Concept Reality

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Vancouver, WA 98665

ISO 9001:2015/AS9100D
CERTIFIED

ITAR Registered

QUALITY MANUAL INDEX

1. Scope

The true measure of quality at Concept Reality is customer satisfaction because customer satisfaction and the quality of our products continue to be the keys to our success. It is increasingly vital to understand and use our QMS to do the best job, the first time, every time.

Scope of the quality management system

The company's scope of the quality management system for AS9100D is: Concept Reality is a provider of multi-axis precision CNC machining and assembly supporting commercial and aerospace industries.

Non-Applicable: 8.3 Design and Development of Products and Services. 8.3 does not apply because no design and develop activities occur at Concept Reality. Product requirements are provided to Concept Reality by the customers.

Strategic direction of the company

It is the goal of Concept Reality to implement a quality standard to improve the daily and overall processes currently in place. By doing this implementation, Concept Reality will be able to measure, improve, and maintain the highest level of quality and safety for all products manufactured. This will guarantee success for both the company and its customers.

2. Normative references

The following referenced documents are indispensable for the application of this document. ISO 9000:2015, Quality management systems - Fundamentals and vocabulary
ISO 9001:2015, Quality management systems – Requirements

3. Terms and definitions

For this document, the terms and definitions given in AS9100D and ISO 9000:2015 apply.

4. Context of the organization

4.1 Understanding the organization and its context

External Issues: Volatility in material costs, market demand for available services, availability of resources, lead time for outside services, and regulations of governing bodies.
Internal Issues: Lack of properly implemented QMS, inability to branch into more lucrative fields, balancing customer expectations/OTD/Quality, resource challenges of small company.

4.2 Understanding the needs and expectations of interested parties.

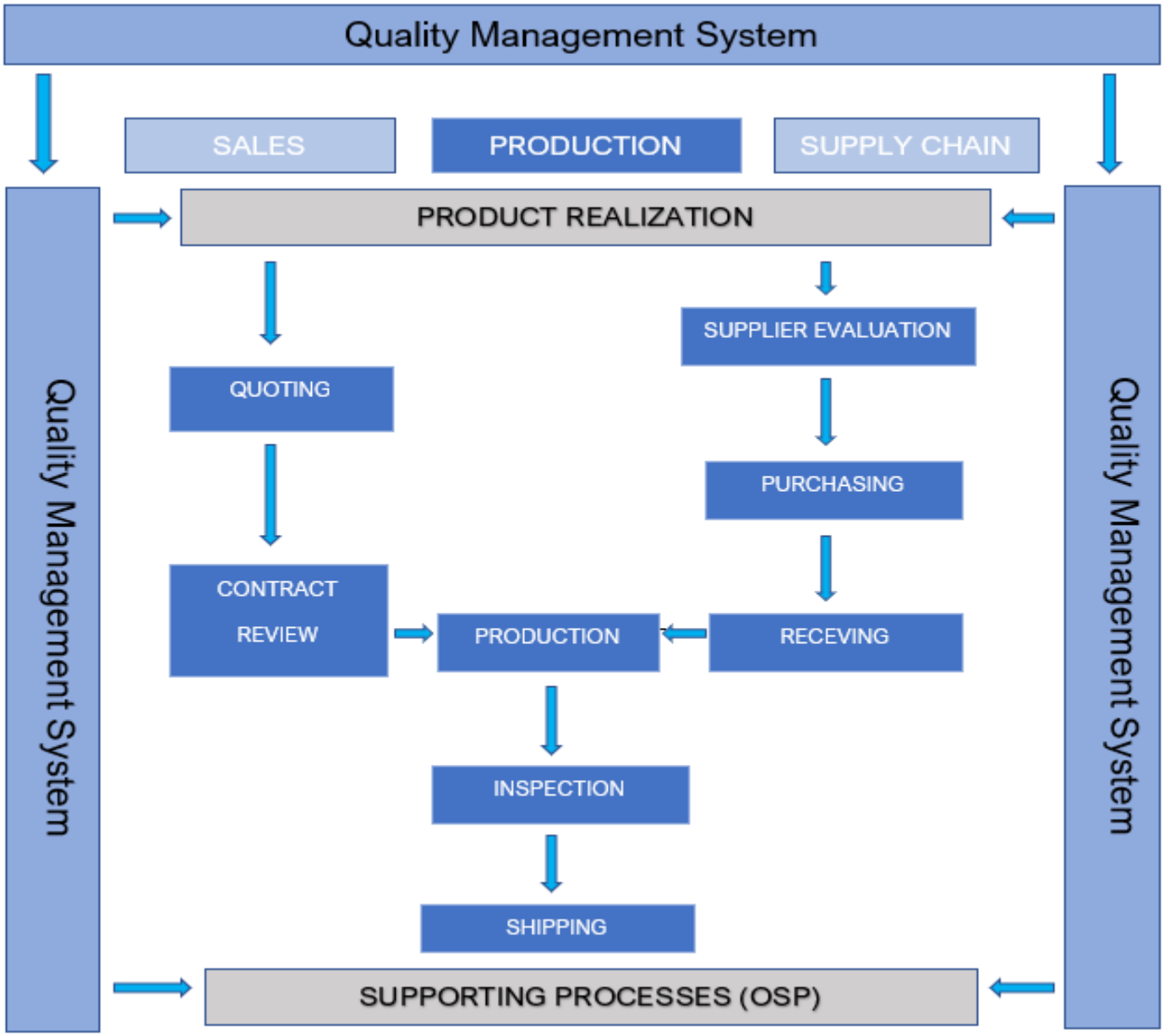
- **Customers**: Have confidence in a reliable source that can consistently produce quality products and services that meet their specifications.
- **Employees**: Safe and healthy working environment with job security and the possibility to receive promotions, recognition, and rewards for increased performance.
- **Owners**: Growth in market value of organization, profitability, and return on investments.
- **Management**: Increased efficiency of operations and performance that in turn increases employee satisfaction and profitability.
- **Suppliers**: Receive clear purchasing requirements with achievable lead times and increased business from customers.
- **Statutory and Regulatory Bodies**: Compliance to laws and regulations under their auspices. Prompt response to requests for information.

