Oxebridge Q001

Quality Management System Requirements

Ver. 1.3

To be used for implementation and audits on or after 21 March 2023.

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Revision History

Ver.	To be used for audits after:	Nature of Changes
1.0	17 February 2020	• Original release.
1.1	15 March 2020	• Updated Appendix B to correct improper clause callouts. • Arranged pages to allow for proper page number alignment when printed. • Minor typographical changes throughout. • Clause 8.5.4: added “shelf life controls for perishable items.” • Added revision history table
1.2	20 March 2020	• Corrected error in prior numbering of clauses 8.5.5 and 8.5.6
1.3	23 March 2023	• Updated wording of all clauses to align with Oxebridge rules on phrasing requirements. No new requirements were added to this revision. Users may continue to use version 1.2 simultaneously with, or in lieu of, this release. • Note added to 5.2 to improve ISO 9001 compliance. • Clause 8.1 rewritten, and a Note added, to broaden statistical methods to both statistical process control and sampling. • Clause 8.2.3 re-organized into bullet points for better clarity. • Clause 8.3.1: note re-written to clarify design models. • Clause 8.3.8 re-organized into bullet points for better clarity. • Clause 8.5.6: added note clarifying when procedures are required for post-delivery activities. • Clause 10.2.3 added to clarify corrective action record requirements. • Clause 10.3.3 added to clarify preventive action record requirements.

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1.0 Purpose

The Oxebridge Q001 (pronounced "*Q Thousand and One*") standard is intended to be used by organizations seeking to implement a formal, documented quality management system that conforms with *ISO 9001 Quality Management Systems – Requirements*. Each organization will have its own rationale for doing so, including to meet customer requirements or to develop a quality system that allows for continual improvement; this standard is agnostic on such reasons, and attempts to satisfy all users, regardless of their rationale.

The Oxebridge Q001 standard was developed to provide an entirely alternate re-imagining of the ISO 9001 standard to:

a) improve comprehension of the requirements;
b) reduce repetition of requirements;
c) clarify commonly misunderstood requirements;
d) add key requirements into the standard, such as risk management, opportunity management, and preventive action management;
e) improve sub-clause numbering and structure;
f) improve the ability of service providers to utilize the standard; and
g) simplify internal and external auditing against the standard.

The Oxebridge Q001 standard only adopts ISO 9001's top-level clause number structure. It utilizes none of the original ISO 9001 language, and is therefore clear of any copyright or trademark infringement claims by ISO.

Compliance to Oxebridge Q001 should result in near-total compliance to ISO 9001:2015. The Oxebridge website (www.oxebridge.com) provides a crosswalk table which identifies potential gaps which will need to be closed to ensure the resulting system fully conforms with ISO 9001. Readers will have to purchase a licensed copy of ISO 9001:2015 in order to ensure full conformity; go to www.iso.ch to buy the official standard.

Where "Notes" are indicated these do not include requirements, but instead provide clarifying language intended to help the reader. Where the Standard calls out required documents, these are highlighted in **green**; requirements for records are highlighted in **purple**.

2.0 References

ISO 9000:2015 Quality Management Systems – Fundamentals and Vocabulary

ISO 9001:2015 Quality Management Systems – Requirements

3.0 Terms and Definitions

3.1 Uncertainty: a deficiency of information related to the understanding or knowledge of an event, its consequence, or likelihood. *[Adapted from ISO Guide 73:2009 Risk Management - Vocabulary.]*

3.2 Risk: a negative effect of uncertainty. *[Oxebridge definition.]*

3.3 Opportunity: a positive effect of uncertainty. *[Oxebridge definition.]*

NOTE: For other definitions, refer to ISO 9000:2015 Quality Management Systems – Fundamentals and Vocabulary

4.0 Quality Management System Scope

4.1 Identifying Stakeholders

The organization shall create and maintain a **record** of internal and external stakeholders who are affected by, or have an effect on, the organization's products, services and/or quality management system.

The organization shall ensure that its external stakeholders include customers and suppliers at a minimum.

The organization shall ensure that its internal stakeholders include employees and top management at a minimum.

NOTE 1: Additional stakeholders may include regulatory bodies, product end-users, distributors, subcontractors, partners, owners, dealers, sales representatives, competitors, etc.

NOTE 2: "Top management" is typically a subset of "employees," since top management will have additional concerns and requirements under 4.2.

4.2 Identifying Stakeholders' Concerns and Requirements

The organization shall maintain a **record** of the concerns and requirements of the stakeholders identified in 4.1.

NOTE: "Concerns" would be issues not deemed mandatory by the stakeholder, but nevertheless important; "requirements" would be issues deemed mandatory by the stakeholder.

4.3 Quality Management System Processes

4.3.1 Internal Processes

The organization shall determine the processes within the scope of the quality management system. The organization shall prepare a **documented process definition** for each process which defines:

a) the process owner(s);
b) a general description of the process flow and how it interacts with other processes;
c) process quality objectives, which shall be text statements defining the intended purpose of the process; and
d) process metrics, which shall be the data collected and measured in order to determine if the process quality objective is being met.

NOTE 1: "Process metrics" are sometimes referred to as "key performance indicators."

The process owner(s) shall oversee the collection of process data and measurement of the process metrics. Top management shall establish goals for the process quality objectives based on the process measurement data. Top management shall either adjust the goal or **record** a plan for improving the process when a process does not meet a goal.

NOTE 2: The corrective action system (see 10.2) can be used as a means of recording process improvement plans.

The organization shall ensure that changes to internal processes are performed in accordance with the change management requirements of 6.2.

4.3.2 Outsourced Processes

The organization shall ensure that outsourced processes are performed by suppliers subject to the requirements of 8.4. The organization shall develop additional controls to be implemented to ensure each outsourced process meets requirements, and define these additional controls in a **documented procedure**.

NOTE: "Outsourced processes" are those activities which, from the customer's perspective, the organization would be responsible for, but for which the organization has chosen to have performed by a third party.

4.3.3 Process Design

The organization shall **record** a process design plan when it seeks to implement a new internal quality management system process. The organization shall ensure that this plan defines:

a) the intent of the process;
b) stakeholders;
c) responsibilities and authorities;
d) required resources;
e) associated risks and opportunities;
f) process quality objective(s) and associated metrics (see 4.3.1);
g) control points (reviews, inspections, tests, gates, etc.);
h) process control parameters; and
i) supporting documents and records.

Appropriate organization management shall review and approve the process design plan before implementation of the process. The organization shall ensure the requirements of 4.3.1 are satisfied for the new process once the process is implemented.

NOTE: This Standard recognizes that most organizations will have processes in place before implementation of the Standard; therefore, the "process design" requirements will only apply when the organization implements a new process.

4.4 Quality Management System Scope

The organization shall **document** a scope statement that defines the locations, products, services and processes to be included in the quality management system, based on the information gained from 4.1, 4.2 and 4.3

The organization shall ensure that the scope statement includes a justification as to why any clause of this standard is to be excluded. The organization shall ensure that clauses are only excluded when the requirements of a clause are not applicable to the organization's activities.

