



PP05 Certification process

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1 PURPOSE

This procedure defines the certification process of 3EC International a. s. (3EC, also COMS) covering the fulfilment of international standards ISO/IEC 17021-1:2015, ISO/IEC 17021-2:2016, ISO/IEC 17021-3:2017, ISO/IEC TS 17021-9:2016 , ISO/IEC TS 17021-10:2018, IAF MD 4:2023, IAF MD 9:2023 and IAF MD22:2023.

2 VALIDITY RANGE

All personnel of COMS (internal and external) shall follow this procedure.

3 TERMS, DEFINITIONS AND ABBREVIATIONS

- **3EC International a. s.** – independent certification organization accredited for the performance of management systems certifications
- **COMS** – Certification organization for management systems
- **Client** – any organization whose management system is being audited for the certification purpose
- **certified Client** – organization whose management system has been certified
- **audit** – is systematic, independent and documented process of audit evidence gaining and their objective evaluation with the purpose of determining the scope in which audit criteria are fulfilled
- **certification audit of management system** – first verification of the Client's management system
- **surveillance audit of management system** – surveillance over the management system performed in the form of regular annual audits of management system
- **following audit of management system** – physical verification of the implementation of corrective actions proposed by the Client in response to a nonconformity and/or nonconformities found during certification, surveillance or short-notice audit
- **special audit of management system** – verification of the management system out of the program defined by 3EC scheme over management system, which is performed on the Client's request for the certification scope extension, if extension of the scope of already granted certification is not carried out during a regular surveillance audit. At Clients with certified OH&S management system 3EC shall perform special audit in the event that the 3EC becomes aware that there has been a serious incident related to occupational health and safety, for example, a serious accident, or a serious breach of regulation, in order to investigate if the Clients management system has not been compromised and did function effectively
- **short-notice audit of management system** – verification of management system out of the program defined by 3EC scheme over management system, which is performed on the basis of third party complaint, or in case of significant changes in the management system of the Client or as follow up on suspended Clients, in such cases can 3EC perform also verification by the form of unannounced audit

- **recertification audit of management system** – verification of management system after 3-year certification cycle expiration
- **transfer audit of management system** - verification of management system during transfer of the certification already granted to the Client from another accredited certification organization during the validity of certification cycle
- **3EC documents** – *POL08 Policy – Use of 3EC Management System Certification Marks* and other documents in applicable versions, with which the Client was acknowledged, resp. are available on 3EC website

4 CERTIFICATION PROCESS

4.1 APPLICATION

First step of certification process is filling in the application [F01 Request for management system certification](#), which is publicly available on web site www.3ec.sk. Through this application, the applicant sends specific required information and specific data about each site which is object of the certification. If needed, [F01-EMS Annex to request for a quote for environmental management system certification](#), [F01-IMS Annex to request for a quote for integrated management system certification](#), [F01-M Annex to the Request for Management System Certification as per ISO 13485](#), [F01-OHS Annex to the Application for OHSMS certification](#), [F01 MDSAP](#) are filled. In case of superior MDR / IVDR scheme together with ISO 13485, COMS uses form [F01Q NR Questions for Quoting](#), [P01 F01Q NR List of products according to MDR to Questions for Quoting](#), [P02 F01Q NR List of products according to IVDR to Questions for Quoting](#), [P03 F01Q NR List of products according to AXVI MDR to Questions for Quoting](#). After delivery of filled application COMS conducts a review of the application and supplementary information for certification [F01-R Review of request for management system certification / Review before recertification audit](#) with relevant attachments.

COMS informs the applicant whether is able to perform the certification process within the scope of its accreditation. If yes, the price offer for the Client is elaborated and after its approval, also the contract (F03/F27) is elaborated. After the signing of the contract COMS continues with the certification process.

