CERTIFICATION RULES

GRUPPO
ISTITUTO ITALIANO DELLA SALDATURA

RULE FOR CERTIFICATION OF MANAGEMENT SYSTEM

Document n° CER_QAS 019 R

CONTENTS

1 SCOPE AND FIELD OF APPLICATION

1.1 This Rule defines the criteria that IIS CERT applies in the certification activities of management systems (quality, environment, health and safety).

It is about how to apply for, obtain, retain and use, as well as the possible suspension and revocation of the certification.

The Rule is divided in:

- a General Part, common to all three of the aforementioned schemes;
- three Annexes, specific for each scheme (quality, environment, health and safety).

The Annexes refer, in the numbering of the paragraphs, to the corresponding paragraphs of the Rule for which additional requirements have been introduced.

1.2 For matters not covered by this document, refer to the general terms and conditions laid down in Rule CER_QAS 017 R (see § 2) available on the IIS CERT website.

1.3 IIS CERT issues the certification in accordance with the requirements of the standard EN ISO/IEC 17021-1 to Organizations whose management system has been recognized as complying with all the requirements provided by the standard or regulatory document of reference.

1.4 Access to the certification is open to all Organizations and is not conditioned by the affiliation or otherwise to any Association or Group.
For its certification activity, IIS CERT applies its own fees and guarantees fairness and uniformity of application.
IIS CERT is legally entitled to refuse requests for certification by organizations that are subject to, or whose production or activities are subject to restrictive measures, suspension or proscription by a public authority.

1.5 The certification issued by CERT IIS pertains exclusively to a single organization, where organization means a group, company, firm, enterprise, authority or institution, or part or combination thereof, whether incorporated or not, public or private, that has its own functional and administrative structure.
For organizations with multiple operating units, each operating unit can be defined as an Organization.

1.6 The Body guaranteeing the certifications issued by IIS CERT (ACCREDIA) may require its observers to participate in the audits performed by IIS CERT, in order to verify that the assessment methods adopted by IIS CERT comply with the applicable standards; the participation of the these observers is agreed in advance between IIS CERT and the Organization.

Moreover, ACCREDIA can require to directly make own audits at the sites of certified Organizations, in the modality named Market Surveillance, which consists of a brief one-day audit to verify the degree of confidence in the conformity of management system to specific requirements and the effectiveness of accredited certification process.

If the Organization does not agree to the aforementioned participation, the validity of the certificate can be suspended and afterwards revoked.

2 REFERENCES

CER_QAS 002 R	Rules for the use of the IIS CERT mark
CER_QAS 017 R	Rule for the assessments of systems, personnel, products – General Contract Conditions
CER_QAS 024 R	Rule for the certification of manufacturers according to: - EWF/IIW (ISO 3834, EMS, SMS) Schemes - EN 15085
EN ISO 9000	Quality Management Systems – Fundamentals and vocabulary
EN ISO 9001	Quality Management Systems – Requirements

EN ISO 14001	Environmental management systems – Requirements with guidance for use
BS OHSAS 18001	Occupational health and safety management systems – Requirements
EN ISO 3834-2	Quality requirements for the welding for fusing metal materials – Part 2: Comprehensive quality requirements
EN ISO 3834-3	Quality requirements for the welding for fusing metal materials – Part 3: Standard quality requirements
EN ISO 3834-4	Quality requirements for the welding for fusing metal materials – Part 4: Basic quality requirements
EN ISO 19011	Guidelines for auditing management systems
EN ISO/IEC 17000	Conformity assessment – Vocabulary and general principles
EN ISO/IEC 17021-1	Conformity assessment – Requirements for bodies providing audits and certification of management systems – Part 1: Requirements
IAF MD 1	Certification of Multiple Sites Based on Sampling
IAF MD 2	Transfer of Accredited Certification of Management Systems
IAF MD 5	Duration of QMS and EMS Audits
IAF MD 11	Application of ISO/IEC 17021 for Audits of Integrated Management Systems
IAF ID 4	Market Surveillance Visits to Certified Organizations
EA-6/02	Guidelines on the use of EN 45011 and ISO/EC 17021 for certification to EN ISO 3834
EA-7/04	Legal Compliance as a part of Accredited ISO 14001:2004 certification
RG-01 (doc. ACCREDIA)	Regulation for the accreditation of Certification and Inspection Bodies – General Requirements
RG-01-01 (doc. ACCREDIA)	Regulation for the accreditation of management system Certification Bodies
RG-09 (doc. ACCREDIA)	Regulation for the use of the ACCREDIA Mark
RT-05 (doc. ACCREDIA)	Directives for accreditation of Bodies operating the assessment and certification of QMS of construction companies (EA 28)
RT-09 (doc. ACCREDIA)	Directives for the accreditation of Bodies performing the certification of Environmental Management Systems (EMS)
RT-12 (doc. ACCREDIA)	Directives for the accreditation Bodies performing the certification of the workers' Health and Safety Management Systems
ACCREDIA provision	Provision regarding Accreditation in the SCR scheme [of 2012-02-23]

The documents of reference cited are applicable in their latest valid and/or revised edition (see also the following Note.

Note *Regarding ISO 9001 and ISO 14001, both edition 2008 and edition 2015 are applicable, up to the end of the transitional period.*

3 DEFINITIONS

In general the definitions apply of the standards of the ISO/IEC 17000 series (see § 2).
In addition, as regards the general terms relative to quality and the accreditation, the definitions of the EN ISO 9000 and EN ISO/IEC 17000 standards apply (with preference given to the second in case of differences), supplemented by the following.

Finding:	Feedback obtained by IIS CERT during audits conducted on Organizations and formalized in its audit reports. For the purposes of this Rule, findings are divided as follows: - nonconformity; - observations; - comments.
Nonconformity:	An Organization's failure to comply with a requirement established by the applicable regulatory

	references (document of reference (1), this Rule, CER_QAS 002 R and CER_QAS 017 R Rules). The condition of non-fulfillment of a requirement may be due to one or both of the following: a) failure to take into consideration or insufficient consideration of the actual requirement and/or failure to define or insufficiently define criteria and methods adopted to comply with the requirement; b) failure to implement or insufficient practical implementation of the aforementioned implementing criteria and methods. For the purposes of the provisions contained in these Rules, a finding is classified as nonconformity when the failure to meet the corresponding requirement in the manner specified above is such that it may compromise the value of the certificates issued by IIS CERT in terms of the effective and credible assurance of conformity of the object of the certifications. *Note: A finding defined by IIS CERT as "Nonconformity" is indicated on ISO/IEC 17021-1 (see § 2) as "major nonconformity".*
Observation:	The finding recorded by IIS CERT against the Organization is classified as an observation when there is a failure to meet the requirement, although it may be indicative of improper behavior by the Organization and as such requires correction, but is not such as to immediately compromise the value of certification issued under the terms stated above. *Note: A finding defined by IIS CERT as "Observation" is indicated on ISO/IEC 17021-1 (see § 2) as "minor nonconformity".*
Comment:	A finding raised by IIS CERT in regards to an Organization is classified as a comment when it is not followed when it is not the result of a finding of an objective situation of non-fulfillment of a requirement, but it is intended to prevent this situation from occurring (as potentially achievable) and/or provide guidance for improvement in the performance of the Organization.
Results:	Confirmation obtained by IIS CERT exclusively during preliminary and Stage 1 audits. In the first cases, they are instructions on the application status of the standard; in the second case, they are instructions which could, if not appropriately managed by the Organizations, turn into "remarks".
Note: (1) the following are considered as documents of reference: - ISO 9001, or - ISO 14001, or - OHSAS 18001, or - ISO 3834 (Part 2, 3 or 4).	

4 CERTIFICATION REQUIREMENTS

4.1 To get the certification from IIS CERT, a management system must satisfy, initially and over time, the requirements of the standard or the regulatory document of reference and those indicated in the following points, besides possible additional elements provided by the Accreditation Bodies (i.e. "RT" documents issued by ACCREDIA).
As part of the accreditation, in fact, IIS CERT follows specific documents of reference issued by the Accreditation Bodies.
These documents are available by contacting IIS CERT or the Accreditation Bodies directly (for example by visiting the relative websites).

4.2 In particular, to obtain the certification of the management system, the Organization must:

a) have established, kept active and fully operational a Quality Control System in total compliance with the requirements of the standard or regulatory document of reference.

