DEPARTMENT OF DEFENSE
Defense Contract Management Agency

IMMEDIATE POLICY CHANGE

Quality System Audit

Quality Assurance Directorate **DCMA-INST 322 (IPC-1)**
OPR: DCMA-QAA **September 8, 2015**

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1. POLICY. This Immediate Policy Change (IPC) implements changes to DCMA-INST 322, "Quality System Audit," September, 2011.

2. PURPOSE. This IPC is issued to revise Agency policy on the requirements for performing Quality System Audits (QSA) of contractors' Quality Management Systems (QMS). The importance of releasing this IPC is three fold: 1) it closes a gap related to several QSA Mission Review Team (MRT) findings; 2) brings DCMA in line with FAR 52.246-11, "Higher-Level Contract Quality System Requirement;" and 3) positions DCMA Quality Systems for 1.3.1., Detection to Prevention Project and 1.1.3., Supplier Risk System (SRS). This IPC will be reissued in the new DoDI 5025.01, "DoD Issuances Program" format standards at a later date.

3. APPLICABILITY. This IPC applies to all DCMA activities.

4. RESPONSIBILITIES. All DCMA activities are to implement this change immediately.

5. BACKGROUND. This change replaces incremental and partial system audits with an effective risk-based strategy which focuses on the QMS risk causes.

6. NEW GUIDANCE.

a. Add the following new references:

(a) Federal Acquisition Regulation (FAR), Subpart 52.246-11, "Higher-Level Contract Quality Requirement"
(b) DCMA-INST 309, "Government Contract Quality Assurance (GCQA) Surveillance Planning," January 27, 2014
(c) DCMA-INST 326, "Risk Assessment – QA," February 2012
(d) DCMA-INST 323, "Data Collection and Analysis," May 15, 2013
(e) DCMA-INST 207, "Engineering Surveillance," December 8, 2014
(f) DCMA-INST 204, "Manufacturing and Production," August 16, 2012
(g) DCMA-INST 325, "Contract Technical Review," January 23, 2014
(h) FAR 52.246-2 through 52.246.9, "Contractor Inspection Requirements"
(i) DFARS 246.870-2, "Detection and Avoidance of Counterfeit Electronic Parts"

(j) DFARS 252.246-7007, "Contractor Counterfeit Electronic Part Detection and Avoidance System"
(k) DCMA-INST 203, "Software Acquisition Management," June 25, 2013
(l) DCMA-INST 710, "Managers' Internal Control Program," April 21, 2014
(m) DCMA-INST 1201, "Corrective Action Plan" September 23, 2013

b. Change paragraph 1. to read as follows:

1. ~~The System Audit shall be performed using the requirements contained in this instruction which are written with consideration to the general guidelines contained in ISO 19011 Guidelines for quality and/or environment management systems auditing.~~ ***A Quality System Audit (QSA) is a second party audit which focuses on the contractor's QMS compliance with the customer's requirements. A QSA must be performed on any new contractor (supplier) or a contractor receiving a contract with FAR clause 52.246-11, "Higher-level Contract Quality Assurance Requirement" (Reference (a)) for the first time. The QSA will be conducted as soon as possible, but shall not exceed 2 years from the contract receipt date for contracts that have more than a 2-year cycle. The contractors that receive a Higher-level Contract Quality Assurance contract requirement that are less than 2 years from the receipt date, the QSA must be completed prior to the delivery date of the contract.***

c. Change paragraph 1.2. to read as follows:

1.2. ~~A System Audit can be conducted either on the entire QMS or through audits of individual QMS elements. Process reviews also may be conducted in accordance with the Process Review instruction on various processes within the QMS and may be considered as accomplishment of the requirement to audit that portion of the QMS. When multiple QMS processes of the same QMS clause are reviewed (e.g., Purchase Documentation and Verification of Purchased Items are part of ISO 9001, clause 7.4 Purchasing), the System Audit method should be used.~~ ***The QSA is a surveillance method used in the performance of ongoing Government contract quality assurance activities in accordance with (IAW) DCMA-INST 309, "Government Contract Quality Assurance (GCQA) Surveillance Planning" (Reference (b)). Conduct a baseline review of the contractor's documented QMS and implement a risk-based approach for continuing surveillance IAW DCMA-INST 326, "Risk Assessment - QA" (Reference (c)).***

d. Change paragraph 1.3. to read (and add new subparagraphs) as follows:

