

1. Purpose

This procedure describes the measures that TUV USA Inc. – a member of TUV NORD Group (in the following TUV USA) and its employees, agents and Impartiality Board undertake to identify, analyze, evaluate, treat, monitor and document the risks related to conflict of interests arising from provision of certification including any conflicts arising from its relationship on an ongoing basis.

2. Scope

This procedure is applicable to all personnel involved in TUV USA management, as well as subcontractors and impartiality board members and covers the activities of TUV USA's Quality Systems Division (QSD), Medical Products Division (MPD) and Food System Division (FSD).

3. Reference

- ISO 17021-1 Conformity Assessment – Requirements for Bodies Providing Audit and Certification of Management Systems
- IMDRF/MDSAP WG/N3 Requirements for Medical Device Auditing Organization for Regulatory Authority Recognition

4. Responsibilities

4.1. TUV USA Managing Director

TUV USA Managing Director has overall responsibility for hiring and providing appropriate resources and controls to aid in avoiding conflict of interest and assuring impartiality.

4.2. Directors of Divisions

The Director of the corresponding Division and or its designee is responsible to train and develop certification personnel to avoid any conflict of interest and ensure impartiality in delivering its service.

4.3. Lead Auditors

Lead Auditors are responsible to avoid any conflict of interest and to remain impartial at all times.

4.4. Impartiality Board Members

As described on section 7.2 of this procedure.

5. Management of Impartiality

TUV USA Managing Director is committed to safeguard and protect impartiality in all management system certification activities. A declaration of TUV USA Managing Director with regards to Impartiality is provided in form GOP004F001.

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The Managing Director reviews the activities of the organization and verifies that no conflicts exist due to any business relationships. Where identified any residual risk, the Managing Director will also determine whether it is acceptable or not. This review is documented as part of the annual management review.

TUV USA manages conflict of interest to ensure that the objective of its management system certification activities is obtained.

6. Procedure

6.1. Identification of Potential Conflicts of Interest

TUV USA and certification personnel are committed to avoid any situation that could cause a conflict of interest. This effort covers all potential sources of conflict of interests that are identified, whether they arise from TUV USA or from the activities of any other person/s, such as sub-contractors, bodies or organization/s. Threats to impartiality can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing and payment of a sales commission or other inducement for the referral of new clients.

Where there are any threats to impartiality, TUV USA documents and demonstrate how it eliminates or minimize such threats and documents any residual risks. Some of the methods adopted by TUV USA for documenting these actions are, but not limited to:

- Statements on TUV USA manuals and procedures
- Attendance lists of trainings;
- Notifications;
- Agreements;
- Risk Analysis (GOP034F001 and financial risk report);
- Records of investigation (e.g. ICAR);
- Meeting Minutes (e.g. management Review, impartiality board meeting, etc.)

6.2. Measures to Eliminate or Minimize Potential Threats

Measures taken by TUV USA in preventing situations concerning conflict of interest include:

- Training and notifications - To ensure that all personnel working within or for the organization are aware of the potential risk of conflict of interest;
- Define measures in certification procedures;
- Commitment to maintaining Impartiality in the contract with TUV USA’s client;
- Ensure that no conflict of interest exists during the selection of Lead auditor and the audit team;
- Immediately investigate the details of any situation that may be perceived as a potential risk to conflict of interest or threat to impartiality (e.g. by informing any interested party, such as DAKKS, ANAB, TÜV NORD CERT, etc.).

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- Performs a Risk Analysis of its certification process as documented in form GOP034F001 TUV USA Risk Analysis.
- [Communication to all interested parties and stakeholders regarding known and/or potential risks to impartiality and/or conflicts of interest.](#)

6.3. Impartiality on the Services

TUV USA does NOT:

- Provide certification services to any other Certification Bodies Quality Management System (QMS) activities;
- Provide QMS related consultancy services;
- Provide internal audit services to any clients, whether they have been certified by TUV USA or not;
- Provide certification services to any organization where a relationship with TUV USA poses a threat to impartiality;
- Outsource audits required by the certification process to any other organization or other management system consultancy organization.
- Offer its services in such a way that the client has the impression that he would gain advantages if a specified consultancy organization were used.

