving its intended results. This approach enables Next Level Manufacturing to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

At Next Level Manufacturing, our process approach involves the systematic definition and management of processes, and their interactions, to achieve the intended results in accordance with the quality policy and the strategic direction of Next Level Manufacturing Corporation. The management of the processes and the system can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

Our application of the process approach in a quality management system enables the following:

- A. Understanding and consistency in meeting requirements.
- B. The consideration of processes in terms of benefit.
- C. The achievement of effective process performance.
- D. Improvement of processes based on evaluation of data and information.

Figure 1 is a representation of any process and shows the interaction of its elements. The monitoring and measuring checkpoints, which are necessary for control, are specific to each process and will vary depending on the related risks

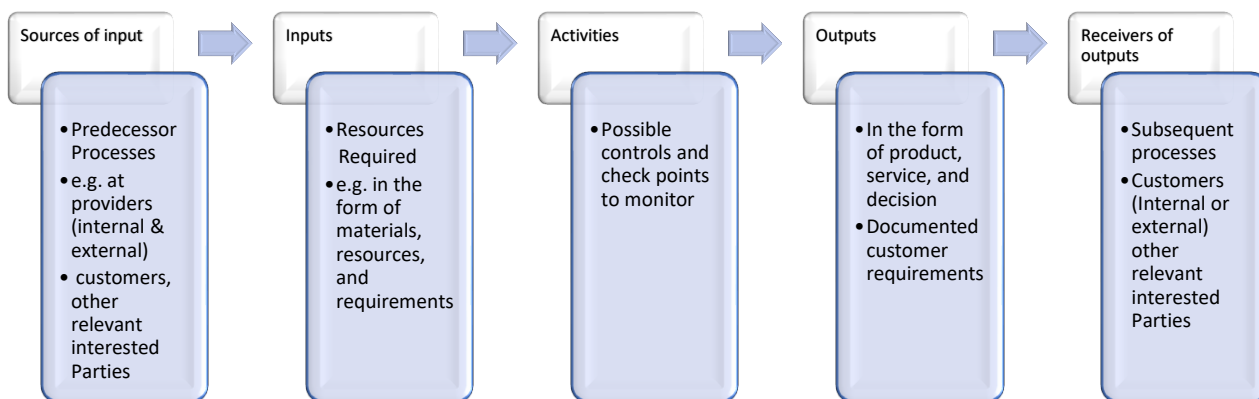


Figure 1 Elements of a single Process

### 3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be applied to all processes and to the quality management system. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.

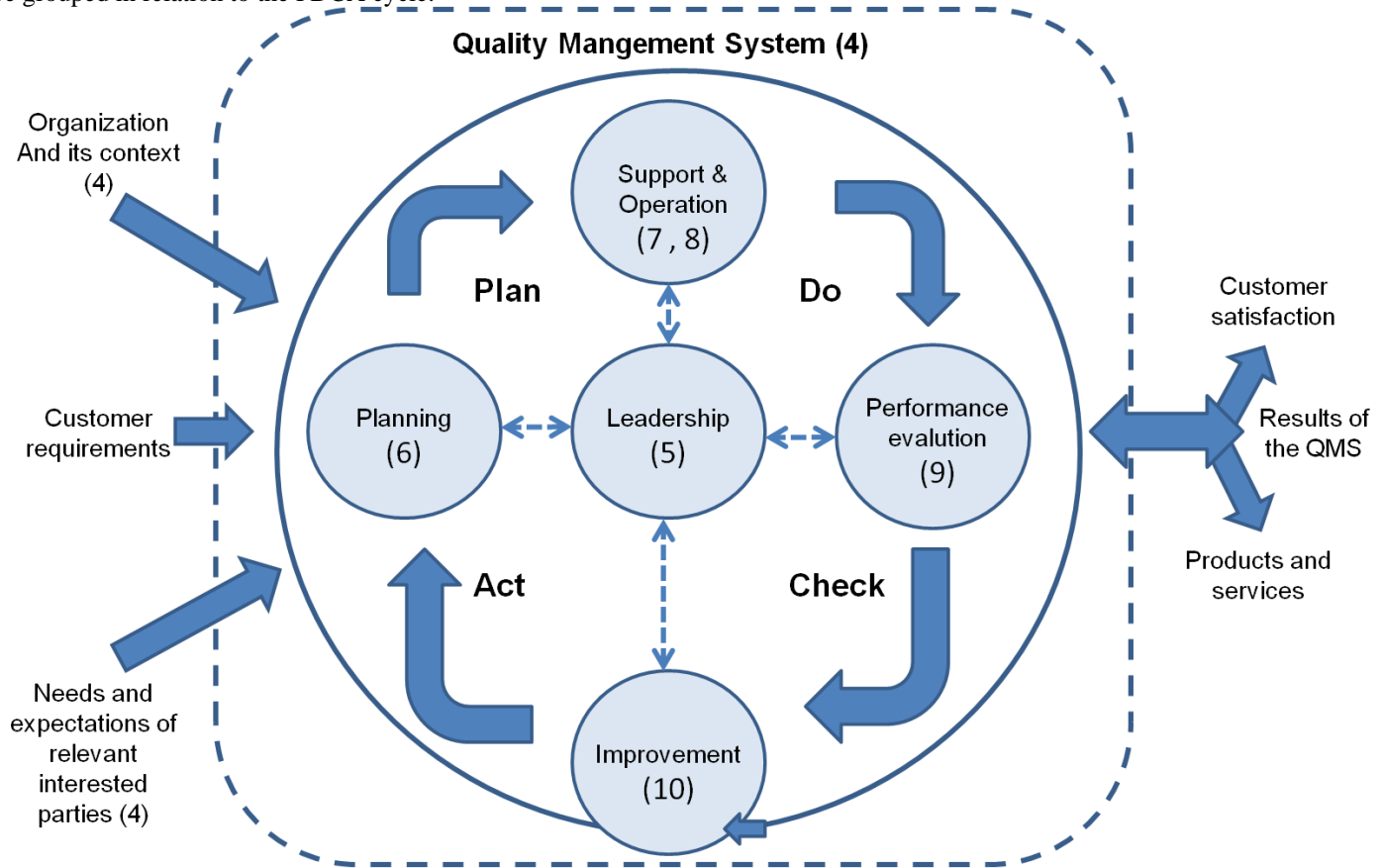


Figure 2 Representation of the structure of the International Standard in PDCA cycle

The PDCA cycle can be briefly described as follows:

- A. **Plan**: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;
- B. **Do**: implement what was planned;
- C. **Check**: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;
- D. **Act**: take actions to improve performance, as necessary.



