4 Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization shall monitor and review the information about these external and internal issues.

NOTE 1 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, and economic environments, whether international, national, regional or local.

NOTE 2 Understanding the internal context can be facilitated by considering issues related to values, culture knowledge and performance of the organization.

4.2 Understanding the needs and expectations of interested parties

Due to their impact or potential impact on the organisation's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

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

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

The organization shall monitor and review the information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider:

a) the external and internal issues referred to in 4.1;

b) the requirements of relevant interested parties referred to in 4.2;

c) the products and services of the organization.

Where a requirement of this International Standard within the determined scope can be applied, then it shall be applied by the organization.

If any requirement(s) of this International Standard cannot be applied, this shall not affect the organization's ability or responsibility to ensure conformity of products and services.

The scope shall be available and be maintained as documented information stating the:

— products and services covered by the quality management system;

— justification for any instance where a requirement of this International Standard cannot be applied.

4.4 Quality management system and its processes

The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization shall determine the processes needed for the quality management system and their application throughout the organization and shall determine:

a) the inputs required and the outputs expected from these processes;

b) the sequence and interaction of these processes;

c) the criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of these processes;

d) the resources needed and ensure their availability;

e) the assignment of the responsibilities and authorities for these processes;

f) the risks and opportunities in accordance with the requirements of 6.1, and plan and implement the appropriate actions to address them;

g) the methods for monitoring, measuring, as appropriate, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results;

h) opportunities for improvement of the processes and the quality management system.

The organization shall maintain documented information to the extent necessary to support the operation of processes and retain documented information to the extent necessary to have confidence that the processes are being carried out as planned.

5 Leadership

5.1 Leadership and commitment

5.1.1 Leadership and commitment for the quality management system

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

a) taking accountability of the effectiveness of the quality management system;

b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the strategic direction and the context of the organization;

c) ensuring that the quality policy is communicated, understood and applied within the organization;

d) ensuring the integration of the quality management system requirements into the organization's business processes;

e) promoting awareness of the process approach;

f) ensuring that the resources needed for the quality management system are available;

g) communicating the importance of effective quality management and of conforming to the quality management system requirements;

h) ensuring that the quality management system achieves its intended results;

i) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

j) promoting continual improvement;

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

NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence; whether the organization is public, private, for profit or not for profit.

5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) customer requirements and applicable statutory and regulatory requirements are determined and met;

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on consistently providing products and services that meet customer and applicable statutory and regulatory requirements is maintained;

d) the focus on enhancing customer satisfaction is maintained.

5.2 Quality policy

5.2.1 Top management shall establish, review and maintain a quality policy that:

a) is appropriate to the purpose and context of the organization;

b) provides a framework for setting and reviewing quality objectives;

c) includes a commitment to satisfy applicable requirements;

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

5.2.2 The quality policy shall:

a) be available as documented information;

b) be communicated, understood and applied within the organization;

c) be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility and authority for:

a) ensuring that the quality management system conforms to the requirements of this International Standard;

b) ensuring that the processes are delivering their intended outputs;

c) reporting on the performance of the quality management system, on opportunities for improvement and on the need for change or innovation, and especially for reporting to top management;

d) ensuring the promotion of customer focus throughout the organization;

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

6 Planning for the quality management system

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);

b) prevent, or reduce, undesired effects;

c) achieve continual improvement.

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its quality management system processes (see 4.4);

2) evaluate the effectiveness of these actions.

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

6.2 Quality objectives and planning to achieve them

6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes.

The quality objectives shall:

a) be consistent with the quality policy,

b) be measurable;

c) take into account applicable requirements;

d) be relevant to conformity of products and services and the enhancement of customer satisfaction;

e) be monitored;

f) be communicated;

g) be updated as appropriate.

The organization shall retain documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

6.3 Planning of changes

Where the organization determines the need for change to the quality management system (see 4.4) the change shall be carried out in a planned and systematic manner.

The organization shall consider:

a) the purpose of the change and any of its potential consequences;

b) the integrity of the quality management system;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization shall consider:

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

b) what needs to be obtained from external providers.

7.1.2 People

To ensure that the organization can consistently meet customer and applicable statutory and regulatory requirements, the organization shall provide the persons necessary for the effective operation of the quality management system, including the processes needed.

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure for the operation of its processes to achieve conformity of products and services.

NOTE Infrastructure can include:

a) buildings and associated utilities;

b) equipment including hardware and software;

c) transportation;

d) information and communication technology.

7.1.4 Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE Environment for the operation of processes can include physical, social, psychological, environmental and other factors (such as temperature, humidity, ergonomics and cleanliness).

