Simtars
Training, Testing and Certification Centre

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Certification Manual – Management Systems Certification

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1.0 PURPOSE

The purpose of this document is to describe how Simtars Certification undertakes management systems certification of suppliers, manufacturers and service providers encompassing the requirements of ISO/IEC17021-1 *Conformity assessment – requirement for bodies providing audit and certification of management systems.*

This document provides high level compliance and is supported by element specific procedures, instructions, manuals, forms and templates.

1.1.1.1 Reason for Change

- Added guidance in preparing the certification scope in 9.0.
- Added country risk analysis in new 10.2.

2.0 SCOPE

This manual applies to all activities within Simtars Certification associated with the certification of customer's quality management systems including customers with multi-site organisations.

3.0 REFERENCES

ISO/IEC 17021-1 – Conformity assessment - Requirements for bodies providing audit and certification of management systems – Part 1: Requirements.

ISO/IEC 17021-3 – Conformity assessment - Requirements for bodies providing audit and certification of management systems – Part 3: Competence requirements for auditing and certification of quality management systems.

IAF MD 1 - IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organisation

IAF MD 2 - IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems

IAF MD 4 – IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes

IAF ID 3 - IAF Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organisations

IAF MD 5 - Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems

4.0 INTRODUCTION

Simtars is a semi-autonomous, professionally independent business unit of Resources Safety & Health Queensland, a statutory body established by Queensland legislation. Simtars' certification activities are offered on an impartial and non-discriminatory basis to applicants on a quoted fee for service arrangement.

Access to Management Systems certification, within the scope of this document, is available to all applicants. It is not restricted for example on grounds such as the applicant not applying for other services or not a member of a particular group or association. Certification to a specific standard or other normative document will not be denied on the grounds that the applicant does not comply with matters not covered by that standard, such as environmental matters, other than where a potential risk in the use of the product is identified and has not been satisfactorily addressed by the applicant.

5.0 STRUCTURE

Simtars is structured with the following operational centres – Mine Safety Technology Research Centre (MSTRC), Training Testing & Certification Centre (TTCC), Occupational Hygiene, Environment & Chemistry Centre (OHECC), Business Support Centre (BSC). In addition there is internal support functions of Integrated Management System Support covering quality, occupational health and safety and environment. The nature and structure of Simtars is described more fully in Section 1.0 *About Simtars* in the Integrated Management System Manual QM0001.

Simtars Certification is a part of the TTCC and undertakes the operational functions of the certification body. The Director TTCC is responsible for the development of policies and establishment and implementation of processes and procedures relating to its operations including:

- ensuring impartiality in accordance with Simtars' quality policy statement
- supervision of finances
- development of certification services and schemes
- performance of audits
- handling of complaints
- role of governing board and advisory committee
- contractual arrangements for audits
- provision and allocation of resources

The governing body for Simtars Certification is the Simtars Certification Governing Board, membership of which is defined in EP0102 *Charter for Simtars Certification Governing Board*.

Simtars Certification Governing Board is advised by Simtars Certification Advisory Committee. Membership of the Committee composition is defined in EP0096 *Charter for Simtars Certification Advisory Committee*. Members are appointed by the Director - TTCC. The selection is such that no single interest predominates. The Certification Advisory Committee shall have access to all the necessary information to enable it to fulfil its functions.

The organisational overview is provided in Figure 1 to demonstrate the legal status of the certification body.

6.0 GENERAL

Simtars Certification is wholly responsible for and retains its decisions relating to certification, including the granting, refusing, maintaining, transferring of certification, expanding or reducing the scope of certification, renewing, suspending or restoring following suspension and withdrawing of certification. It will not outsource any of these activities.

The Director TTCC will periodically review (approximately annually) the operations and financial status of Simtars Certification and will identify, analyse, evaluate, treat, monitor and document the risks related to potential sources of conflict of interest and impartiality in accordance with the Resources Safety & Health Queensland policies to ensure that commercial, financial, conflicts of interest or any other pressures do not affect the confidentiality, objectivity and impartiality of the certification related activities and any residual risk is within the level of acceptability.

Issue of Certificates by Simtars Certification in no way implies that the management system is approved by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) or any regulatory body or government and certification system or scheme.

The Simtars Certification Advisory Committee acts as a Committee of Reference to the Simtars Certification Governing Board for the purpose of ensuring impartiality and independence in the strategic and policy directions of the certification operation. It also promotes participation of significant parties in the development of procedures regarding the functioning of the certification process.

Any claims by any consultancy organisation implying that the certification process is simpler, easier, faster or less expensive if Simtars Certification is used will be immediately refuted by Simtars Certification.

Any of the following persons may be placed in situations where a potential conflict of interest could arise, or be seen to arise:

- Simtars Certification Governing Board Members
- Simtars Certification Advisory Committee Members
- Simtars Personnel
- Members of other accreditation bodies
- Contractors, e.g. auditors and experts

All such persons must act impartially and not allow commercial, financial or other pressures to compromise impartiality and must declare any known interest in, or connections with the applicant, before undertaking the work, or before or when the situation arises. Such known interests or connections apply to past, present and future involvement and may include but not limited to;

- having been involved at some stage with products in its design, supply, manufacture or maintenance by way of any consultancy service or commercial arrangement,
- having worked with, or consulted to the organisation in the past two years; or reasonable future prospect of such work,
- any immediate family member working with or consulting to the organisation in the past two years; or reasonable future prospect of such work,
- owning shares or any immediate family member owning shares in the organisation or parent organisation,
- having an immediate family member having any other commercial or voluntary arrangement or directorship with the organisation,
- having a relationship with either an applicant or any accreditation body, or
- being in direct competition with an applicant or accreditation body.

Declarations would normally be in writing, but the situation may arise (e.g. Advisory Committee Meetings) where a verbal declaration is necessary. Such declarations and the outcomes are recorded in the minutes of the relevant meeting.

It is acknowledged that threats to impartiality could arise from the actions of other persons, bodies or organisations.

Any person in doubt as to whether a potential conflict of interest exists from any person, body or organisation shall immediately place the facts before the Director TTCC or the members of the Certification Advisory Committee, if more appropriate.

Actions taken to respond to any threats to its impartiality arising from the actions of other persons, bodies or organisations shall be investigated and documented in accordance with Simtars corrective and preventive action system.

Conflict of interest and impartiality statements are held on file for all personnel involved in Simtars Certification. Simtars Certification will not use personnel either internally or externally who cannot demonstrate that there is no conflict of interest. Such statements will be reviewed in order to identify threats to impartiality.

All certification personnel are employed under the Queensland Public Service award and have to abide by The Queensland Public Service “Code of Conduct” as a condition of their employment, and their work is subject to review. The Code of Conduct addresses confidentiality, impartiality and conflict of interest.

Simtars Certification will not;

- Offer or provide management system consultancy,
- Offer or provide internal audits to its certified clients,
- Provide management system certification to any organisation on which it provided consultancy services or internal audits within two years following the end of these services,
- Market or offer services as being linked with the activities of an organisation that provides management system consultancy,
- Certify the management system of another certification body,
- Provide certification to any part of Simtars or to any other part of Resources Safety & Health Queensland and
- Outsource certification and auditing services to any other certification body or to a management system consultancy organisation.

