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28/04/2025	Update regarding ISO 19443 requirements	G
11/04/2022	Paragraph change 11.4 (Fraud and Counterfeiting)	F
11/02/2020	Compliance with the requirements of EN 9100 v 2016	E
TYPE OF CHANGE		

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Service qualité - T. WALEK AMECA Quality manager

1. SCOPE OF APPLICATION

The purpose of this instruction is to specify the Quality requirements and obligations required from AMECA's Service Providers (Subcontractors and Suppliers).
The present rules are applicable to orders issued by the AMECA Group to suppliers or subcontractors for products that are part of the final product or that take part in the production process, including those designated by the customer.
It applies to all its subcontractors and raw material suppliers (producers or resellers) of chemical products, manufacturers of manufactured products, and service providers (testing and calibration laboratories, design offices).

2. PRINCIPLES AND RESPONSIBILITIES

To obtain and maintain the confidence of its customers, AMECA must guarantee the quality of its products.
This condition can be satisfied only if the quality of its purchases is controlled. In order to reach this objective, AMECA requires from its Suppliers, as well as it imposes itself, the maintenance of an organization aiming at controlling and improving permanently the quality of the product and/or its services.
Supplier: the term supplier is used in the present instruction in a broad sense (subcontractor, manufacturer, reseller, etc...).
The AMECA Purchasing department is responsible for making this instruction available to the suppliers.
This instruction is specified on our purchase orders, and is compulsory to be followed by the service providers holding an AMECA order.
Despite complying with the instruction, the supplier remains fully responsible for the conformity of the supplies or services delivered to AMECA.
The specific requirements of certain customers will be mentioned on the purchase orders, in addition to the requirements of this instruction or in particular documents.
In case of discrepancies between the requirements defined in this instruction and those specified on the purchase orders, the requirements of the purchase orders will prevail.

3. SOME DEFINITIONS

Key Features

An attribute or characteristic which variation has a significant effect on product size, interchangeability and function, performance, service life, or deliverability, requiring specific actions to control that variation.

FOD (Foreign Object Damage)

A FOD is any foreign body present among the parts. The presence of a FOD may affect the safety or performance of the finished product.

Critical Elements

All elements (e.g. functions, parts, software, features, processes) having a significant effect on the provision and use of the product or service, including safety, performance, space requirements, interchangeability, function, deliverability, service life, etc.; which require specific actions to ensure that they are adequately managed.
Critical elements include, for example, safety-critical elements, rupture resistance, mission accomplishment, key characteristics, etc...

Counterfeit Parts

An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component) knowingly represented as a specified original part from a designer or authorized manufacturer.

Fraudulent Parts

An intentionally misrepresented parts with the intent to deceive.

Suspicious Parts

Parts for which there is an indication or suspicion that they may not be authentic.

Important for nuclear safety

Characteristics of a product, service, article or activity, the failure of which could result in indue exposure to radiation for people and the environment.

Nuclear safety

Achieving correct operating conditions, preventing accidents or mitigating their consequences, resulting in the protection of workers, the public and the environment against undue radiological risks.

External Service Providers

Body delivering materials, components, sub-assemblies, finished products, or services (subcontracting, logistics, archiving, calibration, etc...).

Special Processes

Processes whose output data cannot be verified by monitoring or subsequent action requiring the implementation of specific qualification and monitoring measures.

4. GENERAL CONDITIONS OF ACCESS

Within the framework of dispute resolution or actions to monitor the quality of products, processes or organization, the supplier or subcontractor must authorize AMECA representatives, its customers, its principals and, if necessary, the regulatory authorities, free access to the production sites where the services concerned by the order are carried out. It must grant to these same representatives, the consultation of all documents or records concerning the definition, the manufacturing, the control and the maintenance of the said services. Visits by the latter shall be announced in advance.

5. CONFIDENTIALITY COMMITMENT

AMECA commits to respect the rules of industrial confidentiality towards its suppliers or subcontractors, just as suppliers or subcontractors guarantee to AMECA the non-disclosure to third parties, of documents, data and information provided by AMECA and its customers in the context of the execution of the orders, without written authorization.