**0.3.3 Risk-based thinking**

The process of Risk-based thinking is essential to Next Level Manufacturing for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of the ISO9001 Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur, and acting to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of ISO9001:2015 standard Next Level Manufacturing shall plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of our quality management system, achieving improved results, and preventing negative effects.

At Next Level Manufacturing, we recognize opportunities can arise because of a situation favorable to achieving an intended result, for example, a set of circumstances that allow Next Level Manufacturing to attract customers, develop new products and services, reduce waste, or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

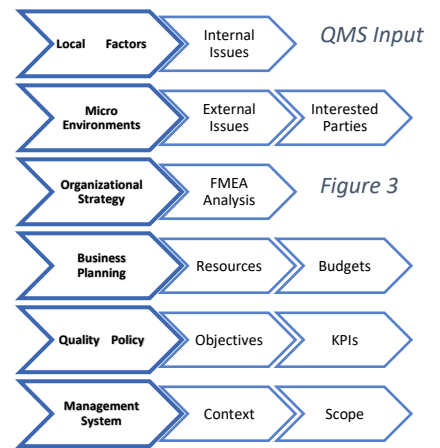
**4.1 Understanding the organization and its context**

Next Level Manufacturing 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. Next Level Manufacturing shall monitor and review information about these external and internal issues.

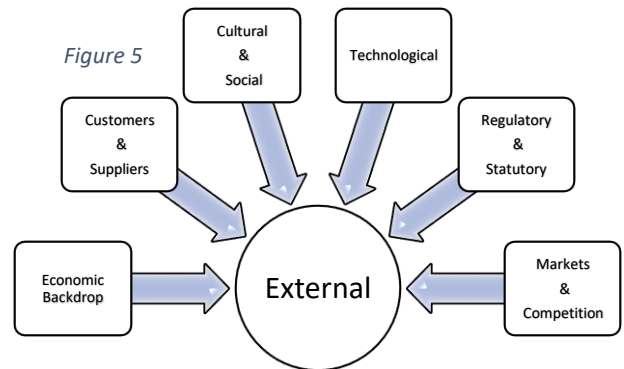
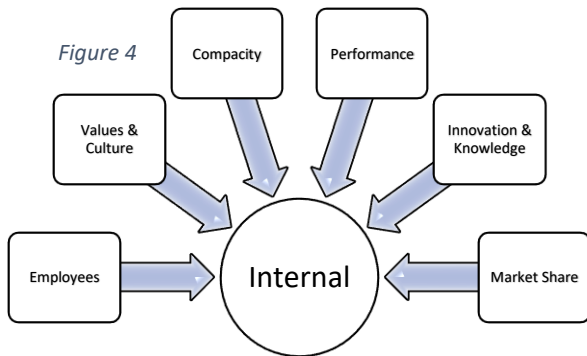
NOTE: Issues can include positive and negative factors or conditions for consideration.

NOTE: 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: Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge, and performance of the organization.



See Figure 3, 4, 5



## **4.2 Understanding the needs and expectations of interested parties**

*The effect or potential effect on our organizations ability to consistently provide products and services that meet our customer and applicable statutory and regulatory requirements, Next Level Manufacturing has determined the following:*

- 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. Next Level Manufacturing shall monitor and review information about these interested parties and their relevant requirements.

*Next Level Manufacturing is committed to continually monitoring, reviewing, and analyzing information and relevant requirements of the interested parties to assure their requirements are effectively managed in the QMS.*

## **4.3 Determining the scope of the quality management system**

*Next Level Manufacturing has determined the boundaries and the applicability of the QMS and how it relates to our Business Core Competency.*

*Next Level Manufacturing has determined the following:*

- 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.

Next Level Manufacturing shall apply all the requirements of ISO9001:2015 & AS9120 Rev B Standard if they are applicable within the determined scope of its quality management system. The scope of Next Level Manufacturing 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 ISO9001:2015 & AS9120 Rev B Standard that Next Level Manufacturing determines is not applicable to the scope of its quality management system. Next Level Manufacturing understands that conformity to ISO9001:2015 & AS9120 Rev B Standard may only be claimed if the requirements determined as not being applicable do not affect the ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

## **4.4 Quality management system and its processes**

**4.4.1** Next Level Manufacturing has established, documented, and implemented our Quality Management System (QMS) in accordance with the requirements of ISO 9001:2015 & AS9120 Rev B. The QMS is maintained and continually improved using the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, and management review.

Next Level Manufacturing utilizes Quality System Procedures (QSP) to provide our employees and external providers (Suppliers), with detailed "How To" instructions and requirements. The documents support the achievement of quality compliance for each of the process steps. Next Level Manufacturing shall retain documentation which provides documented information substantiating the process inputs and outputs have been accomplished as planned.

Next Level Manufacturing shall determine the following:

- A. The inputs required, and the outputs expected from these processes.
- B. The sequence and interaction of these processes.
- C. Determine and apply the criteria and methods (including monitoring, measurements and related).
- D. Performance indicators needed to ensure the effective operation and control of these processes; 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.

4.4.2 To the extent necessary, Next Level Manufacturing has determined the following:

- 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.

Next Level Manufacturing has establish and maintained the documented information that includes:

- A. a general description of relevant interested parties (see 4.2 a);
- B. the scope of the quality management system, including boundaries and applicability (see 4.3);
- C. a description of the processes needed for the quality management system and their application throughout the organization;
- D. the sequence and interaction of these processes;
- E. assignment of the responsibilities and authorities for these processes.