1.3. ~~The entire QMS shall be reviewed every three years, as stated in the~~ GCQA ~~Surveillance Planning Instruction, unless the results of the risk assessment or customer direction warrants more frequent audits.~~ When the contract contains the requirement for QMS, e.g. FAR 52.246-11, the Risk Statement Generator question for a "Higher-Level ***Contract*** Quality Requirement" will be answered as "yes" and a System Audit shall be identified in the GCQA Surveillance plan. The System Audit shall be performed in accordance with this ~~i~~***I***nstruction. ~~The maximum audit frequency of three years is only applicable to contractors with contracts that have duration of greater than three years or who continuously receive contracts with higher-level quality requirements. This provides for the performance of ongoing GCQA activities which form~~

~~a basis of confidence that supplies and services accepted from the supplier conform to contract requirements.~~ This provides for the performance of ongoing GCQA activities, which form a basis of confidence that supplies and services accepted from the supplier conform to the ***higher-level*** contract ***quality level*** requirements. ~~When a contract is received with a performance duration of less than three years and there are no continuing higher-level quality requirements imposed on the supplier, a System Audit shall be scheduled and conducted commensurate with the likelihood risk rating. QMS or QMS elements with high or moderate likelihood risk ratings shall be prioritized for a System Audit early in contract performance, but under no circumstances should the contract expire prior to the System Audit being performed. DCMA System Audit is considered a second party audit of the QMS and as such is more thorough than what will be accomplished during a third party audit.~~ ***DCMA personnel are required to establish a baseline QSA of the contractor's QMS for adequacy and compliance to established procedures. The baseline QSA is not performed on an incremental schedule. The baseline QSA will be performed IAW an established audit plan, completed prior to contract performance completion date when possible, or based upon customer requirements (i.e., special contract provisions or specifications that require a higher-level QMS). Result(s) from prior audits performed, conducted either by another Government entity or DCMA personnel, maybe utilized to establish the QMS baseline. The QSA baseline for contractors with performance history should include the data sources identified in paragraph 1.3.1., Data Sources. If QSA baseline data is insufficient or does not exist, a QSA baseline will consist of an adequacy review and compliance verification of the QMS paragraphs 1.3.2., Adequacy and 1.3.3., Compliance.***

1.3.1. <u>Data Sources.</u> Review all available data sources and supplier performance history to identify potential risk as identified IAW the requirements of DCMA-INST 323, "Data Collection and Analysis" (Reference (d)). The technical specialist should coordinate with the first level supervisor (FLS) to determine the risk, scope, depth, and duration of the audit. The following should be analyzed:

- ***Supplier Risk System (SRS) data, third party audit deficiencies***
- ***Quality escapes***
- ***Internal audit results***
- ***Product Data Reporting and Evaluation Program (PDREP)***
- ***Government Industry Data Exchange Program (GIDEP)***
- ***National Aerospace and Defense Suppliers Accreditation Program (NADCAP)***
- ***Online Aerospace Supplier Information System (OASIS) Suppliers'***
- ***Operations Directorate Quality Systems Review (QSR)***
- ***Customer systems audit***
- ***Corrective and preventive action and follow-up***
- ***Customer complaints***
- ***Second Party audits***

NOTE: Third party audit certification/audit results may be used to assist in risk rating the QMS and/or elements for surveillance activities.

1.3.2. Adequacy. Review the QMS procedures against the applicable QMS checklist for adequacy as soon as possible, as outlined in paragraph 1. Identify the adequacy review in the GCQA surveillance plan IAW DCMA-INST 309 (Reference (b)). NOTE: QMS checklist templates are located on the Resource Web page.

1.3.3. Compliance. The contractor's QMS must be verified for compliance to some level or scope as part of the baseline review. The audit scope will identify the specific contractor's QMS processes and procedures selected for verification of compliance with requirements. After the baselines have been established, the processes and procedures should be prioritized based upon high or moderate risk likelihood when developing the audit schedule. Low risk processes and procedures should be evaluated when circumstance warrant it necessary. Document the compliance review in the GCQA surveillance plan IAW DCMA-INST 309 (Reference (b)).

