

## Impartiality Policy

CertX SA (Pty) Ltd. its Directors, internal and external personnel fully understands the importance of impartiality in undertaking its certification activities. CertX SA (Pty) Ltd. will therefore ensure that in all its dealings with clients or potential clients all internal and external personnel are and will remain impartial. To ensure that impartiality is both maintained and can be demonstrated the following principals have been established.

- CertX SA (Pty) Ltd. certificates are only issued following a review by an independent authorised and competent member of the management team (who has not been involved in the audit) to ensure that no interest shall predominate.
- CertX SA (Pty) Ltd. does not offer (and has never offered) management system consultancy or any other form of consultancy to companies or individuals.
- CertX SA (Pty) Ltd. does not offer (and has never offered) an internal audit service to its certified clients.
- CertX SA (Pty) Ltd. does not own or have any interest (financial or otherwise) in any other company that offers management system consultancy services.
- CertX SA (Pty) Ltd. does not have (and will not form) any relationships with companies who offer consultancy or other services that can be construed as having an impact on the certification services provided by CertX SA (Pty) Ltd. Any proposed relationship between CertX SA (Pty) Ltd. and any other company will undergo a risk assessment by an Impartiality Committee prior to that relationship being formalised. Any current relationships with companies, organisations and individuals will be risk assessed on a regular basis to ensure that the relationship does not impact upon the impartiality of the certification process.
- Individuals employed by or otherwise contracted to CertX SA (Pty) Ltd. are required to document and record their current and past relationships with all companies. Any situation past or present which may present a potential conflict of interest is required by CertX SA (Pty) Ltd. to be declared. CertX SA (Pty) Ltd. will use the information to identify any threats to impartiality and will not use that individual in any capacity unless they can demonstrate that there is no conflict of interest.
- CertX SA (Pty) Ltd. will not allocate a member of personnel (internal or external) to take part in any Audit when they have been involved in Management System Consultancy for that client. At the discretion of the Managing Director an individual may be allowed to participate in an Audit, if more than 2 years has lapsed following the end of the consultancy.
- CertX SA (Pty) Ltd. does not and will not offer any commission, ('finders fees' or other inducements) to any individual or company in respect of referrals of clients, except for identified sales personnel (internal or external) of CertX SA (Pty) Ltd.
- CertX SA (Pty) Ltd. does not offer specific training to any company in respect of implementing a particular standard for that company. Any training offered by CertX SA (Pty) Ltd. is general in nature and available to all companies or individuals who wish to attend.
- CertX SA (Pty) Ltd. will ensure that it is not linked or marketed in any way which links it with the activities of a management system consultancy and will take appropriate action should any such link be identified.

- Auditors and others involved in the certification process are not and will not be put under any pressure and will not be influenced in any way to come to a particular conclusion regarding the result of an audit.

**CertX SA (Pty) Ltd. Impartiality Rules:**

- No outsourcing of Audits to Consultancy Organisations.
- No Referral Fees to be paid to Consultancy Organisations.
- Only communicating facts to Clients/ Consultancy Organisations.
- Adherence to all Accreditation and other CertX SA (Pty) Ltd. procedures and policies.
- CertX SA (Pty) Ltd. shall not carry out any other conflicting services other than its core business of Certification.
- CertX SA (Pty) Ltd. shall not employ or contract with any individual conflicting its ethical policies.
- CertX SA (Pty) Ltd. shall not allow any of its auditors to market the services and conduct the audits for the same client.
- CertX SA (Pty) Ltd. shall not allow any of its auditors to carry out financial transactions with clients / consultants.
- CertX SA (Pty) Ltd. shall not carry out business with any consultant inducing pressures to compromise impartiality.
- All employees of CertX SA (Pty) Ltd. shall disclose any situation impairing the business ethics.
- CertX SA (Pty) Ltd. shall not allow any of the auditors to carry out audits for a client they provided consultancy services to for at least 2 years from the end date of the consultancy.
- CertX SA (Pty) Ltd. shall not allow any auditor to compromise on the audit timing as required by the certification requirements.
- CertX SA (Pty) Ltd. shall not allow any auditor to conduct the audit for the client for which it has not been approved for.
- CertX SA (Pty) Ltd. shall maintain transparency with regard to all information.
- No auditor shall divulge any confidential information of the client to any third party without written consent from the client and approval by the Managing Director.
- No auditor shall carry any client information with them after the usage period. All client information shall be returned after usage.
- Utmost care / verification to be carried out for granting the right scope of certification.
- Any unethical practice observed should be notified to the Managing Director at the earliest possible time.
- CertX SA (Pty) Ltd. shall not allow any of its auditors to accept any gifts from the client or a consultant of a value greater than R 250.
- CertX SA (Pty) Ltd. shall not allow any auditor to conduct an audit for the organization where any of its family members / close relatives have a contractual relationship with.
- Disciplinary actions for not adhering to the Impartiality Policy shall be taken by the Managing Director in consultation with the Impartiality Committee.