5.0 Quality Management System Leadership

5.1 Management Commitment

5.1.1 Demonstration of Management Commitment

Top management shall demonstrate its leadership of the quality management system by:

a) **documenting** how it takes accountability for the effectiveness of the quality management system;
b) providing evidence of participation in quality system planning activities;

c) signing the quality policy;
d) providing evidence of participation in management reviews (see 9.3);
e) reviewing and analyzing cost of quality data (see 9.1.2);
f) communicating the quality culture (see 5.1.2); and
g) providing evidence of how it manages, leads and supports subordinate staff.

5.1.2 Quality Culture

Top management shall adopt and implement a culture of quality that focuses on satisfying the customer's requirements. Top management shall ensure the definition of this culture and the plan for its implementation are **documented.**

5.2 Quality Policy

Top management shall develop, **document** and publish a quality policy that:

a) summarizes the organization's culture of quality;
b) is easily understood; and
c) is relevant to the organization's quality culture (5.1.2) and its products or services.

Note: to claim simultaneous compliance with ISO 9001, the quality policy should include a statement to satisfy all applicable requirements, and a statement on the organization's intent to pursue continual improvement.

5.3 Responsibilities and Authorities

The organization shall **document** who it considers "top management" and, thus, who is responsible for the requirements of top management called out by this Standard. The organization shall ensure that "top management" includes the senior-most manager(s) responsible for the organization, giving consideration of the scope limitations defined per 4.4.

Top management shall ensure that responsibilities relative to the quality management system are **documented.** Top management shall ensure that personnel have the necessary authority to carry out their responsibilities.

Top management shall ensure that documented responsibilities and authorities include:

a) who is responsible for collecting process performance data and reporting it to top management;
b) who is responsible for implementing procedures; and
c) who will act as point of contact for third parties when representing the quality management system.

NOTE 1: Identifying responsible persons by title is sufficient.

NOTE 2: Responsibilities and authorities may be documented within procedures.

6.0 Quality Management System Planning

6.1 Risk and Opportunity Management

6.1.1 Approach to Risk and Opportunity Management

The organization shall define its approach to managing risks and opportunities in a **documented procedure**.

The organization shall use the issues identified in 4.2 and determine which of these issues presents a risk, which of these issues presents an opportunity, or which of these issues presents both a risk and opportunity.

6.1.2 Risk Management

The organization shall list risks including:

a) issues identified per 6.1.1 as being risks;
b) additional risks identified by management or staff at any time; and
c) risks that arise from discussions, data analysis or any other reason during operation of the quality management system.

The organization shall ensure that the list of risks is maintained as a **record** and updated as appropriate.

The organization shall develop a **documented procedure** defining how it manages risks. The organization shall ensure that this procedure defines how risks are to be identified, assessed, and rated, and a risk rating method to be used to decide when a risk is acceptable vs. unacceptable. The organization shall develop risk mitigation plans for any risk rated as unacceptable. The organization shall ensure that risk mitigation plans are **recorded**, implemented, and verified after completion.

NOTE 1: The procedure required by 6.1.1 may be used to document this requirement.

NOTE 2: The corrective action system defined in 10.2 or the preventive action system defined in 10.3 may be used to manage risk mitigation plans.

6.1.3 Opportunity Management

The organization shall identify opportunities including:

a) issues identified per 6.1.1 as being opportunities;
b) additional opportunities identified by management or staff at any time; and
c) opportunities that arise from discussions, data analysis or any other reason during operation of the quality management system.

The organization shall ensure that the list of opportunities is maintained as a **record** and updated as appropriate.

The organization shall develop a **documented procedure** defining how it manages opportunities. The organization shall ensure that this procedure defines how opportunities are to be identified, assessed, and rated, and an opportunity rating method to be used to decide when an opportunity is worth pursuing vs. not worth pursuing. The organization shall develop an opportunity pursuit plan for any opportunity rated as worth pursuing. The organization shall ensure that opportunity pursuit plans are **recorded**, implemented, and verified after completion.

NOTE 1: The procedure required by 6.1.1 may be used to document this requirement.

NOTE 2: The preventive action system defined in 10.3 may be used to manage opportunity pursuit plans.

6.2 Change Management

The organization shall ensure that changes to the quality management system are carried out in accordance with a **documented procedure**. The organization shall ensure that this procedure defines how:

a) changes are formally requested;
b) changes undergo review and approval by appropriate management;
c) change plans are **recorded** and implemented;
d) change plans include intended dates of implementation, if appropriate;
e) once implemented, the change is evaluated to ensure it was effective and did not cause unexpected problems; and
f) documents or records are created or updated, if necessary.

NOTE 1: Changes to the quality management system may include changes to processes, the scope of the quality management system, products or services offered, or other major organizational changes.

NOTE 2: Changes to documents are covered by the document control requirements defined in 7.5.

NOTE 3: Change plans may be processed through a corrective action request (see 10.2) or preventive action request (see 10.3.)

7.0 Quality Management System Support

7.1 Resources

7.1.1 Resource Provision

Top management shall promote a culture that allows staff to request resources related to the quality management system. Top management shall give proper consideration to such requests.

NOTE: Resources can be provided within the ability of the organization to do so, considering costs, implementation time, or other factors.

7.1.2 People

The organization shall provide employees, contractors, staff, temporary help, etc., necessary for the effective implementation of the quality management system processes, and/or to ensure quality of products and services.

7.1.3 Infrastructure

7.1.3.1 Provision of Infrastructure

The organization shall provide the infrastructure necessary for the quality management system processes, and/or to ensure quality of products and services. The organization shall ensure that this infrastructure includes, at a minimum:

a) facilities;
b) utilities;
c) equipment;
d) transportation resources; and
e) information technology (IT) resources.

7.1.3.2 Validation of Equipment

The organization shall ensure that equipment directly impacting on product quality is checked prior to regular use to ensure it functions properly and does not introduce nonconformities.

NOTE: The organization can decide on the level of effort to be used for validation of equipment.

7.1.3.3 Preventive Maintenance

The organization shall ensure that a preventive maintenance program is developed to reduce unplanned defects or downtime, specifically for facilities and equipment with a significant effect on product quality. The organization shall ensure that preventive maintenance program is defined in a **documented procedure**. The organization shall ensure that **records** of preventive maintenance are maintained.

NOTE: The organization can decide what constitutes "significant effect on product quality," and therefore the facilities and equipment subject to preventive maintenance.

7.1.3.4 Tooling

The organization shall ensure that tooling, jigs, fixtures and other support items are identified to distinguish them from product, if such confusion is likely. The organization shall ensure that such items are identified as to their intended product or service, unless they are intended for general use. The organization shall ensure that such items are maintained to the extent required to ensure their ongoing suitability.

NOTE: The organization can decide if such tooling maintenance will include preventive maintenance per 7.1.3.3 or simple periodic repairs.

