Quality Assurance Manual, Revision G.

AUTOMATION TECHNOLOGY, LLC

QUALITY ASSURANCE MANUAL

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QUALITY ASSURANCE MANUAL

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QP1100 – Design and Development
QP1150 – Quality Control Inspection
QP1220 – Control of Monitoring & Measuring Devices
QP1240 – Internal Quality Audit
QP1260 – Control of Nonconforming Product
QP1280 – Corrective / Preventive Action
QP1400 – PED Products
QP1600 – Context of the Organization
QP1601 – Risk Management
QP1602 – Management of Change
QP1603 – Organizational Knowledge

Quality Assurance Manual Revision History

Revision	Date	Description of changes	Prepared By
A	4/29/11	Initial Release	Brad Myers
B	10/10/11	Added revision level to page 2, Section 2.0 – changes “automated widgets” to “Valve Automation Devices”, Section 7.3.3 – changed “sage” to “safe”, Section 7.3.5 – changed “be met” to “been met”, Section 7.4.1 – Removed word “Obviously”, Section 7.5.1 – Changed “Our companies” to “ATI’s”	Mitchell Anderson
C	04/27/12	Removed reference to procedures not currently used in QMS, updated all sections to match processes currently followed	Mitchell Anderson
D	9/14/2012	Formatting	Mitchell Anderson
E	6/2/2014	Formatting	Aneil Ali
F	7/6/2015	Updated Quality Policy, Section 5.3	Joseph Pollard
G	6/14/2017	Complete re-write of manual in alignment with ISO 9001:2015 content and structure. Added four new quality procedures (QP1600 – QP1603)	Joseph Pollard

1.0 PURPOSE

The purpose of this quality assurance manual is to establish and state the general policies governing Automation Technology, LLC's (herein referred to as "**ATI")** Quality Management System. These policies define management's intended arrangements for managing our operations and activities in accordance with the framework established by ISO 9001:2015. These are the top-level policies representing the company's plans or protocol for achieving quality assurance and customer satisfaction.

All departmental or functional policies and procedures written must conform and parallel these policies. All changes to policies and procedures are required to be reviewed to ensure that there are no conflicts with these policies stated in this Quality Assurance Manual (QAM).

2.0 TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

3.0 RELATION TO ISO9001:2015

For ease of reference, the sections of this manual are numbered to coincide with the equivalent section numbers of the ISO 9001:2015 standard.

4.0 CONTEXT OF THE ORGANIZATION

4.1 UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT

ATI determines its external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended results of its quality management system, following **QP1600 – Context of the Organization.**

The ATI Management team monitors and reviews information about these external and internal issues at least annually, during the Management Review. Additionally, the weekly management team meetings are used to provide additional monitoring and review when appropriate.

4.2 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

Due to their effect or potential effect on ATI's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, ATI follows **QP1600 – Context of the Organization** to determine:

a) the interested parties that are relevant to the quality management system

b) the requirements of these interested parties that are relevant to the quality management system

The ATI Management team monitors and reviews information about these interested parties at least annually, during the **Management Review**. Additionally, the weekly **management team meetings** are used to provide additional monitoring and review when appropriate.

4.3 DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM

ATI has determined the boundaries and applicability of our quality management system to establish its scope and claims no exclusions, in consideration of:

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 ATI may be stated as:

The design and manufacture of Valve Automation equipment, and provision of post-delivery support services

4.4 QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES

4.4.1 ATI has an established, implemented, maintained, and continuously improved quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO 9001:2015.

ATI has determined the processes needed for the quality management system and their application throughout our organization, and:

a) Determines the inputs required and the outputs expected from these processes through **documented work instructions**

b) Determines the sequence and interactions of these processes via our process map (see below)

c) Determines and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes via our quality inspection log and our **ATI Lean Scorecard**

d) Determines the resources needed for these processes and ensure their availability in our **annual management review**, **strategic planning meetings**, and **management meetings**

e) Assigns the responsibilities and authorities for these processes in our **organizational chart** and through **documented work instructions**.

