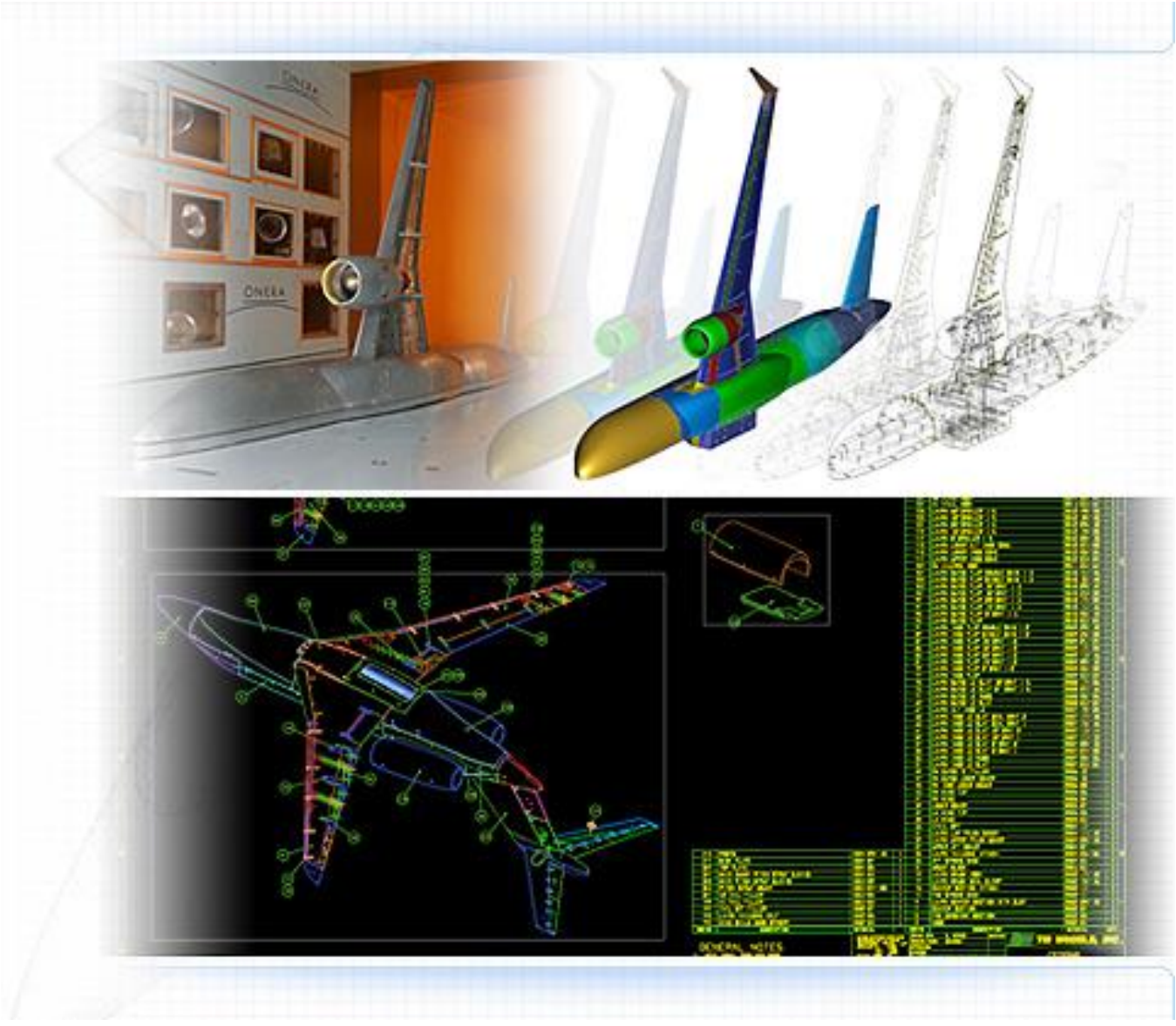
5191 Oceanus Drive
Huntington Beach, CA 92649

TRI MODELS QUALITY MANUAL

REVISION I – APR 21, 2022



TRI MODELS MISSION STATEMENT & QUALITY POLICY

MISSION STATEMENT

TRI MODELS IS THE PREMIER PROVIDER OF WIND TUNNEL MODEL, PROTOTYPE AND GROUND TESTING HARDWARE FOR THE AEROSPACE INDUSTRY. OUR MISSION IS TO JOIN SEAMLESSLY WITH OUR CUSTOMERS IN THEIR PRODUCT DEVELOPMENT PROCESSES.

QUALITY POLICY

TRI MODELS IS COMMITTED TO THE RAPID, ACCURATE TRANSLATION OF DESIGN CONCEPTS INTO TESTABLE MODELS THROUGH:

- A SPECIALIZED ENGINEERING STAFF WHO WORKS INTUITIVELY WITH OUR CUSTOMER'S TEAM
- AN EXPERIENCED & CREATIVE PRODUCTION STAFF FOR INTEGRATED, FAST-TRACK MANUFACTURING
- STAND-BY SERVICES FOR QUICK TURN-AROUND CHANGES AND ADDITIONS
- CONTINUOUS, REAL-TIME COMMUNICATION OF PROJECT STATUS
- COMPLIANCE WITH CUSTOMER, REGULATORY AND STATUTORY REQUIREMENTS
- REGISTRATION TO AS9100D, THE INTERNATIONAL AEROSPACE QUALITY STANDARD
- CONTINUAL IMPROVEMENT TO OUR QUALITY MANAGEMENT SYSTEM