7.1.4 Work Environment

The organization shall provide and control the work environment necessary for the quality management system processes, and/or ensure quality of products and services. The organization shall ensure that controls for the work environment include physical, electronic and atmospheric conditions that would cause a negative impact on quality if not properly managed.

NOTE: "Physical" conditions may include lighting, access control, physical accessibility; "electronic" conditions may include electromagnetic, power, automation, electrostatic discharge; "atmospheric" conditions may include temperature, humidity, air quality/purity.

7.1.5 Inspection and Testing Resources

7.1.5.1 Provision of Inspection and Testing Resources

The organization shall ensure that resources needed for the inspection or testing of products or services are provided. The organization shall ensure that these resources are suitable for the specific type of inspection and testing to be performed (e.g., of sufficient accuracy, suitable tolerances).

7.1.5.2 Calibrated Inspection and Testing Devices

The organization shall ensure that inspection and testing devices used to accept or reject products or services are calibrated or verified in accordance with a **documented procedure**.

NOTE 1: If a device cannot be calibrated, or if a product or service is inspected using something other than a traditional measurement device, then the requirements of 7.1.5.3 would apply.

The organization shall ensure that this procedure defines:

a) the calibration frequency for each device;
b) the calibration method for each device;
c) who will perform the calibration for each device (e.g., the organization or an approved supplier);
d) how devices will be uniquely identified to trace back to the calibration records;

e) how devices will be identified with their current calibration status, so that users know when they are overdue;
f) how such devices are to be maintained to ensure ongoing proper functioning and capability; and
g) how such devices are to be protected from mishandling, damage or deterioration that would invalidate the calibration.

The organization shall ensure that **records** of calibration are maintained.

NOTE 2: These requirements apply to calibrated measurement tools, but can also apply to software programs used to inspect or test product, as well as on-machine inspection probes.

NOTE 3: The organization may apply these requirements to process measurement tools if it chooses, but this is not mandatory. Special processes often require the use of calibrated process measurement devices, however; see 8.1.5.2.

The organization shall ensure that when the organization performs its own calibration, the methods used are defined in one or more **documented procedures**. The organization shall ensure that when the organization chooses to outsource calibration, third-party calibration is defined and managed as an outsourced process per 4.3.2.

NOTE 4: Third party calibration laboratories should be accredited to ISO 17025.

The organization shall ensure that calibration is performed against traceable standards so that there remains an unbroken chain of metrological traceability to recognized national standards. The organization shall **document** the validation of the calibration method employed, if no such traceability is possible.

The organization shall **record** an impact study when a device is reported as being defective, nonconforming or otherwise out of tolerance. The organization shall ensure that this study analyzes the impact of the problem, whether or not any product or services were negatively affected, and what actions are to be taken, up to and including a recall.

NOTE 5: Service companies may elect to exclude this clause if no inspection or test devices are used.

7.1.5.3 Non-Calibrated Inspection and Testing Resources

The organization shall ensure that, when calibrated devices are not suitable for use in inspection or testing of a product or service, non-calibrated resources for inspection and testing are developed and provided.

NOTE: Such non-calibrated resources may include surveys, checklists, validated test methods, or software; typically these are used to inspect a service, but may also be applicable to some forms of products.

The organization shall ensure that these resources are suitable for the specific type of inspection and testing to be performed (e.g., of sufficient accuracy, suitable usability, etc.).

The organization shall ensure that non-calibrated inspection or testing resources are validated in accordance with a **documented procedure**. The organization shall ensure that this procedure defines:

a) the method of validating the resource so that it provides confident results;
b) the frequency and methods of any re-validation of the resource, if necessary;
c) indication of who will perform the validation (e.g., the organization or an approved supplier);
d) how such resources will be identified so that users clearly understand which resources to use; and
e) how such resources are maintained and updated to ensure ongoing usefulness.

The organization shall ensure that **records** of validation of such resources are maintained.

The organization shall ensure that when it chooses to outsource validation of its non-calibrated inspection or testing resources, this is managed as an outsourced process per 4.3.2.

7.1.6 Knowledge

The organization shall determine the knowledge necessary for the quality management system processes, and/or ensure the quality of products and services. The organization shall implement methods to reduce the loss of such knowledge when changes to staff occur.

NOTE: The set of quality management system documents and records may be used as one means of capturing such knowledge.

7.2 Competence & Training

The organization shall **record** the necessary competence of staff in terms of minimum education, training, and experience. The organization shall then provide training or other actions to ensure persons achieve that competence, when needed. The organization shall ensure that when management elects to waive a specific competence requirement for a person, the justification to do so is **recorded**.

The organization shall provide additional training as required (e.g., on-the-job training, skills advancement, process improvement training, etc.) to ensure quality. The organization shall ensure that training includes applicable quality management system documentation for the position. The organization shall maintain a **documented procedure** defining its training program.

The organization shall ensure that **records** of training are maintained.

7.3 Awareness

The organization shall ensure that training includes initial orientation and periodic re-training on:

a) the quality policy (per 5.2);
b) the organizational quality culture (per 5.1.2);
c) each person's relevant process quality objectives (per 4.3);
d) each person's contribution to the quality management system; and
e) how to report quality management system problems and nonconformities.

The organization shall ensure that **records** of training required by 7.2 include evidence of awareness training on the above subjects.

7.4 Communication

7.4.1 Internal Communication

The organization shall ensure that methods are implemented to allow internal communication in all directions (i.e. management to staff, staff to management, staff to staff, between processes, etc.). Top management shall ensure that no retaliation is taken against staff who report valid problems or nonconformities related to the organization's quality management system, products or services. Top management shall periodically communicate the status and health of the quality management to staff, and invite suggestions or opportunities for improvement.

7.4.2 External Communication

The organization shall ensure that communication from customers and suppliers is properly routed, responded to, and any issues addressed as needed. The organization shall ensure that customer complaints are captured and processed per the requirements of 10.2.

7.5 Documents and Records

7.5.1 Development of Documents and Records

The organization shall develop **documents** and **records** to support the quality management system processes. The organization shall ensure that these include the documented procedures and records required by this Standard, as well as any required by the organization itself.

NOTE 1: "Documentation" refers to written information that explains the work to be done (e.g., manuals, procedures, work instructions, process maps, forms, etc.) "Record" refers to a document which then captures evidence of the work having been performed (e.g., completed logs, inspection sheets, etc.) The master "blank" version of a form is a document; when it is filled in by users, it becomes a record.

NOTE 2: This Standard recognizes that different organizations may fulfill requirements for documents or records differently; some organizations may utilize a record where the Standard requires a procedure, or vice-versa. At times a single tool may serve as both a document and a record simultaneously. Provided the method eventually fulfills the requirement, all such approaches are acceptable.

7.5.2 Control of Documents

The organization shall maintain a **documented procedure** which defines how documents are:

a) drafted;
b) reviewed;
c) approved;
d) published; and
e) revised.

The organization shall ensure that all quality system documents which instruct are subject to this procedure.

The organization shall ensure that **records** of document approval and release are maintained.

The organization shall ensure that documents are subject to revision control. The organization shall ensure that revised documents have a means of identifying the changes made to the document, where practical.