f) Addresses the risks and opportunities as determined in accordance with the requirements of 6.1, following **QP1601 Risk Management**

g) Evaluates the processes and implements any changes needed to ensure that these processes achieve their intended results, via our continuous improvement (lean) program monitored by our **ATI Lean Scorecard**

h) Improves the processes and the quality management system via our continuous improvement (lean) program monitored by our **ATI Lean Scorecard**

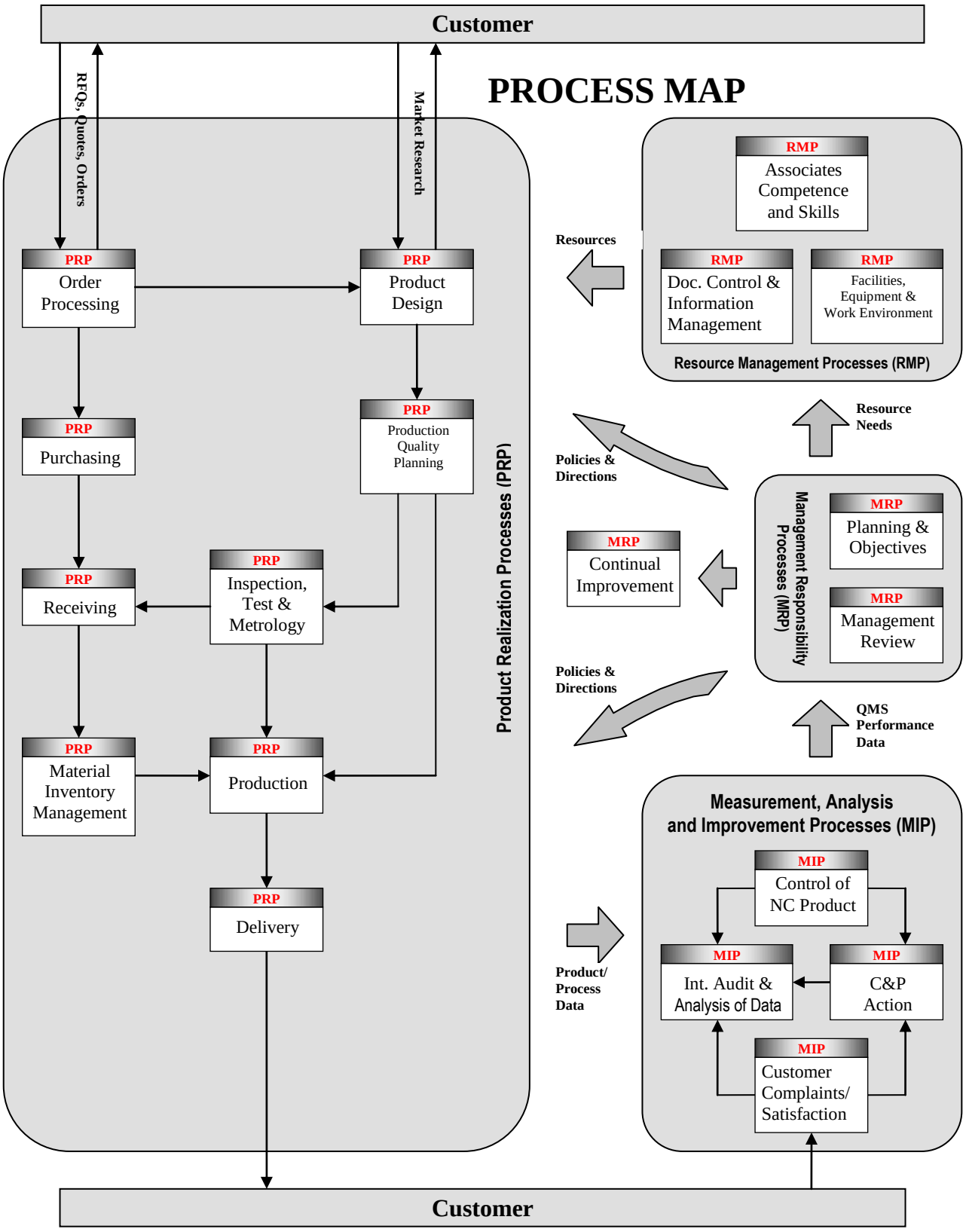

Table 1: General Process Sequence Flow Chart

4.4.2 To the extent necessary, ATI:

a) Maintains documented information to support the operation of our processes through **documented work instructions**
b) Retains documented information to have confidence that the processes are being carried out as planned, following **QP1010 – Control of Records**