The management system is considered completely operational when:
- the internal audit system is fully operational and can demonstrate its effectiveness;
- at least one review of the system has been conducted and documented by management;
- the objectives and processes necessary to achieve results in accordance with the requirements of the customers and the corporate policies have been determined;
- these processes have been developed;
- monitoring and measurements of the processes and products relative to the policies, objectives and requirements for the product have been carried out and recorded;
- actions for the continuous improvement of the processes have been implemented.

b) have a Manual (see Note 1) which:
   - defines the purpose/field of application of the management system, describes the principal processes and elements of the system and their interactions and includes or quotes the relative procedures documented. The description of the processes and their interactions must extend to all those developed by the Organization (even processes outsourced) necessary to achieve a specific product/service, decisive for purposes of the capacity of the product/service to meet the applicable requirements (this description can be made in various ways such as descriptions, flow charts or logograms, tables or matrices, etc.).
   - shows any exclusions of requirements (see Note 2) of the standard and/or production lines, within the limits allowed, adequately explaining the reasons;
   - takes into consideration the requirements of the standard and provides a description, even brief, of the resources and procedures implemented to ensure the conformity with these requirements;
   - includes an adequate description of the Corporate Organization.

Note 1 *The Manual is not required in case of certification of conformity according to ISO 9001:2015 and to ISO 14001:2015.*

Note 2 *The exclusions are not applicable according to ISO 9001:2015 and to ISO 14001:2015.*

4.3 The requirements listed in § 4.2 are checked by IIS CERT through an initial audit process composed of two stages:

a) Stage 1 audit, which can be carried out:
   - partly in the office (for a maximum of 10% of the total time anticipated) and partly at the Organization's site, or
   - completely at the site/s of the Organization.

b) Stage 2 audit, at the site/s of the Organization.

The particular features of the initial audit are itemized in the following chapter.

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5 INITIAL CERTIFICATION

5.1 General conditions

The Organizations which intend to obtain the certification of their management system must provide IIS CERT with the basic data of their Organization and relative activities performed and the location of the site/s, sending the specific application fully completed (available on the site www.iiscert.it), based on which IIS CERT formulates a financial offer (in the form of a contract to be signed).

This information is required in order to check in advance the application of some requirements of the standard and to prepare a suitable offer.

The Organizations, in case of acceptance of the economic offer, formalize the certification request by sending to IIS CERT the certification application, containing information on:

- required scope of certification required;
- sites interested in certification, with their processes and operations, human and technical resources (where applicable), legal obligations;
- processes outsourced by the organization that may affect conformity with the requirements;
- standard against which certification is requested;
- possible presence of external consultants, with details;
- possible presence of shifts.

Upon receipt of the application, IIS CERT carry out a review of the documentation received in order to ensure that:

- the information received is sufficient to develop an audit program;
- any differences of understanding have been clarified;
- IIS CERT itself has the skills to achieve the required certification activities;
- the scope of certification, sites of the applicant, time required for auditing and other factors which could affect the specific requested certification activities have been taken into account.

Carried out the review, IIS CERT sends the organization written confirmation of acceptance of the application.

The application of the Organization, which makes specific mention of these rules, and its acceptance by IIS CERT contractually formalize the relationship between IIS CERT and the Organization and the applicability of these rules.

The contract between IIS CERT and the organization includes:

- the initial audit comprising two stages and, if successful, the issue of the certificate;
- subsequent surveillance and recertification audits;
- any additional services specified in the offer (eg. one preliminary audit, if required).

5.2 Preliminary audit

Following the Organization's formal application, a preliminary audit of the system can be conducted before the evaluation audit, to check the general application status.

The preliminary audit is conducted in order to review the requirements of the standard, without following the formal procedures anticipated for the evaluation activity (i.e. confirmation lists are not used).

The Organization is informed of the result in an audit report.

The results are recorded as "findings" (see § 3).

5.3 Required documentation

Together with the certification application, or afterwards, the Organization must make the following documentation available to IIS CERT:

- management manual of the Organization (not required in case of application for certification of conformity according to ISO 9001:2015 and to ISO 14001:2015), which describes the policy, objectives and programs for the management system;
- copy of the Certificate of Incorporation, as proof of the existence of the Organization and the activity conducted;
- map of the site or sites (not for ISO 9001);
- list of the principal laws and/or regulations applicable (to the product/service provided or necessary for the correct application of the management system);
- list of the current work sites with the description of the activities carried out there, if applicable.

IIS CERT may ask to review, at its discretion, also other documents in addition to those listed above, deemed important in order to assess the management system (see also the following Note).

Note *If IIS CERT take into account a possible certification already granted by others, the company shall also make available the relevant evidences (such as reports, corrective actions, etc.); the transfer of a certification issued under accreditation is covered in detail in § 12 of this Regulation.*

5.4 Stage 1 Audit

IIS CERT notifies to the Organization the names of the Auditors assigned to carry out the Stage 1 and the Stage 2 audits (see also the following Note 1); the Organization can file an objection to the appointment of these Auditors, within 5 days of the appointment, justifying the reasons.

During the initial audit, the Organization must demonstrate that the Quality Control System is fully operational and that it actually applies the system and that the relative procedures are documented.

The purposes of the Stage 1 audit are:

- audit the customer's management system documentation;
- assess the location and particular conditions of the customer's site and have an exchange of information with the customer's staff in order to determine the level of preparation for the Stage 2 audit;
- review the status and the customer's understanding regarding the requirements of the standard, with particular reference to the identification of key services or significant aspects, processes, objective and operation of the management system;
- gather the information necessary concerning the field of application of the management system, the

processes and the location/s of the customer, including the relative legal and regulatory aspects and compliance with them;
- review the assignment of resources for the Stage 2 audit and agree with the customer on the details of that audit;
- focus on the planning of the Stage 2 audit, acquiring sufficient knowledge of the management system and the activities of the customer's site, with reference to the possible significant aspects;
- assess whether the internal audits and the review by management were planned and carried out and whether the implementation level of the management system provides the evidence that the customer is ready for the Stage 2 audit;

The outcome of the Stage 1 audit is communicated to the Organization in a specific Stage 1 audit report (see also the following Note 2), on which the results are listed, among other things, including those that could be classified as nonconformities during the Stage 2 audit: the latter will have to be removed before proceeding with the Stage 2 audit: these will have to be resolved before proceeding with the Stage 2 audit; the presence of particularly critical findings could lead to the postponement or cancellation of the Stage 2, as well as the need for significant changes with an impact on the management system could involve the repetition (total or partial) of the Stage 1 (both conditions would be specified in the report of Stage 1).

The actions undertaken by the Organization for the processing of the results are checked during the Stage 2 audit.

The Stage 2 audit must be carried out within a maximum of 12 months after the conclusion of the Stage 1 audit, after which the Stage 1 audit must be repeated.

Note 1 *In the assignment of auditors, IIS CERT takes into account the following elements:*
- *objectives, scope, criteria and estimated timing of the audit;*
- *possibility to make single combined, joint or integrated audits;*
- *global expertise necessary to achieve the audit objectives;*
- *certification requirements, including those of a legislative, regulatory and / or contractual;*
- *language and culture.*

Audit can also attended by one or more technical experts, upon agreement with the Organization.

Note 2 *If Stage 1 and Stage 2 are carried out consecutively, a single report may be issued which includes the outcomes of both phases.*

5.5 Stage 2 Audit

The Stage 2 audit is carried out at the Organization in order to check the correct implementation of the management system; in particular, the audit activity provides for the search of evidence related to:
- conformity with regard to all the requirements of the standard of the relevant management system;
- monitoring, measuring, reporting and review on the key performance targets;
- ability of the analyzed management system to fulfill all legislative, regulatory and contractual requirements;
- operational control of business processes;
- internal audit and management review;
- the responsibility of management with respect to the customer policies.

IIS CERT sends to the Organization, before carrying out the Stage 2 audit at the site/s, an audit plan which includes the description of the activities and the provisions for conducting the audit.

If the activities to be checked are carried out at several sites, the audit is conducted according to criteria established in advance and communicated by IIS CERT to the Organization.