4.3 Determining the scope of the quality management system

The boundaries of the QMS are all sets of company sanctioned activities relevant to product development.

4.4 Quality management system and its processes

4.4.1 Quality management system and its processes cont.



Every key process has a *QMSF-1016 Process Data Sheet, and QMSF-1045 SWOT Analysis Worksheet* can be utilized.

4.4.2 Quality management system and its processes cont.

The organization maintains and retains all required documented information.

5. Leadership

5.1 Leadership and commitment

5.1.1 General

Top management demonstrates leadership and commitment to the QMS by:

- Implementing a QMS compatible with established business processes.
- Training staff on the benefits of adopting risk mitigating processes and reviewing these benefits at all staff meetings and employee reviews.
- Utilizing the bulletin board to communicate improved progress against intended goals.
- Having periodic Management Review Meetings to support participation of relevant management in decision making and to review:
    - The effectiveness of the QMS.
    - The quality policy, objectives, and strategic direction of the QMS.
    - Resource availability.
    - Process performance indicators against intended process goals.

5.1.2 Customer Focus

Top management demonstrates leadership and commitment to customer focus by:

- Utilizing *QMSP-1003 Requirements Review* and *QMSM-1009 Order Entry* to ensure all known requirements are communicated and met.
- Utilizing *QMSF-1014 Contract Review* to determine and address all risks.
- Reviewing satisfaction using *QMSF-1002 Customer Survey*.
- Reviewing NCR's and OTD against intended goals and opening CAPA's if needed.

5.2 Policy

5.2.1 Establishing the quality policy

Quality Policy: Concept Reality provides safe and satisfactory products through constant and continual scrutiny, implementation, and improvement of a QMS that ensures we are producing deliverables that meet all known requirements.

Quality Objectives will always be displayed, updated, and communicated on the quality board.

5.2.2 Communicating the quality policy

The quality policy is posted on the quality board and available to interested parties upon request.

Organizational roles, responsibilities, and authorities

The Quality Manager is the management representative and is responsible for the requirements in section 5.3 of the AS9100D standard. Additional roles are in *QMSD-1002 Organization chart*.

6. Planning

6.1 Actions to address risks and opportunities.

6.1.1 Actions to address risks and opportunities cont.

When planning for the QMS, sections 4.1 and 4.2 were used to determine the risks and opportunities that need to be addressed to give assurance the QMS can achieve its intended results, enhance desirable effects, prevent, or reduce undesired effects, and achieve improvement.

6.1.2 Actions to address risks and opportunities cont.

The company has planned the actions needed to address identified risks and opportunities using *QMSF-1015 PFMEA* and (or), CAPA's.

6.2 Quality objectives and planning to achieve them

6.2.1 Quality objectives and planning to achieve them cont.

The quality objectives are relevant to the goals of the QMS and reviewed at all MRM. They are posted, updated, and communicated on the quality bulletin board.

6.2.2 Quality objectives and planning to achieve them cont.

The quality manager is responsible for monitoring progress toward quality objectives on an ongoing basis. The company reviews the progress of this planning at all MRM's.

6.3 Planning of changes

When the need for changes to the QMS are identified, all risk factors are considered, and the changes are added to the agenda of the MRM to be evaluated for effectiveness.

7. Support

7.1 Resources

7.1.1 General

During MRM's the company evaluates internal and external resources that need to be obtained for the implementation, maintenance, and continual improvement of the QMS.

7.1.2 People

During MRM's the company evaluates the persons necessary for the operation and control of the QMS.

7.1.3 Infrastructure

Each Manager periodically assesses the necessary infrastructure in his/her area(s) of responsibility, determined during MRMs, for continued suitability.

7.1.4 Environment for the operation of processes

It is the responsibility of each Manager to identify and manage the social, psychological, and physical factors of the work environment that are deemed necessary for a harmonious workplace.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

When monitoring or measuring is used to verify product conformity the company ensures that the resources provided to verify the conformity are suitable, maintained, and retained with the use of *QMSP-1003 Requirements Review* and *QMSP-1014 Calibration Procedure*.

7.1.5.2 Measurement traceability

Where measurement traceability is a requirement measuring equipment is controlled according to *QMSP-1014 Calibration Procedure* and documented using *QMSF-1021 Calibration log*.

7.1.6 Organizational knowledge

All *QMS* documents are available to all employees and the knowledge or need to acquire additional knowledge is evaluated at all MRM's.

