

**Description of the certification procedure**

MS - ISO 9001, MS - ISO 14001, MS - ISO 29001 and  
 MS - ISO 45001, MS - ISO 50001, MS - ISO 37001, MS - ISO 37301,  
 MS - ISO 55001, MS - SCC/SCP, MS - ISO 13485

**Opis certifikacijske procedure**

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<p>The certification of a management system based on standard ISO 9001, ISO 14001, ISO/TS 29001, ISO 45001 ,ISO 50001, SCC-VAZ ISO 55001, ISO 37001 or ISO 37301 consists of the offer and contract phase, the audit preparation, performance of the Stage 1 audit with evaluation of the management documentation, performance of the Stage 2 audit, issue of certificate and surveillance/recertification.</p> <p>The auditors are selected by the Head of the Certification Body of TÜV NORD CERT GmbH in accordance with their approvals for the particular branch (or sector in the case of ISO 50001) and their qualification.</p>	<p>Certifikacija sustava upravljanja temeljenog na normi ISO 9001, ISO 14001, ISO TS 29001, ISO 45001, ISO 50001, SCC-VAZ ISO 55001,ISO 37001 ili ISO 37301 pojedinačno sastoji se od faze nuđenja i ugovaranja, pripreme audita, provođenja audita faze 1 uključujući ocjenu dokumentacije sustava upravljanja, provođenja audita faze 2, izdavanja certifikata i nadzora/recertifikacije.</p> <p>Certifikacijsko tijelo imenuje auditore u skladu s njihovim odobrenjima za određeno tehničko područje (ili sektor u slučaju ISO 50001) i njihovim kvalifikacijama.</p>
<b>1. Certification procedure</b>	<b>1. Certifikacijska procedura</b>
<p>The certification audit consists of the Stage 1 audit and the Stage 2 audit. Both audits are generally performed at the client's site</p>	<p>Certifikacijski audit sastoji se od audita faze 1 i audita faze 2. Oba audita se uglavnom provode na lokaciji klijenta.</p>
<b>1.1 Audit preparation</b>	<b>1.1 Priprema audita</b>
<p>Following signing of the contract, the auditor prepares for the audit based on the questionnaire filled in by the customer and on the calculation sheet, and discusses and agrees the further procedure with the organization to be audited.</p>	<p>Nakon potpisivanja ugovora i primitka prijave za audit s predloženim tekstom djelatnosti od strane klijenta, certifikacijsko tijelo obavještava imenovani audit tim da dogovori daljnji postupak s organizacijom koja se auditira.</p>
<p>During preparation for the surveillance or recertification audit, the organizations to be audited have the duty to report fundamental changes in their organisational structure or changes in procedure to the certification body.</p>	<p>Tijekom pripreme za nadzorni i recertifikacijski audit klijent (auditirana organizacija) je dužan obavijestiti certifikacijsko tijelo o svim bitnim promjenama u svojoj organizacijskoj strukturi, opsegu certifikacije (djelatnosti navedenoj na certifikatu) ili promjenama u procedurama koje imaju bitan utjecaj na sustav upravljanja.</p>