- To supplement internal resources CertX SA (Pty) Ltd. contracts with external personnel for performing audits. At no stage does CertX SA (Pty) Ltd. outsource its audits to management systems consultancy organisations, outsource its certification decisions, or link its marketing activities with management system consultancy. CertX SA (Pty) Ltd. retains full control of all decision making processes regarding granting, maintaining, renewing, extending, reducing, suspending or withdrawing certification.
- CertX SA (Pty) Ltd. continues to evaluate the risks associated with its operations to ensure it can meet liabilities associated with its certification activities. A comprehensive risk analysis is maintained and reviewed annually.
- Conflict of Interest and objectivity is further covered through annual training sessions and contractually binding agreements, to ensure all management system certification activities are conducted in an independent and impartial manner.
- Audit / certification personnel are prohibited from participating in the audit / certification of any organisation to which they have given assistance, by consultancy or training (other than professionally registered auditor training), or where they have any financial or commercial interest for a minimum period of 2 years prior to the date of application of the organisation for registration.
- When allocated to a particular contract, audit / certification personnel shall not disclose or discuss any detail; before or after the audit / certification; to any member of personnel other than their direct Management or other members of the audit / certification team, as required by the confidentiality & impartiality declaration signed on commencement of employment.
- All contracted audit / certification personnel of CertX SA (Pty) Ltd. shall sign an Independent Contractors Agreement and the confidentiality & impartiality declaration.
- CertX SA (Pty) Ltd. employees are prohibited from engaging in consultancy activities, which involve the active design, generation or implementation of a Quality Management System.
- All employees are required to declare all financial interests or business activities on commencement and during the period of employment.
- CertX SA (Pty) Ltd. internal and external personnel shall not suggest or imply that certification would be simpler, easier or less expensive if consultancy or training services were used. In addition, contracted personnel cannot offer consultancy or training services to CertX SA (Pty) Ltd. clients that they have been assigned to audit, during or after the assigned task has been completed.
- Overall the certification of companies who supply a service to CertX SA (Pty) Ltd. is not deemed to be an unacceptable threat to conflict of interest. However, certification of a company in partnership with CertX SA (Pty) Ltd. for providing services is deemed an unacceptable conflict of interest.
- CertX SA (Pty) Ltd. recognizes that the source of revenue for a certification body is the client paying for certification, and that this is a potential threat to impartiality. Therefore CertX SA (Pty) Ltd. is a self-financed independent organisation, with a number of controls to ensure that impartiality is retained. To obtain and maintain confidence, it is essential that CertX SA (Pty) certification decisions are based on objective evidence of conformity or nonconformity, and that any decisions made are not influenced by other interests or by other parties. Certification decisions are made and signed for by a competent Certification Manager who was not responsible for the audit and was not a member of the audit team.

#### **Impartiality rules specific to ISO 13485 certification in addition to the above:**

- CertX SA (Pty) Ltd. and its internal and external personnel shall be impartial and free from engagements and influences which could affect their objectivity, and in particular shall not be:
  1. involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical device, or any associated parts and services of the client organization
  2. involved in the design, construction, implementation or maintenance of the quality management system being audited
  3. an authorized representative of the client organization, nor represent the parties engaged in these activities
- CertX SA (Pty) Ltd. shall not allow any auditor to conduct an audit where the auditor is having a financial interest in the client organization being audited (e.g. holding stock in the organization)
- CertX SA (Pty) Ltd. shall not contract with auditors who are employed by a manufacturer producing medical devices, or who is a member of staff from a research or medical institute.
- CertX SA (Pty) Ltd. shall not allow any auditor to conduct an audit where the auditor is a consultant having a commercial contract or equivalent interest with a manufacturer or manufacturers of similar medical devices to the client organization.

**Public Statement (as it appears on CertX SA (Pty) Ltd.'s website)**

CertX SA (Pty) Ltd., its Directors, Managers, Staff and others involved in the Certification of Organisations fully understand the importance of impartiality in undertaking its Certification Activities.

CertX SA (Pty) Ltd. will therefore ensure that in its dealings with clients or potential clients, all employees or other personnel involved in Certification Activities are, and will remain, impartial.

To ensure that impartiality is both maintained and can be demonstrated, CertX SA (Pty) Ltd. has identified, and risk assessed all relationships which may result in a conflict of interest or pose a threat to impartiality.

Approved by:

Hein Jonck

Managing Director

  
Signature

03 May 2022

Date