5.5.1 Operational Details

5.5.1.1 Opening Meeting

Before performing the evaluation audit, the audit team (GV) holds the opening meeting, recording on the audit report the meeting with the Organization's Management or its Representatives and those responsible for the main departments.

During the meeting, the Responsible for the GV (RGV):
- introduces the members of the GV;

- explain and provide any clarifications on the audit plan;
- provides a brief summary of how the audit is conducted;
- requests the definition of the official channels of communication between the GV and the Organization;
- requests, if applicable, to involve more people in order to allow the Auditors to operate separately;
- confirms the Auditors' commitment to confidentiality and that of all the staff involved in the certification procedure;
- confirms that the possible consultant, used for the preparation of the documentation, strictly respects the role of observer;
- reaffirm that the audit is based on the sample method;
- specifies that the audit concerns the product/service relative to the certification, as defined in Stage 1;
- define the date and time of the closing meeting;
- introduces the ACCREDIA inspectors, when present.

5.5.1.2 Management of the audit

During the audit, the Organization is required to make available the staff and to grant free access to the company areas, the information, the documentation relative to the standard for which the certification has been requested, including the procedures or their equivalent, and to assist the IIS CERT Auditors.

The application of the requirements is checked through:

- interviews with personnel involved in the activities (at all levels);
- examination of the documents, procedures, instructions, Minutes of meetings, reports, etc to assess the conformity to the documents of reference;
- verification of possible exclusions;
- correct definition of the purpose of the certification.

The verification is carried out with the use of the applicable questionnaires on which the observations and shortfalls found can be noted.

Note *If, during the audits, having taken into account their random nature, non-compliances with the requirements of law not involving aspects directly correctly to the system assessed or the product inspected, but correlated to other aspects of the activities performed by the Organization should be incidentally detected by IIS CERT, these faults will be duly recorded by the Auditors separately from the audit report and promptly brought to the attention of the Management of the Organization being assessed so that arrangements can be made and applicable corrective actions arranged. The registration is also sent to the Management of IIS CERT for evaluations of the case.*

5.5.1.3 Audit team Meeting

At the end of the audit and before the closing meeting the AG will meet to;

- verify that is has considered all the requirements applicable to the standard object of the certification;
- describe the possible nonconformities in the appropriate report (Form CSQ 020);
- prepare the audit report in which possible observations and/or comments are listed.

5.5.1.4 Closing Meeting

The evaluation audit ends with the closing meeting, during which the RGV explains to the representatives of the Organization:

- any reports of nonconformity;
- the possible observations and/or comments (described in the audit report);
- the audit report.

The aforementioned documents are delivered to the representative of the Organization, which he signs as acceptance if he agrees and keeps a copy. If he does not agree, he explains his reservations in the special space of the audit report.

5.6 Conclusions of the audit

At the end of the Stage 2 audit, the Organization is given a copy of the audit report (see also the following

Note).

Note *The audit report includes or refers to the following items:*
- *IIS CERT identification;*
- *references and address of the Organization;*
- *type of audit;*
- *criteria, objectives and scope;*
- *any deviation from the audit plan, with justification thereof;*
- *any special circumstances that have had impact on the audit;*
- *identification of lead auditor and other auditors;*
- *dates and places where the audit activities were conducted;*
- *any identified findings;*
- *any significant changes that have occurred since the previous audit having impact on the management system;*
- *eventual performing of a combined, integrated or joint audit;*
- *any unresolved issues;*
- *statement that the audit was based on the sampling of available information;*
- *recommendation by the lead auditor;*
- *evidence of the proper use of the mark of IIS CERT;*
- *checking the effectiveness of the actions taken in response to previous audit findings (if applicable);*
- *statement on compliance and effectiveness of the management system;*
- *synthesis on the management system's ability to meet the requirements and expected results;*
- *conclusions on the adequacy of the scope of certification;*
- *confirmation that the audit objectives have been realized.*

The Organization may note its possible reservations regarding the findings expressed by IIS CERT in a special space of the audit report.

The contents of this report is subsequently confirmed by IIS CERT in a written communication. If no written communication is received from IIS CERT, the report is considered confirmed 15 days after its delivery to the Organization.

All possible nonconformities formalized by IIS CERT based on the criteria listed above must undergo the necessary processes and corrective actions by the Organization, which must be sent to IIS CERT within 30 calendar days of their issue for approval.
IIS CERT reserves the right within 15 calendar days to request changes relative to the contents of the audit report and the possible nonconformities made by the Auditors; after that deadline, both the report and the findings are considered approved, by tacit consent.
In the case of nonconformity, the certification and the extension will not be granted until the confirmation of the application of the necessary treatments, completion of the corresponding corrective actions and assessment of the effectiveness by IIS CERT (normally done by the lead auditor); the acceptance of such proposals and timetable for implementation will be communicated to the Organization in writing.
When it is not possible to verify the implementation of treatments and corrective actions within 6 months from the end of the stage 2, IIS CERT will make a second stage 2 before taking the certification decision.

In the case of observations, the certification is granted subject to approval, by IIS CERT, of a special plan of processes and corrective actions that the Organization must give IIS CERT within 30 calendar days from the issue of the relative observations.

5.7 Additional Audits

When nonconformities exist, the certification process is suspended. In case of observations whose number and/or type, in the audit team's opinion, could prejudice the correct operation of the management system, the certification process is also suspended.
In these cases, IIS CERT will conduct, within 6 months, an additional audit at the headquarters of the Organization, focused on checking the effectiveness of the processes and corrective actions proposed. If this audit is positive, the certification process resumes.

The additional audit can be performed at the Organization's site or based on documents at the IIS CERT office, based on the type of corrective actions to be checked in the audit team's opinion.
All the expenses in regards to any additional audits due to deficiencies in the management system are to be borne by the Organization.

If the additional audit has a negative outcome, IIS CERT revokes the certification (see also § 13).

5.8 Approval of the certification and issue of the certificate

The certification procedures which concluded favorably (closure of the nonconformities, acceptance of the plan for the closing of the observations) are submitted within 5 business days to a special deliberating body which, based on all the evidence collected by the RGV and possible information in the public domain which were significant for the certification, expresses the decision on the issue of the certification, within 5 business days of the submission.
If that decision is favorable, a certificate of conformity is issued for the management system being reviewed: the certification is made available to the Organization in electronic format in the reserved area of the IIS CERT website, within 5 business days from the date of the decision of its issue.
The validity of the certificate is subject to the results of successive annual surveillance audits and the three year renewal.
The frequency and extent of the subsequent audits to retain the certification are established by IIS CERT case by case through the drafting of an annual three-year audit program.
For details on the management and the validity of certificates of conformity issued by IIS CERT, refer to § 8.

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6 RETENTION OF THE CERTIFICATION

6.1 The Organization must maintain its management system in conformity with the standard of reference.

6.2 The Organizations must keep records of possible claims and the relative corrective actions undertaken and must make them available to IIS CERT together with the corrective actions undertaken as a result of observations made during the periodic audits.

6.3 IIS CERT performs periodic audits on the management system in order to assess whether the requirements of the standard of reference are being maintained.

The audits for the retention of the certification are divided into two types:

- monitoring audit, usually at annual intervals and in any case conducted at least once a year (for the management systems on occupational health and safety, see § C.6.3 in particular), performing a partial assessment at random on the system in accordance with the program listed as set forth in § 5.8;
- renewal audit (see § 5), with the reassessment of the management system.

6.4 The monitoring audits are conducted at the site/s of the Organization, according to a three-year program which makes it possible to assess, in the span of the three years, at least once, every point relative to the provisions included in the standard of reference according to which the management system was certified, taking into account the documents included in § 3.4.

During the monitoring audits, the following aspects will be taken into consideration:

a) internal audits and reviews by management;
b) a review of the actions undertaken following findings identified during the preceding audit;
c) the processing of the claims;
d) the effectiveness of the managements system relative to the achievement of the objectives;
e) the progress of the activities planned focused on continuous improvement;
f) the continuous operational control;
g) the review of every change.

The description of the activities and provisions for conducting the monitoring audit at the site/s is provided, in detail, in the monitoring audit plan that IIS CERT sends to the Organization, before carrying out the audit.

6.5 At least one monitoring audit must be performed with a frequency of not more than 12 months (for the management systems on occupational health and safety, see § C.6.3 in particular).
The date by when the audits must be performed is listed in the three-year audit program; this program may be modified by IIS CERT based on the preceding monitoring audits.