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<b>1.2 Audit Stage 1</b>	<b>1.2 Audit faze 1</b>
<p>The Stage 1 audit is conducted in order to</p> <ul style="list-style-type: none"> <li>▪ audit the management system documentation of the customer,</li> <li>▪ assess the site and site-specific conditions of the customer and hold discussions with the personnel of the organization in order to determine the degree of preparedness for the Stage 2 audit,</li> <li>▪ assess the status of the customer and his understanding of the requirements of the standards, particularly with regard to identification of key performance or significant aspects, processes, objectives and operation of the management system,</li> <li>▪ to collect necessary information regarding the scope of the management system, processes and location(s) of the client, compliance obligations as well as quality, environmental, energy, health and safety aspects, and bribery risks</li> <li>▪ review the allocation of resources for Stage 2 audit and agree with the client on the details of the Stage 2 audit</li> <li>▪ to create a special focus for the planning of the Stage 2 audit, by gaining sufficient understanding of the client's management system and the activities at the site, together with possible significant aspects,</li> <li>▪ evaluate if the internal audits and management review are both planned and performed, and that the level of implementation of the management system demonstrates that the client is ready for the Stage 2 audit.</li> </ul>	<p>Cilj audita faze 1 je:</p> <ul style="list-style-type: none"> <li>▪ auditiranje dokumentacije klijentovog sustava upravljanja,</li> <li>▪ procjena klijentove lokacije i posebnih uvjeta na lokaciji i razmatranje raznih aspekta s osobljem u klijentovoj organizaciji u nastojanju da se odredi spremnost za audit fazu 2,</li> <li>▪ procjena klijentovog statusa i klijentovog razumijevanja zahtjeva norme, posebno s pažnjom na identifikaciju ključnih ispunjenja zahtjeva ili drugih bitnih aspekata, procesa, ciljeva i aktivnosti sustava upravljanja,</li> <li>▪ da se prikupe neophodne informacije u smislu opsega (područja primjene) sustava upravljanja, procesa i lokacija klijenta, kao i relevantne zakonske regulative, te da se ustanovi ispunjava li klijent te zahtjeve (npr. koji se odnose na kvalitetu, klijentove aktivnosti vezane uz okoliš i zakonsku regulativu, rizik korupcije itd)</li> <li>▪ da se ocjene resursi koji moraju biti predmet audita faze 2, i da se raspravi i dogovori o detaljima audita faze 2 s klijentom,</li> <li>▪ da se utvrde glavne točke za planiranje audita faze 2, prikupljanjem dovoljnog broja informacija za razumijevanje klijentovog sustava upravljanja i aktivnosti koje se provode na lokaciji te bilo kojih drugih bitnih aspekata koji se odnose na ovo,</li> <li>▪ ocijeniti jesu li interni auditi i upravina ocjena planirani i provedeni te osigurati da razina uvođenja sustava</li> </ul>

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<ul style="list-style-type: none"> <li>▪ verify if the SHE-MS according to SCC- VAZ has been in force for at least three months</li> </ul> <p>If weaknesses were identified in the Stage 1 audit, these must be corrected by the customer before the Stage 2 audit.</p> <p>If at the end it cannot be established positively that the customer is ready for the Stage 2 audit, the audit is broken off after the Stage 1 audit.</p> <p>The lead auditor is responsible for the coordination of the activities of the stage 1 audit and if necessary for coordination and cooperation of the auditors concerned amongst themselves.</p>	<ul style="list-style-type: none"> <li>▪ upravljanja dokazuje da je klijent spremjan za audit fazu 2.</li> <li>▪ provjeriti da je SHE-MS sukladno SCC- VAZ u primjeni minimalno tri mjeseca</li> </ul> <p>Ukoliko se tijekom audita faze 1 utvrde slabosti, iste moraju biti popravljene prije audita faze 2.</p> <p>Ako se na kraju ipak ne može utvrditi da je klijent spremjan za audit fazu 2, audit se prekida nakon audita faze 1.</p> <p>Lead auditor je odgovoran za koordinaciju aktivnosti audita faze 1 uključujući i koordinaciju među auditorima, te definira područje certifikacije u suradnji s klijentom.</p>
<b>1.3 Certification audit (Stage 2 audit)</b>	<b>1.3 Certifikacijski audit (audit faza 2)</b>
<p>The customer receives an audit plan at the beginning of the Stage 2 audit. The plan is agreed with the customer in advance. The audit begins with a kick-off meeting, in which the participants are introduced to each other. The procedure to be followed in the audit is explained. Within the framework of the audit at the organization's premises, the auditors review and assess the effectiveness of the management system which has been installed. This is based on the standards ISO 9001, ISO 14001, ISO 50001, BS OHSAS 18001, ISO 45001 ISO/TS 29001, ISO 55001, ISO 37001 and ISO 37301.</p> <p>The task of the auditors is to compare the practical application of the management system with the documented processes and to assess them in relation to fulfilment of the requirements of the standard. This is achieved by means of questioning of the employees, examining the relevant documents, records, orders and guidelines</p>	<p>Klijent prima plan prije početka audita faze 2. Plan se mora unaprijed usuglasiti s klijentom. Audit počinje uvodnim sastankom, u kojem se učesnici međusobno predstavljaju. Lead auditor objašnjava postupak provođenja audita. U okviru audita u prostorima organizacije auditori pregledavaju i ocjenjuju učinkovitost uvedenog sustava upravljanja. Osnovu za ovo čine norme ISO 9001, ISO 14001, ISO 50001, BS OHSAS 18001, ISO 45001, ISO/TS 29001, ISO 55001, ISO 37001 i ISO 37301.</p> <p>Zadatak auditora je da usporede praktičnu primjenu sustava upravljanja s dokumentiranim procesima i da ih ocjene u vezi s ispunjenjem zahtjeva norme. Ovo se postiže pomoću ispitivanja zaposlenika, pregledom relevantnih dokumenata, zapisa, narudžbi i vodiča te posjetе relevantnih područja auditirane organizacije.</p>