1.3.3.1. Initial QSA Documentation. The baseline QSA documentation audit prior to the onsite audit may have a noncompliance or non-adequacy finding(s) to the contract on a process(es) and/or procedure(s), resulting in findings that require a Corrective Action Request (CAR) to be initiated. The onsite QSA can be established after the contractor's corrective action plan (CAP) IAW DCMA-INST 1201 (Reference (m)) is approved or completed. Document the baseline completed date in the GCQA surveillance plan. The QSA results are a data source for data collection and analysis (DC&A) IAW DCMA –INST 323 (Reference (d)).

1.3.4. Risk-Based Strategy. All subsequent QSAs shall incorporate a risk-based strategy to reduce the likelihood of risk cause occurrence and contribute to establishing confidence that the contractor's QMS is capable of meeting contractual requirements. This should be accomplished IAW DCMA-INST 326 (Reference (c)). The performance factors assessment and DC&A should be used to determine the QMS element(s) identified for follow-on surveillance. All QMS elements identified for surveillance shall be risk assessed separately and audited with a frequency and intensity commensurate with the risk IAW DCMA-INST 309 (Reference (b)).

1.3.5. QMS Risk Factors. The tab titled "Perf. Factors Higher Level," on the Risk Profile Tool, shall be used to identify the minimum QMS risk factors to be addressed during the performance factors assessment. The performance factor assessment shall determine the risk causes that contribute to the contractor's QMS performance IAW DCMA-INST 326 (Reference (c)). The risk assessment process should result in a QSA schedule identified in the GCQA surveillance plan. The overall scope of surveillance activity will be based upon the results of the risk assessment and traceable to each applicable risk statement on the risk profile IAW Figure 1, DCMA-INST 309 (Reference (b)).

1.3.6. Risk Consequence. Risk consequence cannot be influenced by GCQA surveillance. However, the scope of the surveillance is influenced by the level of risk consequence.

1.3.7. Risk Likelihood. Risk likelihood determines frequency and intensity of GCQA surveillance activity. Where the likelihood of occurrence is high, surveillance should be performed more frequently until the likelihood of occurrence is reduced to an acceptable level IAW DCMA-INST 326 (Reference (c)).

1.3.8. Surveillance. The surveillance of element(s) should be performed IAW with the requirements in paragraphs 1.3.2., Adequacy and 1.3.3., Compliance. High and Moderate-risk element(s) may require surveillance of only selected systems, processes and products or services. Surveillance should be performed IAW the requirement in paragraph 1.3.1., whereas low-risk likelihood may only require occasional reviews of the contractor's control mechanisms.

1.3.9. Frequencey and Intensity. For surveillance planning, frequency may be expressed in terms of time (e.g., months, quarterly, bi-annual, or annually) or in terms of throughput (the contractor's specific process/procedure/QMS element). Intensity may be expressed in terms such as the entire process/procedures, or specific portion(s), step(s) of the process/procedures/QMS element(s)).

1.3.10. Systemic Failures. When systemic failures of the QMS elements are identified as a result of surveillance activities, a full QSA should be scheduled and a baseline re-established IAW paragraphs. 1.3.2., Adequacy and 1. 3.3., Compliance.

1.3.11. Short Term Contracts. When a contract is received with a performance duration of less than 2 years and there is no continuing higher-level quality requirements imposed on the supplier, a QSA will be performed based upon risk using data from paragraph 1.3.1 ., Data Sources. QMS or QMS elements with high or moderate likelihood risk ratings will be prioritized for a QSA early in contract performance but under no circumstances should the contract expire prior to the QSA being completed.

e. Delete paragraph 1.4.

f. Change paragraph 2. to read as follows:

2. ~~When the entire QMS or a significant portion of the QMS (partial) is to be reviewed, a formal audit team shall be established to conduct the System Audit. When only a single element or a small number of elements is to be reviewed, the assigned QA personnel, if properly qualified, may conduct the audit alone or with a few other QA personnel.~~ The audit team leader or assigned QA personnel ~~(for partial audits) shall~~ ***will*** notify the supplier, in writing of the pending ~~audit~~ ***Quality System*** and scope**.** When a ~~full~~ System Audit is to be conducted, the assigned QA personnel or ***FLS*** ~~QA organization~~ should consider notifying major customers.

g. Change paragraph 2.1. to read (and add subparagraphs) as follows:

2.1. ~~When a team is to perform the System Audit, an audit team lead and audit team members shall be identified by the CMO.~~ ***Roles and Responsibilities:***

2.1.1. CMO COMMANDER/DIRECTOR. The CMO Commander/Director will inform the applicable Region, Operations, International, or Special Program Directorates when a contractor's QMS is determined to be high risk with a consequence on product/services.