TRI MODELS INC PRIDES ITSELF ON BEING THE

-BEST VALUE IN THE MARKET-

CONTENTS

DOCUMENT HISTORY

REV	DATE	AFFECTED PAGES	DESCRIPTION	APPROVAL
NC	1999	ALL	QUALITY MANUAL IN COMPLIANCE WITH ISO 9001 & AS9100:1995	
A	FEBRUARY 3, 2012	ALL	UPGRADED QUALITY MANUAL TO COMPLY WITH ISO 9001:2008 & AS 9100:2009.	
B	APRIL 13, 2012	PAGE 8 PAGE 18 PAGE 31	CLARIFIED INPUTS/OUTPUTS ON INTERACTIONS CHART CLARIFIED TRAINING REQUIREMENTS ADDED DESCRIPTION OF FOD PROGRAM	
C	APRIL 1, 2014	PAGE 12	ADDED FORM #'S TO REVISION HISTORY	
D	JANUARY 29, 2015	ALL	UPDATED PROCEDURE, WORK INSTRUCTION AND DOCUMENT NUMERATION TO MATCH CURRENT RECORDS	
E	JUNE 16, 2017	PAGE 7	UPDATED PROCESS MAP	
F	NOV 20, 2017	ALL	UPGRADED QUALITY MANUAL TO COMPLY WITH ISO 9001:2015 & AS 9100:2016.	
G	MAR 6, 2018	PAGE 7	UPDATED PROCESS MAP	
H	FEB 2, 2020	ENTIRE DOCUMENT	ELABORATED IN DETAIL ALL INTERNAL PROCESSES AS THEY RELATE TO AS9100D	
I	APR 21, 2022	PAGE 9 PAGE 10 PAGE 19 PAGE 20 PAGE 22 PAGE 23 PAGE 24	IN KPI'S REMOVE PROFIT & ADD OTD. ADD BULLET 5.1.1.E. EXPAND IN CLAUSE 5.2. AMEND MINOR TYPOS IN CLAUSE 8.3.6 ADD CLAUSE 8.4.3 IN CLAUSE 8.5.3 ADD REFERENCE TO SOP 5.1. ADD CLAUSE 8.5.6. DOCUMENTED INFORMATION IS KEPT IN THE JOB FOLDER.	

1. SCOPE OF QUALITY SYSTEM

This Quality Manual describes the Quality Management System at Tri-Models, Inc., the premier supplier of wind tunnel test models for the aviation and aerospace industry. Tri Models designs and builds a wide range of models including force and momentum, pressure integration, propulsion integration, jet effects/STOVL powered lift, icing certification, radio cross section (RCS), and even hot firing engine models.

The Quality Management System at Tri Models has been in conformance with the requirements of *ISO 9001/AS 9100* since 1999.

The scope of the Quality Management System covers the design, fabrication, and instrumentation of wind tunnel test models. The scope includes all requirements of AS 9100D.

2. NORMATIVE REFERENCES

Compliance with the following quality standards, statutes, regulations, and guidelines are maintained:

- *ISO 9000:2015 – Quality Management Systems – Fundamentals and Vocabulary*
- *ISO 9001:2015 – Quality Management Systems –Requirements*
- *AS 9100:2015 – Quality Management Systems – Aerospace- Requirements*
- *ISO 19011:2011 - Guidelines for Quality and/or Environmental Management Systems Auditing*
- *ISO 10012:2003 - Measurement Management Systems – Requirements for Measurement Processes and Measuring Equipment*
- *Defense Federal Acquisition Regulation Supplement - Clause 252.225-7014*
- *22 CFR Part 120 – 130 – International Traffic in Arms Regulations (ITAR)*
- Applicable state and federal Occupational Safety and Health Administration regulations
- Applicable state and federal Environmental Protection Agency regulations
- Applicable state and federal Department of Labor regulations and statutes

3. DEFINITIONS

The definitions contained in *ISO 9000:2015-Quality Management System-Fundamentals & Vocabulary* are used. Listed below are explanations of how the terms “counterfeit parts”, “critical items”, “key characteristics”, “product safety” and “special requirements” are applied at Tri-Models, Inc.

3.1 COUNTERFEIT PARTS

An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer. Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.

3.2 CRITICAL ITEMS

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc

3.3 KEY CHARACTERISTICS

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.

3.4 PRODUCT SAFETY

The state in which a product is able to perform to it's designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.5 SPECIAL REQUIREMENTS

Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, past experience, and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

NOTE: Special requirements (3.5) and critical items (3.2), along with key characteristics (3.3), are interrelated.

Special requirements are identified when determining and reviewing requirements related to the product (See 8.2.2 and 8.2.3).

Special requirements can require the identification of critical items.

Design outputs (see 8.3.5) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.

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4. QUALITY MANAGEMENT SYSTEM *(FROM HERE ON REFERRED TO AS QMS)*

4.1 CONTEXT OF THE ORGANIZATION

Tri Models determines internal and external issues that are relevant to our purpose and our strategic direction through the use of PESTLE and SWOT analysis. These issues are monitored and reviewed once per calendar year during the *Management Review Meeting*, and documented in *TMI R4.3 PESTLE Analysis Record and R4.4 SWOT Analysis Record.*

NOTE 1: Issues can include positive and negative factors or conditions for consideration.

NOTE 2: Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, and economic environments, whether international, national, regional, or local.

NOTE 3: Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge, and performance of the organization.

4.2 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

Interested Parties are those individuals or organizations that can affect, be affected by, or perceive themselves to be affected by a decision or activity. Due to their effect or potential effect on Tri Models ability to consistently provide products and services that meet our customer and applicable statutory and regulatory requirements, interested parties are identified in *TMI R4.2 Interested Parties Record.* The requirements of these interested parties are monitored and reviewed during the day-to-day interactions of upper management at Tri Models, and are also formally monitored and reviewed yearly during the *Management Review Meeting*.