Any differences in the monitoring audits beyond these limits (and in any case not greater than 3 months),

due to justified reasons, must be agreed in advance with IIS CERT and must in any case be recovered at the first subsequent audit.

In any case, the first monitoring audit, following the initial certification, must be performed within twelve months of the closing of the Stage 2 audit (for the management systems on occupational health and safety, see § C.6.5 in particular).

6.6 IIS CERT furthermore reserves the right to perform audits at short notice or without notice (and additional) compared to those provided by the three-year program at the Organization:

- if it receives claims or reports, considered particularly significant, relative to the non-compliance of the management system to the requirements of the standard of reference and this Rule;
- relative to changes which have taken place in the Organization;
- to Organizations whose certification has been suspended.

In such cases, IIS CERT announced in advance of the reduced conditions under which such audits are conducted in a partial exception than indicated above.

In the case of refusal without valid reasons by the Organization, IIS CERT can start the process of suspension/revocation of certification.

If the claims and reports are considered justified by IIS CERT, the cost of performing the unannounced audit notice will be paid by the Organization.

6.7 The dates for the implementation of the monitoring audits are agreed with the Organization with adequate prior notification and are confirmed in a written communication.

The names of the qualified Auditors assigned to carry out the audit are communicated in advance by IIS CERT to the Organization, which may object to their nomination within 5 days of the appointment, justifying its reasons.

6.8 Please see the preceding § 5.5-f for the communication methods of the outcome of the audit.

The validity of the certificate is considered confirmed following the positive outcome of the monitoring audit (see also the following Note).

Note *The decision-making personnel of IIS CERT, in any case, monitor all the surveillance activities.*

6.9 When there are sufficient nonconformities and observations which, in the opinion of the audit team, could prejudice the correct operation of the system, the procedure is submitted to the deliberating body (see § 5.8), which can require the Organization to undergo an additional audit – within the time established by IIS CERT depending on the importance of the nonconformities/observations and in any case no later than 6 months from the end of the monitoring audit – aimed at checking the effectiveness of the procedures and the corrective actions proposed.

Should the nonconformities not be resolved within the time established or should the observations raised jeopardize the compliance of the products/services provided with the requests of the Customers and the applicable legal regulations, IIS CERT may suspend the certification until the nonconformities/ observations have been corrected or in any case in accordance with what is provided by § 13.1

All costs relative to any supplementary audits deriving from shortcomings in the management system are to be borne by the Organization.

7 RENEWAL

7.1 At the time of the recertification audit of the management system, anticipated every three years, the Organization must contact IIS CERT sufficiently in advance compared to the date provided on the three-year audit program, in order to be able to place the activity and agree on the implementation date of the recertification audit.

In particular, it is the Organization's responsibility to update in advance in writing the information necessary to issue renewal offers; without the updating of this information, IIS CERT issues the offer for the renewal bases on the latest information made available (see also the following § 7.2).

The date for the implementation of the recertification audit, agreed with the Organization with adequate prior notification, is officially confirmed in a written communication.

The names of the auditors appointed to perform the audit will be promptly notified by IIS CERT. The Organization may file an objection to the appointment, within 5 days of the appointment itself, giving its reasons.

7.2 The purpose of the recertification audit is to confirm that the conformity and effectiveness of the management system overall has been maintained and is based mainly on an on site audit to be carried, normally, with the same criteria as the Stage 2 audit.

In particular, the recertification audit will include an on-site audit which considers, among other things, the following:

a) the effectiveness of the management system overall in light of internal and external changes and its continuing pertinence and applicability to the field of application of the certification;

b) the commitment demonstrated to maintain the effectiveness and the improvement of the management system in order to improve the overall performance;

c) whether the operational nature of the management system contributes to the achievement of the Organization's policy and objectives.

The description of the activities and instructions for the recertification audit site(s) are reported in detail in the recertification audit plan IIS CERT sends to the organization before performing the audit .

If during the audit a change in the number of employees is noted which significantly influences both the length of the verification compared to the tables of the IAF MD 5 documents (see § 2), IIS CERT issues a special finding (Nonconformity or Observation) which the Organization must take charge of.

7.3 Following the positive outcome of the recertification audit, the audit team will submit to the deliberating body the proposal for recertification of the Organization in order to re-issue the certificate of conformity.
The certificate of conformity is re-issued by IIS CERT following the positive outcome of the review of the aforementioned proposal; the certificate is once again made available to the Organization in electronic format in its reserved area of the IIS CERT website.

The Organization will be informed in writing by IIS CERT of the approval or recertification and the certificate will then be issued.

For the details on the management and the validity of the certificates of conformity issued by IIS CERT, please see § 8.

7.4 The recertification procedure must conclude, with positive outcome before the expiry date of the certification listed on the certificate which cannot be extended by IIS CERT.

Consequently, the recertification audit must conclude positively in time to permit the approval by IIS CERT of the recertification proposal and the resulting re-issue of the certificate by the aforementioned date (at least one month before the expiry date listed on the certificate).

If the organization fails to comply with the above deadlines and does not obtain the reissued certificate within the date of expiry, the certificate must be considered as expired starting from the day following the expiry date shown on the certificate.

Any organization that wishes to be recertified after the date of expiry of the certificate must submit a new application and, as a rule, follow the entire procedure provided for the initial certification.

If the organization fails to comply with the above deadlines and does not obtain the reissued certificate within the date of expiry, the certificate must be considered as expired starting from the day following the expiry date shown on the certificate; IIS CERT will inform the Organization of the consequences.

If the renewal audit is carried out, for different reasons, after the expiry of the certificate, they may experience the following cases:

1) if the practices for the renewal began before the certificate expires, the audit shall follow the procedures laid down for the renewal;

2) if the renewal practices begin after the expiry of the certificate, the renewal audit shall follow the procedures laid down for the audit stage 2, provided the successful conclusion within a period of six months after this date;

3) if six months passed from the expiry of the certificate, the practices for a first assessment must be applied (stage 1 + stage 2).

In each of the cases listed above, in case of positive outcome of the audit, a new certificate is issued as of its approval date, with expiring date coherent with to the previous certification cycle.

Note *Upon request, the certificate can also show the expiry date of the previous certification cycle.*

7.5 If the number of nonconformities or observations, in the audit team's opinion, could prejudice the correct operation of the management system, the Organization must apply, effectively, the relative processes before the expiry date of the certificate of conformity.

IIS CERT will then perform an additional audit for the verification of the closure of those findings in time for the subsequent issue of the certificate.

The times established by which the Organization must undergo additional audit are indicated in the renewal audit report.

The additional audit can be carried out on site or on the documents in relation to the type of remedial actions to be assessed in the opinion of the audit team.

All the expenses in regards to any additional audits due to deficiencies in the management system are to be borne by the Organization.

7.6 In the event that the Organization does not intend to renew the certification, the certificate has to be considered as expired starting from the day following the expiry date shown on the certificate.

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8 MANAGEMENT OF CERTIFICATES OF CONFORMITY

8.1 The certificate of conformity issued by IIS CERT lists, at minimum, the following information:

a) the legal status of the organization undergoing certification (company name);
b) the standard of reference;
c) the types of processes carried out within the context of the corporate management system undergoing certification;
d) the results of the activities performed in terms of products supplied and services dispensed;
e) the operational units (sites) in which the activities being certified are carried out;
f) any specifications and clarifications deemed necessary or useful;
g) the references pertaining to the validity of the certification (issue dates of the certificate, current issue, expiry);
h) the reference to the ACCREDIA Technical Regulations of applicable scheme/sector, if applicable.

The items c) and d) constitute, overall, the "purpose of certification".

The expiry is calculated, for every three-year period of validity, starting from the date of the deliberation of the first certification.

8.2 The validity of the certificate, over the three-year period of validity, is subordinate to the result of the subsequent monitoring audits.

For every renewal audit that has a positive outcome, as listed in the preceding § 7, the certificate of conformity is reissued.

The validity of the certificate can be suspended, revoked or waived in accordance with that which is provided in § 13.

IIS CERT publishes and keeps updated directly on its own website:

a) the list of certified Organizations;
b) the validity status of the certificates issued.

Upon request, IIS CERT provides information on the reasons for the invalidity of the certificate.