Simtars Certification has:

- Adequate insurance to cover liabilities arising from its operations in each of its fields of activities and the geographic area in which it operates. Details are available on request.
- Through legally enforceable agreements, policy and arrangements to safeguard the confidentiality of the information obtained or created during the performance of certification activities at all levels of its structure, including committees and external bodies or individuals acting on its behalf. All other information, except for information that is made publicly accessible by the client, is considered confidential.
- Equipment and facilities that ensure the secure handling of confidential information (e.g. Documents, records). Refer Resources Safety & Health Queensland policies and procedures.

Confidentiality between Simtars Certification, including all parties directly or indirectly involved in the certification process on behalf of Simtars and its clients is addressed in Simtars Integrated Management System Manual QM0001 and in the Simtars “Standard Terms and Conditions of Contract”. Unless compelled by legal process or, in the reasonable opinion of Simtars Certification, the product poses a real or potential risk to the health or safety of users, Simtars Certification will not divulge information relating to testing or certification details of a client to a third party without the written consent of the client. Where required by law or authorised by contractual arrangements to divulge client information or because of a real or potential risk to health and safety, the client shall be advised of the information disclosed.

Information about a client from sources other than the client (e.g. other clients, regulators) is treated as confidential.

Simtars Certification will make publicly available only information regarding certifications granted, suspended or withdrawn. Simtars Certification will on request from any party provide the means to confirm the validity of a given certificate.

Information about the client from sources other than the client (e.g. complainant, regulators) is treated as confidential.

7.0 MANAGEMENT SYSTEM

Simtars Certification operates within and in accordance with the Simtars certified Integrated Management System to ISO 9001. The scope of this independent certification does not include Simtars Certification.

Simtars Certification input to Simtars management review will include information on relevant appeals and complaints from users of certification activities.

When developing a new management system certification scheme, or adapting an existing one to special circumstances, Simtars Certification will ensure that the guidance given in ISO 19011, and which is appropriate to third-party situations, is included as a design input.

When developing its management system, Simtars Certification has considered the credibility of certification and recognises the degree of public trust and confidence that is established by an impartial and competent assessment process. Simtars Certification also takes into consideration the requirements to address the needs of all parties that have an interest in certification. Parties that have an interest in certification can include, but is not limited to:

- The clients of Simtars Certification
- Customers of the organisation whose management system is certified by Simtars Certification
- Certification services
- Government authorities
- Non – government organisations
- Consumers and members of the public

8.0 CERTIFICATION PERSONNEL

8.1 General

Recruitment of personnel and hiring of contract services is carried out in accordance with documented recruitment and purchasing procedures.

The responsibilities and duties of staff are detailed in position descriptions and, more generally, in the Simtars Integrated Management System Manual QM0001. Records of staff qualifications and skills are held in personnel files.

Simtars Certification will ensure that auditors and technical experts have access to an up-to-date set of documented procedures giving audit instructions and all relevant information on the certification activities. Information sessions will be held to ensure that auditors are knowledgeable of the audit processes, certification requirements and other relevant requirements. External auditors and technical experts are required to complete a written agreement to conform to all aspects of auditor requirements as outlined in this manual. Simtars Certification takes responsibility for these outsourced activities.

Simtars Certification shall ensure that individuals who make the decision for granting, refusing, maintaining or transferring certification, expanding or reducing the scope of certification, renewing, suspending, restoring following suspension or withdrawing certification, understands the applicable standard and certification requirements, and has demonstrated competence to evaluate the audit processes and related recommendations of the audit.

8.2 Competence of Personnel

Simtars Certification have procedures (QP0012 *Assessing Competency of Personnel and Approved Signatory Status*, EP0090 *Procedure for Determining and Assessing Competency of TTCC Personnel*) for assessing competency of personnel and approving signatory status to ensure that personnel involved in certification are competent, suitably trained and qualified to undertake the required functions. TTCC maintains a register of personnel deemed competent in performing specific functions relating to certification. Records of competence assessment are maintained in relevant files.

Simtars Certification will maintain up-to-date personnel records, including relevant qualifications, training, experience, affiliations, professional status, competence and any relevant consultancy services that may have been provided. This includes management and administrative personnel in addition to those performing certification activities.

All Simtars Certification personnel involved in any stage of the certification process shall have a general knowledge of quality management system standards and the generic competency requirements under

the standard. Specific roles in the audit process will require detailed knowledge and skills as referenced in ISO/IEC 17021-1 and ISO/IEC 17021-3 and as outlined in this manual.

8.2.1 Personnel Managing the Audit and Certification Processes

The Principal Engineer – Certification and any others delegated to review applications, select the audit team and schedule audits, review audit reports and make certification decisions shall have the following knowledge and skills relating to:

- specific management system standards and related normative documents
- fundamental concepts and quality management principles
- terms and definitions related to quality management
- the process approach
- the application of risk based thinking including the determination of risks and opportunities
- scopes and their applicability to an organisation's management systems
- Simtars certification processes and relevant certification scheme processes
- business sector of clients
- the products, processes and organisation of clients.

8.2.2 Audit Team Members

Audit team members shall have the following knowledge and skills concerning:

- general and sector specific business management practices to assess a client's handling of
    - the external and internal issues, relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its management system
    - the needs and expectations of interested parties relevant to the client's management system including the requirements for the products and services of the organisation
    - the boundaries and applicability of the management system to establish its scope.
- management system standards and related normative documents
- fundamental concepts and quality management principles and their application
- terms and definitions related to quality management
- the process approach including related monitoring and measurement
- the role of leadership in an organisation and its impact on the management system
- application of risk based thinking including the determination of risks and opportunities
- application of the PDAC (plan, do, check, act) cycle
- structures and interrelationships of documented information specific to quality management
- quality management related tools, methods, techniques and their application
- Simtars certification processes
- the business sector of clients and their products, processes and organisation including:
    - terminology and technology specific to the technical area
    - statutory and regulatory requirements applicable to the product or service specific to the technical area
    - characteristics of products, services and processes specific to the technical area
    - the infrastructure and environment for operation of processes affecting product and service quality
    - the provision of externally provided processes, products and services
    - the impact of organisation type, size, governance, structure, functions and relationships on development and implementation of the management system, its documented information and certification activities.
- fundamental concepts of audit principles, practices and techniques including:
    - Language and communication skills appropriate to all levels in a client's organisation
    - Note taking and report writing skills
    - Presentation skills for effective communication of audit findings
    - Interviewing skills for effective for obtaining audit information
    - Audit management skills for planning and executing specific audits.

8.3 Maintenance of Competence

Simtars Certification shall monitor the performance of auditors by:

- conducting on-site witnessing of auditor performance at a frequency based on all performance monitoring information available.
- Reviewing audit reports and feedback from clients during the certification review process.
- Reviewing external assessments by accreditation bodies such as JAS-ANZ and IECEx.

Records of auditor performance monitoring shall be included in the respective auditor's competency files.

Simtars Certification will identify training needs and offer or provide access to specific training to ensure its auditors, technical experts and other personnel involved in certification activities are competent for the functions they perform.

9.0 INFORMATION ON CERTIFICATION

Certificates issued by Simtars Certification remain the property of Simtars Certification.