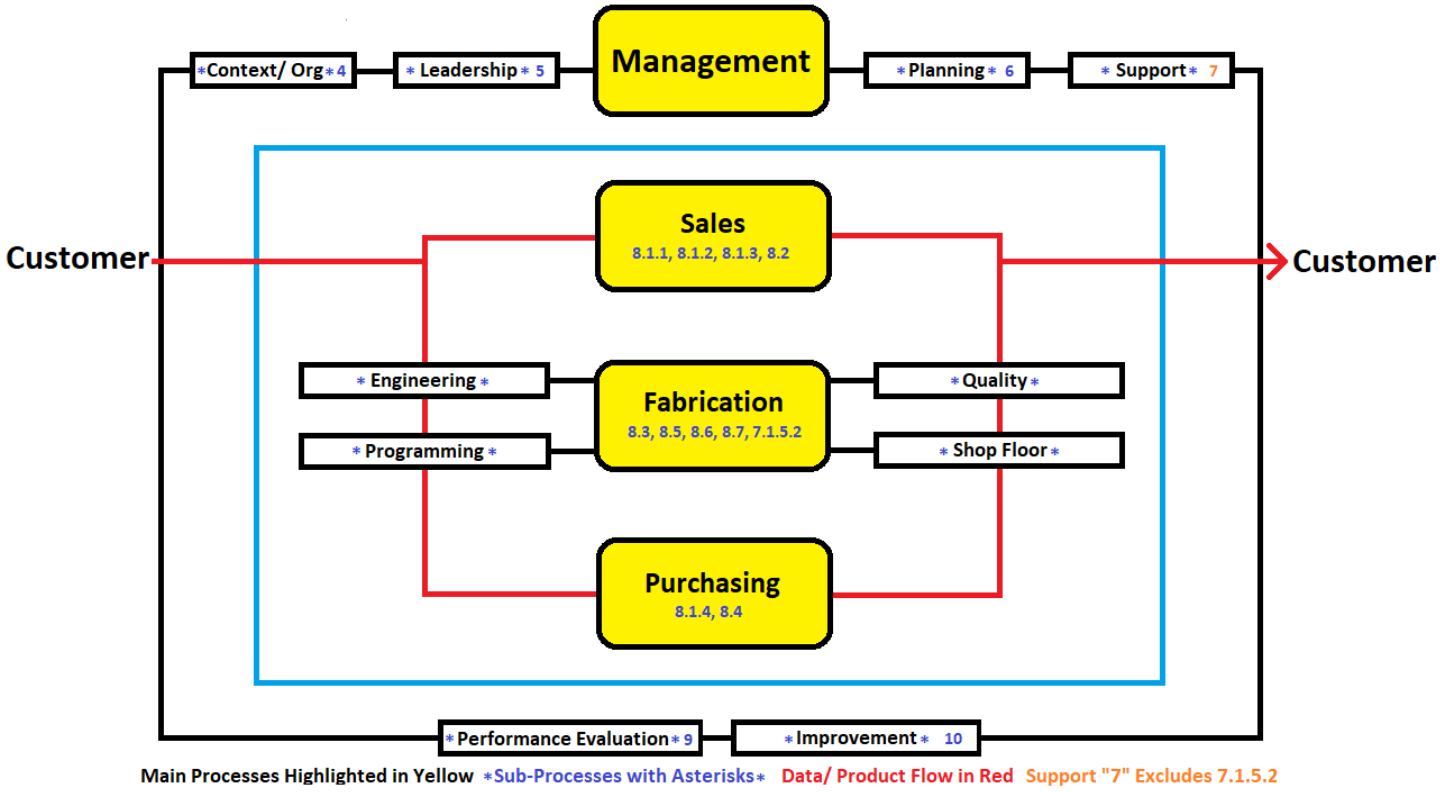
4.3 DETERMINING THE SCOPE OF THE QMS

Tri Models has determined the boundaries and applicability of the QMS to establish its scope, which are maintained as documented information on page 4 of this document. When determining this scope, Tri Models has considered the external and internal issues referred to in 4.1, the requirements of relevant interested parties referred to in 4.2 and the products and services of the organization. All of the requirements of AS9100D have been considered in determining the scope of the QMS.

4.4 QMS AND ITS PROCESSES

Tri Models has established, implemented, maintained, and continually improved upon its QMS, including processes needed and their interactions in accordance with AS9100D, customer, and statutory and regulatory requirements. The inputs required and the outputs expected, criteria and methods of evaluation, responsibilities and authorities, and resources needed are documented and retained *in the TMI SOP's*. The description as well as sequence and interaction of these processes needed for the QMS are identified in the *Tri Models Process Map*, as shown below.

TRI MODELS PROCESS MAP



Process Leaders are assigned below for each process

Management Process: CEO

Sales: Director of New Business Development

Fabrication: President

Purchasing: Buyer

Each process leader is responsible for:

a. Determining the criteria and methods for ensuring control of the process

b. Providing the necessary resources

c. Monitoring, measuring, and analyzing the processes for which they are responsible and,

d. Taking corrective, preventive, and general improvement actions necessary, to achieve planned results

Key Performance Indicators (KPIs)

Key performance indicators are established to monitor the performance of metrics that are considered critical to evaluate the effectiveness of the processes of the QMS.

1. The KPI's monitored for #1 ***"Management"*** is Customer Satisfaction Rates.
2. The KPI monitored for #2 ***"Sales"*** is Total Working Hours.
3. The KPI's monitored for #3 ***"Fabrication"*** are Scrap Rate, Nonconformity Rate and On-Time Delivery.
4. The KPI's monitored for #4 ***"Purchasing"*** are Supplier Quality and Supplier On-Time Delivery.

Documented information to support the operation of these processes is maintained in TMI SOP's and in this document. Documented information in the form of Internal Audits are maintained to have confidence that the processes are being carried out as planned.