NOTE: The above description of the quality management system can be compiled into a single source of documented information and referred to as a quality manual.

## 5 Leadership

### 5.1 Leadership and commitment

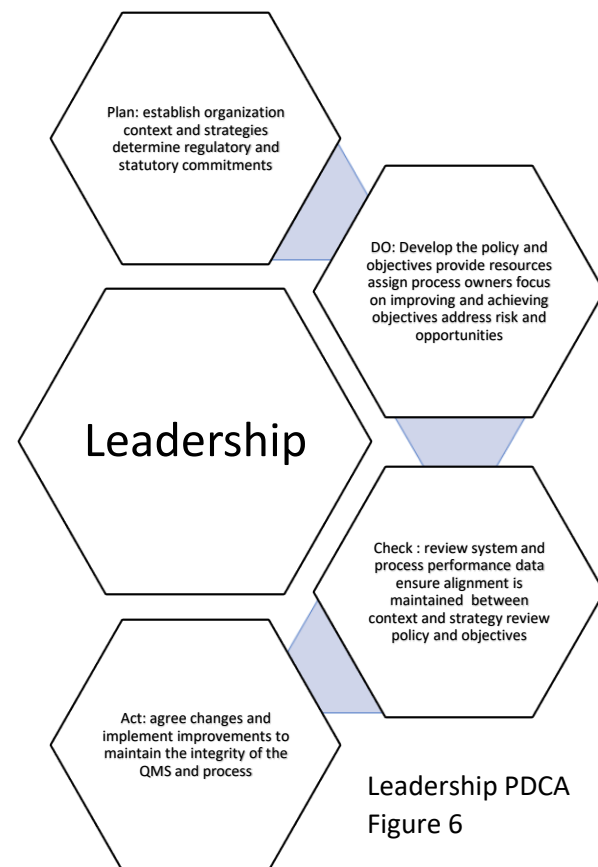
#### 5.1.1 General

Next Level Manufacturing top management shall demonstrate leadership and commitment with respect to the quality management system by:

- A. 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 employees 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 ISO9001:2015 Standard and this Quality Manual can be interpreted broadly to mean those activities that are core to the purposes of the organization’s existence, whether the organization is public, private, for profit or not for profit.

See Figure 6



**5.1.2 Customer focus**

Next Level Manufacturing ensures customer requirements and expectations are clearly defined, understood, and achieved at all levels of the organization. Next Level Manufacturing is committed to achieving 100% customer satisfaction and will accomplish this by understanding and mitigating risks and opportunities that may affect the conformity of products and services and to assure Statutory and Regulatory requirements are identified as.

- 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;
- D. product and service conformity and on-time delivery performance are measured, and appropriate action is taken if planned results are not, or will not be, achieved.

**5.2 Policy**

**5.2.1 Establishing the quality policy**

The management team at Next Level Manufacturing have initiated and communicated the Quality Policy throughout the organization and made it available to relevant interested parties as appropriate. The Quality Policy is appropriate to the purpose and context of the company and supports its strategic direction. It provides the framework for setting quality objectives, satisfying applicable requirements and supports the Company’s commitment for continual improvement of the QMS.

**5.2.2 Communicating the quality policy**

Next Level Manufacturing quality policy shall:

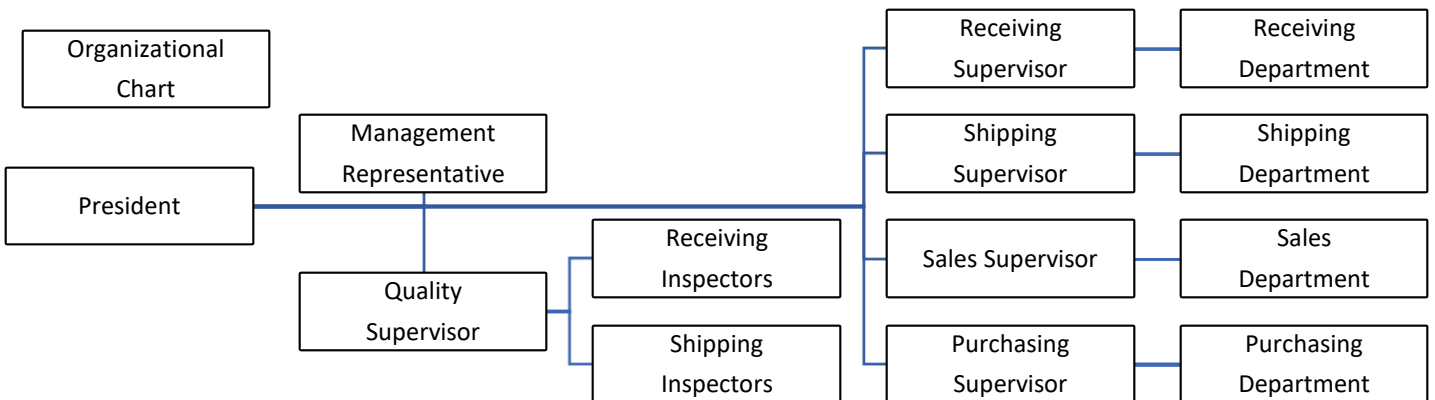
- A. Be available and be maintained as documented information.
- B. Be communicated, understood, and applied within the organization.
- C. Be available to relevant interested parties, as appropriate.

**5.3 Organizational roles, responsibilities, and authorities**

Next Level Manufacturing 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 manual and the requirements of ISO9001:2015 & AS9120 Rev B 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), 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.



## 6 Planning

### 6.1 Actions to address risks and opportunities

6.1.1 During the planning of the quality management system, Next Level Manufacturing 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.