2.1.2. QUALITY ASSURANCE DIRECTOR (QAD). The QAD will:

2.1.2.1. Assist FLS with resources to support the CMO auditing requirements.

2.1.2.2. Assist FLS with the determination of risk consequence on product/services including product already delivered to the customer for a contractor with a high risk rated QMS.

2.1.3. FIRST LEVEL SUPERVISOR (FLS). The FLS will:

2.1.3.1. Determine if the QSA will be performed by a team or an independent QA specialist with support from other technical specialists.

2.1.3.2. Assign lead auditor and audit team members to perform the QSA and assure QA personnel and technical specialists supporting the QSA, possess the necessary competencies to perform the tasks defined in this Instruction as it relates to the assigned facility, contract, or product.

2.1.4. LEAD AUDITOR. The lead auditor will assist the FLS with the development of effective methods to determine acceptability, compliance, developing or tailoring quality system checklists, scheduling, scope, conducts, and finalize reports in support of the QSA.

2.1.5. DCMA CMO TECHNICAL SPECIALISTS/QA PERSONNEL. The DCMA CMO technical specialist/QA personnel will serve as audit team members, lead auditors, or sole auditors who, when assigned by the FLS, will:

2.1.5.1. Comply with this Instruction when performing the QSA. Quality assurance specialist(s) (1910), engineer(s) (08XX), software (2210), manufacturing and production (0896), industrial specialist(s) (1150), contract safety specialist(s) (0018), and supply chain (2003) personnel will audit the QMS elements related to the skill sets required for the specific functional area.

2.1.5.2. Ensure engineering surveillance is conducted IAW DCMA-INST 207, "Engineering Surveillance" (Reference (e)) and manufacturing and production surveillance is conducted IAW DCMA-INST 204, "Manufacturing and Production" (Reference (f)).

2.1.6. THEATER TECHNICAL DIRECTOR (TTD). The TTD or designee, will serve as the team lead and if necessary, identify personnel who will participate in the audit(s) during Contingency Contract Administration Services (CCAS) operations.

h. Change paragraph 2.3. to read as follows:

2.3. The ***QSA*** audit team leader ~~or assigned QA personnel (for partial audits) shall~~ ***will*** prepare an audit plan defining the conduct of the audit. The plan should facilitate scheduling and coordination of the audit activities. The audit team leader ~~or assigned QA personnel (for partial audits) shall~~ ***will*** coordinate the plan with the ~~supplier~~ ***contractor.*** The amount of detail provided in the audit plan should reflect the scope and complexity of the audit. The audit plan should be sufficiently flexible to permit changes, such as changes in the audit scope, which can become necessary as the on-site audit activities progress. The audit plan should cover the following, as appropriate:

- The audit objectives
- The contract number(s) containing the higher-level Quality Requirement (FAR 52.246-11) and cited quality standard(s)
- The audit criteria and any supplier's reference documents
- The audit scope, including identification of the organizational and functional units and processes to be audited
- The dates and places where the on-site audit activities are to be conducted
- The expected time and duration of on-site audit activities
- The roles and responsibilities of the audit team members and accompanying persons (may not be necessary for partial audits)
- The allocation of appropriate resources to critical areas of the audit (may not be necessary for partial audits)
- Identification of the supplier's representative for the audit (may not be necessary for partial audits)
- Logistic arrangements (program, product, on-site facilities, safety, personal protective equipment, etc.)
- Matters related to confidentiality
- Any audit follow-up actions

i. Add new paragraph 2.3.1. and subparagraphs as follows:

2.3.1. Audit Planning. Audit planning begins during the contract technical review (CTR) process accomplished IAW DCMA-INST 325, "Contract Technical Review" (Reference (g)). During the performance of CTR, special attention must be given to the identification of the following contractual requirements:

2.3.1.1. FAR clause 52.246-11, "Higher-Level Contract Quality Assurance Requirement" (Reference (a)) with a higher-level QMS standard or specific QMS specification, clauses/element imposed.