6.4. Impartiality of Finances and Sources of Income

TUV USA performs annual evaluations of its finances and sources of revenue to demonstrate on ongoing basis that commercial, financial or other pressures do not compromise its impartiality. Financial risk analyses are conducted by an independent third party accounting firm, and a Financial Risk Analysis Report issued by them is maintained.

6.4.1. Financial Risk Analysis Report

The report provided by the independent third party accounting firm can demonstrate TUV USA's finances are sound and that there are no commercial, financial or other pressures that may compromise its impartiality. It includes information regarding sales by customer, revenue by customer and customer type (industry), and general information about profitability and cash flow.

The annual Financial Risk Analysis report is presented to the Impartiality Committee. As with other aspects of impartiality, the Committee understands its role in the financial review and their responsibility for questioning aspects of the report that may compromise impartiality.

6.5. Impartiality of TUV USA Certification Personnel

Before providing certification services on behalf of TUV USA, all Certification Personnel, whether subcontractor or employee are required to sign Confidentiality and or a Code of Conduct Agreement where he/she commits to disclose to TUV USA any relationship that may suggest a conflict of interest and/or threat to impartiality. Certification personnel who become aware that they are/have been, in previous times, employed or otherwise

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associated with a TUV USA Client, will bring this to the attention of the Director of the respective division or the Managing Director.

TUV USA shall not certify a management system where there is an unacceptable relationship, as defined in ISO/IEC 17021, between any management system consultancy organization or any person/organization conducting internal audits and TUV USA, for a minimum period of two years following the end of activities associated with the management system or where there is an unacceptable threat to the impartiality of the certification process. More than one pre-audit shall be considered as consultancy

All TUV USA employee or subcontracted auditors are not allowed to consult with the client before, during or after the audits.

All TUV USA employee or subcontracted auditors are required to sign and submit a declaration of independence form for each audit confirming that there is no conflict of interests regarding the audits which he or she is going to conduct and that there are no potential concern/s which needs to be communicated to TUV USA.

All TUV USA Auditors, either direct or subcontract, may not participate directly in certification audits where they are employed, by means of any status, with the TUV USA client being audited.

Each Division of TUV USA may have its own individual form, depending on the certification scheme (i.e. MPD it is attached as enclosure 2 of P11F040e – Audit Schedule, for QSD there is the Workflow assignment acceptance sheet).

6.5.1. Medical Product Division Personnel

If the auditor was associated with the auditee organization in any way, then the said auditor will not be involved in the certification process till a five (5) year time period has elapsed since their association.

Certification personnel acting in the Medical Product Division are required to acknowledge all companies they have provided consultancy services (including internal audit) for the previous five (5) years by completing and signing MF 138 Declaration of Consultancy and Industry Participation Form.

6.6. Consultancy Firm used by the Client

Each new client and existing clients at the time of certification or recertification completes a form that includes references to their use of outside consulting firm. Each Division of TUV USA may have its own form. (ex. MF120 – Application/Questionnaire Form for MPD)

If TUV USA’s client or potential client uses outside consultancy firm, then during the review of this form TUV USA will determines, if there is any conflict of interest, and if a potential conflict of interest exists then what appropriate actions needs to be taken before accepting or scheduling the audit.

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6.7. Disciplinary Actions

Employees may be subjected to disciplinary actions and may include termination of employment, if impartiality requirements are not met.

Subcontractors are subjected to temporary suspension of services, may include cancellation of contracts and termination of all relationships with TUV USA, if impartiality requirements are not met.

Other person, body, and organization not previously covered may be subject to appropriate action, including legal action, in order to ensure that the integrity and impartiality of TUV USA's certification program is not compromised.

7. Committee for Safeguarding Impartiality (Impartiality Board)

An Impartiality Board has been established to provide independent review and oversight of quality management certification activities.

7.1. Composition of the Impartiality Committee

The Impartiality Committee includes representation of a balance of interests such that no single interest predominates. TUV USA employees and paid contractors are considered as a single interest and shall not predominate the Impartiality Board.

Although the board cannot represent every interest, TUV USA will identify and invite key interests. Such interests can include (but not limited to):

- TUV USA clients
- Customers of organizations whose management systems are certified
- Representatives of industry trade associations
- Representatives of governmental regulatory bodies or other governmental services
- Representatives of non-governmental organizations (including consumer organizations).