5.0 LEADERSHIP

5.1 LEADERSHIP AND COMMITMENT

5.1.1 General

ATI 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, monitored and assessed via our **Management Review** and **Strategic Planning**

c) ensuring the integration of the quality management system requirements into the organization's business processes, via **QF0068 ATI Business Management System**

d) promoting the use of the process approach and risk-based thinking, following **QP1601 Risk Management**

e) Ensuring that the resources needed for the quality management system are available, evident in our infrastructure and personnel, monitored and assessed via our **Management Review** and **Strategic Planning**

f) Communicating the importance of effective quality management and of conforming to the quality management system requirements through our monthly company lean meetings, weekly department meetings, and through our **Management Review** following our **internal audits**.

g) Ensuring that the quality management system achieves its intended results, monitored and measured by measuring key performance indicators (KPIs) on our **ATI Lean Scorecard**

h) Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system through our employee performance management system (performance/coaching sessions)

i) Promoting improvement, via our **lean (continuous improvement) program**

j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility, shown in our **organizational chart**

5.1.2 CUSTOMER FOCUS

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

a) Customer and applicable statutory and regulatory requirements are determined, understood and consistently met, following **QP1100 Design and Development**

b) The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed, following **QP1601 Risk Management**

c) The focus on enhancing customer satisfaction is maintained, by upholding our **quality policy** and by our employee bonus incentive program linked directly to customer satisfaction on our **ATI Lean Scorecard**

5.2 POLICY

5.2.1 ESTABLISHING THE QUALITY POLICY

ATI top management has established, implemented, and maintains our **ATI Quality Policy** that:

a) Is appropriate to the purpose and context of our organization and supports our strategic direction (company name is the backbone of the quality policy, promotes key metrics)

b) Provides a framework for setting quality objectives (customer satisfaction, on-time delivery, quality [superior products], and continuous improvement of our QMS)

c) Includes a commitment to satisfy applicable requirements ("Absolute Customer Satisfaction")

d) Includes a commitment to a continual improvement of the quality management system

A

Absolute Customer Satisfaction.

T

Timely delivery of superior products to all customers.

I

Innovation and Continuous Improvement of our Quality Management System.

5.2.2 COMMUNICATING THE QUALITY POLICY

The ATI quality policy is:

a) Made available and maintained as documented information, in our company shared directory – **ATI Quality Policy**

b) Communicated, understood and applied within the organization, evident in our daily processes and monitored in our **internal audits** of all departments

c) Available to relevant interested parties, located in the Quality Assurance Manual and included in our **company website**

5.3 ORGANIZATIONAL ROLES, RESPONSIBILTIES AND AUTHORITIES

ATI top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization, shown in our **organizational chart**

ATI top management assigns the responsibility and authority to its **quality management system representative** for:

a) Ensuring that the quality management system conforms to the requirements of ISO 9001:2015

b) Ensuring that the processes are delivering their intended outputs

c) Reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management

d) Ensuring the promotion of customer focus throughout the organization

e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented

6.0 PLANNING

6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

6.1.1 When planning for the quality management system, ATI takes into consideration the issues referred to in 4.1 and the requirements referred to in 4.2, and determines the risks and opportunities that need to be addressed, following **QP1601 Risk Management** to:

a) Give assurance that the quality management system can achieve its intended results

b) Enhance desirable effects

c) Prevent, or reduce, undesired effects

d) Achieve improvement

6.1.2 Following **QP1601 Risk Management**, ATI plans:

a) Actions to address these risks and opportunities;

b) How to:
   1) Integrate and implement the actions into our quality management system processes (see 4.4);
   2) Evaluate the effectiveness of these actions

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

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

NOTE 2 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 the organization's or its customers' needs.

6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

6.2.1 ATI establishes quality objectives at relevant functions, levels and processes needed for our quality management system.

The quality objectives are:

a) Consistent with the quality policy;

b) Measurable;

c) Taken into account applicable requirements;

d) Relevant to conformity of products and services and to enhancement of customer satisfaction;

e) Monitored;

f) Communicated;

g) Updated as appropriate.