2.3.1.2. FAR 52.246-2 through 52.246-9, "Contractor Inspection Requirements" (Reference (h)) which contains special contract provisions, statement of work, or specifications that require a higher-level QMS, shall submit a Contract Deficiency Report (CDR) for clarification.

2.3.1.3. DFARS 246.870–2, "Detection and Avoidance of Counterfeit Electronic Parts" (Reference (i)) and DFARS 252.246-7007, "Contractor Counterfeit Electronic Part Detection and Avoidance System" (Reference (j)).

2.3.1.4. Contractors with software products. A determination should be made on the location of the place of performance prior to acceptance of the end item or system. If the software is embedded in the end item or system, inspection and/or acceptance of the software element of the system shall be coordinated with Software Professional Development Program (SPDP) certified personnel. Personnel who are SPDP certified shall audit the software IAW DCMA- INST 203, "Software Acquisition Management" (Reference (k)).

i. Add new paragraph 12. and subparagraphs as follows:

12. <u>National Aeronautics and Space Administration (NASA).</u> NASA refers to a QSA as Quality System Evaluation (QSE). The following process shall be executed on all active NASA contracts IAW the NASA delegation. When NASA does not provide specific requirements per a Letter of Delegation (LOD) for their specific contracts, the QSA/QAE team will follow the following instructions:

12.1. Technical specialists must evaluate the contractors' quality system to ensure compliance with contractually imposed quality program requirements including internally developed procedures and delegated requirements. QSA/QSE may be conducted as a single audit or as a combination of discrete audits.

12.2. The QSA/QSE frequency must be based on the contractor's quality history but no less than once every 3 years. Requests to perform audits out-of-cycle or when not delegated, must be supported by a risk determination and/or DC&A results and approved by the NASA delegator. QSA/QSEs may be extended in periodicity, exempted, or limited in scope for circumstances when one of the following conditions exists, with the approval of NASA LOD POC:

12.2.1. The contractor is certified by an accredited SAE AS9100 certification body or the contractors' quality system has been formally evaluated and accepted by another Government agency.

12.2.2. Government surveillance (e.g., Government mandatory inspection points (GMIP), process witnessing)) data where available, indicates satisfactory levels of compliance.

12.2.3. Quality data and other risk factors (e.g., product/process maturity, AS9100 certification audit results, and facility relocation) indicate acceptable risk.

12.2.4. Product delivery data, where available, indicates the contractor has a history of delivering product that meets quality requirements. Contractor quality data can be obtained via the NASA Supplier Assessment System (SAS) located at http://sas.nasa.gov/.

l. Add new paragraph 13. as follows:

13. MANAGERS' INTERNAL CONTROL PROGRAM. In accordance with DCMA-INST 710, "Managers' Internal Control Program" (MICP) (Reference (l)), this Instruction is subject to evaluation and testing. The process flowcharts and key controls are located on the Resource Web page.

7. RELEASABILITY – UNLIMITED. This IPC is approved for public release.

8. EFFECTIVE DATE. This IPC is effective immediately and will remain in effect until superseded, or incorporated in a DCMA policy, whichever is sooner.

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Executive Director
Quality Assurance

Quality System Audit

Revised: September 2011
Next Review: September 2012

Intent/Outcome/Purpose

To provide the requirements for performing effective System Audits of supplier Quality Management Systems (QMS) including principles of auditing, planning, execution, and follow-up.

Process

1. **The System Audit shall be performed using the requirements contained in this instruction which are written with consideration to the general guidelines contained in ISO 19011 Guidelines for quality and/or environment management systems auditing.**

1.1. **System Audits shall be conducted on the QMS standard identified in existing contracts or letters of delegation (LOD).** When a supplier has adopted a QMS standard different than specified in the contract, the supplier may be audited to the adopted standard, but can only be contractually held accountable to the requirement specified in the contract.

1.2. A System Audit can be conducted either on the entire QMS or through audits of individual QMS elements. Process reviews also may be conducted in accordance with the Process Review instruction on various processes within the QMS and may be considered as accomplishment of the requirement to audit that portion of the QMS. When multiple QMS processes of the same QMS clause are reviewed (e.g., Purchase Documentation and Verification of Purchased Items are part of ISO 9001, clause 7.4 Purchasing), the System Audit method should be used.

