# CHECKLIST

for correct audit documents in OASIS



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## 1 Audit Details

### Details as

- Audit Type
- **▶** Audit Reference Number
- Standard
- Certificate Structure Type
- Category (only for Multiple Sites Structure)
- ► Total Audit Days
- Audit Start and End Date
- **▶** Certificate Number
- ► Non-Applicable Clauses
- Certificate Scope

must be 100% identical with all other documents.

## Please double check!

## 2 Form 1: Stage 1 Audit Report

- **Box 3:** Correct audit start and end date
- Box 4: Correct on-site days (mandatory), off-site days mandatory if off-site performed (only applicable for EN9120)
- **Box 5:** Audit report number = will be automatically filled in by OASIS Audit report date = must be the last day of the Stage 1 Audit
- Box 7&35: Sites (OIN), number of employees, number of audit days must be 100% identical with other documents.

  (If the number of employees has been changed, the CB must be informed immediately)
- **Box 8:** Only active representative and OASIS Administrator of the organization (name and contact details)
- Box 10: Use 100% identical scope-wording as in all other documents as well as in certificate (only overall scope in english language) (If the scope-wording has been changed in-between Stage 1 and Stage 2 Audit, the change must be mentioned in Box 37 of Stage 2 Audit Report)
- Box 11: List reason(s) for not applicable in detail per clause defined by the organization. If the justification is not acceptable by the auditor, the auditor must enter a relevant statement/comment in Box 20 (chapter 4.3) and/or Box 27.

(Remark: please use the wording "justification", "not applicable clauses" and do not use the wording "exclusion")

#### ► Note:

The auditor could copy the reason which is mentioned in Organization's quality documents (the organization must describe and justify the non-applicability in their QM documentation. In addition, auditor may use the following wording: "the non-applicability of chapter xyz does not affect the organization's ability, or responsibility, to provide products and services and the enhancement of customer satisfaction, that meets customer and applicable statutory requirements")

- **Box 14:** At minimum the documented information and/or QM manual incl. revision must be mentioned
- **Box 16:** The result of total revenue has to be 100%
- Box 20: Enter "Y/N" to indicate if the requirements have been addressed/not addressed enter comments when issues or areas of concern have been identified enter N/A in comment field for clauses determined as not applicable
- **Box 27:** Minimum a statement about any areas of concern that need to be resolved before stage 2
- **Box 32:** Competency of the audit team for the Stage 2 (including technical experts/translators may be needed).
- **Box 34**: For combination of EN9100/9110/9120 audits only (if no integration use "not applicable")

Enclosures (Form 1: Stage 1 Audit Report)

## **3** Form 2: QMS-Matrix

- **Box 3:** Each assessed site must be listed (incl. correct address or each site requires own matrix). Sites not assessed are not to be mentioned.
- **Box 4:** Audit report number will be automatically filled out by OASIS
- **Box 5:** Issue Date not older than 14 days after last audit day and not date before audit start
- Box 8: All processes and process names are 100% identical with process-list. In case of changes in Process list/organization chart, the changes have to be mentioned in audit-report (Box 37)
- **Box 9&14:** Processes not audited are marked "N/A" in Box 9 and applicable clauses for these processes marked "N/E" in Box 14
- Box 12: Click on all applicable processes per location (Markings and information in Box 12 of the relevant PEARs must be identical)
- **Box 14:** No empty assignment of clauses/Boxes (minimum one mark: C, N, N/E or N/A)
  - Not applicable clauses N/A
  - NC-markings are identical with respective NCR
  - In sum of all processes no blank fields
  - Not assessed clauses (surveillance only) marked with N/E
- **Box 15:** All NCR's must be mentioned in Box 15 and labeled "N" in applicable process in Box 14
- Box 16: Document a summary of objective evidence for clauses 4, 5, 6, 7, 9, and 10. Summarize the relevant audit trails and audit evidence (i.e., statements of fact or information that are relevant to the

audit and verifiable) in relation to the process(es) audited, including statements of nonconformity. In case of nonconformity (NC) in chapter 4, 5, 6, 7, 9 and 10, list NC-number (incl. applicable site) in the text.

#### ► Note:

In the event the source of objective evidence is from multiple locations, the objective evidence should be traceable to that location (mention the name of site)

**Enclosures (Form 2: QMS-Matrix)** 

### 4 Form 3: PEARS

**Box 3,4,5**: Applicable site-address(es) and OIN (identical with QMS-Matrix)

**Box 6:** PEAR ID identical with QMS-Matrix

**Box 7:** Audit report number will be automatically filled out by OASIS

Box 8: Issue date not later than 14 days after last audit day and not date

before audit start

In case of NC in PEAR process, that PEAR must be handed over together with the NC at the closing meeting/last day of audit.

**Box 9:** Process name 100% identical with name in QMS-Matrix

**Box 10:** Name of assessed department or authority (e.g. "head of production")

Box 12: Selected clauses must be identical with clauses labeled in QMS-Matrix in respective process – in PEARs clauses of main chapters sufficient (master is QMS)

**Box 13-16:** Enter relevant details (quoting of references only is regarded insufficient)

**Box 17:** Information about method of determining process results

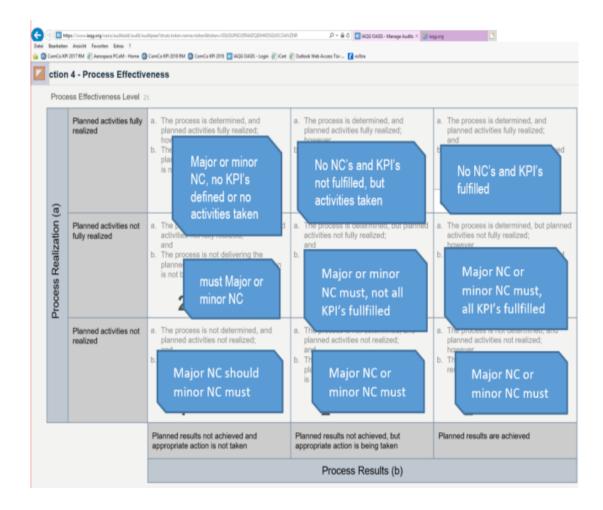
**Box 18:** Enter top performance measures (KPIs) associated with process

**Box 19:** Min. one KPI incl. target for the audited period (result matched with information about result in Box 21 (Process effectiveness))

Comment in Box 19, whether the target(s) have been fulfilled or not fulfilled (recommendation: please use min./max. or % for the targets in the Box of audited period.)

**Box 20:** Summarize audit trails and audit evidences of the relevant site (in case of Multiple Sites, Campus and Several Sites) incl. statement of nonconformity

#### **Box 21:**



Box 22: Enter supporting comment to justify the selected level (with/without NC). If no supporting comment entered, then mark with "none" or "N/A" (never a blank box). Supporting information must reflect the classification situation of Box 21 and NC situation.

**Enclosures (Form 3: PEARS)** 

## 5 Form 4: NCR

**Box 3,4:** Correct site-address(es) and OIN where the NC has been detected (cross check with QMS-Matrix)

**Box 6:** NC-No. (cross check with QMS-Matrix)

**Box 5:** Audit report number will be automatically filled out by OASIS

**Box 7:** Issue date not later than last audit day

**Box 9:** Enter applicable clause (cross check with QMS-Matrix)

**Box 10:** Process name and area/department (cross check with QMS-

Matrix)

**Box 11:** NC-classification (cross check with QMS-Matrix)

**Box 13:** Enter objective evidences

**Box 15:** If containment is required (box 14), due date max. 7 days after

issue date of NC (automatically filled out by OASIS)

Box 16/17: Not later than issue date of NC/last onsite audit day (handover

and acceptance of NC to client)

**Box 18:** Response Due Date max. 30 days after issue date of NC

**Box 21:** Not later than 60 days after issue date of NC - (in case of

containment required, max. 14 days after issue date)

**Box 22:** Not later than 60 days after issue date of NC

(in case of containment required, max. 14 days after issue date)

**Box 24:** Cause code must be entered

**Box 26:** Not later than 60 days of issue date of NC

**Box 27:** Not later than 60 days of issue date of NC

Box 28: Date not later than max. 30 days after issue date of NC (not later than response due date box 18)

#### Note:

If deadline exceeded, please use comment field for justification and do not backdate. Reflect actual situation (e.g. customer has not entered a date and auditor could not sign off)

Box 29: Should be not later than 30 days after the last audit day – acceptance of planned actions

#### ► Note:

If deadline exceeded, please use comment field for justification and do not backdate. Reflect actual situation (e.g. customer has not entered a date and auditor could not sign off)

**Box 30:** Enter a brief summary of the viewed evidence to confirm corrective action implementation and effectiveness of actions taken to prevent recurrence.

(This entry is mandatory, whether attachments are uploaded or not)

#### Note:

If attachments are used to provide further detailed information the auditor should describe the information in summary format and then refer to the respective attachment – only reference "see attached" is not permitted.

with attachments:

Comment about each attachment (number or name, describe the

reason and result of verification ("verified because of...; "based on...; "....fulfills the requirements of EN91XX...")

without attachments

The description of verification - result must be as detailed as required to understand the reason of release

- Box 29: Name of Audit team leader and/or relevant auditor
- Box 31: Name of audit team leader and/or relevant auditor (Date of closing NC by auditor/lead-auditor not later than 60 days after last audit day)
- Box 32: Name of Audit team Leader and/or relevant auditor (Date of closing NC by auditor/lead-auditor not later than 60 days after last audit day)

#### ► Note:

The lead auditor can accept all NC's, even if the NC has been issued by one of the team members

Enclosures (Form 4: NCR)

## 6 Form 5: Stage 2 Audit Report

**Box 3:** Correct audit type

**Box 4:** Correct audit start and end date

**Box 5:** Correct total on-site days (mandatory)

**Box 6:** Audit report number will be automatically filled in by OASIS

**Box 7:** Issue Date of report (not before audit start or during

the audit and no later than 14 days after last audit day)

**Box 8&36:** All sites (OIN), address, OIN, number of employees, number of audit days

(If the number of employees has been changed, the CB must be informed immediately)

ALL sites, number of employees and on-site audit time (Note in case of multiple sites certification: sites not audited during surveillance audit must be listed and marked with "audited: no").

**Box 9:** OASIS Representative (must be the same person as in Box 40).

**Box 10:** correct structure

**Box 11:** ASPR always "no"

**Box 12:** CAAT always "no"

Category (only for Multiple Sites Structure)

**Box 13:** Actual valid certificate number

- **Box 14:** Expiration date of actual valid certificate (if initial audit use "N/A" or leave blank)
- Box 17: Name of and function of any AB/OP/CB witness Assessors/
  Observers/Translators/Technical Experts etc.
  according to audit plan
  (if no AB/OP/CB witness Assessors/ Observers/Translators/
  Technical Experts etc. than enter "none" or "N/A")
- **Box 19:** Enter "yes" or "no" (explanation: "yes" only for integrated/combined audits)
- Box 20: Information to confirm that the documented information and/or QM-Manual (incl. revision) has been established
- Box 21: Enter information regarding the audit objectives (e.g. determination of conformity of clients QMS to defined audit criteria, to ensure compliance with statutory, regulatory, and contract requirements. The audit team has to evaluate the effectiveness of the QMS in meeting the specified objectives, identification of areas for potential improvement of the QMS).
- Box 22: Overall scope necessary (must be 100% identical with overall scope in OASIS details and on certificate.

  Clear statement for subarea certifications.

  (English language required).
- **Box 23:** Justification for "not applicable clauses" don't use the wording "exclusion".

List reason(s) for not applicable in detail defined by the organization. If the justification is not acceptable, the auditor must open an NC and mention a relevant statement/comment in Box 23.

#### ► Note:

The auditor could copy the reason which is mentioned in Organizations quality documents (the organization must describe and justify the non-applicability in their QM documentation.) In addition, auditor may use the wording as well: "The non-applicability of chapter??? do not affect the organization's ability, or responsibility, to provide products and services and the enhancement of customer satisfaction, that meets customer and applicable statutory requirements".