Simtars Certification will:

- Provide and update clients on the certification process.
- Give its certified clients due notice of any changes to its requirements for certification, and will verify that each certified client complies with the new requirements.
- Maintain and make publicly accessible, and/or provide upon request, information describing its certification and audit processes including:
    - processes for granting, refusing, maintaining, expanding or reducing the scope of certification, renewing, suspending or restoring following suspension or withdrawing certification
    - fees for application, initial certification and continuing certification
    - types of management systems and certification schemes in which it operates
    - policy on impartiality
    - geographical areas in which it operates. (on request)
    - Status of a given certificate (on request)
- Ensure that information provided to any client or to the marketplace, including advertising, is accurate and not misleading.
- Maintain records on the audit and other certification activities for all clients for a period of at least two certification cycles.
- On request from any party, provide the means to confirm the validity of a given certification. In exceptional cases, access to certain information can be limited on the request of the client (e.g. For security reasons). Information kept and able to be accessed will be only - scope, site address/s and certificate number.
- Keep the records on applicants and clients secure to ensure that the information (including transportation, transmission and transferred) is kept confidential.
- Provide certification documents to the certified client through notification by mail/emails.

The certification document(s) will identify the following:

- The name and geographic location of the client whose management system is certified (or the geographic location of the headquarters, the part of the organisation responsible for and centrally controlling the management system and any sites within the scope of a multi-site certification);
- The dates of granting, extending, reducing or renewing certification;
- The expiry date or recertification due date consistent with the recertification cycle;
- Dates on the certificate shall be:
    - Originally certified by Simtars or other certification body if certification transferred to Simtars (date that the first certificate was issued);

  - Indication that certification was by another certification body before a certain date when certification transferred to Simtars;
  - Current certification (date that the certificate was originally issued, or last re-assessment date);
  - Revision issued (date certificate was updated during the certification cycle);
  - Expires (date certificate expires, three years from current certification).
- A unique identification code in the form of the certificate number in the format SIMQ#### (where #### is a sequential number starting at 0001;
- The standard and/or other normative document, including issue number and/or revision, used for the audit of the certified client;
- The scope of certification with respect to the type of activities, products, services, and process, etc., as applicable at each site;
  Note: Care needs to be exercised when determining the scope to be accurate but also not misleading or implying conformity with any particular service Standards (refer ISO/IEC 17021-1 Clause 8.2.2(f)).
- The name, address and certification mark; other marks (e.g. Accreditation symbol) may be used provided they are not misleading or ambiguous;
- Any other information required by the standard and/or other normative document used for certification.

Where separate certification documents are issued for individual sites of a multi-site organisation, the individual certificates shall include:
- that it is the management system of the whole organisation which is certified;
- the activities performed for that specific site / legal entity which are covered by this certification;
- traceability to the main certificate for the multi-site organisation;
- a statement saying “the validity of this certificate depends on the validity of the main certificate”.

In the event of issuing any revised certification documents, Simtars Certification will distinguish a revised document from any prior obsolete document by stating that the document is a revised version such as “This is a revised version of …….”.

Any alleged misuse of Simtars Certification issued certificates including incorrect references found in catalogues, advertisements, brochures, packaging, etc., will be investigated and dealt with by suitable actions including corrective action, suspension and cancellation of certificate or legal action.

Simtars Certification requires that the client organisation:

- Conforms to the requirements of this document when making reference to its certification status in communication media such as the internet, brochures, packaging or advertising, or other documents.
- Does not make or permit any misleading statement regarding its certification. Any statements used by client organisations shall include:
  - brand or name of the client
  - type of management system certified and the applicable standard
  - indicate Simtars as the certifying body
- Does not use or permit the use of a certification document or any part thereof in a misleading manner.
- Upon suspension or withdrawal of its certification, discontinues references to the certificate number or reference to Simtars Certification on all advertising matter.
- Amends all advertising matter when the scope of certification has been reduced or amended.
- Does not allow reference to its management system certification to be used in such a way as to imply that Simtars Certification certifies a product (including service) or process, such as the use of the certificate number or the logo on laboratory test, calibration or inspection reports.
- Does not imply that the certification applies to activities that are outside the scope of certification, and does not use its certification in such a manner that would bring the Simtars Certification and/or its certification system into disrepute and loss of public trust.

Certified client shall inform Simtars Certification, without delay, of matters that may affect the capability of the management system to continue to fulfil the requirements of the standard used for certification. These include, for example, changes relating to:

- The legal, commercial, organisational status or ownership.
- The organisation and management (e.g. Key managerial, decision-making or technical staff).
- The contact address and sites.
- The scope of operations under the certified management system.
- Major changes to the management system and/or processes.

Simtars Certification will retain records pertaining to certification for the duration of the current cycle plus one full certification cycle.

10.0 CERTIFICATION PROCESS

10.1 Receipt and Review of Applications for Certification

Simtars Certification audit programme includes a two-stage initial process, with surveillance audits in the first and second years, and a recertification audit in the third year prior to expiration of certification.

In determining the audit program, the size of the client organisation, the scope and complexity of its management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits, will be taken into account. An audit schedule shall be prepared for the full cycle to demonstrate that the clients' management system fulfils all the requirements for certification.

Simtars Certification will provide a quote to or have a formal contract with clients outlining the fees for application, initial certification, continuing certification, and for expanding the scope of certification.

For multi-site organisations, Simtars Certification will collect and retain sufficient, verifiable information to support the eligibility requirements for multi-site organisations in IAF MD 1 relating to:

- The identification of the part of the organisation that centrally controls its management system (the central function) and that the single management system is deployed across all relevant parts of the organisation.
- The organisational authority or contractual arrangements that allows the central function to define, establish and maintain the single management system controlling matters such as:
    - System documentation and system changes
    - Management review
    - Complaints
    - Evaluation of corrective actions
    - Internal auditing
    - Statutory and regulatory requirements of the applicable standards
- The scope and nature of the processes/activities performed at each individual site sufficient to determine whether sampling during the certification audit program in accordance with IAF MD 1 may be appropriate.

For applications for the addition of sites to existing or potential multi-site organisations, Simtars Certification will collect and retain sufficient, verifiable information concerning the nature of the processes/activities performed at the additional site(s) to determine the extent of the initial audit for the new site and the impact on subsequent audits in a revised audit plan for the multi-site organisation.

When taking account of certification or other audits already granted to the client, Simtars Certification will collect and retain sufficient, verifiable information to support the fulfilment of ISO/IEC 17021-1 and ISO/IEC 17021-3, and justify and record any adjustments to the audit programme including the follow up of any previous nonconformities.

An authorised representative of the applicant organisation shall provide the necessary information to establish:

- The desired scope of the certification.
- The general features of the applicant organisation, including its name and the address/es) of its physical location(s), significant aspects of its process and operations, the levels of controls established particularly for multi-sites and any relevant legal obligations.
- General information, relevant for the field of certification applied for, concerning the applicant organisation, such as its activities, human and technical resources, functions and relationship in a larger corporation, if any; information concerning all outsourced processes used by the organisation that will affect conformity to requirements.
- The standards or other requirements for which the applicant organisation is seeking certification.
- Information concerning the use of consultancy relating to the management system.

Before proceeding with the audit, Simtars Certification will conduct a review of the application and supplementary information for certification to ensure that:

- The information about the applicant organisation, its management system, products, processes, organisation structure and functions is sufficient for the development of an audit plan for the conduct of the audit including the selection of an appropriate audit team and determining the expected duration of the audit.
- The use of sampling of sites for multi-site organisations is appropriate and can be incorporated into audit plans over the audit cycle.
- The requirements and objectives for certification are clearly defined and documented, and have been provided to the applicant organisation.
- Any known difference in understanding is resolved with the applicant organisation.
- The certification body has the competence and ability to perform the certification activity.
- Records of the justification for the decision to undertake the audit are maintained.
- The client is informed of any on site activities required in stage 1.

