Regulations for the certification of management systems

08	22/06/2021	Transposition of Accredia findings for EMAS renewal	HEAD OF OPE	HEAD OF ISG	PRE
07	02/04/2020	Incorporation of requirements IAF MD11:2019 + COVID 19 measures + remote audit + elimination of references to RT-12	OPE	HEAD OF ISG	CEO
06	07/11/2019	Update on request of ACCREDIA para. 1.0	OPE	HEAD OF ISG	CEO
05	15/09/2019	Update on request of Accredia on the directives. Para. 1.0, 2.0, 4.4.2,	OPE	ISG	CEO
04	04/10/2018	Included: reference to the standard UNI ISO 45001 in point “1.0 PURPOSE AND SCOPE”	OPE	HEAD OF ISG	HEAD OF OPE
03	10/09/2018	MD modifications	OPE	HEAD OF ISG	HEAD OF OPE
02	20/07/2018	Changes introduced by document IAF MD 22:2018	SG	ISG	DIV
01	2/11/2017	Changes introduced by document EA 3/13 M:2016	SG	ISG	DIV
00	24/01/2017	Replaces the following documents for the general part: 0007CR, 0011CR, 0014CR and other certification regulations pertaining to the Management Systems	SG	ISG	DIR-AD
Rev.	***Date***	***Description***	***Drawn up***	***Verified***	***Approved***
IDENTIFICATION: 0002CR_08_EN					

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SUMMARY

1.0 PURPOSE AND SCOPE

This Regulation defines the methods and conditions that an Organisation must comply with to achieve and maintain the certification of its Management System issued by ICIM and to be registered in the ICIM Registry of Organisations in possession of the Certification.

Certification of the Management System means the certification of Organisations in compliance with one or more certification schemes, whose basic regulatory reference consists of regulations or regulatory documents in which the management system governs their applicability, such as, for example, UNI EN ISO 9001, EN 9100, EN 9110, UNI IEC EN ISO 13485, UNI EN 14001, UNI ISO 20121, BS OHSAS 18001, UNI ISO 45001, UNI IEC EN ISO/IEC 27001, UNI IEC EN ISO 50001, etc.

The certifications proposed by ICIM are applicable to any Organisation, who may be requesting them in compliance with this Regulation; these services do not include consulting activities related to the preparation of the management system documentation or its implementation.

Further details, for the different types of management system, are contained in the relevant "Certification Schemes" (doc. ICIM SCSxxxx). The SCSxxxx Certification Schemes refer to one or more specific regulatory documents. If the said documents are not part of a specific national, European or international reference standard or a specific technical specification governed by national laws, directives or European regulations, are developed by Work Groups. The Work Groups are composed of ICIM technicians, technicians listed in the ICIM List of Expert Technicians and/or external expert technicians, representing the stakeholders pertaining to Certification.

In some cases, linked to national laws, European directives or regulations, the SCSxxxx are replaced by specific verification and control documents.

In case of EU Regulations or European Directives that define, as the certification procedure for mandatory products, modules to which the corporate management systems apply (e.g. modules H, D, E, or for Regulation (EU) 2017/745 annexes IX and XI part A), this Regulation applies in combination with the Regulation for the Certification of Products and Services ICIM doc. 0003CR, each for the matters under its purview.

The Certification, issued by ICIM, grants the Organisation the right to use the ICIM Conformity Mark and other conformity marks, for which use is explicitly authorised, resulting from memberships and/or recognition agreements with national and international Organisations or for specific certification schemes on technical and advertising documentation, as long as it is carried out so as not to be interpreted as product/service certification and the ICIM requirements for the use of the Conformity Mark are met (Also see the User Manual of the ICIM S.p.A. Certification Mark - 0260CR).

2.0 REFERENCES

2.1 Input documents

Standards and documents valid at the issue date of this document.

UNI IEC EN ISO/IEC 17000	Assessment of conformity - Glossary and general principles
UNI EN ISO 9000	Quality Management Systems - Fundamentals and glossary
UNI IEC EN ISO/IEC 17021-1	Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements

IAF MD 1	IAF Mandatory Document for the Certification of Multiple Sites based on Sampling
IAF MD 2	IAF Mandatory Document for Transfer of Accredited Certification of Management Systems'
IAF MD 12	IAF Mandatory Document Accreditation Assessment of Conformity Assessment Bodies with activities in multiple countries
IAF MD 4	IAF Mandatory Document for the use of information and communication technology (ICT) for auditing/assessment purposes
IAF MD 5	IAF Mandatory Document for duration of QMS and EMS Audits'
IAF MD 11	IAF Mandatory Document for application of ISO/IEC 17021 for audits of integrated management systems
IAF MD 9	IAF Mandatory Document for application of ISO/IEC 17021 – 1 in the field of medical device quality management system
IAF-MD 8	IAF Mandatory Document for the application of ISO/IEC 17011 in Medical Device Quality Management Systems (ISO 13485)
IAF ID3	Management_of_Extraordinary_Events_or_Circumstances
IAF ID 12	Principles on Remote Assessment
UNI EN ISO 19011	Guidelines for management system audits
RG-01	Accreditation regulation of certification bodies
ACCREDIA Circular No. 11/2016	Market Surveillance Visit sector IAF 28 – ISO 9001 scheme
0001CR	ICIM General Regulation
0003CR	Regulation for the certification of products and services
0260CR	User manual of the ICIM S.p.A. Certification Mark
Document IAF MD 22:2018	Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)

3.0 DEFINITIONS

For the terminology regarding the Certification of the Management System, the definitions reported in standards UNI IEC EN ISO/IEC 17000, UNI EN ISO 9000 and in the ICIM regulation 0001CR generally apply. Below are some definitions of terms used repeatedly herein.

- **Production Unit**

  Site in which the Organisation produces the product or service.

- **Certification extension**

  Extension of the scope of the certificate issued to an Organisation, to new sites and/or processes of the same Organisation.

- **ICIM mark**

  This is the graphic identification for certification issued by ICIM. It is under the exclusive ownership of ICIM and, as such, is covered by a collective mark with a patent that is filed and registered in Italy, Europe and around the world at the relative Offices. Also see chapter 1 of this regulation

  Use of the ICIM Mark is granted to the Organisation that has been issued with the Management System Certification and is applied under its responsibility, in compliance with the requirements of the applicable Certification Scheme.

