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Invisio Policy – P03 – Quality Manual

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1. Introduction

This document forms part of Invis Quality Management System, focused on achieving the ISO 9001 Certification. It is to be used in conjunction with other documents that form Invis Quality management Library.

2. Purpose

The Purpose of this Manual is to ensure that Invis has a clear alignment with, and understanding of, the requirements of the ISO 9001 Standard. It is a key document in achieving this certification.

3. Scope

3.1. General

- a) Company Name (Invis) has implemented a quality management system based on ISO 9001 (the standard). The resultant quality management system describes Invis's need to;
- b) demonstrate its ability to consistently provide services that make customer and applicable statutory and regulatory requirements and,
- c) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements

3.2. Applicability

All clauses of the standard are applicable to Invis with the exception of;

- a) Yes to be Defined.

4. Normative reference

ISO 9001 Standards References

5. Terms and definitions

All terms and references are as per those specified in the standard.

6. Context of Invis

6.1. Understand Invis and Its Context

Invis has determined external and internal issues that are relevant to its purpose and its strategic direction and that affect our ability to achieve the intended results of its quality management system. Invis monitors and reviews information about these external and internal issues.



6.2. Understanding the Needs and Expectations of Interested Parties

Due to the effect or potential effect on Invis's ability to consistently provide products and services and that meet customer and applicable statutory and regulatory requirements, Invis has determined:

- 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.

Invis monitors and reviews information about these interested parties and their relevant requirements.

6.3. Determining the Scope of the Quality Management System

Invis has determined the boundaries and applicability of the quality management system to establish its scope.

The scope of the quality management system for certification is; the design, development, implementation and ongoing support of documented management systems.

In determining the scope, Invis considered:

- 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 and of Invis.

Invis has applied all the requirements of the standard as applicable within the determined scope of its quality management system. The scope of Invis's quality management system is available and maintained as documented information. The scope states the types of products and services and covered and provides justification for any requirements of the standard that Invis determines is not applicable to the scope of its quality management system. These are described in 1.2.

Conformity to the standard is only claimed when the requirements determined do not affect Invis's ability or responsibility to ensure the conformity of its products and services and enhancement of customer satisfaction.

6.4. Quality Management System and Its Processes

6.4.1.

Invis has established, implemented, maintains and continually improves our quality management system, including the processes needed and their interactions, in accordance with the requirements of the standard. Invis has determined the processes needed for the quality management system and their application throughout Invis and has:



- a) determined the inputs required and the outputs expected from these processes;
- b) determined the sequence and interaction of these processes;
- c) determined and applies the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) determined the resources needed for these processes and ensure their availability;
- e) assigned the responsibilities and authorities for these processes;
- f) addressed the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) evaluated these processes and implements any changes needed to ensure that these processes achieve their intended results;
- h) improved the processes and the quality management system.

6.4.1.1.

To the extent necessary, Invisive:

- a) maintains documented information to support the operation of its processes;
- b) retains documented information to have confidence that the processes are being carried out as planned.

7. Leadership

7.1. Leadership and commitment

7.1.1. General

The Company's top management demonstrates leadership and commitment with the respect to the quality manager of system by:

- a) taking accountability for the effectiveness of the quality management system;
- b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of Invisive;
- c) ensuring the integration of the quality management system requirements into Invisive's business processes;
- a) promoting the use of the process approach and risk-based thinking;
- b) ensuring that the results are measured for quality management system are available;
- c) communicating the importance of effective quality management and of conforming to the quality management system requirements;
- d) ensuring the quality management system achieves its intended results;
- e) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- f) promoting improvement and;
- g) promoting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.



7.1.2. Customer Focus

Invisive's top management demonstrates leadership and commitment with respect to customer focus by ensuring that:

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) the risks and opportunities can affect the conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained.

7.2. Policy

7.2.1. Establishing the quality policy

Invisive's top management has established, implemented and maintains a quality policy that:

- a) is appropriate to the purpose and context of Invisive and supports its strategic directions;
- b) provides a framework for setting quality objectives;
- c) includes a commitment to satisfy applicable requirements and;
- d) includes a commitment to continue with improvement of the quality management system.