1.3. **The entire QMS shall be reviewed every three years, as stated in the GCQA Surveillance Planning Instruction, unless the results of the risk assessment or customer direction warrants more frequent audits. When the contract contains the requirement for QMS, e.g. FAR 52.246-11, the Risk Statement Generator question for a "Higher Level Quality Requirement" shall be answered as "yes" and a System Audit shall be identified in the GCQA Surveillance plan. The System Audit shall be performed in accordance with this instruction.** The maximum audit frequency of three years is only applicable to suppliers with contracts that have duration of greater than three years or who continuously receive contracts with higher-level quality requirements. This provides for the performance of ongoing GCQA activities which form a basis of confidence that supplies and services accepted from the supplier conform to contract requirements. **When a contract is received with a performance duration of less than three years and there are no continuing higher-level quality requirements imposed on the supplier, a System Audit shall be scheduled and conducted commensurate with the likelihood risk rating. QMS or QMS elements with high or moderate likelihood risk ratings shall be prioritized for a System Audit early in contract performance, but under no circumstances should the contract expire prior to the System Audit being performed.** DCMA System Audit is considered a second party audit of the QMS and as such is more thorough than what will be accomplished during a third party audit.

1.4. If an Operations Directorate Quality Systems Review (QSR) or a customer systems audit is accomplished on the supplier's Quality Management System, the extent to which the system is audited and confidence in the conformity of the system is established may be used to satisfy all or some of the requirements of paragraph 1.2 and 1.3. Records of audits performed by Operations or Customer representatives that are used for this purpose shall be maintained by the assigned quality assurance personnel.

2. **When the entire QMS or a significant portion of the QMS (partial) is to be reviewed, a formal audit team shall be established to conduct the System Audit.** When only a single element or a small number of elements is to be reviewed, the assigned QA personnel, if properly qualified, may conduct the audit alone or with a few other QA personnel. **The audit team leader or assigned QA personnel (for partial audits) shall notify the supplier, in writing of the pending audit and scope.** When a full System Audit is to be conducted, the assigned QA personnel or QA organization should consider notifying major customers.

2.1. **When a team is to perform the System Audit, an audit team lead and audit team members shall be identified by the CMO.**

2.2. The team composition should include the appropriate functional specialists as necessary to assure the adequate skills for the scope of the supplier's operation, type and complexity of the weapons system or space based systems produced. Members can include other disciplines, such as Software Specialists and Engineers, as needed. The audit team leader is responsible to ensure the team has all the needed competencies to achieve audit objectives.

2.3. **The audit team leader or assigned QA personnel (for partial audits) shall prepare an audit plan defining the conduct of the audit.** The plan should facilitate scheduling and coordination of the audit activities. **The audit team leader or assigned QA personnel (for partial audits) shall coordinate the plan with the supplier.** The amount of detail provided in the audit plan should reflect the scope and complexity of the audit. The audit plan should be sufficiently flexible to permit changes,

such as changes in the audit scope, which can become necessary as the on-site audit activities progress. The audit plan should cover the following, as appropriate:

· The audit objectives

· The contract number(s) containing the higher-level Quality Requirement (FAR 52.246-11) and cited quality standard(s)

· The audit criteria and any supplier's reference documents

· The audit scope, including identification of the organizational and functional units and processes to be audited

· The dates and places where the on-site audit activities are to be conducted

· The expected time and duration of on-site audit activities

· The roles and responsibilities of the audit team members and accompanying persons (may not be necessary for partial audits)

· The allocation of appropriate resources to critical areas of the audit (may not be necessary for partial audits)

· Identification of the supplier's representative for the audit (may not be necessary for partial audits)

· Logistic arrangements (program, product, on-site facilities, safety, personal protective equipment, etc.)

· Matters related to confidentiality

· Any audit follow-up actions

2.4 After the audit plan has been coordinated with the supplier, any audit plan revisions should be discussed with the supplier before continuing the audit.

3. The audit team leader, in consultation with the audit team, should assign each team member specific processes, functions, sites, areas or activities to be audited. Such assignments should take into account the experience and background of the auditors, the effective use of resources, and the different roles and responsibilities of auditors, auditors-in-training and technical experts. Changes to the work assignments may be made as the audit progresses to ensure the achievement of the audit objectives.