- **Observation (OSS)**

  Observation formulated by the Organisation, having the reference regulatory document and/or Certification Schemes as reference, in cases where some requirements are only partially fulfilled. These unfulfilled requirements must not compromise the conformity of the Management System that the assessment refers to and the corrective measures, proposed by the Organisation, must be considered easily implementable according to the proposed methods and schedule. One or more OSS do not block the certification sequence and ICIM's verification of implementation of the corrective action by the Organisation is carried out during the next auditing visit.

- **Non-conformities (NC)**

  Non-conformity formulated by the Organisation, having the reference regulatory document and/or Certification Schemes as reference, in cases where some requirements of the Certification Scheme are not fulfilled. These findings block the initial/renewal certification process. ICIM's verification of implementation of the corrective action could require an additional auditing visit to the Organisation.

- **Recommendation (REC)**

  A guideline formulated by the Organisation, using the reference regulatory document or Certification Schemes as reference. One or more recommendations do not pose any variation to the final assessment expressed by the Inspection Group, nor the requirement of the Organisation to implement corrective action.

- **Initial Assessment Visit (VV)**

  An action used by ICIM to ascertain that the requesting Organisation fulfils the technical-organisational requirements set forth in the applicable Certification Scheme. This visit includes the Assessment of the Quality System of the Organisation's production unit. Unless otherwise specified in the SCSxxxx scheme, the VV is divided into two phases:

  Phase 1 Audit adequacy review (document examination and on site preliminary audit)

  Phase 2 Audit on-site evaluation audit.

- **Surveillance (VS)**

  An activity by which ICIM verifies maintenance of conformity of the Organisation with the requirements of the applicable Certification Scheme.

- **Renewal (VR)**

  An activity by which ICIM confirms the conformity and effectiveness of the Organisation's management system and the relevance and applicability of the scope of its certification.

- **Transfer**

  Process of transferring the certificate issued by a CB to an organisation, to another CB.

- **Surprise audits**

  Audits aimed at investigating complaints or in response to changes or as a consequent action for customers whose certification has been suspended.

4.0 CERTIFICATION PROCESS OF MANAGEMENT SYSTEMS

4.1 General conditions

The conditions set forth in the General Regulation ICIM 0001CR apply. In addition, the following specific general conditions must also be taken into account.

ICIM operates as an ACCREDIA accredited body for the certification of management systems. In this context, the general conditions valid for the certification of the systems in question have been supplemented by Technical Regulations and/or specific circulars which, although addressed to certification bodies, also indirectly involve obligations for Organisations that request certification (see specification SCSxxxx).

The Organisation must therefore be aware of the provisions of the specific documentation concerning the relevant scheme and must also be aware that failure to comply with these requirements entails the suspension/revocation of the certification.

An Organisation intending to obtain and maintain the certification of its management system must meet the requirements of the specific standard referred to in the SCSxxxx scheme in the edition chosen among those applicable.

4.1.1 In order for the certification process to be activated by ICIM, the requesting Organisation must:

- have a Management System that meets the needs of the model chosen in the reference legislation and any specific requirements established for the specific scope of certification;
- accept the conditions established by this Regulation and by the SCSxxxx certification scheme, as well as the contractual conditions for certification.

4.1.2 The contractual conditions for certification:

- define the model of the applicable Management System, identifying the reference legislation/regulatory document;
- identify the Organisation and the Operational Unit/s where the activities entailed for the certification process are carried out;
- define the scope of certification for the specific Management System;
- define the stages of the certification process (initial audit and audit for maintaining certification);
- establish any special methods for applying this Regulation.

4.1.3 To obtain the certification, the Organisation must have prepared a Management System, keeping it active and fully operational in compliance with the requirements of the reference standard referred to in the SCSxxxx scheme: in the chosen edition and/or other regulatory reference contractually applicable to the management system.

If the Organisation has put in place and maintained active a single management system to manage the multiple aspects of the organisation's performance (integrated management system), the latter must meet the requirements of all preselected reference standards in force, as well as the reference regulatory requirements that contractually apply to the management system. In such case, the integrated Management System must meet the requirements of the reference standards that apply to the relevant SCSxxxx certification schemes, in the preselected version and/or those of other regulatory references that contractually apply to the individual schemes.

The Management System is considered fully operational when:

- the internal audit system is fully implemented for all the sites falling within the scope of the management system and its effectiveness can be demonstrated;
- at least one complete review of the system has been carried out and documented by Management;
- the necessary objectives to achieve results have been defined in accordance with the applicable requirements;
- the necessary processes to ensure the objectives of the Organisation have been defined, checked and monitored in compliance with the Customer's requirements and applicable legal requirements;
- actions for continuous improvement have been implemented.

4.1.4 During the initial assessment or surveillance or renewal of the Management System, the Organisation that has activated the certification process with ICIM must grant ICIM auditors free access to the operational areas, information and documentation necessary to carry out the audit programme.

In order to ascertain that the evaluation methods adopted by ICIM comply with the reference standards, the Accreditation or qualification Body (e.g. ACCREDIA, Ministries, etc.) may request:

- the participation of its observers in the audits carried out by ICIM;
- visits to the certified Organisation, directly through the use of its own personnel.

The participation of observers in the audits and/or any visit conducted directly through the use of the Accreditation Body personnel, is agreed in advance between ICIM and the Organisation, unless indicated otherwise in the SCSxxxx certification scheme.

If the Organisation does not grant its approval, the validity of the certificate is suspended until approval for the audit is granted, up to a maximum of 6 months. After which, in the absence of approval for the audit, the certification is revoked.

In the event of a visit by Accredia, the Organisation must provide it with the documentation that ICIM has used as reference during the previous audits.

4.1.5 The Organization, to comply with the provisions of paragraph 2 of Italian Legislative Decree 81/08 art. 26, in terms of cooperation and coordination for the safety and health of workers, provides the audit team (GVI) and its observers, considering the audit programme and the areas involved,with information on specific risks existing in the work environments in which the audit will be carried out, also providing them with any specific PPE if necessary.