7.2.2. Communicating the quality policy

The quality policy is:

- a) available and be maintained as documented information;
- b) communicated, understood and applied within the organisation and;
- c) available to relevant interested parties, as appropriate.

7.3. Organizational roles, Responsibilities and Authorities

Invisive's top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within Invisive. Invisive's top management has assigned the responsibility and the authority for:

- a) ensuring that the quality management system conforms to the requirements of the standard;
- b) ensuring that the processes are delivering their intended output;
- c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to The Oberon NSW Pty Limited Top management;
- d) ensuring the promotion of customer focus throughout organization and;



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

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, Invis considers the issues referred to in 4.1 and the requirements referred to in 4.2 and determines the risks and opportunities that need to be addressed to:

- a) give assurance that the quality management system can achieve its intended result(s);
- b) enhanced desirable effects;
- c) prevent, or reduce, undesired effects;
- d) achieve improvement.

6.1.2 Invis plans:

- a) actions to address risks and opportunities;
- b) how to:
 - i) integrate and implement the actions into its quality management system processes, see 4.4;
 - ii) evaluate the effectiveness of those actions.

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services and . Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood of consequences, sharing the risk, or retaining risk by informed decision. Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address Invis's or its customer's needs.

6.2 Quality objectives and planning to achieve them.

7.3.1.

Invis establishes the quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives are:

- a) consistent with the quality policies;
- b) measurable;
- c) take into account applicable climate;



- d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) are monitored;
- f) communicated;
- g) updated as appropriate.

Invis maintains documented information on the quality objectives.

7.3.2.

When planning how to achieve its quality objectives, Invis determines:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

7.4. Planning of changes

When Invis determines the need for changes to the quality management system, the changes are carried out in a planned manner (see 4.4). Invis considers the:

- a) purpose of the changes and the potential consequences;
- b) integrity of the quality management system;
- c) availability of resources;
- d) allocation or reallocation of responsibilities and authorities.

8. Support

8.1. Resources

8.1.1. General

Invis determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. Invis considers:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

8.1.2. People

Invis determines and provides the persons necessary for the effective implementation of its quality management system and for the proper operation and control of these processes.



8.1.3. Infrastructure

Invisive determines, provides and maintains the infrastructure necessary for the operation of these processes and to achieve conformity in products and services and . Infrastructure can include but not limited to buildings and associated utilities. Equipment including hardware and software. Transportation resources. Information and communication technology.

8.1.4. Environment for the operational processes

Invisive determines, provides and maintains the environment necessary for the operational process and to achieve conformity of products and services and . A suitable environment can be the combination human and physical factors such as social, psychological and physical. These factors can differ substantial depending on the products and services and provided.

8.1.5. Monitoring and Measuring Resources

8.1.5.1. General

Invisive determines and provides the resources to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services and to requirements. Invisive shall ensure that the resources provided:

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

Invisive retains appropriate documented information as evidence of fitness of purpose of the monitoring and measurement resources.

8.1.5.2. Measurement and Measurement Traceability

When measurement traceability is a requirement, or is considered by Invisive to be essential part of providing confidence in the validity of measurement results, measurement equipment is:

- a) calibrated or verified or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exists, the basis used for calibration verification shall be retained as documented information;
- b) identified in order to determine their status;
- c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.



Invis determines if the validity of previous measurement results has been adversely effected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

8.1.6. Organisational knowledge

Invis determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services and . This knowledge is maintained and made available to the extent necessary.

When addressing changing needs and trends, Invis considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates. Such knowledge specific to Invis is generally gained by experience. It is information that is used and shared to achieve Invis's objectives. Organizational knowledge can be based on internal resources and external sources.

8.2. Competence

Invis has:

- a) determined the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management systems;
- b) ensured that these persons are competent on the basis of appropriate education, training or experience;
- c) where applicable, taken actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d) retained appropriate documented information as evidence of competence.

Such applicable actions can include, but not limited to the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

8.3. Awareness

Invis ensures that persons doing work under Invis's control are aware of:

- a) the quality policy;
- b) relevant quality objectives;
- c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- d) the implications of not conforming with the quality management system requirements.



8.4. Communication

Invis determines the internal and external communications relevant to the quality manual system, including:

- a) on what it will communicate;
- b) when to communicate;
- c) with whom to communicate;
- d) how to communicate;
- e) who communicates.