See Figure 8, 9



Figure 9

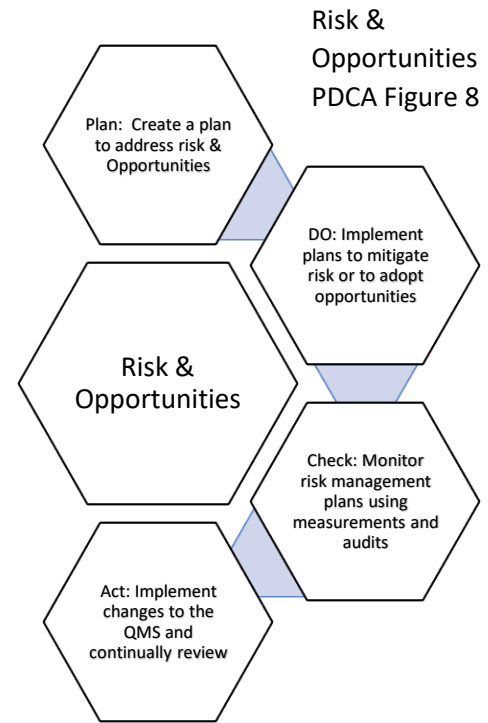
6.1.2 Next Level Manufacturing shall plan for the following to include:

- 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.

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

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

NOTE: Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address Next Level Manufacturing Corporation or the needs of customers.



Risk & Opportunities  
PDCA Figure 8

## **6.2 Quality objectives and planning to achieve them**

**6.2.1** Next Level Manufacturing shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

Next Level Manufacturing quality objectives shall:

- A. Be consistent with the quality policy.
- B. Be measurable.
- C. Consider 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.

### **Quality Performance Objectives**

are targets that shall be measured and monitored for improving operational performance to ensure process conformity and customer satisfaction. They apply to all departments and functions having direct responsibility for activities that require improvement. Performance objectives and goals are established by management and through employee involvement and are monitored during management reviews process.

### **Quality Objectives and Planning to Achieve Them**

Quality Objectives have been established at all corresponding levels and processes throughout the organization to implement the quality policy, meet and exceed requirements for product and processes, and to improve the QMS and its performance. Next Level Manufacturing maintains documented information on the quality objectives.

Next Level Manufacturing Objectives

- 1. Quotes: (Wins Vs Loss per Month) 15%
- 2. Purchasing: (See vendor / supplier matrix)
- 3. Quality: (Delivery Vs Returns) 3 per Month
- 4. On Time Customer Delivery: 85%

**6.2.2** During the planning on how to achieve its quality objectives, Next Level Manufacturing shall determine the following:

- 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**

Next Level Manufacturing determines the need for changes to the quality management system; the changes shall be carried out in a planned manner (see 4.4).

Next Level Manufacturing shall consider the following:

- 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.

## **7 Support**

### **7.1 Resources**

#### **7.1.1 General**

Next Level Manufacturing shall determine and provide the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system.

Next Level Manufacturing shall consider following:

- A. The capabilities of, and constraints on, existing internal resources.
- B. What needs to be obtained from external providers?

#### **7.1.2 People**

Next Level Manufacturing identifies personnel training needs, provides required training, and evaluates the effectiveness of the training provided. Personnel assigned to perform specific tasks, operations and processes are qualified based on appropriate education, experience, or training. Employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives. Records of personnel qualifications and training shall be maintained.

#### **7.1.3 Infrastructure**

Next Level Manufacturing is fully committed to providing adequate resources required for the establishment, implementation, maintenance, and continual improvement of our QMS. Our committed resources include: competent employees, equipment, well maintained work environment and financial resources. The process for determining and communicating resource requirements is an integral part of our management review process. Our infrastructure resource considerations include:

- A. buildings, workspace and associated utilities;
- B. equipment including (hardware and software);
- C. transportation resources;
- D. information and communication technology.

Note: As new infrastructure requirements are determined to be necessary, they will be documented in quality plans and other documents as needed.

#### **7.1.4 Environment for the operation of processes**

Next Level Manufacturing identifies personnel training needs, provides required training, and evaluates the effectiveness of the training provided. Personnel assigned to perform specific tasks, operations and processes are qualified based on appropriate education, experience, or training. Employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives. Records of personnel qualifications and training are maintained.

The human and physical factors of the work environment considered to be important to control processes and to achieve conforming of products and services. Evaluations include:

- A. Assessment of product requirements to identify where human and/or physical factors will affect product quality this is also conducted during advanced product quality planning,
- B. Assessment of current working environment conditions to determine if the work environment is suitable to achieve conforming product.
- C. Implementation of work environment improvements needed to achieve conforming product.
- D. Continual assessment of work environment to ensure that adequate human and physical factors are maintained.

## 7.1.5 Monitoring and measuring resources

### 7.1.5.1 General

Next Level Manufacturing 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.

Next Level Manufacturing Corporation shall ensure that the resources provided:

- A. Monitoring and measuring equipment;
- B. Documented procedures and forms;
- C. Competent and qualified personnel

Next Level Manufacturing shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

### 7.1.5.2 Measurement traceability

#### Not applicable to the Next Level Manufacturing QMS

(7.1.5.2) Measurement traceability

##### Justification:

Next Level Manufacturing is a 3<sup>rd</sup> party Distributor of manufactured products and relies on documentation and test reports from suppliers. (i.e., but not limited to First Article Report, In-Process Inspection Reports, CofC, Raw Material Test Reports)

### 7.1.6 Organizational knowledge

Next Level Manufacturing considers the specific knowledge necessary for each operation and considers this as an important resource to ensure our people and processes are consistent and will achieve conformity of the product and services provided by the Company. Specific organizational knowledge is defined, maintained and available to the extent necessary within appropriate procedures. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, Next Level Manufacturing shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

Knowledge can be based on following:

- A. Internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services).
- B. External sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

### 7.2 Competence

Next Level Manufacturing has determined to the extent necessary the below elements of competence for people performing work that may affect the effectiveness of the QMS.

- A. ensure employees are competent based on their education, training and experience;
- B. measure job performance for each employee on an annual basis;
- C. provide job and career training programs to the extent necessary;
- D. take actions when necessary to assist employees that exhibit less than desirable results.

