This Quality Manual defines the quality management system requirements of Alaark Tool & Automation, Inc. as defined by ISO 9001:2015.

Alaark Tooling & Automation, Inc. Sheboygan, WI 53081 www.alaark.com

I.   Table of Contents

II.   Approval of Quality Manual

President – Mark Koenig

III.   Scope of Quality Management System

The scope of Alaark's quality management system includes:

➢ Alaark Tooling & Automation:

   The design, manufacture, assembly, repair, & servicing of dies, molds, fixtures, specialty machinery, and automation cells; and the manufacture of precision EDM, CNC, and conventionally machined parts;

➢ Stainless Steel Solutions:
   The design, manufacture, assembly, repair and servicing of stainless steel equipment, and the precision manufacture and fabrication of stainless steel parts;

➢ Jenkins Systems & Service:

   The manufacture of machinery for the woodworking industry, including providing replacement parts, upgrades, retrofits and rebuilds for all existing Jenkins machines;

➢ US Concepts:
   The manufacture of machinery for the woodworking industry, including providing replacement parts.

   All of these divisions of Alaark are located at 4336 Gateway Drive in Sheboygan, WI 53081.

NOTE: Whenever the quality management system documentation refers to Alaark Tooling & Automation or Alaark, it encompasses all above-noted facilities, unless otherwise noted.

The quality management system meets the requirements of *ISO 9001:2015 – Quality Management Systems – Requirements.* All requirements of ISO 9001:2015 are applicable to Alaark's quality management system.

IV.   CompanyHistory

Alaark Tooling & Automation, Inc. is a growing, privately held company located in Sheboygan, Wisconsin. Alaark was formed in 1987 with the assets of the old RCS Machining. The company was originally located in rented space in the rear of K/P Welding located on Crocker Avenue in Sheboygan. Alaark's main business consisted of machine shop services, but quickly expanded into tool and die design, building, and repair, as well as custom machine and fixture design and construction including electrical controls.

During the same time period, Alaark invested heavily into new and modern equipment to stay on the cutting edge of technology. This investment fostered a considerable increase in business which lead to a significant increase in employees and created the need for two plant expansions.

In 1998, Alaark purchased K/P Machining in Sheboygan to further foster a greater diversity of machining operations that can now be performed.   In 2000, K/P merged into Alaark Tooling & Automation.

In 2008, Alaark purchased the assets of Jenkins Systems, Inc., and renamed the company as Jenkins Systems and Service LLC.

In 2009, Alaark added a 6000-foot building in the Town of Sheboygan Business Park to house Stainless Steel Solutions.

In 2017, Alaark acquired the assets of US Concepts, Inc.

With a commitment to skilled personnel, modern equipment, quality products, and an aggressive growth plan, Alaark is poised for success in the future.

V.   Mission Statement & Core Values

➢ Mission Statement (Our Strategic Direction)

Alaark Tooling & Automation, Inc. is an industry leader focused on maximizing your productivity.

While emphasizing workplace safety and personal development, we will continually improve our products and services though innovation and creative thinking to meet our customers' needs.

Alaark relentlessly strives for on-time delivery of the highest quality product, and believes that following this mission will allow Alaark and our business partners to prosper.

➢ Core Values (Our Fundamental Beliefs)

Honesty
We tell the truth, we keep our promises, and we act ethically and with integrity.

Teamwork
We work together with mutual respect, trust and cooperation.

Accountability
We fulfill our commitments, lead by example and proudly guarantee our work.

Initiative
We empower and enable our employees to make great things happen.

Knowledge
We never stop learning, and we believe in sharing our insights and ideas.

VI.   Quality Policy & Quality Objectives

➢ **Quality Policy (Our Commitment to Quality)**

Our quality management system will continually improve through the cooperative effort of all employees to meet or exceed our customers' requirements and to become their first choice for the products and services we provide.

➢ **Quality Objectives (Our Key Performance Indicators)**

➢ Improve on-time delivery

➢ Improve productivity

➢ Improve customer satisfaction

➢ Improve internal and external quality

➢ Improve vendor performance

➢ Improve the effectiveness of the quality management system

NOTE: Specific measurable targets and additional detail supporting these quality objectives are defined and tracked by top management through the management review process.