7.2 Competence

The organization evaluates competence at time of hire and during annual employee evaluations. Records of employee competence are kept on forms *QMSF-1011 Employee Performance Evaluation*, *QMSF-1018 Job Description,* and in the ERP/NAS Drive training records.

7.3 Awareness

The company ensures that people doing work under the organization's control are aware of all QMS requirements by communication through the quality bulletin board and training.

7.4 Communication

Management or designers communicate on an ongoing basis with both external and internal parties. Communication occurs via email, the quality board, verbal interactions, etc.

7.5 Documented Information

7.5.1 General

The company's QMS includes documentation required by the AS9100D standard as well as any information it has deemed necessary for its operation and effectiveness.

7.5.2 Creating and updating

When creating and updating documented information the organization has ensured appropriate controls with *QMSP-1001 Control of Documents*.

7.5.3 Control of documented information

7.5.3.1 Control of documented information cont.

Documented information required by the QMS is controlled according to *QMSP-1001 Control of Documents*.

8. Operation

8.1 Operational planning and control

The company can responsibly implement the actions in Clause 6 through project planning, training, process controls, inspection, CAPA's, and MRM's.

8.1.1 Operational Risk Management

The company has planned, implemented, and controlled a process for managing operational risks with *QMSP-1008 Risk Management.*

8.1.2 Configuration Management

The organization has planned, implemented, and controlled a process for configuration management with *QMSP-1007 Configuration Management*.

8.1.3 Product Safety

When a product has characteristics related to human safety, the company assures that safety is maintained for the entire product life cycle by identifying safety critical items during the sales process, recording safety incidents, and evaluating changes or training needs during MRM's.

8.1.4 Prevention of Counterfeit Parts

The company provides training for all personnel on awareness and prevention of counterfeit parts as well as maintains a quarantined area for counterfeit, suspect, or NC product until dispositioned. When required, the company checks the traceability of products to their original source or authorized manufacturers/distributors during receiving process.

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers may include product and service-related information, job-related feedback, handling of customer property, or requirements for contingency actions.

8.2.2 Determining requirements for products and services

The company reviews product/service requirements per *QMSP-1003 Requirements Review*.

8.2.3 Review of the requirements related to products and services

8.2.3.1 Review of the requirements cont.

The company reviews product/service requirements per *QMSP-1003 Requirements Review*.

8.2.3.2 Review of the requirements cont.

As needed, the company retains information on reviews per *QMSP-1003 Requirements Review.*

8.2.4 Changes to requirements for products and services

When the requirements for products and services are changed, relevant documented information is amended, re-released, and relevant persons are notified of changes.

8.3 Design and development of products and services (not applicable)

This clause is Not Applicable because all designs are supplied to the company by its customers.

Control of externally provided processes, products, and services

8.4.1 General

The company ensures that externally provided processes, products, and services, including those from sources defined by the customer, conform to requirements with *QMSP-1009 Control of external products and services*

8.4.1.1 General cont.

The criteria for the evaluation, selection, performance monitoring, re-evaluation, and control of external providers is outlined in *QMSP-1004 Supplier Evaluation*.

8.4.2 Type and extent of control

The company ensures that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers using *QMSP-1004 Supplier Evaluation*.

8.4.3 Information for external providers

The company communicates to external providers using PO's, its terms and conditions, and a flow down of any customer requirements.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

The customer print and Job Traveler/Router is designed to ensure that all risks, requirements, and specifications of the product are identified, communicated, and recorded. It is the top level of control during product provision and outlines all the criteria for inspection, infrastructure and handling, configuration, needed processes, workmanship, and final acceptance/release to customer. Compliance to the router is supported by all processes, trainings, and applicable QMS documents.

a. See Job Travelers/Routers.
b. See *QMSP-1014 Calibration Procedure* and *QMSP-1021 Calibration Log.*
c. See Job Travelers/Routers.
d. See Job Travelers/Routers.
e. See *QMSF-1018 Job Description*'s and training records.
f. If the company develops any special processes, they will be validated and periodically revalidated. The documented information regarding the validation will be retained.
g. See *QMSP-1008 Risk Management.*
h. Post-delivery activities are not standard practice and will be assessed and agreed on with the customer should the need arise.

i. See Job Travelers/Routers and customer supplied documents for the criteria for workmanship.
j. See job travelers/routers.
k. See job travelers/routers and inspection reports.
l. See *QMSP-1014 Calibration Procedure and regular maintenance*.
m. See job travelers/routers.
n. See job travelers/routers and inspection reports.
o. All employees are trained for FOD and work benches are organized to mirror 5S standards.
p. SDS are kept for all production products and supply monitoring occurs during maintenance.
q. See Job Travelers/Routers, permanent parts library, and inspection reports.

8.5.1.1 Control of Equipment, Tools, and Software Programs

All equipment, tools, and software programs are validated prior to final release for production. Storage requirements for production equipment or tooling in storage are defined, if necessary.

8.5.1.2 Validation and Control of Special Processes

The organization will establish arrangements for special processes should they occur.

8.5.1.3 Production Process Verification

The routers may include a first piece or in-process inspection after each production process to verify process conformity. When required, an FAI is performed to verify the process is capable of producing conforming product, the results of this inspection and verification are kept on AS9102 FAIR or, CMM inspection report, and *QMSF-1012 In process Inspection Report* (if applicable).

