

Independence, Impartiality & Conflict of Interest

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Change History

1	February 15, 1995	Initial release
2	May 1, 1995	Changed “Department Manager” to “C.S. Department Manager” throughout; Changed “Applicable Documents” to “Supporting Documentation” on page 4.
3	June 1, 1995	Updated roles and responsibilities section to better define member requirements.
4	October 16, 1995	Change title to “Advisory Board”
5	April 28, 1997	Change text from ‘quality’ to ‘management systems’
6	June 20, 1997	Add block for handling appeals, correct titles. Clarify roles to ensure impartiality
7	June 30, 1997	Added Confidentiality block
8	May 24, 2000	Added requirement to list industry codes for each member
9	July 20, 2000	Added SCC requirements to the Handling Appeals Block
10	April 9, 2001	Aligned wording with TMS quality manual for membership and responsibilities; added meeting minutes to “supporting documentation”
11	June 18, 2001	Update document Purpose, Membership, Meetings and Handling Appeals; Added Impartiality and Industry Representation sections
12	April 2, 2002	Added member training; added measures should advice not be followed.
13	July 7, 2003	Updated role and membership; clerical changes;
14	November 12, 2004	Expanded scope to include accreditations other than Management Service; Clarified how industries are represented on board. Changed name to “Advisory Committee”
15	March 22, 2006	Removed description of appeals process contained in ISO2-02; Clarified Selection of Committee Members; Clerical corrections
16	June 19, 2007	Added role of committee to review and approve annual risk analysis; Added Risk Analysis section; Updated memberships; Clerical updates
17	August 7, 2007	Changed title to Independence, Impartiality and Conflict of Interest; Added Policy section. Added reference to MED_P_09.09; Clerical updates
18	2008-02-07	Added to role of Advisory Committee and Membership; Added reference to sector specific issues
19	2008-09-02	Added policy that TÜV will not certify clients where finder’s fee was paid to consultant
20	2009-09-18	Clarified scope; Added reference to committee reviewing liability insurance; Added reference to forms used to document commitment to comply with impartiality and confidentiality;
21	2010-06-07	Added section on Discovery of Conflict of Interest; Added ref to USA_F_04.01;
22	2012-07-30	Added reference to TÜV SÜD Code of Ethics, Added specific policy regarding product design; Added Definitions to section 3, grammatical changes
23	2013-10-21	Added reference to ITC_P_10.07; Removed reference to GHG; Added reference to CG-CC-002, “Prevention of conflicts of interests and corruption.”
24	2014-02-14	Revised section 13, all voting members non-TÜV employees; Clerical corrections; added new policies to comply with MDSAP N3 Document requirements in sections 4, 5, 6 and 8; added section 5.2
25	2014-04-03	Revised section 5 to add more requirements regarding MDSAP_F_18.02
26	2016-09-27	Numbered bullets in sections 4 & 5; updated the Roles and Responsibilities of the



Advisory Committee (Section 6) to include developing the principles relating to impartiality of TÜV's certification activities. Revised section 7 to include reference to residual risks.

27 2017-08-03

Revisions to reflect the departmental reorganizations that occurred on 2017-08-01. Removed second row of footer on page 1 as this information is detailed in roXtra.

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Independence, Impartiality & Conflict of Interest

1. Purpose

This procedure defines TÜV SÜD America Inc. (TÜV) policy regarding maintaining independence, impartiality and avoiding potential conflicts of interest. It also defines the roles and responsibilities of the TÜV SÜD America Advisory Committee.

2. Scope

This procedure applies to all testing, auditing, field evaluation and certification services offered by TÜV SÜD America Inc. and its subsidiaries. TÜV SÜD America shall adhere to requirements of its own recognitions / accreditations as well as to relevant requirements of other TÜV SÜD companies whose services are offered such as in MED_P_09.09.

3. Definitions

Consultancy

- participation in designing, manufacturing, installing, maintaining or distributing of a certified product or a product to be certified, or
 - participation in designing, implementing or maintaining a management system (e.g., preparing or producing manuals or procedures; giving specific advice, instructions or solutions towards the development and implementation of a management system.)
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4. Policy

- a) TÜV shall comply with the latest edition of the TÜV SÜD Code of Ethics, CG-CC-001 and CG-CC-002, *“Prevention of conflicts of interests and corruption.”*
- b) TÜV shall be independent of any organization for which it conducts audits, testing or certification services. TÜV shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the organization.
- c) When a relationship poses an unacceptable threat to impartiality (such as certifying a wholly owned subsidiary of TÜV SÜD), then certification shall not be provided.
- d) TÜV shall not certify the management system of another certification body.
- e) TÜV and any part of the same legal entity shall not offer or provide management system consultancy.
- f) TÜV and any part of the same legal entity shall not offer or provide internal audits to its certified clients. TÜV shall not certify a management system on which it provided