**Box 24-28:** 100% identical with number and information in PEAR's, QMS-Matrix and NCR's.

(sum of numbers of PEARs in Box 28 must be identical with total number of PEARs in Box 27; number of total NCRs in Box 24 must be identical with sum of numbers in Boxes 25 + 26)

**Box 30:** Audit summary (in english language) about information of:

- The effectiveness of the QMS and the organization's approach to continual improvement
- The capability of the QMS to meet applicable requirements and expected outcomes
- Deviation from the audit plan and their reasons
- Significant issues impacting on the audit program
- Unresolved issues (if identified)
- Appropriate use of the certification documents and marks (if applicable)
- Effectiveness of the internal audit and management review processes
- Conclusion on the appropriateness of the certification scope
- Clear statement for subarea certifications

- Confirmation that the audit objectives have been fulfilled
- **Box 31:** If no key issues/concerns requiring top management attention, then use "none" or "N/A"
- **Box 33:** Soft grading of "hidden non-conformities" is not permitted if supplemental report issued, summarize all OFIs identified
- Box 35: List NC by number of previous audit incl. verified evidence. Enter a brief summary regarding the verification of effectiveness of corrective actions taken for nonconformities identified during the previous audit (if applicable). If not applicable, enter "N/A".
- Box 37: Enter information on significant changes: e.g. key changes to the organization and/or facilities, changes to the QMS, changes to the scope of certification, changes to the level of QMS integration, changes in scope (wording) between stage 1 and stage 2 (if initial audit)
- Box 38: Enter a summary of the arrangements agreed upon between the audit team leader and organization's representative relating to planned audit follow-up, as applicable (e.g., containment, corrective action and NCR closure, plus any other activities associated to audit close out)
- **Box 40:** OASIS representative (must be the same person as in Box 9)
- **Box 41:** Not later than 14 days after last audit day

Enclosures (Form 5: Stage 2 Audit Report)

## 7 Form 6: Supplemental Audit Report

A supplemental report is needed if the audit team leader has not visited a site (name of the AEA which was on site must be mentioned in the supplemental report).

- Box 3,4,5: Correct audit date, audit type, on-site days (site-specific)
- Audit report number as pre-populated by OASIS. A different in the relevant D number of supplemental report and stage 2 report must be mentioned in the Box 36 of report stage 2 (Box "supplemental report no"). A revision number of this report-number is desirable.
- Box 7: Issue date of supplemental report before issue date of stage 2 and not later than 14 days after last audit day (site-specific)
- **Box 8&28:** Address, OIN, number of employees, number of audit days (sitespecific) in case of Multiple Sites, Campus and Several Sites: more than one site per supplemental report is possible if the same AEA has visited the site.
- **Box 9&30:** Must be an OASIS registered person should be identical in Boxes 9 & 30
- **Box 13:** Audit team leader of the entire audit necessary
- **Box 14:** AEA of assessed site plus team members
- **Box 17:** Enter "Y" or "N" ("Y" only for integration/combi audits)
- **Box 18:** Only site-specific scope (in english language). Site specific scope must be identical with site scope on certificate

## Box 19–21: Only NC's from assessed site

- Box 24: Audit summary in english language (site-specific) additional local language possible:
  - The effectiveness of the QMS and the organization's approach to continual improvement
  - The capability of the QMS to meet applicable requirements and expected outcomes
  - Deviation from the audit plan and their reasons
  - Significant issues impacting on the audit program
  - Unresolved issues (if identified)
  - Appropriate use of the certification documents and marks (if applicable)
  - Effectiveness of the internal audit and management review processes
  - Conclusion on the appropriateness of the certification scope
  - confirmation that the audit objectives have been fulfilled
  - NC's and OFI's relevant of this site

## **Box 29:** Enter information on significant changes (site-specific) e.g.:

- key changes to the organization and/or facilities
- changes to the QMS
- changes to the scope of certification
- -changes to the level of QMS
- integration since the last visit
- changes in scope wording between stage 1 and stage 2 (if initial audit)

## **Box 30:** Must be an OASIS registered person - should be identical in boxes 9 & 30

## Enclosures (Form 6: Supplemental Audit Report)

## 8 Reference Table

	OASIS-Calculation	OASIS Audit Details	OASIS Supplier Site	OASIS F 1 Stage 1	OASIS F4 NCR Report	OASIS F5 Report Stage 2	OASIS F6 Supplemental Report	OASIS F 2 QMS Matrix	OASIS F 3 PEARS	Audit Plan	Request document for Certificate (if appl.)	Certificate OASIS	Certificate draft (if applicable)
Date of Audit		х	х	х		х	х			х			
Company name										х	х		х
Employees	х		х	х		х	х						
Part certification?						х				х		х	
EAC Code													
- main - additional													
EAC main													
EAC additional													
8.3 not applicable?	х	х		х		х	х	х				х	
Another chapter not applicable		х		х		х	х	х				х	
Numbers of PEAR						х	х		х				
- Level 1 - Level 2						х	х		х				
- Level 3 - Level 4						х	х		х				
- Level 5						х	х		х				
						х	х		х				
Audit time	х	х	х	х		х				Х			
Numbers NCR					х	х	х	х					
- MA - mi					х	х	х	х					
- 1111					х	х	х	х					
Scope(s)		х		х		х	x (site scope)			х	х	х	х

	means Master	Document
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## 9 Enclosures

## 9.1 Enclosure Form 1: Stage 1 Audit Report

This document is: (1) Filling aid for auditors, (2) Form for audit documentation, (3) Checklist for veto reviewer, (4) Knowledge pool for CBs

IAQG	9101 Form 1: Stage 1 Audit Report								
<sup>3</sup> Audit Start Date (Date in American style! => MM/DD/YYYY)	ate in American style! (Date in American style		<sup>4</sup> On-Site A with dot (1.0) (instead of cor	! Only poss		<sup>4</sup> Off-Site Audit Days Only possible with 9120! See audit contract!		Report Date  1-Audit End Date (Box 3)!  ccording to 9101 4.2.3 the age 1 Report must be nded over to the customer the end of the Stage 1 adit)	
<sup>5</sup> Report Number (au	tomatically) Check CB's a	audit numb	er						
<sup>6 &amp; 15</sup> Organization Si	te & OASIS Data								
Import all related sites, also non-audited sites, and check data!  (Automatically for Single Site)		Audit Days: check				Number of Em  Enter - if different f CB immediately!		yees the audit contract, inform	
( tate matter) is a single out	-,	Audited: check							
<sup>7</sup> Contact Details									
Representative: Import active ones only - ed	it if necessary			OASIS Administrator: Import active ones only - edit if necessary					
<sup>8</sup> Preferred Language		<sup>9</sup> Interpret	er Need	ed? enter yes / no					
<sup>10</sup> Proposed Certifica	tion Scope			•					
Check Scope in audit contract and check if conditions on site are matching. Transfer the scope and edit if necessary!									
Changes of the scope betwe	en St.1 + St.2 must be do	ocumented	in the audit rep	ort (Form 5) Box	37 !				
The scope must be in English, but should also be entered in national language!									

In the case of sub-area certification, this must be clearly recognisable in the certificate scope, e.g: - Business Subsection Aerospace: Organization Subsection Aviation, Space, and Defence:									
11 Requirements	determined as "not ap	oplicable" (clause	number(s))						
Justification Copy/paste definition from the customer manual - it must address the following topics! Work/production is only carried out according to the customer's specifications/drawings (Build to Print Shop). Interested parties have no expectations/requirements to fulfil the requirements of EN9100 8.3. The requirement is not applicable for the above mentioned reason and the non-application of the requirement has no effect on the ability or obligation of the organisation to ensure conformity of its products and services and increase customer satisfaction. If insufficient justification is given, enter accordingly in Box 20 + complain Chapter 4.3 in Box 27. May be different in St.2, in that case a comment must then be entered in St.2 Report Box 37! If there are no non-applicable clauses, enter "N/A".									
(QMM Text)	in the QMM of the co	mpany (required	by 9100 4.3)	is comprehens	ible and matches reality:				
Audit Team									
<sup>12</sup> Audit Team Lea	ader select								
Audit Criterion	I								
<sup>13</sup> AQMS Standard	d/Revision check								
<sup>14</sup> QMS Documen	ted Information (e.g.,	Quality Manual)	·						
Reference to QMM (or o	documents required according	to 4.4.2), including revi	sion status / date.						
QMM xxx, Revision	on xx / from xx.xx.202	2x							
If not included in QMM:									
Process landscape, revision xx / from xx.xx.202x									
Organization chart, revision xx / of xx.xx.202x									
Business									
	<sup>16</sup> Organization Reve	nue 17 Personn	el Numbers	% of Total	<sup>18</sup> Organization Shift Patterns				
	% of Total Revenue	F/P/T		Workforce (each could be	Number of Employees E/D/L/N E= Early Shift / D=Day Shift / L=Late Shift /				
	The sum of all = 100%!	F=Full Time / F Temporary (er	P=Part Time / T= nter so!)	100% also)	N=Night Shift (enter so!)				

Aviation	, Space,										
and Def	ense										
Other											
Custome	ers			I							
<sup>19</sup> List of	Current (0	C) / Potent	ial (P) – Aviation	, Spa	ce, and D	efense Key	Custor	ners			
			nd potential custome nents require this.	rs with	ı "(P)".						
Custome		tiality agreen	Address			Contact				% of Business	
<sup>20</sup> CONFI	RMATION	OF REQU	IREMENTS (Y=Ye	es, N=	No, N/A	not applica	ble)			L	
9100 Ser	ries Clause	<u>.</u>			Docume	ented Inforn	nation	Y/N	Con	nments	
					/ Reference				Enter "N/A" for "not applicable" clauses, otherwise enter comments only if problems		
					Do not en	ter "N/A" here!				e identified.	
4.	Context	of the Org	anization								
4.1	Understan Context	ding the Org	anization and its								
4.2	Understan Interested		eds and Expectations	s of							
4.3		ng the Scope ent System	of the Quality								
4.4	Quality Ma	anagement S	ystem and its Proces	sses							
4.4.1	Quality Ma	anagement S	ystem and its Proces	sses							
4.4.2	4.4.2 Quality Management System and its Processes		sses								
5	Leadership										
5.1	1 Leadership and Commitment										
5.1.1	General										
5.1.2	Customer	Focus									
5.2	Policy										
5.2.1	Establishin	g the Quality	y Policy								

5.2.2	Communicating the Quality Policy		
5.3	Organizational Roles, Responsibilities, and Authorities		
6.	Planning		
6.1	Actions to Address Risks and Opportunities		
6.1.1	Actions to Address Risks and Opportunities		
6.1.2	Actions to Address Risks and Opportunities		
6.2	Quality Objectives and Planning to Achieve Them		
6.2.1	Quality Objectives and Planning to Achieve Them		
6.2.2	Quality Objectives and Planning to Achieve Them		
6.3	Planning of Changes		
7.	Support		
7.1	Resources		
7.1.1	General		
7.1.2	People		
7.1.3	Infrastructure		
7.1.4	Environment for the Operation of Processes		
7.1.5	Monitoring and Measuring Resources		
7.1.5.1	General		
7.1.5.2	Measurement Traceability		
7.1.6	Organizational Knowledge		
7.2	Competence		
7.3	Awareness		
7.4	Communication		
7.5	Documented Information		
7.5.1	General		

7.5.2	Creating and Updating		
7.5.3	Control of Documented Information		
7.5.3.1	Control of Documented Information		
7.5.3.2	Control of Documented Information		
8.	Operation		
8.1	Operational Planning and Control		
8.1.1	Operational Risk Management		
8.1.2	Configuration Management		
8.1.3	Product Safety		
8.1.4	Prevention of Counterfeit Parts		
8.2	Requirements for Products and Services		
8.2.1	Customer Communication		
8.2.2	Determining the Requirements for Products and Services		
8.2.3	Review of the Requirements for Products and Services		
8.2.3.1	Review of the Requirements for Products and Services		
8.2.3.2	Review of the Requirements for Products and Services		
8.2.4	Changes to Requirements for Products and Services		
8.3	Design and Development of Products and Services		
8.3.1	General		
8.3.2	Design and Development Planning		
8.3.3	Design and Development Inputs		
8.3.4	Design and Development Controls		
8.3.4.1	Design and Development Controls		
8.3.5	Design and Development Outputs		
8.3.6	Design and Development Changes		