VII.   Organizational Chart

```
                              ┌──────────────┐
                              │  President   │
                              └──────┬───────┘
          ┌──────────────────────────┴───────────────────────────────┐
┌─────────────────────┐                                    ┌──────────────────────┐
│ Managing Director   │                                    │ CFO                  │
│ Sales, Customer     │                                    │ Payroll, A/P, A/R,   │
│ Service, Quality,   │                                    │ Inventory,           │
│ HR, Marketing       │                                    │ Purchasing           │
└─────────────────────┘                                    └──────────────────────┘
```
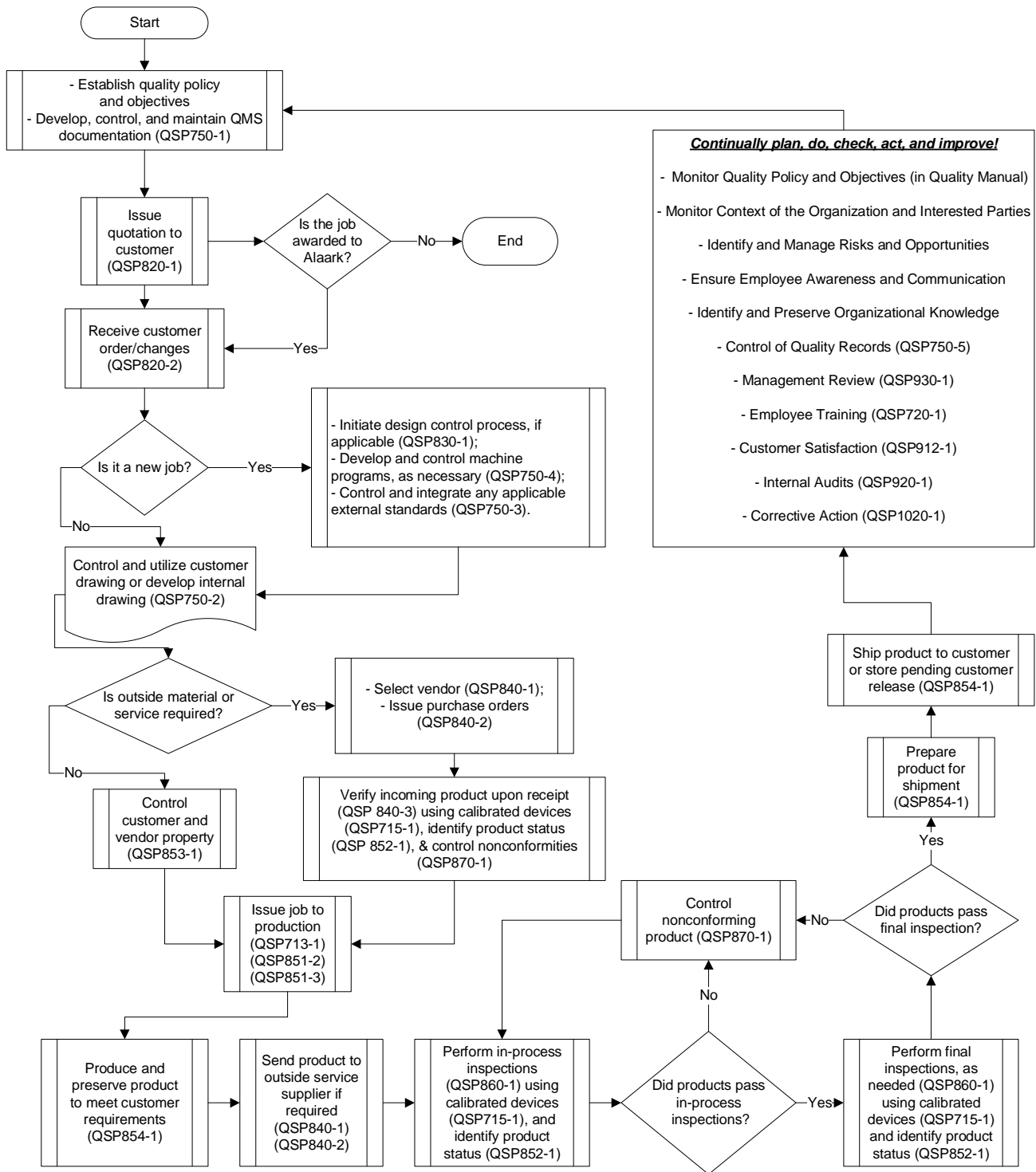
| Sales Engineering Woodworking | Sales Engineering Alaark & SSS | Sales Team Alaark | Engineering Manager | Production Manager | | | | | Purchasing Team Member | Accounting & Administrative Support Team |