Following the review of the application, Simtars Certification decides whether to either accept or decline an application for certification. When Simtars Certification declines an application for certification, the reasons for declining an application will be documented and made clear to the client.

Based on this review, Simtars Certification will determine the competencies it needs to include in its audit team and for the certification decision.

Simtars Certification personnel involved in the review and the selection of the audit team shall have knowledge of:

- Relevant quality management system standards and associated documents
- Generic terminology and processes related to the relevant business of the applicant organisation.

The Simtars Certification audit team is appointed and composed of auditors (and technical experts, as necessary), who, between them, have the totality of the competencies identified for the certification of the applicant organisation.

10.2 Risk management – Country Specific Certification Risks

In addition to the government requirements for travel approvals and DFAT recommendations Simtars acknowledges and manages the risks associated with the certification services provided to overseas entities which include but not limited to:

- Social and Cultural values and practices
- Misuse or misrepresentation of the certification

Simtars testing, auditing and certification staff shall conduct themselves in no way any different from how they would conduct a national certification and comply with the government Code of Conduct and Ethical Decision Making.

At present, Simtars has no ISO 9001 QMS certificates issued outside of Australia. Risks related to the travel and the onsite conduct of the audit shall be reviewed and documented prior to the audit. Where an analysis is required, only after the risk has been analysed and accepted should the certification proceed. There are several useful guides available on the internet, two such pages are:

https://www.austrade.gov.au/australian
https://www.allianz-trade.com/en_US/resources/country-reports.html

10.3 Applications for Transfer of Certification to Simtars

Where the application is for the transfer of certification from another certification body to Simtars, all the information as outlined in section 10.1 shall be requested as well as:

- Information associated with the previous certification including assessment and surveillance audit reports.
- Client authorisation for Simtars to request relevant information from the previous certification body. Where it has not been possible to communicate with the previous certification body, Simtars shall record the reasons and make every effort to obtain the information from other sources.
- Evidence of closure of any outstanding corrective actions
- Any changes not reflected in the previous certification related to the ownership of the organisation, its management structure, sites at which it operates or scope of operations under its certified management system.

In order to accept the application to transfer, this information will be reviewed to ensure that:

- The previous certification was conducted by a certification body accredited under an IAF or regional MLA signatory at the appropriate signatory level.
- The site(s) to be transferred are covered by the previous certification
- The certification is current and not suspended.

If it is decided to proceed with the transfer, a more detailed pre-transfer review of the information shall be conducted by Simtars' personnel with the same competence required of an audit team for the scope of accreditation being reviewed and different to those making the certification decision. The pre-transfer review shall follow the process outlined in section 10.1 but shall also concentrate on:

- Confirming the client's certification falls within the accredited scope of both Simtars and the previous issuing certification body.
- The reasons for seeking a transfer
- Confirming that the initial or most recent recertification audit reports and the latest surveillance reports are available and completed in the required audit schedule timeframe.
- The status of any outstanding nonconformities and the implementation of corrective actions for major nonconformities and plans for addressing any minor nonconformities.
- Any complaints that may have been received and actions taken.
- The audit program of the previous certification body if available.
- Any current engagement by the transferring client with regulatory bodies relevant to the scope of accreditation in respect of legal compliance.
- Determining whether a pre-transfer visit to clarify any of the above information is necessary. Such a visit will not be considered as an audit.

The results of the pre-transfer review and visit, if conducted, shall be documented and forwarded to the certification officer for a certification review and decision in accordance with section 10.13.

Where the relevant audit reports are not available or the pre-transfer review or visit, if required, identify issues that prevent the completion of the transfer, Simtars shall treat the organisation as a new client with documented explanation forwarded to the client.

Where the previous certification body has not provided requested information relevant to the transfer, or suspends or withdraws the transferring client's certification without due cause, Simtars shall advise the accreditation body that accredited the previous certification body.

Where clients seek to transfer certification from Simtars to another certification body, Simtars agrees to cooperate in the transfer process and provide information relevant to the transfer to the client and/or other certification body and shall not suspend or withdraw the client's certification following the notification of intention to transfer if the client continues to satisfy the requirements for certification.

10.4 Audit Team Selection

The Director and/or Principal Engineer – Certification, shall assign the audit team leader (lead assessor) and assessment team including any technical experts, translators and interpreters as necessary based on competency required for the scope of work. The Principal Engineer – Certification will inform the client of the Assessment Team (initial assessments only) and obtain their acceptance. A client can reject at most two assessment teams.

The Director will appoint an assessment team if the client does not accept the proposed team. An audit file shall be raised for each client or certificate holder. Upon confirmation of the assessment team, the audit file is sent to the Lead Auditor for conducting the assessment. The Lead Auditor will obtain the necessary documentation from the client.

In deciding the audit team, the following shall be considered:

- Audit objectives, scope, criteria and estimated time of the audit.
- Whether the audit is a combined, integrated or joint audit.
- The overall competence of the audit team needed to achieve the objectives of the audit.
- Certification requirements (including any applicable statutory, regulatory or contractual requirements).
- Language and culture.
- Whether the members of the audit team have previously audited the client's management system.
- Whether any other conflicts of interest exist which may pose a possible risk to impartially.

Where the quality system assessment is carried out in conjunction with product certification, a Hazardous Area Equipment (HAE) technical expert should be included in the audit team.

Simtars Certification will provide to the client the name of and, when requested, make available background information on each member of the audit team.

The client shall provide a guide to accompany the audit team except where otherwise agreed by the team leader and the client.

The presence and justification of observers or technical experts to accompany the audit team at any stage of the audit shall be agreed to by Simtars Certification and the client.

Personnel, including those acting in a managerial capacity, who have provided management system consultancy towards the client in question within two years following the end of the consultancy, will not take part in an audit or other certification activities.

10.5 Audit Team Leaders

Audit Team leaders should have the knowledge and skills outlined in Section 8.2.2 in order to facilitate the efficient and effective conduct of the audit and the Team Leader shall also be able to:

- Plan the audit and make effective use of resources during the audit, assess audit progress and adjust the plan or terminate/change the scope of the audit where necessary and to represent the audit team in communications with the audit client and auditee throughout the audit.
- Organise and direct audit team members, to be able to provide guidance to and evaluate auditors in training, to lead the audit team to reach audit conclusions.
- Review audit findings and classify nonconformities for presentation at the closing meeting.
- Prevent and resolve conflict and to prepare and complete audit reports.

- Arrange for an audit date and communicate the audit plan at least seven days prior to the agreed audit date.
- Ensure that guides, observers, technical experts, translators and interpreters accompanied by an auditor do not unduly influence the audit.

10.6 Audit Team Tasks

The Audit Team tasks include, but are not limited to:

- Examine and verify the structure, policies, processes, procedures, records and related documents of the client organisation relevant to the management system.
- Obtain and record information throughout the audit by interviews, observations of processes and activities and review of documentation of records.
- Record findings including evidence of observations and the classification of nonconformities against specific requirements
- Determine that these meet all the requirements relevant to the intended scope of certification.
- Determine that the processes and procedures are established, implemented and maintained effectively, to provide a basis for confidence in the client's management system.
- Communicate to the client, for its action, any inconsistencies between the client's policy, objectives and targets (consistent with the expectations in the relevant management system standard or other normative document) and the results.
- Review the audit findings, and any other appropriate information collected during the audit, against the audit objectives.
- Agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process.
- Identify any necessary follow-up actions.
- Confirm the appropriateness of the audit programme or identify any modification required (e.g. Scope, audit time or dates, surveillance frequency, competence).