NOTE: The Standard recognizes that identifying changes may not be practical for forms.

The organization shall ensure that obsolete documents kept for reference are identified as obsolete, to ensure they are not accidentally confused with current documents.

The organization shall ensure that documents of external origin are managed to ensure the proper revision is obtained and used, per requirements.

The organization shall ensure that all documents are readily available where and when they are needed by staff.

7.5.3 Control of Records

The organization shall maintain a **documented procedure** which defines how records are:

a) created;
b) filed;
c) preserved, including backup and protection of electronic records;
d) retained, including minimum retention times; and
e) disposed of.

The organization shall flow down requirements for quality system record retention to any suppliers who hold such records for the organization; see 8.4.

7.5.4 Internal Compliance with Documents and Records

The organization shall ensure that its employees and staff comply with the requirements of its quality management system documents and complete necessary quality system records as directed.

The organization's employees and staff shall perform work according to the latest revision of quality management system documents unless otherwise directed by specific work requirements.

8.0 Operation

8.1 Operational Process Planning and Control

The organization shall ensure that, before work commences, the operational processes are included in the defined quality management system processes (see 4.4), and that the process objectives, metrics and controls are adequate and implemented.

NOTE: "Operational processes" are those QMS processes directly responsible for the activities defined in Clause 8 of this standard.

The organization shall ensure that if statistical methods are to be implemented, these methods are defined in a **documented procedure.** The organization shall ensure that statistical methods are statistically valid and/or based on published and industry-accepted methods.

NOTE: Statistical methods may include statistical process control and sampling.

8.2 Capture and Review of Requirements

8.2.1 Capture of Requirements

The organization shall ensure all applicable requirements are captured before a decision to accept work is finalized. The organization shall ensure that the methods for capture of requirements are defined within a **documented procedure**.

The organization shall ensure that the capture of customer requirements includes:

a) requirements provided by the customer directly;
b) requirements not provided by the customer, but known to the organization as being applicable;
c) related statutory and regulatory requirements related to the product or service; and
d) information from any applicable prior work.

The organization shall ensure that requirements are **recorded** prior to review.

8.2.2 Review of Requirements

The organization shall ensure all applicable requirements are reviewed before a decision to accept work is finalized. The organization shall ensure that the methods for review of requirements are defined in a **documented procedure.**

The organization shall ensure that the review of customer requirements ensures the organization:

a) has the capability and capacity to perform the work;
b) can meet required quality levels or expectations; and
c) can satisfy any applicable statutory and regulatory requirements related to the product or service.

The organization shall negotiate with the customer to resolve any issues, or decline the work entirely, if it is determined that the organization cannot meet all requirements,.

The organization shall ensure that a **record** of the review of requirements is maintained, along with the final decision to accept or decline the work.

The organization shall ensure that if the organization provides a preliminary proposal or quotation for the work, it reviews any subsequent orders received from the customer against the original proposal or quotation. The organization shall ensure that if any differences are noted, these are resolved with the customer before beginning work.

8.2.3 Changes to Requirements

The organization shall maintain a **documented procedure** that defines how it shall address changes to requirements once work has begun. The organization shall ensure that the procedure addresses:

a) changes prompted by the customer as well as changes prompted by the organization itself; and
b) how any work currently underway will be processed to address the change, if applicable.

The organization shall ensure that **records** of changes to requirements are maintained.

8.3 Design

8.3.1 Design Approach

The organization shall define its approach to design activities in a **documented procedure**. The organization shall ensure that this procedure includes a description (design model) of how the organization meets all the other requirements of clause 8.3. The organization shall ensure that its design model addresses the design of products at a minimum, but may be applied to the design of services if deemed appropriate by the organization.

NOTE: This may include a particular design model, such as waterfall or agile, or a model developed by the organization itself.

8.3.2 Design Planning

The organization shall develop and **document** one or more design plans.

NOTE: In some cases, the procedure required by 8.3.1 above constitutes the design plan, and no other document is required; in other cases, the organization may choose to develop separate design plans for different products or customers.

The organization shall ensure that each design plan defines:

a) the design approach, if not already defined from the documentation in 8.3.1;
b) the responsibilities and authorities for the design activities;
c) how design requirements will be captured (8.3.3);
d) how designs will be produced (8.3.4);
e) the required design reviews (8.3.5);
f) the required verification (8.3.6) and validation (8.3.7) activities;
g) methods for requesting and controlling design changes (8.3.8);
h) the internal and external resources needed for the design activities;
i) any intended customer or third-party interactions for the design activities;
j) the requirements for subsequent manufacturing of the designed product or provision of the designed services;
k) the expected completion dates for the design-related activities or milestones; and
l) the specific records required.

8.3.3 Design Requirements

The organization shall determine the requirements for the intended product or service being designed. The organization shall consider:

a) functional and performance requirements;
b) information derived from prior designs;
c) information derived from similar designs;
d) applicable statutory and regulatory requirements; and
e) standards, specifications or codes relevant to the design.

The organization shall ensure that the requirements are clear and complete, and any conflicting design requirements are resolved.

The organization shall ensure that design requirements are **recorded**.

8.3.4 Designs

The organization shall ensure that the outputs of the design activity are **documented** and approved. The organization shall ensure that designs include, as appropriate:

a) adequate definition of the product or service with the intent of ensuring it can be manufactured or delivered at a later date;
b) applicable acceptance criteria, including acceptable tolerances, to allow for subsequent inspection and testing during production or service provision;
c) raw materials to be used, including any certification requirements for such materials;
d) specific suppliers to be used for raw materials or outsourced processes; and
e) applicable tools, jigs, fixtures, production equipment and/or inspection equipment to be used.

The organization shall ensure that designs are subject to revision control and have **records** of initial review and approval.

NOTE 1: "Designs" may include drawings, models, schematics, procedures, specifications, lists, software code, etc., as applicable to the product or service under design.

NOTE 2: For electronic design outputs, such as 3D models, the model itself is understood as sufficient "documentation" provided all other applicable requirements of clause 8.3.4 are met, including revision control.

8.3.5 Design Reviews

The organization shall arrange other design reviews, as appropriate, for the chosen design approach (8.3.1) and design plan(s) (8.3.2); this shall be in addition to those required by 8.3.4. The organization shall ensure that when such additional reviews are performed, **records** are maintained of the results of the review and any actions to be taken, including design improvements or revisions.

NOTE: Such design reviews may include preliminary design reviews or critical design reviews; these may include third parties such as the customer or regulatory bodies.

8.3.6 Design Verification

The organization shall ensure that design verification is performed to ensure the design satisfactorily addresses all design requirements as appropriate for the chosen design approach (8.3.1) and design plan(s) (8.3.2). The organization shall ensure that **records** of design verification are maintained.

NOTE: Design verification is typically a comparison of the design requirements against the resulting design itself; it is therefore typically a review of documents, records or software code.