6. QUALITY CONTROL REQUIREMENTS

The Supplier or subcontractor shall maintain a quality management system that defines the structure, responsibilities, procedures and means to ensure and demonstrate the conformity of the product to the requirements specified by AMECA. This system must be in line with the ISO 9001 standard.

AMECA evaluates the quality system deployed at its Service Providers by means of an evaluation questionnaire given during the initial prospection.

AMECA reserves the right to evaluate by audit, the quality system of the supplier or subcontractor according to the information collected in the questionnaire.

Attestations and certificates justifying the recognition of the supplier or subcontractor's quality system must be sent to AMECA's quality department, during the initial and renewal process.
The following paragraphs underline the additional requirements of AMECA, with regard to the normative references defined above.

7. DOCUMENTATION REQUIREMENTS

The provider's quality system must be described by documented Information that can be presented to AMECA upon request. The supplier must ensure that he is in possession of all documents specified in the purchase order or cascaded by it, and at the right index.
He must ensure the management of these documents (documents issued initially, during the update and on request of the supplier). The supplier must prohibit the use of documents that are outdated, in poor condition (legibility) or carrying non-validated information. The retention period of records made for AMECA is at least 30 years.
The supplier must inform any documentary evolution concerning the product and process and wait for the validation of AMECA before application.

8. RESOURCE MANAGEMENT

8.1 COMPETENCY MANAGEMENT

The competence of personnel carrying out special processes or performing product monitoring and measurement tasks must be demonstrated through initial and continuing training.
The authorisations of controllers, personnel carrying out specific processes or carrying out Non Destructive Testing must be recorded.
These authorisations must be renewed at regular intervals, on the basis of monitoring of skills in the field.

In the case of an order related to a nuclear matter, the supplier ensures that the workers involved are trained in the activity and are aware of the risk and the impact of a failure on nuclear safety, with a recorded document (skills matrix, etc.).

8.2 STAFF AWARENESS

The provider must make its staff aware of:
- their contribution to the conformity of the product or service,
- their contribution to product safety,
- prevention of the use of counterfeit coins,
- FOD hazard (Foreign Object Damage),
- the importance of ethical behaviour.

9. CLIENT PROCESS

The offer: Any Service Provider who submits an offer, commits himself to the feasibility, in manufacturing, delivery, deadlines and controlling.

The order: AMECA will give to the Service Providers all the documents necessary for the realization of the order.

The Provider must conduct contract reviews in order to ensure that all the clauses of the order will be respected: that he has all the documents specified on the order and at the right indices; that he is

able to carry out the product or the service in any point in conformity with the contract and that he is able to respect the deadline specified on the order.
Any discrepancy between the terms of the order and its feasibility must be reported in writing to AMECA, and the agreed agreements formally identified.
The Service Providers must acknowledge receipt of the order within 2 days from receipt of the order. Failing this, any order will be considered as accepted if it has not been subject to reservations.
The Service Providers must not make any modification to the technical definition of the products, without formal authorization from AMECA. If a discrepancy is identified on the definition of a product (representation anomaly, quotation error, etc...), the Provider must inform AMECA's purchasing and quality departments for analysis and decision.

Purchase Order Requirements: on the purchase order documents must be included the following purchasing data:
- the date, name and address of the supplier or subcontractor;
- possibly the name of the correspondent, his telephone number and the offer reference;
- the product reference (if catalogued), the reference of the technical data sheet;
- references and indices of applicable reference documents and customer specifications, drawings, process requirements, test instructions and other relevant technical data;
- unit price, discount, total price;
- the required delivery documents (PV analysis, certificates of conformity...);
- the accompanying documents necessary for the successful completion of the order.

10. PURCHASES

AMECA's quality requirements and those of its customers must be fully passed on to subcontractors.
The supplier or subcontractor commits himself to refrain from subcontracting a part or the totality of the service object of the contract, without the formal authorization of AMECA. The supplier must keep an updated list of its qualified service providers, and keeps it at AMECA's disposal for consultation.