5. LEADERSHIP

5.1 LEADERSHIP & COMMITMENT

5.1.1 GENERAL

At Tri Models, Top Management demonstrates leadership and commitment with respect to the QMS by:

a. taking accountability for the effectiveness of the QMS. *(This is achieved by closely monitoring the day to day operations at Tri Models, and reviewing available KPI's at least once per year during the Management Review Meeting.)*
b. ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the organization. (*These are reviewed yearly at the Management Review Meeting and updated when required.)*
c. ensuring the integration of the QMS requirements into the organization's business processes;
d. promoting the use of the process approach and risk-based thinking. (*This is achieved through the QMS itself).*
e. ensuring that the resources needed for the quality management system are available.
f. communicating the importance of effective quality management and of conforming to the QMS requirements. (*This communication is initiated by Top Management towards management and is disseminated down to all employees.)*
g. ensuring that the QMS achieves its intended results. (*The intended results are documented and monitored in the form of KPI's.)*
h. engaging, directing, and supporting persons to contribute to the effectiveness of the QMS. (*Ideas for the improvement of the QMS are integrated daily by Upper Management and are reviewed annually at the Management Review Meeting).*
i. promoting improvement. (*Improvement at Tri Models is promoted through the continual improvement of the QMS).*
j. supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. *(Managers are given general autonomy by Top Management, with general oversight).*

5.1.2 CUSTOMER FOCUS

At Tri Models, 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. *(These requirements are established from data provided by the customer in the form of the SOW, CAD, drawings and/or other pertinent documents or information).*
b. the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed. (*These risks and opportunities are documented in the Contract Review).*
c. the focus on enhancing customer satisfaction is maintained**.** *(Customer satisfaction is monitored in customer satisfaction surveys).*
d. product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved. *(These are measured and reviewed during Management Review).*

5.2 Quality Policy

The Quality Policy at Tri Models has been established by Top Management, is appropriate to the purpose and context of the organization and supports its strategic direction. The Quality Policy provides a framework for setting quality objectives and includes a commitment to satisfy applicable requirements and a commitment to continual improvement of the QMS. The Quality Policy is available and maintained as documented information (*TMI QA-2 Quality Policy*), communicated, understood, and applied within the organization and is available to relevant interested parties, as appropriate.

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 assigns the responsibility and authority for:

a. ensuring that the QMS conforms to the requirements of AS9100D
b. ensuring that the processes are delivering their intended outputs;
c. reporting on the performance of the QMS 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 QMS is maintained when changes to the QMS are planned and implemented

The ***Quality Manager*** has been appointed by Top Management as Tri Models ***Management Representative***, who has the responsibility and authority for oversight of the above requirements. The management representative has the organizational freedom and unrestricted access to top management to resolve quality management issues.

6. Planning

6.1 Actions to Address Risks and Opportunities

When planning for the QMS, Tri Models has considered the issues referred to in 4.1, and the requirements referred to in 4.2. Top Management determines the risks and opportunities that need to be addressed to give assurance that the QMS can achieve its intended results, enhance desirable effects, prevent or reduce undesired effects, and achieve improvement. Actions planned to address these risks and opportunities are discussed annually between

all management personnel at the *Management Review Meeting,* which include PESTLE and SWOT analyses. Plans on how to integrate these actions into the QMS processes and how to evaluate the effectiveness of these actions are also made during the *Management Review Meeting.*

6.2 Quality Objectives and Planning to Achieve Them

Tri Models has established quality objectives at relevant functions, levels, and processes needed for the QMS. These quality objectives are: consistent with the quality policy; measurable; take into account applicable requirements; relevant to conformity of products and services and to enhancement of customer satisfaction; monitored; communicated; and updated; as appropriate. These quality objectives are maintained as documented information in *TMI SOP's*. When planning how to achieve our quality objectives, Tri Models determines what will be done, what resources will be required, who will be responsible, when it will be completed and how the results will be evaluated. These determinations also located in TMI SOP's.

6.3 Planning of Changes

When Tri Models determines the need for changes to the QMS, the changes are carried out in a planned manner. This plan is spelled out in *TMI SOP 7.3 Documented Information*. Items that are considered are the purpose of the changes and their potential consequences, the integrity of the QMS, the availability of resources and the allocation or reallocation of responsibilities and authorities.

7. Support

7.1 Resources

7.1.1 General

Tri Models has determined and provided the resources needed for the establishment, implementation, maintenance, and continual improvement of the QMS. *Existing resources are continually monitored and evaluated by Top Management, as well as the requirements of external providers.*

7.1.2 People

Tri Models has determined and provided the persons necessary for the effective implementation of its QMS and for the operation and control of its processes. *Personnel needs are formally reviewed and documented annually during the Management Review Meeting.*

7.1.3 Infrastructure

Tri Models has determined, provided, and maintained the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Infrastructure at Tri Models includes but is not limited to; our buildings and their associated utilities, equipment including hardware and software, transportation and information resources, and communication technology. *Determinations are made on an ongoing basis by top management.*

7.1.4 Environment for the Operation of Processes

Tri Models has determined, provided, and maintained the environment necessary for the operation of our processes and to achieve conformity of products and services. The environmental issues that have been considered includes a combination of human and physical factors, such as social, psychological, and physical. *Determinations are made on an ongoing basis by top management.*

7.1.5 Monitoring and Measuring Resources

Tri Models has determined and provided 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. Tri Models ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken and are maintained to ensure their continuing fitness for their purpose. Documented information regarding the suitability of monitoring and measurement equipment as it applies to finished product is located in *TMI R7.6 Calibration Record*. When measurement traceability is a requirement, or is considered by Tri Models to be 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 is retained in TMI R7.6 Calibrations Record).*
b. identified *by means of physical engraving of ID number on the item or labeling of the instrument case in order to determine their status.*
c. safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results. *The Quality Manager ensures that measuring equipment is safeguarded from faulty adjustments by ensuring that only individuals authorized in TMI R8.6 In-House Calibration Authorization Record make adjustments, and that equipment is stored in the locations assigned to them in TMI 7.6 Calibrations Record when not in use.*