4.1.6 Should the need arise for audits on the processes outsourced to suppliers, during the initial assessment or surveillance or renewal, the Organisation (Customer) must grant ICIM auditors and, when required, the accompanying auditors (see previous par. 4.1.4) free access to its suppliers' operating areas.

4.2 Offer Request and Offer

The Organisation that intends to start the certification process must provide ICIM with all the necessary data to prepare a correct and complete financial offer. Namely, the following need to be provided:

1. the applicable reference rule(s) and regulation(s);
2. the essential details of the Organisation and relative activities;
3. any exclusions of elements in the standard and the reasons;
4. identification of the Organisation's processes, internal and outsourced, which affect conformity with the applicable requirements;
5. number of permanent, detached and temporary sites involved in certification and related activities.
6. Possible additional data and/or information provided in the ICIM documents "Offer request_Systems" (0001CM) and List of Sites_Detached Sites (0002CM).
7. (only for requests for the certification of an integrated management system) The information listed below to understand the level of integration of the system the certification of which is requested:
   - The level of integration of the set of documents prepared;
   - Management reviews that take into account the general corporate strategy and plan;
   - An integrated approach to internal audits;
   - An integrated approach to the policy and objectives;
   - An integrated approach to system processes;
   - An integrated approach to improvement mechanisms (corrective and preventive actions; measurement and continuous improvement); and
   - Integrated management support and responsibilities.

An offer request must be made by the Organisation by submitting the appropriate form "Offer Request_Systems", filled out in its entirety.

In this phase, the Organisation, on serious and proven grounds, may request from ICIM an offer for the performance of the audit(s) with remote audit techniques.

Based on the data specified in the "Offer Request_Systems" and in compliance with the applicable provisions of the legislation and accreditation rules, ICIM prepares and sends the offer to the Organisation.

In order to prepare offers concerning remote audits, ICIM personnel will ask the Organisation to fill out the form RISK ASSESSMENT AND DECLARATION OF ACCEPTANCE OF REMOTE AUDIT (1040CM) and, following the risk assessment that will performed, will evaluate whether to accept or reject the customer's request, preparing a reasonable offer.

Before issuing the offer for certification of the Management System for an Organisation based in the USA (United States of America) and/or Canada, ICIM will have to assess the need for insurance coverage for these countries. ICIM will therefore have to integrate the current coverage with what is necessary for these countries, if it intends to proceed with the offer. If necessary, ICIM may reassess the offer made to the Organisation to partially cover the additional insurance costs.

Offer requests to extend/reduce the scope of certification by an Organisation already certified by ICIM, require specific revaluation of the current offer, in order to establish its adequacy or otherwise.

The revaluation of the latter must take place on the basis of the following data and information:

- subject of the extension/reduction;
- updated key Organisation information (e.g. staff, number of sites, activities, etc.);
- expected period of implementation of the extension/reduction.
- Specific requirements envisaged by the relevant scheme regulation

In the event that the extensions/reductions made by the requesting Organisation have an impact on the existing audit timing (significant extensions/reductions), ICIM adjusts the existing offer differently and reconfirms its validity to the requesting Organisation (non-significant extensions/reductions).

The requests to extend/reduce the scope of certification must be submitted to ICIM well in advance (at least 1 month) with respect to the date of the scheduled extension/reduction audit requested to ICIM.

4.3 Presentation of the application for certification

In the event of acceptance of the financial offer, the Organisation formalises the certification request by sending the Management System Certification Application (hereinafter referred to as "Application") to ICIM, using the appropriate form, duly filled out, stamped and signed by the legal representative of the Organisation, recalling the offer that constitutes an integral part and enclosing the documentation referred to in it or specified in the SCSxxxx certification scheme.

The form must be filled out in its entirety and be accompanied by the documentation required in order for the Application to be considered valid. The parts that do not apply must be crossed out.

The Organisation must inform ICIM of any subsequent changes to the contents of the aforementioned documentation.

For certification requested by foreign Organisations, all the conditions that govern the granting of certification to national Organisations apply, in compliance with of international agreements made with ICIM (in which case the technical regulations of the national Audit Body may not be applicable).

4.4 Review of the Application

Upon receipt of the Application and its annexes, ICIM shall process it, in order to verify the completeness of the information therein, with particular reference:

- to the definition of the scope of certification;
- to the definition of the relevant EA and NACE product sectors (where applicable);
- to the applicability of the certification scheme(s) corresponding to the reference regulatory document(s) indicated by the Organisation in the Application;
- to the level of integration of the management system(s) that form(s) the subject of the application (where applicable)
- to verifying the completeness and adequacy of the general information in the Application;
- to verifying the expertise and ability of ICIM to perform the specific certification activities.

If some information differs from that reported for the preparation of the offer or if the submitted documentation is incomplete and inadequate, ICIM will report the results of its assessment to the Organisation. The application will be suspended until the requesting Organisation officially fulfils ICIM's requests (this evaluation could also lead to an update of the offer). If, on the other hand, the review is

successful, the Organisation is registered in the Information System and is informed of the acceptance of the certification request.

In case the Customer requests remote audit techniques, ICIM will proceed in accordance with the procedures indicated in the document 0176BI_ Audit da remoto in compliance with national and international provisions on the subject.

The Organisation's application, which makes specific mention of this Regulation and the SCSxxxx scheme, and related acceptance by ICIM contractually formalises the relationship between ICIM and the Organisation and the applicability of this Regulation. Unless otherwise required by the SCSxxxx certification scheme, the contractual agreement between ICIM and the Organisation includes:

- the initial certification audit consisting of two phases;
- the subsequent surveillance and recertification audits.

4.5 Selection of auditors

Following a successful review of the Application, ICIM informs the Organisation of the name of the personnel responsible for carrying out the Phase 1 audit and the Phase 2 audit, selected from the list of auditors according to the Technical Area of interest, specific experience, the geographical location of the Organisation and any incompatibilities.

4.6 Preparation of the audit

Upon agreement with the Organisation, at least 15 (fifteen) days before the agreed audit date, ICIM notifies the Organisation of the audit.

Within 5 working days of receipt of the notice and, nonetheless no more than 5 working days from the expected date of the visit, the Organisation can ask for, by highlighting the reasons:

- the replacement of one or more members of the audit group;
- a new audit date.

ICIM, after having evaluated the reasons, shall implement the Organisation's requests, where appropriate, reporting the new names of the audit team (GVI) and/or any new audit date.