### 7.3 Awareness

Next Level Manufacturing has determined to the extent necessary persons performing work are:

- 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 to the quality management system requirements.
- E. relevant quality management system documented information and changes thereto;
- F. their contribution to product or service conformity;
- G. their contribution to product safety;
- H. the importance of ethical behavior.



## 7.4 Communication

Next Level Manufacturing has determined internal and external communication relevant to QMS, including the subject of the communication, when communication occurs, participant and ways of effective communication.

- A. On what it will communicate. Updates to system (i.e. Procedures, Work Instructions, Documents needed)
- B. When to communicate? At time of updates or changes in the system
- C. With whom to communicate. Next Level employees
- D. How to communicate. Through Training
- E. Who communicates? Next Level Management

## 7.5 Documented information

### 7.5.1 General

Next Level Manufacturing maintains a documented QMS to ensure that products and services conform to specified requirements. The QMS consists of the following three levels of documented information:

**Level 1 Quality Manual:** provides the scope of the QMS and the applicable ISO 9001:2015 (E) Clauses contained and supported by our QMS.

**Level II Quality System Procedures/Work Instructions:** provides detailed requirements for each of our processes with the intent to specify who does what, when, where, how the process or action/task is performed, and what documentation is used to verify that all required quality related activities had been executed as required.

**Level III: Quality System Documents:** provides objective evidence that required product or service quality and customer requirements were achieved, and that the company's quality management system has been implemented as stated. QSD refers to tags, labels, stickers, preprinted sheets, stamps, and other means to identify the status of materials, products, equipment, gauges, and other devices used in the company to achieve the specified requirements.

### 7.5.2 Creating and updating

When creating, and updating documented information, Next Level Manufacturing shall ensure as 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.

Note: Electronic signatures are accepted from the following President, Management Representative, and Quality Supervisor

### 7.5.3 Control of documented information

**7.5.3.1** Documented information required by Next Level Manufacturing quality management system and ISO9001:2015 & AS9120 Rev B Standard shall be controlled to ensure:

- A. Available and suitable for use, where and when it is needed.
- B. Adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

**7.5.3.2** For the control of documented information, Next Level Manufacturing 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.
- E. prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

Documented information of external origin determined by Next Level Manufacturing necessary for the planning and operation of the quality management system shall be identified as appropriate and be controlled. The 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.

NOTE: Where the term “Documented Information “appears within this manual, this means that the procedure is established, documented, implemented, and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

Note: Documented Information (e.g. Inspection Reports, Material Test Reports, FAIs) are maintained for a period of 5 years and per customer requirements.

### 8.1 Operational planning and control

Next Level Manufacturing defines the expectation and implements controls for each of our QMS processes. The planning of controls is required to ensure consistent acceptability of products and services. Planning processes include the definition of quality objectives, development for required processes, establishment for appropriate verification programs and the requirement for records necessary to demonstrate the process and products conform to intended requirements.

Operational planning and control is required prior to new and/or revised products or processes being implemented. Management shall do the following:

- A. Determine the requirements for the products and services.
- B. Establishing criteria for:
  - 1. The processes.
  - 2. The acceptance of products and services.
- C. Determine the resources needed to achieve conformity to the product and service requirements.
- D. Implement control of the processes in accordance with the criteria.
- E. Determining, maintaining and retaining 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.
- F. engaging representatives of affected organization functions for operational planning and control;
- G. determining the products and services to be obtained from external providers;
- H. establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

The output of this planning shall be suitable for Next Level Manufacturing operations.

Next Level Manufacturing shall control planned changes and review the consequences of unintended changes, acting to mitigate any adverse effects, as necessary.

Next Level Manufacturing shall ensure that outsourced processes are controlled (see 8.4).

See figure 10

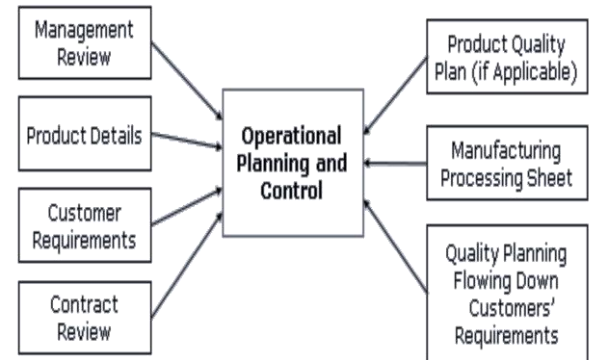


Figure 10

### 8.1.1 (AS9120 Rev B Not Required)

#### 8.1.2 Configuration Management

The organization shall plan, implement, and control a process for configuration management as appropriate to the organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process shall:

- A. control product identity and traceability to requirements, including the implementation of identified changes;
- B. ensure that the documented information (e.g., requirements, design, verification, validation, and acceptance documentation) is consistent with the actual attributes of the products and services.

### 8.1.3 (AS9120 Rev B Not Required)

#### 8.1.4 Prevention of Counterfeit Parts

Next Level Manufacturing has established and implemented, and has control processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

NOTE: Counterfeit part prevention processes should consider:

- A. training of appropriate persons in the awareness and prevention of counterfeit parts;
- B. application of a parts obsolescence monitoring program;
- C. controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources;
- D. requirements for assuring traceability of parts and components to their original or authorized manufacturers;
- E. verification and test methodologies to detect counterfeit parts;
- F. monitoring of counterfeit parts reporting from external sources;
- G. quarantine and reporting of suspect or detected counterfeit parts.

#### 8.1.5 Prevention of Suspected Unapproved Parts

Next Level Manufacturing has established and implemented a control process appropriate to the organization and the product that identifies and prevents the release of unapproved and suspected unapproved parts.

NOTE: Suspected unapproved parts prevention processes should consider:

- A. training of appropriate persons in the awareness and identification of suspected unapproved parts;
- B. requirements for assuring traceability of parts and components to an authorized source;
- C. inspection processes to detect suspected unapproved parts;
- D. monitoring of suspected unapproved parts reporting from external sources;
- E. quarantine and reporting of suspected unapproved parts in accordance with applicable requirements from the competent authority or customers, as required.