7.1.5 Monitoring and measuring resources

Where monitoring or measuring is used for evidence of conformity of products and services to specified requirements the organization shall determine the resources needed to ensure valid and reliable monitoring and measuring results.

The organization shall ensure that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;

b) are maintained to ensure their continued fitness for their purpose.

The organization shall retain appropriate documented information as evidence of fitness for purpose of monitoring and measurement resources.

Where measurement traceability is: a statutory or regulatory requirement; a customer or relevant interested party expectation; or considered by the organization to be an essential part of providing confidence in the validity of measurement results; measuring instruments shall be:

— verified or calibrated at specified intervals or prior to use against measurement standards

traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification shall be retained as documented information;

— identified in order to determine their calibration status;

— safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when an instrument is found to be defective during its planned verification or calibration, or during its use, and take appropriate corrective action as necessary.

7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained, and made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.

NOTE 1 Organizational knowledge can include information such as intellectual property and lessons learned.

NOTE 2 To obtain the knowledge required, the organization can consider:

a) internal sources (e.g. learning from failures and successful projects, capturing undocumented knowledge and experience of topical experts within the organization);

b) external sources (e.g. standards, academia, conferences, gathering knowledge with customers or providers).

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects its quality performance;

b) ensure that these persons are competent on the basis of appropriate education, training, or experience;

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

d) retain appropriate documented information as evidence of competence.

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

7.3 Awareness

Persons doing work under the organization’s control shall be aware of:

a) the quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance;

d) the implications of not conforming with the quality management system requirements.

7.4 Communication

The organization shall determine the internal and external communications relevant to the quality management system including:
a) on what it will communicate;
b) when to communicate;
c) with whom to communicate;
d) how to communicate.

7.5 Documented information

7.5.1 General

The organization's quality management system shall include
a) documented information required by this International Standard;
b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

NOTE The extent of documented information for a quality management system can differ from one organization to another due to:
a) the size of organization and its type of activities, processes, products and services;
b) the complexity of processes and their interactions;
c) the competence of persons.

7.5.2 Creating and updating

When creating and updating documented information the organization shall ensure appropriate:
a) identification and description (e.g. a title, date, author, or reference number);
b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
c) review and approval for suitability and adequacy.

7.5.3 Control of documented Information

7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure:
a) it is available and suitable for use, where and when it is needed;
b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:
a) distribution, access, retrieval and use;
b) storage and preservation, including preservation of legibility;
c) control of changes (e.g. version control);
d) retention and disposition.

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

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

8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes, as outlined in 4.4, needed to meet requirements for the provision of products and services and to implement the actions determined in 6.1, by:

a) determining requirements for the product and services;

b) establishing criteria for the processes and for the acceptance of products and services;

c) determining the resources needed to achieve conformity to product and service requirements;

d) implementing control of the processes in accordance with the criteria;

e) retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate conformity of products and services to requirements.

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

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled in accordance with 8.4.

8.2 Determination of requirements for products and services

8.2.1 Customer communication

The organization shall establish the processes for communicating with customers in relation to:

a) information relating to products and services;

b) enquiries, contracts or order handling, including changes;

c) obtaining customer views and perceptions, including customer complaints;

d) the handling or treatment of customer property, if applicable;

e) specific requirements for contingency actions, when relevant.

8.2.2 Determination of requirements related to products and services

The organization shall establish, implement and maintain a process to determine the requirements for the products and services to be offered to potential customers.

The organization shall ensure that:

a) product and service requirements (including those considered necessary by the organisation), and applicable statutory and regulatory requirements, are defined;

b) it has the ability to meet the defined requirements and substantiate the claims for the products and services it offers.

8.2.3 Review of requirements related to products and services

The organization shall review, as applicable:

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

b) requirements not stated by the customer, but necessary for the customers' specified or intended use, when known;

c) additional statutory and regulatory requirements applicable to the products and services;

d) contract or order requirements differing from those previously expressed.
NOTE Requirements can also include those arising from relevant interested parties.
This review shall be conducted prior to the organization's commitment to supply products and services to the customer and shall ensure contract or order requirements differing from those previously defined are resolved.
Where the customer does not provide a documented statement of their requirements, the customer requirements shall be confirmed by the organization before acceptance.
Documented information describing the results of the review, including any new or changed requirements for the products and services, shall be retained.
Where requirements for products and services are changed, the organization shall ensure that relevant documented information is amended and that relevant personnel are made aware of the changed requirements.