8.3.7 Design Validation

The organization shall ensure that design validation is performed to ensure a product or service resulting from the design meets the design requirements, as appropriate for the chosen design approach (8.3.1) and design plan(s) (8.3.2). The organization shall ensure that when tests are used for design validation, these are done in accordance with **documented test methods**. The organization shall ensure that **records** of design validation are maintained.

NOTE: Design validation may be performed through measurement of a design prototype against the design criteria, first piece or first article inspections of designed product, witnessing of the designed service through trial runs, simulations, test runs, user polling, etc.

8.3.8 Design Changes

The organization shall ensure that:

a) changes to designs are reviewed and approved prior to implementation;
b) revised designs have their revision levels advanced to distinguish them from prior designs;
c) **records** of design changes and approvals are maintained; and
d) design revision records include a suitable description of the nature of the changes.

8.4 Purchasing and Subcontracting

8.4.1 Evaluation and Approval of Suppliers

The organization shall evaluate and approve suppliers of materials, products and support services in accordance with a **documented procedure**. The organization shall ensure that this evaluation includes any subcontractors, including those used to support quality management system activities.

NOTE 1: Where the organization uses subcontract workers for its daily operations, these do not constitute "subcontractors" subject to this requirement.

The organization shall ensure that **records** are maintained of suppliers, their approval status, and their scope of approval.

NOTE 2: "Scope of approval" should include what items, materials or services each supplier is approved to provide. The level of detail for this can be determined by the organization. This can be satisfied by either maintaining a list of suppliers and the items or services for which they are approved, or a list of items or services and the applicable approved suppliers for each.

The organization shall ensure that, in all cases, it retains final responsibility for products or services provided by suppliers or subcontractors.

8.4.2 Purchasing

The organization shall conduct purchasing of items and services in accordance with a **documented procedure**.

The organization shall only purchase from suppliers who have been evaluated and approved. The organization shall ensure that a temporary supplier approval condition is **recorded** when the organization makes purchases for evaluation purposes. The organization shall ensure that temporary supplier approvals are updated when the evaluations are complete.

The organization shall provide the supplier with a purchase request for the items or services to be purchased. The organization shall ensure that such purchase requests include, at a minimum:

a) description of the items or services to be purchased;
b) any required delivery dates requested by the organization;
c) any applicable organizational requirements related to the item or service; and
d) any applicable statutory or regulatory requirements related to the item or service.

The organization shall ensure that **records** of purchases, including the purchase requests, are retained.

NOTE: The "purchase request" may take the form of a purchase order, contract, online order, or other documented request.

8.4.3 Subcontracting

The organization shall maintain a **documented procedure** defining how it manages activities or services performed by subcontractors.

The organization shall use contracts or other **records** to define the required services to be provided by subcontractors and outsourced process providers. The organization shall ensure that such records clearly define any applicable requirements, limitations, and scope of work.

8.4.4 Verification of Received Items or Services

The organization shall ensure that purchased items or services are verified as conforming to requirements before use. The organization shall ensure that verification of received items and services is performed in accordance with a **documented procedure**.

The organization shall ensure that **records** of the verification of received items or services are maintained.

8.4.5 Ongoing Evaluation of Suppliers

The organization shall perform ongoing evaluation of suppliers to monitor their performance in accordance with a **documented procedure**. The organization shall ensure that the level of evaluation and control over each

supplier is determined based on the criticality of the supplier and/or the products or services provided. The organization shall advise the supplier when performance is found to be unacceptable, and work to resolve the issue with the supplier or disqualify them from future purchasing consideration.

The organization shall ensure that **records** of ongoing supplier evaluation and actions taken are maintained.

NOTE: The verification activities defined in 8.4.4 may simultaneously satisfy this requirement provided the verification information is analyzed for overall supplier performance.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

8.5.1.1 Production and Service Controls

The organization shall implement appropriate controls to ensure work is performed which meets requirements. The organization shall ensure that the controls include, as appropriate:

a) **documentation** and/or **records** which define the work to be performed, product or service requirements, and inspection and test criteria;
b) equipment required for the work, including inspection and testing devices;
c) suitable equipment and facilities;
d) description of the records to be completed during work;
e) any specific training for the work; and/or
f) tooling, devices or special methods to reduce human error.

The organization shall ensure that changes or revisions to work-specific instructions or documentation are made by authorized personnel and subject to formal document change rules, per 7.5.2.

8.5.1.2 Special Processes

The organization shall ensure that when any special process work or activity cannot be verified by the organization through normal inspection or testing, the organization implements additional controls, including as applicable:

a) additional training of personnel responsible;
b) additional documented work instructions;
c) additional records of special process validation;
d) validation of the equipment used;
e) calibration of process equipment;
f) additional inspection or testing methods;
g) use of applicable industry standards or specifications; and/or
h) special process accreditation.

8.5.2 Product Identification and Traceability

8.5.2.1 Product Identification

The organization shall identify product at all times to ensure it is not misplaced, commingled, or misidentified. The organization shall ensure that this includes the status of inspection and testing, as appropriate. The

organization shall ensure that product is identified so that it cannot be mistaken for raw materials, tooling or equipment.

The organization shall define the controls for product identification in a **documented procedure**.

NOTE: Nonconforming product must be identified per the requirements of 8.7.

8.5.2.2 Product Traceability

The organization shall ensure that if products require individual serialization, traceability and/or batch identification, then the organization implements appropriate methods to control such traceability. The organization shall ensure that when serial or batch numbers are used, these are not duplicated. The organization shall ensure that, where necessary, any records related to the product reference the applicable individual product serial numbers or batch numbers.

The organization shall define the controls for product traceability in a **documented procedure**.

8.5.2.3 Configuration Management

The organization shall ensure that when it produces or works with assemblies or complex parts requiring configuration management controls, these controls are implemented so that sub-components and sub-assemblies are traceable to the final assembly. The organization shall ensure that all applicable paperwork is representative of the configuration.

The organization shall ensure that configuration management methods are defined in a **documented procedure**.

NOTE: The level of complexity of configuration management may be determined by the organization.

8.5.3 Control of Third-Party Property

The organization shall ensure proper handling, identification, protection, and preservation of property belonging to third parties, including customers or suppliers, when the organization has control over the property. The organization shall ensure that this includes both physical property and intellectual property, including third-party data.

The organization shall ensure that when third-party property is lost, damaged, or compromised, it reports this to the property's owner and retains **records** of the issue.

The organization shall define its control of third-party property in a **documented procedure**.

8.5.4 Preservation

The organization shall preserve product and raw materials to the extent necessary to ensure quality. The organization shall ensure that preservation activities include handling, packaging, contamination control, commingling control, shelf life controls for perishable items, internal storage, transmission or transportation, and protection.

The organization shall ensure that define preservation activities in a **documented procedure**.

8.5.5 Delivery

The organization shall deliver completed products and/or services in accordance with applicable requirements. The organization shall ensure that these requirements include, as applicable:

a) customer's preferred or required delivery method;
b) required packaging; and
c) required documentation and/or records to accompany the product or service.

The organization shall preserve the quality of product throughout transit and delivery, when it performs product delivery.