9 MODIFICATION OF CERTIFICATION AND COMMUNICATION OF CHANGES

9.1 The Organization in possession of the certification can request its modification or extension by submitting a new request for certification, complete with the documentation list in § 5.2 duly updated.
IIS CERT reserves the right to examine the requests case by case and to decide on the assessment methods for the purposes of the release of a new certification, in conformity with what is provided by the general contract terms and conditions established in the ‘‘General Rules for the Certification of System, Personnel, Product - General Contract Terms and Conditions” (see § 2) and the standard of reference for the management system.

9.2 During the period of validity of the certification the organization must promptly communicate any significant changes to IIS CERT in regards to:

- company organization;
- change in company name and/or change in the address of the registered office and/or of the production units;
- production sites;
- procedures;
- products;
- company staff.

In relation to the type of changes made, IIS CERT reserves the right to:

a) conduct an unscheduled monitoring audit to assess the influence of the changes on the management system;
b) review the contract terms for subsequent visits.

Below please find some cases.

9.3 In cases in which the legal entity owner of the certificate or within which the certified Organization is not included, IIS CERT takes all the information necessary to understand the entity and the nature of the changes in the policies, activities and organization of the Organization; in cases in which there is or could be a change in policy and/or activity and/or organization, IIS CERT assesses the possibility of activating a new certification procedure with an initial visit of adequate dimension and planning to ensure the implementation of all the necessary checks: the purpose and all the other information in the certificate will be adjusted to the new situation.

The certificate will be reissued changing:

- the number of the certificate;
- name of the Organization;
- the first issue date;
- current issue date.

9.4 In cases in which the changes in the legal entity do not have any significance for the organization (i.e. the purpose of the Articles of Association does not change, the ownership structure and/or the Board of Directors or the Managing Director, etc. do not change), IIS CERT assesses the conditions and may review the possibility of retaining the number, the issue date and possibly the purpose of the certificate.

9.5 In cases in which the Organization requests changes or extensions to the certification (i.e.: addition of products, processes, materials, sites other than those certified), the changes are to be considered as an extension of the field of application of the certification(for occupational health and safety management systems, see § C.9.6 in particular), with the start of the relative decision process.

9.6 IIS CERT reserves the right to examine the requests case by case and to decide on the assessment methods, including contractual changes, implementation of unscheduled audits (additional), for the purposes of the release of a new certification or the extension of the currently valid certification.
The decision made in this regard are recorded.
The Organization's refusal is equivalent to withdrawal from the contract.

10 MULTISITE ORGANIZATIONS

10.1 Should an Organization operate in several permanent sites and a single certification is requested, the audit activities can be carried out at random of the sites undergoing the audit, provided:

- the processes of all the sites are basically the same and are performed with similar methods and procedures. When faced with different processes in different locations, they must be connected (i.e. production of electronic components in one place, assembly of those same components performed by the same Organization in various other locations);
- the management system is managed and administered centrally and is reviewed by central management.

In addition, the Organization must demonstrate that the central office has established a management system that complies with the standard of reference and that the entire Organization meets its requirements.

In particular, at least the following activities must be managed by the central department of the Organization:

- Assessment of the training needs;
- Check of the documentation and its amendments;
- Review of the Management System by management;
  Management of the claims;
- Assessment of the effectiveness of the corrective and preventive actions;
- Planning and implementation of the internal audits and assessment of their results;
- Existence of different legal requirements.

Before the initial audit by IIS CERT, the Organization must have performed an internal audit at every site and checked the conformity of its management system with the standard of reference.

10.2 If the Organization complies with the preceding requirements, IIS CERT in any case checks the feasibility of sampling all the sites and, if need be, assesses whether to limit this sampling due to:

- Requirements connected to variable local factors;
- Sectors or activities which do not come under the purpose;
- Dimensions of the sites suitable for a multi-site audit (for the management systems on occupational health and safety, see §§ C.9.6 and C.10.1 in particular).
- Changes in the local implementation of the management system, such as the need to turn often to the use, within the framework of the management system, of plans related to different activities or to different contractual or regulatory systems;
- Use of temporary sites (operational work sites).

In case of Organizations that provide services, if the sites in which the activities subject to certification are not all ready at the same time to be submitted for the certification, the Organization must inform IIS CERT in advance the sites that it wishes to have included in the certification and those which should be excluded.

10.3 Based on the information provided by the Organization, IIS CERT prepares the applicable sampling plan, based on the rules of the IAF MD 1 document (see § 2).

In general, this activity is performed during the audit process and may also be performed after the audit has been completed at the central office, which must always undergo an audit; in any case, IIS CERT notifies the central office which sites must be part of the sampling.

10.4 IIS CERT issues a single certificate with the name and address of the Organization's central office.

A list of all the sites to which the certificate refers will be made on the certificate itself, or on an attachment.

The Organization can be issued with an extract of the certificate for each site covered by certification, provided it indicates the same purpose or sub-element and includes a clear reference to the main certificate.

10.5 For any nonconformities and/or observations found in an individual site during the audits, the Organization must assess whether they refer to shortfalls attributable to several sites and if need be must adopt corrective actions both at the central office and at the other sites.

If, instead, the nonconformities and/or observations are not the aforementioned type, the Organization must provide sufficient evidence and reasons to limit its follow-up corrective action.

If nonconformities are found even in a single site, the certification procedure is suspended for the entire network of sites listed, until the nonconformities have been correct and in any case in accordance with what is provided in § 10.1.

It is not admissible for the Organization to exclude from the purpose of the certification process that/those site/s to get around the obstacle created by the existence of a nonconformity in a single site.

10.6 The Organization must keep IIS CERT informed on the closing of any site covered by the certification. If this information is not communicated, IIS CERT can assess whether to proceed in accordance with § 10.1.

In regards to certification that already exists, additional sites can be inserted as a result of surveillance or recertification audits or following specific extension audits.

11 SPECIFICS FOR THE EA 28 AND EA 35 SECTORS

In the case of Organizations operating in the EA 28 or EA 35 Sectors, the following applies:

a) at the time of the initial certification, all the types of activities must undergo audits at the building site, with the following clarifications:
   - if at a single site procedures have been carried out attributable to several implementation processes, the audit at the building site can be considered valid for all of them;
   - at least one site must be at stages of significant progress in the works;

b) annual monitoring anticipates at least one audit at the building site/site so that, during the period of validity of the certification, all the implementation processes coming under the purpose of the certification undergo assessment (see also following Notes).

Note 1 *The purpose of the certification will in any case only list the implementation processes that were assessed at least twice in the past three-year certification period, barring possible extensions which occurred during the three-year period and/or during the same renewal assessment.*

Note 2 *Any changes relative to what was scheduled or defined must be recorded and, in the most critical cases (for example, the lack of open building sites), submitted to the Decision-making Body*.

12 TRANSFER OF ACCREDITED CERTIFICATES

12.1 If an Organization with valid certification issued by another Certification Body (CB) of management systems (hereinafter "*issuing CB*"), accredited by an Accreditation Body (AB) belonging to the IAF MLA mutual recognition agreement, wants to transfer its certification to IIS CERT, the request for certification pursuant to § 5.1. must be sent to IIS CERT, specifying the reasons for the transfer request.

The Organization, if the financial quotation is accepted, must send to IIS CERT the request for certification attaching the following documents:

a) copy of the certificate issued by the *issuing CB*, which is still valid;

b) copy of the certification audit report, or the last renewal audit report, and the subsequent surveillance audit reports;

c) copy of the last management review.

The Organization must furthermore communicate to IIS CERT:

- any observations or reports received by the national or local authorities;
- any claims received and the relative actions undertaken.

The aforementioned documentation is reviewed to assess whether the purpose of the certification is

included among the purposes for which IIS CERT is accredited, the validity of the certification issued by the *issuing CB* and the closing status of certain findings.

If the certification issued by the *issuing CB* is suspended, or if it is not possible to assess the validity of the certificate, this certification cannot be accepted to the transfer procedure.

The aforementioned assessments may include an audit at the Organization which requested the transfer of the certification, lasting one day.

In particular, the audit at the Organization site is mandatory if it is not possible:

- to establish any contact with the *issuing CB*;
- to receive a confirmation of the validity of the certificate by the *issuing CB*;
- get hold of the entire audit documentation described above (including check lists duly compiled) relevant to the certification cycle in progress.