11. PRODUCTION CONTROL

The purchase order must be carried out according to all the purchasing data stated on the purchase order. The supplier must establish and validate workflows including:
- the chronological order of the operations to be carried out;
- the information describing the characteristics of the product or the reference of the documents describing them;
- the significant parameters of the processes to be respected;
- the definition of the means to be used (tools, specific measuring equipment, machines, etc.);
- the key points for controls, with a compulsory final control operation authorising the release of the product.

This concerns in particular: the change of production site, the subcontracting of the ordered service, the change of production process must be the subject of a preliminary information with the AMECA Purchasing department.

11.1 MASTERY OF SPECIAL PROCEDURES

The supplier using special procedures must periodically ensure:
- verification of the accuracy and variability of the equipment used (equipment monitoring)
- monitoring and recording of special media (time, temperature, pressure, and other factors influencing quality)

- records relating to process qualification and personnel qualification

11.2 PRODUCT MONITORING AND MEASUREMENT

All contractual product characteristics must be checked and recorded. Where sample testing is used to certify the conformity of the product, the testing plan must be appropriate to the risks. (Applicable standard: ISO 2859-1 Sampling rules)
The supplier is required to provide, at the request of the AMECA Buyer, all information necessary to execute the order, in particular, information concerning its organization and quality.

In the case of an order related to a nuclear project, and throughout the entire duration of the order execution:
- The supplier must allow AMECA (represented by the buyer or the technical manager or the nuclear quality and safety manager), as well as our customers and the Nuclear Safety Authorities and the relevant approved organizations, to monitor and/or verify the proper execution of the order by the supplier. This includes providing access to its premises, the place of performance of the Goods/Services, and the documentation relating to the order.
-AMECA reserves the right to carry out checks on the execution of the order by all appropriate means, either at the place of manufacture of the Goods or at the place of performance of the Services, or in a laboratory of its choice. If during the checks, control and/or monitoring, AMECA and/or its customer and/or the Nuclear Safety Authorities and/or approved bodies identify one or more non-conformities and/or non-compliance with contractual obligations, AMECA will notify the supplier in writing. The supplier must take all necessary corrective measures to fully comply with the order, at its own expense and within a reasonable time.
-The supplier undertakes to comply with this article 11.2 in its subcontracting contracts so that the corresponding obligations are applicable to any subcontractors.

11.3 CONTROL OF CHANGES IN PRODUCTION PROCESSES

Any change in the manufacturing process must be communicated to AMECA before actual implementation. This cannot take place before written acceptance by AMECA.
These changes must be identified, recorded with an application date and validated by authorized personnel at the supplier.
Any change of manufacturing site or supplier must be communicated to AMECA.

11.4 FRAUD AND COUNTERFEITING

In the fight against fraud and counterfeiting context, the whole staff will be trained on the risks of fraud and counterfeiting and detection methods must be put in place by the supplier.
The supplier must also ensure that the staff in charge of Quality assurance and Quality control is independent from the operations staff.

Each staff member must have the possibility, without disclosing his identity, to alert on any deviation, anomaly or suspicious practices that could impact the compliance with the requirements through:

- the designated representative of the supplier

The supplier must inform AMECA as soon as it becomes aware of any case of fraud, suspicious practice or counterfeiting taking place in its own activities. He will also have to analyze, if necessary, the extent of such a practice (duration, volume, etc...), their causes and the implementation of all necessary corrective actions in order to prevent their recurrence.

11.5 FOD PREVENTION

The supplier shall put in place provisions for the prevention, detection and elimination of foreign bodies during the manufacturing, assembly, inspection, storage, maintenance, packaging and shipping operations.

11.6 OBSOLESCENCE CONTROL

The Service Provider must set up a process to monitor obsolescence (components, materials, etc.) on supplies within its scope of responsibility. AMECA must be systematically warned of any announcement of obsolescence by the Service Provider as soon as he has the information.