The organization shall maintain **records** of product and/or service delivery.

The organization shall define product and/or service delivery activities in a **documented procedure.**

8.5.6 Post-Delivery Activities

The organization shall determine what post-delivery activities it is responsible for and perform them in accordance with all applicable requirements.

The organization shall define post-delivery activities in one or more **documented procedures.**

The organization shall ensure that **records** of post-delivery activities are maintained when required.

NOTE: Post-delivery activities can include repair or rework, technical support services, maintenance, or any other activity required by the customer after delivery of the product or service.

NOTE: if the same procedures used for normal work are also used for post-delivery work, then no additional procedures are required.

8.6 Inspection and Testing

8.6.1 Inspection and Testing Requirements

The organization shall perform inspection and/or testing on products and services to ensure all requirements have been met before final delivery or service conclusion. The organization shall define how inspections and tests are performed in one or more **documented procedures.**

The organization shall ensure that for all applicable inspection and test types listed in 8.6.2 through 8.6.6, **records** are maintained and include, at a minimum:

a) the results of the inspections or tests; and
b) the person(s) conducting the inspections or tests.

The organization shall ensure that when sampling plans are used for inspection or testing, these are **documented**, and meet the controls for statistics defined in 8.1.

The organization shall ensure that product that is not inspected or tested is not delivered unless under waiver by the customer or other relevant authority, and that waivers are **recorded**.

The organization shall ensure that work does not proceed until the required inspections and tests are completed, and the results show that the requirements have been met. The organization shall ensure that when requirements have not been met, the controls for nonconforming product defined in 8.7 are implemented.

NOTE: The organization may decide on the level of inspection utilized throughout its processes.

8.6.2 Receiving Inspection

The organization shall ensure that, when deemed appropriate to meet the requirements of 8.4.4, inspection or testing of received items or services is performed.

8.6.3 First Piece Inspection

The organization shall ensure that, when deemed appropriate, a representative product or batch from the beginning of an operation is inspected or tested to ensure the operation is reliable for ongoing production. The organization shall ensure that first piece inspection is repeated when significant changes to the production operation are made.

NOTE: The organization may decide when such changes are considered "significant."

8.6.4 First Article Inspection

The organization shall ensure that, when deemed appropriate or required by the customer, a first article inspection is performed utilizing a designated sample part or batch. The organization shall ensure that first article inspection includes activities necessary to ensure all applicable production steps, materials, certifications, suppliers, equipment and methods result in a product that meets all requirements, including physical characteristics.

NOTE: The level of detail for First Article Inspections (FAI) may be determined by the customer, by the organization, or by external FAI standards or software.

8.6.5 In-Process Inspection

The organization shall ensure that, when deemed appropriate, inspections and/or tests of products being produced, or services being delivered, are performed to ensure quality.

8.6.6 Final Inspection

The organization shall ensure that final inspections and/or tests are performed to ensure products or services meet requirements before delivery or completion.

8.7 Control of Nonconforming Product or Service

8.7.1 General Control of Nonconforming Product or Service

The organization shall ensure that nonconforming product is not used or delivered, and/or that nonconforming service is not provided. The organization shall maintain a **documented procedure** on the controls for nonconforming product or service, which shall cover how the organization conforms with 8.7.2 and 8.7.3.

8.7.2 Discovering and Recording Nonconforming Product or Service

The organization shall segregate nonconforming product, or cease nonconforming services, and subject them to review. The organization shall ensure that this review includes:

a) identification of the nonconforming product or service;
b) review of the nature of the nonconformity;

c) initial correction of the nonconformity;
d) determination of the cause(s) of the nonconformity;
e) disposition (see 8.7.3).

The organization shall ensure that **records** of the nonconforming product or service are maintained.

8.7.3 Dispositioning Nonconforming Product or Service

The organization shall ensure that dispositions of nonconforming product or service include, as appropriate:

a) scrap / discard product;
b) cancel service;
c) rework to bring the nonconforming product into conformity without altering the design;
d) repair, to bring the nonconforming product into conformity by altering the design;
e) providing alternate or improved service to address the nonconforming service;
f) return to supplier;
g) use-as-is;
h) regrade; or
i) other dispositions determined by the organization.

The organization shall ensure that **records** of the nonconformity dispositions are maintained.

The organization shall ensure that dispositions of repair or use-as-is are approved by the customer and/or design authority holder, and that **records** of such approvals are maintained.

The organization shall ensure that product subjected to rework or repair is re-inspected, with **records** of the reinspection maintained.

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 Overall QMS Evaluation

The organization shall evaluate the performance and effectiveness of the quality management system in accordance with a **documented procedure**.

9.1.2 Analysis and Evaluation

The organization shall analyze and evaluate quality system data related to the following, at a minimum:

a) product / service quality;
b) cost of quality;
c) customer satisfaction;
d) process performance against the defined process quality objectives; and
e) the performance of suppliers and subcontractors.

NOTE: Alternative methods of calculating cost of quality, such as cost of poor quality, P-A-F models, ABC models, Crosby's model, etc., are all acceptable means of satisfying this requirement.

9.2 Internal Audits

9.2.1 Purpose of Internal Audits

The organization shall conduct internal quality system audits to ensure the quality management system:

a) conforms to the organization's requirements and procedures;
b) conforms to the requirements of this Standard;
c) is effectively implemented and maintained.

9.2.2 Conducting Internal Audits

The organization shall perform internal audits in accordance with a **documented procedure** which shall cover how the organization meets all the requirements of clause 9.2, as well as:

a) the frequency of internal audits;
b) the scope of internal audits;
c) the internal audit method(s) to be used;
d) records to be completed;
e) the internal auditors assigned to each audit.

NOTE: "Internal audit methods" may include process-based auditing, requirements-based auditing, departmental auditing, or any other method that can be shown to satisfy the requirements of this clause.

The organization shall schedule audits according to the results of prior audits, process performance issues, or other concerns, but the frequency of internal audits shall ensure that all quality management system processes and/or clauses of this Standard are audited at least annually. The organization shall maintain a schedule of internal audits as a formal **record**.

The organization shall select internal auditors to ensure objectivity and the impartiality of the audits. The organization shall ensure that training of internal auditors conforms with requirements established by the organization per 7.2.

The organization shall ensure that when it utilizes third parties to perform internal audits, this is controlled as an outsourced process per 4.3.

9.2.3 Internal Audit Evidence

The organization shall ensure that auditors gather and capture objective evidence to support audit findings. The organization shall ensure that evidence is captured in a manner that is verifiable by third parties at a later date.

The organization shall ensure that findings of internal audits include:

a) evidence of conformity;
b) evidence of actual nonconformities (see 9.2.4);
c) evidence of potential nonconformities (see 9.2.4); and/or
d) opportunities for improvement made by the internal auditors.

9.2.4 Reporting Internal Audit Nonconformities

The organization shall ensure that, where either actual or potential nonconformities are identified, these are reported in a manner that includes the following three details:

a) a clear description of the requirement (e.g., clause reference, procedure citation, etc.);
b) a clear description of the objective evidence reviewed or observed; and
c) a clear description of why the objective evidence shows the requirement was not met.