4.2 INITIAL CERTIFICATION – Stage 1 of the certification audit

COMS realizes Stage 1 in accordance with the requirements of standard EN ISO / IEC 17021-1: 2015 and other abovementioned standards, if relevant. Stage 1 is realized as mandatory step of the certification process. With very small organizations, or organizations with simple activities, it is possible to decide within the application review that the Stage 1 will be performed in administrative form in the COMS Office by reviewing of documentation after the requesting of needed information. During the administrative review of information, the Lead Auditor is in contact with the Client via phone or internet and discusses with the Client possible uncertainties. During the Stage 1, the Lead Auditor assesses the state of readiness of the Client for the certification and for the performance of Stage 2. Lead Auditor mainly verifies the existence of prescribed documented information of the management system, internal audits, documented information review, risk analysis, performance indicators, organization processes and identifies weaknesses, which might be in Stage 2 be classified as non-conformities. He can highlight strengths and weaknesses and

opportunities for improvement of the Client's management system. The required scope of certification, non-applicable requirements and boundaries are discussed and specified. It serves for the preparation for the Stage 2 of the certification. The result of Stage 1 of the certification audit is a report about the state of readiness of the organization for the Stage 2 of certification audit. After the review the report is sent by COMS to the Client electronically, if relevant.

4.3 INITIAL CERTIFICATION – Stage 2 of the certification audit

Between Stage 1 and Stage 2 COMS considers the client's need to resolve the areas of dispute identified during the Stage 1. COMS reviews the arrangements related to the Stage 2. If there are any significant changes to the client's system that have a significant impact on its management system, COMS must reconsider the performance of the entire Stage 1 or relevant parts. If necessary, COMS informs the client that the results of the Stage 1 may postpone or cancel the Stage 2.

The Stage 2 of the audit must be initiated in accordance with applicable GENERAL TERMS & CONDITIONS of 3EC International a. s. available on company's website. During Stage 2 COMS evaluates implementation and effectiveness of client's management system. The Stage 2 must take place at the client's workplaces. During Stage 2 are audited all identified process of the organization, all applicable standards requirements and related requirements of interested parties within the scope and context of the organization, in reviewed and approved scope of certification which was approved based on application for the certification and during Stage 1.

During the audit are identified the strengths and weaknesses or nonconformities, in case of failure to comply the requirements of reference standard/s, audit criteria, as well as opportunities to improve the efficiency of the management system. Identified nonconformities can be small (non-systemic nonconformities) or large (systemic nonconformities). Lead Auditor informs about their solution during the opening and closing meeting. The Client must perform a root cause analysis and a description of specific correction and corrective actions taken or planned, consider the risks and opportunities and send them to the Lead Auditor (in accordance with the agreed deadlines according to [F20 Nonconformity Report](#)). Nonconformities must be resolved before a final decision on the certification. There must exist an objective evidence and Lead Auditor closes them in the Nonconformity Report, which is sent after review to the Client electronically together with final report [F06 Audit Report](#).

4.4 CERTIFICATION DECISION

On the closing meeting of Stage 2 of certification audit the Lead Auditor informs representatives of the Client about audit results.

Following recommendations are included:

- Recommendation for certification with chosen accreditation of COMS,
- Recommendation for certification after the closure of nonconformities – after the verification of efficiency of corrective actions,
- Recommendation to withhold certification, when Lead Auditor does not recommend certification, Lead Auditor recommends repeated audit at the Client (on-site audit) for the verification of the efficiency of the correction, corrective actions (with large number

of large (systemic) nonconformities, i.e. for example with total absence of standard/s requirements or Client's own documentation, etc.)

Certification decision is issued after the review of all available outputs from Stage 1 and 2 of the certification audit. Record about the final result from the review is completed on the form [F13 Certification decision - CBR Review](#), [F14 Decision on Certification / Recertification](#).

4.5 SURVEILLANCE AUDIT

COMS verifies the functionality and degree of the implementation of the management system through surveillance audits at the certified Client, which the contractual parties agreed to and planned for the entire contractual period. The purpose of surveillance audits is to confirm the eligibility of previous successful certification process.

Term of surveillance audit will be set so that the audit took place in accordance with the requirements of the international standard ISO/IEC 17021-1:2015 and other abovementioned standards, if relevant, i.e. in the case of the first surveillance audit, the audit to be carried out within 12 months from the date of the initial certification decision at the latest. COMS conducts surveillance audits at least once in a calendar year. Preliminary date is agreed on a specific previous audit with accuracy to calendar days, which the auditor shall record in the audit report.