		1		
8.4	Control of Externally Provided Processes, Products, and Services			
8.4.1	General			
8.4.1.1	General			
8.4.2	Type and Extent of Control			
8.4.3	Information for External Providers			
8.5	Production and Service Provision			
8.5.1	Control of Production and Service Provision			
8.5.1.1	Control of Equipment, Tools, and Software Programs			
8.5.1.2	Validation and Control of Special Processes			
8.5.1.3	Production Process Verification			
8.5.2	Identification and Traceability			
8.5.3	Property Belonging to Customers or External Providers			
8.5.4	Preservation			
8.5.5	Post-delivery Activities			
8.5.6	Control of Changes			
8.6	Release of Products and Services			
8.7	Control of Nonconforming Outputs			
8.7.1	Control of Nonconforming Outputs			
8.7.2	Control of Nonconforming Outputs			
9.	Performance Evaluation			
9.1	Monitoring, Measurement, Analysis, and Evaluation			
9.1.1	General			
9.1.2	Customer Satisfaction			
9.1.3	Analysis and Evaluation			
9.2	Internal Audit			

9.2.1	Internal Audit					
9.2.2	Internal Audit					
9.3	Management Review					
9.3.1	General					
9.3.2	Management Review In	puts				
9.3.3	Management Review O	utputs				
10.	Improvement					
10.1	General					
10.2	Nonconformity and Cor	rective Action	n			
10.2.1	Nonconformity and Cor	rective Action	n			
10.2.2	Nonconformity and Cor	rective Actior	n			
10.3	Continual Improvement					
<sup>21</sup> Key Cı	ustomer Performance	е				
Custome	2r		Conformit	Product or Service by Performance story / unsatisfactory	ormance satisfactory / unsatisfactory	
enter a sho				er customer performance inform	ation gathered	d, including complaints)
Custome	er/Regulatory		Approval			
<sup>24</sup> Additi	onal Aviation, Space	, and Defe	nse Custo	mer/Regulatory Require	ements ente	er if available, otherwise "N/A"
Custome	stomer/Regulatory Description of Add			tional Requirements		Document Reference
<sup>25</sup> Comm	ents enter if available, other	erwise "N/A"				1

<sup>26</sup> Other Information (specific informa	tion obtained from t	the organization, including summary comments)
Activities / Subjects	Comments enter if a	vailable, otherwise "N/A"
Restricted areas / proprietary information / confidentiality		
Export limitations / controls		
Customer presence in organization (e.g., on-site representatives, regular meetings, reason)		
Customer delegated inspection, authorized direct ship / direct delivery		
<sup>27</sup> Areas of Concern	•	
Entry required, at least "N/A"!		
Audit Team Leader Recommendation	s	
<sup>28</sup> The Organization is Ready to Procee	d with the Stage 2	<sup>29</sup> If No, Enter Reason(s)
Audit Must be "Yes" before St.2 can be performe	d!	Entry only if it is not possible to start with St. 2!
<sup>30</sup> Proposed Stage 2 Auditor-days required  Check OASIS against audit contract	<sup>31</sup> Proposed Date( Enter date!	(s) of the Stage 2 Audit
<sup>32</sup> Composition/Competency of the Au	udit Team for the St	age 2 Audit
Enter the composition and competence of the audit		technical experts or translators if necessary.
At least 1 AEA and EA Scopes according to audit assignment of the state of the stat	_	
List further required participants (lead for further loc	cations, Co's,) accordingly	·.
1 AEA, # AA, Scope XX + 21		
<sup>33</sup> Certification Structure Verified	The Certification Structu  For Multi-Site in St.2 Rep	re must be verified!  port Box 12 specify Category 1 or 2!

34 Level of QMS Integration	Comments		
Only answer for 9100 and 9110 or/and 912 combined audits!	0		
Otherwise => "Not Applicable"!			
<sup>35</sup> Organization Representative			
Name			
Select/import accordingly - should be the sai	ne person as in box 7!		
<sup>36</sup> Audit Team Leader			
Name		Date (Audit Team Leader) Audit End Date (Box 3)!	
<sup>37</sup> Report Distribution			
Enter the names of persons who should rece	ive a copy of the report, e.g. custon	ner, trainee, consultant, witness assessor.	
If the report is not sent to agreed persons, th	en enter "N/A".		
Confirmation			
Disclaimer Statement: This audit	was conducted based on	a sampling process of the availab	le information.
I confirm this form is cor	nplete. If properly and comple	etely filled in, select/click to complete the forn	n.
Attention for later changes: First	uncheck the box, then save, then ed	dit and save again - after that check the box ag	gain!

The respective OASIS Form Instructions are guidelines for the content of the boxes!

OASIS Instructions for Form 1

https://www.iagg.org/exdomains/oasis/elements/docs/9101-form-1-reference.pdf?20180507

NOTE: The completeness of this Form may be supplemented by the use of attachments to provide further detailed

information. When attachments are provided, the respective box on the Form should describe the information in

summary format and then refer to the respective attachment - it is not permissible to simply say "see attached".

The CBMC Germany generally does not want any empty boxes (at least fill in "N/A" where possible/sensible)!

CBMC Germany Checkliste for 9101 Form 1 - 6

https://www.bdli.de/sites/default/files/global\_upload\_upload/190405%20-%20General%20Checklist%20-%20Quality%20of%20OASIS%20Audit%20documentation%20-%20prefinal\_v02\_0.pdf

Legend:

**Text in red** = requirement and/or information on the form boxes

Text in blue = Default for the content of the form boxes - Attention: This has to be adapted to the situation!

**Text in magenta** = Alternatives, which must be considered situation-related in each case and adapted or deleted accordingly!

### 9.2 Enclosure Form 2: QMS-Matrix

This document is: (1) Filling aid for auditors, (2) Form for audit documentation, (3) Checklist for veto reviewer, (4) Knowledge pool for CBs

IAQG		9101 Form 2: QMS Process Matrix Report								
<sup>3</sup> Organization S	Site									
Select/import only a	ll audited sites (this will fill Box 1	.0 + 11, automat	tically for single	site). Check add	lresses against a	udit contract. D	o not import no	n-audited sites!	L	
OIN	Central Function									
Address										
<sup>4</sup> Audit Report	Number (automatically)						5	Issue Date	Enter the last au	udit date
(max. 14 days afterwards!) (For DEKRA max. 5 days afterw									•	
<sup>6</sup> Type of Certif	ication Structure	<sup>7</sup> AQMS St	andard/Re	vision						
check => Single Site / Multiple Sites / Campus / Several Sites / Complex Organization  check => EN9100:2018 / EN9110:2018 / EN9120:2018										
Organization C	QMS Processes									
	es from the process landscape or esses / process names must be o					create PEARs in	OASIS 3. sele	ct/import proce	esses to QMS Pro	ocess Matrix.
<sup>8</sup> Process Nam	ie									
	Use all processes from the Process List! Info: Box 9 + 13 will be filled automatically.								0	
	per matrix possible - if	1	2	3	4	5	6	7	8	

<sup>9</sup> Related Process Effectiveness Assessment Report (PEAR) Identification Do not create a PEAR for non-audited processes! (are automatically marked with N/A)									
Select PEAR number (as soon as PEARs have been generated), if not already done when selecting the process.									
Check that "N/A" is preset for processes not concerned with chapter 8 and that no PEAR has been generated.									
Check that at least one PEAR # is displayed.									
<sup>10</sup> Site (automatically)				12 Process A	Application				<sup>11</sup> OIN
<sup>10</sup> Site (automatically)		S		<sup>12</sup> <b>Process</b> A			ļ.		<sup>11</sup> OIN (automatically)
<sup>10</sup> Site (automatically)	For PEAR		Select/check the		ox for each locat	ion and process		n) scope	
<sup>10</sup> Site (automatically)	For PEAR		Select/check the	e appropriate bo	ox for each locat	ion and process		n) scope	
<sup>10</sup> Site (automatically) <sup>13</sup> Process Effectiveness Level (automatisch)	For PEAR		Select/check the	e appropriate bo	ox for each locat	ion and process		n) scope	
<sup>13</sup> Process Effectiveness Level	For PEAR		Select/check the	e appropriate bo	ox for each locat	ion and process		n) scope	

Clauses Each clause must be evaluated (C, N, N/A, N/E) - no blank lines!  If "N" the relevant NCR must be selected/imported in box 16!		1	2	3	4	5	6	7	8	and Classification  All NCRs must be selected/imported. In addition, an "N" must be entered in the respective line of Box 14 for the corresponding process!
4.	Context of the Organization									
4.1	Understanding the Organization and its Context									
4.2	Understanding the Needs and Expectations of Interested Parties									
4.3	Determining the Scope of the Quality Management System									
4.4	Quality Management System and its Processes									
4.4.1	Quality Management System and its Processes									
4.4.2	Quality Management System and its Processes									

## <sup>16</sup>Summary of Objective Evidence

Document a summary of objective evidence for clauses 4, 5, 6, 7, 9, and 10.

Summarize the relevant audit trails and audit evidence (i.e., statements of fact or information that are relevant to the audit and verifiable) in relation to the process(es) audited, including statements of

#### nonconformity.

If the source of objective evidence is from multiple locations, it must be traceable to that location.

If more than one matrix exists: For each chapter where C / N / N/E has been entered, a summary is required, otherwise a corresponding reference to the other matrix.

IAQG 9100 Evaluation Guidance Material https://www.sae.org/iaqg/organization/auditor guidance%20 9100 2016.pdf

#### **Reviewed processes / documents:**

Active certifications: xxxxxx

OASIS Admin verified, access to OASIS verified, no open access requests.

Management manual, status xx.xx.xxxx, incl.

- Process Landscape
- Interactions
- List of Stakeholders
- Organization chart (or see chapter 5.3)

The scope of application is defined - duly substantiated non applicable requirements: None

The EN9100 certified sub-sector is defined accordingly.

#### **Conclusion:**

The following recommendations (OFI) were made on the basis of the processes and documents examined: None or OFI ## #.# and OFI ## #.# he following non-conformities (NCR) were identified on the basis of the processes and documents examined: None or NCR ## Mi #.# and NCR ## Ma #.#

Recommendations / non-conformities from previous audit: None or E## #.#/2019 and E## #.#/2019 correct handled / implemented NCR ## Mi #.#/2019 and NCR ## Ma #.#/2019, appropriate corrective actions have been effectively implemented. (See above + 9101 Form 5 -Audit Report, Box 34 + 35) NCR ## Mi #.#/2019 and NCR ## Ma #.#/2019, appropriate corrective actions have not been effectively implemented, therefore an additional NCR##Ma 10.2 was created against the corrective action system. (See above + 9101 Form 5 - Audit Report, Box 34 + 35) Conformity with the audit criteria was demonstrated by the procedures and documents inspected. Conformity with the audit criteria was not fully demonstrated by the procedures and documents inspected. Measures have to be initiated in order to achieve conformity with the standard. Leadership 5. 5.1 Leadership and Commitment 5.1.1 General 5.1.2 Customer Focus 5.2 Policy 5.2.1 Establishing the Quality Policy 5.2.2 Communicating the Quality Policy Organizational Roles, 5.3 Responsibilities, and Authorities

## **Reviewed processes / documents:** Policy, status xx.xx.xxxx (process "policy") The continuous improvement of customer satisfaction - product conformity + delivery performance (OTD) is measured. Responsibilities and authorisations are assigned by the top management - Organization chart (or see chapter 4) The Mgt representative is defined and announced. Job description QMR, status xx.xx.xxxx List of representatives in the company, status xx.xx.xxxx, List of process owners, status xx.xx.xxxx **Conclusion:** The following recommendations (OFI) were made on the basis of the processes and documents examined: None or OFI ## #.# and OFI ## #.# he following non-conformities (NCR) were identified on the basis of the processes and documents examined: None or NCR ## Mi #.# and NCR ## Ma\_#.# Recommendations / non-conformities from previous audit: None or

E## #.#/2019 and E## #.#/2019 correct handled / implem	entec
--	-------

NCR ## Mi\_#.#/2019 and NCR ## Ma\_#.#/2019, appropriate corrective actions have been effectively implemented. (See above + 9101 Form 5 - Audit Report, Box 34 + 35)

NCR ## Mi #.#/2019 and NCR ## Ma #.#/2019, appropriate corrective actions have not been effectively implemented, therefore an additional NCR##Ma 10.2 was created against the corrective action system. (See above + 9101 Form 5 - Audit Report, Box 34 + 35)

Conformity with the audit criteria was demonstrated by the procedures and documents inspected.