The organization shall require that actual nonconformities are processed per 10.2.

The organization shall ensure that potential nonconformities are processed per 10.3.

9.2.5 Internal Audit Reports

The organization shall maintain **records** of internal audits. The organization shall ensure that these records contain at a minimum:

a) the audit plan details per 9.2.2;
b) evidence reviewed per 9.2.3; and
c) descriptions of nonconformities per 9.2.4.

9.3 Management Review

9.3.1 Management Review Approach

Top management shall review the quality management system's performance in accordance with a **documented procedure**. The organization shall ensure that this procedure defines:

a) the methods for management review;
b) the minimum frequency for management review;
c) the minimum personnel required to attend the management review; and
d) the aspects to be reviewed at management review (see 9.3.2).

The organization shall ensure that the management reviews are conducted at least annually.

9.3.2 Management Review Requirements

The organization shall ensure that, at a minimum, the management review includes a review of the following aspects:

a) necessary changes and updates to stakeholders (per 4.1);
b) necessary changes and updates to stakeholders' issues (per 4.2);
c) risks and related mitigation plans (per 6.1.2);
d) opportunities and related pursuit plans (per 6.1.3);
e) process performance metrics (per 4.3);
f) customer satisfaction (per 9.1.2);
g) cost of quality (per 9.1.2);
h) performance of suppliers and subcontractors (per 8.4.1);
i) training effectiveness and related needs (per 7.2);

j) the adequacy of resources (per7.1);
k) trends related to corrective and preventive actions (per 10.2 and 10.3);
l) internal and external audit results (per 9.2);
m) status of incident investigations (per 10.4);
n) the status of actions from previous management reviews;
o) changes to the organization or the quality management system; and
p) opportunities for improvement for the quality management system.

The organization shall maintain **records** which capture evidence of the review of the aspects listed above, and any decisions made as a result.

10.0 Improvement

10.1 Pursuing Continual Improvement

The organization shall pursue continual improvement of its products, services, and quality management system processes by:

a) following up and updating the opportunities pursued as defined in 6.1.3; and
b) implementing additional opportunities based on the analysis of data in 9.1.2 and management review results of 9.3.

10.2 Corrective Action

10.2.1 Requesting Corrective Action

The organization shall empower employees and staff to request corrective action on existing nonconformities related to:

a) poor quality management system process performance and/or failure of a process to meet a goal;
b) trends in product or service nonconformity;
c) internal or external audit findings of nonconformity;
d) customer complaints;
e) reductions in levels of customer satisfaction; and
f) any other reason determined appropriate by management.

10.2.2 Processing Corrective Action Requests

The organization shall define the method for processing corrective actions in a **documented procedure**.

The organization shall ensure that each corrective action request:

a) is recorded;
b) is assigned to a subject matter expert or team for resolution;
c) has documented containment taken to correct the immediate nonconformity, if applicable to the issue;
d) has a root cause analysis conducted and documented by the subject matter expert or the team;
e) has a corrective action plan documented and implemented which seeks to resolve the root cause(s) and prevent the nonconformity from recurring;
f) is reviewed for effectiveness upon completion of the corrective action plan;

g) is re-issued or some other action taken when the corrective action plan is found deficient;
h) is closed when the corrective action plan is found sufficient; and
i) is be escalated to higher management when the corrective action request is not responded to properly.

10.2.3 Records of Corrective Actions

The organization shall maintain **records** of corrective actions. The organization shall ensure that these records:

a) include the corrective action request itself;
b) include the evidence of the completion of (a) through (h) above; and
c) allow the organization to conduct trend analysis of corrective actions.

10.3 Preventive Action

10.3.1 Requesting Preventive Action

The organization shall empower employees and staff to request preventive action on potential nonconformities related to the organization's products, services or quality management system processes.

10.3.2 Processing Preventive Action Requests

The organization shall define the method for processing preventive actions in a **documented procedure**.

NOTE: This may be a shared procedure with that required by 10.2 for corrective action.

The organization shall ensure that each preventive action request:

a) is recorded;
b) is assigned to a subject matter expert or team for resolution;
c) has a root cause analysis conducted and documented by the subject matter expert or the team, if deemed appropriate based on the nature of the request;
d) has a preventive action plan documented and implemented which seeks to prevent the nonconformity from occurring;
e) is reviewed for effectiveness upon completion of the preventive action plan;
f) is re-issued or some other action taken when the preventive action plan is found deficient;
g) is closed when the preventive action plan is found sufficient.

10.3.3 Records of Preventive Actions

The organization shall maintain **records** of preventive actions. The organization shall ensure that these records:

a) include the preventive action request itself
b) include evidence of the completion of (a) through (g) above
c) allow the organization to conduct trend analysis of corrective actions.

NOTE: The preventive action trend analysis tool (log, etc.) may be shared with that required by 10.2 for corrective action.

10.4 Incident Investigation

The organization shall investigate any incident involving defective or nonconforming products or services delivered to customers or released to the market, whether reported by the customer, media reports, or other

third parties. The organization shall, at a minimum, perform incident investigations according to the corrective action requirements of 10.2.

NOTE 1: Such "incidents" typically include reports of product defects, recalls, accidents, disasters, injuries, unsafe conditions, or other harmful occurrences.

Top management shall oversee the investigations.

NOTE 2: If the corrective action system is used to investigate an incident, the corrective action record itself is sufficient to satisfy this requirement.

The organization shall maintain **records** of incident investigations.

Appendix A: Documented Procedures Called Out by Q001

The following table provides a summary of the documented procedures called out by this Standard. Note that the organization reserves the right to decide how to develop these procedures; in many cases, a single procedure may be used to cover multiple requirements. Where lines below share coloring, these are typically combined into a single procedure.