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<p>and also by visiting relevant areas of the organization.</p> <p>A final meeting takes place at the end of the on-site audit. At least those employees take part in the audit who have management functions within the organization and whose areas were included in the audit. The lead auditor reports on the individual elements and explains the positive and negative results. If nonconformities are established, the lead auditor can only recommend issue of the certificate to the organization after acceptance or verification of the corrective actions by the audit team, see Section 8 "Management of nonconformities". Attention must be drawn to this fact in the final meeting.</p> <p>The audit is documented in the audit report (the documentation must be separate for Stage 1 and Stage 2 audits) and is completed by means of further records (e.g. audit questionnaire and hand-written records).</p>	<p>Na kraju on-site audita održava se završni sastanak kojem prisustvuju barem oni zaposlenici koji imaju upravljačku ulogu unutar organizacije i čija su područja bila uključena u audit. Lead auditor izvještava o pojedinačnim elementima i objašnjava pozitivne i negativne nalaze audita. U slučaju utvrđenih nesukladnosti, lead auditor može predložiti da se organizaciji dodjeli certifikat tek nakon što audit tim prihvati ili verificira popravnu radnju (vidi poglavlje 8, Upravljanje nesukladnostima). Posebna pažnja mora biti posvećena ovoj činjenici tijekom završnog sastanka.</p> <p>Audit se dokumentira u izvještaju s audita (odvojeno za fazu 1 i fazu 2) i kompletira se kroz ostale zapise (npr. audit upitnu listu i rukom pisani zapisi).</p>
<p><b>1.4 Issue of certificate</b></p> <p>The certificate is issued when the certification procedure has been reviewed and released by the head of the certification body or his deputy or nominated representative. The person who reviews and releases the procedure may not (i.e. is not permitted to) have participated in the audit.</p> <p>The certificate can only be issued when the nonconformities have been corrected, i.e. when the corrective actions have been accepted or verified by the audit team.</p> <p>Normally the certificates are valid for 3 years.</p>	<p><b>1.4. Izdavanje certifikata</b></p> <p>Certifikat se izdaje nakon što imenovana osoba, njen zamjenik ili imenovani predstavnik od strane certifikacijskog tijela pregleda i odobri certifikacijsku proceduru. Osoba koja je sudjelovala u auditu ne smije pregledati i odobriti proceduru.</p> <p>Certifikat se može izdati tek nakon što audit tim prihvati ili verificira popravne radnje radi oticanjanja eventualno utvrđenih nesukladnosti.</p> <p>Period važenja certifikata je uglavnom 3 godine.</p>
<p><b>2. Surveillance audit</b></p> <p>Surveillance audits must be conducted once per year during the period of validity of the</p>	<p><b>2. Nadzorni audit</b></p> <p>Nadzorni auditi moraju se provoditi jednom godišnje tijekom perioda važenja certifikata (3 godine).</p>