Conformity with the audit criteria was not fully demonstrated by the procedures and documents inspected. Measures have to be initiated in order to achieve conformity with the standard.

6.	Planning					
6.1	Actions to Address Risks and Opportunities					
6.1.1	Actions to Address Risks and Opportunities					
6.1.2	Actions to Address Risks and Opportunities					
6.2	Quality Objectives and Planning to Achieve Them					
6.2.1	Quality Objectives and Planning to Achieve Them					
6.2.2	Quality Objectives and Planning to Achieve Them					
6.3	Planning of Changes					

<sup>16</sup>Summary of Objective Evidence

### **Reviewed processes / documents:**

Evaluation of risks and opportunities, status xx.xx.xxxx

Process "Define company and division targets", status xx.xx.xxxx

Quality objectives, status xx.xx.xxxx

The organization considers the purpose of the change and its potential impact on the QMS.

### **Conclusion:**

The following recommendations (OFI) were made on the basis of the processes and documents examined: None or OFI ## #.# and OFI ## #.# he following non-conformities (NCR) were identified on the basis of the processes and documents examined: None or NCR ## Mi #.# and NCR ## Ma #.#

Recommendations / non-conformities from previous audit: None or

E##\_#.#/2019 and E##\_#.#/2019 correct handled / implemented

NCR ## Mi\_#.#/2019 and NCR ## Ma\_#.#/2019, appropriate corrective actions have been effectively implemented. (See above + 9101 Form 5 - Audit Report, Box 34 + 35)

NCR ## Mi #.#/2019 and NCR ## Ma #.#/2019, appropriate corrective actions have not been effectively implemented, therefore an additional NCR##Ma 10.2 was created against the corrective action system. (See above + 9101 Form 5 - Audit Report, Box 34 + 35)

Conformity with the audit criteria was demonstrated by the procedures and documents inspected.

Conformity with the audit criteria was not fully demonstrated by the procedures and documents inspected. Measures have to be initiated in order to achieve conformity with the standard.

7.	Support					
7.1	Resources					
7.1.1	General					
7.1.2	People					
7.1.3	Infrastructure					
7.1.4	Environment for the Operation of Processes					
7.1.5	Monitoring and Measuring Resources					
7.1.5.1	General					
7.1.5.2	Measurement Traceability					
7.1.6	Organizational Knowledge					
7.2	Competence					
7.3	Awareness					
7.4	Communication					
7.5	Documented Information					
7.5.1	General					

7.5.2	Creating and Updating					
7.5.3	Control of documented information					
7.5.3.1	Control of documented information					
7.5.3.2	Control of documented information					

### <sup>16</sup>Summary of Objective Evidence

### **Reviewed processes / documents:**

### Personnel mgt.

Code of conduct / Ethical principles, status xx.xx.xxxx

Training plan, status xx.xx.xxxx

x-Training, from xx.xx.xxxx

Qualification overview, status xx.xx.xxxx

### **Production facilities/equipment, Operating resources**

Necessary infrastructure and process environment is identified, provided and maintained (buildings, equipment, transport, information and communication technology).

Machinery, equipment, buildings and property are in good condition and are well serviced and maintained.

All systems/machines are maintained and serviced according to schedule in accordance with process "xxxxxxxxxx", status xx.xx.xxxx

### **Measuring and Testing equipment**

All measuring and testing equipment is maintained and serviced according to the process "xxxxxxxxx", status xx.xx.xxxx

Measuring and test equipment list, status xx.xx.xxxx

Measuring equipment xxxxx calibrated on xx.xx.xxxx, valid until xx.xx.xxxx, calibration protocol xxxxx, from xx.xx.xxxx

#### **Documented information:**

Records are legible, identifiable and traceable.

EDP data daily backup of all data, monthly and annual full backups are secured. Financial data is archived.

Process data archiving, status xx.xx.xxxx

Process data protection concept, status xx.xx.xxxx

Process control and storage of documents and quality records, status xx.xx.xxxx

Process Creating and modifying instructions, status xx.xx.xxxx

#### **Conclusion:**

The following recommendations (OFI) were made on the basis of the processes and documents examined: None or OFI ## #.# and OFI ## #.# he following non-conformities (NCR) were identified on the basis of the processes and documents examined: None or NCR ## Mi\_#.# and NCR ## Ma #.#

Recommendations / non-conformities from previous audit: None or

E## #.#/2019 and E## #.#/2019 correct handled / implemented

NCR ## Mi\_#.#/2019 and NCR ## Ma\_#.#/2019, appropriate corrective actions have been effectively implemented. (See above + 9101 Form 5 - Audit Report, Box 34 + 35)

NCR ## Mi #.#/2019 and NCR ## Ma #.#/2019, appropriate corrective actions have not been effectively implemented, therefore an additional NCR##Ma 10.2 was created against the corrective action system. (See above + 9101 Form 5 - Audit Report, Box 34 + 35)

Conformity with the audit criteria was demonstrated by the procedures and documents inspected.

Conformity with the audit criteria was not fully demonstrated by the procedures and documents inspected. Measures have to be initiated in order to achieve conformity with the standard.

8.	Operation					
8.1	Operational Planning and Control					
8.1.1	Operational Risk Management					
8.1.2	Configuration Management					
8.1.3	Product Safety					
8.1.4	Prevention of Counterfeit Parts					
8.2	Requirements for Products and Services					
8.2.1	Customer Communication					
8.2.2	Determining the Requirements for Products and Services					
8.2.3	Review of the Requirements for Products and Services					
8.2.3.1	Review of the Requirements for Products and Services					

8.2.3.2	Review of the Requirements for Products and Services					
8.2.4	Changes to Requirements for Products and Services					
8.3	Design and Development of Products and Services					
8.3.1	General					
8.3.2	Design and Development Planning					
8.3.3	Design and Development Inputs					
8.3.4	Design and Development Controls					
8.3.4.1	Design and Development Controls					
8.3.5	Design and Development Outputs					
8.3.6	Design and Development Changes					
8.4	Control of Externally Provided Processes, Products, and Services					
8.4.1	General					
8.4.1.1	General					
8.4.2	Type and Extent of Control					
8.4.3	Information for External Providers					
8.5	Production and Service Provision					
8.5.1	Control of Production and Service Provision					

8.5.1.1	Control of Equipment, Tools, and software programs					
8.5.1.2	Validation and Control of Special Processes					
8.5.1.3	Production Process Verification					
8.5.2	Identification and Traceability					
8.5.3	Property Belonging to Customers or External Providers					
8.5.4	Preservation					
8.5.5	Post-delivery Activities					
8.5.6	Control of Changes					
8.6	Release of Products and Services					
8.7	Control of Nonconforming Outputs					
8.7.1	Control of Nonconforming Outputs					
8.7.2	Control of Nonconforming Outputs					
9.	Performance Evaluation					
9.1	Monitoring, Measurement, Analysis, and Evaluation					
9.1.1	General					
9.1.2	Customer Satisfaction					
9.1.3	Analysis and Evaluation					

9.2	Internal Audit					
9.2.1	Internal Audit					
9.2.2	Internal Audit					
9.3	Management Review					
9.3.1	General					
9.3.2	Management Review Inputs					
9.3.3	Management Review Outputs					

### <sup>16</sup>Summary of Objective Evidence

### **Reviewed processes / documents:**

The performance indicators of the company are controlled by the top management. The targets are measurable and are monitored by the top management.

Product conformity and timely delivery, as well as customer feedback requests to the company, including those via the OASIS database, are considered in the customer satisfaction evaluation.

Process "internal audit", status xx.xx.xxxx
Audit plan, status xx.xx.xxxx
List of auditors, status xx.xx.xxxx
Audit report, of xx.xx.xxxx

Management review, from xx.xx.xxxx Review Action List, status xx.xx.xxxx Link to risk management?

#### **Conclusion:**

The following recommendations (OFI) were made on the basis of the processes and documents examined: None or OFI ##\_#.# and OFI ##\_#.# he following non-conformities (NCR) were identified on the basis of the processes and documents examined: None or NCR ## Mi #.# and NCR ## Ma #.#

Recommendations / non-conformities from previous audit: None or

E## #.#/2019 and E## #.#/2019 correct handled / implemented

NCR ## Mi\_#.#/2019 and NCR ## Ma\_#.#/2019, appropriate corrective actions have been effectively implemented. (See above + 9101 Form 5 - Audit Report, Box 34 + 35)

NCR ## Mi\_#.#/2019 and NCR ## Ma\_#.#/2019, appropriate corrective actions have not been effectively implemented, therefore an additional NCR##Ma\_10.2 was created against the corrective action system. (See above + 9101 Form 5 - Audit Report, Box 34 + 35)

Conformity with the audit criteria was demonstrated by the procedures and documents inspected.

Conformity with the audit criteria was not fully demonstrated by the procedures and documents inspected. Measures have to be initiated in order to achieve conformity with the standard.

10.	Improvement					
10.1	General					
10.2	Nonconformity and Corrective Action					
10.2.1	Nonconformity and Corrective Action					
10.2.2	Nonconformity and Corrective Action					_
10.3	Continual Improvement					

## <sup>16</sup>Summary of Objective Evidence

### **Reviewed processes / documents:**

Boeing Report Card was considered - no abnormalities - Company xxx has been on Gold Status (100%) for 6 months

Boeing Report Card was considered - relevant improvement measures were viewed: XXX

Process "handling non-conformities and corrections", status XX.XX.XXXX

### Records of corrective/preventive actions:

Completion of the recommendations (OFI) and NCRs from the previous audit => No recommendations. NCR 01 - xx was effectively closed. (See 9101 Form 5 - Audit Report, Box 34 + 35, PEARs and Matrix)

Corrective action list, status xx.xx.xxxx (also from audits?)

8D - Report incl. Ishikawa, 5Why - is executed.

Opportunities for improvement are identified and selected.

=> Risk mgt, Mgt. Review, business planning, corrective actions from audits, corrective actions from complaints, corrective actions from non-conforming products.

The improvement of products and services with regard to future use and customer expectations, as well as the correction, avoidance and reduction of undesirable effects and the improvement of the performance and effectiveness of the QMS are taken into account.

#### **Conclusion:**

The following recommendations (OFI) were made on the basis of the processes and documents examined: None or OFI ## #.# and OFI ## #.# he following non-conformities (NCR) were identified on the basis of the processes and documents examined: None or NCR ## Mi #.# and NCR ## Ma #.# Recommendations / non-conformities from previous audit: None or E## #.#/2019 and E## #.#/2019 correct handled / implemented NCR ## Mi #.#/2019 and NCR ## Ma #.#/2019, appropriate corrective actions have been effectively implemented. (See above + 9101 Form 5 -Audit Report, Box 34 + 35) NCR ## Mi #.#/2019 and NCR ## Ma #.#/2019, appropriate corrective actions have not been effectively implemented, therefore an additional NCR##Ma 10.2 was created against the corrective action system. (See above + 9101 Form 5 - Audit Report, Box 34 + 35) Conformity with the audit criteria was demonstrated by the procedures and documents inspected. Conformity with the audit criteria was not fully demonstrated by the procedures and documents inspected. Measures have to be initiated in order to achieve conformity with the standard. **Attachments** (only if necessary, add attachments) <sup>17</sup>Auditor Name(s) Select all participating auditors. Confirmation Disclaimer Statement: This audit was conducted based on a sampling process of the available information. I confirm this form is complete. If properly and completely filled in, select/click to complete the form. Attention for later changes: First uncheck the box, then save, then edit and save again - after that check the box again!