The Organisation's request to move the audit, with notice of less than 5 working days, may result in ICIM applying a penalty against the Organisation.

The audit team Manager (RGVI), as a rule, prepares the audit by studying the documentation provided by the Organisation. On the basis of the information acquired, it prepares the audit plan (and any other supporting documentation) and submits it to the organisation at least 5 days before the date of the audit.

The audit planning must also take into consideration:

- Activities, products, services under the control or influence of the organisation, which can have an impact on system performance
- Include controlled temporary sites, even if decentralised (requirement based on risk assessment)
- The verification of all requirements of the management system(s) that form(s) the subject of the audit (with the exception of surveillance audits, where a sampling of the requirements is allowed);
- (only for integrated audits) the confirmation or otherwise of the level of integration of the integrated system.

In case of audits to be performed with remote techniques, ICIM personnel will operate in accordance with what is indicated in chap. 4 of ICIM Instructions 0176BI - Remote audits.

4.7 Initial Assessment Audit (VV) - Phase 1 Audit

The Phase 1 audit is aimed at assessing the adequacy of the document system in relation to the scope of certification and to ascertain whether the Organisation is ready for Phase 2. In particular, it must be carried out[1] to:

- verify the correctness of the general information provided by the Organisation (headquarters, personnel, operational units, etc.);
- verify the completeness, adequacy and audit the documentation of the Organisation's Management System;
- assess the location and particular conditions of the Organisation's site and exchange information with the Organisation's personnel in order to establish the level of preparation for the Phase 2 audit;
- complete, by means of the audit team (GVI), the identification of the Organisation, the context in which it operates, the aspects and risks related to its activities and consequent determination of the significant ones; review the Organisation's status and understanding of the standard requirements, with particular reference to the identification of key services or significant aspects, processes, objectives and operation of the Management System;
- collect the necessary information regarding the scope of the Management System, the processes and the location/s of the Organisation, including the related legal and regulatory aspects and compliance with them;
- confirm and review the data and resources required for planning and conducting the Phase 2 audit;
- focus on the planning of the Phase 2 audit, acquiring sufficient knowledge of the Management System and of the Organisation's website activities, with reference to possible significant aspects;
- assess whether the internal audits and the review conducted by Management have been planned and carried out and that the level of implementation of the Management System provides evidence that the Organisation is ready for the Phase 2 audit;
- confirm or otherwise the integration level of the integrated system (where applicable)

The documentation that the Organisation must make available to the ICIM personnel responsible for carrying out the Phase 1 audit, is indicated in par.4.3 of this Regulation.

At the beginning of the visit, the audit team (GVI) holds an opening meeting with the Organisation to present the members of the audit team (GVI) and to organise the visit. The purpose of the opening meeting with the Organisation is to:

- confirm the audit plan (if it has been prepared);
- clarify how the audit is conducted;
- establish an official channel for communication between the audit team (GVI) and the Organisation;

[1] When deemed technically appropriate, ICIM reserves the right to conduct the examination of the organisation's quality management system (QMS) documentation off-site, in order to better prepare for the field audit.

- offer the Organisation being audited the opportunity to ask questions;
- establish whatever else is necessary to carry out the audit.

Phase 1 is normally conducted at the headquarters of the Organisation, to protect the confidentiality of documentation and to facilitate the collection and analysis of information.

In the event of a small Organisation, with simple and/or traditional processes, upon agreement with the Organisation, the review of the adequacy of the Management System (Phase 1) is carried out on a documental basis at ICIM.

At the end of Phase 1, the ICIM auditor issues the Phase 1 audit report to the Organisation, reporting any findings including those that could be classified as non-conformities during the Phase 2 audit. This report must be signed by the audit team Manager (RGVI) and by the Organisation for acceptance.

The actions taken by the Organisation for the resolution of these findings are, generally, verified during the Phase 2 audit.

In the presence of findings deemed to be particularly significant, in the opinion of the personnel who conducted the Phase 1 audit, their complete resolution may be requested in writing before the Phase 2 audit is carried out at the Organisation.

Based on the results of the Phase 1 Visit Report, ICIM assesses the need for the Organisation to make changes, thus suspending the certification process until the findings are resolved successfully. In this case the Organisation is informed in writing.

In the event that, after completing the Phase 1 Visit, the certification process is suspended for over 12 months and in any case, when the conditions verified in the Phase 1 audit change, ICIM will have to carry out a second preliminary visit before proceeding with the assessment visit.

In case of audits to be performed with remote audit techniques, ICIM personnel will apply what is indicated in this paragraph, in the context of the means defined in chap. 4 of ICIM Instructions 0176BI - Remote audits.

4.8 Initial Assessment Audit (VV) - Phase 2 Audit

The Phase 2 audit to be carried out at the Organisation is conducted after Phase 1 is completed successfully, in order to verify the scope and effectiveness of the Management System in the field, as documented in Phase 1, in compliance with the requirements of the reference legislation.

The Phase 2 audit cannot usually be performed beyond 90 days from the date of the Phase 1 audit, however, if the Organisation points out different requirements for the resolution of the potential critical areas identified during Phase 1, ICIM may grant a longer time period, in any case not exceeding 12 months. After this deadline and in any case when the conditions verified in the Phase 1 audit change, ICIM will have to perform a second Phase 1 audit before proceeding with the assessment audit.

The Phase 2 Audit is planned and executed with procedures similar to those of Phase 1, but must include at least the following activities:

- the collection of information and evidence about the compliance of the Management System with all the requirements of the reference standard and of the applicable mandatory requirements;
- the review of the performance of the Management System being audited, with reference to the objectives and targets defined and with reference to compliance with the applicable mandatory requirements;
- Operational control of the Organisation's processes;

- The internal audit verification for all sites falling within the scope of the management and review system.

At the end of the audit, the audit team (GVI) communicates, at the closing meeting and in the presence of the Management of the requesting Organisation or its delegates, the conclusions regarding the compliance of the Organisation's Management System with respect to the reference model, specifying any discrepancies found and any recommendations for improvement.

In the context of integrated audits, ICIM must take into account the impact of a non-conformity found for a standard on the conformity with the other standards. If the organisation does not comply with one of the common requirements of the integrated system, the non-conformity shall apply to the entire integrated system. If the organisation does not comply with a specific requirement of a standard, this only affects the standard in question.