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- internal audits within two years following the end of the internal audits.
- g) TÜV shall not certify a management system on which a client has received management system consultancy or internal audits, where the relationship between the consultancy organization and TÜV poses an unacceptable threat to the impartiality of TÜV.
 - h) TÜV services shall not be marketed or offered as linked with the activities of an organization that provides management system consultancy. TÜV shall take action to correct inappropriate claims by any consultancy organization stating or implying that certification would be simpler, easier, faster or less expensive if TÜV were used. TÜV shall not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.
 - i) TÜV shall not advertise, commit to, guarantee, or imply the outcome of the audits or certification services, on the basis of financial or other inducements.
 - j) TÜV shall not outsource audits to management system consultancy organizations. This does not apply to individuals contracted as auditors. However, a contracted auditor cannot audit an organization if a consulting company that the auditor also represents provided consulting services to that organization within the prior two years.
 - k) To ensure that there is no conflict of interests, personnel who are former employees of or have provided consultancy services to the client, their authorized representative or a supplier being audited by TÜV, including those acting in a managerial capacity, shall not be used by TÜV to take part in an audit or other certification activities within three years following the end of the consultancy/employment for the MDSAP program and two years following the end of the consultancy/employment for all other certification programs.
 - l) TÜV shall take action to respond to any threats to its impartiality arising from the actions of other persons, bodies or organizations.
 - m) All TÜV personnel, either internal or external, or committees, who could influence the certification activities, shall act impartially and shall not allow commercial, financial or other pressures to compromise impartiality.
 - n) TÜV requires personnel, internal and external, to reveal any situation known to them that can present them or the certification body with a conflict of interests. TÜV shall use this information as input to identifying threats to impartiality raised by the activities of such personnel or by the organizations that employ them, and shall not use such personnel, internal or external, unless they can demonstrate that there is no conflict of interests.
 - o) TÜV shall document any involvement in consultancy services undertaken by personnel, internal and external, prior to taking up employment with TÜV, at the time of employment.
 - p) If TÜV provides a commission, finder's fee or other incentive to a management system consultant, TÜV shall not audit or certify the subject organization for at least two years after the consultancy ended.

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- q) TÜV shall not offer design advice or participate in the design of a certified product or a product to be certified
 - r) TÜV shall also comply with global procedure ITC_P_10.07, Product certification versus consultancy
 - s) Using the Risk Analysis document, TÜV shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect the independence, impartiality, or objectivity of its services.
 - t) For MDSAP to enhance the commitment to impartiality and the appearance of impartiality, an auditor may not be lead auditor for more than three consecutive audits for the same client, although the auditor may be a member of an auditing team for the client in question. TÜV will make every effort to change the composition of the audit team for a site over time to strengthen the perception of impartiality.
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5. Personnel commitment to Impartiality & Confidentiality requirements

Individual programs may have specific requirements that go beyond this procedure that will be documented elsewhere. However, all personnel working for TÜV as an employee or contractor must comply with requirements for impartiality, conflict of interest and confidentiality. Applicable personnel must sign one of several documents depending on their roles. Examples include:

- a) TÜV SÜD America Employee Confidentiality Agreement located in Human Resources personnel file. (all TÜV SÜD employees must sign this document)
- b) Form ISOF-50, Obligation form for auditors and certification committee members located in Certification Body authorization file.
- c) Form MDSAP_F_18.02 MDSAP Formal Obligation for Auditors and involved Personnel and Code of Conduct located in Certification Body authorization file. The formal Obligation shall be reaffirmed by all personnel participating in MDSAP audits on an annual basis. Top Managers involved in MDSAP program, as identified below, shall also sign form MDSAP_F_18.02:
 - Global Head of MHS
 - Head of MHS Europe
 - Head of MHS Asia
 - Head of MHS Americas
 - Head of Global Active Division
 - Head of Global Non-Active Division
 - Head of MHS-CRT/CRT2 Certification Body
- d) Form PSS_F_18.01, Obligation Agreement for Contractors & Part-Time Employees located in HR or Certification Body authorization file.

Form MHS_AGR_06.04, Framework Agreement for “internal” Subcontractors as TPS Notified Body Auditor, Specialist and/or Experts located with relevant Certification Body.

Personnel directly involved in MDSAP shall sign the ISOF-50 form, as well as the MDSAP_F_18.02 form, regardless if they work on behalf of TÜV SÜD America, the parent company, TÜV SÜD AG, or any other related body.

Any violations to the policies and requirements agreed to by TÜV SÜD personnel shall be investigated, documented and appropriate action taken.

5.1 Discovery of Conflict of Interest

If TÜV identifies a situation where work was performed with a potential conflict of interest, TÜV shall take the following actions.

- The Quality Department will enter a nonconformity into the ICPA system.
- The head of the applicable business unit will conduct an investigation and risk assessment of the situation, and present recommendations for needed actions to remedy and prevent recurrence.
- The Quality Manager shall review and approve the proposed actions. Investigation, outcome and resolution will be recorded in the ICPA system.

5.2 Attempts to Exert or Hide Undue Influence

If TÜV identifies a situation where an internal or external party has attempted to exert or hide undue influence over audit, test, field evaluation or certification results, the following actions must be taken:

- a) The Quality Manager shall be notified immediately.
- b) The head of the applicable business unit will conduct a thorough investigation of the situation, and present recommendations for needed actions to remedy and prevent recurrence.
- c) If the project in question involved work done for the Energy Star® Program, the EPA/DOE must be notified immediately.