| Sales Team Jenkins Parts | | | Engineering Team Members | South East Zone | North Zone | West Central Zone | North West Zone | | | |

| | | | | Production Team Members | Production Team Members | Production Team Members | Production Team Members | | | |

Shipping & Receiving Team Members

VIII.   QualityManagement System Process Flow Diagram

Start

- Establish quality policy and objectives
- Develop, control, and maintain QMS documentation (QSP750-1)

Issue quotation to customer (QSP820-1)

Is the job awarded to Alaark?

No → End

Yes

Receive customer order/changes (QSP820-2)

Is it a new job?

Yes →
- Initiate design control process, if applicable (QSP830-1);
- Develop and control machine programs, as necessary (QSP750-4);
- Control and integrate any applicable external standards (QSP750-3).

No

Control and utilize customer drawing or develop internal drawing (QSP750-2)

Is outside material or service required?

Yes →
- Select vendor (QSP840-1);
- Issue purchase orders (QSP840-2)

No

Control customer and vendor property (QSP853-1)

Verify incoming product upon receipt (QSP 840-3) using calibrated devices (QSP715-1), identify product status (QSP 852-1), & control nonconformities (QSP870-1)

Issue job to production (QSP713-1) (QSP851-2) (QSP851-3)

Produce and preserve product to meet customer requirements (QSP854-1)

Send product to outside service supplier if required (QSP840-1) (QSP840-2)

Perform in-process inspections (QSP860-1) using calibrated devices (QSP715-1), and identify product status (QSP852-1)

Did products pass in-process inspections?

No

Control nonconforming product (QSP870-1)

Yes →

Perform final inspections, as needed (QSP860-1) using calibrated devices (QSP715-1) and identify product status (QSP852-1)

Did products pass final inspection?

No →

Yes

Prepare product for shipment (QSP854-1)

Ship product to customer or store pending customer release (QSP854-1)

Continually plan, do, check, act, and improve!

- Monitor Quality Policy and Objectives (in Quality Manual)

- Monitor Context of the Organization and Interested Parties

- Identify and Manage Risks and Opportunities

- Ensure Employee Awareness and Communication

- Identify and Preserve Organizational Knowledge

- Control of Quality Records (QSP750-5)

- Management Review (QSP930-1)

- Employee Training (QSP720-1)

- Customer Satisfaction (QSP912-1)

- Internal Audits (QSP920-1)

- Corrective Action (QSP1020-1)

IX.   Quality Management System Requirements

4. Context of the organization

4.1 Understanding the Organization and its Context

We have determined the external and internal issues that are relevant to our purpose and strategic direction, as expressed in our Mission Statement (see Section V), and that may affect our ability to achieve the intended results of our quality management system (also referred to as "QMS" in this quality manual).

We monitor and review information about these external and internal issues and discuss their changes and impacts at our management review meetings. We consider issues that may be positive and negative factors or conditions.

We understand that external issues can arise from legal, technological, competitive, market, cultural, social, and economic environments, whether international, national, regional, or local. We also understand that internal issues can relate to our values, culture, knowledge, and performance.

4.2 Understanding the Needs and Expectations of Interested Parties

Due to their effect, or potential effect, on our ability to consistently provide products and services that meet customer and applicable statutory and regulatory (legal) requirements, we have determined the:

     a.) Interested parties that are relevant to our QMS;
     b.) Requirements of these interested parties that are relevant to our QMS.

We monitor and review information about these interested parties and their relevant requirements. We consider feedback from these interested parties at our management review meetings.

