TÜVNORD

# DESCRIPTION OF THE CERTIFICATION PROCEDURE EN 9100, EN 9110 AND EN 9120

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If you should require any further information then please do not hesitate to contact us. We will be please to help you.

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# DESCRIPTION OF THE CERTIFICATION PROCEDURE EN 9100, EN 9110 AND EN 9120

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The certification procedure for AQMS (Aerospace Quality Management System, EN 9100ff) consists of offer-/contract phase, audit preparation, conduction of stage 1 audit including evaluation of management review, conduction of stage 2 audit (evaluation on-site), granting of certification and surveillance and following recertification.

This description is based on the specifications of the standards EN 9101 and series EN 9104 as well as the applicable rules of the accreditation body DAkkS and the aviation industry and/or its committees. In particular the national RMS GERMANY, EAQG and IAQG and must be adapted if necessary in the event of changes to these specifications, in order to guarantee the validity of the certifications on a permanent basis

The auditors are selected by the Head of the certification Body of TÜV NORD CERT GmbH depending on their authorization and qualification. Additional requirement for the selection of aerospace auditor are given in the EN 9104-3. Furthermore, auditor shall be listed in the OASIS-Database with status AA (Aerospace auditor) or AEA (Aerospace Experienced Auditor) before he/she can be assigned to an aerospace audit.

## 1. CERTIFICATION PROCEDURE

### 1.1. Additional external rules and requirements applicable

The Following external rules are applicable in addition to the basic rules and requirements defined by IAF, ISO and TÜV NORD CERT GmbH.

- DIN EN 9101
- DIN EN 9104-01
- DIN EN 9104-02
- DIN EN 9104-03
- IAQG OPMT ICOP Resolutions Log
- IAQG 9100:2016 Series Clarification
- IAQG FAQ 9101: 2016
- 9104-001 Frequently Asked Questions (FAQ)
- Special Rules issued by IAQG in case of special circumstances, e.g. transition phase

IAQG confirms (www.iaqg.org) the technical equivalence of the European standards with appropriate international standards from America or Asia.

### 1.2. Additional Duties

#### 1.2.1. Certified Organizations (clients) and certification body

AQMS certified organizations allow Certification Body to provide Level 1 data (i.e., information on the issued AQMS standard certificate - public domain) and Level 2 data (e.g. information and results of audits, assessments, non-conformances, corrective action, scoring, and suspensions - private domain) to the OASIS database.

AQMS certified organizations shall provide access to the Level 2 data in the OASIS database to their aviation, space, and defense customers and authorities, upon request, unless justification can be provided (e.g. competition, confidentiality or conflict of interest).

AQMS certified organizations are contractually required to provide copies of the audit report and associated documents/records to their customers and potential customers, upon request, unless justification can be provided (e.g. competitor confidentiality, conflict of interest). The organization may provide access to this data through the OASIS database or by providing the audit report directly to the customer.

If AQMS certified organizations lose their AQMS standard certification, they shall provide immediate notification to their aviation, space, and defense customers.

AQMS certified organizations shall identify an OASIS administrator who shall maintain his OASIS status permanently “active”.

AQMS certified organizations shall maintain their master data in OASIS actively and regularly.

AQMS certified organizations are responsible for notifying TÜV NORD CERT (without request) of significant changes within the organization (e.g. changes related to address, ownership, key management, number of employees, scope of operations, customer contract requirements).

AQMS certified organizations shall provide to TÜV NORD CERT on request all information required to perform audits and certification.

Based on the additional rules of the national RMS GERMANY, TÜV NORD CERT is obliged to fix a realistic date for the next regular audit one year in advance. This date has to be reported back to RMS GERMANY by TÜV NORD CERT.

TÜV NORD CERT shall not publish certificates (i.e., initial, recertification, modifications) without an OASIS database administrator identified and listed for the client in the OASIS database and knowing all necessary OIN.

**Failure of a certified organization to abide by these expectations shall be cause for withdrawal from the ICOP scheme and the OASIS database listings.**

**In the case of modifications of mandatory requirements (standards, rules of DAkkS, RMS GERMANY/IAQG as especially short term modifications of IAQG ICOP Resolutions Log) this document will be modified at any time as necessary.** The mandatory modifications become effective latest at defined deadline without necessity for any agreement by certified clients.