4. The audit team members should review the information relevant to their audit assignments and prepare work documents as necessary for reference and for recording audit proceedings. Such work documents may include:

- Checklists
- Audit sampling plans
- Forms for recording information, such as supporting evidence, audit findings and records of meetings

4.1. The use of checklists and forms should not restrict the extent of audit activities, which can change as a result of information collected during the audit. However, the audit checklist shall be appropriate for and shall not exceed the contractual requirements.

4.2. Work documents, including records resulting from their use, should be retained at least until audit completion. **Those documents involving confidential or proprietary information shall be suitably marked and safeguarded at all times by the audit team members.**

5. **Regardless of the scope of the System Audit (full or partial), an opening meeting shall be held with the audit members and the supplier's management or, where appropriate, those responsible for the functions or processes to be audited. The purpose of an opening meeting is to:**

- C**onfirm the audit plan**
- P**rovide a short summary of how the audit activities will be undertaken**
- **Review the audit schedule**
- C**onfirm communication channels**
- P**rovide an opportunity for the supplier to ask questions**

5.1. Depending upon the scope and complexity of the audit, it can be necessary to make formal arrangements for communication within the audit team and with the supplier during the audit. The audit team should confer daily to exchange information, assess audit progress, and to reassign work between the audit team members as needed.

5.2. During the audit, the audit team leader should periodically (may be done daily or every other day) communicate the progress of the audit and any concerns to the supplier, as appropriate. **Evidence collected during the audit that suggests an immediate and significant risk (e.g. safety, environmental or quality) shall be reported without delay to the supplier and, as appropriate, to CMO QA management.** Any concern about an issue outside the audit scope should be noted by the audit member and reported to the audit team leader, for possible communication to the supplier and CMO QA management.

5.2.1. **Where the available audit evidence indicates that the audit objectives are unattainable, the audit team leader shall report the reasons to the CMO QA management and the supplier to determine appropriate action.** Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit.

5.2.2. Any need for changes to the audit scope which can become apparent as on-site auditing activities progress should be reviewed with and approved by the CMO QA management, and, as appropriate, the supplier.

6. Supplier guides and observers (government or supplier) may accompany the audit team but are not a part of it. They should not influence or interfere with the conduct of the audit. Guides appointed by the supplier should assist the audit team and only

act on the requests of the audit team leader. Their responsibilities may include the following:

- Establishing contacts and timing for interviews
- Arranging visits to specific parts of the site or organization
- Ensuring that rules concerning site safety and security procedures are known and respected by the audit team members
- Witnessing the audit on behalf of the supplier
- Providing clarification or assisting in collecting information

7. During the audit, information relevant to the audit objectives, scope and criteria should be collected and verified by appropriate sampling. Only verified information can be audit evidence and shall be recorded. The audit evidence is based on samples of the available information and therefore there is an element of uncertainty. Those acting upon the audit conclusions should be aware of this uncertainty.

8. **Audit evidence shall be evaluated against the audit criteria to generate the audit findings. Audit findings address nonconformity with audit criteria. Nonconformities and their supporting audit evidence shall be recorded.**

8.1. The audit team should meet as needed to review the audit findings at appropriate stages during the audit.

8.2. Nonconformities should be reviewed with the supplier to obtain acknowledgement that the audit evidence is accurate, and that the nonconformities are understood. Every attempt should be made to resolve any diverging opinions concerning the audit evidence and/or findings, and unresolved points shall be recorded.

9. The audit team should confer prior to the closing meeting to:

- Review the audit findings, and any other appropriate information collected during the audit, against the audit objectives
- Prepare recommendations to the CMO, if specified by the audit objectives
- Discuss audit follow-up, if included in the audit plan
- Agree on the audit conclusions and resolve any diverging opinions regarding the audit findings and/or conclusions (Team Leader decision whether or not to include a finding)

10. **A closing meeting with the supplier, chaired by the audit team leader, shall be held to present the audit findings and conclusions in such a manner that they are understood and acknowledged by the supplier, and to agree, if appropriate, on the timeframe for the supplier to present a corrective and preventive action plan.** Participants in the closing meeting should include audit team members and may also include the customer and other parties. In a small organization, the closing meeting may consist of just communicating the audit findings and conclusions. For other audit situations, the meeting should be formal and minutes, including records of attendance, should be kept.