The respective OASIS Form Instructions are guidelines for the content of the boxes!

OASIS Instructions for Form 2

https://www.iagg.org/exdomains/oasis/elements/docs/9101-form-2-reference.pdf?20180507

NOTE: The completeness of this Form may be supplemented by the use of attachments to provide further detailed information. When attachments are provided, the respective box on the Form should describe the information in summary format and then refer to the respective attachment - it is not permissible to simply say "see attached".

The CBMC Germany generally does not want any empty boxes (at least fill in "N/A" where possible/sensible)!

CBMC Germany Checkliste for 9101 Form 1 - 6

https://www.bdli.de/sites/default/files/global\_upload\_upload/190405%20-%20General%20Checklist%20-%20Quality%20of%20OASIS%20Audit%20documentation%20-%20prefinal\_v02\_0.pdf

Legend:

**Text in red** = requirement and/or information on the form boxes

Text in blue = Default for the content of the form boxes - Attention: This has to be adapted to the situation!

**Text in magenta** = Alternatives, which must be considered situation-related in each case and adapted or deleted accordingly!

# 9.3 Enclosure Form 3: PEARS

This document is: (1) Filling aid for auditors, (2) Form for audit documentation, (3) Checklist for veto reviewer, (4) Knowledge pool for CBs

IAQG	9101 Form 3: Process Effectiveness Assessment Report (PEAR)								
Do not import non-audited si	d sites that are applicable to the process (automatically for single sit	ie).							
<sup>6</sup> <b>PEAR Number</b> Unique number per PEAR (starting with 1, ascending)	<sup>7</sup> Audit Report Number (automatically)	8 Issue Date Enter the last audit date (max. 14 days afterwards!) (For DEKRA max. 5 days afterwards!)  If NC in PEAR process, the NCR + PEAR must be delivered in the closing meeting!							
Section 1 - Process D  9 Process Name select									
	e process owner according to the process landscape/organizational								
<sup>11</sup> AQMS Standard/Re (automatically)	,,,	MS Process Matrix is the master! That means there can more							
· ·	usibility (e.g. process output Order confirmation requires order as incesto QMS documents of the customer are not sufficient and not								
•	usibility (e.g. process output Order confirmation requires order as incesto QMS documents of the customer are not sufficient and not								

<sup>15</sup> Outputs

Check plausibility (e.g. process output Order confirmation requires order as input and order processing as activity).

References to QMS documents of the customer are not sufficient and not required here.

<sup>16</sup> Interactions/Interfaces

Enter processes from the process landscape that interact with this process.  $\label{eq:landscape}$ 

In addition, where necessary/possible, enter interfaces, e.g. customers, suppliers, authorities, IT systems.

#### Section 2 - Process Results

- <sup>17</sup> Organization's method for determining process results The method is in question, not the individual activities!
- Identification of process performance indicators (KPIs) and the associated individual objectives
- Balanced Score Card (BSC)
- Statistical process control (SPC)
- Process capability study with control card evaluation
- Evaluation from tables/databases/ERP software (e.g. SAP)
- Project plans
- Employee self-inspection according to inspection plan (inspection plan is created by QS)

## <sup>19</sup> Auditor Observations and Comments Supporting Process Result Determination

<sup>18</sup> <b>Performance Measures</b> Enter only the relevant top KPIs for the process (min 1, normal 3) In general: Process measurement with KPI on quality, time and costs!	19 Target for Audited Measured Period for Audited   (Min/Max better than ≤ ≥ < >)   Period		<sup>19</sup> Comments  Comments and results must match Box 21 + 22! indicate if targets are reached or not!
KPI 1:	Reviewed period and target (≤ ≥ < > = min. max.)	Reviewed period and result	Monthly (?) measurement and evaluation by the GF (?) in the Mgt Review (?).  Measured / evaluated is (what, when, where)  => Target reached => no measures  => Target not reached => Measures:
KPI 2:			
KPI 3:			

#### Section 3 - Process Realization

### <sup>20</sup> Summary of Audit Trails and Sources of Evidence

Summarize the relevant audit trails and audit evidence (i.e., statements of fact or information that are relevant to the audit and verifiable) in relation to the process audited, including statements of nonconformity.

If the source of objective evidence is from multiple locations, it must be traceable to that location.

INFO: EN9100:2018, 4.4 Quality management system and its processes

The organization shall determine the processes needed for the quality management system and their application throughout the organization and shall:

- a) determine the inputs required and the outputs expected from these processes;
- b) determine the sequence and interaction of these processes;
- c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) determine the resources needed for these processes and ensure their availability;
- e) assign the responsibilities and authorities for these processes;
- f) address the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- h) improve the processes and the quality management system.

#### Reviewed processes / documents:

Checkpoints/Examples/Topics see below - do not enter standard chapters here - audit process-oriented!

#### **Conclusion:**

Following recommendations (OFI) were made for the process: None or E## #.# and E## #.#
Following non-conformities (NCR) were identified in the process: None or NCR ## Mi #.# und NCR ## Ma #.#

Recommendations / non-conformities from previous audit: None or

E## #.#/2019 and E## #.#/2019 correct handled / implemented

NCR ## Mi\_#.#/2019 and NCR ## Ma\_#.#/2019, appropriate corrective actions have been effectively implemented. (See above + 9101 Form 5 - Audit Report, Box 34 + 35)

NCR ## Mi #.#/2019 and NCR ## Ma #.#/2019, appropriate corrective actions have not been effectively implemented, therefore an additional NCR##Ma 10.2 was created against the corrective action system. (See above + 9101 Form 5 - Audit Report, Box 34 + 35)

Key performance indicators (KPI) have been defined, related targets have been achieved, the process is effectively managed.

Key Performance Indicators (KPI) have been defined, related targets have not been fully achieved, actions have been initiated, the process is effectively managed.

Key Performance Indicators (KPI) have been defined, related targets have not been fully achieved, measures have not been initiated, the process is not effectively managed (NCR).

Key Performance Indicators (KPI) have been defined, related targets have been achieved but planned/requested activities have not been fully implemented, the process is not effectively managed (NCR).

Key Performance Indicators (KPI) were not defined and planned/requested activities were not fully implemented the process is not effectively managed (NCR Ma).

Conformity with the audit criteria (see above) was proven by the reviewed operations and documents. Conformity with the audit criteria (see above) was not completely proven by the reviewed operations and documents. Actions have to be initiated in order to achieve conformity with the standard. **Section 4 - Process Effectiveness** <sup>21</sup> Process Effectiveness Level Planned activities fully realized and appropriate action is not Process Realization (a) but planned activities not fully **Planned** b) The process is delivering the activities not fully realized and appropriate action is not 2 determined, and planned Planned b) The process is not activities not realized 2 2 1 Planned results not achieved Planned results not achieved, Planned results are achieved and appropriate action is not but appropriate action is being taken taken **Process Results (b)** 

<sup>22</sup> Supporting Comments	<sup>22</sup> Supporting Comments						
Enter supporting comments to justify the selected process effectiveness level. If Conclusion entered in Box 20 as suggested, then enter "N/A"							
N/A							
Attachments (add attachments only if necessary)							
<sup>23</sup> Auditor(s) Select all auditors participating in the PEAR. <sup>24</sup> Organization Representative							
Confirmation							
Disclaimer Statement: This audit was conducted based on a sampling process of the available information.							
I confirm this form is complete. If properly and completely filled in, select/click to complete the form.							
Attention for later changes: First uncheck the box, then save, then edit and save again - after that check the box again!							

The respective OASIS Form Instructions are guidelines for the content of the boxes!

OASIS Instructions for Form 3

https://www.iagg.org/exdomains/oasis/elements/docs/9101-form-3-reference.pdf?20180507

NOTE: The completeness of this Form may be supplemented by the use of attachments to provide further detailed

information. When attachments are provided, the respective box on the Form should describe the information in

summary format and then refer to the respective attachment - it is not permissible to simply say "see attached".

The CBMC Germany generally does not want any empty boxes (at least fill in "N/A" where possible/sensible)!

CBMC Germany Checkliste for 9101 Form 1 - 6

https://www.bdli.de/sites/default/files/global\_upload\_upload/190405%20-%20General%20Checklist%20-%20Quality%20of%20OASIS%20Audit%20documentation%20-%20prefinal\_v02\_0.pdf

### Legend:

**Text in red** = requirement and/or information on the form boxes

Text in blue = Default for the content of the form boxes - Attention: This has to be adapted to the situation!

**Text in magenta** = Alternatives, which must be considered situation-related in each case and adapted or deleted accordingly!

### IAQG 9100 Evaluation Guidance Material

https://www.sae.org/iagg/organization/auditor\_guidance%20\_9100\_2016.pdf

### Checkpoints/Examples/Topics for Reviewed processes / documents:

Translated with www.DeepL.com/Translator (free version)

#### 8 Operation

- 8.1 Operational planning and control
- Product and service requirements are defined.
- Criteria for processes and for the acceptance of products and services are introduced.
- Control of processes based on these criteria, including time and quality, is defined and implemented.
- Documented information is created and stored.
- Planning changes are controlled and evaluated for possible effects.
- Outsourced processes (relocation of work) are also controlled with a risk concept.

#### 8.1.1 Operational risk management

- this chapter refers to risks of the operational processes

#### 8.1.2 Configuration management

#### 8.1.3 Product safety

### 8.1.4 Prevention of counterfeit parts

- To prevent the use of counterfeit or suspected counterfeit products

#### 8.1.5 Prevention of parts of doubtful origin (9120 only)

- To prevent the use of counterfeit or suspected counterfeit products

#### 8.2 Requirements for products and services

#### 8.2.1 Communication with customers

- Processes for customer communication have been introduced for product and service information, inquiries, contracts, order processing, changes, customer opinions, customer perceptions, complaints, handling of customer property and, if necessary, requirements for emergency measures.

### 8.2.2 Determining requirements for products and services

- When preparing offers, the following points are taken into account when determining necessary requirements for products and services:
- -- applicable legal and official requirements => e.g. REACH
- -- further requirements necessary for the organization => company goals

- The ability of the organization to meet the demands placed on products or services is proven.

#### 8.2.3 Review of requirements for products and services

- Assessment of customer requirements (including delivery and post-delivery activities), determination of requirements for intended use, applicable legal and regulatory requirements and elimination of differences and necessary contract adjustments are taken into account during contract review.
- In the absence of documented customer requirements, a written confirmation of the performance in relation to the customer requirements is provided (e.g. by catalogues, ...).
- Documented information on the result of the evaluation and new customer requirements are available.
- Included requirement that the test be coordinated with the corresponding functions of the company
- Included requirement for necessary measures if some customer requirements cannot be met

#### 8.2.4 Changes in requirements for products and services

- Changes in requirements are updated in documented information and known to all parties involved.

#### 8.3 Development of products and services

#### 8.3.1 General information

- Development process is defined, introduced and maintained.

#### 8.3.2 Development planning

- Development planning process is defined and includes development phases and associated controls. The following points are considered and defined in the development planning for the development project:
- -- Type, duration and complexity
- -- necessary development phases with associated assessment, verification and validation
- -- Responsibilities and authorities
- -- necessary internal and external resources
- -- Interface consideration of participants
- -- necessary integration of customers and users
- -- Requirements for follow-up of products and services
- -- expected involvement of customers and interested parties
- Necessary documented information for verification is available.

#### 8.3.3 Development inputs

- Necessary development inputs such as functional and performance requirements, information from previous similar projects, legal and regulatory requirements and obligations to which the company is committed and the potential impact of defective products and services are available.
- Development inputs are clear, appropriate and complete. Conflicting development inputs are resolved.
- Necessary documented information is available.
- Consideration of the possibility of product obsolescence and the consequences, if applicable

#### 8.3.4 Control measures for development

- Possible development results are defined, evaluated, verified and validated.
- Necessary corrective actions are in place.
- Necessary documented information is available.
- The transition to the next phase is released.

