Suspension, Withdrawal Procedure – Medical Product Division

1. Objective

This procedure describes TUV USA's Medical Products Division (MPD) procedure in suspending and/or withdrawing the certification document and cancelling the certification.

2. Reference Documents

- GOP016 Complaints, Appeals and Disputes
- A99VA03 TNC Suspension, Withdrawal, cancellation and expiration of certificates under the CMDCAS Certification program

3. Definitions

- N/A

4. Description and Responsibilities

TÜV USA MPD certified customers are informed by the contract of their responsibilities to maintain conformance to quality system requirements and to follow the rules in the proper use of the certification documents and logos. They are also informed of TÜV USA MPD surveillance process in assuring continuing maintenance of conformance, and that failure to do so can lead to remedial actions, such as suspension of certification. Suspension of certification may also be termed "restricting the use" of the document. In the event of a serious infringement of the certification TÜV USA will take appropriate action to suspend and/or withdraw a certificate and cancel certification. Customer/s will be duly informed about the status of the certificate.

4.1. Responsibility

During the annual surveillance audit of a customer, the lead auditor is responsible to assure that the owner of the certificate continues to conform to all the needs and requirements surrounding its quality systems certification. When a non-conformance of serious nature is discovered, the lead auditor informs the Certification office who may decide to suspend and/or withdraw the certificate and cancel the certification, if the detected serious non-conformity is not addressed according to the time frame set. The customer is immediately informed of this action by the Certification office.

4.2. Procedure

During surveillance audits, the lead auditor will contact the client and schedule an audit on-site to conform to all requirements surrounding its system certification as per the standard/s requirements.

When a non-conformance of serious nature is discovered, the lead auditor informs the client and at the same time communicates this through the audit documentation submission. The Certification office will perform subsequently its review of the audit documentation and appropriate action/s of suspending the certificate will be taken if the serious non-conformity detected is not addressed by the client.

Formal, documented complaints from a certified client's customer or from the general public relating to certified client issues are also forwarded to the Certification office / and Director of MPD for review.
The Certification office / Director of MPD, upon review of the available information, comes to a decision on the further procedure. Should the initiator of the request not agree with the decision, an appeal can be lodged with TUV USA Managing Director, whose decision will be binding.
Suspension is usually the first step in resolution of an identified issue; however, depending on the seriousness of the nonconformity, the Certification Office may proceed directly to withdrawal. The major causes requiring a suspension of certification follow:

- The client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system,
- The certified client does not allow/declined surveillance or recertification audits to be conducted at the required frequencies,
- Improper use of the certificate or the logo is discovered,
- Required corrective actions are not implemented in the specified timeframes,
- Required special audits or reaudits cannot be scheduled in specified timeframes,
- An unacceptable change to the quality system has occurred, or
- The certified client has voluntarily requested a withdrawal.

The Certification office / Director of MPD / TUV USA Quality Manager informs the customer immediately of the reason for the suspension and confirms this situation by a registered letter or equivalent means. The details of corrective action or other means by which the suspension may be removed shall be described in these communications along with a requested date of completion (usually limited to three months), and the means by which verification shall be made. The client will be required to discontinue the use of all advertising or promotional materials indicating that the customer is registered.

If the conditions causing suspension are corrected by the customer and verified by the Director of MPD, the suspension will be removed and the customer notified of this action. However, if the customer's system infringements continue after the suspension period, the certification may be canceled and the certificate withdrawn.

The customer has the right to request withdrawal of their certificate. In this case, the request must come to the Certification office / Director of Division / Quality Manager in writing. The requirements of lifting the suspension shall be described in the communications along with a requested date of reevaluation of the QMS (usually limited to three months), and the means by which verification shall be made. The customer will be required to discontinue the use of all advertising or promotional materials indicating that the customer is registered, till the suspension of the certificate is lifted,.
In the situation where TÜV USA MPD discovers a serious infringement of certification, which leads to nonconformance, the Certification office may impose the withdrawal of certificates,

and cancel the certification including agreements to use TÜV USA MPD and accreditation body logos.

Related to the MDSAP Certificates:
TUV-USA informs the recognizing Regulatory Authority(s) that performed its initial recognition when it becomes aware of any fraudulent activities or counterfeit products of any of its existing clients. TUV-USA is not responsible for establishing objective evidence but must report such activities or products in writing within 5 working days from the date of discovery.

The following cases are relevant causes for this action:

- Certification system rules are changed and not complied with by the customer,
- The customer ceases to do business with the product or service for an extended period,
- The customer fails to meet financial obligations of TÜV USA MPD,
- The certified client has voluntarily requested a withdrawal, or
- Other relevant grounds.

The Certification office / Director of MPD / Quality Manager exercises the action by sending the customer a certified letter, return receipt requested, or similar communication. In the least, customers notified of certification withdrawal and cancellation is asked to return the certification document immediately. In the case of suspension and/or withdrawal, the customer will be required to discontinue the use of all advertising or promotional materials indicating that the customer is registered.

The customer has the right to appeal to TÜV USA MPD against a decision to suspend or withdraw and cancel certification. TÜV USA MPD will discuss the procedure for appealing with the customer.

The Certification Body shall follow up the communication to withdraw and cancel, requesting confirmation from the customer, and further verification as needed by other means. Detailed records shall be kept by Certification Body of all such action, the customer's responses and any ensuing appeals action.

The customer has the right to request cancellation of their certificate. In this case, the request must come to the Certification office / Director of MPD / Quality Manager in writing. The customer will be required to discontinue the use of all advertising or promotional materials indicating that the customer is registered by TÜV USA MPD.
In the case where the certificate expires, the customer will be required to discontinue the use of all advertising or promotional materials indicating that the customer is registered by TÜV USA MPD.

Suspension, withdrawal, cancellation or expiration of an ISO13485 certificate issued under CMDCAS requires the notification of Health Canada and SCC, within 15 days of the effective suspension or withdrawal of the certificate. To notify Health Canada use form F201 available at the website < http://www.hc-sc.gc.ca >. At the same time a notice in the letter head of TUV USA need to be sent to SCC informing about the suspension or withdrawal of the Certificate. The Quality Manager will be responsible for filing the form with Health Canada and notifying Health Canada and SCC.

MDSAP Certificates:
TUV-USA notifies the recognizing Regulatory Authority(s) in writing within 5 working days from the date of a decision to refuse, suspend, reinstate, restrict, or withdraw a certificate. The notification includes a rationale for such action.

MP124 rev. 9