8.5.2 Identification and traceability

Unless otherwise stated on the Job Traveler/Router, all final inspections are performed using measurement equipment controlled according to *QMSP-1014 Calibration*. Records of actual measurement outputs are recorded on the customer print, or an inspection report. Verification of inspection and validation are recorded on the Job Traveler/Router. When traceability is a requirement, records of the product manufacturing are kept from material to its final destination.

8.5.3 Property belonging to customers or external providers

All customer/vendor property is inspected and labeled as such when it arrives at the company. All customer/vendor property is verified during all inspections and documented information is retained. When customer/vendor property is found to be nonconforming, applicable reports are created per *QMSP-1005 Nonconformance Procedure* and customer is notified of instance.

8.5.4 Preservation

All products are properly identified, handled, packaged, shipped, and stored with care throughout the entire production or service process as outlined in the Job Traveler/Router.

8.5.5 Post-delivery activities

Concept Reality produces parts to customer specifications and often does not know the nature, use, and intended lifetime. Customer feedback/support handling are standard practice and post-delivery problems are handled according to *QMSP-1005 Nonconformance Procedure*. Associated NCR's and data updates are handled by the quality manager during job review.

8.5.6 Control of changes

Changes to processes, equipment, tools, or software that could affect product conformity can only be approved by management. Inspection will occur after changes are made and if required, a full or partial FAI will be completed to verify continuing conformity of products. A deviation letter or email from the customer should be obtained to authorize changes. Additionally, a deviation letter may need to be sent with the new FAI or product shipment.

8.6 Release of products and services

The Job Traveler/Router outlines the intervals, verification activities to be performed, and applicable documentation required for final product release. Inspection reports with review data are kept and inspector signatures captured on the Job Traveler/Router.

8.7 Control of nonconforming outputs

8.7.1 Control of nonconforming outputs cont.

Outputs that do not conform to communicated requirements are controlled per *QMSP-1005 Control of Nonconforming Product*.

8.7.2 Control of nonconforming outputs cont.

Documented nonconformity information is retained in the ERP system nonconformance/CAPA module.

9. Performance evaluation

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1 General

All objectives and KPI's necessary to evaluate the performance/effectiveness of the QMS are monitored on an ongoing basis. Process audits occur periodically, and the result of this monitoring is evaluated during MRM's and recorded on *QMSF-1013 Management Review.*

9.1.2 Customer satisfaction

Customer Satisfaction is determined using *QMSF-1002 Customer Survey.* Any deficiencies identified by customers is reviewed during MRM's where plans for improvement are proposed. Actions taken to address open customer issues will be reviewed at the following MRM.

9.1.3 Analysis and Evaluation

The company uses periodic MRMs to analyze and evaluate monitoring and measurement data.

9.2 Internal Audit

9.2.1 Internal audit cont.

Internal audits of key processes are planned and conducted per *QMSD-1003 Internal Audit Plan.*

9.2.2 Internal audit cont.

QMSD-1003 Internal Audit Plan outlines the frequency and requirements of key process audits. Internal audits may be conducted by process owners or qualified external providers. Audits are conducted by gathering objective evidence and recorded on *QMSF-1022 Process Audit Sheet.*

9.3 Management review

9.3.1 General

The effectiveness and suitability of the QMS is reviewed during management review meetings.

9.3.2 Management review inputs

Every 6 months, an MRM is held to review all the subjects outlined on *QMSF-1013 Management Review* and any other issues relevant to the performance or needs of the QMS.

9.3.3 Management review outputs

The decisions/actions arising from the MRM are recorded on *QMSF-1013 Management Review*.

10. Improvement

10.1 General

OFI's are decided at MRM's and audits, based off the performance of the QMS and customer satisfaction.

10.2 Nonconformity and corrective action

10.2.1 Nonconformity and corrective action cont.

All nonconformances are handled in accordance with *QMSP-1005 Control of Nonconforming Product* and *QMSP-1006 Corrective Actions.*

10.2.2 Nonconformity and corrective action cont.

All nonconformances and CAPA information is documented in ERP system.

10.3 Continual improvement

Concept Reality uses monitoring and measurement activities, corrective actions, audits, and MRMs to fix known issues, implement the best practices, and continually improve the QMS.

- **Appendix A**

For the purposes of this document, the following terms and definitions given in ISO 9000:2015 apply, with five new definitions in AS9100D:

3.01 Organization
Person or group of people that has its own *functions* (3.25) with responsibilities, authorities, and relationships to achieve its *objectives* (3.08)
Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, association, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

3.02 Interested party
Person or *organization* (3.01) that can affect, be affected by, or perceive themselves to be affected by a decision or activity

3.03 Requirement
Need or expectation that is stated, generally implied or obligatory
Note 1 to entry: "Generally implied" means that it is custom or common practice for the *organization* (3.01) and *interested parties* (3.02) that the need or expectation under consideration is implied.
Note 2 to entry: A specified requirement is one that is stated, for example in *documented information* (3.11).
Note 3 to entry: A qualifier can be used to denote a specific type of requirement e.g. *product* (3.47) requirement, *quality management* (3.30) requirement, *customer* (3.26) requirement, and quality requirement.
Note 4 to entry: Requirements can be generated by different *interested parties* (3.02).
Note 5 to entry: It can be necessary for achieving high *customer satisfaction* (3.57) to fulfill an expectation of a *customer* (3.26) even if it is neither stated nor generally implied or obligatory.