### 1.2.2. Disclosure of information and right to access

Audit Team

Using this description TÜV NORD CERT informs its aviation, space, and defense clients, that client shall disclose classified material or export control requirements.

Other Parties

TÜV NORD CERT allows IAQG members, ABs, and regulatory agencies access to its facilities and records to ensure conformity with DIN EN 9104-1. That includes as well oversight assessments of processes and activities associated with DIN EN 9104-01, and accreditation and recognition as a

Certification Body under the ICOP scheme. The 'right of access' includes the witnessing of TÜV NORD CERT audits of organizations.

Using this description TÜV NORD CERT ensures this 'right of access' as contractually extended to its client facilities and associated records.

**Clients of TÜV NORD CERT agree that Assessors from Accreditation Body, Other Party (e.g. RMS GERMANY) assessors, customer representatives, and regulatory authorities may accompany a Certification Body audit for the purpose of oversight witness or the confirmation of the effectiveness of the Certification Body audit process.**

### 1.3. Audit Preparation

#### 1.3.1. General Remarks

**Upgrading from a certification according to ISO 9001 or any other standard to an AQMS standard is not possible.**

A full certification audit including stage 1 audit following DIN EN 9104-01 shall be performed independent on existing knowledge about QM-Systems.

The client shall name a contact person (Supplier Representative) responsible for the handling of audits by the management and the administrator for OASIS (OASIS Administrator). This named contact person receives an invitation email from OASIS, initiated by the certification body, to create an account. Once the account is active, the certification body can generate an OIN for this location (each physical location requires an individual OIN). If a location is relocated, the address of an existing OIN must be changed in order to maintain the certification history.

Within the framework of the planning phase, it must be ensured that a regular surveillance audit or re-certification audit takes place in each calendar year and is concluded by the end of the respective calendar year with the full-calculated on-site audit time. This also applies in the event that an audit is carried out as a partial audit. Otherwise, the certificate shall be suspended in accordance with paragraph 8 of this document.

Auditing of AQMS (certification audit including stage 1 and 2 audits, surveillance audits, recertification audits, special audits) is done fulfilling the requirements of clause 4 of DIN EN 9101:2018.

#### 1.3.2. General workflow:

- An audit program will be created based on evaluation of all relevant aspects of the implemented quality management system, including mandatory identification of the certification structure (see Chapter 6 for non-single site companies) in cooperation with client to be certified. Criteria to be used as defined in Annex B of **Fehler! Verweisquelle konnte nicht gefunden werden.**.
  - **Limitation**: According to IAQG 9100:2016-Series Clarifications organization shall consider: If an organization provides any post-delivery activities (such as warranty work), clause 8.5.5 cannot be excluded in its entirety. At a minimum, the sub-chapter "When problems are detected after delivery, the organization shall take appropriate action including investigation and reporting." shall be applicable.

- Audit team in cooperation with client shall define an audit plan containing details on sites, auditors, schedules and duration for every auditor and every site.
  - **Limitation: TÜV NORD CERT shall allow rejections by clients for AQMS auditor assignment/ changes/substitutions only in the case of substantiated evidence of improper activity and/or contract violations as well as in case of conflict of interest or necessary conformance to rules concerning export controls (auditor nationalities).**
- The audit will be reported using OASIS functions and applicable form sheets of TÜV NORD CERT only.
- In the case of any NCR, the clearance of NCR shall happen only using adequate functions of OASIS. That requires active participation of nominated representative of client in OASIS.
- At the closing meeting, the head of the audit team must have documented and submitted in OASIS at least all NCRs identified in accordance with DIN EN 9101:2018 as well as the PEARs affected by these non-conformities.
- Audit team leader shall deliver the full audit report latest two weeks after closing meeting using form sheet defined in DIN EN 9101:2018 or OASIS functionality.

### 1.4. Audit Stage 1

Stage 1 audit generally shall be an on-site audit (exceptions are only allowed for certifications according to EN9120) and Stage 1 audits shall fulfill all the requirements from clause 4.3.2 from DIN EN 9101:2018.