10.7 Prepare Assessment /Audit Plan

10.7.1 General

The Lead Auditor, based on the desktop review of the documentation submitted, prepares an assessment plan. The assessment plan will detail the number of auditors on the team, their identity and the duration of the audit as well as the schedule of audit activities. The auditee shall be consulted to determine a mutually agreeable time to conduct the assessment. The assessment plan shall be provided to the auditee at least seven days prior to the onsite assessment.

Quality Management Systems audit durations are to be based upon IAF MD5. In determining the audit time, consideration is given to the ISO 9001 requirements, size and complexity of the client and its management system, technical and regulatory context, subcontracting, previous audit results, number and size of sites, the risks associated with the products, processes or activities of the organisation and when audits are combined, joint or integrated. Where the quality system assessment is carried out in conjunction with product certification for Hazardous Area Equipment (HAE) or Service Facilities, the planning for the audit shall ensure adequate on-site auditing to provide confidence in the certification.

Where the client operates shifts, the activities that take place during shift working shall be considered when developing the audit programme and audit plans.

For multi-site organisations where site sampling is deemed to be not appropriate:

- The initial and recertification audits shall cover all sites
- 30% of sites (rounded up) shall be covered in surveillance audits each year and shall include the main central site.
- Where possible, the sites selected for the second surveillance audit shall be different to those selected for the first surveillance audit.
- The audit program shall include all processes covered by the certification scope at least once in each audit cycle.

10.7.2 Multi-Site Organisations

10.7.2.1 Qualifying for sampling of Multi-Site Organisation

Before considering whether multi-site organisations are eligible for multi-site sampling, the following points shall be used to determine if the facility qualifies:

- A “primary” site must be identified
- A single management system must be implemented across all sites and centralised management review
- All sites considered for multi-site sampling must be subjected to continual surveillance and internal audits (may require formal agreement)
- One Simtars auditor must be appointed to cover all sites for the duration of the audit cycle (3 years)
- The relevant accreditation scope must be implemented at each site
- Any actions taken on any non-conformity identified during audits must be considered at all other applicable sites

10.7.2.2 Sampling of Multi-Site Organisations

Where the client has multiple sites with a management system covering very similar processes/activities, if required a sampling program will be developed in accordance with IAF MD 1 to ensure a proper audit of the management system.

When preparing the sampling program and the selection of sites to be sampled, consideration will be given to:

- The company structure
- Primary site shall be included in the audit scheduled for each Simtars audit
- Demonstration of control by the “Primary” site of all activities at all sites
- The range and complexity of a site’s processes/activities and the assessment of risks to the organisation’s outputs and to the explosion protection properties of certified products where audits are in conjunction with product certification for Hazardous Area Equipment (HAE) or Service Facilities
- Variations in the processes/activities undertaken
- The size of the sites and any significant variations in the size of sites in the multi-site organisation
- Variations in the local implementation of the management system to address different processes/activities or different contractual or regulatory systems
- Any use of temporary sites that operate under the management system of the organisation even if they are not listed in the certification documents
- Results of internal site audits and management reviews or previous certification audits
- Records of complaints and other relevant aspects of corrective and preventive action
- Variations in shift patterns and work procedures
- Modifications since the last certification audit
- Maturity of the management system and knowledge of the organisation
- Differences in culture, language and regulatory requirements
- Geographical dispersion
- Whether the sites are permanent, temporary or virtual

All sites shall undergo re-certification. All sites are expected to be audited at least every two years. A re-certification shall be completed every three years and include all sites. Multi-site audits should not be considered in the first cycle (3 years) from the initial audit.

Notwithstanding the above considerations, 25% of the sample shall be selected at random. The sampling program does not necessarily need to be completed up front but may be prepared after the audit of the main central site.

10.7.2.3 Identifying Site Audits for Sampling of Multi-Site Organisations

The number of sites sampled needs to be sufficient to give confidence in the integrity of the organisation's integrated management system but will not be less than:

- **Initial audit:** the size of the sample shall be the square root of the number of sites: ($y=\sqrt{x}$), rounded up to the next whole number, where y = number of sites to be sampled and x = total number of sites.
- **Surveillance audit:** the size of the annual sample shall be the square root of the number of sites with 0.6 as a coefficient ($y=0.6\ \sqrt{x}$), rounded up to the next whole number.
- **Re-certification audit:** the size of the sample shall be the same as for an initial audit. Nevertheless, where the management system has proved to be effective over the certification cycle, the size of the sample could be reduced to, $y=0.8\ \sqrt{x}$, rounded up to the next whole number.

The main central site shall be audited during the initial certification and every recertification audit and at least once a calendar year as part of surveillance.

Where the multi-site organisation has a hierarchical system (e.g. national office, regional offices, local branches) the sampling shall be applied to each level.

For multi-site organisations where sampling is deemed not appropriate for all sites, sampling in line with this section may be applied to those sites where sampling is deemed appropriate.

Where multi-site organisations are audited on a sample basis, the audit times shall be determined in accordance with AIF MD 5 with considerations as outlined in Section 10.6.1 except that where the considerations indicate a possible reduction of audit times as listed in AIF MD 5, those reductions shall not be greater than:

- 20% for the main central location
- 50% for any sampled site.

After each audit round, the considerations listed above will be reviewed to determine whether the size and frequency of the sample needs to be increased or decreased to provide the necessary confidence that the integrated management system is operating effectively.

The basis of sampling and the results of reviews shall be recorded.

10.7.3 Audit Plan Content

The audit plan shall cover the following:

- The audit objective.
- Audit criteria and reference documents.
- Audit scope, including identification of the organisational and functional units and processes to be audited.
- The dates and places where the on-site audit activities, including temporary and remote sites, and meetings with the auditee's management and audit team meetings.
- The expected time and duration of the on-site activities, including meetings with the auditee's management and audit team meetings.
- The roles and responsibilities of the audit team members and accompanying persons.
- The allocation of appropriate resources to critical areas of the audit.
- The identification of the auditee's representative for the audit.
- The audit report topics.
- Logistical arrangements (travel, on-site facilities etc.).
- Matters related to confidentiality.
- Any audit follow-up actions.

The plan should be reviewed by the audit client and presented to the auditee before the on-site audit activities begin.

For multi-site organisations, a separate audit plan shall be prepared for each site.

Any objections raised by the auditee should be resolved between the audit team leader, the auditee and the audit client. Any revision to the audit plan shall be agreed upon among the parties concerned before continuing the audit.

10.8 Assessment at Site

The assessment at site commences with an opening meeting, chaired by the Lead Auditor. The purpose of this meeting is to introduce the assessment team and confirm the purpose, scope, plan and confidentiality of the assessment. The sequence of the assessment, communication channels and relevant work safety, emergency and security issues shall be confirmed and the availability of guides and a room for the assessment team shall be arranged.

It is essential that the assessment be conducted in accordance with the agreed schedule to allow sufficient time for the closing meeting. If, due to delays or other influences, it is expected that the planned activities will not be achieved, this shall be discussed with the auditee and, by agreement, the schedule revised.