TMI SOP 8.5 Control of Hardware & Software establishes the process for the recall of monitoring and measuring equipment requiring calibration or verification. *TMI R7.6 Calibration Record* is maintained as the register of monitoring and measuring equipment relevant to finished product which includes the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria. Monitoring and measuring equipment can include, but is not limited to: test hardware, test software, automated test equipment (ATE), and plotters used to produce verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity. Calibration or verification of monitoring and measuring equipment is carried out under suitable environmental conditions. When measuring equipment has been found to be unfit for its intended purpose, Tri Models determines if the validity of previous measurement results has been adversely affected, and takes appropriate action when necessary. *Appropriate action includes the review of recent jobs in which the tool has been used, and if invalid measurement results would affect the operability of the parts measured.*

7.1.6 Organizational Knowledge

Tri Models organizational knowledge is the collective inner workings of our advanced prototype manufacturing facility, necessary for the operation of our processes and to achieve product & service conformity. This knowledge has accumulated over the course of our nearly half-century of operation. This knowledge is determined, maintained, and is available to the extent necessary where it is used and

shared internally to achieve Tri Models objectives. When addressing changing needs and trends, Upper Management considers our current knowledge and determines how to acquire or access any necessary additional knowledge and required updates. *This knowledge is obtained through advanced training of current employees, the acquisition of new talent that furthers our capabilities, or by any other means deemed necessary.*

7.2 COMPETENCE

Tri Models determines the necessary competence of person(s) doing work under our control that affects the performance and effectiveness of the QMS. This determination is obtained by Upper Management and can be based on the presence of appropriate education, training, or experience, or any combination of these. *A yearly evaluation of employee performance is performed by individual managers and documented information in the form of Training Records is retained as evidence of competence.*

7.3 AWARENESS

Management ensures that persons doing work under Tri Model's control are aware of:

a. the quality policy
b. relevant quality objectives
c. their contribution to the effectiveness of the quality management system, including the benefits of improved performance
d. the implications of not conforming with the QMS requirements
e. relevant QMS documented information and changes thereto
f. their contribution to product or service conformity
g. their contribution to product safety
h. the importance of ethical behavior

This communication can take place in many forms such as one on one conversations, during employee evaluations, through emails, or during all-hands meetings.

7.4 COMMUNICATION

Tri Models has determined the internal and external communications relevant to the QMS, including on what it will communicate, when to communicate, with whom to communicate, how to communicate and who communicates. This communication includes internal and external feedback relevant to the QMS. *This communication is ongoing and continual between management and all Tri Models personnel.*

7.5 DOCUMENTED INFORMATION

7.5.1 GENERAL

Tri Models QMS includes documented information required by AS9100D as well as documented information determined by Tri Models as being necessary for the effectiveness of the QMS. *This documented information is retaining in the form of Procedures, Work Instructions, Records, Quality Manual, Quality Policy and Internal Audit documents.*

7.5.2 CREATING AND UPDATING

When creating and updating documented information, Tri Models ensures appropriate identification and description, format, and review and approval for suitability and adequacy before release. The process for creating and updating documented information is documented in *TMI SOP 7.3 Documented Information*. All documented information updates relevant to the QMS are retained in *TMI R4.1 Document History Record*.

7.5.3 Control of Documented Information

Documented information required by the QMS and by AS9100D is controlled to ensure it is available and suitable for use, where and when it is needed and it is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity). All documented information relevant to the QMS is controlled by the applicable authority defined in Table 7.1 in *TMI SOP7.3 Documented Information.* For the control of documented information, Tri Models addresses the following activities, as applicable:

a. distribution, access, retrieval, and use;
b. storage and preservation, including preservation of legibility;
c. control of changes (e.g., version control);
d. retention and disposition*;*
e. prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

All documented information is managed electronically at Tri Models and is protected from loss, unauthorized changes, unintended alteration, corruption, and physical damage. Documented information of external origin determined by Tri Models to be necessary for the planning and operation of the QMS is identified as appropriate, and controlled. Documented information retained as evidence of conformity is protected from unintended alterations through write protection of the QA Directory accessible only by QA employees.

8. Operation

8.1 Operational Planning and Control

Tri Models plans, implements, and controls the processes needed to meet the requirements for the provision of products and services, and implements the actions determined in clause 6, by:

a. determining the requirements for the products and services, which includes consideration of personal and product safety; producibility and inspectability; reliability, availability, and maintainability; suitability of parts and materials used in the product; selection and development of embedded software; product obsolescence; prevention, detection, and removal of foreign objects; handling, packaging, and preservation; and recycling or final disposal of the product at the end of its life.
b. establishing criteria for the processes and the acceptance of products and services;
c. determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;
d. implementing control of the processes in accordance with the criteria;
e. determining, maintaining, and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products and services to their requirements:
f. determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;

g. engaging representatives of affected organization functions for operational planning and control;
h. determining the process and resources to support the use and maintenance of the products and services;
i. determining the products and services to be obtained from external providers;
j. establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

Tri Models controls planned changes and reviews the consequences of unintended changes during Management Review, taking action to mitigate any adverse effects, as necessary. All outsourced processes/work transfers are controlled at Tri Models according to TMI SOP 8.4 Control of External Sources.