8.3 Design and development of products and services

8.3.1 General

Where the detailed requirements of the organization's products and services are not already established or not defined by the customer or by other interested parties, such that they are adequate for subsequent production or service provision, the organization shall establish, implement and maintain a design and development process.
NOTE 1 The organization can also apply the requirements given in 8.5 to the development of processes for production and services provision
NOTE 2 For services, design and development planning can address the whole service delivery process. The organization can therefore choose to consider the requirements of clauses 8.3 and 8.5 together.

8.3.2 Design and development planning

In determining the stages and controls for design and development, the organization shall consider:
a) the nature, duration and complexity of the design and development activities;
b) requirements that specify particular process stages, including applicable design and development reviews;
c) the required design and development verification and validation;
d) the responsibilities and authorities involved in the design and development process;
e) the need to control interfaces between individuals and parties involved in the design and development process;
f) the need for involvement of customer and user groups in the design and development process;
g) the necessary documented information to confirm that design and development requirements have been met.

8.3.3 Design and development Inputs

The organization shall determine:
a) requirements essential for the specific type of products and services being designed and developed, including, as applicable, functional and performance requirements;

1283 b) applicable statutory and regulatory requirements;
1284 c) standards or codes of practice that the organization has committed to implement;
1285 d) internal and external resource needs for the design and development of products and services;
1286 e) the potential consequences of failure due to the nature of the products and services;
1287 f) the level of control expected of the design and development process by customers and other
1288 relevant interested parties.
1289 Inputs shall be adequate for design and development purposes, complete, and unambiguous.
1290 Conflicts among inputs shall be resolved.
1291 **8.3.4 Design and development controls**
1292 The controls applied to the design and development process shall ensure that:
1293 a) the results to be achieved by the design and development activities are clearly defined;
1294 b) design and development reviews are conducted as planned;
1295 c) verification is conducted to ensure that the design and development outputs have met the design
1296 and development input requirements;
1297 d) validation is conducted to ensure that the resulting products and services are capable of meeting
1298 the requirements for the specified application or intended use (when known).

8.3.5 Design and development 1299 **outputs**
1300 The organization shall ensure that design and development outputs:
1301 a) meet the input requirements for design and development;
1302 b) are adequate for the subsequent processes for the provision of products and services;
1303 c) include or reference monitoring and measuring requirements, and acceptance criteria, as
1304 applicable;
1305 d) ensure products to be produced, or services to be provided, are fit for intended purpose and their
1306 safe and proper use.
1307 The organization shall retain the documented information resulting from the design and development
1308 process.
1309 **8.3.6 Design and development changes**
1310 The organization shall review, control and identify changes made to design inputs and design outputs
1311 during the design and development of products and services or subsequently, to the extent that there
1312 is no adverse impact on conformity to requirements.
1313 Documented information on design and development changes shall be retained.
1314 **8.4 Control of externally provided products and services**
1315 **8.4.1 General**
1316 The organization shall ensure that externally provided processes, products, and services conform to
1317 specified requirements.
1318 The organization shall apply the specified requirements for the control of externally provided products
1319 and services when:
1320 a) products and services are provided by external providers for incorporation into the organization’s
1321 own products and services;

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

c) a process or part of a process is provided by an external provider as a result of a decision by the organization to outsource a process or function.

The organization shall establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers based on their ability to provide processes or products and services in accordance with specified requirements.

The organization shall retain appropriate documented information of the results of the evaluations, monitoring of the performance and re-evaluations of the external providers.

8.4.2 Type and extent of control of external provision

In determining the type and extent of controls to be applied to the external provision of processes, products and services, the organisation shall take into consideration:

a) the potential impact of the externally provided processes, products and 1334 services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

b) the perceived effectiveness of the controls applied by the external provider.

The organization shall establish and implement verification or other activities necessary to ensure the externally provided processes, products and services do not adversely affect the organisation's ability to consistently deliver conforming products and services to its customers.

Processes or functions of the organization which have been outsourced to an external provider remain within the scope of the organization's quality management system; accordingly, the organization shall consider a) and b) above and define both the controls it intends to apply to the external provider and those it intends to apply to the resulting process output.

8.4.3 Information for external providers

The organization shall communicate to external providers applicable requirements for the following:

a) the products and services to be provided or the processes to be performed on behalf of the organization;

b) approval or release of products and services, methods, processes or equipment;

c) competence of personnel, including necessary qualification;

d) their interactions with the organization's quality management system;

e) the control and monitoring of the external provider's performance to be applied by the organization;

f) verification activities that the organization, or its customer, intends to perform at the external provider's premises.

The organization shall ensure the adequacy of specified requirements prior to their communication to the external provider.