During this meeting, the Organisation has the opportunity to confront the audit team (GVI), to clarify its position relating to the findings and to propose any corrective actions, as well as to express any reservations regarding the conclusions of the audit.

The outcome of the audit assessment is documented in a Phase 2 audit Report, prepared by the audit team (GVI), which points out any discrepancies relating to the requirements of the reference model for the Management System being certified and any recommendations formulated for improvement purposes.

This report, within the closing meeting, is signed and issued officially by the audit team Manager (RGVI), to the Organisation's Management, which must in turn sign it for acceptance of the findings set out therein.

In the event of disagreement with the audit team (GVI), with regard to the audit results, the Organisation has the possibility to raise any reservations. The latter must be motivated and formalised in the visit report by the audit team Manager (RGVI) and signed by the Organisation and the audit team Manager (RGVI).

Once ICIM receives the Report from the audit team Manager (RGVI), if ICIM believes changes need to be made, it shall inform the Organisation in writing. In the event of reservations raised by the Organisation, ICIM activates the process for the management of appeals governed by the ICIM procedure 0211BP – Appeals.

The assessed Organisation must identify the causes of the Observations and Non-Conformities, define processing operations and/or corrective actions to remove the causes and transmit them in writing to the audit team Manager (RGVI) and to ICIM, within 10 (ten) working days from the date of the audit.

ICIM assesses the corrective actions proposed by the Organisation and:

- in the absence of comments, considers the proposed resolutions accepted;
- if it does not accept the proposals for the resolution of the Observations and Non-Conformities found with regard to timing and to how these are carried out, it shall inform the Organisation in writing.

In the presence of Non-Conformities (NC), the certification process is temporarily interrupted.

In the event of NC, processing operations and the related corrective actions must be implemented within 6 (six) months from the end of the Phase 2 audit, except in the case of exemptions granted by ICIM. ICIM reserves the right to carry out a supplementary audit to ascertain the correct application of the corrective actions and reactivate the certification process.

If the term of 6 (six) months or the term of the exception granted by ICIM cannot be met, the Organisation’s Management System may undergo a new Phase 2 audit.

These terms may be changed, in special cases (e.g. transition to new editions of the standard), at the discretion of ICIM, upon a motivated request by the Organisation.

In case of audits to be performed with remote audit techniques, ICIM personnel will apply what is indicated in this paragraph, in the context of the means defined in chap. 4 of ICIM Instructions 0176BI - Remote audits.

5.0 ISSUING THE CERTIFICATION

5.1 Final review

Audit reports (e.g. Phase 1 and Phase 2, extension, renewal), together with other relevant information concerning the Organisation's application, are made available to the decision-maker to issue the certification (or its extension/reduction), after the final review of the relevant ICIM representative for the certification scheme being assessed[2] and if the following conditions are met:

- successful analysis of the submitted audit documentation.

The final review is carried out directly by the decision-maker if the relevant ICIM representative for the certification scheme being assessed has taken part directly in the certification process (e.g. present in the audit team GVI), unless indicated otherwise in the SCSxxxx certification schemes.

In the event of a failed final review, ICIM will ask for clarifications or for the documentation necessary to complete the review successfully. Only after having approved the proposals for the resolution of non-conformities and having verified (through the examination of relevant documentation or audits in the field) the implementation and effectiveness of the proposed solutions, ICIM, in the event of a successful closure of the Non-Conformity(ies), reactivates the certification process (or extension/reduction), by submitting the Organisation to the ICIM approval process, to assess whether it can be certified (or the maintenance of the certification, limited to cases of certification scope extensions/reductions).

5.2 Certification

The documentation for certification is made available to the ICIM[3] decision-making department, according to a specific procedure, only if the final review has been successful.

- ICIM provides at least the following documents: audit report (e.g. for Phase 1 and Phase 2, extension, renewal);
- Internal approval review;
- proposals for corrective Actions and any objective evidence proving the resolution of the NC;
- any other documentation required by the SCSxxxx certification scheme;
- audit programme.

Consequently to the COVID-19 health emergency, concessions and derogations from what has been mentioned above for the issue of the certification are possible, within the limits of what has been expressly indicated in the Circulars and communications issued by the competent supervisory bodies per specific scheme (e.g. Accredia, IAF, IAQG, etc.) in March and April 2020[4].

[2] In the case of integrated audits, the final review may be performed by different ICIM representatives for each relevant certification scheme subject to integration or by a single competent ICIM representative for all schemes subject to integration.
[3] In the case of integrated audits, the decision-making ICIM department may be different for each pertinent certification scheme subject to approval or may be the same, on the condition that they are competent for all schemes subject to approval.
[4] Accredia technical circular DC no. 02/2020 dated 11 March 2020; Accredia technical circular DC no. 04/2020 dated 12 March 2020; Accredia technical circular DC no. 06/2020 dated 17 March 2020; IAQG notice dated 17 March 2020; Accredia technical

If the decision-making department does not grant certification (or its extension/reduction), the reasons for such decision are notified to the Organisation (in writing), specifying the discrepancies, with respect to the requirements of the certification scheme chosen by the Organisation. The Organisation must agree to correct the discrepancies within the time limit agreed with ICIM, which in any case should not exceed six (6) months, providing evidence.

On the agreed deadline, ICIM assesses whether the evidence received is complete. If the assessment fails, it decides whether another assessment audit is necessary or whether a written declaration by the requesting Organisation, accompanied by appropriate documentation, confirming that the corrective actions have been implemented, is enough. This implementation can be verified during the first surveillance audit.

At the end of this period, in the event that the Organisation has failed to provide the required feedback, the certification Application is no longer valid and the Organisation will have to start the certification process again (or, in the case of certification scope extensions/reductions, the certification will be suspended until the required feedback is received and in any case for a maximum of 6 months).

An Organisation that does not accept the decision made by ICIM can request an additional investigation or appeal, explaining the reasons for its disagreement, according to the procedures indicated in this Regulation.

