

Inspection Regulation



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Introduction

This Clients' Assessment Manual contains regulations regarding the assessment and certification activities of Control Union Italia s.r.l (CUC). It mentions what the Client's rights and obligations are, as well as those of CUC. This may include additional rules for specific programs as addressed in the applicable addendums. The Clients' Assessment Manual is complementary to the applicable standards as well as to the Terms of Contract. It explains what you, as a Client, may expect from CUC and what CUC may oblige you to do.

1. Scope and applicability

CUC provides its services to legal entities, which can be persons, firms or companies and are referred to as "Client". CUC may provide its services directly by use of its own employees or, in its own discretion, through a CUC affiliated company or any other organisation. Where CUC does subcontract part of its work to others, it will under all circumstances retain full authority and responsibility for having a contractual agreement in place with the Client and for granting, maintaining, extending, reducing, suspending or withdrawing certification. CUC will notify its Clients of any changes to the requirements for certification within a reasonable timeframe. The Clients' Assessment Manual and any amendments are published on the CUC website and/or through the CUC Client Information System (CIS).

This Clients' Assessment Manual is an integral part of the set of normative documents as referred to in the Service Agreement. CUC has the right to change or extend this Clients' Assessment Manual as it feels fit, provided that it continues to comply with the requirements from the harmonised standards (i.e. ISO/IEC 17020, ISO/IEC 17065 and ISO/IEC 170210, as applicable. For any change or extension of this Clients' Assessment Manual, a transition period of three months from the date of adoption may be given, clearly stating the end date of the transition period.

In all cases where this Clients' Assessment Manual or any other applicable regulation or agreement does not provide sufficient guidance, the CUC Director will decide.

2. Confidentiality

CUC and its employees at all levels of its organisation, including any committee members, contractors, personnel of external bodies or individuals acting on behalf of CUC, are obliged to consider all information obtained in the course of its business activities to be proprietary information and to regard it to be confidential. CUC is not allowed to disclose such information to any third party without the written consent of the Client. CUC does this by applying the same care that it uses for its own information. It will use the Clients' confidential information only for the purpose of its activities and not disclose that confidential information or give access to a third party, without your prior written consent. However, we are obliged to inform anybody about the status of your certification, when asked to do so. We may also be required to disclose information by law or to the Scheme Owner or our Accreditation Body, provided that this information is needed by that particular organisation to fulfil its natural and contractual obligations and unless prohibited by law. And we may of course have to disclose information to our employees, including any committee members, contractors, affiliate offices, personnel of external bodies or individuals acting on behalf of CUC, to be able to conduct the agreed services to you.

You as a Client may disclose confidential information about our procedures and methods to your affiliates (meaning any person which directly or indirectly controls you, is controlled by you, or is under

your direct or indirect control) and to your officers, employees or subcontractors only on a need to know basis. Disclosure to any other third party is prohibited.

Information is not considered to be confidential is that information is or becomes shortly generally known or available to the public. Or if that information evidently is developed by CUC independently from your information or activities. Or if that information is disclosed to CUC in good faith by a third party who has an independent right to that information. Or of course when it is agreed between you and CUC (e.g. for the purpose of responding to complaints). Information about you that was obtained by CUC from sources other than you (e.g. from a complainant or from regulators) will be treated by CUC as confidential, unless both the source of information and you, the Client, give written consent to disclose it.

CUC personnel, including any committee members, contractors, personnel of external bodies or individuals, acting on behalf of CUC, shall keep confidential all information obtained or created during the performance of CUC's activities except as required by law. Any people present in the assessment that are not subject to certification activities, nor acting on behalf of CUC, must sign a non-disclosure agreement in order to prevent them from breaching the CUC objective and impartial position (see Annex A18 "Non-disclosure and confidentiality agreement Experts" and Annex A19 "Non-disclosure and confidentiality agreement Observers"). Anybody refusing to sign the applicable non-disclosure agreement shall not be present in the assessment.

3. Types of certification

CUC uses a number of assessment methods, depending on the type of certification that applies. In general we distinguish between three types of certification:

Inspection:

This is an evaluation of materials, products, installations, plants, processes, work procedures or services, and the determination of their conformity with requirements. The validity of the outcome of the assessment only relates to the moment of assessment. The statement of conformity of an inspection states that the inspection body has assessed a specified product or process etc. at a specified date against a specified set of requirements and has found them to be in conformance at that time. The statement of conformity does not contain a validity. In other words, there is no certification, just a declaration of conformity. Where an statement of conformity is issued, this is not referred to as a certificate, but as a declaration. This also means that an inspection statement cannot be suspended or withdrawn. The person conducting an inspection is known as inspector. It also means that basically every assessment is the same, every time a new statement of conformity has to be issued. Inspection schemes normally do not apply a mark or logo. Accredited inspection activities are based on ISO/IEC 17020.