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<p>certificate with the exception of the years when a recertification audit is performed. The first surveillance audit which follows the initial certification has to be carried out by the planning-relevant date, at the latest 12 months after the date of the certification decision. All the subsequent surveillance audits are planned on the basis of the planning-relevant date and must be conducted at least once per calendar year. Surveillance audits including the verification of measures for the correction of nonconformities, audit reporting and the certification decision must be completed no later than 3 or 4 months (in case of nonconformities) from the last day of the audit. The client receives a report following the surveillance audit.</p>	<p>Prvi nadzorni audit koji slijedi inicijalni certifikacijski audit mora se provesti prema referentnom datumu najkasnije 12 mjeseci nakon certifikacije. Svi naknadni nadzori planiraju se prema relevantnom datumu i moraju biti provedeni minimalno jednom godišnje.  Svi nadzorni auditi – uključujući i pregled popravnih radnji povezanih s identificiranim nesukladnostima, izvještavanje s audita i procesi odobravanja– moraju biti završeni najkasnije 3 ili 4 mjeseca (u slučaju nesukladnosti) od zadnjeg dana audita.  Nakon provedbe audita klijentu se na daljnje postupanje ostavlja izvještaj.</p>
<p><b>3. Recertification audit</b></p> <p>The audit for recertification has to be conducted before the expiry date of the certificate. A tolerance period of max. 6 months is then available for evaluation of the corrective actions and for any necessary re-audits and also for the decision on recertification within the framework of the release procedure. In the recertification audit, a review of the documentation of the management system of the organization is undertaken, as well as an on-site audit. Here, the results of the previous surveillance programme(s) over the term of the certification have to be taken into consideration. All the requirements of the standard are audited. Activities related to the recertification audit may include a stage 1 audit if there are significant changes in the management system or in connection with the activities of the organization (e.g. changes to the law).</p>	<p><b>3. Recertifikacijski audit</b></p> <p>Recertifikacijski audit mora biti završen prije isteka perioda važenja certifikata. Za ocijenu korektivnih radnji ili potrebnih ponovljenih audit kao i za odluku o recertifikaciji unutar okvira procedure odobrenja tolerira se period od maksimalno 6 mjeseci. U recertifikacijskom auditu pregledava se dokumentacija sustava upravljanja i provodi se on site audit pri čemu se u obzir uzimaju i rezultati prethodnih nadzornih audita u prethodnom certifikacijskom periodu. Audit program obuhvaća sve zahtjeve norme. U slučaju značajnih promjena u sustavu upravljanja ili promjena vezanih uz aktivnosti organizacije (npr. promjena zakonske regulative) u recertifikacijski audit može se uključiti i audit faze 1.</p>

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The audit methods used in the recertification audit correspond to those used in a Stage 2 audit.	Metode audita koje se koriste u recertifikacijskom auditu odgovaraju onima korištenim u auditu faze 2.
<b>4. Extension audit</b>	<b>4. Audit proširenja/suženja</b>
If it is intended to extend the scope of an existing certificate, this can be implemented by means of an extension audit. An extension audit can be conducted within the framework of a surveillance audit, a recertification audit or at a time which is set independently. The period of validity of a certificate does not change as a result. Exceptions must be justified in writing.	Proširenje područja certifikacije postojećeg certifikata moguće je provesti pomoću audita proširenja. Audit proširenja može se provesti u okviru nadzornog auditu, recertifikacijskog auditu ili u neko drugo određeno vrijeme. Period važenja certifikata ostaje nepromijenjen. Izuzeća moraju biti opravdana pisanim putem.
<b>5. Short-notice audit</b>	<b>5. Izvanredan audit</b>
It may be necessary to perform audits at short notice to investigate complaints, in response to changes or as follow up on suspended clients. In such cases, <ul style="list-style-type: none"> <li>• the certification body shall describe the conditions under which these short notice audits are to be conducted,</li> <li>• it is not possible to object to members of the audit team.</li> </ul>	Možda će biti potrebno provesti izvanredni audit kako bi se istražile pritužbe, u slučaju promjena ili kao ponovljeni audit u slučaju suspenzija certifikata. U tim slučajevima, <ul style="list-style-type: none"> <li>• Certifikacijsko tijelo će definirati uvijete zbog kojih će se izvanredni audit provoditi</li> <li>• Klijent nema mogućnosti prigovora članovima audit tima</li> </ul>
<b>6. Transfer of certificates from other certification bodies</b>	<b>6. Preuzimanje certifikata od drugih certifikacijskih tijela</b>
In general, only certificates from accredited certification bodies can be taken over where the accreditation body is a signatory to the Multilateral Agreement (MLA) of the EA (European co-operation for Accreditation). Organizations with certificates which originate from non-accredited certification bodies are treated as new clients. The issuing certification body is informed about the planned transfer. As soon as no reasons are known from the issuing certification body and the customer that exclude a transfer of the valid certificate	U pravilu, preuzimati se mogu samo certifikati od akreditiranih certifikacijskih tijela koje su potpisnik Multilateralnog sporazuma (MLA) EA (Europska kooperacija za certifikaciju). Organizacije koje posjeduju certifikate izdane od neakreditiranih certifikacijskih tijela tretiraju se kao novi klijenti.  O planiranom transferu obavještava se certifikacijsko tijelo koje je izdalо certifikat. Čim od certifikacijskog tijela i kupca ne budu poznati razlozi koji isključuju transfer važećeg