The Impartiality Committee consists of (minimum) three externals members and two TUV USA employees. Although the number of members can increase, the number of external members must always be higher than the number of TUV USA members. TUV USA is responsible to provide any information requested by the committee and may invite additional experts on the areas it provides services as guest to the meetings, if required.

The chairman of the Impartiality Committee shall be an external member and is elected by the Impartiality Board for a term of at minimum 1 year. At the opening of each meeting the chairman will be confirmed.

The composition and competencies of the Impartiality Board will be reviewed and recorded as part of the annual management review meetings.

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The position of the Impartiality Committee within the structure of TUV USA is referenced in a chart of the GOP005 TUV USA Inc. Company Structure.

7.1.1. Selection and inclusion of a New Board Member

To be a TUV USA Impartiality Board member, the potential candidate is requested to submit the resume for review. If the resume is considered satisfactory (according annex 1 of this procedure), TUV USA will invite this person to participate in the next Impartiality Committee Meeting, initially as a guest. The Impartiality Committee will vote at the start of the meeting about accepting the membership of the new committee member.

Once accepted, the Chairman confirms and welcomes the new member to the committee.

He/ she will also be required to sign the Non-Disclosure and Confidentiality Agreement (GOP004F004) and be introduced to this procedure.

Records shall be maintained for the duration of the member’s involvement with the Board (plus three years).

7.2. Duties and Responsibilities of the Impartiality Board

The role of the Board is to verify that certification activities are performed in an impartial manner without undue influences that might negatively impact the impartiality of services rendered.

The composition, terms of reference, duties, authorities, competence of members and responsibilities of this committee is documented and authorized by the Managing Director in the form of an appointment letter.

The principle responsibilities of the Impartiality Board include:

- Assistance in developing the policies relating to impartiality of its certification activities;
- Counteract any tendency on the part of the Quality Systems, Medical Products and Food divisions to not allow commercial or other considerations to prevent the consistent objective provision of certification activities;
- Provide advice on matters affecting confidence in certification, including openness and public perception, and
- Conduct a review, as least annually, of the impartiality of the audit, certification and decision making processes of TUV USA.

Other tasks or duties may be assigned to the Impartiality Board provided these additional tasks or duties do not compromise its essential role of ensuring impartiality.

As a part of its activities, the Impartiality Board will be made aware that if TUV USA top management does not respect its advice, the Board has the right to take independent action (e.g. informing relevant authorities, accreditation bodies, stakeholders, shareholders).

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In taking independent action, the board shall respect the confidentiality requirements of clients and TUV USA.

7.3. Impartiality Board Meeting

The board discharges their responsibility by attending and participating in the board meetings which takes place at least once in a year.

During its annual meeting, the Impartiality Board will have access to all the information necessary to enable it to fulfill its functions. The meeting will include review of the impartiality of the audit, certification and decision making processes of TUV USA.

In case of a deadlock situation, the Chairman/woman of the Impartiality Committee can take the final decision.

The standard Impartiality Board Meeting Agenda is in the Annex 2 of this procedure.

During the meeting, the Impartiality Board Members will to the best of their ability remain a neutral party who through the use of objective evidence review, determine and make recommendations on the potential risks/threats to impartiality which may impact TUV USA’s process or business practices, These risks/ threats may include but not be limited to self-review threats, financial perspective, review of one’s own work, familiarity and intimidation. If either risk/threat is identified, the Impartiality Board Member will make recommendations on how to remove, reduce or prevent the risk entirely to the management of TUV USA.

The outcome of the meeting will be recorded in the Impartiality Board Meeting Minutes by a TUV USA representative, distributed to the participants via e-mail and saved in TUV USA server.