8.1.1 Operational Risk Management

TMI SOP 8.1 Operational Risk Management defines the process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to Tri Models and the products and services:

a. assignment of responsibilities for operational risk management;
b. definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);
c. identification, assessment, and communication of risks throughout operations;
d. identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;
e. acceptance of risks remaining after implementation of mitigating actions

8.1.2 Configuration Management

TMI SOP 8.8 Configuration Management defines the process as appropriate to Tri Models and its products and services that describe the requirements for identification and control of physical and functional attributes throughout the product lifecycle. This process controls product identity and traceability to requirements, including the implementation of identified changes as well as ensures that documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.

8.1.3 Product Safety

Tri Models plans, implements, and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to Tri Models and the product through engineering a factor of safety into applicable hardware.

8.1.4 Prevention of Counterfeit Parts

TMI SOP 8.4 Control of External Sources defines the process for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with customers includes providing information relating to products and services; handling enquiries, contracts, or orders, including changes; obtaining customer feedback relating to products and services, including customer complaints; handling or controlling customer property and establishing specific

requirements for contingency actions, when relevant. Communication with the customer at Tri Models is seamless, ongoing and daily. Tri Models exchanges information with our customers via transmission through secure servers, email, and/or telephone.

8.2.2 Determining the Requirements for Products and Services

When determining the requirements for the products and services to be offered to customers, Tri Models ensures that:

a. the requirements for the products and services are defined, including any applicable statutory and regulatory requirements or those considered necessary by Tri Models. These requirements are defined by the CUSTOMER'S *Statement of Work (SOW)*, CAD, Drawings, PowerPoint Presentations, or any other applicable documents or communication. Any updated requirements are retained as documented information in the *Job Action Item List* in the Communications folder of the Engineering directory.
b. Tri Models can meet the claims for the products and services it offers; (Contract Review)
c. special requirements of the products and services are determined; (Contract Review)
d. operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified. (Contract Review)

8.2.3 Review of the Requirements for Products and Services

Tri Models ensures that it has the ability to meet the requirements for products and services to be offered to customers by conducting a contract review before committing to supply products and services to the customer. This includes requirements specified by the customer, including the requirements for delivery and post-delivery activities; requirements not stated by the customer, but necessary for the specified or intended use, when known; requirements specified by Tri Models; statutory and regulatory requirements applicable to the products and services; and contract or order requirements differing from those previously expressed. If upon review it is determined that some customer requirements cannot be met or can only partially be met, Tri Models negotiates a mutually acceptable requirement with the customer. Any contract or order requirements differing from those previously defined are resolved. Customer requirements are confirmed by Tri Models before acceptance when the customer does not provide a documented statement of their requirements.

Tri Models retains documented information in the form of the *Contract Requirements Review* on the results of the review and on any new requirements for the products and services.

8.2.4 Changes to Requirements for Products and Services

Tri Models 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. These changes are documented in the form of an Engineering Work Order (EWO) for new requirements or in the form of and Engineering Change Notice (ECN) in the form of revised requirements.

9.2 Design and Development of Products and Services

8.3.1 General

TMI SOP 8.3 Design & Development defines the process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and Development Planning

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

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

8.3.3 Design and Development Inputs

The organization determines the requirements essential for the specific types of products and services to be designed and developed. The organization considers:

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***;***
f. when applicable, the potential consequences of obsolescence (e.g., materials, processes, components, equipment, products)

8.3.4 Design and Development Controls

Tri Models 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***;***
g. progression to the next stage is authorized

Participants in design and development reviews include representatives of functions concerned with the design and development stage(s) being reviewed. When tests are necessary for verification and validation, these tests are planned, controlled, reviewed, and documented to ensure and prove the following:

a. test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria;
b. test procedures describe the test methods to be used, how to perform the test, and how to record the results;
c. the correct configuration of the test item is submitted for the test;
d. the requirements of the test plan and the test procedures are observed;
e. the acceptance criteria are met

At the completion of design and development, the organization ensures that reports, calculations, test results, etc., can demonstrate that the design for the product or service meets the specification requirements for all identified operational conditions.

8.3.5 Design and Development Outputs

Tri Models 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 products and services that are essential for their intended purpose and their safe and proper provision***;***
e. specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items;
f. are approved by authorized person(s) prior to release. Release of a part in *Planning Tools* constitutes review and authorization of the part. Those individuals authorized to release data in *Planning Tools* are identified in *TMI R8.3 Data Release Authority Record.*

Tri Models defines the data required to allow the product to be identified, manufactured, verified, used, and maintained as CAD, drawings, part lists, and specifications necessary to define the configuration and the design features of the product; the material, process, manufacturing, assembly, handling, packaging, and preservation data needed to provide and maintain a conforming product or service; or the technical data and repair schemes for operating and maintaining the product.

Documented information on design and development outputs is retained definitively in the form of the *Parts List* in *Planning Tools*.

8.3.6 Design and Development Changes

Tri Models identifies, reviews, and controls changes made during, or subsequent to, design and development, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. *TMI SOP 8.3 Design & Development* defines the criteria for notifying our customers, prior to implementation, about changes that affect customer requirements. Tri Models retains documented information on design and development changes; the results of reviews; the authorization of the changes; and the actions taken to prevent adverse impacts. Updated requirements are retained as documented information in the form of an Engineering Work Order (EWO) for new requirements or in the form of an Engineering Change Notice (ECN) for revised requirements in *Planning Tools*. In order for a Design and Development change to be released, it must first be reviewed and authorized by an individual approved to do so. These individuals are documented in *TMI R8.3 Data Release Authority Record.* Therefore, the existence of an EWO or ECN

constitutes review and approval, with the date of release documenting the date of review. These design and development changes are controlled in accordance with the configuration management process identified in *TMI SOP 8.8 Configuration Management*.