3.04 Management system
Set of interrelated or interacting elements of an *organization* (3.01) to establish *policies* (3.07) and *objectives* (3.08) and *processes* (3.12) to achieve those *objectives*
Note 1 to entry: A management system can address a single discipline or several disciplines e.g. *quality management* (3.30), financial *management* (3.29) or environmental *management*.
Note 2 to entry: The management system elements establish the *organization's* (3.01) structure, roles and responsibilities, planning, operation, *policies* (3.07), practices, rules, beliefs, *objectives* (3.08) and *processes* (3.12) to achieve those *objectives*.
Note 3 to entry: The scope of a management system may include the whole of the *organization* (3.01), specific and identified *functions* (3.25) of the *organization*, specific and identified sections of the *organization*, or one or more *functions* across a group of *organizations*.

3.05 Top management
Person or group of people who directs and controls an *organization* (3.01) at the highest level
Note 1 to entry: Top management has the power to delegate authority and provide resources within the *organization* (3.01).
Note 2 to entry: If the scope of the *management system* (3.04) covers only part of an *organization* (3.01), then *top management* refers to those who direct and control that part of the *organization*.

3.06 Effectiveness
Extent to which planned activities are realized and planned results achieved

3.07 Policy
Intentions and direction of an *organization* (3.01), as formally expressed by its *top management* (3.05)

3.08 Objective
Result to be achieved
Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, *product* (3.47), *service* (3.48), and *process* (3.12)).
Note 3 to entry: An objective can be expressed in other ways (e.g. as an intended outcome, a purpose, an operational criterion, as a *quality* objective (3.37)), or by the use of other words with similar meaning(e.g. aim, goal, or target).
Note 4 to entry: In the context of *quality management systems* (3.33), quality objectives are set by the *organization* (3.01), consistent with the *quality policy* (3.34), to achieve specific results.

3.09 Risk
Effect of uncertainty on an expected result
Note 1 to entry: An effect is a deviation from the expected — positive or negative
Note 2 to entry: Uncertainty is the state, even partial, of deficiency of *information* (3.50) related to, understanding or *knowledge* (3.53) of, an event, its consequence, or likelihood.
Note 3 to entry: Risk is often characterized by reference to potential "events" (as defined in ISO Guide 73:209, 3.5.1.3) and "consequences" (as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.
Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated "likelihood" (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.
Note 5 to entry: The term "risk" is sometimes used when there is only the possibility of negative consequences.

3.10 Competence
Ability to apply *knowledge* (3.53) and skills to achieve intended results
Note 1 to entry: Demonstrated competence is sometimes referred to as qualification.

3.11 Documented information
Information (3.50) required to be controlled and maintained by an *organization* (3.01) and the medium on which it is contained
Note 1 to entry: Documented information can be in any format and media and from any source.
Note 2 to entry: Documented information can refer to:
- The *quality management system* (3.33), including related *processes* (3.12);
- *Information* (3.50) created in order for the *organization* (3.01) to operate (documentation);
- Evidence of results achieved (records).

3.12 Process
Set of interrelated or interacting activities which transforms inputs into *outputs* (3.46)
Note 1 to entry: Inputs to a process are generally outputs (3.46) of other processes.
Note 2 to entry: In some processes, some inputs become *outputs* (3.46) without any transformation e.g. a blueprint used in a manufacturing process or a catalyst in a chemical process.
Note 3 to entry: Processes in an *organization* (3.01) are generally planned and carried out under controlled conditions to add value.
Note 4 to entry: A process where the *conformity* (3.18) of the resulting *output* (3.46) cannot be readily or economically validated is frequently referred to as a "special process".

3.13 Performance
Measurable result
Note 1 to entry: Performance can relate either to quantitative or qualitative findings.
Note 2 to entry: Performance can relate to the *management* (3.29) of activities, *processes* (3.12), *products* (3.47), *services* (3.48), *systems* (3.31) or *organizations* (3.01).

3.14 Outsource (verb)
Arrange where an external *organization* (3.01) performs part of an organization's
function (3.25) or *process* (3.12)
Note 1 to entry: An external *organization* (3.01) is outside the scope of the *management system* (3.04), although the outsourced *function* (3.25), or *process* (3.12), is within the scope.

3.15 Monitoring

Determining (3.67) the status of a *system* (3.31), a *process* (3.12) or an activity
Note 1 to entry: To determine the status, there may be a need to check, supervise or critically observe.
Note 2 to entry: Monitoring is generally a *determination* (3.67) of the *object* (3.36) being monitored, carried out at different stages or at different times.

3.16 Measurement
Process (3.12) to *determine* (3.67) a value
Note 1 to entry: According to ISO 3534-2:2006 the value determined is generally the value of a quantity.