11. **The audit team leader with assistance from the audit team shall prepare the audit report. If the audit results require the supplier to take corrective action, the appropriate level Corrective Action Request (CAR) shall be issued in accordance with the Corrective Action Process instruction with responsibility for follow up and closure assigned to the assigned QA personnel.** Nonconformities detected during a System Audit, should not be issued as individual CARs. **The CAR issued shall include all nonconformities found during System Audit. Any nonconformities found during a System Audit that require root cause analysis and action to prevent recurrence shall result in the issuance of a level II CAR, as a minimum.** Multiple nonconformities associated with a single clause or indicative of a system wide breakdown of the QMS should result in a level III CAR. This decision of the CAR level should be made by the audit team leader. **The audit report shall provide a complete, accurate, concise and clear record of the audit, and as applicable shall include the:**

- **Audit objectives**
- **Audit scope, particularly identification of the organizational and functional units or processes audited and the time period covered**
- **Identification of audit team leader and members**
- **Dates and places where the on-site audit activities were conducted**
- **Audit criteria**
- **Audit findings**
- **Audit conclusions**
- **Audit CAR**
- **Reference to the audit plan**
- **Confirmation the audit objectives as defined in the audit plan were or were not accomplished**
- **Any areas within the audit scope not covered**
- **Agreed-to follow-up action plans**
- **Distribution for the audit report**

11.1. The audit is considered complete when all activities described in the audit plan have been carried out and the audit report has been distributed. **The audit report shall be distributed, as a minimum, to all parties notified of the audit within 10 working days of the closing meeting.**

11.2. **The audit plan and audit report shall be maintained in accordance with the DCMA Records Management instruction. If necessary to support the audit report, copies of supplier's documentation shall also be retained in accordance with the DCMA Records Management instruction. If not needed to support the audit report, copies of these documents shall be destroyed.**

Competencies/Certifications

Audits should be led by an individual that meets the lead auditor core plus competency described in the Quality System Skill Set. Audit team members should meet the auditor core plus competency described in the Quality System Skill Set. All the competency and certification requirements are described in the QA Development instruction.

Training Matrix

"Process Title" Training Matrix Template

What TASKS are required to accomplish this process?	Methods of training, including KSAs					
	On-the-Job Training (OJT)	Computer Based Training (CBT)	Course (Commercial, College/ Vocational)	Supplier Sponsored Training	Guidebooks	DCMA Developed
Task 1 - Determine Need to Conduct Audit						QUAL 101-201
Task 2 - Determine Audit Team & Plan						QUAL 101-201
Task 3 - Make Audit Team Assignments						QUAL 101-201
Task 4 - Prepare Work Documents						QUAL 101-201
Task 5 - Conduct Opening Meeting						QUAL 101-201
Task 6 - Determine Guides & Observers						QUAL 101-201
Task 7 - Gather Audit Evidence						QUAL 101-201
Task 8 - Determine Audit Findings						QUAL 101-201
Task 9 -Audit Team Meeting (Prior to Closing Meeting)						QUAL 101-201
Task 10 - Conduct Closing Meeting						QUAL 101-201
Task 5 - Write & Issue Audit Report						QUAL 101-201

Higher Level Regulatory Documents

· FAR 52.246-11,Higher Level Contract Quality Requirement

Performance Metrics/Standards

- **Process Indicator/s:**
  - TBD
- **Workload Indicator/s:**
  - TBD
- **Resource Indicator/s:**

  - TBD
- **Supplier Indicator/s:**
  - QA Most Active Suppliers

PLAS

- PLAS Process code: 085C

Tools & Additional Guidance

- AS9100 Rev C ISO Checklist
- AS9100C_Electronic_Checklists
- AS9100C_Handcarry_Checklists
- Audit Checklist for the Evaluation of Calibration Systems
- Quality Management System Check List Rev FY13
- ISO 9001-2008 modified cklst list
- ISO9001-1994 audit-checklist
- ISO90012000cl
- Mil-I-45208A Checklist
- Mil-Q-9858A Checklist

Successful Practices

- TBD

Portal/Community of Practice

- Quality Assurance Community

Points of Contact

DCMA Instruction Point of Contact information is not available to the general public.

DCMA employees please click here for the process POC's