4.3 Determining the Scope of the Quality Management System

We have determined the boundaries and applicability of our QMS to determine its scope. When we determined this scope, we considered:

     a.) External and internal issues referred to in 4.1;
     b.) Requirements of relevant interested parties referred to in 4.2;
     c.) Our products, services, and locations.

We have applied all of the ISO 9001:2015 requirements that are applicable within the scope of our QMS. The QMS scope is documented, maintained, and available within our organization and to all relevant interested parties.

The QMS scope in Section III of this Quality Manual includes a description of the types of products and services included, and states that all ISO 9001 requirements are applicable.

4.4 Quality Management System and its Processes

We have established, implemented, maintain, and continually improve our QMS, including the processes needed and their interactions, in accordance with the ISO 9001:2015 requirements.

We have determined the processes needed for our QMS and their application throughout our organization. Our approach has been to:

    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 our quality management system.

See the QMS Process Flow Diagram in Section VIII for a description of sequence and interaction of our QMS processes. To the extent necessary, we:

    a.) Maintain documented information (documents) to support the operation of our processes.
    b.) Retain documented information (records) to have confidence that the processes are being carried out as planned.

5. Leadership

5.1 Leadership and Commitment

5.1.1 General

Our top management demonstrates its leadership and commitment with respect to our QMS 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 our QMS requirements into our business processes;
    d.) Promoting the use of the process approach and risk-based thinking;
    e.) Ensuring that the resources needed for our QMS are available;
    f.) Communicating the importance of effective quality management and of conforming to the QMS requirements;
    g.) Ensuring that the QMS achieves its intended results;
    h) Engaging, directing, and supporting persons to contribute to the effectiveness of the QMS;
    i.) Promoting improvement;

j.) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus

Our top management demonstrates its leadership and commitment with respect to customer focus by ensuring that:

a.) Customer and applicable legal requirements are determined, understood, and consistently met;
b.) Risks and opportunities that can affect conformity of products and services, and the ability to enhance customer satisfaction, are determined and addressed;
c.) Our focus on enhancing customer satisfaction is maintained.

5.2 Policy

5.2.1 Establishing the Quality Policy
Top management has established, implemented, and maintains a quality policy (see Section VI of this Quality Manual) that:

a.) Is appropriate to the purpose and context of our 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.

5.2.2 Communicating the Quality Policy
Our quality policy is:

a.) Available and maintained as documented information;
b.) Communicated, understood, and applied within our organization;
c.) Available to relevant interested parties.

5.3 Organizational Roles, Responsibilities, and Authorities
Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization.

Top management has assigned the responsibility and authority for:

a.) Ensuring that the QMS conforms to the ISO 9001:2015 requirements;
b.) Ensuring that the processes are delivering their intended outputs;
c.) Reporting on the performance of the QMS and on opportunities for improvement (see section 10.1), in particular to top management;
d.) Ensuring the promotion of customer focus throughout our organization;
e.) Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

The Quality Manager has been assigned by top management with the responsibility and authority for the development and improvement of our quality management system.

6. Planning

6.1 Actions to Address Risks and Opportunities
We have considered 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 our QMS can achieve its intended result(s);
    b.) Enhance desirable effects;
    c.) Prevent, or reduce, undesired effects;
    d.) Achieve improvement.

We plan:

    a.) Actions to address these risks and opportunities;
    b.) How to:

        1.) Integrate and implement the actions into our QMS processes (see section 4.4);
        2.) Evaluate the effectiveness of these actions.

The actions taken to address these risks and opportunities will be proportionate to the potential impact on the conformity of our products and services. Our 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.

We understand that opportunities can lead to adopting new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology, and other desirable and viable possibilities to address our needs or those of our customers.

6.2 Quality Objectives and Planning to Achieve Them
We have established quality objectives at relevant functions, levels, and processes needed for our QMS. These quality objectives are included in Section VI of this Quality Manual.

Our quality objectives are:

    a.) Consistent with the quality policy;
    b.) Measurable;
    c) Based on applicable requirements;
    d.) Relevant to conformity of products and services and to enhancement of customer satisfaction;
    e.) Monitored;
    f.) Communicated;
    g.) Updated as appropriate.