#### 8.3.5 Development results

- Results are adequate and consistent with the specifications.
- Results include or refer to measurement and monitoring requirements.
- Results ensure that products can be manufactured and services provided.
- Documented information on development results is available.
- Authorized persons have approved the release.
- The organization has defined data that enables the identification, manufacture, verification, use and maintenance of the product.

#### 8.3.6 Development changes

- Changes in specifications or results are determined, evaluated and controlled.
- Documented information with details of development changes, result evaluations, change authorizations and measures to avoid negative effects are taken into account.
- Has the organization established a customer notification process when changes occur that affect customer requirements.

#### 8.4 Control of externally provided processes, products and services

#### 8.4.1 General information

- Externally provided processes, products and services meet the requirements. Associated controls at suppliers and such processes are defined.
- Criteria for evaluation, selection, monitoring performance and reassessment are introduced and applied.
- Documented information on supplier evaluation is available.
- The organization has agreed with the external suppliers on controls at their external suppliers.
- There is an agreement with the external providers to create / retain documented information.

#### 8.4.2 Type and scope of controls

- Externally provided processes are subject to the control of the QMS. Supplier and result controls are in place.
- Possible effects of externally provided processes, products and services on the company, customer requirements as well as on official and legal requirements have been considered, as well as the effectiveness of the supplier's controls. Necessary control measures have been introduced and implemented, including testing for counterfeit products
- Has a process been introduced and implemented for evaluating the data from external providers and their test reports.

#### 8.4.3 Information for external providers

- Communication with external suppliers is adequately available (including requirements for deliveries, competence, interactions, control, testing, verification, validation).
- This also applies to approvals of products, services, methods, processes, etc. that are carried out at the external supplier.
- The requirement that the external supplier must introduce a quality management system.
- The contribution to product safety is known to all persons.
- The requirement to introduce a quality management system

#### 8.5 Production and service provision

### 8.5.1 Control of production and service provision

- Controlled conditions for production and service provision have been introduced.

The following points should be observed:

- -- the availability of documented information / the intended results / appropriate monitoring and measurement activities (with recognized sampling methods) with availability of appropriate resources / validation and revalidation of intended results, where monitoring and measurement activities cannot be used for verification
- -- adequate infrastructure and process environment / competent persons including the required qualifications / measures to avoid human error
- -- Release and delivery activities, activities after delivery
- -- Precautions to prevent, locate and remove foreign bodies
- -- Validation and control of special processes, including the release of equipment and qualification of personnel and storage of the associated

#### documented information.

-- Consequences of obsolescence (9120)

#### 8.5.1.1 Control of equipment, tools and software programs

#### 8.5.1.2 Validation and control of specific processes

#### 8.5.1.3 Verification of the production process

#### 8.5.2 Labelling and traceability

- Status of the process results in relation to monitoring and measurement requirements is marked.
- Traceability is given and documented information is available.
- If stamps / electronic signatures are used, these are controlled in an appropriate manner.

#### 8.5.3 Property of the customers or external providers

- Third party property is marked, verified and protected.
- In the event of damage, loss, incorrect handling or unusability, there is a demonstrable obligation to notify us.

#### 8.5.4 Conservation

- receipt of (interim) results during production and service provision is traceable (including labelling, handling, packaging, storage and necessary protective measures)
- Assurance of shelf life and stock turnover.
- Storage of hazardous materials.

#### 8.5.5 Activities after delivery

- Requirements for products and services after delivery are known and considered. (customer requirements / customer satisfaction / type, use and service life / risks associated with products and services / legal and official requirements).
- The regulation for the provision of technical documentation for use, maintenance, repair / overhaul / in the event of complaints about a product is given.

#### 8.5.6 Monitoring of changes

- Changes are evaluated and monitored.
- Documented information such as evaluation results, authorizations of persons and necessary measures are available.

#### 8.6 Release of products and services

- Planned regulations regarding the verification of product and service requirements have been implemented.
- The release will only take place after the customer requirements have been met in full or by special release(s).
- Documented information for release (compliance with customer requirements and traceability to the responsible persons) is available and is available upon delivery

#### 8.7 Control of non-conforming results

- Non-compliant process results, products and services are identified and controlled.
- Appropriate measures are implemented and verified with the requirements.
- Documented information such as error description, immediate measures and special approvals are defined
- Establish responsibility and authority to assessment/treat non-conforming results, including the approval process for personnel,
- Specification for the handling for scrapping a

# 9.4 Enclosure Form 4: NCR

This document is: (1) Filling aid for auditors, (2) Form for audit documentation, (3) Checklist for veto reviewer, (4) Knowledge pool for CBs

IAQG	91	01 Form 4: N	01 Form 4: Nonconformity Report (NCR)					
Unique number per NCR / Audit		<sup>7</sup> Issue Date Last audit day (not later)!		dit Report Number natically)				
<sup>3, 4</sup> <b>Organization Site</b> Select the location where th		ance was identified (no	other o	ones)! Check with QMS Matrix!				
Section 1 - Nonconf	formity Det	ails						
<sup>8</sup> AQMS Standard/R (automatically)	levision		-	0/9110/9120 requirement/clause se - cross-check with QMS Matrix!				
10 <b>Process</b> Select process name - verify with QMS Matrix!		trix!	<sup>10</sup> Area/Department Affected area, unit, department		<sup>11</sup> Classification (acc. to presentation opening meeting)			
12 Statement of Non	nconformity	Briefly describe non-	-conforr	mity (maybe negated standard t	ext), but do not copy/pa	ste standard texts.		
<sup>13</sup> Objective Evidenc	<b>e</b> Evidence whe	ere the NC was recogniz	zed (clea	ar evidence with revision status/i	ssue date!)			
14 Containment Required?  Info see A-09Q-01 6.6  15 Due Date automatically 7 days. Only shorter is possible!			=> Afterwards the "Okay	of the lead must be obt	tained within 14 days!			
				12				
<sup>16</sup> <b>Auditor</b> Select originator / date of last onsite audit day!			<sup>17</sup> Organization Re day!	presentative select /	date of last onsite audit			
<sup>18</sup> Section 2 - Organization's Planned Actions					Response Due Da Max. 30 days after last onsite audit day!	ate		
<sup>19</sup> Containment Action	on(s): If requir	red in field 14/15, ente	r action	S.				

<sup>20</sup> Correction(s) Correct the non-conformity!		<sup>21</sup> Planned Completion Date
(Desired by CBMC-Germa	any is to carry out the correction within 30 days!)	Max. 60 days after NCR issue!
		<sup>22</sup> Actual Completion Date Max. 60 days after NCR issue!
(Desired by CBMC-Germa	any is to carry out the correction within 30 days!)	
<sup>23</sup> <b>Root Cause(s)</b> Cause for the non-conformance.  Do not repeat or reformulate the non-conformance!		<sup>24</sup> Cause Code select, must match Box 23 Root Cause!
DO HOL Tepeat of Teloffidiate the non-conformance.		BUX 23 NOOL Cause:
<sup>25</sup> Corrective Action(s) Correction of the cause!	<sup>26</sup> Planned Completion Date Max. 60 days after NCR issue!	
		<sup>27</sup> Actual Completion Date Max. 60 days after NCR issue!
<sup>28</sup> Organization Representative and Date	<sup>29</sup> Auditor Acceptance and	
Max. 30 days after last onsite audit day! (Latest according to date in box 18!) (if applicable - enter reason for delayed OASIS entry!)	day! yed OASIS entry!)	
Attachments	,	
Evidence can be uploaded to OASIS, but can also be sent to or shown	to the auditor if there are data protection / expo	ort concerns.
Id		Attached

#### **Section 3 - Auditor Verification and NCR Closure**

NOTE 1 Containment action and correction can be reviewed during the audit.

Evaluation and closing of the corrective action plan and associated corrective actions relating to a nonconformity shall not be performed during the audit in which the nonconformity was issued.

Verification activities shall be carried out, as determined by the audit team leader. Verification shall be carried out on-site, if the verification of the corrective action cannot be carried out based on a review of the documentation and supporting objective evidence provided by the organization. A completed NCR shall be recorded in the OASIS database, after verification.

NOTE 2 Requirements for the closure of identified nonconformities are defined in EN 9104-001 clause 8.4.

### 30 Details

Describe the information of attachments in summary format and refer to the respective attachment - it is not permissible to simply say "see attached"!

- Summary of the verification activities performed by the auditor to confirm corrective action implementation and effectiveness of actions taken to prevent

(What was reviewed? - Does it deal with the error/finding and the root cause? - Does this exclude / reduce the possibility of error recurrence? - Is the conformity to standards re-established?)

- Summary of the reason for rejection (using the Discussion and Notes functionality) if the implementation and/or the effectiveness of the corrective actions cannot be confirmed.

#### Reject reasons:

- 1. the root cause (box 23) is the repetition of the non-conformity.
- 2. the corrective action (box 25) does not eliminate the root cause (could be achieved, e.g. by specification in the process description, training of the process participants, ...)

The evidence reviewed demonstrates that corrective actions have been taken which have eliminated the error and its cause. Therefore the possibility of recurrence is **greatly reduced** // systematically (that means by processes/forms introduced in the QMS including appropriate instruction) **excluded** and conformity to the standard is re-established.

#### Evidence:

- QM document version/date,
- others if available
- associated training date

#### (if applicable)

containment action

Already on xx.xx.202x the immediate actions were reported back - these were found to be acceptable and were sufficiently proven by the documentation sent along with the report.

The QMR also received a corresponding response on xx.xx.202x

31 Auditor(s) Should be checked by Lead	Date (Auditor(s))
	Max. 60 days after NCR issue!
<sup>32</sup> Audit Team Leader Must be checked by Lead!	Date (Audit Team Leader)
	Max. 60 days after NCR issue!

Disclaimer Statement: This audit was conducted based on a sampling process of the available information.

The respective OASIS Form Instructions are guidelines for the content of the boxes!

OASIS Instructions for Form 4

https://www.iagg.org/exdomains/oasis/elements/docs/9101-form-4-reference.pdf?20180507

NOTE: The completeness of this Form may be supplemented by the use of attachments to provide further detailed

information. When attachments are provided, the respective box on the Form should describe the information in

summary format and then refer to the respective attachment - it is not permissible to simply say "see attached".

The CBMC Germany generally does not want any empty boxes (at least fill in "N/A" where possible/sensible)!

CBMC Germany Checkliste for 9101 Form 1 - 6

https://www.bdli.de/sites/default/files/global\_upload\_upload/190405%20-%20General%20Checklist%20-%20Quality%20of%20OASIS%20Audit%20documentation%20-%20prefinal\_v02\_0.pdf

### Legend:

**Text in red** = requirement and/or information on the form boxes

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**Text in magenta** = Alternatives, which must be considered situation-related in each case and adapted or deleted accordingly!