12. VALIDATION OF PRODUCTION PROCESSES

The supplier must define provisions to validate the industrial process during the first realizations and constitute a 1st article file composed of the records justifying the conformity of the expected results with the order.
The special processes implemented by the supplier (processes which expected results cannot be verified by monitoring or measurement carried out afterwards) must be identified and be the subject of a registered qualification.
Evidence of this qualification must be kept by the supplier and presented to AMECA on request.

13. IDENTIFICATION AND TRACEABILITY

The supplier shall maintain a documentary recording and archiving system to be able to link to the delivered product:
- the manufacturing history (tracking sheet);
- the non-conformities or anomalies observed (recording of non-conformities);
- the batch numbers of the raw materials used and their characteristics (conservation of the material certificates mentioning the batch number);
- the requested derogations, and the answers given by AMECA;
- the qualification of operators and special processes (operator qualification or authorisation sheets, process qualification files).
- control and test results (control, measurement or test reports, etc...).
- the releasing documents (declaration of conformity...).

The traceability set up by the supplier must make it possible to find for a product all the component batches or raw material batches used. It must also make it possible to identify all sub-assemblies and products manufactured with a given batch of material or components.

14. PROPERTY OF AMECA

Raw materials and blanks:

When AMECA supplies the raw material or blanks for the execution of the order, the supplier commits himself to use only the supplied material or blanks, in particular, in case of scrap or shortage.
The supplier must inform AMECA of the scraps in order to balance the order or to trigger a replenishment of material or blanks.

15. PRESERVATION OF THE PRODUCT

Packaging:

For delivery, the subcontractor must provide packaging at his own expense that preserves the product according to its nature and destination, avoiding deterioration of the items (oxidation of untreated areas, shocks, scratches, etc. ...).
Access to the delivery note must be possible without breaking the packaging (glued to the outside of the packaging).

Storage of AMECA articles:

If the supplier stores articles intended for AMECA (excess manufacturing quantities), these must be stored in conditions that guarantee their preservation from any degradation and identified with their applicable configuration state (article reference and index).

Delivery of the products:

The supplier must identify the product delivered to AMECA with a delivery note accessible without opening the package (transparent pocket stuck on the outside of the package).
The BL must indicate at least:
- the designation of the product,
- the reference,
- the quantity,
- the batch number or production order
- the Order Number
- the control records, declarations of conformity and other documents specific to the order must be placed in an envelope inside the package.

16. CONTROL OF MONITORING AND MEASURING ARRANGEMENTS

The supplier shall establish a procedure for controlling the checking, measuring and testing equipment.
The supplier must keep at the disposal of AMECA, the records proving the attachment of his equipment to standards connected to approved metrology laboratories (COFRAC...).

17. MEASUREMENT ANALYSIS AND IMPROVEMENT

Inspection and tests on receipt:

For subcontracting services, when the raw material or blanks are not supplied by AMECA, the supplier must set up monitoring devices at reception to guarantee their conformity.
Records must be established and kept in order to demonstrate the conformity of raw materials and subcontracting services (heat treatments, surface treatments, special processes, etc...).
If contractually specified, a copy of the records must be provided to AMECA.

Control and tests during production:

The supplier must define the key points for the execution of production control tasks, and provide proof that these tasks have been carried out by trained and competent personnel.

First item control:

If the AMECA requirements specify in the order the constitution of a first material release file, a first material control report is attached to the order.

The completed specification must be returned to AMECA, with the required supporting documents and the identified item that was subject to the first item conformity check.

Final check:

The release of the product to AMECA should only be authorized after a final inspection has been carried out (phase to be included in the product realization range).
The final inspection must be carried out by the quality department or personnel authorized by the supplier's quality department.
The final inspection and the release of the finished product must be sanctioned by the drawing up of a declaration of conformity in accordance with NF L00-015, approved by the supplier's quality control department.
With regard to our suppliers of raw materials, and with regard to the purchase specifications mentioned on the order, a certificate of analysis must be provided with each delivery and for each of the batches delivered.

