

# CHECKLIST

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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")

### **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)*

## 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:**

Process Realization (a)		Process Results (b)		
Planned activities fully realized	a. The process is determined, and planned activities fully realized; however, b. The planned results are not achieved	Major or minor NC, no KPI's defined or no activities taken	No NC's and KPI's not fulfilled, but activities taken	No NC's and KPI's fulfilled
Planned activities not fully realized	a. The process is determined, but planned activities not fully realized; and b. The process is not delivering the planned results	must Major or minor NC	Major or minor NC must, not all KPI's fulfilled	Major NC or minor NC must, all KPI's fulfilled
Planned activities not realized	a. The process is not determined, and planned activities not realized; and b. The planned results are not achieved	Major NC should minor NC must	Major NC or minor NC must	Major NC or minor NC must
		Planned results not achieved and appropriate action is not taken	Planned results not achieved, but appropriate action is being taken	Planned results are achieved

**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.

## 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
- Box 21:** Not later than 30 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)
- Box 29:** Should be not later than 30 days after the last audit day –  
acceptance of planned actions
- Box 30:** Enter a summary of the verification activities performed by the  
auditor to confirm corrective action implementation and  
effectiveness of actions taken to prevent recurrence

► **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*

## 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 any Observers/Translators/Technical Experts according to audit plan (if no Observers/Translators/ Technical Experts 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  
**(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
- 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



## 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)

**Box 6:** 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 (site-specific) 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 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

## 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		x	x	x		x	x			x			
Company name										x	x		x
Employees	x		x	x		x	x						
Part certification?										x		x	
EAC Code													
- main													
- additional													
EAC main													
EAC additional													
8.3 not applicable?	x	x		x		x	x	x				x	
Another chapter not applicable		x		x		x	x	x				x	
Numbers of PEAR						x	x		x				
- Level 1						x	x		x				
- Level 2						x	x		x				
- Level 3						x	x		x				
- Level 4						x	x		x				
- Level 5						x	x		x				
Audit time	x	x	x	x		x				x			
Numbers NCR					x	x	x	x					
- MA					x	x	x	x					
- mi					x	x	x	x					
Scope(s)		x		x		x	x (site scope)			x	x	x	x



means Master Document