For organizations having more than one site for stage 1 audit an adequate sample of sites shall be visited beneath site with central function (which is not necessarily identical to headquarter)

Audit findings shall be recorded in report for stage 1 audit, a copy is delivered to client

TÜV NORD CERT shall review the status of areas of concern to evaluate, if organization is ready for stage 2 audit. If, in conclusion, it cannot be positively determined that the customer is ready for stage 2 of the audit, the certification procedure is terminated after stage 1.

Audit Stage 1 and 2 shall not be performed on the same day or on consecutive days (back-to-back). In the event the period between stage 1 and stage 2 exceeds six months, an additional stage 1 audit shall be conducted.

In addition all other requirements for audits are applicable (see 1.3)

### 1.5. Audit Stage 2 – Certification Audit

Latest at beginning with stage 2 audit the certification body shall have created data in OASIS database for all sites including necessary data to generate required OIN.

Stage 2 audit fulfills requirements of clause 4.3.3 of DIN EN 9101:2018.

- It is task of audit team (and therefore audit objective) to verify conformity of documented management system with requirements of the standards and to evaluate the effectiveness of system and its processes. This is realized by Interviewing employees, reviewing documented information, inspection of relevant areas and others like using any other available information (e.g. OASIS database).

- Records of audit results will be done in report for stage 2 audits as defined in DIN EN 9101:2018 and shall be completed by other records as required by DIN EN 9101:2018 (e.g. QMS process matrix, PEAR, NCR) or any other requirement from IAQG or TÜV NORD CERT.

In addition, all other requirements for audits are applicable (see 1.3)

### 1.6. Award of Certificate

Once the complete audit documentation has been prepared, it must be checked for completeness and correctness by designated persons who did not participate in the audit. This veto process is used to determine whether the audit process has been completed in accordance with all applicable requirements, whether the documentation meets all requirements of DIN EN 9101:2018 and whether all non-conformities found have been rectified, (see also 7).

After successful passing the three-stepped veto process, including a final certification decision by TÜV NORD CERT a certificate can be issued in OASIS.

Certificates are valid for 3 years after certification decision.

In the case of recertification - irrespective of the date of the certification decision - a maximum period of validity of three years from the expiry date of the previous period shall be granted.

The necessary data for audit and certificate shall be published latest 30 days after certification decision by TÜV NORD CERT into OASIS database.

Validity of AQMS certificates is bound to corresponding OASIS item and certificates shall not be delivered to client before successful publication in OASIS.

## 2. SURVEILLANCE AUDIT

Within the validity period of certificate (3 years) surveillance audits shall happen regularly. Surveillance audits shall be conducted at least once a calendar year, except in recertification years.
**The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date.**
To ensure keeping the deadlines TÜV NORD CERT plans following audits to be performed 9 months (plus x years) after date of certification.
Surveillance activities fulfill requirements of clause 4.3.4 of DIN EN 9101:2018

- Before starting the surveillance audit, the audit program shall be verified or updated using inquiry (see 1.3).
- The results of surveillance audits shall be recorded according to requirements of DIN EN 9101:2018 and IAQG or TÜV NORD CERT.
- The necessary data for surveillance audit shall be published in OASIS database latest 90 days after end of on-site activity (clause 8.5 of DIN EN 9104-01:2013). By decision of the German RMS GERMANY in the case, this deadline cannot be kept (independent on any root cause), the surveillance audit becomes invalid.

- Depending on individual situation, certification shall be suspended or withdraw, e.g. if deadlines are not kept or because of the audit results.

If suspended, after successful repetition of the audit (including successful upload into OASIS Database within deadline) suspended certificates shall be reinstated.
In addition, all other requirements for audits apply (see 1.3).

## 3. RECERTIFICATION AUDIT

Recertification audit shall be performed latest three months before expiry date of certificate, but should not be started earlier than 6 months before expiry date. If audit is started earlier than 6 months the validity of the certificate has to be adjusted accordingly.
It is possible to deviate from the three-month-rule only, if customer explicitly accepts the risk and specialist manager approves in advance.