We maintain documented information on the quality objectives. When planning how to achieve our quality objectives, we 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 for Changes

When we determine the need for changes to our QMS, the changes are carried out in a planned manner (see section 4.4).

We consider the:

    a.) Purpose of the changes and their potential consequences;
    b.) Integrity of the quality management system;
    c.) Availability of resources;
    d.) Allocation or reallocation of responsibilities and authorities.

7. Support

7.1 Resources

7.1.1 General

We determine and provide the resources needed for the establishment, implementation, maintenance, and continual improvement of our quality management system.

We consider:

    a.) The capabilities of, and constraints on, existing internal resources;
    b.) What needs to be obtained from external providers.

7.1.2 People

We determine and provide the persons necessary for the effective implementation of our QMS and for the operation and control of its processes.

7.1.3 Infrastructure

We determine, provide, and maintain the infrastructure necessary for the operation of our processes and to achieve conformity of our products and services.

Our infrastructure includes:

    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

We determine, provide, and maintain the environment necessary for the operation of our processes and to achieve conformity of our products and services.

A suitable operating environment may 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).

7.1.5 Monitoring and Measuring Resources
7.1.5.1 General

We determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of our products and services to requirements.

We ensure that the resources provided are:
a.) Suitable for the specific type of monitoring and measurement activities being undertaken;
b.) Maintained to ensure their continuing fitness for their purpose.

We retain appropriate documented information (records) as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or considered to be an essential part of providing confidence in the validity of measurement results, our measuring equipment is:

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 is retained as documented information (records);
b.) Identified to determine their status;
c.) Safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results.

We 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 we take appropriate action as necessary.

7.1.6 Organizational Knowledge

We determine the knowledge necessary for the operation of our processes and to achieve conformity of our products and services. This knowledge is maintained and made available to the extent necessary. We use methods such as notes on Job Travelers, Work Instructions, cross-training, corrective actions, management review minutes, etc. to preserve organizational knowledge.

When addressing changing needs and trends, we consider our current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. We understand that our organizational knowledge is generally gained by experience. It is information that is used and shared to achieve our objectives. Our organizational knowledge is based on:

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; and the results of improvements in processes, products, and services);

b.) External sources (e.g., standards; academia; conferences; and gathering knowledge from customers or external providers).

7.2 Competence
We ensure the necessary level of competence for our organization by:

   a.) Determining the necessary competence of persons doing work under our control that affects the performance and effectiveness of our quality management system;
   b.) Ensuring that these persons are competent based on appropriate education, training, or experience;
   c.) Where applicable, taking actions to acquire the necessary competence, and evaluating the effectiveness of the actions taken;
   d.) Retaining appropriate documented information (records) as evidence of competence.

Our actions may include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

7.3 Awareness
We ensure that persons doing work under our control are aware of:

   a.) Our quality policy (see section 3.2);
   b.) Relevant quality objectives (see section 3.3);
   c.) Their contribution to the effectiveness of our QMS, including the benefits of improved performance;
   d.) The implications of not conforming to our QMS requirements.

7.4 Communication
We have determined the internal and external communications relevant to our QMS, including:

   a.) On what we will communicate;
   b.) When to communicate;
   c.) With whom to communicate;
   d.) How to communicate;
   e.) Who communicates.

We use various methods of internal communication including but not limited to, electronic boards, whiteboards, employee meetings, electronic screens, email, etc. External communications primarily related to customers and suppliers through purchase orders, quotations, order acknowledgements, email, etc.

7.5 Documented Information

7.5.1 General
Our quality management system includes:

a.) Documented information required by ISO 9001:2015;
b.) Documented information determined to be necessary for the effectiveness of our QMS.

The extent of our documented information may vary from process to process based on their complexity and the competence of the people that operate or use those processes.

 Our quality management system documentation is a four-tier structure including:

1.) This Quality Manual (QMS-1);
2.) Quality System Procedures (QSPs), which are numbered to correspond to this Quality Manual. A listing of the QSP's are included in Section IX of this Quality Manual;
3.) Work Instructions;
4.) Forms and Records.