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<p>according to IAF MD 2:2017, the transfer can be carried out.</p> <p>A "Pre-Transfer-Review" must be conducted by a competent person from the certification body which is taking over the certificate. This review generally consists of an examination of important documents and a visit to the client.</p> <p>After positive completion of the pre-transfer review, TÜV NORD CERT, as the accepting certification body, can carry out the transfer of certification.</p> <p>The normal certification decision making process shall be followed, including the requirement that the personnel making the certification decision are different from those carrying out the pre-transfer review.</p> <p>TÜV NORD CERT, as the accepting certification body, shall take the decision on certification before any surveillance or recertification audits are initiated.</p> <p>The certification cycle of the transferred certificate is based on the previous one. TÜV NORD CERT shall establish the audit programme for the remainder of the certification cycle.</p> <p>Where the accepting certification body is required to treat the client as a new client as a result of the pre-transfer review, the certification cycle shall begin with the certification decision.</p> <p>Certificates which have been suspended, or where there is risk of suspension, may not be taken over.</p> <p>The issuing certification body is informed as soon as the certificate has been successfully transferred.</p>	<p>certifikata prema IAF MD 2:2017, ptransfer se može izvršiti.</p> <p>Pregled prije preuzimanja mora biti proveden od strane kompetentne osobe iz certifikacijskog tijela koje preuzima certifikat. Ovaj pregled obično obuhvaća ocjenu važnih dokumenata i posjet klijentu.</p> <p>U slučaju pozitivnog završetka pregleda prije preuzimanja, TÜV NORD CERT kao certifikacijsko tijelo koje klijent prihvata može provesti preuzimanje certifikata.</p> <p>Uobičajeni postupak odlučivanja o certifikaciji se mora provesti, uključujući i zahtjev da se osoblje koje donosi odluku o certifikaciji razlikuje od onoga koje provodi pregled prije preuzimanja.</p> <p>TÜV NORD CERT, kao certifikacijsko tijelo koje klijent prihvata, mora donijeti odluku o certifikaciji prije nego se pokrenu ili nadzorni audit ili recertifikacijski audit.</p> <p>Certifikacijski ciklus preuzetog certifikata temelji se na prethodnom ciklusu. TÜV NORD CERT mora uspostaviti audit program za ostatak certifikacijskog ciklusa.</p> <p>Gdje se od certifikacijskog tijela koje klijent prihvata bude na osnovu pregleda prije preuzimanja zahtjevalo da klijenta tretira kao novog klijenta, certifikacijski ciklus mora početi s odlukom o certifikaciji.</p> <p>Certifikati koji su suspendirani, ili postoji rizik od suspenzije, ne mogu se preuzeti.</p> <p>Certifikacijsko tijelo koje je izdalo certifikat obaveštava se čim je transfer certifikata uspješno obavljen.</p>
<b>7. Certification of multi-site organizations</b>	<b>7. Certifikacija multi-site organizacija</b>
<p>A sampling procedure can be used for organizations with several sites ("multisite certification"). In this case, the client assures the certification body that the following requirements are met for all the sites which</p>	<p>Procedura uzorkovanja može se koristiti za organizacije sa više lokacija ("multisite certifikacija"). U tom slučaju klijent mora osigurati da su zahtjevi norme ispunjeni na svim lokacijama koje su uključene u područje</p>

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fall within the scope of the certificate. Any changes or non-fulfilment of one or several prerequisites shall (i.e. must) be communicated to the certification body immediately.

**Prerequisites for multisite certification:**  
 A multi-site organization does not have to be one single legal entity. However, all the sites shall (i.e.must) have a legal or contractual relationship with the headquarters ("central office") of the organization and be subject to a common management system, which is specified and installed by the central office and is subject to regular monitoring and internal audits by the central office. This means that the central office has the right to require the sites to implement corrective actions, if these are necessary at a particular site.