- Recertification audits shall be completed before expiry date of certification – including verification of corrections and corrective actions for any non-conformity and certification decision.
- Review of documentation of management system as well as audit on-site are performed in recertification audit. The results of previous audits in the validity period shall be taken into account. All requirements of the standards shall be audited.
- Activities for recertification may require stage 1 audit if significant modifications in management system or corresponding to other activities of the client exist (e.g. modifications of statutory requirements)
- Recertification activities fulfill requirements of clause 4.3.5 of DIN EN 9101:2018

Recertification audit corresponds to stage 2 of a certification audit including reporting, veto process and OASIS upload and fulfills all other requirements for audits (see 1.3)

## 4. SPECIAL AUDIT

These audits shall be coordinated with the certified client prior to the visit. TÜV NORD CERT gives information about the specific reason and subject of the visit.

The results for special audits shall be documented at least on Form 5 (Audit report) and Form 2 (QMS), Form 3 (PEAR) and Form 4 (NCR), as applicable.

As result of the veto process following the audit decision about transfer, maintenance, suspension, reinstating, withdrawal or modification of scope or site(s) information is done.

If certificates are to be modified, they shall contain a “re-issue date” corresponding to date of certification decision.

In the case of any relevant modification between regular surveillance audits a special audit can be performed on behalf of certification Body or request of certified client.

A special audit may become necessary to reinstate certificate after suspension.

Special audits fulfill requirements of clause 4.3.6 of DIN EN 9101:2018

In addition, all other requirements for audits apply (see 1.3).

Typical cases in which special audits shall be conducted:

### 4.1. On Request of certified Client

If the number of sites in existing certification shall be modified, this shall be done performing a special audit, which could be combined with regular surveillance audits.

### 4.2. On request of interested party

It may become necessary to perform short time announced audits to investigate a serious issue (supported by objective evidence) identified by any interested party as e.g. client of certified client and/or feedback via OASIS.

### 4.3. Transfer of Certification

The accepting Certification Body ensures to perform a special audit (on-site) to verify validity of certification to be transferred conducted by an AEA before issuing a certificate.
(More details for transfer see chapter 5)

### 4.4. Extension of Scope

Extension of Scope can be done in addition to a regular audit or using a special audit (see also Chapter 4). In any case on-site time needed to audit the additional aspects of the scope have to be determined by specials management together with lead auditor and customer as necessary.

## 5. TRANSFER OF CERTIFICATION FROM OTHER CERTIFICATION BODIES

**Certificates being suspended or in risk to become suspended shall not be transferred.**

Certificates can be transferred only, if they are valid and issued by a Certification Body being valid accredited for ICOP scheme according to EN 9104-series. Organizations presenting certificates from other Certification Body will be handled as clients for initial certification

Certificate transfer between CBs shall not occur, when the Certification Body issuing the existing certificate has nonconformities documented that are awaiting corrective action closure and acceptance, unless the current Certification Body has ceased its activities or is unable to close the corrective actions.

In cases of open corrective actions, the new Certification Body shall ensure closure of corrective actions, prior to certificate issuance.

The accepting Certification Body verifies in a pre-transfer-review if these general conditions preparing a transfer are fulfilled.

The accepting Certification Body ensures that, prior to certificate issuance, a special audit (on-site) is carried out by an AEA to confirm the validity of the certification being transferred.)

Transfer of existing certificates expiring within the next 12 months requires a two-staged special audit.

A new certificate shall not be issued, unless all minor and major nonconformities have been contained and satisfactorily corrected, including root cause analysis completed and planned corrective actions implemented, reviewed, accepted, and verified by the accepting Certification Body.

If the closure of nonconformities takes more than 90 days, transfer of the existing certificate is not allowed.

Review/verification of the corrective action by the accepting Certification Body shall take place on-site (except for corrective actions related to AQMS documentation).

If any authenticated member of designated audit team for transfer has been part of audit team in any AQMS audit in the last three years at the new clients premises, TÜV NORD CERT shall document situation as a risk from a potential conflict of interest.

If yes, mitigation actions shall be planned and implemented during application and pre-transfer review process (in accordance with ISO 17021-1 clause 5.2.3) relating to the potential conflict of interest arising from this situation. The analysis and treatment (i.e. actions taken) shall be retained as documented information.