3.17 Audit
Systematic and independent *process* (3.12) for obtaining *objective evidence* (3.61) and evaluating it objectively to determine the extent to which the *audit criteria* (3.60) are fulfilled
Note 1 to entry: An audit can be an internal audit (first party), or an external audit (second party or third party), and it can be a combined audit or a joint audit.
Note 2 to entry: Internal audits, sometimes called first-party audits are conducted by, or on behalf of, the *organization* (3.01) itself for *management* (3.29) *review* (3.68) and other internal purposes and may form the basis for an organization's declaration of *conformity* (3.18). In many cases, particularly in smaller *organizations*, independence can be demonstrated by the freedom from responsibility for the activity being audited.
Note 3 to entry: External audits include those generally called second and third-party audits. Second party audits are conducted by parties having an interest in the *organization* (3.01), such as *customers* (3.26), or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations.

3.18 Conformity
Fulfillment of a *requirement* (3.03)
Note 1 to term: In English the word 'conformance' is synonymous but deprecated. In French the word 'compliance' is synonymous but deprecated.

3.19 Nonconformity
Non-fulfillment of a *requirement* (3.03)

3.20 Corrective action
Action to eliminate the cause of nonconformity (3.19) and to prevent recurrence
Note 1 to definition: There can be more than one cause for nonconformity (3.19).
Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

3.21 Continual improvement
Recurring activity to enhance *performance* (3.13)
Note 1 to entry: The *process* (3.12) of establishing *objectives* (3.08) and finding opportunities for *improvement* (3.28) is a continual *process* through the use of *audit findings* (3.62) and audit conclusions, analysis of *data* (3.49), *management* (3.29) *reviews* (3.68) or other means and generally leads to *corrective action* (3.21) or preventive action.

3.22 Correction
Action to eliminate a detected *nonconformity* (3.19)
Note 1 to entry: A correction can be made in conjunction with a *corrective action* (3.21).
Note 2 to entry: A correction can be, for example, rework or regrade.

3.23 Involvement
Engagement in, and contribution to, shared *objectives* (3.08)

3.24 Context of the organization
Business environment combination of internal and external factors and conditions that can have an effect on an *organization's* (3.01) approach to its *products* (3.47), *services* (3.48) and investments and *interested parties* (3.02)
Note 1 to entry: The concept of context of the organization is equally applicable to not-for-profit or public *service* (3.48) *organizations* (3.01) as it is to those seeking profits.

Note 2 to entry: In English this concept is often referred to by other phrases such as business environment, organizational environment or ecosystem of an *organization* (3.01).

3.25 Function
Role to be carried out by a designated unit of the *organization* (3.01)

3.26 Customer
Person or *organization* (3.01) that could or does not receive a *product* (3.47) or a *service* (3.48) is intended for or required by this person or *organization*
Note to entry: A customer can be internal or external to the *organization* (3.01). Customers outside of the *organization* are external customers. The *output* (3.46) of each internal *process* (3.12) is the input of the next *process*. The next *process* is the internal customer of the preceding *process*.

3.27 Supplier/Provider
Person or *organization* (3.01) that provides a *product* (3.47) or a *service* (3.48)

Note 1 to entry: A provider can be internal or external to the *organization* (3.01).
Note 2 to entry: In a contractual situation, a supplier is sometimes called a "contractor".

3.28 Improvement
Activity to enhance *performance* (3.13)
Note to entry: Improvement can be achieved by a recurring or by a singular activity.

3.29 Management
Coordinated activities to direct and control an *organization* (3.01)
Note 1 to entry: Management can include establishing *policies* (3.07) and *objectives* (3.08) and *processes* (3.12) to achieve these *objectives*.
Note 2 to entry: The term "management" sometimes refers to people, i.e. a person or group of people with authority and responsibility for the conduct and control of an *organization* (3.01). When "management" is used in this sense, it should always be used with some form of qualifier to avoid confusion with the concept of "management" as a set of activities defined above. For example, "management shall…" is deprecated whereas "*top management* (3.05) shall…" is acceptable. Otherwise, different words should be adopted to convey the concept when related to people e.g. managerial or managers.

3.30 Quality management
Management (3.29) with regard to *quality* (3.37)
Note to entry: Quality management generally includes establishment of the *quality policy* (3.34) and *quality objectives* (3.45), quality planning, quality control, quality assurance and quality improvement.

3.31 System
Set of interrelated or interacting elements

3.32 Infrastructure
System (3.31) of facilities, equipment, and *services* (3.48) needed for the operation of an *organization* (3.01)

3.33 Quality management system
Management system (3.04) with regard to *quality* (3.5.2)

3.34 Quality policy
Policy (3.07) related to *quality* (3.37)
Note 1 to entry: Generally, the quality policy is consistent with the overall *policy* (3.07) of the *organization* (3.01), can be aligned with the *organization's* vision and mission and provides a framework for the setting of *quality objectives* (3.45).
Note 2 to entry: *Quality management* (3.30) principles presented in this International Standard can form a basis for the establishment of a *quality policy* (3.34)

3.35 Strategy
Planned activities to achieve an *objective* (3.08).

3.36 Object
Entity anything perceivable or conceivable
Note 1 to entry: Objects may be material (e.g. an engine, a sheet of paper, a diamond), immaterial (e.g. conversion ratio, a project plan) or imagined (e.g. a unicorn).

3.37 Quality
Degree to which a set of inherent *characteristics* (3.65) of an *object* (3.36) fulfills *requirements* (3.03)
Note 1 to entry: The term "quality" can be used with adjectives such as poor, good or excellent.
Note 2 to entry: "Inherent", as opposed to "assigned", means existing in the *object* (3.36).