In any case, IIS CERT issues a report on all the assessments performed before the audit on site, also taking into account the provisions of the *pre-transfer review* document listed in the IAF MD 2 guide (see § 2).

If the aforementioned activities conclude positively, IIS CERT will make a special *pre-transfer* decision, followed or not by the issuing of the certificate (in any case valid in all respects) and its relevant availability to the client, depending on the timing for the audit on site; the certificate keeps, as a rule, the expiring date already established by the CB that issued the previous certificate.

In general, also for the surveillance audits and renewal audit, the same programming, already established by the CB that issued the previous certificate, is maintained.

13 SUSPENSION, RESTORATION AND REVOCATION OF THE CERTIFICATION

13.1 The validity of the certificate of conformity can be suspended in accordance with the general terms and conditions established in the “General Rules for the Certification of the System, Personnel, Product - General Contract Terms and Conditions” (see § 2) and in the following specific cases:

- if the Organization does allow the scheduled audits to be conducted at the intervals requested;
- if nonconformities are found and not resolved within the time limits set by IIS CERT;
- if the Organization has not respected the terms set for the notification of corrective actions following nonconformity/observations indicated by the audit report;
- if the organization has made significant modifications to the Site(s) or moves to other site(s) without advising IIS CERT of the changes;
- if the Organization has made significant changes to its Quality Control System that had not been accepted by IIS CERT;
- in the presence of major restructuring of the Organization not disclosed to CERT IIS;
- due to refusal or barrier to the participation in the audits by the observers of an Accreditation Agency;
- due to the proof that the management system does not ensure compliance with the binding laws and Rules applicable to the products/services supplied, the activities and/or the site/s;
- identification of any justified and serious claims received by IIS CERT.

The Organization may furthermore ask IIS CERT, with justified reasons, to suspend the certification for a period of time generally not longer than 6 months and in any case not past the expiry date of the certificate.

The suspension is notified in writing, specifying the conditions for restoring the certification and the deadline by when they must be implemented: during the suspension period, the certification of the management system of the Organization is temporarily not valid.

The suspension of the validity of the certificate is made public by IIS CERT directly on its website as provided in § 8.2.

13.2 The restoration of the certification is subordinate to the verification that the shortfalls have been eliminated which had caused the suspension through an in-depth audit which assesses the compliance of the management system with all the requirements of the standard of reference.

The restoration will be notified to the organization in writing and made public by IIS CERT on its website as required by § 8.2.

13.3 Failure to comply with the conditions pursuant in § 13.2. by the prescribed deadline entails the revocation of the certificate of conformity.

The revocation of the certificate of conformity can be decided in accordance with the general terms and conditions of the contract established in the "Rule for the assessments of systems, personnel, products – General Contract Conditions" (see § 2) and in the following specific cases:

- when circumstances arise, such as those listed in § 10.1 for the suspension, which are judged particularly serious;
- if the Organization suspends its activities or services included in the certified management system for a period of time generally over 6 months;
- if the organization does not accept the new economic conditions established by IIS CERT for any modification of the contract;
- in the case of multisite organizations, if the headquarters or one of the sites does not meet the criteria necessary for the maintenance of the certificate;
- for any other serious reason, in the opinion of IIS CERT, such as for example, but not limited to, the proven inability of the system to pursue its objectives of complying with the legislative or contractual or product safety obligations.

The revocation of the certificate of conformity is notified in writing to the Organization and is made public by IIS CERT as provided in § 6.3.

Following this revocation, the Organization may not under any circumstance use the certificate of conformity.
The Organization's certificate of conformity will also withdrawn from the restricted area of the IIS CERT website, after prior and formal information.

The revocation is furthermore notified by IIS CERT the SOA concerned (applicable only in Italy, within the deadlines provided by this administrations.

Any Organization which after the revocation wishes to be re-certified must submit a new application and follow the entire procedure.

14 WAIVER OF THE CERTIFICATION

14.1 The certified Organization can send a formal notification of waiver of the certification to IIS CERT, before the certificate's expiry, including in the case in which the Organization does not wish or cannot adapt to the new instructions imparted by IIS CERT.
Upon receipt of this information IIS CERT will begin the process of changing the status of the certificate to not valid. In general, within one month from the date of the communication IIS CERT will update the status of validity of the certificate.
At the expiry, the Organization's certificate of conformity will also be withdrawn from its reserved area of the IIS CERT website.

15 ALLIGNEMENT OF THE VISIT DATES FOR VARIOUS CERTIFICATIONS

15.1 If an Organization certified at different times, according to different standards, files an official request to combine the dates of the subsequent audits, IIS CERT may agree following review of the request and registration of the considerations/reasons which led to the decisions, by reissuing the certificates, without however performing audits at intervals of greater than 12 months.

If the surveillance audits should be combined with audits of other schemes of management systems both the planning of the audits and the report will indicate clearly the aspects relative each system (see also the following Note).

Note *In case of a combined audit, IIS CERT will appoint a lead auditor with in-depth knowledge of at least one standard*

regarding the interested management systems and with awareness of the other(s).

16 REGISTRATION DOCUMENTS

16.1 The registrations of the activities performed are stored electronically.

In general are the following documents are kept (each as applicable):

- quotation request,
- quotation/order,
- application for certification,
- acceptance of the application,
- registration in the CCIIA,
- procedures,
- appointment of the Lead Auditor and other Auditors (if required),
- justification for the determination of audit duration,
- justification for the methodology used for the sampling,
- comments on the quality manual or the procedures,
- preliminary audit report (if any),
- closing of the document review,
- notification of the audits,
- audit plan and program,
- questionnaires used during the audits,
- reports of nonconformity and/or observations (if any),
- audit report,
- evidences of treatments and corrective actions (if any),
- decision records;
- copies of the certificates issued by IIS CERT,
- complaints and appeals (if any), with relevant subsequent actions,
- communications from and to the Organization.

Records on organizations with certification that is no longer valid shall be kept for six years from the date of the last audit performed.

17 CONTRACTUAL CONDITIONS

17.1 The provisions included in the “General Rules for the Certification of the System, Personnel, Product - General Contract Terms and Conditions” (see § 2), in the version in force, apply for the contract terms and conditions.

ANNEX A Particular aspects for the certification of quality management systems

A.1 Scope and Field of Application

A.1.1 The additional, not replacement, rules applied by IIS CERT for the certification of quality management systems compared to what has already been defined previously in the General Part, are defined in this Annex.
Only the points of the General Part are included for which additional rules are applicable and the relative numbering corresponds.

A.1.3 IIS CERT issues the certification in accordance with the requirements of EN ISO/IEC 17021-1 (see § 3) to Organizations whose management system on quality has been recognized as complying with all the requirements provided by the standard ISO 9001.
Furthermore, upon request, IIS CERT can conduct assessments of conformity on a Quality Management System in accordance with other regulatory documents of reference and, if need be, issue the relative certification.
In particular, these Rules also apply for the certification of conformity to the ISO 3834 series of standards, when the activity is managed within the framework of the ISO/IEC 17021-1 accreditation: for the details on this activity, please see Annex A of the CER_QAS 024 R Rules (see § 2).

A.3 Definitions

SGQ: Quality Management System.

A.4 Requirements

A.4.1 To earn the certification from IIS CERT, an SGQ must satisfy, initially and over time, the requirements of the ISO 9001 standard and the additional ones provided by the Accreditation Bodies (example: Documents ACCREDIA RT-04, RT-05, RT-20).

A.4.2 The SGQ is considered completely operational when, in addition to that which is established in the General Part:

- actions have been implemented which ensure constancy in the production methods and in the quality of the products/services supplied.

A.4.3 In addition to what is established by the Rules, the Organization must notify the IIS CERT:

- possible elements of the standard of reference that it does not consider applicable to its Organization or which require interpretation or adaptation, clearly indicating the reasons.

A.4.4 In case of application for the certification of conformity according to ISO 9001:2008, together with the application, or afterwards, the Organization, in addition to what is established by the Rules, must also make the SGQ Manual available to IIS CERT which must include:

- description of the processes and their interactions;
- the reasons for excluding possible elements of the standard of reference that it does not consider applicable, or which require interpretation or adaptation;
- the list of the principal laws and/or regulations applicable (to the product/service provided or necessary for the correct application of the quality management system.

