TITLE	HANDLING PROCEDURE FOR NON-CONFORMITIES AND FINDINGS
CODE	SGQ-P-02-19
REVISION	Rev.1
DATE	10.10.2022

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NOTE: in case of discrepancies, the Italian version of this document prevails

Rev.	Date	Issued by	Approved by	Description of the modifications
1	10.10.2022	Quality manager	Director technician	Modification of paragraphs 4 and 5
0	07.04.2022	Quality manager	Director technician	First issue

SUMMARY

1. SCOPE

This procedure has the purpose of defining the procedures for issuing and handling the findings that are eventually found and recorded during the audit, inspection and / or surveillance activities.

The specific procedures containing the technical details are reported in the individual scheme regulations available on the AREAS Certificazioni S.r.l. website.

2. REFERENCES

SGQ-M-01-01_Manuale del Sistema qualità (Manual of the Quality Management System)

SGQ-E-10-04_Elenco dei documenti di origine interna (List of Documents of Internal Origin)

Scheme Regulations

3. NORMATIVE REQUIREMENTS

ISO / IEC 17000: 2020 Conformity assessment - Vocabulary and general principles

ISO / IEC 17065: 2012 Conformity assessment - Requirements for certification bodies for products, processes and services

ISO / IEC 17021-1: 2015 Conformity assessment - Requirements for bodies providing audits and certification of management systems

ISO / IEC 17020: 2012 Conformity assessment - Requirements for the operation of various types of bodies performing inspections

ISO / IEC 17024: 2012 Conformity assessment - General requirements for bodies performing certification of persons

The following paragraphs describe the general procedures adopted by the body for the issue of any findings that may be found during the certification, surveillance and renewal activity for the product scheme for which they must be taken as guidelines. The methods adopted for each specific product certification scheme are indicated in the technical certification regulations available on the Body's website.

4. FINDINGS CLASSIFICATION

For the classification of the findings highlighted during the documentary and / or on-site checks, reference is made to the following criterion:

Major Non-Conformities
Major non-conformities are considered:

- the total absence of consideration of one or more requirements of the reference regulatory documents;
- the non-compliance of the results of the tests / calculations / verifications / verifications with the criteria established by the reference regulatory documents;
- any non-compliance or situation that could result in the delivery of a product whose performance is lower than those declared or does not comply with the laws in force or which could result in the failure or reduced use of the product for the purpose for which it is intended;
- failure to comply with one or more requirements of the regulation;

- a non-compliance or a situation which, based on judgment and experience, could cause deficiencies in the product / PFC / system and / or materially reduce the manufacturer's ability to ensure controlled products or processes;
- variations of the product / PFC, construction procedures and / or materials of certified products not authorized by AREAS

Major Non-Conformities are all findings that jeopardize the safety of the certified product or process.

Minor Non-Conformities

Minor non-conformities are considered:

- non-conformity / situation which, based on the judgment and experience of the Verification Group, is not such as to cause deficiencies on the "product" such as to reduce its ability to ensure performance compliant with what has been declared or cause the shipment of a product with do not comply with what has been declared;
- non-conformity / situation which, based on the judgment and experience of the Verification Group, is not such as to cause significant deficiencies in the production control system such as to reduce its ability to ensure controlled products or processes or cause the delivery of a product does not comply with what has been declared;
- the partial absence of an element of the system compared to the applicable reference standards (lack of application and / or documentation) which, on the basis of available objective evidence, does not affect the functioning of the system itself;
- the lack of documentation of an element of the system, against the technical specification of reference, which is in any case implemented;
- occasional errors that require timely intervention.

For all NCs detected, the Manufacturer is required to communicate to AREAS, within 10 working days, the methods identified for their resolution and any corrective action, indicating the deadline for implementation.

For the only major Non-Conformities that can lead to safety risks jeopardizing the conformity and safety of the product placed on the market, AREAS reserves the right to apply additional control and verification methods at the discretion of the Scheme Manager.

AREAS will verify the effective resolution of all NCs detected by analyzing the documentation, any additional audit at the Manufacturer and / or other verification activities depending on the situation.

AREAS will notify the customer of the acceptance of the resolution of the findings or, in case of non-satisfaction, will request the necessary additions. The CE marking and the issue of the Certificate of Conformity are subject to the resolution of the NC found during the audit.

Furthermore, AREAS will verify the effective implementation of the corrective actions approved during an ad hoc supplementary check or subsequent audit.

Observations / Recommendations

They are issued in the event that a partial fulfillment of a requirement is found that:

- It does not have or reasonably presumes not to have as a consequence the non-compliance with a requirement applicable to the product supplied as part of the activities concerning the Families of products subjected to CE marking
- It does not have or reasonably assume that it does not result in the inability of the practices adopted to achieve the expected and / or planned results in the context of the activities concerning the families of products subjected to CE marking

For the Observations, the Manufacturer must explain the methods identified for their resolution and any corrective action taken during the subsequent surveillance. The inspector has the discretion to request evidence of the methods of resolution within a time he deems reasonable (maximum 60 days) and must indicate this on the inspection / audit report; in this case AREAS verifies the adequacy of the actions identified by the Manufacturer, approves their content and will verify their effective implementation at the next audit.

The CE marking and the issue of the Certificate of Conformity are subject to the resolution of the Observations found.

Comments / opportunities for improvement

They represent ideas for improvement of the management system that the audit team recommends to the Manufacturer to put in place. They assume full compliance with applicable requirements.