18. CONTROL BY THE SUPPLIER OF NON-CONFORMING PRODUCTS

Suppliers and subcontractors must have a system for managing non-compliance. Non-conforming supplies must be identified and segregated so that they are not mixed with conforming products.

Non-Conformity detected by the supplier:

Any non-conformity with the order must be identified and reported to AMECA on a non-conformity / deviation declaration document (or equivalent) for decision.
Non-conforming products awaiting a decision must be isolated in a quarantine zone and identified as non-conforming parts.
Products subject to delivery agreement must be isolated from products deemed to be in conformity, clearly identified and accompanied by the derogation that will have been previously signed by the AMECA quality that authorizes the delivery.
The products will be duly referenced (for example: "non-conforming part", "product subject to derogation").

Non-Compliance detected by AMECA:

Non-conforming products are returned to the supplier or subcontractor at their expense and billing is blocked.
Any non-conformity identified by AMECA is the subject of a non-conformity report which is sent to the supplier for analysis of the causes of the non-conformity and treatment in terms of proposals for corrective and preventive actions.
According to the AMECA decision, the non-compliant product can:
- be accepted as is,
- be returned freight collect, for replacement or alteration,
- be declared rejected. In this case, a request may have been made to the supplier,
- be retouched at AMECA (for reasons of delay). In this case the supplier is informed by the quality department for acceptance of the cost of retouching that will be charged to him (before the beginning of the retouching by us).

The supplier has to return us the non-conformity report within the mentioned time limits, filled with the causes of the appearance of the non-conformity and the corrective and preventive actions, implemented to avoid the reappearance of the non-conformity.

The absence of response will be the subject of a reminder and will be taken into account during the supplier's performance review when the reminders are recurrent.
The buyer may reserve the right to block new orders from the supplier or subcontractor if the latter does not systematically respond to requests for corrective action.

19. CORRECTIVE/PREVENTIVE ACTION

The supplier must establish procedures enabling him to control the management of corrective and preventive actions.
Any disputes or complaints transmitted must be dealt with by the supplier on the non-conformity report or on his own document. This document must be returned to AMECA's Quality department.

20. INVOICING

The prices and terms of payment are stipulated on the order of AMECA. Invoices will be paid after complete delivery of the order. The invoice will have to bear the following indications:
- the order number,
- the vendor's BL number,
- the description of the delivered material,
- the exact quantity delivered.

21. MONITORING OF SUPPLIERS AND SUBCONTRACTORS

The supplier or subcontractor must be ISO 9001 or EN 9100 certified or have done so or prove that it is in a continuous improvement process.
Where applicable, it undertakes to send its valid certification(s) or approval(s) to
AMECA.
The supplier or subcontractor may be subject to selection and follow-up audits by us or by our customers and a particular follow-up of non-conformities in reception.
AMECA carries out a regular follow-up of its suppliers or subcontractors.
AMECA may at any time have one or more audits (or inspections) carried out on its behalf at its own expense or on behalf of its client, where applicable under agreed special conditions, which may include, in particular, compliance with the supplier's contractual obligations. A copy of the audit report will be provided to the supplier free of charge.

22. FIGHT AGAINST FRAUD

The Supplier declares that it sources its components from the original manufacturer or authorized distributor of the Goods in question in order to ensure the authenticity and traceability of the components. The Supplier implements all necessary measures to prevent and combat any fraud, suspicious practices, or counterfeiting relating to the subject of the order and, more broadly, within the framework of its activities or those it subcontracts. In the context of an order related to a nuclear or aeronautical project, the supplier will implement and impose the following measures on its own subcontractors in particular:
- A procedure guaranteeing the independence of the personnel responsible for quality assurance and control from the rest of the operational organizations,
- The introduction of tools to detect this type of practice in the control and inspection methods,
- A procedure/instruction allowing each employee the opportunity to alert (without necessarily revealing their identity):
- A representative of the supplier's organization and
- AMECA and

- In the case of a nuclear project, the applicable safety authority (ASN, ONR, etc.)