7.5.2 Creating and Updating
When creating and updating documented information, we 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
The documented information required by our QMS and ISO 9001:2015 is controlled to ensure it is:

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).

For our control of documented information, we have addressed 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 as necessary for the planning and operation of our quality management system has been identified as appropriate and controlled.

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

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

We plan, implement and control the processes (see section 4.4) needed to meet the requirements for the provision of our products and services, and to implement the actions determined in clause 6, by:

    a.) Determining the requirements for our products and services;
    b.) Establishing criteria for the:

        1.) Processes;
        2.) Acceptance of products and services;

    c.) Determining the resources needed to achieve conformity to our product and service requirements;
    d.) Implementing control of the processes in accordance with the criteria;
    e.) Determining, maintaining, and retaining documented information to the extent necessary to:

        1.) Have confidence that the processes have been carried out as planned;
        2.) Demonstrate the conformity of our products and services to their requirements.

The output of this planning is in a form suitable for our operations. We control planned changes and review the consequences of unintended changes, and act to mitigate any adverse effects, as necessary.

We also ensure that any outsourced processes are controlled (see section 8.4).

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with our customers includes:

    a.) Providing information relating to our products and services;
    b.) Handling inquiries, contracts, or orders, including changes;
    c.) Obtaining customer feedback relating to our products and services, including customer complaints;
    d.) Handling or controlling any 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, we ensure that:

    a.) The requirements for our products and services are defined, including:

        1.) Any applicable legal (statutory and regulatory) requirements;
        2.) Those considered necessary by our organization;

    b.) We can meet the claims for our products and services.

8.2.3 Review of the Requirements for Products and Services

We ensure that we can meet the requirements for our products and services to be offered to customers. We conduct a review before committing to supply products and services to a customer that includes:

   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 our organization;
   d.) Statutory and regulatory requirements applicable to our products and services;
   e.) Contract or order requirements differing from those previously expressed.

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

In some situations, such as internet sales, a formal review is impractical for each order. Instead, our review would cover the relevant product information used during the automated process.

We retain documented information (records), as applicable, on:

   a.) The results of the review;
   b.) Any new requirements for the products and services.

8.2.4 Changes to Requirements for Products and Services

We ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for our products and services are changed.

8.3 Design and Development of Products and Services

8.3.1 General

We have established, implemented, and maintain a design and development process that is appropriate to ensure the subsequent provision of our products and services.

8.3.2 Design and Development Planning

In determining the stages and controls for design and development, we consider the:

   a) nature, duration, and complexity of the design and development activities;
   b) required process stages, including applicable design and development reviews;
   c) required design and development verification and validation activities;
   d) responsibilities and authorities involved in the design and development process;
   e) internal and external resource needs for the design and development of our products and services;
   f) need to control interfaces between persons involved in the design and development process;
   g) need for involvement of customers and users in the design and development process;
   h) requirements for subsequent provision of our products and services;

i) level of control expected for the design and development process by our customers and other relevant interested parties;
j) documented information needed to demonstrate that design and development requirements have been met.

8.3.3 Design and Development Inputs

We determine the requirements essential for the specific types of products and services to be designed and developed. We consider:

a) functional and performance requirements;
b) information derived from previous similar design and development activities;
c) legal (statutory and regulatory) requirements;
d) standards or codes of practice that we have committed to implement;
e) potential consequences of failure due to the nature of our products and services.

The inputs will be adequate for design and development purposes, complete, and unambiguous. Any conflicting design and development inputs will be resolved.

We will retain documented information (records) on the design and development inputs.

8.3.4 Design and Development Controls

We have applied controls to the design and development process to ensure that:

a) 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 (records) of these activities is retained.

Design and development reviews, verification, and validation have distinct purposes. They may be conducted separately, or in any combination, as is suitable for our products and services.

8.3.5 Design and Development Outputs

We ensure that design and development outputs:

a) meet the input requirements;
b) are adequate for the subsequent processes for the provision of our products and services;
c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
d) specify the characteristics of our products and services that are essential for their intended purpose and their safe and proper provision.

We retain documented information (records) on design and development outputs.