AREAS will verify the management of comments at the next audit.

5. OUTCOME OF THE CERTIFICATION ACTIVITIES

In carrying out the certification activities, findings may be found that demonstrate the failure to satisfy a requirement or a deviation from the reference specifications; in particular, the conclusion of the conformity assessment can present the following 4 situations:

1. No non-conformities, no recommendations, any comments
2. None Non-compliance, presence of recommendations, any comments
3. None Major non-conformities, presence of minor non-conformities, any recommendations and any comments
4. It has major non-conformities

5.1. Case 1

If no evidence has been found that leads to the issue of non-conformities or recommendations, the inspection / audit team draws up the report which is sent to the CDD.

If only comments are formulated, it is not necessary for the Customer to send AREAS Certificazioni S.r.l. any treatment plan. During the subsequent audit AREAS will verify that the customer has taken charge of the reports received and the consequent actions taken or the reasons that led to the decision not to take any consequent action.

5.2. Case 2

If there is evidence that leads to the issue of recommendations and in the absence of non-conformities, the inspection / audit team draws up the report with the description of the aforementioned recommendations and delivers the report to the organization. It is at the discretion of the inspector to define a maximum time for carrying out the necessary actions (max 2 months) or to postpone the control of the same during the next surveillance.

The implementation and effectiveness of the corrective actions will be verified during the subsequent surveillance audit; if the actions are found not to be implemented or not effective, they will lead to the issue of major non-conformities, and therefore the need to perform a post-audit.

5.3. Case 3

If there is evidence that leads to the issue of minor non-conformities, the inspection / audit team draws up the report with the description of the aforementioned non-conformities and delivers the report to the organization.

The Organization must define the corresponding actions (treatments, analysis of causes and corrective actions) and plans the timing of their implementation within a maximum of 10 days.

The head of the inspection / audit team examines the proposed actions; if the outcome of this evaluation is not satisfactory, the organization is invited to modify its proposal for a second treatment proposal; if, on the other hand, the outcome is favorable, the team manager proposes to AREAS the need for an additional audit to verify the effectiveness of the corrective action taken by the organization.

In this case, the scheme manager (or his / her representative) will carry out a verification of the contents of the audit report to ensure the correct classification of the findings and that the combination of minor non-conformities does not compromise the safety of the product and / or the integrity of the system. If the verification is positive, the process will continue, otherwise the CDD will be summoned to submit the decision regarding the maintenance or suspension of the certification, following what has been decided by the same.

If the second documentary assessment or any post-audit has a negative outcome, the certification process is definitively interrupted; in this case the certification process must be retraced from the beginning.

In the event that the Organization does not proceed with the communication of the timing and treatments, AREAS Certificazioni S.r.l. will arrange for the suspension of the certification.

If the documentary assessment and any post-audit are successful, the audit team draws up the post-audit report which is sent to the CDD, together with the previous report.

5.4. Case 4

If there is evidence that leads to the issue of major non-conformities, the inspection / audit team draws up the report with the description of the aforementioned non-conformities and delivers the report to the organization.

In the event of safety risks that compromise the conformity and safety of the product placed on the market, the head of the inspection / audit team has the right to propose suspension of the certificate directly on the report to the AREAS CDD until the closure of major non-conformities.

The Organization must define the corresponding actions (treatments, analysis of causes and corrective actions) and plans the timing of their implementation within a maximum of 10 days.

The head of the inspection / audit team examines the proposed actions; if the outcome of this evaluation is not satisfactory, the organization is invited to modify its proposal; if, on the other hand, the outcome is favorable, the manager plans a mandatory supplementary audit to verify the effectiveness of the corrective action taken by the organization. Within 6 months from the date of detection of the non-conformities AREAS Certificazioni S.r.l. will have to carry out an additional assessment activity; the cost of this activity will be borne by the customer.

If the post-audit has a negative result, the certification process is definitively interrupted; in this case the certification process must be retraced from the beginning.

In the event that the Organization does not proceed in this sense (communication of timing and processing), AREAS Certificazioni S.r.l. will suspend the certification.

If the post-audit is successful, the audit team draws up the post-audit report which is sent to the CDD, together with the previous report.

The rules described above also apply during the renewal phase. All decisions on the granting or denial of certification are taken by the CDD convened by the scheme manager.

6. SUSPENSION OF CERTIFICATION

The suspension of a conformity assessment cannot exceed 180 days. Within this period, the customer must provide evidence of the adoption of the treatments and corrective actions as well as of their effectiveness.

Any additional inspections or audits carried out by AREAS to verify the treatments and the closure of non-conformities are the responsibility of the customer.

If the outcome of the audit conducted is positive because it has been found that the technical measures to ensure future compliance have been adopted, AREAS Certifications S.r.l. will restore the validity of the certificate.

After 180 days, if the customer has not demonstrated the adoption of the treatments and corrective actions as well as their effectiveness, AREAS Certificazioni S.r.l. will revoke or limit the EC certifications concerned.

All decisions on the suspension, restoration, reduction of the scope, or revocation of the certification are taken by the CDD convened by the manager of the scheme.

AREAS Certificazioni S.r.l. also informs the competent Authority and the other bodies of what has been done in accordance with the provisions of the relevant European harmonization legislation (Regulation / Directive).

7. REVISIONS

Rev.0	07/04/2022	First issue from document SGQ-P-02-06
Rev.1	10/10/2022	Amendment of the definition of recommendations in par. 4 Modification of case 2 (presence of recommendations) to par. 5