Where any part of the audit is made by electronic means or where the site to be audited is virtual, the Audit Team Leader shall ensure that such activities are conducted by personnel with appropriate competence. The evidence obtained during such an audit shall be sufficient to enable the auditor to take an informed decision on the conformity of the requirement in question.

A closing meeting will be held to present audit findings and conclusions in such a manner as to ensure that they are understood and acknowledged by the auditee. Where nonconformities are identified, they will be reviewed with the auditee's representative to obtain acknowledgement or clarification of the audit evidence, any follow up action and any modifications for future audits. The Lead Auditor will prepare the assessment report. A copy/summary of the report will be provided to the management representative at the closing meeting and a final report within ten working days after the audit. The report will include strengths and weaknesses, observations, non-conformities and surveillance period. Time spent by others other than auditors such as observers, auditors in training, shall not be included in the audit duration. A copy of the assessment notes and records of the closing meeting including any diverging opinions of the client will be kept in the audit file.

10.9 Major Non-conformances

Deficiencies in the quality plan or procedures resulting in non-conforming product are to be identified as Major non-conformances (C) and will may require a revisit to the facility to verify implementation prior to issue of the Certificate.

10.10 Minor Non-conformances

Minor non-conformances (M) will require proposed corrective action from the manufacturer within the agreed time. Minor non-conformances will be closed if the Lead Auditor considers the proposal to be satisfactory and evidence of compliance will be reviewed in subsequent visits.

10.11 Observation

Areas of improvement or suggestion should be included in the assessment report as Observations (O). The manufacturer is not required to formally address Observations but is encouraged to consider them for preventive action and continual improvement.

10.12 Initial Audits

The initial certification audit of a management system is conducted in two stages: Stage 1 and Stage 2.

The Stage 1 audit is performed to:

- Audit the client's management system documentation and for multi-site organisations to determine whether or not a single management system is claimed to be deployed across the organisation.
- Evaluate the client's location and site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for the stage 2 audit.
- Review the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system.
- Collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliance (e.g. Quality, environmental, legal aspects of the client's operation, associated risks, etc.) and for a multi-site organisation, confirm that a single management system is deployed across the organisation.
- Review the allocation of resources for stage 2 audit and agree with the client on the details of the stage 2 audits.
- Provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the client's management system and site operations and whether site sampling would be appropriate.
- Evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 audit.

For most management systems, Simtars Certification will conduct at least part of the Stage 1 audit at the client's premises in order to achieve the objectives stated above.

Stage 1 audit findings will be documented and communicated to the client. They include identification of any areas of concern that could be classified as nonconformity during the Stage 2 audit.

In determining the interval between Stage 1 and Stage 2 audits, consideration is given to the needs of the client to resolve areas of concern identified during the Stage 1 audit.

The purpose of the Stage 2 audit is to evaluate the implementation, including effectiveness, of the client's management system.

The stage 2 audit will take place at the site(s) of the client and will include at least the following:

- Assessment of any significant changes which may require a repeat of aspects of the stage 1 audit.
- Information and evidence about conformity to all requirements of ISO 9001 and this document
- Evaluation of the effectiveness of the management system to ensure the client organisation is continually meeting its specified objectives.
- Performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in ISO 9001).
- Evaluation of the ability of the management system to ensure the client organisation meets applicable legal, statutory, regulatory and contractual requirements.
- Operational control of the client's processes.
- Internal auditing and management review.
- Management responsibility for the client's policies.

- Links between the normative requirements, policy, performance objectives and targets (consistent with the expectations in ISO 9001), any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data, internal audit findings and conclusions.
- Identification of areas for potential improvement of the management system.

The Simtars Certification audit team will analyse all information and audit evidence gathered during the Stage 1 and Stage 2 audits to review the audit findings and agree on the audit conclusions. Non-conformities are to be addressed within 20 working days from the last day of the site audit and the evidence presented to the audit team leader. The Team Leader shall review the evidence provided and verify the effectiveness of any correction and corrective actions taken to resolve the nonconformities. The client is then informed of the result of the review and verification. Where effective corrective action on major nonconformities has unable to be provided or verified within six months of a stage 2 audit, a further stage 2 audit shall be conducted.

Major non-conformities (C) are to be rectified within this timeframe. Proposed corrective actions are needed to close out minor non-conformities (M). Although Observations (O) are raised to assist in identifying improvements and potential weaknesses, the client organisation should attempt to address such issues.

The information provided by the audit team to the person(s) making the certification decision will include, as a minimum:

- The audit report
- Comments on the nonconformities and actions taken by the client, and where applicable, the correction and corrective action
- Confirmation of the information provided has been used in the application review
- A recommendation whether or not to grant certification, together with any conditions or observations

10.13 Audit Report

The Audit Team Leader shall be responsible for the preparation and contents of the written Audit report. The Audit report shall provide a complete, accurate, concise and clear record of the audit, and shall include or refer to the following:

- Simtars Certification identification.
- The name and address of the client and the client's management representative.
- The type of audit (e.g. initial, surveillance or recertification audit);
- The Audit objectives.
- The Audit scope, particularly identification of the organisational and functional units or processes audited and the time period covered.
- Identification of the Audit Team leader and Audit Team members.
- The dates and places where the on-site audit activities were conducted.
- Whether the audit was combined, joint or integrated if applicable
- The Audit criteria.
- The Audit findings.
- Recommendations of the Audit Team leader.
- The Audit conclusions including the satisfactory resolution of previous nonconformities.
- A disclaimer statement indicating that auditing is based on a sampling process of the available information.
- A statement on the effectiveness of the management system, the appropriateness of the scope of certification and confirmation that the audit objectives have been met.

The following may be referenced in the Audit report if appropriate.

- The Audit plan
- A list of auditee representatives,

- A summary of the audit process, including the uncertainty and / or any obstacles or significant issues encountered that could decrease the reliability of the audit conclusions.
- any deviation from the audit plan and their reasons
- Confirmation that the Audit objectives have been accomplished within the scope and in accordance with the Audit plan
- Any areas not covered, although within the Audit scope.
- Any unresolved issues or diverging opinions between the audit team and the auditee.
- Any significant changes that affected the management system since the last audit
- Recommendations for improvement, if specified in the Audit objectives.
- Agreed follow-up action plans – if any.
- A statement of the confidential nature of the contents of the report.
- A statement that the client is effectively controlling the use of certification documents and marks if applicable.
- The distribution list for the Audit report.

The final assessment report will be completed by the Lead Auditor and reviewed by the certification officer. The final report should take into account any changes resulting from comments received from either the manufacturer or the certification officer. A second draft will be sent to the auditee for acceptance if changes are made to the category of non-conformities such as Minor changed to Major or Observation to Minor.

Simtars Certification personnel conducting the review of the audit report and making the certification decision shall have knowledge of:

- Quality management system standards and related documentation, terms and definitions
- Scope of audit and the applicability of any exclusions
- The application of quality management tools, methods and techniques to the certification process
- Generic terminology and business practices of the applicant organisation.

In the case of assessments carried out to EN 13980, the report will be prepared on forms supplied by the Ex Notified Body and reviewed by the certification officer. A draft of the report is to be sent to the Notified Body for comments.

10.14 Certification Decision

Simtars Certification will make the certification decision on the following basis:

- New client -on an evaluation of the audit findings, report and conclusions and any other relevant information (e.g. public information, comments on the audit report).
- Transferring client – on an evaluation of the pre-transfer review and visit if conducted.