8.5 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement controlled conditions for production and service provision, including

delivery and post-delivery activities.
Controlled conditions shall include, as applicable:
a) the availability of documented information that defines the characteristics of the products and services;
b) the availability of documented information that defines the activities to be performed and the results to be achieved;
c) monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met.
d) the use, and control of suitable infrastructure and process environment;
e) the availability and use of suitable monitoring and measuring resources;

f) the competence and, where applicable, required qualification 1372 of persons;
g) the validation, and periodic revalidation, of the ability to achieve planned results of any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement;
h) the implementation of products and services release, delivery and post-delivery activities.

8.5.2 Identification and traceability

Where necessary to ensure conformity of products and services, the organization shall use suitable means to identify process outputs.
The organization shall identify the status of process outputs with respect to monitoring and measurement requirements throughout production and service provision.
Where traceability is a requirement, the organization shall control the unique identification of the process outputs, and retain any documented information necessary to maintain traceability.
NOTE Process outputs are the results of any activities which are ready for delivery to the organization's customer or to an internal customer (e.g. receiver of the inputs to the next process); they can include products, services, intermediate parts, components, etc.

8.5.3 Property belonging to customers or external providers

The organization shall exercise care with property belonging to the customer or external providers while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard the customer's or external provider's property provided for use or incorporation into the products and services.
When property of the customer or external provider is incorrectly used, lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider.
NOTE Customer property can include material, components, tools and equipment, customer premises, intellectual property and personal data.

8.5.4 Preservation

The organization shall ensure preservation of process outputs during production and service provision, to the extent necessary to maintain conformity to requirements.
NOTE Preservation can include identification, handling, packaging, storage, transmission or transportation,

1400 and protection.

1401 **8.5.5 Post-delivery activities**

1402 As applicable, the organization shall meet requirements for post-delivery activities associated with the
1403 products and services.

1404 In determining the extent of post-delivery activities that are required, the organisation shall consider:

1405 a) the risks associated with the products and services;

1406 b) the nature, use and intended lifetime of the products and services;

1407 c) customer feedback;

1408 d) statutory and regulatory requirements.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations 1409 such as
1410 maintenance services, and supplementary services such as recycling or final disposal.

1411 **8.5.6 Control of changes**

1412 The organization shall review and control unplanned changes essential for production or service
1413 provision to the extent necessary to ensure continuing conformity with specified requirements.

1414 The organization shall retain documented information describing the results of the review of changes,
1415 the personnel authorizing the change, and any necessary actions.

1416 **8.6 Release of products and services**

1417 The organization shall implement the planned arrangements at appropriate stages to verify that
1418 product and service requirements have been met. Evidence of conformity with the acceptance criteria
1419 shall be retained.

1420 The release of products and services to the customer shall not proceed until the planned
1421 arrangements for verification of conformity have been satisfactorily completed, unless otherwise
1422 approved by a relevant authority and, as applicable, by the customer. Documented information shall
1423 provide traceability to the person(s) authorizing release of products and services for delivery to the
1424 customer.

1425 **8.7 Control of nonconforming process outputs, products and services**

1426 The organization shall ensure process outputs, products and services that do not conform to
1427 requirements are identified and controlled to prevent their unintended use or delivery.

1428 The organization shall take appropriate corrective action based on the nature of the nonconformity and
1429 its impact on the conformity of products and services. This applies also to nonconforming products and
1430 services detected after delivery of the products or during the provision of the service.

1431 As applicable, the organization shall deal with nonconforming process outputs, products and services
1432 in one or more of the following ways:

1433 a) correction;

1434 b) segregation, containment, return or suspension of provision of products and services;

1435 c) informing the customer;

1436 d) obtaining authorization for:

1437 — use “as-is’;

1438 — release, continuation or re-provision of the products and services;

1439 — acceptance under concession.
1440 Where nonconforming process outputs, products and services are corrected, conformity to the
1441 requirements shall be verified.
1442 The organization shall retain documented information of actions taken on nonconforming process
1443 outputs, products and services, including on any concessions obtained and on the person or authority
1444 that made the decision regarding dealing with the nonconformity.

9 Performance 1445 evaluation

1446 9.1 Monitoring, measurement, analysis and evaluation

1447 9.1.1 General

1448 The organization shall determine:
1449 a) what needs to be monitored and measured;
1450 b) the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid
1451 results;
1452 c) when the monitoring and measuring shall be performed;
1453 d) when the results from monitoring and measurement shall be analysed and evaluated.
1454 The organization shall ensure that monitoring and measurement activities are implemented in
1455 accordance with the determined requirements and shall retain appropriate documented information as
1456 evidence of the results.
1457 The organization shall evaluate the quality performance and the effectiveness of the quality
1458 management system.