#### Counterfeit Part Prevention Policy

Next Level Manufacturing is committed in ensuring all manufactured parts and components delivered and/or used in the Manufacturing of deliverable products shall be from the Original Component Manufacturer (OCM) / Original Equipment Manufacturer (OEM), or their franchised distributor. Parts shall not be used or reclaimed and misrepresented as new.

## 8.2 Requirements for products and services

### 8.2.1 Customer communication

Communication with customers shall include the following:

- 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 for products and services

When determining the requirements for the products and services to be offered to customers, Next Level Manufacturing 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 the requirements for products and services

**8.2.3.1** Next Level Manufacturing shall ensure that we can meet the requirements for products and services to be offered to customers. Next Level Manufacturing shall conduct a review before committing to supply products and services to a customer, to include the following:

- A. Requirements specified by Next Level Manufacturing customer, including the requirements for delivery and if required post-delivery activities.
- B. Requirements not stated by the customer, but necessary for the specified or intended use, when known.
- C. Requirements specified by Next Level Manufacturing.
- D. Statutory and regulatory requirements applicable to the products and services.
- E. Contract or order requirements differing from those previously expressed.

Note: Next Level Manufacturing shall ensure that contract or order requirements differing from those previously defined are resolved.  
Note: Next Level Manufacturing before acceptance shall confirm the customer's requirements, when the customer does not provide a documented statement of their requirements.

**8.2.3.2** Next Level Manufacturing shall retain documented information, as applicable:

- A. On the results of the review.
- B. On any new requirements for the products and services.

## 8.2.4 Changes to requirements for products and services

Next Level Manufacturing 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

### Not applicable to the Next Level Manufacturing QMS

**Justification** Next Level Manufacturing does not perform design activities therefore the fulfillment to the requirements of this Clause are not applicable to our QMS.

## 8.4 Control of externally provided processes, products, and services

### 8.4.1 General

Next Level Manufacturing shall ensure that all external provided processes, products, and services conform to requirements and 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 products and services.
- B. External providers on behalf of the Next Level Manufacturing provide products and services directly to the customer.
- C. An external provider because of a decision by Next Level Manufacturing provides a process, or part of a process.

Next Level Manufacturing shall determine and apply requirements for the evaluation, selection, monitoring of performance, and the re-evaluation of vendors/suppliers on their ability to provide processes, products, and or services in accordance with established requirements. Next Level Manufacturing shall retain documented information of these activities and any actions taken from evaluations.

**8.4.1.1** Next Level Manufacturing has established and implemented:

- A. define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;
- B. maintain a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family, authorized approval to distribute);
- C. periodically review external provider performance including process, product and service conformity, and on-time delivery performance;
- D. define the necessary actions to take when dealing with external providers that do not meet requirements;
- E. define the requirements for controlling documented information created by and/or retained by external providers.

**8.4.2 Type and extent of control**

Next Level Manufacturing shall ensure that no vendors/supplier's processes, products, and or services affect our ability to provide conforming products and or services to our customer/s.

Next Level Manufacturing shall do the following

- A. Ensure that all vendor/suppliers processes remain within the control of its quality management system.
- B. Define both the controls that it intends to apply to vendor/suppliers and those it intends for the resulting output.
- C. Take into consideration the following.
  - 1. The potential impact of vendor/supplier's processes, products, and or services on our ability to provide conforming products, services and or applicable statutory requirements to our customer/s.
  - 2. The effectiveness of the controls applied by vendor/suppliers.
  - 3. the results of the periodic review of external provider performance (see 8.4.1.1 c);
- D. Determine the verification or other activities necessary to ensure that the vendor/suppliers processes, products, and or services on our ability to provide conforming products, services and or applicable statutory requirements.

### 8.4.3 Information for external providers

Next Level Manufacturing uses purchase orders to define the product or services to be purchased. Purchase Orders are created in the company QuickBooks System, by designated individuals within the Company. Purchasing documents are reviewed for adequacy and approved by purchasing personnel prior to release. Purchasing documents clearly describe the product or service to be provided. Next Level Manufacturing maintains a documented Approved Vendor/Supplier List (AVL). Next Level Manufacturing Reviews Vendor/Supplier performance as part of the management review process.

- A. Processes, product, and services to be provided.
- B. Approval of:
  - 1. Product and services.
  - 2. Methods, processes, and equipment.
  - 3. The release of product and services.
- C. Competence, including any required qualifications of personnel.
- D. Vendor/supplier interactions with Next Level Manufacturing.
- E. Control and monitoring of vendor/supplier performance by Next Level Manufacturing.
- F. Verification/validation of activities that Next Level Manufacturing and or our customer/s, intends to perform at vendor/supplier site/location.
- G. test, inspection, and verification;
- H. the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;
- I. the need to:
  - 1. implement a quality management system;
  - 2. use customer-designated or approved external providers, including process sources (e.g., special processes);
  - 3. notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;
  - 4. prevent the use of suspected unapproved, unapproved, and counterfeit parts (see 8.1.4 and 8.1.5);
  - 5. notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture;
  - 6. flow down to external providers applicable requirements including customer requirements;
  - 7. provide a certificate of conformity, test reports, or authorized release certificate, as applicable;
  - 8. retain documented information, including retention periods and disposition requirements;
- J. the right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;
- K. ensuring that persons are aware of:
  - 1. their contribution to product or service conformity;
  - 2. their contribution to product safety;
  - 3. the importance of ethical behavior.