3.38 Statutory requirement
Obligatory *requirement* (3.03) specified by a legislative body

3.39 Regulatory requirement
Obligatory *requirement* (3.03) specified by an authority mandated by a legislative body

3.40 Defect
Nonconformity (3.19) related to an intended or specified use
Note 1 to entry: The distinction between the concepts defect and *nonconformity* (3.19) is important as it has legal connotations; particularly those associated with *product* (3.47) *and service* (3.48) liability issues.
Note 2 to entry: The intended use as intended by the *customer* (3.26) can be affected by the nature of the *information* (3.50), such as operating or maintenance instructions, provided by the *supplier* (3.27).

3.41 Traceability
Ability to trace the history, application, or location of an *object* (3.36)
Note 1 to entry: When considering *a product (3.47) or a service* (3.48), traceability can relate to:
- The origin of materials and parts.
- The processing history; and
- The distribution and location of the *product* (3.47) *or service* (3.48) after delivery.
Note 2 to entry: In the field of metrology the definition in ISO/IEC GUIDE 99: 2007, is the accepted definition.

3.42 Innovation
Process (3.12) resulting in a new or substantially changed *object* (3.36)
Note 1 to entry: The *object* (3.36) for the purpose of innovation can be e.g. a *management system* (3.04), a *process* (3.12), a *product* (3.47), *a service* (3.48) or technology.

3.43 Contract
Binding agreement

3.44 Design and development
Set of processes (3.12) that transforms *requirements* (3.03) for an *object* (3.36) into more detailed requirements
Note 1 to entry: The *requirements* (3.03) forming input to design and development can be expressed in a broader, more general sense than the requirements forming the *output* (3.46) of design and development. In a project there can be several design and development stages.
Note 2 to entry: In English the words "design" and "development" and the term "design and development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development. In French the words "conception" and "development" and the term "conception et development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development.
Note 3 to entry: A qualifier can be applied to indicate the nature of what is being designed and developed, e.g. *product* (3.47) design and development, or *process* (3.12) design and development.

3.45 Quality objective
Objective (3.08) related to *quality* (3.37)
Note 1 to entry: Quality objectives are generally based on the *organization*'s (3.01) *quality policy* (3.34).
Note 2 to entry: Quality objectives are generally specified for relevant *functions* (3.25) and levels in the *organization* (3.01).

3.46 Output
Result of a *process* (312)
Note 1 to entry "output": There are four generic output categories, as follows:
- Services (e.g. transport);
- Software (e.g. computer program, dictionary);
- Hardware (e.g. engine mechanical part);
- processed materials (e.g. lubricant).

Many outputs comprise elements belonging to different generic output categories. Whether the output is then called service, product, software, hardware, or processed material depends on the dominant element. For example, a car consists of hardware (e.g. tires), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).
Note 2 to entry "output": The ownership of a product can usually be transferred. This is not necessarily the case for a service.

3.47 Product
Output (3.46) that is a result of activities where none of them necessarily is performed at the interface between the *provider* (3.27) and the *customer* (3.26)
Note 1 to entry "product": Hardware is generally tangible, and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods. Software consists of information and is generally intangible and can be in the form of approaches, transactions or *documented information* (3.11).

3.48 Service
Intangible *output* (3.46) that is the result of at least one activity necessarily performed at the interface between the provider and the customer
Note 1 to entry "service": Provision of a service can involve, for example, the following:
- an activity performed on a customer-supplied tangible product (e.g. a car to be repaired);
- an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);
- the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);
- the creation of ambience for the customer (e.g. in hotels and restaurants);

A service is usually experienced by the customer.

3.49 Data
Facts about an *object* (3.36)

3.50 Information
Meaningful *data* (3.49)

3.51 Objective evidence
Data (3.49) supporting the existence or verity of something
Note 1 to entry: Objective evidence may be obtained through observation, *measurement* (3.16), test, or other means.
Note 2 to entry: Objective evidence for the purpose of *audit* (3.17) generally consists of records, statements of fact or other *information* (3.50) which are relevant to the *audit criteria* (3.60) and verifiable

3.52 Information system
<QMS> network of communication channels used within an *organization* (3.01)

3.53 Knowledge

Available collection of *information* (3.50) being a justified belief and having a high certainty to be true

3.54 Verification
Confirmation, through the provision of *objective evidence* (3.51), that specified *requirements* (3.03) have been fulfilled
Note 1 to entry: The objective evidence needed for verification can be the result of an inspection or of other forms of *determination* (3.67) such as performing alternative calculations or reviewing *documented information* (3.11).
Note 2 to entry: The activities carried out for verification are sometimes called a qualification *process* (3.12)
Note 3 to entry: The word "verified" is used to designate the corresponding status.

3.55 Validation
Confirmation, through the provision of objective evidence, that the *requirements* (3.03) for a specific intended use or application have been fulfilled
Note 1 to entry: The *objective evidence* (3.51) needed for a validation is the result of a test or other form of *determination* (3.67) such as performing alternative calculations or reviewing *documented information* (3.11).
Note 2 to entry: The word "validated" is used to designate the corresponding status.
Note 3 to entry: The use conditions for validation can be real or simulated.