Document / Procedure		Oxebridge Q001 Callout
Required	Process definitions	4.3.1 Internal Processes
Required	Outsourced process procedure	4.3.2 Outsourced Processes
Required	QMS Scope Statement	4.4 Quality Management System Scope
Required	Documentation of management's accountability approach	5.1.1 Demonstration of Management Commitment
Required	Quality culture definition and plan	5.1.2 Quality Culture
Required	Quality policy	5.2 Quality Policy
Required	Documentation of who shall be considered "top management"	5.3 Responsibilities and Authorities
Required	Responsibilities and authorities	5.3 Responsibilities and Authorities
Required	Documentation of approach to managing risks and opportunities	6.1.1 Approach to Risk and Opportunity Management
Required	Risk management procedure	6.1.2 Risk Management
Required	Opportunity management procedure	6.1.3 Opportunity Management
Required	Change management procedure	6.2 Change Management
Required	Preventive maintenance procedure	7.1.3.3 Preventive Maintenance
Required	Calibration procedure	7.1.5.2 Calibrated Inspection and Testing Devices
If applicable	Calibration methods (work instructions)	7.1.5.2 Calibrated Inspection and Testing Devices
If applicable	Validation methods for non-calibrated resources	7.1.5.3 Non-Calibrated Inspection and Testing Resources
Required	Training procedure	7.2 Competence & Training
As needed	Documents needed to support the QMS processes	7.5.1 Development of Documents and Records
Required	Document control procedure	7.5.2 Control of Documents
Required	Records control procedure	7.5.2 Control of Records
As needed	Statistical process control methods	8.1 Operational Process Planning and Control
Required	Capture of requirements procedure	8.2.1 Capture of Requirements
Required	Review of requirements procedure	8.2.2 Review of Requirements
Required	Changes to requirements procedure	8.2.3 Changes to Requirements
If applicable	Overall design approach	8.3.1 Design Approach
If applicable	Individual design plans	8.3.2 Design Planning
If applicable	Designs (in whatever form)	8.3.4 Designs
If applicable	Design validation test methods	8.3.7 Design Validation
Required	Supplier evaluation and approval procedure	8.4.1 Evaluation and Approval of Suppliers
Required	Purchasing procedure	8.4.2 Purchasing
Required	Subcontracting procedure	8.4.3 Subcontracting
Required	Verification of received items and services procedure	8.4.4 Verification of Received Items or Services
Required	Ongoing supplier evaluation procedure	8.4.5 Ongoing Evaluation of Suppliers
As applicable	Necessary procedures for work	8.5.1.1 Production and Service Controls
If applicable	Work instructions for special processes	8.5.1.2 Special Processes
Required	Product identification procedure	8.5.2.1 Product Identification
If applicable	Product traceability procedure	8.5.2.2 Product Traceability
If applicable	Configuration management procedure	8.5.2.3 Configuration Management
Required	Control of third-party property	8.5.3 Control of Third-Party Property
Required	Preservation	8.5.4 Preservation
If applicable	Delivery activities	8.5.5 Delivery

Document / Procedure		Oxebridge Q001 Callout
If applicable	Post-delivery activities	8.5.6 Post-Delivery Activities
Required	Inspection and testing procedures	8.6.1 Inspection and Testing Requirements
If applicable	Sampling Plans	8.6.1 Inspection and Testing Requirements
Required	Control of nonconforming product/service procedure	8.7.1 General Control of Nonconforming Product or Service
Required	Overall QMS evaluation procedure	9.1.1 Overall QMS Evaluation
Required	Internal audits procedure	9.2.2 Conducting Internal Audits
Required	Management review procedure	9.3.1 Management Review Approach
Required	Corrective action procedure	10.2.2 Processing Corrective Action Requests
Required	Preventive action procedure	10.3.2 Processing Preventive Action Requests

Appendix B: Records Called Out by Q001

The following table provides a summary of the records called out by this Standard.

Record		Oxebridge Q001 Callout
Required	List of stakeholders	4.1 Identifying Stakeholders
Required	List of stakeholder concerns and requirements	4.2 Identifying Stakeholders' Concerns and Requirements
As needed	Actions taken when process does not meet goal(s)	4.3.1 Internal Processes
As needed	Process design plans (new processes only)	4.3.3 Process Design
Required	Risk list	6.1.2 Risk Management
Required	Risk mitigation plans	6.1.2 Risk Management
Required	Opportunity list	6.1.3 Opportunity Management
Required	Opportunity pursuit plans	6.1.3 Opportunity Management
As needed	QMS change management plans	6.2 Change Management
Required	Preventive maintenance records	7.1.3.3 Preventive Maintenance
Required	Calibration records	7.1.5.2 Calibrated Inspection and Testing Devices
As needed	Out-of-calibration impact studies	7.1.5.2 Calibrated Inspection and Testing Devices
As needed	Records of validation of non-calibrated resources	7.1.5.3 Non-Calibrated Inspection and Testing Resources
Required	Competency requirements for staff	7.2 Competence & Training
As needed	Competency waivers	7.2 Competence & Training
Required	Training records	7.2 Competence & Training & 7.3 Awareness
As needed	Any other records required by the organization	7.5.1 Development of Documents and Records
Required	Records of document approval and release	7.5.2 Control of Documents
As needed	Records needed for process control	8.1 Operational Process Control
Required	Records of requirements	8.2.1 Capture of Requirements
Required	Records of review of requirements	8.2.2 Review of Requirements
As needed	Records of changes to requirements	8.2.3 Changes to Requirements
Required	Design requirements	8.3.3 Design Requirements
Required	Design initial review and approval records	8.3.4 Designs
Required	Design review records	8.3.5 Design Reviews
Required	Design verification records	8.3.6 Design Verification
Required	Design validation records	8.3.7 Design Validation
Required	Design change records	8.3.8 Design Changes
Required	Approved supplier records	8.4.1 Evaluation and Approval of Suppliers
Required	Temporary supplier approval records	8.4.2 Purchasing
Required	Purchase records	8.4.2 Purchasing
As needed	Subcontract agreements or contracts	8.4.3 Subcontracting
Required	Records of verification of received items or services	8.4.4 Verification of Received Items or Services
Required	Ongoing supplier evaluation records	8.4.5 Ongoing Evaluation of Suppliers
As needed	Production control records	8.5.1.1 Production and Service Controls
As needed	Special process validation records	8.5.1.2 Special Processes
As needed	Records of lost, damaged or compromised third-party property	8.5.3 Control of Third-Party Property
Required	Records of product or service delivery	8.5.5 Delivery
As needed	Records of post-delivery activities	8.5.6 Post-Delivery Activities
Required	Inspection and test records	8.6.1 Inspection and Testing Requirements
As needed	Waivers for inspection	8.6.1 Inspection and Testing Requirements
Required	Records of nonconforming product or service	8.7.2 Discovering and Recording Nonconforming Product or Service
Required	Records of nonconformity dispositions	8.7.3 Dispositioning Nonconforming Product or Service
Required	Records of repair or use-as-is disposition approval	8.7.3 Dispositioning Nonconforming Product or Service
Required	Records of reinspection for reworked or repaired product	8.7.3 Dispositioning Nonconforming Product
Required	Internal audit schedule	9.2.2 Conducting Internal Audits
Required	Internal audit records	9.2.5 Internal Audit Reports
Required	Management review records	9.3.2 Management Review Requirements
Required	Corrective action records	10.2.2 Processing Corrective Action Requests

Record		Oxebridge Q001 Callout
Required	Preventive action records	10.3.2 Processing Preventive Action Requests
As needed	Incident investigation records	10.4 Incident Investigation

Oxebridge Q001 Certification?

Oxebridge Quality Resources International is launching an exploratory mission into determining if Q001 certification is of interest to industries.

Oxebridge will not provide certification services itself. Instead, we are discussing the formation of a global accreditation program that will allow select individuals and bodies to issue Oxebridge Q001 certifications under strict conditions designed to eliminate conflicts of interest and ensure that only companies that satisfy Q001 get certified to Q001.

If you are interested in offering Oxebridge Q001 certification, contact Oxebridge today by writing to OQR@oxebridge.com.

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