- The processes must be basically the same at all sites and must be implemented using similar methods and procedures.
- The management system of the organization must be administered under a centrally controlled plan and must be subject to a central management review. All the individual sites within the multi-site system including the central administration (central office) function must be subject to the internal audit programme of the organization and must be audited in compliance with this programme.
- It must be demonstrated that the central office of the organisation has installed a management system in compliance with the relevant management system standard(s) which form the basis for the audit and that the entire organization fulfils the requirements of the standard.
- The organization must demonstrate its ability to collect and analyze data from all sites, including the central

(scope) certifikacije. Certifikacijsko tijelo mora biti obaviješteno o eventualnim promjenama ili neispunjenu jednog ili više preduvjeta

**Preduvjeti za Multi-site certifikaciju:**  
 Multi site organizacija ne mora biti jedna pravna osoba. Međutim, sve lokacije (članice) moraju imati pravni ili ugovorni odnos sa središnjim uredom (centralom) organizacije i imati isti zajednički sustav upravljanja definiran od strane središnjeg ureda koji redovno prati i provodi interne audite. To znači da središnji ured ima pravo zatražiti određenu lokaciju (članicu) da provede korektivnu radnju ukoliko smatra potrebnim za tu određenu lokaciju.

- Procesi u osnovi moraju biti isti na svim lokacijama i moraju se primjenjivati koristeći slične metode i procedure
- Sustav upravljanja organizacije mora biti upravljan i kontroliran od strane sjedišta i mora biti podvrgnut pregledu uprave središnjeg ureda. Sve pojedinačne lokacije unutar multi-site organizacije (uključujući i sjedište) moraju biti predmet u programu internog audita i moraju biti auditirani u skladu s tim programom
- Potrebno je dokazati da središnji ured ima sustav upravljanja sukladno odgovarajućim standardima koji čine osnovu za audit i da cijela organizacija ispunjavaa zahtjeve standarda
- Organizacija mora dokazati svoju sposobnost prikupljanja i analize podataka sa svih lokacija, uključujući i

MS - ISO 9001, MS - ISO 14001, MS - ISO 29001 and  
 MS - ISO 45001, MS - ISO 50001, MS - ISO 37001, MS - ISO 37301,  
 MS - ISO 55001, MS - SCC/SCP, MS - ISO 13485

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<p>administration function (central office) and its management, and shall instigate any necessary organizational changes, including those related to:</p> <ul style="list-style-type: none"> <li>- Management review,</li> <li>- Complaints,</li> <li>- Evaluation of the corrective actions,</li> <li>- Planning of internal audits and evaluation of the results,</li> <li>- Legal requirements.</li> </ul> <p>• A contract must be concluded between the client and the certification body which is legally enforceable at all branches/production sites.</p>	<p>sjedište (upravu), te da će poticati sve organizacijske promjene koje budu potrebne, uključujući one vezane za:</p> <ul style="list-style-type: none"> <li>- Upravnu ocjenu</li> <li>- Pritužbe</li> <li>- Ocjenu korektivnih radnji</li> <li>- Planiranje internog audit-a i ocjenu rezultata</li> <li>- Pravne zahtjeve.</li> </ul> <p>• Između organizacije i certifikacijskog tijela potrebno je sklopiti Ugovor koji je zakonski provediv na svim lokacijama/članicama.</p>
<b>8. Management of nonconformities</b>	<b>8. Upravljanje nesukladnostima</b>
<p>An analysis of the causes must be performed for each nonconformity and corresponding corrective actions must be implemented. The organization has the duty, depending on the seriousness of the nonconformity, to inform the audit team within 6 weeks after the last day of the audit either with regard to the corrective actions which have been laid down and the dates for their implementation or that the corrective actions have been implemented. If this period is not observed, the audit is considered not to be successful, i.e. not to be passed. No certificate can be issued, or an existing certificate is withdrawn.</p>	<p>Analiza uzroka mora se provesti za svaku pojedinu nesukladnost i odgovarajuća se popravna radnja mora provesti. Organizacija je obvezna ovisno o ozbiljnosti nesukladnosti unutar 6 tjedana obavijestiti audit tim bilo o utvrđenim popravnim radnjama i datumu primjene istih ili o provedenim popravnim radnjama. Ukoliko se navedeni rok neispoštuje, audit se smatra neuspješnim. U tom se slučaju certifikat ne može izdati ili se postojeći certifikat povlači.</p>