1459 9.1.2 Customer satisfaction

1460 The organization shall monitor customer perceptions of the degree to which requirements have been
1461 met.
1462 The organization shall obtain information relating to customer views and opinions of the organisation
1463 and its products and services.
1464 The methods for obtaining and using this information shall be determined.
1465 NOTE Information related to customer views can include customer satisfaction or opinion surveys, customer
1466 data on delivered products or services quality, market-share analysis, compliments, warranty claims and dealer
1467 reports.

1468 9.1.3 Analysis and evaluation

1469 The organization shall analyse and evaluate appropriate data and information arising from monitoring,
1470 measurement and other sources.
1471 The output of analysis and evaluation shall be used to:
1472 a) demonstrate conformity of products and services to requirements;
1473 b) assess and enhance customer satisfaction;
1474 c) ensure conformity and effectiveness of the quality management system;
1475 d) demonstrate that planning has been successfully implemented;
1476 e) assess the performance of processes;
1477 f) assess the performance of external provider(s);

1478 g) determine the need or opportunities for improvements within the quality management system.
1479 The results of analysis and evaluation shall also be used to provide inputs to management review.

9.2 1480 **Internal audit**
1481 **9.2.1** The organization shall conduct internal audits at planned intervals to provide information on
1482 whether the quality management system;
1483 a) conforms to:
1484 1) the organization's own requirements for its quality management system;
1485 2) the requirements of this International Standard;
1486 b) is effectively implemented and maintained.
1487 **9.2.2** The organization shall:
1488 a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods,
1489 responsibilities, planning requirements and reporting, which shall take into consideration the
1490 quality objectives, the importance of the processes concerned, customer feedback, changes
1491 impacting on the organisation, and the results of previous audits;
1492 b) define the audit criteria and scope for each audit;
1493 c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
1494 d) ensure that the results of the audits are reported to relevant management;
1495 e) take necessary correction and corrective actions without undue delay;
1496 f) retain documented information as evidence of the implementation of the audit programme and the
1497 audit results.
1498 NOTE See ISO 19011 for guidance.
1499 **9.3 Management review**
1500 **9.3.1** Top management shall review the organization's quality management system, at planned
1501 intervals, to ensure its continuing suitability, adequacy, and effectiveness.
1502 The management review shall be planned and carried out taking into consideration:
1503 a) the status of actions from previous management reviews;
1504 b) changes in external and internal issues that are relevant to the quality management system
1505 including its strategic direction;
1506 c) information on the quality performance, including trends and indicators for:
1507 1) nonconformities and corrective actions;
1508 2) monitoring and measurement results;
1509 3) audit results;
1510 4) customer satisfaction;
1511 5) issues concerning external providers and other relevant interested parties;
1512 6) adequacy of resources required for maintaining an effective quality management system;

7) process performance and conformity of products 1513 and services;
1514 d) the effectiveness of actions taken to address risks and opportunities (see clause 6.1);
1515 e) new potential opportunities for continual improvement.

9.3.2 The outputs of the management review shall include decisions and actions related to:

a) continual improvement opportunities;

b) any need for changes to the quality management system, including resource needs.

The organization shall retain documented information as evidence of the results of management reviews.

10 Improvement

10.1 General

The organization shall determine and select opportunities for improvement and implement necessary actions to meet customer requirements and enhance customer satisfaction.

This shall include, as appropriate:

a) improving processes to prevent nonconformities;

b) improving products and services to meet known and predicted requirements;

c) improving quality management system results.

NOTE Improvement can be effected reactively (e.g. corrective action), incrementally (e.g. continual improvement), by step change (e.g. breakthrough), creatively (e.g. innovation) or by re-organisation (e.g. transformation).

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including those arising from complaints, the organization shall:

a) react to the nonconformity, and as applicable:

1) take action to control and correct it;

2) deal with the consequences;

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

1) reviewing the nonconformity;

2) determining the causes of the nonconformity;

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

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) make changes to the quality management system, if necessary.

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

NOTE 1 In some instances, it can be impossible to eliminate the cause of a nonconformity.

NOTE 2 Corrective action can reduce the likelihood of recurrence to an acceptable level.

10.2.2 The organization shall retain documented information as evidence of:

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

b) the results of any corrective action.

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy, and effectiveness of the quality management system.

The organization shall consider the outputs of analysis and evaluation, and the outputs from

1555 management review, to confirm if there are areas of underperformance or opportunities that shall be
1556 addressed as part of continual improvement.
1557 Where applicable, the organization shall select and utilise applicable tools and methodologies for
1558 investigation of the causes of underperformance and for supporting continual improvement.
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