# 9101 Form 4 - Annex A

# **Cause Codes**

	Resources			Manag	gement	Methods		Methods		Human Factors		
Co	de Title	Definition	Code	Title	Definition	Code	Title	Definition	Code	Title	Definition	
R	Inadequate people capability.	Appropriate education, training or experience was not adequately determined, or competent people were not available.	MG1	Lack of training provision.	Identified training and competency requirements were not adequately deployed and/or sustained to meet the ongoing needs of the organization.	ME1	Lack of operational planning and control.	The organization did not adequately deploy planning and control activities to ensure that operational tasks were conducted in accordance with requirements.	HF1	Lack of attention or concentration.	A state of being unfocused or uninterested in the task.	
R	Inadequate operating infrastructure.	Operating infrastructure such as utilities, information technology, buildings, transportation was not adequate to support operational requirements.	MG2	Unclear roles and responsibilities.	Authorities, responsibilities or duties lacked clarity or were not fully understood. As a result operational tasks and related authorities/approvals were improperly assigned.	ME2	Inadequate documented information.	Documented information did not clearly describe the applicable requirements for the process, product or service.	HF2	Pressure and stress.	A state of being overloaded or pressurised by urgent and changing or conflicting demands. A lack of time or resource to perform the task.	
R	E3 Inadequate operating environment.	Operating environment elements such as temperature, humidity, lighting, noise and cleanliness were not adequate to support operational requirements.	MG3	Inadequate organizational governance.	The organization did not determine or implement sufficient arrangements to ensure continued application and effectiveness of the QMS and its processes.	ME3	Inadequate control of documented information.	Documented information was not adequately maintained, retained or made available to demonstrate effective control.	HF3	Distraction.	A state caused by being disturbed or side-tracked by other people or by any other disruption in the workplace.	
R	_4 Inadequate provision of equipment.	Equipment was not capable of meeting and sustaining operational requirements, or was not adequately controlled or available.	MG4	Inadequate communication.	Key information was not adequately communicated within the organization within a timeframe that makes the information relevant and allows for feedback as required.		Inadequate verification or validation of process, product or service.	Verification / validation activities were not conducted in accordance with the stated requirements.	HF4	Fatigue.	A state caused by being physically and / or mentally tired as a result of workplace ergonomics, workload, working hours, personal situations etc.	

# 9.5 Enclosure Form 5: Stage 2 Audit Report

This document is: (1) Filling aid for auditors, (2) Form for audit documentation, (3) Checklist for veto reviewer, (4) Knowledge pool for CBs

IAQG		9101	Form 5:	Audi	t Re	port	
<sup>3</sup> Audit Type  Check audit type (for Special Audit enter the reason i.e. "Remote Audit" => see Instuctions / also check entry in Audit Details and Audit Calculation)		ay, of all sites! erican style!	Last audit	End Dat day of the dit! r remote)		<sup>5</sup> On-Site Audit Days  Total days across all sites (with dot (1.0)! (instead of comma (1,0))  Do not enter Remote Audit Days (if 100% Remote => enter 0.0)	
<sup>6</sup> <b>Report Number</b> (automatically) Check CB's audit no	umber						<sup>7</sup> Report Date  Last audit date (max. 14 days afterwards! For DEKRA max. 5 days afterwards!)
<sup>8 &amp; 36</sup> Organization Site &	OASIS Dat	:a					
Import all related sites, also non- audited sites! For non-audited sites, enter "No" at "Audited". (Automatically for Single Site)	Number of Employees: check If different from the audit contract, inform immediately!  Auditor Days: check			ı CB	<b>N/A</b> - SR - if	plemental Report No.: if no SR was created! a site has been audited by the	
	Audited:	check					
<sup>9</sup> Contact Details							
Representative: Import active ones only - edit if necessary						nistrator: nes only - edit if necessary	
<sup>10</sup> Certification Structure check - for Multiple Sites only (category <u>1</u> or 2)	<sup>11</sup> ASRP check (No)	12 CAAT check (No)	, ,				14 Expiration Date: Enter the expiry date of the existing certificate. For Initial audit => empty
Audit Team	1	ı	I	ı			•

<sup>15</sup> Audit Team Leader	<sup>16</sup> Audit Team Members
Select	Select (do not select Team Leader again)

# <sup>17</sup> Observers/Translators/Technical Experts

Name and function of AB/OP/CB Witness Assessors, Technical Experts, Translators etc. Must be consistent with audit plan! **N/A** - if no other persons accompany the audit.

#### **Audit Criterion**

<sup>18</sup> AC	QMS Standard/Revision	<sup>19</sup> Integrated Audit Yes - only for combined audits of 9100 and 9110 or/and 9120! Otherwise =>
CHECK		No! (OASIS shows only "Y" o "N")

### <sup>20</sup> QMS Documented Information (e.g., Quality Manual):

Reference to QMM (or documents required according to 4.4.2), including revision status / date.

### QMM xxx, Revision xx / from xx.xx.202x

If not included in QMM:

Process landscape, revision xx / from xx.xx.202x

Organization chart, revision xx / of xx.xx.202x

#### **Audit Details**

### <sup>21</sup> Audit Objectives

Copy audit objectives from the audit plan. If no NCRs were created in the previous year, delete point e). If it is not a subarea certification, delete within point a) the passage in brackets!

- a) Verification of the conformity of the management system (or the 9100 relevant parts of the management system) with the audit criteria (standard and QMH).
- b) Assessment of the ability of the QMS to ensure compliance with legal, regulatory, customer and contractual requirements.
- c) Assessment of the effectiveness of the QMS in relation to the achievement of its defined objectives.
- d) Identification of improvement opportunities.
- e) Verification of corrective actions for non-conformities from the previous audit (extra time)

### <sup>22</sup> Audit Scope

At least enter the overall Certificate Scope (compare audit contract and OASIS, as well as certificate) - not the individual site scopes!

Document changes to the scope (between St.1 + St.2) in Box 37 and 39!

The scope must be in English, but should also be entered in national language!

In the case of sub-area certification, the Business Subsection Aerospace: Organization Subsection Aviation, Spa	is must be clearly recognisable in the ce ace, and Defence:	rtificate scope, e	g:				
<sup>23</sup> Requirements Determine	d as 'Not Applicable' (Clause	Number(s))	Select according	ly.			
	licability of the chapter on development nat the following two conditions are met	•	other part of the	standar	d, the au	uditors must be p	provided with
Shop) and Interested parties have	<b>blied</b> since Work/production is only ca no expectations/requirements to fulfil all <b>not affect the ability or</b> obligation <b>of</b>	I the requirement	nts of EN9100 8	3.3 <b>; and</b>	•	J	•
Only if this can be demonstrated shoul	ld an auditor accept non-applicability.						
This applies to virtually every potential	I case of "non-applicability" and must be	documented as	justification.				
	ustomer manual - it <u>must address t</u> a comment must then be entered in St.2 , enter "N/A".			wise is	sue <mark>NC</mark>	R against cha	pter 4.3!
	M of the company (required	by 9100 4.3)	is compreh	ensibl	e and	matches rea	ality:
Nonconformity (issued du	ring the audit)						
<sup>24</sup> Total Number of Nonconfo	ormities	<sup>25</sup> Major No	onconformit	ies	<sup>26</sup> Mi	nor Nonconf	formities
CHECK		CHECK			CHECK		
Process Effectiveness Asse	essment Reports (PEARs) (is:	sued during	this audit)				
<sup>27</sup> Total Number of PEARs check	Process Effectiveness Level Results:	<sup>28</sup> Level 1 check	<sup>28</sup> Level 2 check	<sup>28</sup> Le <sup>x</sup>	vel 3	<sup>28</sup> Level 4 check	<sup>28</sup> Level 5 check
Report Issue							
<sup>29</sup> <b>Report Distribution</b> Enter the names of persons who shoul If the report is not sent to agreed persons	d receive a copy of the report, e.g. custoons, then enter "N/A".	omer, trainee, co	nsultant, witness	assesso	r.		
Audit Conclusions							
<sup>30</sup> Audit Summary							
						_	

Enter a summary of the audit results including, comments (as applicable) related to:
The effectiveness of the QMS and the organization's approach to continual improvement.
The capability of the QMS to meet applicable requirements and expected outcomes.

• Deviation from the audit plan and their reasons.

• Significant issues impacting on the audit program.

• Unresolved issues, if identified.

• Appropriate use of the certification documents and marks, if applicable.

• Effectiveness of the internal audit and management review processes.

• Conclusion on the appropriateness of the certification scope.

• Confirmation that the audit objectives have been fulfilled.

In addition (if applicable):

- statement on Trainee, Witness or Consultant

- statement to Boeing Report Card.

- statement on OASIS feedback (received via CB)

- statement on NCRs

- Participants of the final meeting - enter name/position <u>or</u> reference to list of participants + upload the list to the audit plan in OASIS!

The summary must be in English, but can also be entered in local language!

### If applicable:

### - Remote Audi

=> Due to travel restrictions and Corona protection for Customer, Auditors and surounding human beings during travel and visit, the audit must be executed completely via web sessions.

=> The Customer has agreed to facilitate the Remote Audit.

=> The Customer provided xxxx (e.g. Zoom, TEAMS, WebEx, GTM,...) sessions for the/each Auditor

=> up to xx independent sessions where held parallel acc. to the Auditplan.

(only DEKRA)

**Participants of Audit Closure Meeting:** 

- Name/Position

- ...

- Name, DEKRA Lead-Auditor

## <sup>31</sup> Key Issues/Concerns Requiring Top Management Attention

e.g.: In case of major NCR or ineffective process.

Otherwise N/A.

### N/A

(In case of Ma NCR)

The proper handling of Major NCR XX in accordance with the corrective action process should lead to a general strengthening of the QMS, so management should pay attention to this.

(In case of process weakness)

The efficient organisation of Process XXX should lead to a general strengthening of the QMS, therefore, the management should pay attention to this.

### <sup>32</sup> Strengths and Good Practices

Something should be entered (N/A is possible, but exception!)

(if applicable - examples)

- Technically and socially very competent management team
- Close customer contact through CEO
- Customer focus has a very high priority
- Motivated, flexible employees with quality awareness
- Good working atmosphere
- Order and cleanliness at a good level
- State of the art machinery
- Very well trained employees in the aerospace sector
- Q-Wiki Software involves all employees in the further development of the QMS
- strong KPI system with good visualization

### <sup>33</sup> Opportunities for Improvement

If the basic requirement of the standard is implemented, but the potential for improvement of the QMS in terms of effectiveness and efficiency is identified, a recommendation (OFI) can be issued.

Hidden non-conformities are not permitted!

A reference to standard / process / department would be desirable.

The improvement potential itself should not contain any concrete statements on how it can be implemented.

For example, "In process B, test step B must take the following tests/etc. into account" would not be permissible.

N/A is possible.

#### N/A

Example:

OFI#\_Chap#: The basic requirements of EN9100, Chapter xxxx are fulfilled, but in process XY it should be checked whether test step B could be changed in order to shorten the processing time".

<sup>34</sup> Previous Audit Nonconformity Status					
NCRs Issued (during last audit)  NCRs Closed  NCRs Open					
Enter number	Enter number				
	NCRs Closed				

### <sup>35</sup> Verification of Effectiveness of Corrective Action(s) Taken:

Provide a summary on the verification of the effectiveness of the corrective actions taken for any deficiencies identified during the previous audit. If not applicable, enter "N/A".

(Without previous NCRs)

#### N/A

(With previous NCRs + follow-up audit)

All corrective actions for the NCRs have already been checked for effectiveness, assessed and accepted at DD.MM.YYYY, on site in a follow-up audit.

(With previous NCRs, no follow-up audit)

All corrective actions to the NCRs were already checked, assessed and approved for effectiveness after the last audit.

The NCRs/corrective actions were checked again as part of this audit.

For NCR / Chapter / QMS Matrix Process / Finding:

- NCR #mi\_ma / #.#.# / Process name / Finding
- NCR 2mi / 7.2 / Mgt-Pz / effectiveness of training

no identical or similar non-conformance was found in the sample.

Conformity to the standard was verified in this respect and the NCRs were found to be "effectively closed".

### <sup>37</sup> Changes to Organization / Facilities / Quality Management System / Scope (since last visit)

Information on significant changes since the last visit (e.g. major changes in the organization and/or facilities, changes in the QMS / process structure, changes in the scope of certification, also changes between St.1 and St.2, e.g. scope or N/A clauses, changes in the level of QMS integration) (add more lines if necessary)

Reference Number	Dilei Description	~	9100 / 9110 / 9120 Clause Reference(s)

<sup>38</sup> Agreed Follow-up Arrangements

Entry required, N/A not possible!

(without NCRs)

No further action from this audit.

- If less than 100% of the calculated audit time was audited during the remote audit,
- a) state the remaining audit time in days and indicate the additional audit time in the follow-up audit
- b) list postponed audit activities (possibly with audit duration)
- c) give reasons why the postponement is necessary ("covid19" or similar is not sufficient!)
- d) Additionally list the open audit topics postponed to the next year with audit duration in the current audit plan at the end.

Remote audit, 100% of the calculated audit time audited - no audit time for follow-up audit.

