



## POL05 POLICY OF IMPARTIALITY

**3EC International a.s. (3EC) operates Policy of Impartiality in relation to its certification services.**

**3EC proactively controls by risk management any threat of a conflict of interests, real or perceived, having effect on 3EC certification services.**

**It is necessary for 3EC to be impartial and to be understood as impartial in order to provide certification that evokes trust. It is important that entire internal and external personnel are aware of the need of impartiality.**

**To obtain and maintain confidence in 3EC, it is essential that 3EC decisions are based on objective evidence of conformity (or non-conformity) which is obtained by 3EC during the process of certification of management systems, and that 3EC decisions are not influenced by other interests or other parties.**

**The threat of impartiality might include, but is not limited to the following:**

**a) 3EC self-interests: threats that are created by acting person or acting organ in their own interests. A concern related to certification as a threat of impartiality is one's personal financial interest;**

**b) Self-review: threats which occur with a person or organ that review self-performed work; a threat from self-review would include auditing of management systems of the client to which has been provided consultations by 3EC;**

**c) Familiarity (or trust) threats that occurs with a person or organ that are too familiar with the situation or believe that another person rather than to seek the audit evidence;**

**d) Harassment: threats that occur with a person or organ under the impression that they are openly or secretly forced to something, such as the threat of replacement or of reporting to superior.**

**3EC commitment to impartiality is monitored and controlled within risk management. It is also monitored by an independent „Commission for the Protection of impartiality“, which oversees the impartiality throughout the whole certification process.**

**3EC understands the significance of impartiality during the certification of management systems and the significance of managing conflicts of interests and ensuring the objectivity of its certification services in terms of accreditation rules.**

**To ensure the maintenance of the policy of impartiality throughout the whole certification process, 3EC undertakes to implement, maintain and comply with the following aspects / elements:**

- 1. Certification organ for management system (COMS) 3EC International a.s. is impartial, financially independent and its management and personnel is not under the influence of commercial, financial or other interests that might endanger the impartiality and objectivity of performance of activities for which the organ is accredited. Employees are remunerated according to quality, not quantity of performed work.**



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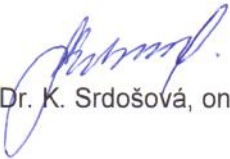
2. COMS has Board for certification and Commission for the Protection of Impartiality that includes members of those parties which are involved in certification system and are independent and impartial.
3. COMS is not engaged in any activities that could degrade the trust in certification activities and adherence of moral or ethical principles.
4. Employees of COMS perform the certification process in accordance with requirements of applicable standards and in the range of their competence so as not to challenge any objections or distrust in granted certificate or accreditation organ. All employees of COMS who are involved in certification process are acknowledged with the text of currently valid documentation and these documents are readily available.
5. Requirements, evaluations and decisions of COMS are in all phases of certification processes limited to clearly defined and contractually agreed scope of certification.
6. COMS has permanent internal and external employees who are liable to the Head of COMS. These employees have a personal responsibility for the activities they perform in the field of certification.
7. Employees of COMS are guided to follow the content of Policy of Impartiality and rules of ethics and to continuously increase their professional qualification.
8. Lead auditors/Auditors/Technical experts/members of Certification board as well as other personnel of COMS are forbidden to participate in the audit/documentation review in the organization to which they have provided advisory services, consulting, trainings (excluding professionally registered open courses of auditors), or have participated on design, manufacture, installation, sales, service or distribution, supply of certificated medical devices and in vitro diagnostic medical devices, or have been involved in the design, construction, implementation and maintenance of a quality management system which is being audited, or have been authorized representatives of the organization which is being audited by COMS. They are even forbidden to represent any parties involved in the audit, or parties in which they were financially or commercially interested before the date of the request for certification of management systems.
9. In case of allocation to individual audit, Lead auditors/Auditors/Technical experts/members of Certification board as well as other personnel of COMS must not reveal or discuss any information before and after the audit/certification activities are performed to any other employee than direct management and to members of audit team/team for documentation review, as required in signed contract and General commercial terms which are part of the contract.
10. All external co-workers who are employed by 3EC for the performance of certification activities must sign Confidentiality/Conflict of interest – Declaration of confidentiality, and are mentioned in 3EC risk analysis as a part of potential conflicts of interest.
11. Direct employees of 3EC are forbidden to perform any consultancy and training activities which involve active design, development or implementation of management system. In case of ISO 13485 system they are forbidden to be involved in design, manufacture, installation, sales, service or distribution, supply of certified medical devices and in vitro diagnostic medical devices, or to be involved in design, construction, implementation or maintenance of quality management system which is being audited, they are forbidden to be authorized representative of the company which is being audited. All employees and 3EC management must at the beginning and during the period of employment reveal all financial interests and commercial activities (information on which records are kept in risk analysis).



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12. 3EC internal nor external employees, neither they co-workers must not claim or guide the client to the conclusion that the certification process would be easier, faster and cheaper, If the company applied consultancy services or training services. External employees and co-workers are forbidden to provide consultancy and training activities to 3EC clients to whom they were allocated for audit or after the completion of the work within the period of 2 years.

  
Elaborated by: Dr. M. Tomin

  
Reviewed and approved by: Dr. K. Srdošová, on 03.10.2016