## 8.5 Production and service provision

### 8.5.1 Control of production and service provision

Next Level Manufacturing plans and implements production and service provision under controlled conditions and as required by job specific requirements. Examples of the controls include:

- A. availability of information that define characteristics and results to be achieved;
- B. availability of competent and effectively trained personnel and adequate equipment;
- C. availability and use of suitable monitoring and measuring devices and resources;
  - 1. ensuring that documented information for monitoring and measurement activity for product acceptance includes:
    - criteria for acceptance and rejection;
    - where in the sequence verification operations are to be performed;
    - measurement results to be retained (at a minimum an indication of acceptance or rejection);
    - any specific monitoring and measurement equipment required and instructions associated with their use;
  - 2. ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use.
- D. evidence that all Manufacturing and inspection operations have been completed as planned;
- 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;
- I. The establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);
- J. the accountability for all products (e.g., parts quantities, split orders, nonconforming product);
- K. the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
- L. the provision for the prevention, detection, and removal of foreign objects;
- M. the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);
- N. the consequences of obsolescence (e.g., materials, components, equipment, products).

Manufacturing procedures, job travelers, inspection plans, and other documents deemed necessary, define the acceptance for Manufacturing and service operations. The plans provide detailed instruction and guidance for all production and service phases including the methods and equipment to be used and workmanship criteria. Records for each job number of product produced provide unique traceability and identify the quantity manufactured and released for delivery. This record is maintained as required by customer contract requirements.

#### 8.5.1.1 Control of Equipment, Tools, and Software Programs

Next Level Manufacturing shall ensure that equipment, tools, and software programs used to automate, control, monitor, or measure processes shall be validated and maintained. And storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

### **8.5.2 Identification and Traceability**

Next Level Manufacturing identifies products by suitable means throughout production. Marking methods will be described in the applicable operations procedures for affected departments where traceability is a requirement, per the level of traceability required by contract, regulatory or other established requirement, our procedures provide for:

- A. identification to be maintained throughout the processes including delivery and post-deliver

*Note:* Traceability requirements can include:

- A. the identification to be maintained throughout the product life;
- B. the ability to trace all products manufactured from the same batch of raw material, or from the same Manufacturing batch, to the destination (e.g., delivery, scrap);
- C. for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;
- D. the identification of the product's condition in inventory (e.g., new, overhauled, repaired, altered, rebuilt).

*Note:* The organization shall maintain product identification and traceability by suitable means (e.g., labels, bar codes) from receipt; during splitting, storage, packaging, and preservation operations and until delivery. This includes handling or packing operations outsourced to external providers.

*Note:* When delivering split product, the following information shall be retained:

- A. amount delivered relative to amount received from external provider,
- B. purchase order number(s),
- C. customer's name(s).

### **8.5.3 Property belonging to customer or external providers**

Next Level Manufacturing shall provide care with property belonging to our customers and vendor/suppliers while it is under control and or being used by Next Level Manufacturing. Customer, vendor/supplier property shall be identified, verified, and safeguarded from damage. When property belonging to customer, vendor/supplier is lost, damaged, or otherwise found to be unsuitable for use, Next Level Manufacturing shall report this to the customer, vendor/supplier and maintain documented information on issue

*Note:* Customer, vendor/supplier property can include the following but not limited to materials, components, tools/equipment, premises, intellectual property, and personal data.

### **8.5.4 Preservation**

Next Level Manufacturing preserves the conformity of parts and products during internal processing and delivery to the intended destination including outside services. Procedures include instructions for identification, handling, packaging, storage, and protection. Preservation of outputs also includes, where applicable:

- A. cleaning;
- B. prevention, detection and removal of foreign objects;
- C. special handling for sensitive outputs;
- D. marking and labeling including safety warnings;
- E. special handling.
- F. special handling and storage for hazardous materials.

The shipping department ensures that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

*Note:* Preservation of product can include the following identification, handling, contamination/FOD control, packaging, storage, transmission/transportation, and protection



### 8.5.5 Post-delivery activities

Next Level Manufacturing maintains documented information of all products delivered to our customers. The extent of post-delivery activities includes the consideration of our customer's requirements and received feedback.

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;
- F. product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

Note: When problems are detected after delivery, the organization shall take appropriate action including investigation and reporting.

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

Next Level Manufacturing shall review and control changes for production or service operations to the extent necessary to ensure continuing conformity of customer or internal requirements. Changes for production may be initiated because of:

- A. modernization based on the context of the organization analysis results;
- B. needs of interested parties, or customer feedback;
- C. Manufacturing department when vulnerability is detected and (or) opportunities for improvement are identified.

Management reviews and monitors changes that affect production or outside services and ensures change documentation and information is distributed and controlled. Records of results of the review of changes, the persons authorizing the change, and any necessary actions arising from the review are maintained in accordance with applicable procedures.

### 8.6 Release of product and services

Next Level Manufacturing monitors the characteristics of the product in receiving inspection, and final inspection to verify that requirements have been met. Documented Records and information of inspection include evidence of conformity with the acceptance criteria and traceability to the person authorizing the release. Records of inspection are maintained.

Note: 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 (Products & Services)

8.7.1 Next Level Manufacturing ensures that products and or services that do not conform to established requirements is identified and controlled to prevent their unintended use or delivery. Records of nonconformities are maintained as required and include:

- A. Correction;
- B. Segregation, containment, return or suspension of provision of product or services;
- C. Informing the customer;
- D. Obtaining authorization for under concession.

Note: Dispositions of nonconforming product shall be limited to:

- A. scrap;
- B. rejection for return to the external provider;
- C. rejection for revalidation by the manufacturer;
- D. submittal to either the customer or design authority for use-as-is disposition, as applicable.

Note: Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Note: Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.

When nonconforming product is corrected, it is re-inspected to the original specifications and requirements to ensure it conform to customer stated requirements. When a nonconforming product is detected after delivery, Next Level Manufacturing will act appropriate to the effects or potential effects of the nonconformity.

**8.7.2** Next Level Manufacturing shall retain documented information for nonconforming product or services

- A. Describes the nonconformance.
- B. Describes the action/s taken.
- C. Describes any concessions obtained.
- D. Identifies the authority deciding the action taken in respect of the nonconformance.

## **9 Performance evaluation**

### **9.1 Monitoring, measurement, analysis, and evaluation**

#### **9.1.1 General**

The objectives of monitoring, measurement, analysis and evaluation are: process criteria, product characteristics, performance and effectiveness of the QMS. Results from monitoring and measurement are evaluated. Informational reports are presented to management for general review and making decision on opportunities for improvement.