When certification is granted, ICIM issues a certificate defining:

- company name and address of the headquarters and Operational Units for which certification is requested;
- the reference legislation and other applicable regulatory documents with edition and/or revision number;
- the scope and the application limits of the Management System for which certification is issued;
- the date of issue and the period of validity of the certification;
- any other information required by the standard and/or other regulatory document used for certification.

In the event that the certification is granted with reservations (e.g. partial existence of NC), the decision-maker can request surveillance audits, anticipated or unscheduled, which are notified in writing to the Organisation.

When certification has been issued, ICIM enters the Organisation in the Register of Organisations in possession of ICIM certification, with at least the following details:

- Name of the Organisation
- Geographical location
- Certificate number
- Regulatory reference of the Management System
- Applied certification scheme (SCSxxxx)
- Scope
- State of certificate validity

circular DC no. 08/2020 dated 19 March 2020; Accredia technical circular DC no. 09/2020 dated 23 March 2020 - Specifications for the EMAS scheme; EA communication dated 23 March 2020; IAQG notice dated 25 March 2020; Initial IATF release dated 27 March 2020

and sends this information to the Bodies (national and international) that ICIM has agreements of mutual recognition with and/or who are required to receive this information by standard or law. This register is updated at least quarterly and is available to anyone requesting to consult it.

Any limitations on the duration of the certificate can be specified by ICIM to ensure the correct application of special rules dictated by the Accreditation Bodies (e.g. compliance with the timing for transition to new editions of the reference standards).

At the written request of any party, ICIM provides the means to confirm the validity of the certification.

The certification issued by ICIM refers exclusively to the Management System's ability to ensure observance of the commitment to legal compliance, therefore it does not constitute a guarantee of compliance with the mandatory requirements, which is the specific responsibility of the organisation undergoing certification.

ICIM, following its membership and/or recognition agreements with national or international organisations or for specific certification schemes, can issue additional certificates as well as the ICIM certificate related to the basic certification scheme.

For the accredited certification of foreign Organisations, all the conditions that govern the concession of certification to national organisations apply, except for what is provided for by specific rules defined at national level by the Accreditation Body (Technical Scheme Regulations - RT).

6.0 SURVEILLANCE PROCEDURE

ICIM performs surveillance audits at the Organisations in possession of certification, in order to verify that the conditions which allowed the certificate to be issued still exist.

The surveillance procedure must include at least the verification of the following aspects:

- internal audits and reviews conducted by the Management;
- a review of the actions taken as a result of the non-conformities identified during the previous audit;
- processing of complaints or analysis of any reports by interested parties;
- effectiveness of the Management System in achieving the objectives;
- progress of planned activities, aimed at continuous improvement;
- continuous operational control of activities;
- review of any changes;
- the integration level of the integrated system (where applicable);
- the use of marks and/or any other reference to certification.

The audit team (GVI) must have full access to the documentation of the system(s) being certified with the procedures established by this regulation and the SCSxxxx certification scheme.

Failure to produce one of the aforementioned documents can lead to the suspension of the certification process. In the context of an integrated management system, the suspension, restriction or withdrawal of the certification for one or more standards pertaining to the integrated management system shall result in ICIM assessing the impact of this measure on the certificates relating to the other standards that are subject to integration.

On the occasion of the surveillance audits, if formally and previously requested to ICIM by the certified Organisation, compliance with the transition to new editions of the reference standards may also be verified. This audit will be conducted in compliance with the provisions of this Regulation and with

timing that ICIM reserves the right to reassess, with possible increases up to a maximum of 20% on the total time.

If, during these audits, with reference to the new requirements of the reference standards, one or more Non-Conformities that lead to an unsatisfactory outcome of the audit are found, the certification process for compliance with said requirements will be temporarily interrupted, blocking the ability of the Organisation to be certified, until evidence about the resolution of the shortcomings is made available by the latter. In this case, ICIM must simultaneously verify the compliance of the organisation's management system with the requirements of the reference standard, in its previous edition (old standard), confirming whether or not the certification is valid.

If the necessary time for the resolution of the aforementioned Non-Conformities, under the new editions of the standards, requires longer than the deadlines set, the Organisation shall formally notify ICIM that, despite the certification no longer being valid, it will have the possibility to maintain the conducted transition visit valid and therefore reactivate the certification process, by submitting the Organisation to the ICIM approval process, to assess whether it can be certified, if it is able to approve the proposals for the resolution of non-conformities and to assess their implementation and effectiveness, within 3 months of the aforementioned deadline.

The timing of such extensions can be changed, in particular cases, at the discretion of ICIM, upon motivated request of the Organisation.

In case of audits to be performed with remote audit techniques, ICIM personnel will apply what is indicated in this paragraph, in the context of the means defined in chap. 4 of ICIM Instructions 0176BI - Remote audits.

6.1 Scheduled surveillance (VS)

The scheduled surveillance audits are carried out with frequencies and methods similar to those adopted for conducting Phase 2 and in any case described by the SCSxxxx certification scheme. The frequency is usually at least annual.

If expressly requested by the decision-maker and for clear and well-founded reasons, ICIM reserves the right to change such frequency.

Surveillance is notified to the Organisation at least 15 (fifteen) working days in advance. Within 5 (five) working days of receiving the notice and, nonetheless no more than 5 (five) working days from the expected date of the visit, the Organisation can ask for, by pointing out the reasons:

- the replacement of one or more audit team (GVI) members if there are motivated conflicts of interest;
- a new visit date.

ICIM assesses the Organisation's request and provides an official reply regarding acceptance, or not, of the submitted requests.

Failure to carry out surveillance audits as scheduled, without valid reasons submitted by the customer Organisation, may result in the suspension of the certification.

Some surveillance audits, in the event of obligations of the SCSxxxx certification schemes, or on the basis of explicit requests of the Approval Committee, can be conducted by ICIM through surprise surveillance visits without prior notice to the Organisation.

At the same time as scheduled surveillance visits, audits can be carried out to extend/reduce the scope of the ICIM certification. In these cases, in addition to the usual activities and procedures for conducting the monitoring, ICIM will dedicate the time required to conduct the extension / reduction activity (see par. 4.2) and ascertain the following elements:

- the continuous compliance of the Management System implemented by the Organisation with the criteria of the audit, with the requirements of the reference standard and with other applicable mandatory and contractual requirements;
- the continuous effectiveness of the Management System in guaranteeing the achievement of improvement objectives;
- the identification of possible areas for improvement of the Management System.

