Procedure for evaluation, granting certification, maintaining, extending, or reducing the scope of certification, suspension, withdrawal, or refusing certification.

Upon completion of each certification activity, ISO Certification Services (ISOCS) shall conduct an independent and impartial review of the conformity assessment activities to evaluate the outcomes of the audit and technical documentation processes including related recommendations of the auditing and technical documentation team prior to issuing certification. Based on the audit and technical documentation assessment conclusions, ISOCS makes a decision to grant, maintain, renew and/or restore certification if there is sufficient objective evidence of conformity; or to refuse, suspend or withdraw certification if there is not sufficient evidence of conformity or significant evidence of nonconformity. A decision to include expansion or reduction of the scope of certification may also be taken.

Granting certificate(s)
The decision to grant a certificate is made by ISOCS once all the criteria's have been met to sufficiently address the completeness and fulfilment of applicable requirements.

Refusal of certificate(s)
The decision to refuse a certificate is made by ISOCS due to incomplete conformity assessment activity.

Maintain certification and renewing of certificate(s)
ISOCS maintains certification based on demonstration that the client continues to satisfy the requirements of the management system standard and applicable regulations.

Suspension of certificate(s)
The suspension of a certificate implicates the temporary status of a client's certification is temporarily invalid. The decision to suspend a certification should be assessed and decided by ISOCS.
Suspension of certification may be done in the following cases:
• The certified client's management system has failed to meet certification requirements, including requirements for the effectiveness of the management system.
• The certified client does not allow surveillance or recertification audit or technical

documentation assessments to be conducted at the required frequencies.
• In case of not applying applicable requirements that has changed.

•   Product safety issues or lack of insufficient clinical evidence.
• Misuse of certification mark.
• In case of providing false information or document during the conformity assessment activities performed by ISOCS.
• Violate contract or agreement of certification.

Withdrawing of certification
ISOCS shall withdraw certification in case failure to resolve the issues that have resulted in the suspension within six month or if the certified client has voluntarily requested for withdrawal.

Restoring of Certificate(s)
The decision to reinstate a certificate is made by ISOCS post suspension activities if all the criteria has been met.
If the reason for the initial suspension has been rectified within the reported timeframe and with documented evidence, then an investigation will be initiated to attain approval for the re-instatement of the certificate.
Following expiration of certification, ISOCS can restore certification within 6 months provided that the outstanding activities are completed, otherwise at least a stage 2 audit and or a review of technical documentation shall be conducted. The effective date on the certificate shall be on or after the decision and the expiry date.

Expanding or Reducing the scope of certification

ISOCS shall, in response to an application for expanding the scope of a certification already granted, undertake a review of the application and determine any conformity assessment activities necessary to decide whether or not the extension may be granted.

Outsourcing

ISOCS may outsource any systems certification activities where required. ISOCS will use the services of its service providers (External Auditors & Technical Experts) and will have procedures in which we define the conditions under which such certification services are rendered. ISOCS may subcontract with another organisation to provide part of the certification activities on behalf of the client. ISOCS will have a legally enforceable agreement covering the arrangements, including confidentiality and conflicts of interests, with each auditor and technical expert that provides certification services.

Refer to Subcontracting.

1. Where ISOCS does not conduct testing activities itself, ISOCS shall outsource evaluation activities only to bodies that meet the applicable requirements of the relevant International Standards and as specified by the certification scheme, of other documents. For testing, it shall meet the applicable requirements of ISO/IEC 17025:2017; for inspection, it shall meet the applicable requirements of ISO/IEC 17020:2012; and for management system auditing, it shall meet the applicable requirements of ISO/IEC 17021-1:2015. The impartiality requirements of the evaluation personnel stipulated in the relevant standard shall always be applicable. [ISO/IEC 17065 (6.2.2.1)]

NOTE 1: Examples of reasons as to why some requirements are not applicable include the following:

- expertise is available within ISOCS when using the results of the evaluation activity.
- the extent of control ISOCS has over-testing (including witnessing the testing), inspection (e.g. specifying inspection methods or parameters) or management system assessment (e.g. requiring specific details of a management system);
- a requirement is covered in an equivalent way by ISO/IEC 17065:2012 or is not needed to give confidence in the certification decision.