4.6 RECERTIFICATION AUDIT

In case that at the end of the first contractual period, the results of surveillance audits are complying and satisfying, the recertification of Client's management system comes after. If the certified client expresses an intention to continue in the certification process, the contract is automatically extended for the same contract period (unless the parties agree otherwise). In case the Client does not want to continue in certification, the Client must give a written notice to COMS no later than three months before the end of the first and the following contractual period. This rule of prolongation of the contractual period is applied accordingly for the following contractual periods.

During the audit are identified strong and weak sides or nonconformities, if there comes to failure to comply with reference standard/s, audit criteria, as well as opportunities for improvement of effectiveness of management system. Identified nonconformities may be small (non-systemic nonconformities) or large (systemic nonconformities). Lead Auditor informs about their solution during the opening and closing meeting. The Client must perform a root cause analysis and a description of specific correction and corrective actions taken or planned, consider the risks and opportunities and send them to the Lead Auditor (in accordance with the agreed deadlines according to [F20 Nonconformity Report](#)). Nonconformities must be resolved before a final decision on the recertification. There must exist an objective evidence and Lead Auditor closes them in the Nonconformity Report, which is sent after review to the Client electronically together with final report [F06 Audit Report](#).

If the recertification activities are successfully completed before the expiry date of the existing certification, the new expiry date of the certification may be based on the termination date of the existing certification. Release date of the new certificate is the day or after the recertification decision.

If COMS has not completed the re-certification audit or is unable to verify the implementation of correction and corrective actions for any systemic nonconformity before the end of certification, recertification is not recommended and the validity of the certification will not be extended. The Client is informed about that in writing and the consequences are explained to the Client.

After the end of certification, COMS renews certification during the six months provided that the emergency recertification activities are completed, otherwise the Stage 2 is at least carried out. Effective date of the certificate will be at the day or after the recertification decision and the expiry date of the certificate is based on the previous certification cycle.

4.7 TRANSFER OF THE CERTIFICATE

Before the performance of transfer audit of management system is the Client obliged to submit to COMS valid certificate of management system, the last audit management system report, documentation of corrective actions to all nonconformities alternatively other relevant documents based on the mutual agreement between contractual parties. The validity of the certificate in case of successful completion of the transfer of management system certification is the same as the validity of the original certificate issued which is transferred from another certification organization.

4.8 SUSPENDING, WITHDRAWING OR REDUCING THE SCOPE OF CERTIFICATION

If during the audit occur facts that indicate that the certified management system does not fulfil requirements of the standard/s, COMS can suspend, withdraw or reduce the scope of certification.

COMS has the right to suspend the certification in cases when:

- Client's certified management system permanently or seriously fails to meet the certification requirements, including requirements for the effectiveness of the management system (based on the findings of the audit and substantiated complaints, motions of third parties),
- certified Client does not allow surveillance audits, recertification audits, follow-up audits, special audits or short-notice audits to be held at desired intervals,
- certified Client requests for suspension,
- certified Client does not resolve conclusively in time discrepancies found during audit,
- certified Client knowingly withholds complaints about his management system,
- certified Client does not notify certification body about specific or announced changes in organization that are decisive for the certification,
- management system of the Client with certified OH&S management system seriously failed to meet the OH&S certification requirements in case of a serious incident or breach of regulation necessitating the involvement of the competent state authority.

By official letter in printed or electronic form, COMS suspends the validity of the certificate, until the problem is resolved, but not for more than 6 months. In this letter, the reason for the suspension of the certificate and the conditions that must be met for the renewal of the certificate will be stated. During this time the Client cannot use the certificate and all promotional materials that contain a reference to certification. COMS disclose that fact on its website.

If conditions necessary for the renewal of a certificate were met by the time, COMS will renew validity of the certificate by an official letter. This will be published on the COMS website. Otherwise, i.e., if reasons for the suspension of the certificate were not removed at the time specified by the COMS, COMS will withdraw (cancel) certification or reduce the scope of the certification. By official letter in printed or electronic form, COMS shall reduce the scope of certification to exclude the parts not meeting the requirements, when the certified client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification. Any such reduction shall be in line with requirements of the standard used for certification.

By official letter in printed or electronic form, COMS can withdraw the certificate, resp. can declare certificate as invalid if:

- certificate or certification mark is exploited,
- certification or maintenance of certification is prohibited by law or by court,
- agreed by the contracting parties,
- at the time specified by the certification body, the reasons for the suspension of the certificate were not removed by the Client,
- management system of the Client with certified OH&S management system seriously failed to meet the OH&S certification requirements in case of a serious incident or breach of regulation necessitating the involvement of the competent state authority.