The successful outcome of significant extension/reduction audits involves the activation of a decision-making process as described in par. 5.1 and 5.2 of this regulation.

6.2 Unscheduled surveillance

Unscheduled surveillance can be performed:

- if ICIM receives complaints and reports, deemed particularly significant, relating to the shortcomings and/or non-compliance of the Management System with the requirements of the reference standard and with this regulation;
- in the case of direct or indirect knowledge of serious accidents and/or accidents or legislative infractions in order to verify if the OH&S has been compromised or has not worked.
- in relation to changes that have occurred in the Organisation (e.g. management system scope extensions and reductions);
- to Organisations whose certification has been suspended;
- if ICIM is not successful in acquiring information, documents or operational evidence from the Organisation that are deemed important for the maintenance of the existing certification(s) and/or the certification(s) requested by the accreditation body and/or by the competent public authorities;

unless indicated otherwise in the SCSxxxx certification schemes;

Unscheduled surveillance visits are normally scheduled with prior notice of at least 5 working days, nonetheless, for particularly serious cases or if indicated otherwise in the certification schemes, ICIM reserves the right to make surprise visits without any prior notice.

The costs of this surveillance are charged to ICIM if the results are positive, unless specified otherwise in the offer.

The remote audit technique does not apply to unscheduled surveillance.

6.3 Results

If Non-Conformities (NC) are ascertained during both scheduled and unscheduled surveillance, these must be resolved (either by examining additional documentation or through an additional visit) within 2 (two) months from the date of the visit; in the event that this is not possible, unless an exception is granted, ICIM will suspend the certificate and will adopt the provisions of ICIM Regulation 0001CR, charging the costs incurred to the Organisation.

The suspension is only revoked when ICIM has ascertained compliance with the certified requirements has been duly restored.

In the event of serious shortcomings or continuation of the conditions that led to the suspension of certification beyond 6 (six) months, ICIM will proceed, at its sole discretion, with the revocation of the certification.

In the context of integrated audits, a non-conformity found for a standard may have consequences for the conformity with the other standards. If the organisation does not comply with one of the common

requirements of the integrated system, the non-conformity shall apply to the entire integrated system. If the organisation does not comply with a specific requirement of a standard, this only affects the standard in question.

7.0 CERTIFICATION VALIDITY

7.1 Duration of Certification

The Certificate is valid for 3 (three) years from the date of issue, unless stated otherwise in the certification scheme. The certificate can be renewed as indicated in chap. 8, unless indicated otherwise in the SCSxxxx.

Consequently to the COVID-19 health emergency and only for the time during which such health emergency conditions are in force, concessions and derogations from what has been mentioned above for the issue of the certification are possible, within the limits of what has been expressly indicated in the Circulars and communications issued by the competent supervisory bodies per specific scheme (e.g. Accredia, IAF, IAQG, etc.) in March and April 2020 (see note 4).

7.2 Conditions of certificate validity

The Organisation agrees to maintain the conditions that allowed the certificate to be issued unaltered:

- the certification only applies to the management system identified in the ICIM certificate[5]
- the Organisation maintains the requirements established by this regulation, by the certification scheme and by the standards, draft standards and/or applicable regulatory documents;
- ICIM must be promptly informed of any variations to the company conditions that allowed certification to be issued.

Any non-compliance with the above will be examined from time to time by ICIM which reserves the right to intervene in this regard, with specific actions, in order to bring any discrepancies to the regulatory certification conditions.

8.0 RENEWAL PROCEDURE

8.1 Renewal audit (VR)

ICIM activates the renewal procedure in the 6 (six) months prior to the expiry of the certificate, by sending appropriate estimates to the Organisation for conducting the audit activities in the subsequent period of validity of the certification.

ICIM guarantees the execution of the renewal audit at least one month before the expiry date of the certificate issued to the Organisation for the specific certification scheme. Any exceptions to the aforementioned deadlines can be granted by ICIM for valid reasons put forward by the customer organisations.

The certification is normally renewed according to the same criteria as for Phase 2.

In particular, the renewal audit takes into consideration the following aspects:

[5] The conformity of an integrated management system (e.g. on two or more certification schemes) is certified by two or more different certificates (one for each scheme subject to integration), each of which certifies conformity exclusively for the management system identified in said certificate.

- the effectiveness of the Management System as a whole, taking into account internal and external changes, its continued relevance and applicability for the scope of certification;
- the integration level of the integrated system (where applicable);
- the commitment shown, over the three-year certification period, to maintain the effectiveness and improvement of the Management System in order to improve overall performance;
- if the effectiveness of the Management System contributes to the achievement of the Organisation's policy and objectives;
- the review of the Management System documentation;
- fulfilment of the provisions of art. 7 of ICIM Regulations 0001CR (financial conditions).

At the same time as the renewal audit, audits can be carried out to extend/reduce the scope of the ICIM certification, with the same procedures described in this paragraph.

In the presence of significant changes to the Management System or the context in which the Organisation operates, ICIM may need to conduct a Phase 1 audit before performing the Phase 2 renewal audit.

The renewal audit must be completed successfully, giving sufficient time for ICIM to approve the renewal proposal and consequently reissue the certificate.

If it is not possible to perform or conclude the renewal audit (including verification of the implementation of corrective actions in response to Non-Conformities) within the certificate expiry date, after signing the three-year certification and scheduling contract for the renewal audit within the expiry date of the existing certificate, the renewal audit can be performed/terminated by ICIM within 6 (six) months from the certificate expiry date[6]. The consequent renewal approval will allow the certificate to be renewed in continuity with the previous one, maintaining evidence of the non-validity period of the certificate. Any exceptions to this requirement will be analysed from time to time by ICIM.

Beyond 6 (six) months from the certificate expiry date, if an Organisation wants to renew the certification, it will have to start a new certification process (Phase 1 + Phase 2).

On the occasion of the renewal audits, if formally and previously requested to ICIM by the certified Organisation, compliance with the transition to new editions of the reference standards may also be verified. This audit will take place with procedures consistent with the provisions of this Regulation and with unchanged timing compared to those envisaged for traditional renewal audits.