8.5. Documented information

8.5.1. General

Invis's quality management system includes:

- a) documented information required by the standard;
- b) documented information determined by Invis as being necessary for the effectiveness of the quality management system.

8.5.2. Creating and updating

When creating and updating documented information Invis ensures 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.

8.5.3. Control of document information

8.5.3.1.

Document information required by the quality management system and by the standard is 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).

8.5.3.2.

For the control of documented information Invis addresses the following activities as applicable:



- a) distribution, access, retrieval and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes (e.g. version control);
- d) retention and disposition.

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

Documented information retained as evidence of conformity is protected from unintended alterations. Access implies decisions regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

9. Operation

9.1. Operational planning and control

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

- a) determine the requirements for the products and services and ;
- b) establishing criteria for the processes and the acceptance of products and services and ;
- 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) determining, maintaining and retaining documented information to the extent necessary:
 - I. to have confidence that the processes have been carried out as planned;
 - II. to demonstrate the conformity of products and services and to their requirements.

The output of this planning is suitable for Invis's operations. Invis controls plan changes and reviews the necessary consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

Invis ensures outsourced processes are controlled (see 8.4).

9.2. Requirements for products and services and

9.2.1. Customer communication

Communication with customers includes:



- a) providing the information relating to products and services and ;
- b) handling enquiries, contracts or orders, including changes;
- c) containing customer feedback related to products and services and , including customer complaints;
- d) handling or controlling customer product;
- e) establishing specific requirements for contingency actions, when relevant.

9.2.2. Determining the requirements for products and services

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

- a) the requirements for the products and services and are defined, including:
 - i) any applicable statutory and regulatory requirements;
 - ii) those considered necessary by Invisé;
- b) Invisé can meet the claims for products and services and it offers.

9.2.3. Review of the requirements for products and services and

9.2.3.1.

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

- 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 specified or intended use, when known;
- c) requirements specified by Invisé;
- d) statutory and regulatory requirements applicable to products and services and ;
- e) contract or order requirements differing from those previously expressed.

Invisé ensures that contract or order requirements differing from those previously defined are resolved. The customer's requirements are confirmed by Invisé before acceptance, when the customer does not provide a documented statement of their requirements. In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

9.2.3.2.

Invisé shall retain documented information, as applicable:



- a) on results of the review;
- b) on any requirements for the products and services and .

9.2.4. Changes to requirements for products and services

Invisive ensures relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services and are changed.

9.3. Design and development of products and services

9.3.1. General

Invisive has established, implemented and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services and .

9.3.2. Design and development planning

In determining the stages and controls for design and development Invisive considers the:

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

9.3.3. Design and development inputs

Invisive determines the requirements essential for the specific types of products and services and to be designed and developed. T company considers:

- a) functional and performance requirements;
- b) information derived from previous similar design and development activities;
- c) statutory and regulatory requirements;
- d) standards or codes of practice that Invisive has committed to implement;



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

Input is adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs are resolved. Invisive retains documented information of design and development inputs.

9.3.4. Design and development controls

Invisive applies controls to the design and development process to ensure that:

- a) the results to be achieved are defined;
- b) reviews are conducted to evaluate the ability of the results of the design and development to meet requirements;
- c) verification activities conducted to ensure that the design and development efforts meet the input requirements, also;
- d) validation activities are conducted to ensure that the resulting products and services and meet the requirements for the specified application or intended use;
- e) any necessary actions are taken on problems determined during the reviews, or verification of validation activities;
- f) documented information of these activities is retained.

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

9.3.5. Design and development outputs

Invisive ensures design and development outputs:

- a) meet the input requirements;
- b) are adequate for the subsequent processes for the provision of products and services and ;
- c) included are reference monitoring measuring requirements, as appropriate, and acceptance criteria;
- d) specify the characteristics of the products and services and that are essential for their intended purpose and their safe and proper provision.

Invisive retains documented information on design and development outputs.

9.3.6. Design and development changes

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

- a) design and development changes;



- b) the results of review;
- c) the authorisation of changes;
- d) the actions taken to prevent adverse impacts.