Where the certification review for a transferring client indicates that a re-certification or surveillance audit is necessary before a certificate could be issued, the client shall be treated as a new applicant with a new certification cycle initiated.

Where the certification is transferred to Simtars, the certification cycle shall be based on the previous certification cycle with Simtars' audit program covering the remainder of the certification cycle. The Simtars' certificate shall show the date of initial certification with an indication that the client was certified by a different certification body before the transfer date.

Where certification is being transferred from a certification body which has ceased trading or whose accreditation has expired, been suspended or withdrawn, Simtars will complete the transfer within 6 months or prior to the expiration of the certification. In such cases, Simtars will advise JAS-ANZ of the intention to issue the certification prior to the transfer.

When a transfer has been finalised and a certificate issued, Simtars shall advise the previous certification body.

At the completion of a certification decision, Simtars Certification will review the overall certification process for a particular audit or transfer and confirm that all certification activities have been completed correctly and that the overall certification process is operating effectively.

10.15 Maintaining Certification

Simtars Certification maintains certification based on demonstration that the client continues to satisfy the requirements of the management system standard.

Simtars Certification maintains a client's certification based on a positive conclusion by the audit team leader without further independent review, provided that;

- for any nonconformity or other situation that may lead to suspension or withdrawal of certification, Simtars Certification has a system that requires the audit team leader to report to the Simtars Certification governing board the need to initiate a review by appropriately competent personnel, different from those who carried out the audit, to determine whether certification can be maintained, and
- competent personnel of Simtars Certification monitor its surveillance activities, including monitoring the reporting by its auditors, to confirm that the certification activity is operating effectively.

Simtars Certification will develop its surveillance activities so that representative areas and functions covered by the scope of the management system are monitored on a regular basis, and take into account changes to its certified client and its management system.

The surveillance activities will include on-site audits assessing the certified client's management system's fulfilment of specified requirements with respect to ISO 9001.

Other surveillance activities include:

- Enquiries from Simtars Certification to the certified client on aspects of certification.
- Reviewing any client's statements with respect to its operations (e.g. promotional material, website).
- Requests to the client to provide documents and records (on paper or electronic media).
- Other means of monitoring the certified client's performance.

Surveillance audits are not necessarily full system audits. Surveillance audits are planned together with the other surveillance activities so that Simtars Certification can maintain confidence that the certified management system continues to fulfil requirements between recertification audits.

The surveillance audit programme will include, at least;

- internal audits and management review,
- a review of actions taken on nonconformities identified during the previous audit,
- a review of the client’s processes for analysing the cause of any nonconformities and taking timely and appropriate corrective actions to eliminate identified nonconformities.
- treatment of complaints,
- effectiveness of the management system with regard to achieving both the certified client's objectives and the intended results of the management system,
- progress of planned activities aimed at continual improvement,
- continuing operational control,
- review of any changes, and
- use of marks and/or any other reference to certification.

Surveillance audits will be conducted at least once a year.

The date of the first surveillance audit following initial certification will be no more than 12 months from the certification decision date.

The decision for maintaining, cancelling, expanding or reducing the scope, suspending or restoring certification will be made by the Principal Engineer – Certification who is independent of the audit team. Where the Principal Engineer – Certification has conducted or is involved with the audit, the audit shall be referred to an independent officer for review and acceptance as part of the decision process.

The audit team leader shall make recommendation to the Principal Engineer – Certification based on the audit findings. Records of the process and basis of certification decisions shall be maintained.

Recertification audits are planned and conducted to evaluate the continued fulfilment of all of the requirements of ISO 9001 and this document. The recertification audit will consider the performance of the management system over the period of certification and will include the review of previous surveillance audit reports.

Recertification audit activities will have a Stage 1 audit in situations where there have been significant changes to the management system, the client, or the context in which the management system is operating (e.g. changes to legislation), otherwise the recertification audit shall be planned and conducted as required for a stage 2 audit.

In the case of multiple sites or certification to multiple management system standards being provided by Simtars Certification, the planning for the audit will be timely to ensure renewal before the certificate expiry date and to ensure adequate on-site audit coverage to provide confidence in the certification.

The recertification audit will include an on-site audit that addresses the following:

- The effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification.
- Demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance.
- Whether the operation of the certified management system contributes to the achievement of the organisation's policy and objectives.

During a recertification audit, where instances of nonconformity or lack of evidence of conformity are identified, Simtars Certification will allow corrective actions to be implemented prior to the expiration of certification.

When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certification can be based on the expiry date of the existing certification but the issue date of the new certificate shall be on or after the recertification decision.

When recertification activities are not completed prior to the expiration of the existing certification, Simtars can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise a further stage 2 audit shall be conducted. The effective date on the new certificate shall be on or after the recertification decision and the expiry date shall be based on the prior certification cycle.

After the successful completion of the recertification audit, a new certificate with a new expiry will be issued. Where the expiration date is due, the new certificate may be issued for maintaining certification if there are no outstanding major non-conformances, and all proposed actions for any minor non-conformances have been reviewed and accepted.

Simtars Certification will make decisions on renewing certification based on a review of the results of the recertification audit including the timely and satisfactory addressing of corrective actions, as well as the results of the review of the system over the period of certification and complaints received from users of the client organisation.

Simtars Certification will, in response to an application for extension to the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance audit.

In the case of short-notice or unannounced audits, the Simtars Certification will describe and make known to the certified clients, the conditions under which these short notice or unannounced visits are to be conducted, and exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

Simtars Certification policy is to suspend certification in cases when, for example:

- The client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system.
- The certified client does not allow surveillance or recertification audits to be conducted at the required frequencies.
- The certified client has voluntarily requested a suspension.

Simtars Certification:

- Has enforceable arrangements with its clients to ensure that in case of suspension the client understands that the certification is temporarily invalid and refrains from further promotion of its certification.
- Will make the suspended status of the certification publicly accessible.
- Will take any other measures it deems appropriate.

Simtars Certification will reduce the client's scope of certification to exclude the parts not meeting the requirements, when the client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification.

Simtars Certification does have enforceable arrangements with the certified client concerning conditions of withdrawal ensuring upon notice of withdrawal of certification that the client discontinues its use of all advertising matter that contains any reference to a certified status.

Upon request by any party, Simtars Certification will correctly state the status of certification of a client's management system as being suspended, withdrawn or reduced. Simtars Certification will take any other measures it deems appropriate.

Simtars Certification shall restore the suspended certification if the issue that has resulted in the suspension has been resolved. Failure to resolve the issues that have resulted in the suspension in a time established by the Simtars Certification will result in withdrawal or reduction of the scope of certification.

11.0 APPEALS, COMPLAINTS AND DISPUTES

The process to receive, evaluate and make decisions on appeals is documented in EP0117 *Certification Complaints and Appeals*, which is publicly accessible on the Simtars' web site or on request. Simtars Certification will gather and verify all necessary information to validate an appeal or a complaint. The appeals and complaint processes shall be strictly non-discriminatory and shall not result in any discriminatory actions against the appellant.

Upon receipt of a complaint, Simtars Certification will confirm whether the complaint relates to certification activities for which it is responsible. If the complaint relates to a certified client, the examination of the complaint will consider the effectiveness of the certified management system and Simtars Certification is responsible for all decisions throughout the complaints handling process.