## 6. CERTIFICATION OF COMPANIES WITH MULTIPLE LOCATIONS (MULTI-SITE)

The regulations of DIN EN 9104-01:2013 provide detailed requirements for organizations that are active at several locations. After consultation with the customer, the certification structure according to DIN EN 9104-01:2013 must be determined.
Currently five different structures are defined in EN 9104-001:2013:

- Single Site – An organization having one location (one address, one company). The organization may be operating under one large building or several buildings at that location. The organization may have one or multiple products or product families flowing though one or multiple processes.
- Multiple Site – An organization having an identified central function (the central office, but not necessarily the headquarters of the organization) at which certain activities are planned, controlled, or managed and a network of sites at which such activities are fully or partially carried out. With the exception of the central office, the processes within each of the sites are substantially the same and are operated to the same methods and procedures (see IAF MD 1, "Multi-site Organization" definition and eligibility requirements).
- Campus – An organization having an identified central function (the central office, but not necessarily the headquarters of the organization) at which certain activities are planned, controlled, or managed; and that has a decentralized, sequential, linked product realization process. For the purposes of this standard, it is referred to as a value stream where the outputs from one site are an input to another site, which ultimately results in the final product or service.
- Several Sites – An organization having an identified central function (the central office, but not necessarily the headquarters of the organization) at which certain activities are planned, controlled, or managed and a network of sites, that do not meet the criteria for either a multiple site or a campus organization.
- Complex – An organization having an identified central function (the central office, but not necessarily the headquarters of the organization) at which certain activities are planned, controlled, or managed and a network of locations that are any combination of multiple site, campus, several sites, or more than one campus.

The criteria for taxonomy are defined in clause 8.1 or annex B of DIN EN 9104-01:2013
In the case of “Complex” the rational for the subset organizational types shall be documented by the client and TÜV NORD CERT. In all cases the applied methodology, audit duration calculation, planned audit program, sampling plan for multiple site organizations, processes for campus organizations, and associated justification shall be submitted for review to the IAQG OPMT Certification Structure Review Sub-Team (CSOC) and approval before beginning with stage 2 audit.

In addition, all other requirements for audits apply (see 1.3).

## 7. MANAGEMENT OF NON-CONFORMITIES

After issuance of a nonconformity the audit team leader submits all NCs via signature in OASIS latest at the end of the on-site audit.

All customers have the obligation to sign the NCRs in OASIS at the last day of the audit latest. The signature is a proof that NCRs have been successfully submitted. The right to file an objection against an NC is not affected by this signature.

To handle all NCs in conformity with applicable rules, it has to be ensured that all deadlines are met:

- within 7 calendar days, after the audit, the specific containment actions, including correction have to be reported back to the lead auditor via OASIS and reach agreement on those actions with the audit team leader within the next 14 calendar days.
- Within a maximum of 30 calendar days from the end of the on-site audit,
  a) the organization has to fill Section 2 of Form 4 in OASIS including correction, root cause analysis, corrective action(s), and corrective action plans and
  b) the lead auditor has to accept root cause analysis, corrective action(s), and corrective action plans
- In general 45 calendar days after the last on-site audit day, customer shall submit (or has already submitted) all necessary proofs for verification of planned and agreed corrections and corrective actions.
- In individual cases this deadline can be extended up to 55 calendar days, if a valid proof can be given and accepted by audit team leader

TÜV NORD CERT shall initiate the suspension process, when a certified client fails to demonstrate that conformance to the applicable standard has been re-established within 60 calendar days from the issuance of a Nonconformity Report (NCR). Demonstrate includes, the lead auditor signs the form in OASIS that everything has been successfully verified and closed the NCR.

The upload function provided by OASIS can be used for the transmission of evidence. In this case, the uploading person/organization must ensure that the documents do not violate export restrictions such as **ITAR/EAR**. All information in the documents that is not absolutely necessary can be blackened. It is also recommended to use encryption or password protection. In this case, the auditors or, in case of major non-conformities, the Certification Body must be informed of the password.

**In the case of major non-conformities, the transmission of evidence to the certification body is mandatory. This should be done via the OASIS functionality, if not possible via the lead auditor.**

If audit team leader does not accept the proofs delivered or corrections / corrective actions planned or implemented he/she can ask for correction.

If no agreement can be achieved between both certified organization and audit team leader, the specialist management of TÜV NORD CERT has to be informed.