A.9 Modification to certification: transition from ISO 9001:2008 to ISO 9001:2015

An Organization holding the certification of conformity according to 9001:2008 can ask the transition to ISO 9001:2015 during a surveillance audit already planned or during a renewal or extra audit (therefore with a single audit): in the first two cases IIS CERT will add an additional time than the existing contract to have certainty that all activities are covered both in the face of the existing standard and of the new standard.

ANNEX B Particular aspects for the certification of Environmental Management Systems

B.1 Purpose and Field of Application

B.1.1 The additional and/or replacement rules applied by IIS CERT for the certification of environmental management systems compared to what has already been defined previously in the General Part, are defined in this Annex.
Only the points of the General Part are included for which additional rules are applicable and the relative numbering corresponds.

B.1.3 IIS CERT issues the certification in accordance with the requirements of EN ISO/IEC 17021-1 (see § 3) to Organizations whose environmental management system has been recognized as complying with all the requirements provided by the standard ISO 14001.

B.3 Definitions

SGA: Environmental Management System.

B.4 Requirements

B.4.1 To earn the certification from IIS CERT, an SGA must satisfy, initially and over time, the requirements of the ISO 14001 standard and the additional ones provided by the Accreditation Bodies (for example: ACCREDIA RT-09).

B.4.2 As replacement of that which is established by the corresponding § 4.2 of the General Part, to obtain the certification of its SGA, the Organization must:

a) have performed a preliminary environmental analysis of the site/s which includes:
   - a description of the type of activities carried out at the Site/s for which the certification of the SGA is requested;
   - identification of the environmental aspects associated with its activities and the relative impact;

b) have a Manual which:
   - defines the scope of application of the SGA, describes the principal elements of the system and their interactions and includes, or refers to, the relative documented procedures;
   - takes into consideration the requirements of the Standard and provides a description, even brief, of the resources and procedures implemented to ensure the conformity with these requirements;
   - includes an adequate description of the Corporate Organization.

c) have established, kept active and completely operational an SGA in total compliance with the requirements of the standard ISO 14001.

The SGA is considered completely operational when:

- it has been applied for at least three months;
- the internal audit system is fully operational and can demonstrate is effectiveness;
- at least one review of the system has been conducted and documented by Management;
- the significant environmental aspects have been assessed and identified;
- the objectives and the relative environmental programs have been established and documents;
- monitoring has been conducted and recorded of the environmental impacts and checks of the activities associated with them;
- actions for the continuous improvement an d prevention of the pollution have been implemented.

B.5 Initial Certification

B.5.1 In addition to what is established by the corresponding § 5.1 of the General Part, the Organization must inform IIS CERT of possible activities/sites excluded from the field of application of the SGA in order to assess the admissibility of these exclusions.

B.5.2 As replacement of that which is established by the corresponding § 5.2 of the General Part, together with the certification application, or afterwards, the Organization must make the following documentation available to the IIS CERT:

a) final report of the preliminary analysis of the site/s including

- lay-out of the site/s;
- manual of the environmental management that describes the Environmental Policy, Environmental Objectives and Program(s) and SGA of the Organization (last valid revision)
- organization chart of the Organization;

b) list of the internal procedures significant for environmental management purposes;

c) list of the environmental authorizations held by the Organization and list of the environmental requirements applicable to the Organization by filling out the “List of Environmental Authorizations and Requirements” form (attached to the offer) or by providing equivalent documentation;

d) Copy of the Certificate of Incorporation or equivalent document, as proof of the existence of the Organization and the activity conducted;

e) List of the current work sites with the description of the activities carried out there, if applicable.

IIS CERT may ask to review, at its discretion, also other documents in addition to those listed above, deemed important in order to assess the management system.

The aforementioned documentation is assessed by the IIS CERT for conformity with the standard of reference and the requirements of this Rule.
The result of this review is communicated to the application with a copy of the document review report (if conducted at the offices of the IIS CERT); any findings encountered in the documentation that are considered critical must be resolved by the Organization, at the satisfaction of IIS CERT before continuing the certification process.
The aforementioned documentation is, in general, kept for the archives by IIS CERT.

If the Stage 1 audit is conducted completely on-site, the result of the documentation review is included in any case in the document review report and will be delivered to the Organization together with the Stage 1 report as provided in § 5.3 of the General Part.

B.5.3 As replacement of that which is established by the corresponding § 5.3 of the General Part, during the Stage 1 audit, the following will be checked:

a) that the Organization has documented the assessment of the significant environmental aspects and the reliability of that assessment in relation to the type of Organization;

b) that the Organization has all the necessary valid environmental authorizations, relative to its activity;

c) that the Organization is in compliance with the requirements included in the documents listed in letter b) as well as with the requirements required by the environmental legislation applicable to it.

If the items specified in the aforementioned letters a) and b) are not formally satisfied, please refer to the explanation in § 5.6.

B.5.4 In addition to that which is established by the corresponding § 5.4 of the General Part,

- the audit is also conducted based on the Preliminary Environmental Analysis document in the updated revision;
- during the visits to the site/s, assessments will also be conducted on the installations and meetings will be held with the Organization's personnel involved in the SGA.

B.5.6 In addition to that which is established by the corresponding § 5.6 of the General Part, a situation which could reduce the ability of the SGA to ensure the control of the environmental aspects/impacts and/or the compliance with the legislation is also considered a nonconformity.

Furthermore, without the environmental authorizations or equivalent documents, required by current legislation, the certification process is suspended unless the Organization is at least able to demonstrate:

a) that it has submitted the complete and correct request for authorization at least far enough in advance to allow the Competent Authority to issue the authorization and to have correctly implemented all the steps anticipated for the authorization process;

b) to reproduce objective proof pertaining to formal reminders forwarded to the authorities in question, following the legal expiries to which those authorities are required to comply;

c) in any case comply, if present, with the limits provided by the law.

The deadline listed in point a) can be considered interrupted until the response is sent when the Authority requires additions to the documentation sent. Should the law not indicate a specific deadline, it may be found in regulations of a general nature, in administrative procedures or in internal regulations which the competent Authority follows to manage specific procedures.

If no deadline can be found, a six-month deadline can be considered reasonable and prudential (except in the cases in which the legislations anticipates the so-called “silent denial”).

If findings are verified during the audit, connected to the failure to comply with the binding legislative requirements in the environmental field(namely legal limits and/or provisions and limits and/or requirements listed on authorizations or other prescribing documents, etc.),the certification process is suspended, except in particular cases, until the Organization demonstrates its compliance with these requirements.

B.6 Retention of the Certification

B.6.2 In addition to that which is established by the corresponding § 6.2 of the General Part, the Organization must maintain registrations relative to:

- environmental aspects/impacts;
- environmental incidents/emergencies which occurred at the site/s and other events which could potentially have had a negative effect on the environment;
- possible claims relative to the environmental impacts produced by it;
- possible observations or reports received by the national or local authorities in charge of environmental control

and must make them available to IIS CERT together with the corrective actions undertaken during the periodic audits.

The Organization must keep IIS CERT quickly informed regarding the existence of possible observations/reports received by the national or local authorities in charge of environmental control or situations of legislative nonconformity for all the activities carried out by the Organization regardless of the field of application of the SGA.

B.9 Modification to certification: transition from ISO 14001:2008 to ISO 14001:2015

An Organization holding the certification of conformity according to 14001:2008 can ask the transition to ISO 14001:2015 during a surveillance audit already planned or during a renewal or extra audit (therefore with a single audit): in the first two cases IIS CERT will add an additional time than the existing contract to have certainty that all activities are covered both in the face of the existing standard and of the new standard.

B.10 Multi-Site Organizations

B.10.1 In addition to that which is established by the corresponding § 10.1 of the General Part, the following activities must also be managed by the central office of the Organization:

- environmental analysis of the sites;
- changes to the associated aspects and impacts for the environmental management systems.

ANNEX C Particular aspects for the certification of the Occupational Health and Safety Management Systems

C.1 Purpose and Field of Application

C.1.1 The additional and/or replacement rules applied by IIS CERT for the certification of occupational health and management systems compared to what has already been defined previously in the General Part, are defined in this Annex.
Only the points of the General Part are included for which additional rules and/or changes are applicable and the relative numbering corresponds.

