

15 July 2021

The policy on impartiality promoted by the Management System Certification division of CERE S.L., Certification Entity for Renewable energies, S.L., (hereinafter CERE) as a Certification Body is based on the following principles:

- CERE is dedicated to undertaking certification activities impartially and eliminating risks to impartiality which arise from its activities and the activities of its personnel. Conflicts of interest cast doubt on the accuracy and validity of conformity assessment activities and cannot be allowed to influence certification activities. All CERE staff shall sign a confidentiality and impartiality declarations in order to avoid potential conflict of interest in the certification activities.

While CERE program goals include objectives for the conformity assessment processes as a Certification Entity under ISO/IEC 17021-1:2015 of Management Systems, employee salaries and promotion are not dependent upon the commercial or technical success of any specific commercial activity.

CERE shall not hold shares in the companies and organizations interested in the results of the certifications, neither work for nor perceive remuneration of the same.

- CERE ensures its senior executives and staff are free from any commercial, financial and other pressures which might influence the results of the certification process. The Managing Director and the Certification Director are respectable businesspeople free from any commercial, financial or other pressures that might influence decisions and sign Conflict of Interest agreements stating as such.

The Certification director is not responsible to collect the revenue etc., which is engaged in audit planning, review and issue of certification, to prevent potential threat to the impartiality.

CERE has a quality policy to carry out its management certification activities.

- CERE routinely identifies risks to impartiality that arise from its activities and relationships, and the activities and relationships of its personnel. Risks are identified and evaluated through the following means:
 - Personnel conflict of interest questionnaire at the time of hiring, before undertaking any certification process, and before any job reassignment.
 - Written assessments of the impartiality of personnel which is reviewed by the Certification Director.
 - Annual impartiality committee reviews.
 - Annual management reviews.

When risks to impartiality are identified, CERE takes steps to eliminate or minimize those risks. Possible actions are included in a CERE Risk analysis and QF4.1. This shall contain the risk acceptance criteria, the risks identified and their consequences, the control measures and the overall assessment.

- CERE shall not offer or provide any certification service to another certification body for its quality management system.
- CERE shall not offer or provide management system consultancy service in the implementation of quality systems for Medical Device or their maintenance, such as, preparing or drawing up manuals, procedures or files, advising, giving instructions or specific solutions.
- CERE shall not provide internal audits to its clients.
- CERE is an independent entity and is not linked to any organisation which itself provides consultancy services. Such restriction does not preclude general training activities that are not specific for the client and that relate to regulation of devices or to related standards.
- CERE does not outsource audits for their certification activities.

- CERE cannot recommend any organization to a client for consultancy purposes. The activities of CERE will not be marketed or linked with any organization whose activities offer quality system, regulatory or design consultancy to any medical device manufacturer or related economic operator. Consultancy shall be considered work or advice that directly provides a specific solution to a compliance, regulatory or quality management system issue.
- Personnel who have provided consultancy or have any other identified risks to conflict of interest, impartiality shall be subject to restrictions on work assignments. Personnel who were formerly employed by a specific client, or provided consultancy services in the field of devices to that specific client prior to taking up employment with CERE, shall not be assigned for conformity assessment activities for that specific client or companies belonging to the same group for a period of three years
- In order to safeguard the integrity and reputation of the Certification Body, CERE takes actions to respond to any identified risk to impartiality.
- Internal and freelance auditors in CERE conformity assessment activities must sign an agreement to commit to being free from any commercial, financial and other internal and external pressures that may adversely affect the quality, accuracy, or impartiality of their work.
- Participants (internal and external) in CERE conformity assessment, and certification activities must sign an agreement to commit to reveal any situation known to them that can present them or the certification body with a conflict of interests.