8. Records

- GOP004F001 Declaration of the TUV USA Managing Director with regard to Impartiality
- GOP034F001 TUV USA Risk Analysis
- GOP004F004 Impartiality Committee Member Non-Disclosure and Confidentiality Agreement
- P11F040 Enclosure 2 (Declaration of Independence)
- MF120 (Application/Questionnaire Form)

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**Annex 1
IMPARTIALITY BOARD MEMBER COMPETENCIES / EVALUATION FORM**

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|--------------------|--|
| Member Name | |
| Stakeholder | |
| Industry | |

| Areas of competence | Evaluation criteria | Evaluation methods | Result (ok/not ok) |
|---|---|---|---------------------------|
| Ethical, open-minded, diplomatic, observant, perceptive | Employment history Industry reputation | Interview Resume recommendation of a board member | |
| Knowledge of certification processes | Employment history | Resume | |
| Applicable laws, regulations and other requirements for the stakeholder group they are representing | Employment history | Resume Feedback from e.g. board members | |
| Representation of Key Interests / industry or stakeholder group they are representing | Employment history | Resume Comparison of employment history to key interest representation | |

| | Signature | Date |
|-------------------------------------|------------------|-------------|
| Reviewer (Approval) | | |
| Managing Director (Approval) | | |

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Annex 2

IMPARTIALITY BOARD MEETING AGENDA

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|---|--|
| Opening of the Meeting | <ul style="list-style-type: none"> • Welcome to the board members and other attendees (guests, technical specialists, etc.) and introduction as required; • Approval of the quorum; • Approval of the previous meeting minutes • Reiteration of the additional actions that the board can take in case they felt that top management of TUV USA does not respect their advice. • Reiteration of the requirements of Confidentiality |
| Status Report | <ul style="list-style-type: none"> • Status report of open actions from previous meeting; |
| Communication Of Changes | <ul style="list-style-type: none"> • Communication of TUV USA Organizational Changes; • Board Members updates; • Changes of Duties and Responsibilities • Significant changes in TUV USA processes |
| Accreditation/ Regulatory Audits Results | <ul style="list-style-type: none"> • Office and Witness audits conducted by Accreditation Bodies and Regulatory Authorities in TUV USA (dates, results, status of related actions etc.); |
| Internal Audits Results | <ul style="list-style-type: none"> • Internal Audits conducted by TUV USA (dates, results, status of related actions etc.) |
| Review of Impartiality | <p>Based on the Risk Analysis, demonstrate how TUV USA ensures:</p> <ul style="list-style-type: none"> • Impartiality on TUV USA Top Management and Personnel; • Impartiality on Services; • Impartiality of Finances and Source of Income; • Impartiality in the Certification Process; • Investigation of customer feedback, appeals, complaints and disputes that may be linked to a threat to impartiality; |
| Final Considerations | <ul style="list-style-type: none"> • Recommendation/ Feedback of the Impartiality Board Members; • Actions to be taken; |
| Closing | <ul style="list-style-type: none"> • Communication of the planned date for the next meeting; • Confirmation of Attendance (e.g. signature of chairman and responsible for the minutes) • Thank you note |

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Revision History

| Revision | Date | Description of the Change | Approved by | Communication |
|-----------------|-------------|---|--------------------|----------------------|
| Orig. | Unk. | Record not available | Unk. | Unk. |
| 1 | Unk. | Record not available | Unk. | Unk. |
| 2 | Unk. | Record not available | Unk. | Unk. |
| 3 | 03/23/2017 | Section 7.2 Updated – Last bullet point related to list of individuals was removed. Added on section 7.1 the sentence: <i>TUV USA is responsible to provide any information requested by the committee and may invite additional experts on the areas it provide services as guest to the meetings, if required.</i> | R. Thomsen | |
| 4 | 09/04/2017 | The form GOP004F002 was deleted from the QMS and the procedure was updated accordingly on section 6.4.1 | R. Thomsen | Release in Workflow |
| 5 | 11/30/2019 | Annex 2 was updated to describe how the attendance is confirmed | R. De Souza | Release in Workflow |
| 6 | 4/10/2023 | Updated References from old Risk Analysis Matrix (GOP004F003) to New Risk Analysis Matrix (GOP034F001). | S. Stephen | Release in Workflow |
| 7 | 9/5/2023 | Updated References to Impartiality of auditors/subcontractors per individual assignment. | S. Stephen | Release in Workflow |
| 8 | 12/6/2023 | Section 6.2: Add statement for communication of known/potential risk to impartiality. | D. Minamino | Release in Workflow |

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| | | Section 6.5: Add "shall" statement of non-direct participation of Auditors/Client Employees. | | |
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