In a letter about the withdrawal of the certificate COMS will mention the reason for the withdrawal, together with the legal implications of the withdrawal of the certificate. By the withdrawal of the certificate, the Client must return the certificate to COMS, must stop using the 3EC logo and all advertising media with reference to certification. COMS will disclose this fact on its website.

4.9 SPECIAL AUDITS, EXPANDING SCOPE OF CERTIFICATION

Certified Client can apply for the extension of the scope of granted certification. COMS decides on the method of the certification scope extension, what is documented in the application review and informs the Client. Usually the certification contract is updated.

The Client may also apply for the certification extension for its other sites. COMS decides on the method of the certification scope extension for the other sites of Client, what is documented in the application review and informs the Client. Usually the certification contract is updated.

COMS conducts special audit of management system upon the Client's request on the granted certification scope extension, if the scope extension of granted certification is not performed during the surveillance audit.

The procedure follows according to part 4.4., i.e. confirmation of the certification decision is performed based on the review of all available outputs from the audit. As record of review result is the form [F13 Certification decision - CBR Review](#), [F14 Decision on Certification / Recertification](#).

4.10 SHORT-NOTICE AUDITS OF MANAGEMENT SYSTEM

COMS must conduct a short-notice audit of certified Client with the aim to investigate complaint or in response to changes at the Client mentioned in part 4.11 or as follow up on suspended Clients; in these cases, 3EC may perform verification in form of unannounced audit. In such cases, COMS describes to Client the conditions under which the audit is conducted and in advance informs the Client with them. 3EC also pays attention to audit team compilation because of the lack of opportunity for the Client to object to audit team members.

COMS in these cases behaves particularly sensitively and considerately and in full cooperation with the certified Client, in order such audit disrupts the organization's operation minimally and to prevent any objections.

The confirmation of certification decision is performed based on the review of all available outputs from the audit. As record of review result is the form [F13 Certification decision - CBR Review](#), [F14 Decision on Certification / Recertification](#).

4.11 CLIENT'S CHANGES

The certified Client is obliged to immediately inform COMS of any significant changes to its operations and/or products (goods and/or services, number of employees, etc.) within the management system, or change in any other circumstances that may affect the further competence of its management system to meet the requirements of the relevant standard (standards) used for the certification or the validity of the certificate. These include, for example, changes relating to the:

- changes in legal, commercial, organizational or ownership statute,
- changes in organization and management (e.g. key management personnel, decision-makers, professionals),
- contact addresses and workplaces,
- operation scope of activities covered in the certified management system,
- major changes in the management system and procedures.

Significant changes include everything, what can be a reason to perform short-notice or follow-up audit or to change existing certificate. COMS reserves right to assess significance of these changes and adopt adequate measures which will be communicated to the Client without delay.

Client with certified OH&S management system is obliged to inform COMS without delay of the occurrence of a serious incident or breach of regulation necessitating the involvement of the competent state authority.

4.12 APPEALS AND COMPLAINTS

If the client does not agree with the final decision of COMS to withhold issuing the certificate, on certification suspension or withdrawal or scope reduction, the Client can file an appeal which must be delivered to COMS in written form by registered mail or courier service at latest 15 calendar days after the Client receives the document which is the object of an appeal. The Client may complain against practices and activities of COMS. Same right has third party in case of complaint against Clients certified management system. The complaint must be submitted in writing via registered mail or courier.

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In general, the appeal or complaint must be lodged in the first instance to COMS. If the appeal or complaint is not accepted in the first instance by COMS, the Client, resp. third party has the right to contact the relevant accreditation body in writing. COMS informs the Client or a third party about the result of the appeal proceedings or the outcome of a complaint proceedings in writing via registered mail or courier within 30 days (in case of complaint can COMS, in justified cases, extend the deadline to 60 days) after their receipt.

In the case of complaint, appeal against COMS, COMS in the review and decision on the complaint, appeal does not act in a discriminatory manner towards the complainant, appellant.

Policy of complaints resolving and Policy of appeal resolving are available on the web site www.3ec.sk.