The next audit is planned on \_\_\_\_\_.2021.

(with NCRs)

The actions to the NCRs must be defined, planned and communicated to the auditor within the agreed time frame.

(Confirmation of the implemented immediate actions within 7 days after issue.

Feedback of the planned actions within 30 days after the last onsite audit day and accordingly to be signed in form 4 NCR, Box 28 by audited organization and Box 29 by auditor).

The completion of the actions and/or restoration of conformity to the standard, and corresponding entries in form 4 NCR, Box 22 and 27 by the audited organization and Box 31 and 32 by the auditor must be made within the specified period (at the latest 60 days after issue).

(if necessary) Date for follow-up audit: DD.MM.YYYY

(if necessary) Additional time for next audit for verification of NCRs: xx h

- If less than 100% of the calculated audit time was audited during the remote audit,
- a) state the remaining audit time in days and indicate the additional audit time in the follow-up audit
- b) list postponed audit activities (possibly with audit duration)

c) give reasons why the postponement is necessary ("cov	id19" or similar is not sufficient!)			
d) Additionally list the open audit topics postponed to the next year with audit duration in the current audit plan				
at the end.				
Remote audit, 100% of the calculated audit time audited	- no audit time for follow-up audit.			
The next audit is planned on2021.				
The lead auditor has already acted as lead in 2 cycles, therefore another auditor	must take the lead in the next audit.			
An offer for the recertification audit will be made after completion of the audit. re-certification.	The assignment must be made in a timely manner so as not to jeopardize the			
The revision of ISO9001 (20xx) or EN9100 (20xx) should be taken into account at an early stage in order to evaluate and implement any changes required in the QMS and to contact the certification body regarding transition audit. Currently, audits according to EN9100-20xx to TT.MM.YYYY are permitted.				
<sup>39</sup> Audit Team Leader Recommends				
Select accordingly. For Surveillance or Recert with Special Audit also select record For special audits, the certification recommendation can refer to an existing or recommendation.	•			
Based on the Stage 2 audit result:				
☐ Initial certification (subject to closure of all NCRs if applicable)				
☐ Initial certification not recommended				
Based on the Surveillance audit result:				
☐ Continued certification (subject to re-establishment of conformance for asso	ociated NCRs if applicable)			
Based on the Recertification audit result:				
☐ Recertification (subject to closure of all NCRs if applicable)				
Based on the Special audit result:				
☐ Continued certification of existing scope (subject to re-establishment of continued certification of existing scope (subject to re-establishment of continued certification of existing scope (subject to re-establishment of continued certification of existing scope (subject to re-establishment of continued certification of existing scope (subject to re-establishment of continued certification of existing scope (subject to re-establishment of continued certification of existing scope (subject to re-establishment of continued certification of existing scope (subject to re-establishment of continued certification of existing scope (subject to re-establishment of continued certification of existing scope (subject to re-establishment of continued certification of existing scope (subject to re-establishment of continued certification of existing scope (subject to re-establishment of certification of existing scope (subject to re-establishment of certification of existing scope (subject to re-establishment of existing scope (subject to re-establishm	formance for associated NCRs if applicable)			
☐ Certification of revised scope (subject to closure of all NCRs if applicable) => select only if Scope Text in Box 22 has been changed!				
☐ Transfer of certification (subject to closure of all NCRs if applicable)				
Based on any audit result:				
□ Suspension of Certification				
☐ Withdrawal of Certification				
Organization Confirmation				
40 Organization Confirmation	<sup>41</sup> Audit Team Leader Approval			

Select/import accordingly - should be the same person as in box 9! Last audit	Select/import accordingly.		
date (max 14 days afterwards!)	Last audit date (max 14 days afterwards!		
	Add comment if a later date is entered due to subsequent corrections by the auditor.  (For DEKRA max. 5 days afterwards!)		
Disclaimer Statement: This audit was conducted based on a sampling process of the available information.			

The respective OASIS Form Instructions are guidelines for the content of the boxes!

OASIS Instructions for Form 5

https://www.iagg.org/exdomains/oasis/elements/docs/9101-form-5-reference.pdf?20180507

NOTE: The completeness of this Form may be supplemented by the use of attachments to provide further detailed

information. When attachments are provided, the respective box on the Form should describe the information in

summary format and then refer to the respective attachment - it is not permissible to simply say "see attached".

The CBMC Germany generally does not want any empty boxes (at least fill in "N/A" where possible/sensible)!

CBMC Germany Checkliste for 9101 Form 1 - 6

https://www.bdli.de/sites/default/files/global\_upload\_upload/190405%20-%20General%20Checklist%20-%20Quality%20of%20OASIS%20Audit%20documentation%20-%20prefinal\_v02\_0.pdf

Legend:

**Text in red** = requirement and/or information on the form boxes

Text in blue = Default for the content of the form boxes - Attention: This has to be adapted to the situation!

Text in magenta = Alternatives, which must be considered situation-related in each case and adapted or deleted accordingly!

# 9.6 Enclosure Form 6: Supplemental Audit Report

This document is: (1) Filling aid for auditors, (2) Form for audit documentation, (3) Checklist for veto reviewer, (4) Knowledge pool for CBs

IAQG	AQG 9101 Form 6: Supplemental Audit Report							
<sup>3</sup> Audit Type  Check audit type (site specific!) (for Special Audit enter the rea => see Instuctions / also check entry in Audit Details and Audi Calculation)	(Date in Amo => MM/DD/	erican style!	<sup>4</sup> Audit Site speci	End Dat	:e	<sup>5</sup> On-Site Audit Day Site specific! (with dot (1.0)! (instead of comma (1,0))	ys	
<sup>6</sup> <b>Report Number</b> Check CB's audit number. If se to a location and enter it in the			ed, amend nur	nber so that	t each	n report can be clearly assign	ned	<sup>7</sup> Report Date Last site audit date (max. 14 days afterwards!) (For DEKRA max. 5 days afterwards!) Not later than Form 5!
<sup>8 &amp; 28</sup> Organization Site	e & OASIS Dat	ta						
Only relevant Site!  (More than 1 Site is possible, if audited by the same AEA)	different fro	of Employee m the audit con						
		Auditor Days: check Audited: check						
<sup>9</sup> Contact Details								
Representative:  Import active ones only - edit if necessary					inistrator:	/		
<sup>10</sup> <b>Certification Structu</b> check - for Multiple Sites only (category <u>1</u> or 2)		check	Category check (empty)					
Audit Team	<b>1</b>							
<sup>13</sup> Audit Team Leader			<sup>14</sup> Audit Te	eam Mer	mbe	ers		

Select team leader of the entire audit  Select only sit		ite-specific audit	te-specific auditors					
<sup>15</sup> <b>Observers/Translators/Te</b> Name and function of AB/OP/CB Without N/A - if no other persons accompany to	ess Assessors, Technical Experts, Transl	ators etc. Must b	e consistent with	ı audit pla	an!			
Audit Criterion								
<sup>16</sup> AQMS Standard/Revision check	17 Integrated Audit Yes - only for combined audits of 9100 and 9110 or/and 9120! Otherwise => No! (OASIS shows only "Y" o "N")							
Audit Details								
Document changes to the scope (betw	Scope (compare audit contract and OA een St.1 + St.2) in Box 37! Ild also be entered in national language		rtificate)!					
Nonconformity (issued du	ring the audit)							
<sup>19</sup> Total Number of Nonconformities Only the <u>site-specific!</u>		<sup>20</sup> Major Nonconformities			<sup>21</sup> Minor Nonconformities check			
Process Effectiveness Asse	ssment Reports (PEARs) (is	sued during	g this audit)					
<sup>22</sup> Total Number of PEARs Only the <u>site-specific</u> !	Process Effectiveness Level Results:	<sup>23</sup> Level 1 check	<sup>23</sup> Level 2 check	<sup>23</sup> Lev	el 3	<sup>23</sup> Level 4 check	<sup>23</sup> Level 5 check	
Audit Conclusions								
<sup>24</sup> Audit Summary								

Enter a summary of the audit results including, comments (as applicable) related to:

- The effectiveness of the QMS and the organization's approach to continual improvement.
- The capability of the QMS to meet applicable requirements and expected outcomes.
- Deviation from the audit plan and their reasons.
- Significant issues impacting on the audit program.

- Unresolved issues, if identified.
- Appropriate use of the certification documents and marks, if applicable.
- Effectiveness of the internal audit and management review processes.
- Conclusion on the appropriateness of the certification scope.
- Confirmation that the audit objectives have been fulfilled.

In addition (if applicable):

- statement on Trainee, Witness or Consultant
- statement to Boeing Report Card.
- statement on OASIS feedback (received via CB)
- statement on NCRs
- Participants of the final meeting enter name/position <u>or</u> reference to list of participants + upload the list to the audit plan in OASIS!

The summary must be in English, but can also be entered in local language!

- Remote Audit

=> Due to travel restrictions and Corona protection for Customer, Auditors and surounding human beings during travel and visit, the audit must be executed completely via web sessions.

=> The Customer has agreed to facilitate the Remote Audit.

=> The Customer provided xxxx (e.g. Zoom, TEAMS, WebEx, GTM,...) sessions for the/each Auditor

=> up to xx independent sessions where held parallel acc. to the Auditplan.

(only DEKRA)

**Participants of Audit Closure Meeting:** 

- Name/Position

- ...

- Name, DEKRA Lead-Auditor

### <sup>25</sup> Key Issues/Concerns Requiring Top Management Attention

In case of major NCR or ineffective process. Otherwise N/A.

N/A

(In case of Ma NCR)

The proper handling of Major NCR XX in accordance with the corrective action process should lead to a general strengthening of the QMS, so management should pay attention to this.

(In case of process weakness)

The efficient organisation of Process XXX should lead to a general strengthening of the QMS, therefore, the management should pay attention to this.

### <sup>26</sup> Strengths and Good Practices (site specific)

Something should be entered (N/A is possible, but exception!)

(if applicable - examples)

- Technically and socially very competent management team
- Close customer contact through CEO
- Customer focus has a very high priority
- Motivated, flexible employees with quality awareness
- Good working atmosphere
- Order and cleanliness at a good level
- State of the art machinery
- Very well trained employees in the aerospace sector
- Q-Wiki Software involves all employees in the further development of the QMS
- strong KPI system with good visualization

### <sup>27</sup> Opportunities for Improvement (site specific)

If the basic requirement of the standard is implemented, but the potential for improvement of the QMS in terms of effectiveness and efficiency is identified, a recommendation (OFI) can be issued.

Hidden non-conformities are not permitted!

A reference to standard / process / department would be desirable.

The improvement potential itself should not contain any concrete statements on how it can be implemented.

For example, "In process B, test step B must take the following tests/etc. into account" would not be permissible.

N/A is possible.

#### N/A

Example:

OFI#\_Chap#: The basic requirements of EN9100, Chapter xxxx are fulfilled, but in process XY it should be checked whether test step B could be changed in order to shorten the processing time".

### <sup>29</sup> Changes to Organization / Facilities / Quality Management System / Scope (since last visit)

Site specific information on significant changes since the last visit (e.g. major changes in the organization and/or facilities, changes in the QMS / process structure, changes in the scope of certification, also changes between St.1 and St.2, e.g. scope or N/A clauses, changes in the level of QMS integration) (add more lines if necessary)

Reference Number	Brief Description	~	9100 / 9110 / 9120 Clause Reference(s)

Organization Confirmation					
<sup>30</sup> Organization Confirmation	<sup>31</sup> Audit Team Leader Approval				
Select/import accordingly - should be the same person as in box 9! Last audit date (max 14 days afterwards!)	Select/import accordingly. Last audit date (max 14 days afterwards!)				
Disclaimer Statement: This audit was conducted based on	a sampling process of the available information.				

The respective OASIS Form Instructions are guidelines for the content of the boxes!

OASIS Instructions for Form 6

https://www.iagg.org/exdomains/oasis/elements/docs/9101-form-6-reference.pdf?20180507

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CBMC Germany Checkliste for 9101 Form 1 - 6

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