**In the case of formal objections to a part of the audit documentation, this does not have a suspensive effect on the 30-day and 60-day periods.**

If nonconformities from initial stage 2 audit can't be closed within 6 months after end of stage 2 audit the stage 2 audit shall be repeated.

Remark on Confidentiality of Data in OASIS:

As OASIS Database is an externally provided database, TÜV NORD CERT cannot vouch for the safety of documents uploaded, e.g. during nonconformity management. Therefore, using the upload option is at your own risk and TÜV NOR CERT will not request you to upload any internal documents. We will deviate from that rule, if the accreditation body or relevant members of the ICOP Scheme explicitly wants us to do so.

All our auditors are also instructed not to upload any files to OASIS also.

## 8. SUSPENSION OF CERTIFICATION

The process for suspending the certificate will be initiated automatically as soon as a relevant deadline has been exceeded. This includes, but is not limited to, the following:

- Deadline not met during handling of non-conformities,
- If no regular audit has been carried out or only partially carried out by 31.12. of the respective calendar year.
- If the audit leader recommends suspension as a result of an audit.

If a suspension is deemed necessary or recommended, it is mandatory for the specialist management to check whether all criteria for a suspension are actually fulfilled.

A Suspension decision may only be carried out by authorized members of the accredited certification body TÜV NORD CERT Germany. A Suspension decision by third parties, e.g. local offices or their members is forbidden.

If declared, a suspension is valid from day of decision and is generally limited to maximal three months. A prolongation is possible only on request by audit team or client, presenting a valid justification. Specialist management does the decision on prolongation.

The CB informs the client on suspension and deadlines. The client is to be informed, that he is not allowed to use certificate or certification signs and that he has to give correct feedback on questions concerning his certification status.

The CB ensures, that modified certification status will be published in OASIS latest 14 calendar days after day of suspension.

Within the specified suspension period, a special cause audit, a regular on-site audit or, if appropriate and possible, an assessment of documents and records shall be carried out to determine whether a

compliant condition has been restored. If this is the case, the responsible assessor, e.g. the audit leader in the audit documentation of the next regular or special audit, recommends revoking the suspension.

In the following veto process, it is verified whether all the criteria for revoking the suspension have actually been met. If yes, a new certificate with the date of the decision to restore shall be issued in OASIS.

The client will be informed about the decision and within 14 calendar days after decision, the status in OASIS database will be updated.

If no audit or evaluation has taken place at the end of the suspension period, TÜV NORD CERT will initiate the revocation of the certificate.

If, in the course of a planned audit or a special audit, it is determined that conformity has not been restored, the audit leader shall complete the documentation of the planned or special audit and recommend the withdrawal of certification.

## 9. WITHDRAWAL OF CERTIFICATION

The procedure for withdrawal of the certificate(s) will be initiated automatically, if it is already suspended and no valid justification for the extension of the suspension phase exists, within the meaning of Chapter 8.

If audit team leader recommends withdrawal because of an audit result, withdrawal of a Certificate in the following veto process it has to be verified, if all criteria for withdrawal are really fulfilled. The decision on withdrawal is valid from day of decision.

The CB recalls all certificates from client and forbids the usage of appropriate certification marks. The client is in charge to send back the certificates on request and not to use any certification mark any longer.

Withdrawal may only be carried out by authorized members of the accredited certification body TÜV NORD CERT Germany. Withdrawal by third parties, e.g. local offices or their members is forbidden.

The CB ensures publication of withdrawal in OASIS latest 14 calendar days after date of withdrawal.

## 10. COMPLAINT MANAGEMENT

TÜV NORD CERT has established a complaint/issue resolution process ensuring:

- all requests for corrective action are responded to within 30 calendar days from receipt of complaint;.
- all feedback received is reviewed and, if response requested, the response is provided within 30 calendar days from receipt of complaint
- That after determination, that a special audit is necessary, this audit shall be completed within 90 calendar days from receipt of the complaint; and
- an effective corrective action process that provides for containment activities, conformance to the applicable standard is re-established, completion of root cause analysis, corrective actions addressing all root causes, and a completion date for the implementation of all corrective actions is defined

TÜV NORD CERT is responsible for the resolution of all complaints. Complaints that cannot be resolved by the Certification Body shall be referred to the Accreditation Body (DAkkS).