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

Tri Models ensures that externally provided processes, products, and services conform to requirements, and is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer. When required, customer-designated or approved external providers, including process sources (e.g., special processes), are used. Risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers are identified and managed. Subsequently, Tri Models requires that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

Tri Models 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

Tri Models 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. Documented information of these activities and any necessary actions arising from the evaluations is retained as defined below.

TMI SOP 8.4 Control of External Sources defines the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;

TMI R7.1 Approved Supplier Record is maintained as a register of external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);

External provider performance is reviewed at least once per calendar year, including quality performance and on-time delivery performance. When external providers do not meet requirements, they are placed on a *"Conditional"* approval status until further investigation may be completed.

The requirements for controlling documented information created by and/or retained by external providers are defined in *TMI SOP 8.4 Control of External Providers.*

8.4.2 Type and Extent of Control

Tri Models ensures that externally provided processes, products, and services do not adversely affect our ability to consistently deliver conforming products and services to our customers by:

a. ensuring that externally provided processes remain within the control our QMS
b. defining both the controls that we intend to apply to our external providers and those we intend to apply to the resulting output;
c. taking into consideration:
    i. the potential impact of the externally provided processes, products, and services on our ability to consistently meet customer and applicable statutory and regulatory requirements;
    ii. the effectiveness of the controls applied by the external provider;
    iii. the results of the periodic review of external provider performance
d. determining the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements

Verification activities of externally provided processes, products, and services are performed according to the risks identified by Tri Models. These include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.

When externally provided product is released for production use pending completion of all required verification activities, it is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

When Tri Models delegates verification activities to the external provider, the scope and requirements for delegation are defined and a register of delegations is maintained. In this rare instance, Tri Models periodically monitors external provider's delegated verification activities.

When external provider test reports are utilized to verify externally provided products, Tri Models implements a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), Tri Models can verify that material in-house using a spectrometer.

8.4.3 Information for External Providers

Tri Models ensures the adequacy of requirements prior to their communication to the external provider. This is achieved by issuing Purchase Orders and flowing down requirements by referencing *TMI D7.1 Purchasing Quality Clauses Supplier Record*.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

Tri Models implements production and service provision under controlled conditions. Controlled conditions include, as applicable:

a. the availability of documented information that defines the characteristics of the products to be produced, the services to be provided, the activities to be performed, or 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;
    i. ensuring that documented information for monitoring and measurement activity for product acceptance includes:
    - criteria for acceptance and rejection;

- where in the sequence verification operations are to be performed;
- measurement results to be retained (at a minimum an indication of acceptance or rejection);
- any specific monitoring and measurement equipment required and instructions associated with their use;

ii. ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability)

d. the use of suitable infrastructure and environment for the operation of processes, which may include product specific tools (e.g., jigs, fixtures, molds) and software programs
e. the appointment of competent persons, including any required qualification;
f. the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
g. the implementation of actions to prevent human error;
h. the implementation of release, delivery, and post-delivery activities;
i. the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations)
j. the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);
k. the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
l. the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);
m. the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
n. the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
o. the provision for the prevention, detection, and removal of foreign objects;
p. the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products)
q. to the extent they affect conformity to product requirements (see 7.1.3);
r. the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

8.5.1.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to final release for production and records are maintained in *TMI R7.8 Production Equipment Record.* Storage requirements are defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

8.5.1.2 Validation and Control of Special Processes

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, Tri Models establishes arrangements for these processes including, as applicable:

a. definition of criteria for the review and approval of the processes;
b. determination of conditions to maintain the approval;

c. approval of facilities and equipment;
d. qualification of persons;
e. use of specific methods and procedures for implementation and monitoring the processes;
f. requirements for documented information to be retained.

8.5.1.3 Production Process Verification

Tri Models implements production process verification activities to ensure the production process is able to produce products that meet requirements. These activities can include risk assessments, capacity studies, capability studies, and control plans.

Tri Models uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements. This production process verification most often is referred to as First Article Inspection (FAI). The FAI is repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes). Documented information is retained on the results of the FAI in the form of *Inspection Reports*. First Article Inspections may not be required for parts that are deemed to be Fit-Form-Function (FFF).

8.5.2 Identification and Traceability

Tri Models uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The identification of the configuration of the products and services are maintained in order to identify any differences between the actual configuration and the required configuration. In addition, Tri Models identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. Controls for acceptance authority media (stamps) are identified in *TMI R7.3 Stamp Record.*

Tri Models controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability as required. This identification may come through a part's immediate proximity to identifying paperwork or by the identification of the part number on the part itself through physical means including laser etching, acid etching or marker.

8.5.3 Property Belonging to Customers or External Providers

Tri Models exercises care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. All externally owned property is identified, verified, protected, and safeguarded for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, Tri Models report this to the customer or external provider and documented information is retained on what occurred. When Tri Models receives or discharges Customer Property, it is documented into the *Customer Property Database*.

Also, see *TMI SOP 5.1 ITAR & EAR Compliance*.

8.5.4 Preservation

Tri Models preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. This may include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Preservation of outputs also includes, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:

a. cleaning;
b. prevention, detection, and removal of foreign objects;
c. special handling and storage for sensitive products;
d. marking and labeling, including safety warnings and cautions;
e. shelf life control and stock rotation;
f. special handling and storage for hazardous materials.

TMI R7.7 Age Control Log documents shelf life of items with a finite use life.

8.5.5 Post-Delivery Activities

Tri Models meets requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, Tri Models 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;
f. collection and analysis of in-service data (e.g., performance, reliability, lessons learned);
g. control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;
h. controls required for work undertaken external to the organization (e.g., off-site work);
i. product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

If problems are detected after delivery, Tri Models takes appropriate action including investigation, inspection and/or reporting where deemed necessary.