9.4. Control of externally provided processes, products and services and

9.4.1. General

Invisive ensures that externally provided processes, products and services and conform to requirements. Invisive determines the controls to be applied to externally provided processes, products and services and when:

- a) products and services and from external providers are intended for incorporation into Invisive's own products and services and ;
- b) products and services and are provided directly to the customer by external providers on behalf of Invisive;
- c) a process or part of a process provided by external provider as a result of a decision by Invisive;
- d) Invisive shall determine 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 and in accordance with requirements. Invisive retains documented information of these activities and any necessary actions arising from the evaluations.

9.4.2. Type and extent of control

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

- a) ensures that externally provided processes remain within the control of its quality management system;
- b) defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting outputs;
- c) takes into consideration the:
 - i) potential impact of the externally provided processes, products and services and Invisive's ability to consistently meet customer and applicable statutory and regulatory requirements;
 - ii) effectiveness of the controls applied by the external provider;
- d) determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services and meet requirements.



9.4.3. Information for external providers

Invisé ensures the adequacy of requirements prior to their communication to the external provider.

Invisé communicates to external providers its requirements for:

- a) the processes, products and services and to be provided;
- b) the approval of:
 - i) products and services and ;
 - ii) methods, processes and equipment;
 - iii) release of products and services and ;
- c) competence, including any required qualification of persons;
- d) the external providers interactions with Invisé;
- e) control and monitoring of external providers' performance to be applied by Invisé;
- f) verification or validation activities that Invisé, or its customer, intends to perform at the external providers' premises.

9.5. Production and service provision

9.5.1. Control of production and service provision

Invisé implements production and service provision under control conditions. Control conditions include, as applicable the:

- a) availability of documented information that defines the:
 - i) characteristics of the products to be produced, the products and to be provided, or the activities to be performed;
 - ii) results to be achieved;
- b) availability and use of suitable monitoring measuring resources;
- c) implementation of monitoring and measurement activities at appropriate stages to verify criteria for control of processes or in/outputs, and acceptance criteria for products and services and , have been met;
- d) use of suitable infrastructure and environment for the operation of processes;
- e) appointment of confident persons, including any required qualification;
- f) validation, and periodic re-evaluation, of the ability to achieve plan results of the processes for production and so is provision, with the resulting output cannot be verified by subsequent monitoring or measurement;
- g) implementation of actions to prevent human error;
- h) implementation of release, delivery and post delivery activities.



9.5.2. Identification and traceability

Invisé uses suitable means to identify outputs when it is necessary to ensure the conformity products and services and . The Zoo] identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. Invisé controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

9.5.3. Property belonging to customers or external providers

Invisé exercises care with property belonging to customers or external providers while it is under Invisé's control or being used by Invisé. Invisé identifies, verifies, protects, and safeguards customers' or external providers' property provided for use or incorporation with the products and services and . When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, Invisé reports this to the customer or external provider and retains documented information on what has occurred. A customer's or external provider's property can include but not limited to materials, components, tools and equipment, premises, intellectual property and personal data.

9.5.4. Preservation

Invisé preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. Preservation can include identification handling, contamination control, packaging, storage transmission or transportation and protection, as needed.

9.5.5. Post delivery activities

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

- a. statutory and regulatory requirements;
- b. the potential undesired consequences associated with its products and services and ;
- c. the nature, use and intended lifetime of its products and services and ;
- d. customer requirements;
- e. customer feedback.

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



9.5.6. Control changes

Invis reviews and controls changes for production or service provision to the extent necessary to ensure continuing conformity with requirements. The company retains documented information describing the results of the review of change, the person(s) authorising the change, and any necessary actions arising from the review.

9.6. Release of products and services and

Invis implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services and to their customers does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. Invis retains documented information on the release of products and services and . The documented information includes:

- a) evidence of conformity with the acceptance criteria;
- b) traceability to the person(s) authorising the release.

9.7. Control of nonconforming outputs

9.7.1.

Invis ensures that outputs that do not conform to their requirements are identified and controlled to prevent unintended use or delivery. Invis takes appropriate action based on the nature of the non conformity and its effects on the conformity of products and services and . This also applies to nonconforming products and services and detected after delivery of products, during or after the provision of products and . Invis deals with nonconforming outputs in one or more of the following ways:

- a) correction;
- b) segregation, containment, return or suspension of the provision of products and services and ;
- c) informing the customer;
- d) obtain authorisation for acceptance under concession.