ATI maintains documented information on our quality objectives, located on the **ATI Lean Scorecard** as a result of annual **Strategic Planning.**

6.2.2 When planning how to achieve its quality objectives, ATI determines:

a) What will be done;

b) What resources will be required;

c) Who will be responsible;

d) When it will be completed;

e) How the results will be evaluated.

6.3 PLANNING OF CHANGES

When ATI determines the need for changes to the quality management system, the changes shall be carried out in a planned manner, following **QP1602 - Management of Change,** in which ATI takes into consideration:

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.

7.0 SUPPORT

7.1 RESOURCES

7.1.1 GENERAL

ATI determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system in annual **Strategic Planning**, and is guided by **QP1600 – Context of the Organization.**

ATI takes into consideration:

a) the capabilities of, and constraints on, existing internal resources;

b) what needs to be obtained from external providers

7.1.2 PEOPLE

ATI determines and provides the persons necessary for the effective implementation of our quality management system and for the operation and control of our processes, taking into consideration the "interested parties" identified in **QP1600 – Context of the Organization.**

7.1.3 INFRASTRUCTURE

ATI determines, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services, including:

a) buildings and associated utilities;

b) equipment, including hardware and software;

c) transportation resources;

d) information and communication technology

7.1.4 ENVIRONMENTAL FOR THE OPERATION OF PROCESSES

ATI determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services. We support our work environment with our company infrastructure, and with the policies set forth in our **ATI Employee Handbook**.

NOTE A suitable environment can be a combination of human and physical factors, such as:

a) social (e.g. non-discriminatory, calm, non-confrontational);

b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

7.1.5 MONITORING AND MEASURING RESOURCES

7.1.5.1 GENERAL

ATI determines and provides 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.

By following **QP1220 – Control of Monitoring & Measuring Devices,** ATI ensures that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;
b) are maintained to ensure their continuing fitness for their purpose

ATI retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources, via our **Monitoring & Measuring Devices database.**

7.1.5.2 MEASUREMENT TRACEABILITY

Measurement traceability is considered by Automation Technology, LLC as an essential part of providing confidence in the validity of measurement results. 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 shall be retained as documented information, located in our **calibration records.**

b) Identified in order to determine their status, named and tracked by our **Monitoring & Measuring Devices database.**

c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results

If the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, ATI shall take appropriate action as necessary.

7.1.6 ORGANIZATIONAL KNOWLEDGE

ATI determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services, following **QP1603 – Organizational Knowledge.**

This knowledge is maintained and is made available to the extent necessary, using **QF0068 ATI Business Management System.**

When addressing changing needs and trends, ATI considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

NOTE 1 Organizational knowledge is knowledge specific to ATI; it is generally gained by experience. It is information that is used and shared to achieve our objectives.

NOTE 2 Organizational knowledge can be based upon:

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

ATI:

a) Determines the necessary competence of person(s) doing work under our control that affects the performance and effectiveness of our quality management system;

b) Ensures that these persons are competent on the basis of appropriate education, training, or experience, documented by our **training & skills matrix;**

c) Where applicable, takes actions to acquire the necessary competence, and evaluates the effectiveness of the actions taken.

d) Retains appropriate documented information as evidence of competence, through our training records.

7.3 AWARENESS

ATI ensures that persons doing work under the organization's control are aware of:

a) Our **quality policy**, posted on the company shared directory and throughout the facility;.

b) Relevant quality objectives, posted on the **ATI Lean Scorecard;**

c) Their contribution to the effectiveness of the quality management system, including the benefits of improved performance, through our lean program and monthly "all-hands" meetings, which ties the **ATI Lean Scorecard;** outputs directly to employee bi-annual bonuses.

d) The implications of not conforming to the quality management system requirements, supported by the policies set forth in our **ATI Employee Handbook**.