The supplier will allow AMECA inspectors and auditors access to its industrial facilities, workshops, as well as to the documentation, software, and machine data associated with the order:

- According to the meeting points defined in the order, or
- Unannounced. The supplier authorizes AMECA to carry out contradictory checks on the Goods and/or Services, subject to the order, or on the documentation, by comparison between the certificates issued by the supplier and the original reports, issued by subcontractors or laboratories used by the supplier. In this respect, it authorizes AMECA to request the original reports from its subcontractors, and accepts that the latter transmit them directly to AMECA.

When AMECA becomes aware of fraud, suspicious practices, or counterfeiting within a company, it may ask the supplier whether it uses or has used this company as a subcontractor for AMECA orders. If applicable, the supplier will provide a list of affected part/activity references and the orders concerned.

When fraud, suspicious practices, or counterfeiting are identified in its own activities or in its subcontracting chain, the supplier must:

- Inform AMECA and, where applicable, the applicable nuclear safety authority
- Analyze the extent of such practices (duration, volume, etc.), their causes, and implement all necessary corrective actions to prevent their recurrence. AMECA and, where applicable, the applicable nuclear safety authority must be promptly notified of the results of the analyses and the corrective actions implemented by the supplier.

23. LEGAL AND REGULATORY REQUIREMENTS

It is the supplier's responsibility to identify and implement established and applicable regulatory or legal requirements (national, European, or international). This includes, in particular, the following:

- Safety,
- Environment,
- REACH – European Regulation for the Registration, Evaluation, and Authorization of Chemicals
- RoHS – European Directive for the Restriction of Hazardous Substances
- Air, sea, and road transport
- Labor (Labor Code),
- Customs
- Export Control / Dual Use
- Conflict Minerals
- IPSN (Nuclear safety activity) or AIP activity (or equivalent).

REACH:

The supplier must inform AMECA when one of its products or materials contains more than 0.1% by weight of a substance of very high concern (SVHC) under REACH Regulation EC 1907/2006. This list is available at http://echa.europa.eu/web/guest/candidate-list-table.

The supplier undertakes, upon request from AMECA, to provide certificates guaranteeing the REACH compliance of its products.

The supplier must ensure that its own suppliers also comply with REACH regulations.

RoHS:

The supplier must inform AMECA of the compliance or non-compliance of its supplied products with European Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic

equipment. It undertakes, upon request from AMECA, to provide certificates guaranteeing the RoHS compliance of its products.

Export Control / Dual Use:

The supplier must inform AMECA when one of its products or materials is subject to export and final destination controls (Export Control) such as ITAR, ML-US, or DU-US.
The supplier must inform AMECA of any restrictions and constraints relating to the export of products and/or components.
Regulatory Requirements for Dual-Use Products & Export Control:
The supplier is aware of and accepts the regulatory requirements applicable to dual-use products and technologies, whether of American origin (EAR Regulation), European origin (European Regulation EC No. 428/2009), or any other country. This includes, but is not limited to:
- The supplier's obligation to ensure compliance with these regulations with respect to the components and materials delivered to AMECA,
- The obligation to provide AMECA with an Export Control Certificate (ECC) where applicable.

Conflict Minerals:

The supplier undertakes to deliver only products that comply with the Conflict Minerals Regulations (Dodd-Frank Act, Section 1502) regarding the sourcing of tantalum, tin, tungsten, and gold from mines in the Democratic Republic of Congo and neighboring states.

IPSN (Nuclear safety activity), AIP, and CT AIP activities (or equivalent):

In the case of an order related to a nuclear project, the supplier undertakes to deliver products or activities that comply with the AMECA specifications defining IPSN characteristics. This includes compliance with the following regulations:
- INB Order of February 7, 2012,
- French Environmental Code,
- ISO 19443 standard (IPSN characteristics and graded approach).

24. AMECA SPECIFICATIONS

The supplier ensures that it complies with the requirements of the AMECA specifications provided with the order and must provide the requested documentation in complete transparency.