3.56 Feedback
Opinions, comments, and expressions of interest in a product, a service or a complaints-handling process

3.57 Customer satisfaction
Customer's (3.26) perception of the degree to which the customer's expectations have been fulfilled
Note 1 to entry: It can be that the *customer's* (3.26) expectation is not known to the *organization* (3.01) or even to himself/herself until the *product* (3.47) or *service* (3.48) is delivered. It can be necessary for achieving high customer satisfaction to fulfill the expectations of a *customer* even if it is neither stated nor generally implied or obligatory.
Note 2 to entry: *Complaints* (3.58) are a common indicator of low customer satisfaction, but their absence does not necessarily imply high customer satisfaction.
Note 3 to entry: Even when *customer* (3.26) *requirements* (3.03) have been agreed with the *customer* and fulfilled, this does not necessarily ensure high customer satisfaction.
Note 4 to entry: See ISO 10004, *Quality Management — Customer satisfaction — Guidelines for monitoring and measuring*.

3.58 Complaint
<customer satisfaction> expression of dissatisfaction made to an *organization* (3.01), related to its *product* (3.47) or *service* (3.48), or the complaints-handling *process* (3.12) itself, where a response or resolution is explicitly or implicitly expected

3.59 Audit program
Set of one or more *audits* (3.17) planned for a specific time frame and directed towards a specific purpose

3.60 Audit criteria
Set of *policies* (3.07), *documented information* (3.11) or *requirements* (3.03) used as a reference against which *audit evidence* (3.61) is compared

3.61 Objective / audit evidence
Records, statements of fact or other *information* (3.50), which are relevant to the *audit criteria* (3.60) and verifiable

3.62 Audit findings
Results of the evaluation of the collected *audit evidence* (3.61) against *audit criteria* (3.60)
Note 1 to entry: Audit findings indicate *conformity* (3.18) or *nonconformity* (3.19).
Note 2 to entry: Audit findings can lead to the identification of opportunities for *improvement* (3.28) or recording good practices.

Note 3 to entry: In English, if the *audit criteria* (3.60) are selected from *statutory requirements* (3.38) or *regulatory requirements* (3.39), the audit finding can be called compliance or non-compliance.

3.63 Concession

Permission to use or *release* (3.64) a *product* (3.47) or *service* (3.48) that does not conform to specified *requirements* (3.03)

Note to entry: A concession is generally limited to the delivery of *products* (3.47) and *services* (3.48) that have *nonconforming* (3.19) *characteristics* (3.65) within specified limits and is generally given for a limited quantity of products and services, for a period of time, and for a specific use.

3.64 Release

Permission to proceed to the next stage of a *process* (3.12)

Note to entry: In English, in the context of software and *documented information* (3.11), the word "release" is frequently used to refer to a version of the *software* or the *documented information* itself.

3.65 Characteristic

Distinguishing feature

Note 1 to entry: A characteristic can be inherent or assigned.

Note 2 to entry: A characteristic can be qualitative or quantitative.

Note 3 to entry: There are various classes of characteristic, such as the following:

- physical (e.g. mechanical, electrical, chemical or biological characteristics);
- sensory (e.g. related to smell, touch, taste, sight, hearing);
- behavioral (e.g. courtesy, honesty, veracity);
- Temporal (e.g. punctuality, reliability, availability).
- ergonomic (e.g. physiological characteristic, or related to human safety);
- Functional (e.g. maximum speed of an aircraft).

3.66 Performance indicator

Performance metric

characteristic (3.65) having significant impact on realization of the *output* (3.46) and *customer satisfaction* (3.57)

Note to entry: The *characteristic* (3.65) can be quantitative or qualitative

3.67 Determination

Activity to find out one or more *characteristics* (3.65) and their *characteristic* values

3.68 Review

Determination (3.67) of the suitability, adequacy or e*ffectiveness* (3.06) of an *object* (3.36) to achieve established *objectives* (3.08)

Note to entry: Review can also include the *determination* (3.67) of efficiency.

3.69 Measuring equipment

Measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a *measurement* (3.16) *process* (3.12)

3.70 Counterfeit part

1.0 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.

NOTE: 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.

3.71 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.

3.72 Key characteristic
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.

3.73 Product safety
The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.74 Special requirements
2.0 Those requirements identified by the customer, or determined by the organization, 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, 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 output (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.

Date	Revision	Author	Status	Comments
09/06/2018	1.0	ERP Manifested	Retired	Initial Release
01/18/2019	2.0	Tai Miller	Retired	Updates to Quality Policy and objectives
05/15/2019	3.0	Tai Miller	Retired	Manual Overhaul/Update
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06/29/2021	8.1	Rakesh Prasad	Retired	4.4.1 Changed Process Map to Include Contract Review.
10/21/2021	9.1	Rakesh Prasad	Retired	Removed all reference to E2 as ECI is referenced ERP system
03/23/2022	10.1	Rakesh Prasad	Retired	Document Layout Overhaul **Removed:** PFMEA requirement from sect. 4.1.1 **Added**: SWOT Worksheet as alternate process assessment tool.
06/09/2022	10.2	Rakesh Prasad	Retired	Updated Process Interaction Map
01/06/2023	10.3	Rakesh Prasad	Released	New Logo