7.4 COMMUNICATION

ATI determines the internal and external communications relevant to the quality management system, following **QP1600 – Context of the Organization,** including:

a) On what it will communicate

b) When to communicate;

c) With whom to communicate;

d) How to communicate;

e) Who communicates

7.5 DOCUMENTED INFORMATION

7.5.1 GENERAL

ATI's quality management system includes:

a) Documented information required by ISO 9001:2015;

b) Documented information determined by ATI as being necessary for the effectiveness of the quality management system

NOTE The extent of documented information for ATI's quality management system can differ from one organization to another due to:

- The size of organization and our type of activities, processes, products and services;
- The complexity of our processes and its interactions;
- The competence of our persons

7.5.2 CREATING AND UPDATING

When creating and updating documented information, ATI follows **QP1000 – Document Control** to ensure appropriate:

a) Identification and description (e.g. a title, date, author, or reference number);

b) Format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) Review and approval for suitability and adequacy.

7.5.3 CONTROL OF DOCUMENTED INFORMATION

7.5.3.1 Documented information required by ATI's quality management system and by ISO 9001:2015 shall be controlled, following **QP1000 – Document Control** to ensure:

a) It is available and suitable for use, where and when it is needed

b) It is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

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

a) Distribution, access, retrieval and use;

b) Storage and preservation, including preservation of legibility;

c) Control of changes (e.g. version control);

d) Retention and disposition.

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

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

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

8.0 OPERATION

8.1 OPERATION PLANNING AND CONTROL

ATI plans, implements, and controls its processes (see Section 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6 by:

a) Determining the requirements for the products and services, following **QP1100 – Design & Development;**

b) Establishing criteria for:

1) The processes;
2) The acceptance of products and services;

a) Determining the resources needed to achieve conformity to the product and services requirements;

b) Implementing control of the processes in accordance with the criteria;

c) 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.

The output of this planning shall be suitable for ATI's operations.

ATI controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

ATI ensures that outsourced processes are controlled (see Section 8.4).

8.2 REQUIREMENTS FOR PRODUCTS AND SERVICES

8.2.1 CUSTOMER COMMUNICATION

Communication with customers, following **QP1600 – Context of the Organization,** shall include:

a) Providing information relating to products and services;

b) Handling enquiries, contracts or orders, including changes;

c) Obtaining customer feedback relating to products and services, including customer complaints;

d) Handling or controlling customer property;

e) Establishing specific requirements for contingency actions, when relevant.

8.2.2 DETERMINING THE REQUIREMENTS FOR PRODUCTS AND SERVICES

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

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

1) Any applicable statutory and regulatory requirements;
2) Those considered necessary by the organization;

b) The organization can meet the claims for the products and services it offers.

8.2.3 REVIEW OF THE REQUIREMENTS FOR PRODUCTS AND SERVICES

8.2.3.1 ATI ensures that it has the ability to meet the requirements for products and services to be offered to customers. ATI conducts a review before committing to supply products and services to a customer, to include:

c) Requirements specified by the customer, including the requirements for delivery and post-delivery activities;

d) Requirements not stated by the customer, but necessary for the specified or intended use, when known;

e) Requirements specified by the organization;

f) Statutory and regulatory requirements applicable to the products and services;

g) Contract or order requirements differing from those previously expressed.

ATI ensures that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by ATI before acceptance, when the customer does not provide a documented statement of their requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

8.2.3.2 ATI 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

ATI ensures 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, following **QP1000 – Document Control.**

8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

8.3.1 GENERAL

ATI has an established, implemented, and maintained design and development process, following **QP1100 – Design and Development** that is appropriate to ensure that subsequent provision of products and services.

8.3.2 DESIGN AND DEVELOPMENT PLANNING

In determining the stages and controls for design and development, ATI considers:

a) The nature, duration and complexity of the design and development activities;

b) The required process stages, including applicable design and development activities;

c) The required design and development verification and validation activities;

d) The responsibilities and authorities involved in the design and development process;

e) The internal and external resource needs for the design and development of products and services;

f) Then need to control interfaces between persons involved in the design and development process;

g) The need for involvement of customers and users in the design and development process;

h) The requirements for subsequent provision of products and services;

i) The level of control expected for the design and development process by customers and other relevant interested parties;

j) The documented information needed to demonstrate that design and development requirements have been met.