Any valid complaint about a certified client will be referred to the certified client in question at an appropriate time. This process is subject to requirements for confidentiality, as it relates to the complainant and to the subject of the complaint.

Simtars Certification complaints-handling process includes at least the following elements and methods:

- An outline of the process for receiving, validating, investigating the complaint, and for deciding what actions are to be taken in response to it.
- Tracking and recording complaints, including actions undertaken in response to them ensuring that any appropriate correction and corrective actions are taken.

Simtars Certification upon receiving a complaint is responsible for gathering and verifying all necessary information to validate the complaint. Whenever possible, an acknowledgment of receipt of the complaint will be provided. The complainant will be provided with progress reports and the outcome.

The decision to be communicated to the complainant is made by, or reviewed and approved by, individual(s) not previously involved in the subject of the complaint. Whenever possible, Simtars Certification will give formal notice of the end of the complaints-handling process to the complainant.

Simtars Certification will determine, together with the client and the complainant, whether and, if so, to what extent, the subject of the complaint and its resolution shall be made public.

Simtars Certification shall keep a register of all formal complaints, disputes and appeals received, detailing the circumstances of each complaint and the action taken.

The internal handling of appeals, complaints and disputes shall be in accordance with instruction QI0006 *Instruction for Processing Customer Feedback* and AS ISO 10002 *Guidelines for complaints management in organisations* and any corrective action arising as a result of any appeal or complaint process shall be handled in accordance with instruction QI0004 *Raising, Processing, Monitoring and Verifying Actions*.

12.0 CONDITIONS FOR THE USE OF THE SIMTARS CERTIFICATION SERVICES MARK

1. The Mark can only be used by the certified client.
2. The certified client shall not use the Mark in a way that could be misleading or bring Simtars Certification into disrepute.
3. The certified client must not allow a third party to use the Mark.
4. The certified client shall, as soon as it becomes aware, inform Simtars Certification of any third party that is using the Mark.
5. The format of the Mark and any accompanying statements shall be verified and approved, in writing, by Simtars Certification.
6. Once approved by Simtars Certification, the certified client shall not use, alter or modify the Mark or any accompanying statements in any way without the approval of Simtars Certification.
7. The Mark may be included in internet, brochures, advertising or other documents on condition that the Mark refers to the Quality Management System certification and is within its scope and does not infer product conformity.
8. Any accompanying statement shall:
    - Identify the certified client
    - Reference the ISO 9001 standard to which they are certified
    - The certification body, Simtars
9. The mark shall not be used on products, test/calibration/inspection reports or certificates.
10. The certified client shall on request give to Simtars Certification any information as to the use of the Mark, which Simtars Certification may require, and will render any assistance reasonably required by Simtars Certification with respect to the protection of the Mark or in prosecuting any misuse.

11. The certified client shall appoint a senior member of its Management Team with the responsibility and authority to control use of the Mark and shall provide written notification to Simtars Certification of any changes to this position.
12. The certified client agrees to an extension of its existing on-going surveillance audits, as required by Simtars Certification to allow Simtars Certification the opportunity to verify the certified clients' compliance with these terms and conditions.
13. Upon suspension or withdrawal of certification, the certified client will discontinue the use of the Mark.

13.0 THE USE OF ICT FOR AUDITING/ASSESSMENT PURPOSES

The use of Information and Communication Technology (ICT) for auditing/assessment purposes allows for remote location auditing and should normally be reserved for extraordinary circumstances beyond the control of Simtars certification which prevents travel or entry to site. However, there are times that ICT may be used to complement a site audit where it can be shown that the use of ICT does not diminish the quality and outcomes of the audit.

Where a site audit is not possible for any reason, it is not acceptable to do nothing. A plan to ensure continued compliance of the quality management system shall be prepared and include the extent of ICT used in the audit.

Before considering remote auditing, determine whether the audit can proceed onsite with travel.

1. If yes we can travel, then the audit should proceed as normal.

2. If no we can't travel, can the audit proceed using alternative methods and has the client agreed to an audit using ICT?

    a. If yes, proceed with the remote audit. The following methods or combination of methods may allow the audit to proceed using ICT but facilities need to be verified prior to confirming the audit:

        i. Video conferencing (e.g. Skype) to enable (entry and exit) meetings, sighting of documents, facilities and testing/measurements.
        ii. Required access to documents either directly (e.g. remote access to the QMS documents) or send documents directly to the auditor (e.g. emails, file sharing).

    b. If no, consider deferring the audit or suspension and document the decisions in the client file noting the limitations for deferral in IAF ID 3 up to a maximum 6 months with no outstanding non-conformances or no known complaints or concerns.

Should the remote audit proceed, all other audit requirements should be adhered to and an audit report issued. The audit report summary shall include details of the extent of any ICT used in the audit and its effectiveness. Security and confidentiality needs to be maintained during the audit and assessment activities.

Any selected auditor shall have been trained in the use of ICT and it is advisable to choose an auditor who has previously audited the facility and is conversant with their quality system and operations.

Simtars does not include virtual sites in its scope of audits (manufacturing).

FIGURE 1. – ORGANISATION OVERVIEW

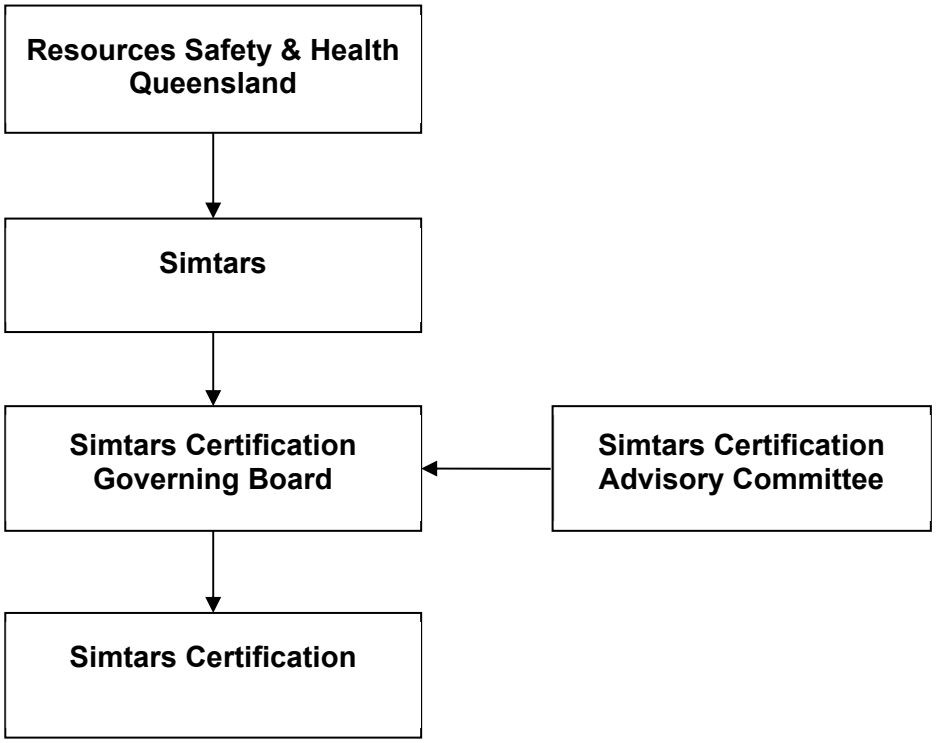

FIGURE 2 – SIMTARS ORGANISATION RELATED TO CERTIFICATION