8.5.6 Control of Changes

Tri Models reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The CEO, the President, the VP of Contracts-Sales-FSO and the VP of Engineering are authorized to approve production or service provision changes. Tri Models 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

Tri Models implements planned arrangements, at appropriate stages, to verify that 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. These planned arrangements exist in many forms such as verbal communication, assigned tasks in *Project Manager,* emails, set up sheets, buy-offs, or any other requirements not stated.

Tri Models retains documented information on the release of products and services. This documented information includes evidence of conformity with the acceptance criteria as well as traceability to the person(s) authorizing the release. This documented information is kept in the job folder.

When required to demonstrate product qualification, Tri Models ensures that retained documented information provides evidence that the products and services meet the defined requirements. Documented information required to accompany the products and services are present at delivery.

Confirmation of product conformity from the Customer, either written or verbal, authorizes release of the product for delivery to the customer.

8.7 Control of Nonconforming Outputs

8.7.1 Nonconformities

Tri Models ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. In the case of nonconformities, appropriate action is taken based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

Tri Models nonconformity control process is maintained as documented information in the form of *TMI SOP 8.7 Control of Nonconforming Outputs*. This document includes provisions for:

a. defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
b. taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;
c. timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
d. defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).

Tri Models 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 by a relevant authority and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming products are only implemented:

a. after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;

b. after authorization by the customer, if the nonconformity results in a departure from the contract requirements. Product dispositioned for scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Counterfeit, or suspect counterfeit, parts are controlled to prevent reentry into the supply chain.

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

8.7.2 NCR Documentation

Tri Models retains documented information in the form of *TMI D8.4 Non-Conformity Report* 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

Tri Models periodically evaluates and retains appropriate documented information as evidence of the results on the performance and the effectiveness of the QMS. In regards to monitoring and measuring, Tri Models 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

9.1.2 Customer Satisfaction

Tri Models monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. *Customer Surveys* may be sent out to our customers after the completion of a project to gather information on the perception of Tri Models overall performance. These customer surveys include information on, but are not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. Verbal customer feedback is also taken into account and discussed between management on a continual basis. Tri Models develops and implements plans for customer satisfaction improvement that address deficiencies identified by customer feedback evaluations and assesses the effectiveness of the results. These plans may come in the form of day to day interaction or may come from more structured meetings such as the *Shop Load Meeting* or the *Management Review Meeting.*

9.1.3 Analysis and Evaluation

Tri Models analyzes and evaluates 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 QMS;
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 QMS

9.2 INTERNAL AUDIT

9.2.1 GENERAL

Tri Models conducts internal audits once per calendar year to provide information on whether the QMS conforms to the organization's own requirements for its QMS and the requirements of AS9100D and is effectively implemented and maintained. Documented information in regards to Internal Audit scheduling, evaluation dates, and records of the results are retained in *TMI R8.5 Internal Audit Record*.

9.2.2 AUDIT PROGRAM

In regards to the audit program at Tri Models, the organization ensures to:

a. plan, establish, implement, and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements, and reporting, which takes into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
b. define the audit criteria and scope for each audit;
c. select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
d. ensure that the results of the audits are reported to relevant management;
e. take appropriate correction and corrective actions without undue delay;
f. retain documented information as evidence of the implementation of the audit program and the audit results

Documented information regarding the Internal Audit program at Tri Models is retained in *TMI R8.5 Internal Audit Record*.

9.3 MANAGEMENT REVIEW

9.3.1 GENERAL

Top management at Tri Models reviews the organization's QMS, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with our strategic direction. This review occurs at least once per calendar year at the *Management Review Meeting.*

9.3.2 MANAGEMENT REVIEW INPUTS

The management review is 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 QMS;
c. information on the performance and effectiveness of the QMS, including trends in:
    i. customer satisfaction and feedback from relevant interested parties;
    ii. the extent to which quality objectives have been met;
    iii. process performance and conformity of products and services;

iv. nonconformities and corrective actions;
v. monitoring and measurement results;
vi. audit results;
vii. the performance of external providers*;*
viii. on-time delivery performance

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 include decisions and actions related to:

a. opportunities for improvement;
b. any need for changes to the QMS;
c. resource needs;
d. risks identified

Documented information as evidence of the results of management reviews is retained in the form of the *Management Review* document.

10. Improvement

10.1 General

Tri Models determines and selects opportunities for improvement (eg. correction, corrective action, continual improvement, breakthrough change, innovation, and re-organization), and implements any necessary actions to meet customer requirements and enhance customer satisfaction. These may 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 QMS

10.2 Nonconformity and Corrective Action

10.2.1 Nonconformity & CA Process

In the instance of nonconformity, Tri Models takes action to:

a. react to the nonconformity and, as applicable, take action to control and correct it and 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:
   i. reviewing and analyzing the nonconformity;
   ii. determining the causes of the nonconformity, including, as applicable, those related to human factors;
   iii. 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 QMS, if necessary;

g. flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;
h. take specific actions when timely and effective corrective actions are not achieved

Corrective actions are appropriate to the effects of the nonconformities encountered. *TMI SOP 10.1 Improvement* is maintained as documented information that defines the nonconformity and corrective action management processes.

10.2.2 NCR & CA Documented Information

Tri Models retains documented information of as evidence of the nature of the process nonconformities and any subsequent actions taken, as well as the results of any corrective action

10.3 Continual Improvement

Tri Models continually improves the suitability, adequacy, and effectiveness of our QMS. The results of analysis, evaluation, and the outputs from management review are considered to determine if there are needs or opportunities that must be addressed as part of this continual improvement. The implementation of improvement activities and evaluation of the effectiveness of the results are monitored in the *Management Review Meeting document,* and may also be monitored in *TMI D8.2 Corrective Action Report* and *TMI R8.2 Corrective Actions Record.*