8.3.3 DESIGN AND DEVELOPMENT INPUTS

ATI, following **QP1100 – Design and Development,** determines the requirements essential for the specific types of products and services to be designed and developed, in consideration of:

a) Functional and performance requirements;

b) Information derived from previous similar design and development activities;

c) Statutory and regulatory requirements;

d) Standards or codes of practice that the organization has committed to implement;

e) Potential consequences of failure due to the nature of the products and services.

Inputs are adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs are resolved.

ATI retains documented information on design and development inputs.

8.3.4 DESIGN AND DEVELOPMENT CONTROLS

ATI applies 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 of these activities is retained.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

8.3.5 DESIGN AND DEVELOPMENT OUTPUTS

ATI ensures that design and development outputs:

a) Meet the input requirements;

b) Are adequate for the subsequent processes for the provision of products and services;

c) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d) Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs.

8.3.6 DESIGN AND DEVELOPMENT CHANGES

ATI identifies, reviews and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

ATI retains documented information on:

a) Design and development changes;

b) The results of reviews;

c) The authorization of the changes;

d) The actions taken to prevent adverse impacts.

8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES

8.4.1 GENERAL

ATI ensures that externally provided processes, products and services conform to requirements.

ATI determines the controls to be applied to externally provided processes, products and services when:

a) Products and services from external providers are intended for incorporation into the organization's own products and services;

b) Products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) A process, or part of a process, is provided by an external provider as a result of a decision by the organization.

ATI determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 TYPE AND EXTENT OF CONTROL

ATI ensures that externally provided processes, products and services do not adversely affect its ability to consistently deliver conforming products and services to its customers. ATI:

a) Ensures that externally provided processes remain within the control of its quality management system;

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:

   1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

   2) the effectiveness of the controls applied by the external provider;

d) 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

ATI ensures the adequacy of requirements prior to their communication to the external provider, following XX and recorded in our **External Provider Audits** directory. ATI communicates to external providers its requirements for:

a) The processes, products and services to be provided;

b) The approval of:

   1) products and services;

   2) methods, processes and equipment;

3) the release of products and services;

c) Competence, including any required qualification of persons;

d) The external providers' interactions with the organization;

e) Control and monitoring of the external providers' performance to be applied by the organization;

f) Verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

8.5 PRODUCTION AND SERVICE PROVISION

8.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

ATI has implemented production and service provision under controlled conditions. Controlled conditions include, as applicable:

a) The availability of documented information that defines:

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2) the results to be achieved;

b) The availability and use of suitable monitoring and measuring resources;

c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

d) The use of suitable infrastructure and environment for the operation of processes;

e) The appointment of competent persons, including any required qualification;

f) The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) The implementation of actions to prevent human error;

h) The implementation of release, delivery and post-delivery activities.

8.5.2 IDENTIFICATION AND TRACEABILITY

ATI uses 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.

ATI controls the unique identification of the outputs when traceability is a requirement, and retain the documented information necessary to enable traceability.

8.5.3 PROPERTY BELONGING TO CUSTOMERS OR EXTERNAL PROVIDERS

ATI exercises care with property belonging to customers or external providers while it is 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, documented by our **ATI Visitor Register, External Property Log.**

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 on what has occurred, using the **ATI Inspection Log.**

NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

8.5.4 PRESERVATION

ATI preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

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

8.5.5 POST-DELIVERY ACTIVITIES

ATI meets requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, ATI considers:

a) Statutory and regulatory requirements;

b) The potential undesired consequences associated with its products and services;

c) The nature, use and intended lifetime of its products and services;

d) Customer requirements;

e) Customer feedback.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 CONTROL OF CHANGES

ATI reviews and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

ATI retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 RELEASE OF PRODUCTS AND SERVICES

ATI has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met, following **QP1150 – Quality Control Inspection.**

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

ATI retains documented information on the release of products and services. The documented information shall include:

a) Evidence of conformity with the acceptance criteria; **ATI Inspection Log** and **QF0013 – Inspection Certificate**

b) Traceability to the person(s) authorizing the release.