6. Roles and Responsibilities of the Advisory Committee

The main role of the Advisory Committee is to safeguard and promote independence, objectivity and impartiality of TÜV's auditing, testing, field evaluation and certification activities. It exists to counteract any tendency to allow commercial or other considerations to prevent the consistent objective provision of activities. The committee reviews and approves the Impartiality Risk Analysis document on an annual basis.

The committee assists in developing the principles and policies relating to impartiality of TÜV's certification activities. They also review finances, sources of income and liability insurance to ensure that commercial, financial or other pressures do not compromise impartiality. They advise on matters affecting confidence in certification, including openness and public perception.

At least once annually the committee reviews the impartiality of TÜV's audit, certification and decision making processes.

The committee will have full access to departmental information including customer complaint files and internal audit results.

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7. Impartiality Risk Analysis

On an annual basis TÜV Quality Department will perform a risk analysis to identify, analyze, evaluate, treat, monitor, and document the risks related to conflict of interests and identify potential threats to impartiality, including relationships that could pose threats to impartiality. Unit Directors will provide control measures to eliminate or minimize risks. If needed, business services will be changed to prevent risks and document any residual risk. The results of the analysis and control measures will be documented and presented to the Advisory Committee.

8. Advisory Committee Membership

The committee is open to representatives from all key interests to ensure that no single interest dominates committee decisions.

There shall be a reasonable diverse representation. Membership will include:

- Quality Manager, TÜV SÜD America (chairperson)
- Various TÜV business unit management
- Outside key interests from various stakeholders (e.g.: manufacturing / service industries, customers, regulatory bodies, trade associations, etc.) This includes, representative from key sectors that TÜV does business in. (e.g., related to standard sector schemes and/or product types.) Should TÜV add new businesses with other key interests, additional members will be considered.

In order to ensure that all interests are properly represented, the committee may draw from external sources as necessary. It is not required to have each industry code represented at the meetings. If needed, based on the agenda, additional personnel may be requested to provide input on behalf of that industry. These non-voting participants could come from within TÜV SÜD America or be outside experts.

The committee shall have access to individual(s) who have experience and knowledge related to medical devices in order to obtain independent expert opinion related to the Medical Device Single Audit (MDSAP) Program.

TÜV maintains a biography for each member of the committee.



9. Advisory Committee Member Training

Before or at their first Advisory Committee meeting, TÜV trains new members in:

- Relevant Operations and processes
- Role and Responsibilities of Advisory Committee Members
- Conflict of Interest and Confidentiality

TÜV maintains training records.

10. Advisory Committee Meetings

The chairperson will convene a meeting at least once per year and provide an agenda. There must be a minimum of four members present to convene a meeting including at least three voting members.

If deemed necessary the committee members may call special meetings at any time with the approval of the chairperson or by majority vote.

The chairperson or delegate must be present at every meeting. They are responsible for presenting the current status. They may participate in discussions and propose changes to policy matters for vote by the committee.

Any issue that arises to be voted on requires a majority rule to be enacted.

The chairperson or delegate maintains meeting minutes.

Action items that result from the meeting are assigned and tracked for timely resolution.

11. Handling Appeals

The Advisory Committee can be used as part of the appeals process. See procedure PD_AUD_23 for requirements.

12. Following Advice of Advisory Committee

Should TÜV not take the advice of the Advisory Committee, the committee members may appeal directly to the TÜV SÜD America Board of Directors and/or applicable accreditation agency. TÜV will document reasons for not following advice.

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13. Impartiality of the Advisory Committee

The Advisory Committee maintains impartiality by adhering to the following requirements:

- Voting members shall be limited to non-TÜV employees.

The members of the Advisory Committee shall guarantee independence in the execution of their function. Each member must sign a document (e.g., USA_F_04.01) attesting to being free from any commercial, financial and other pressures that might influence decisions.

14. Advisory Committee Confidentiality

All information discussed at any committee meeting will be regarded with strict confidence. Each member of the Advisory Committee will sign confidentiality agreement USA_F_04.01. The chairperson maintains the signed agreements.

15. Supporting Documentation

- Advisory Committee Meeting Minutes
 - Member C.V.'s
 - PD_AUD_23, Appeals
 - MED_P_09.09, Independence, Impartiality, Conflict of Interest and Confidentiality Requirements
 - TÜV SÜD America Employee Confidentiality Agreement
 - Form ISOF-50, Obligation form for auditors and certification committee
 - Form PSS_F_18.01, Obligation Agreement for Contractors & Part-Time Employees
 - Form MHS_AGR_06.04, Framework Agreement for “internal” Subcontractors As TPS Notified Body Auditor, Specialist and/or Experts
 - USA_F_04.01, TÜV SUD America Advisory Committee Confidentiality / Conflict of Interest Agreement
 - CG-CC-001, TÜV SÜD Code of Ethics
 - ITC_P_10.07, Product certification versus consultancy
 - CG-CC-002, Prevention of conflicts of interests and corruption
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