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

9.7.2.

Invis retains documented information that:

- a) describes the nonconformity;
- b) describes the actions taken;



- c) describes any concessions obtained;
- d) identifies the authority deciding the action in respect of the conformity.

10. Performance evaluation

10.1. Monitoring, measurement and evaluation

10.1.1. General

Invisive determines:

- a) what needs to be monitored and measured;
- b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) when the monitoring and measuring are performed;
- d) when the results from monitoring and measurement are analysed and evaluated.

Invisive evaluates the performance and the effectiveness of the quality management system. T company retains appropriate documented information as evidence of the results.

10.1.2. Customer satisfaction

Invisive monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. T company determines the methods for obtaining, monitoring and reviewing this information. Examples of monitoring customer perceptions can include but not limited to customer surveys, customer feedback on delivered products and services and , meetings with customers, market share analysis, compliments, warranty claims and dealer reports.

10.1.3. Analysis and evaluation

Invisive analyses and evaluates appropriate data and information arising from monitoring and measurement. T results of analysis are used to evaluate;

- a) conformity of products and services and ;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the quality management system;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the quality management system.

Methods to analyse data can include statistical techniques such as but not limited to sampling plans, acceptability limits, standard deviations, etc.



10.2. Internal audit

10.2.1.

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

- a) Conforms to:
 - i) Invisé's own requirements for its quality management system;
 - ii) the requirements of this standard;
- b) is effectively implemented and maintained.

10.2.2. Invisé:

- a) plans, establishes, implements and maintains an audit program, including the frequency, methods, responsibilities, planning, requirements and reporting which shall take into consideration the importance of the process concerned, changes affecting Invisé, and the results of previous orders;
- b) defines the order criteria and scope for each order;
- c) selects auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensures that results of the audits are reported to the relevant management;
- e) takes appropriate correction and corrective actions without undue delay;
- f) retains documented information as evidence of the implementation of the audit program and the audit results.

10.3. Management review

10.3.1. General

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

10.3.2. Management review inputs

The management reviews are planned and carried out taking into consideration:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the quality management system;



- c) information on the performance and effectiveness of the quality management system, including trends in:
 - i) customer satisfaction and feedback from relevant interested parties;
 - ii) the extent to which quality objectives have been met;
 - iii) process performance in conforming products and services and ;
 - iv) non-conformities and corrective actions;
 - v) monitoring and measurement results;
 - vi) audit results;
 - vii) the performance of external providers;
- d) the adequacy of resources;
- e) the effectiveness of actions taken to address risks and opportunities [see 6.1];
- f) opportunities for improvement.

10.3.3. Management review outputs

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

- a) opportunities for improvement;
- b) any need for changes to the quality managed system;
- c) resource needs.

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

11. Improvement

11.1. General

Invisive determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction. These include:

- a) improving products and services and to meet requirements as well as to address future needs and expectations;
- b) correcting, preventing, or reducing undesired effects;
- c) improving the performance and effectiveness of the quality management system.

Examples of improvement can include but not limited to correction, corrective action, continual improvement, breakthrough change, innovation, and reorganization.



11.2. Nonconformity and corrective action

11.2.1.

When a nonconformity occurs, including any arising from complaints, Invisive will:

- a) react to the nonconformity and, as applicable:
 - i) take action to control and correct it;
 - ii) 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 or swear, by:
 - i) reviewing and analysing the nonconformity;
 - ii) determining the causes of the nonconformity;
 - iii) determining if similar nonconformities exist, or could potentially occur;
- c) implement any action noted;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during planning, if necessary;
- f) make changes to the quality management system, if necessary.

Corrective actions are appropriate to the effects of the nonconformities encountered.

11.2.2.

Invisive retains documented information as evidence of the:

- a) nature of the nonconformities and any subsequent actions taken;
- b) results of any corrective action.

11.3. Continual improvement

Invisive continually improves the suitability, adequacy, and effectiveness of the quality management system. Invisive considers the results of analysis and evaluation, and the outputs from the management review, to determine if there are needs or opportunities that shall be addressed as part of the continual improvement.