If, in the course of these audits, with reference to the new requirements of the reference standard, one or more Non-Conformities that lead to an unsatisfactory outcome of the audit are found, the certification renewal process for simultaneous compliance with the new requirements will be temporarily interrupted, blocking the ability of the Organisation to be certified, until evidence about the resolution of the shortcomings is made available by the latter.

If the necessary time for the resolution of the aforementioned Non-Conformities, requires exceeding the expiry date of the existing certificate or the deadline for the transition, the Organisation shall formally notify ICIM that, despite the certification no longer being valid, it will have the possibility to maintain the conducted renewal and transition visit valid and therefore reactivate the certification process, by submitting the Organisation to the ICIM approval process, to assess whether it can be certified, if it is able to approve the proposals for the resolution of non-conformities and to assess their implementation and effectiveness, within 6 months of the aforementioned deadline.

[6] Solely for the IAF 28 ISO 9001 Sector, please note that if the renewal is not carried out and completed by the certification expiry date, the certificate automatically loses its validity, with related consequences for the maintenance of the SOA certification.

The timing of such extensions can be changed, in particular cases, at the discretion of ICIM, upon motivated request of the Organisation.

In case of renewal audits to be performed with remote audit techniques, ICIM personnel will apply what is indicated in this paragraph, in the context of the means defined in chap. 4 of ICIM Instructions 0176BI - Remote audits.

8.2 Negative renewal results

In the presence of non-conformity situations, ICIM requires the Organisation to analyse the causes and implement specific processing operations and corrective actions for the resolution of the Non-Conformities before the expiry of the certification.

In this phase of the certification procedure, as well, in the context of integrated audits, the Organisation must take into account that a non-conformity found for a standard may have consequences for the conformity with the other standards. If the organisation does not comply with one of the common requirements of the integrated system, the non-conformity shall apply to the entire integrated system. If the organisation does not comply with a specific requirement of a standard, this only affects the standard in question.

When the Organisation fails to meet this deadline or the corrective actions taken do not guarantee the resolution of the Non-Conformity/ies and therefore the Organisation does not obtain the reissued certificate within the deadline, the relative certification must be considered expired from the day after the expiry date shown on the certificate. Any transmission to ICIM of the evidence for the resolution of non-conformities preventing the renewal of the certification, after the expiry of the certificate but within 6 months from that date, allow the certificate to be renewed in continuity with the previous one, but with the current issue date (date of renewal approval), such as to highlight the non-validity period of the certificate.

In the context of an integrated management system, the failure to renew the certification for one or more standards pertaining to the integrated management system shall result in ICIM assessing the impact of this measure on the certificates relating to the other standards that are subject to integration.

8.3 Positive results and re-issuing the certificate

The decision regarding the renewal of the certification is based on the results of the renewal audit, as well as on the results of the system review over the previous certification period (three years) and on the complaints received.

The positive results of the visit are binding in order to proceed with issuing a new certificate with 3-year validity, unless stated otherwise in the SCSxxxx certification scheme, and which will be identified by the same alphanumerical code as the previous one, except for the revision index. The certificate also shows the date of issue of the first certificate and the renewal (current issue) and expiry date[7].

Organisations that do not intend to renew the Certificate must give official notice.

Organisations can withdraw from the Contract/Certificate based on the conditions set forth in chapter 9 of this Regulation and the ICIM General Regulation.

[7] If the decision to renew the certification is taken after the certificate's expiry date, it is necessary for the certificate to mentioned the following 3 additional dates that identify the period of non-validity of said certificate.

9.0 CHANGES TO CERTIFICATION CONDITIONS

If the Organisation decides to make significant changes concerning the aspects listed below:

- organisational;
- relating to legal aspects;
- commercial;
- changes in staff;
- of the ownership structure;
- of the scope of certification;
- operational sites, operational units;
- Management System (including its level of integration with other certification schemes);
- extension/alteration of the Management System model chosen as a reference;
- extension/alteration of the products/processes/services involved in the certification of the Management System;

the Organisation must notify ICIM in advance that, if it considers such changes capable of influencing the compliance of the Management System with the applicable Certification Scheme, it will assess the impact on the certification in order to decide any actions to be requested to the Organisation and/or taken, such as (non-exhaustive list):

- request to integrate the Management System documentation and consequent review of the same (document examination);
- update of the offer concerning certification activities for the three-year period of validity of the same;
- certificate update (variation);
- execution of an additional audit (e.g. extension of scope).

Within 30 (thirty) days of receiving the notice relating to the Organisation changes, ICIM shall inform the Organisation of the decision taken.

If the Organisation does not accept ICIM's decisions, it must waive certification of the modification, giving notice, according to the procedure described herein.

The expenses for the new assessments are charged to the Organisation.

Other changes are described in chap. 8 of the ICIM General Regulations 0001CR.

10.0 TRANSFER OF ACCREDITED CERTIFICATES

If an Organisation with valid certification issued by another Body accredited in the sector under examination by an Accreditation Body adhering to the EA/IAF mutual recognition agreement, applies for the transfer of certification, ICIM carries out an audit that includes:

- The review of the certification application as described in par. 4.4 of this Regulation;
- the review of the initial audit/last renewal Reports and of those of the last surveillance audit performed
- the review of the status of any open non-conformities and of the related corrective actions;

- any on-site audits at the Organisation (pre-transfer visit) to be performed during the certificate's transfer, in case of negative result of the "document review" of the previous list points (this check is not to be considered an audit)

The Organisation must also notify ICIM about the following:

- A copy of the certificate(s) being transferred (issued by a previous CB).
- A statement on the reasons for the certification transfer request.
- A self-declaration by the Organisation that has requested the transfer, in which it confirms the certificate's validity.
- any observations or reports received from the national or local authorities in charge;
- any complaints received and related actions taken.

The contractual agreement between ICIM and the requesting Organisation is managed with the same procedures indicated in par. 4.4 depending on the extent of the audit activity.

When the aforementioned activity is completed successfully, ICIM issues the Management System certification which normally maintains the expiry date indicated in the previous certification.

In general, the scheduling established by the body that issued the certificate previously is maintained, even for the conduct of Management System surveillance and renewal audits.

If the certificates being transferred refer to a single integrated management system, the aforementioned conditions must be considered valid and applicable to each conformity certificate with the schemes subject to integration.

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