8.3.6 Design and Development Changes

We identify, review, and control any changes made during or after the design and development of our products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

We retain documented information (records) on the:

    a) design and development changes;
    b) results of reviews;
    c) authorization of the changes;
    d) actions taken to prevent adverse impacts.

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

We ensure that externally provided processes, products, and services conform to requirements.

We 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 our own products and services;
    b.) Products and services are provided directly to our customers by external providers on our behalf;
    c.) A process, or part of a process, is provided by an external provider because of a decision by us.

We 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. We retain documented information (records) of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and Extent of Control

We ensure that externally provided processes, products, and services do not adversely affect our ability to consistently deliver conforming products and services to our customers.

Our organization:

    a.) Ensures that externally provided processes remain within the control of our QMS;
    b.) Defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
    c.) Takes into consideration the:

        1.) Potential impact of the externally provided processes, products, and services on our ability to consistently meet customer and applicable legal (statutory and regulatory) requirements;
        2.) Effectiveness of the controls applied by the external provider;

d.) Determines 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

We ensure the adequacy of requirements prior to their communication to the external provider. We communicate to external providers our 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;

c.) Competence, including any required qualification of persons;
d.) The external providers' interactions with us;
e.) Control and monitoring of the external providers' performance to be applied by us;
f.) Verification or validation activities that we, or our customer, intends to perform at the external providers' premises.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

We implement production and service provision under controlled conditions. Those controlled conditions include, as applicable, the:

a.) Availability of documented information that defines the:

1.) Characteristics of the products to be produced, the services to be provided, or the activities to be performed;
2.) Results to be achieved;

b.) Availability and use of suitable monitoring and measuring resources;
c.) 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.) Use of suitable infrastructure and environment for the operation of processes;
e.) Appointment of competent persons, including any required qualification;
f.) 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.) Implementation of actions to prevent human error;
h.) Implementation of release, delivery, and post-delivery activities.

8.5.2 Identification and Traceability

We use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

We identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

We control the unique identification of the outputs when traceability is a requirement and retain the documented information (records) necessary to enable traceability.

8.5.3 Property belonging to Customers or External providers

We exercise care with property belonging to customers or external providers while it is under our control or being used by us.

We identify, verify, protect, and safeguard customers' or external providers' property provided for use or incorporation into our products and services.

When the property of a customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, we report this to the customer or external provider and retain documented information (records) on what has occurred.

The property of our customers and external providers may include materials, components, tools and equipment, premises, intellectual property, and personal data.

8.5.4 Preservation
We preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

Preservation may include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.5 Post-delivery activities
We meet the requirements for post-delivery activities associated with our products and services.

In determining the extent of required post-delivery activities, we consider:

    a.) Legal (statutory and regulatory) requirements;
    b.) The potential undesired consequences associated with our products and services;
    c.) The nature, use, and intended lifetime of our products and services;
    d.) Customer requirements;
    e.) Customer feedback.

Post-delivery activities may 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
We review and control changes for production and service provision (to the extent necessary to ensure continuing conformity with requirements).

We retain documented information (records) describing the results of the review of changes, the persons authorizing the change, and any necessary actions arising from the review.

8.6 Release of Products and Services

We implement planned arrangements, at appropriate stages, to verify that our product and service requirements have been met.

The release of products and services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

We retain documented information (records) on the release of products and services. The documented information includes:

    a.) Evidence of conformity with the acceptance criteria;
    b.) Traceability to the persons authorizing the release.

8.7 Control of Nonconforming Outputs

We ensure that outputs that do not conform to our requirements are identified and controlled to prevent their unintended use or delivery.
We take the appropriate action based on the nature of the nonconformity and its effect on the conformity of our products and services. This also applies to nonconforming products and services detected after delivery of products, and during or after the provision of services.

We 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 is verified when nonconforming outputs are corrected.

We retain documented information (records) 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

We determine:

    a.) What needs to be monitored and measured;
    b.) Methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results;
    c.) When the monitoring and measuring must be performed;
    d.) When the results from monitoring and measurement must be analyzed and evaluated.

We evaluate the performance and the effectiveness of our quality management system. We retain appropriate documented information (records) as evidence of the results.

9.1.2 Customer Satisfaction
We monitor our customers' perceptions of the degree to which their needs and expectations have been fulfilled. We have determined the methods for obtaining, monitoring, and reviewing this information.