8.7 CONTROL OF NONCONFORMING OUTPUTS

8.7.1 ATI ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery, following **QP1260 – Control of Nonconforming Product** and documented by the **ATI Inspection Log.**

ATI takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

ATI deals with nonconforming outputs in one or more of the following ways:

a) Correction;

b) Segregation, containment, return or suspension of provision of products and services;

c) Informing the customer;

d) Obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 ATI retains documented information that:

a) Describes the nonconformity;

b) Describes the actions taken;

c) Describes any concessions obtained;

d) Identifies the authority deciding the action in respect of the nonconformity.

9.0 PERFORMANCE EVALUATION

9.1 MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION

9.1.1 GENERAL

ATI determines:

a) What needs to be monitored and measured;

b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

c) When the monitoring and measuring shall be performed;

d) When the results from monitoring and measurement shall be analyzed and evaluated.

ATI evaluates the performance and the effectiveness of the quality management system. We retain appropriate documented information as evidence of the results.

9.1.2 CUSTOMER SATISFACTION

ATI monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. ATI determines the methods for obtaining, monitoring and reviewing this information.

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

9.1.3 ANALYSIS AND EVALUATION

ATI analyzes 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 the quality management system;

d) If planning has been implemented effectively;

e) The effectiveness of actions taken to address risks and opportunities;

f) The performance of external providers;

g) The need for improvements to the quality management system.

NOTE Methods to analyze data can include statistical techniques.

9.2 INTERNAL AUDIT

9.2.1 ATI conducts internal audits at planned intervals to provide information on whether the quality management system:

a) Conforms to:

1) ATI's own requirements for its quality management system;

2) the requirements of ISO 9001:2015;

b) Is effectively implemented and maintained.

9.2.2 Following **QP1240 - Internal Quality Audits**, ATI:

a) Planned, established, implemented and maintains an audit program 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) 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 as evidence of the implementation of the audit program and the audit results.

9.3 MANAGEMENT REVIEW

9.3.1 GENERAL

ATI top management reviews the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of our organization.

9.3.2 MANAGEMENT REVIEW INPUTS

The management review shall be planned and carried out taking into consideration:

a) The status of actions from previous management reviews;

b) Changes in external and internal issues that are relevant to the quality management system;

c) Information on the performance and effectiveness of the quality management system, including trends in:

1) customer satisfaction and feedback from relevant interested parties;

2) the extent to which quality objectives have been met;

3) process performance and conformity of products and services;

4) nonconformities and corrective actions;

5) monitoring and measurement results;

6) audit results;

7) the performance of external providers;

d) The adequacy of resources;

e) The effectiveness of actions taken to address risks and opportunities (see 6.1);

f) Opportunities for improvement.

9.3.3 MANAGEMENT REVIEW OUTPUTS

The outputs of the management review, documented in our **management review meeting minutes**, include decisions and actions related to:

a) Opportunities for improvement;

b) Any need for changes to the quality management system;

c) Resource needs.

ATI retains documented information as evidence of the results of management reviews.

10.0 IMPROVEMENT

10.1 GENERAL

ATI determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction. Improvement to products and processes are documented in our **Lean (Continuous Improvement) Program Directory** a well as our **Corrective-Preventive Action Directory.**

These include:

a) Improving products and services to meet requirements as well as to address future needs and expectations;

b) Correcting, preventing or reducing undesired effects;

c) Improving the performance and effectiveness of the quality management system.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2 NONCONFORMITY AND CORRECTIVE ACTION

10.2.1 When nonconformity occurs, including any arising from complaints, ATI follows **QP1260 Control of Nonconforming Product** and **QP1280 Corrective – Preventive Action**, and in doing so shall:

a) React to the nonconformity and, as applicable:

1) take action to control and correct it;

2) deal with the consequences;

b) Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1) reviewing and analyzing the nonconformity;

2) determining the causes of the nonconformity;

3) determining if similar nonconformities exist, or could potentially occur;

c) Implement any action needed;

d) Review the effectiveness of any corrective action taken;

e) Update risks and opportunities determined during planning, if necessary;

f) Make changes to the quality management system, if necessary.

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

10.2.2 ATI retains documented information in our **ATI Inspection Log** and our **CCR log** and **CPAR log** as evidence of:

a) The nature of the nonconformities and any subsequent actions taken;

b) The results of any corrective action.

10.3 CONTINUAL IMPROVEMENT

ATI continually improves the suitability, adequacy and effectiveness of our quality management system.

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