NOTE 2: This can include outsourcing to other certification bodies. The use of external personnel under contract is not outsourcing.

NOTE 3: For the purposes of ISO/IEC 17065:2012, the terms "outsourcing" and "subcontracting" are considered to be synonyms.

2. Where evaluation activities are outsourced to non-independent bodies (e.g. client laboratories) ISOCS shall ensure that the evaluation activities are managed in a manner that provides confidence in the results and that records are available to justify the confidence. This will be done through evaluations onsite of the outsourced service provider, maintaining records of such evaluations as well as maintaining records of their accreditations with an accredited body as a laboratory, testing, or inspection authority.
3. ISOCS shall have a legally binding contract with the body that provides the outsourced service, including provisions for confidentiality and conflict of interest as specified in 6.1.3, item c) of ISO/IEC 17065:2012.

ISOCS shall:

1. take responsibility for all activities outsourced to another body.
2. ensure that the body that provides outsourced services, and the personnel that it uses, are not involved, either directly or through any other employer, in such a way that the credibility of the results could be compromised.

3. have documented policies, procedures, and records for the qualification, assessing, and monitoring of all bodies that provide outsourced services used for certification activities.
4. maintain a list of approved providers of outsourced services.
5. implement corrective actions for any breaches of the contract in point d or other requirements of which it becomes aware.
6. inform the client in advance of outsourcing activities, in order to provide the client with an opportunity to object.

NOTE: If the qualification, assessing and monitoring of the bodies that provide outsourced services are performed by other organizations (e.g. by SANAS, peer assessment bodies or governmental authorities), ISOCS can take this qualification and monitoring into an account provided that:

1. it is provided for within the scheme requirements.
2. the scope is applicable to the work being undertaken.
3. the validity of the qualification, assessing, and monitoring arrangements are verified at a periodicity determined by ISOCS.

4. ISOCS and its service providers shall ensure that contracted individual persons are competent and comply with the applicable provisions of these quality manuals and other standards and guides relevant to testing, inspection, or other technical activities.
5. If processes, products, or services are outsourced, the outsourced body shall not provide the design or production of the certified product neither shall it provide management system consultancy. Contracted individuals shall be free of conflict of interest in these respects both directly and through the person's employer.
6. ISOCS requires outsourced organizations and contractors to work within the quality management system and certification processes are defined in our management system and supporting procedures.
7. ISOCS:

- Take responsibility for all activities outsourced to another body;
- Make decisions for granting, maintaining, renewing, extending, reducing, suspending, or withdrawing certification;
- Ensure that where ISOCS uses individuals for outsourced activities, that conform to our requirements and also to the requirements of our Quality Manual as well including ISO/IEC 17021-1:2015, ISO/IEC 17065:2016, ISO/IEC 17067:2013, ISO/TS 22003:2013 requirements. This includes competence, impartiality, and confidentiality;
- Ensure that where ISOCS uses individuals for outsourced activities, that they are not involved, either directly or through any other employer, with an organization to be audited, in such a way that impartiality could be compromised;
- Obtain the consent of the clients first, where ISOCS uses individuals for outsourced activities that they are impartial.

- ISOCS has a process for the approval and monitoring of all bodies that provide certification services for our certification activities and shall ensure that records of the competence of all personnel involved in certification activities are maintained.

NOTE 1: For ISO/IEC 17021-1 clause 7.5.1 to 7.5.4, where ISOCS engages individuals or employees of other organizations to provide additional resources or expertise, these individuals do not constitute outsourcing provided they are individually contracted to operate under ISOCS's management system. (See ISO/IEC 17021-1 (7.3)).

NOTE 2: For ISO/IEC 17021-1 clause 7.5.1 to 7.5.4, the terms "outsourcing" and "subcontracting" are considered to be synonyms.

For more Information, ISOCS clients can contact the Operations Director at 031 563 0409