Examples of monitoring customer perceptions may 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
We analyze and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis are used to evaluate:

    a.) Conformity of products and services;
    b.) The degree of customer satisfaction;
    c.) The performance and effectiveness of our 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.

Methods to analyze the data may include statistical techniques. Our management review process is the primary method used to quantify and analyze data.

9.2 Internal Audit
We conduct internal audits at planned intervals to provide information on whether our quality management system:
    a.) Conforms to:

        1.) Our requirements for our quality management system;
        2.) The requirements of ISO 9001:2015;

    b.) Is effectively implemented and maintained.

Our organization:
    a.) Plans, establishes, implements, and maintains an audit program including the frequency, methods, responsibilities, planning requirements, and reporting, which take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
    b.) Defines the audit criteria and scope for each audit;
    c.) Selects auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
    d.) Ensures that the results of the audits are reported to relevant management;
    e.) Takes appropriate correction and corrective actions without undue delay;
    f.) Retains documented information (records) as evidence of the implementation of the audit program and the audit results.

9.3 Management Review

9.3.1 General
Top management reviews our quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with our strategic direction.

9.3.2 Management Review Inputs
Our management reviews are 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 our quality management system;
c.) Information on the performance and effectiveness of our QMS, including trends in:

1.) Customer satisfaction and feedback from relevant interested parties;
2.) The extent to which our quality objectives have been met;
3.) Process performance and conformity of our 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 section 6.1);
f.) Opportunities for improvement.

9.3.3 Management Review Outputs
The outputs of our management reviews include decisions and actions related to:

a.) Opportunities for improvement;
b.) Any need for changes to our quality management system;
c.) Resource needs.

We retain documented information (records) as evidence of the results of management reviews.

10. Improvement

10.1 General
We determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These actions 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 our quality management system.

We recognize that improvements may include correction, corrective action, continual improvement, breakthrough change, innovation, and re-organization.

10.2 Nonconformity and Corrective Action

When a nonconformity occurs, including any arising from complaints, we:

    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 causes 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 our quality management system, if necessary.

Our corrective actions will be appropriate to the effects of the nonconformities encountered.

We retain documented information (records) as evidence of the:

    a.) Nature of the nonconformities and any subsequent actions taken;
    b.) Results of any corrective action.

10.3 Continual Improvement

We continually improve the suitability, adequacy, and effectiveness of our quality management system.

We consider the results of analysis and evaluation, and outputs from management review, to determine if there are needs or opportunities that should be addressed as part of continual improvement.

X. Quality System Procedure (QSP) List

QSP713-1 – Equipment Maintenance
QSP715-1 – Control of Monitoring and Measuring Devices
QSP720-1 – Employee Training
QSP750-1 – Control of Quality Management System Documentation
QSP750-2 – Control of Drawings
QSP750-3 – Control of External Standards
QSP750-4 – Control of Machine Programs
QSP750-5 – Control of Quality Records
QSP820-1 – Quoting
QSP820-2 – Order Review
QSP830-1 – Design
QSP840-1 – Vendor Selection and Evaluation
QSP840-2 – Purchasing
QSP840-3 – Verification of Purchased Product
QSP851-2 – Tooling Control
QSP851-3 – Process Validation
QSP852-1 – Product Identification and Traceability
QSP853-1 – Customer and Vendor Property
QSP854-1 – Preservation of Product
QSP860-1 – Inspection Process
QSP870-1 – Control of Nonconforming Product
QSP912-1 – Customer Satisfaction
QSP920-1 – Internal Audits
QSP930-1 – Management Review
QSP1020-1 – Corrective Action

XI. Revision History

Rev. Level	Rev. Date	Section#(s)	Description of Change	Training Required? (Yes/No)
A	01/08/19	-------	Initial Release	Yes

Please feel free to contact us with any questions about our capabilities, products, processes, or quality management system. We are here to assist you in developing solutions to your design and manufacturing needs.

Alaark Tooling & Automation, Inc.
Ph: 920-452-8231
Fax: 920-452-8140
www.alaark.com

LAST PAGE