C.1.3 IIS CERT issues the certification in accordance with the requirements of EN ISO/IEC 17021 (see § 17021) to Organizations whose management system on occupational health and safety has been recognized as complying with all the requirements provided by the standard OHSAS 18001.

C.1.5 The certification issued by the IIS CERT refers exclusively to the individual Organization, if by Organization, one means a group, company, activity, firm, agency or institution, or their parts or combinations, in associated form or otherwise, public or private, which has its own operational and functional organization and which depends completely on a single Employer with total responsibility for the occupational health and safety management system.

C.3 Definitions

In general, the terminology listed in the Standard OHSAS 18001 applies.

SGSSL: Occupational Health and Safety Management System (or in the Workplace.

C.4 Requirements

C.4.1 To earn the certification from IIS CERT, an SGSSL must satisfy, initially and over time, the requirements of the OHSAS 18001 standard and the additional ones provided by the Accreditation Bodies (i.e.: ACCREDIA RT-12 regulation).

C.4.2 In particular, to obtain the certification of the SGSSL, the Organization must:

a) make available a formal statement of awareness of the fact that the compliance with the binding standards regarding occupational health and safety are an essential and indispensable prerequisite for the implementation of an SGSSL and that its Organization has already arranged to assess the existence of such a prerequisite;

b) provide the Chamber of Commerce information (copy of the Certificate of Incorporation or equivalent document), the list of the human resources and the technical and logistic resources and the existence or otherwise of prior penalties and/or sentences relative to occupational health and safety aspects;

c) have conducted a preliminary analysis which included:
- a detailed description of the type of activities carried out at the Site/s for which the certification of the SGSSL is requested and the processes to be submitted for assessment, including the laws and regulations that govern them;
- identification of the dangers to occupational health and safety associated with its activities and relative risks and the procedure for promptly identifying the dangers, for the assessment of the risks and for the implementation of the necessary control measures;

d) make available:
- a copy of the documentation that describes the SGSSL including the list of the identifying details of the legislation relative to the health and safety of the workers mandatory for the type of activity carried out by the Organization;
- the procedure for promptly identifying the dangers, for the assessment of the risks and for the implementation of the necessary control measures;
- the procedure for identifying potential accidental events and potential emergency situations;
- all the documents pertaining to the risk assessment, if applicable (DVR, DUVRI, POS PSC, etc.).

C.5 Initial Certification

C.5.1 In addition to what is established in the General Part, the Organization must inform IIS CERT of any sites temporarily excluded from the field of application of the SGSSL in order to assess the admissibility of these exclusions (see also § C.10.1 in this regard).

C.5.2 Together with the certification application, or afterwards, the Organization, in addition to what is established in the General Part, must also make available to the IIS CERT a final report of the Organization's preliminary analysis.

The aforementioned documentation is assessed by IIS CERT for conformity with the standard of reference and the requirements of this Rule.

The result of this review is communicated to the application with a copy of the document review report (if conducted at the offices of the IIS CERT); any findings encountered in the documentation that are considered critical must be resolved by the Organization, at the satisfaction of the IIS CERT before continuing the certification process.

The aforementioned documentation is, in general, kept for the archives by IIS CERT.

If the Stage 1 audit is conducted completely on-site, the result of the documentation review is included in any case in the document review report and will be delivered to the Organization together with the Stage 1 "on-site" report as provided in § 5.3.

C.5.3 During the Stage 1 "on-site" audit, the qualified Auditors of IIS CERT, conducting also visits to the site/s and interviews with the personnel of the Organization, verifies at least:

a) that the documentation of the management system, including the procedures, covers all the requirements of the Standard of Reference;
b) that a complete audit cycle extended to all the sites and the relative review by management has been performed;
c) that the management system includes a solid, dynamic and participated process of identification of the dangers and assessment of the relative risks also including those resulting from the processes implemented by suppliers operating, even sporadically, at the site/s being certified or those relative to visitors being present;
d) the existence or effectiveness of adequate maintenance programs and/or systems;
e) that the identification and analysis process of the dangers and the assessment of the risks is described in a specific procedure, which specifies over time the criteria for monitoring these risks and which involves the personnel assigned to the various processes;
f) that the identification and analysis of the dangers and the assessment of the relative risks are, actually, the input for the process of continuous improvement;
g) that all the applicable documents pertaining to the risk assessment (DVR, DUVRI, POS PSC, etc.) have been prepared;
h) that adequate objectives for occupational health and safety exist and that these objectives are supporting by technical and financial planning and programming; that the objectives and indicators are coherent with the assessment of the risks;
i) that at least the first review has been carried out by management;
j) that the training and information plan of the human resources is defined based on the relative analysis of the requirements and implemented;
k) that a procedure has been defined for the analysis of the nonconformities, the incidents, the "almost incidents" and the accidents;
l) that the Organization has the necessary valid authorizations regarding health and safety, relative to its activities;
m) that the Organization is in compliance with the requirements included in the documents listed in letter k) as well as with the requirements required by the health and safety legislation applicable to it.

If the items specified in the aforementioned letters l) and m) are not formally satisfied, please refer to the explanation in § 5.6.

C.5.4 The audit is conducted by qualified IIS CERT Auditors based on the Stage 1 audit report and the following documents, in addition to those provided by the General Part, prepared by the Organization in the updated revision:

- Stage 1 audit report,
- applicable risk assessment documents (DVR, DUVRI, POS PSC, etc.).

C.5.5 Stage 2 Audit always calls for:

- the assessment of the night shift (if applicable);

- a confidential interview of the Company Physician (MC);
- a confidential interview of the Workers' Safety Representative (RLS).

The evaluation of a site or a process can never be partial.

C.5.6 Without the occupational health and safety authorizations or equivalent documents, required by current legislation, the certification process is suspended.

If findings are verified during the audits, connected to the failure to comply with the binding legislative requirements in the occupational health and safety field(namely legal limits and/or provisions and limits and/or requirements listed on authorizations or other prescriptive documents, etc.),the certification process is suspended, except in particular cases, until the Organization demonstrates its compliance with these requirements.

C.6 Retention of the Certification

C.6.2 In addition to that which is established by the General Part, the Organization must maintain registrations relative to:

a) environmental incidents/emergencies which occurred at the site/s and other events which could potentially have had a negative effect on the health and safety of the workers;

b) any observations or reports received by the national or local authorities in charged of check work places;

and must make them available to IIS CERT together with the corrective actions undertaken during the periodic audits.

The Organization is required to promptly notify IIS CERT, which will evaluate the actions to be undertaken, regarding possible observations or reports received by the national or local authorities in charge of checking work places, referable to § 5.6 for all the activities carried out by the Organization regardless of the field of application of the SGSSL.

In addition, in the cases in which the Body supervising the certifications issued by the IIS CERT and/or the competent authorities report critical issues to IIS CERT connected to occupational health and safety management, § 6.5 applies.

C.6.3 For certifications issued in Italy, 2 or 3 monitoring audits must be carried out at the site/s before the start of the recertification activities with a frequency which varies depending on the activity carried out by the Organization (in particular its "complexity"), based on what ACCREDIA has established in document RT-12 (document which can be viewed on the ACCREDIA website or by contracting IIS CERT).

C.6.5 For Organizations defined as being highly complex by the aforementioned RT-12 document, the first monitoring audit takes place within 6 months of the initial audit.

C.9 Modification of the certification and communication of the changes

C.9.6 The requests for extension of the certification to every new site or process always involve the planning and implementation of additional (extension) audits, for which the procedure leading to the deliberation will be initiated.

C.10 Multi-Site Organizations

C.10.1 If an Organization has several sites, they must all adopt and certify the SGSSL, following a program defined in chronological terms, which provides for the certification of all the sites within 24 months of the initial assessment (barring prompt and justified communication to ACCREDI of particular requirements for dispensation from this criterion).

The sampling of the sites will also follow the rules of the ACCREDIA provision of 2010-02-23 (see § 2).

In addition to the activities defined in the General Part, the analysis and assessment of the risks at the sites must also be managed by the central office of the Organization.

C.12 Transfer of accredited certificates

C.12.1 To transfer accredited certificates, the rules of the ACCREDIA provision of 2010-02-23 also apply (see § 2).