#### **9.1.2 Customer satisfaction**

Next Level Manufacturing monitors information relating to customer perception of our continual ability to fulfill their requirements. Maintaining customer satisfaction is one of the principal objectives of the QMS. Collecting and analyzing customer feedback and complaints, and customer satisfaction is conducted during management review. Customer satisfaction data is used by management to identify opportunities for improvement.

#### **9.1.3 Analysis and Evaluation**

Next Level Manufacturing performs necessary analyses and evaluates appropriate data and information initiated from monitoring and measurement and uses the results to evaluate conformity of products and services, customer satisfaction, the performance and effectiveness of the QMS, the performance of external providers. Next Level Manufacturing shall review data performance and the need for improvement of the QMS as part of the management review process.

### **9.2 Internal audit**

**9.2.1** Next Level Manufacturing plans and conducts internal audits at planned intervals. Internal audits are conducted to verify quality activities and related results comply with planned expectations including customer contractual requirements and other QMS requirements as deemed necessary and applicable. The Business Manager is responsible for organizing and coordinating the internal audit to ensure that the audit scope, the frequency, and methods are defined, and the following requirements are satisfactorily achieved:

- A. definition of audit responsibilities;
- B. definition of requirements for planning and conducting the audit including taking appropriate correction and corrective actions without undue delay;
- C. assurance of auditor independence;
- D. recording of audit results;
- E. communication of audit results to management;

**9.2.2** Next Level Manufacturing plans and implements:

- A. plan, establish, implement, and maintain an audit program(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 program and the audit results.

Note: Reference the ISO 19011 for guidance.

### **9.3 Management reviewed inputs**

#### **9.3.1 General**

Next Level Manufacturing 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.

**9.3.2** Next Level Manufacturing management review process shall be planned and carried out taking into consideration the following:

- A. The status from actions taken from previous reviews.
- B. Changes in external and internal issues that are relevant to the quality management system.
- C. Information on performance and effectiveness of the quality management system including trends in the following:
  - 1. Customer satisfaction and feedback from relevant interested parties.
  - 2. The extent which quality objectives have been met.
  - 3. Process information and conformity of product and services.
  - 4. Nonconformities and corrective actions.
  - 5. Monitoring and measurement results.
  - 6. Audit results.
  - 7. Performance of vendor/suppliers.
  - 8. on-time delivery performance;
- D. Adequacy of resources.
- E. Effectiveness of actions taken to address risk and opportunities.
- F. Opportunities for improvement.

#### **9.3.3 Management review outputs**

Next Level Manufacturing management review process shall include decisions and actions related to the following:

- A. Opportunities for improvement.
- B. Any need for changes to the quality management system.
- C. Resource needs.
- D. risks identified.

## 10 Improvement

### 10.1 General

Next Level Manufacturing shall determine and select the need for opportunities for improvement and implement the actions necessary to meet customer/s requirements and enhance customer satisfaction by the following.

- A. Improving products and services to meet requirements as well to address future needs and expectations.
- B. Correcting, preventing and or reducing undesired effects.
- C. Improving the performance and effectiveness of the quality management system.

Note: Improvement can include but not limited to the following: correction, corrective action, continual improvement, breakthrough change innovation, and re-organization

### 10.2 Nonconformity and corrective action

**10.2.1** *Next Level Manufacturing initiates actions to eliminate the cause of nonconformities to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. When nonconformity occurs, corrective action procedures are initiated and implemented. Examples of actions taken include:*

- A. React to the nonconformity and take necessary steps to:
  - 1. Act to control and correct it.
  - 2. Deal with consequences.
- B. evaluate the need for action/s 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 cause of nonconformity.
  - 3. Determining if similar nonconformities exist or could be potentially occur.
- C. Implement any action/s needed.
- D. Review the effectiveness of corrective actions taken.
- E. Update risk and opportunities determined during planning if necessary.
- F. Make changes to the quality management system if necessary
- G. flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;
- H. take specific actions when timely and effective corrective actions are not achieved.

Corrective actions shall be appropriate to the effects of the nonconformities encountered

**10.2.2** Next Level Manufacturing shall maintain documented information as evidence of:

- A. The nature of the nonconformity and any actions taken.
- B. The results of any corrective action.

### 10.3 Continual improvement

Next Level initiates actions to continually improve the suitability, adequacy, and effectiveness of the QMS. Continual improvement techniques and processes are applied to areas of the business that have an impact on the quality of our products and services. We analyze and take necessary actions on results of improvement projects as well as from the Management Review outputs. The implementation of the “Process Approach” including the PDCA Cycle provides verifications that our QMS is robust, and the achievement of effective process performance. See Figure 12

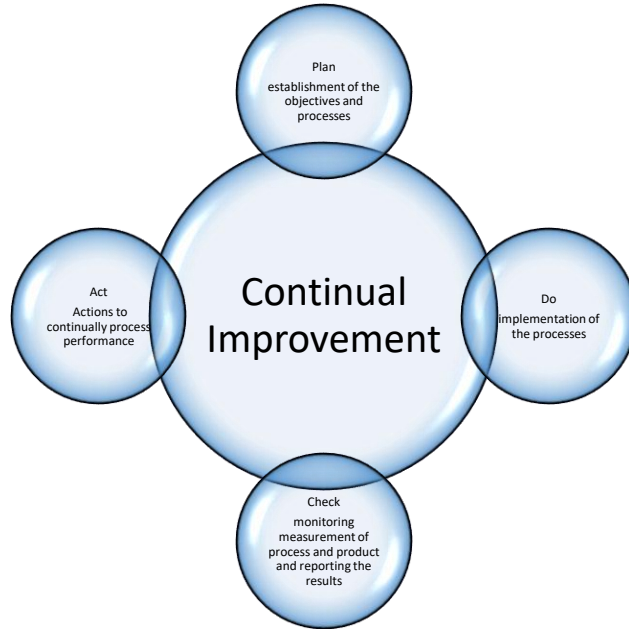


Figure 12