Product certification:

This is a systematic process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which a product, process or service fulfils a specified set of requirements. The aim is to provide confidence to consumers, regulators, industry and other interested parties that products conform to specified requirements, including for example product performance, safety, interoperability and sustainability. A product in this definition may also be read as process or service. And a product certification process may contain elements from inspections or management system certification. The statement of conformity states that the certification body, based on the assessment of a specified product or process etc. at a specified date against a specified set of requirements, has the justified confidence that this specified product or

process etc. will continue to remain in conformance for the set validity period of the statement. The statement is normally referred to as a certificate. In product certification, the very first assessment is always an initial assessment, followed by surveillance assessments and periodically a re-certification assessment, where a new certificate is issued. Product certification schemes normally allow for the use of a logo or mark to be applied on the product. These logos and marks may have to comply with specific requirements. Accredited product certification activities are based on ISO/IEC 17065.

Management system certification:

This is a systematic process for obtaining assessment evidence and evaluating it objectively to determine the extent to which the management system fulfils a specified set of requirements. The aim of management system certification is to provide confidence and trust that the management system is conforms to specified requirements, is capable of consistently achieving its stated policy and objectives and is effectively implemented. A management system assessment is known as an audit and the person performing an audit is an auditor. Management system processes normally concern activities that have more than one possible option to reach the set goal and normally is a framework of policies, processes and procedures used to ensure that the organisation can fulfil all the tasks required to achieve its objectives. Processes, procedures and policies in a management system interact with each other and with their environment. Consequently, a process may be initiated in order to come to a predefined outcome, but it is not guaranteed that this outcome will actually be achieved. Processes in a management system are normally on-going processes. Past performances will most probably affect future results. Making a certification decision therefore cannot be seen without the context of achievements past and must be considered in the judgment whether or not the management system as a whole will be able to continue conformity and effectiveness as well as relevance and applicability for the scope of certification. In management system certification you are never ever allowed to raise the suggestion that the product, process or service coming from that system complies; after all, that is not what has been assessed. Therefore, if there is a logo or mark to be used, you are not allowed to use that directly on the product or product packaging, nor is it allowed to state elsewhere that the product complies or has a certain status. Logos and marks may have to comply with specific requirements. Accredited product certification activities are based on ISO/IEC 17021.

4. Types of assessment

In assessing your subject of assessment, CUC applies the following assessment types:

Initial assessment:

This is the very first assessment CUC applies to your product or organisation for this particular program and scope. In inspections and product certifications, that does not mean much: as said, all inspection are the same. And in product certifications, all (re-)certification assessments are the same. However, in management system assessments can, not surprisingly, be rather complex. In the initial assessment the Client's management system documented information, site-specific conditions, status and understanding of standard requirements within the organisation, information regarding the scope of the management system, applicable statutory and regulatory requirements and implementation and effectiveness of the Client's management system are reviewed and evaluated. In calculating the amount of assessment time to be used, the amount of time used for the initial assessment is set to 100%.

Recertification assessment:

After the initial assessment, a certificate is issued. This certificate has a period of validity. This validity is normally set by the scheme owner and may vary from 1 to 5 years. However, 3 years is a typical validity for certificates. Before the validity of this certificate lapses, CUC needs to assess whether or not a new certificate can be issued. For that reason, the recertification assessment is generally planned 3 months before the validity of the certificate lapses. For inspections, this does not really apply, as each inspection results in a new declaration. In product certification and in management system certification, we use a recertification assessment. It is an assessment similar to the initial assessment, at least for product certification. In management system certification we apply what are called stage 1 and stage 2 assessment. The stage 2 assessment is the actual assessment on site, where we verify documents and registration, interview people, take samples if needed etc. The stage 1 however we only apply in the initial and recertification assessments. The stage 1 is meant to assess the company's documentation, the legislation, its environment etc. In the initial assessment we have no clue yet how that works. In the recertification assessment we already know your organisation, so we only have to apply the stage 1 to changes that have taken place and that need to be re-evaluated. In a product certification there is no consequence for the assessment time to be allocated. For management system assessment it will impact that time, as follows. The 100% allocated for the initial assessment refers to both the stage 1 and the stage 2. Since the stage 1 does not have to be as extensive in a re-certification assessment, the amount of time allocated to a recertification assessment normally is 66% of the time allocated to the initial assessment.

Surveillance assessment:

Between initial and recertification assessments, surveillance assessments are applied. These are meant to ensure that the Client's product, service or management system remains in compliance with set requirements and that the statement we have made on the certificate is still valid. In essence, the activities we deploy in a surveillance assessment are the same as what is done in a stage 2 assessment. We do not issue new certificates based on a surveillance assessment, but the findings in a surveillance assessment can lead to the decision that the certificate has to be suspended. Some schemes give or require the option of unannounced surveillance assessments. Again, in a product certification there will be no consequences for assessment time allocation. For management system assessments, there is no stage 1 in a surveillance assessment, therefore assessment time is normally set to 33% of the time allocated for the initial assessment.

Remote assessment:

Remote assessment may be applied where the extent of involvement between you, the Client, and our assessor does not require face-to-face interaction or verification on site, but can be replaced by electronic communication and/or submission of evidence. It may also be applicable where it is preferable to minimise interference between assessment activities and the Client's operational processes as far as practicable, or where health and safety requirements would render off-site methods applicable. Where remote assessment is applied, it should not reduce the effectiveness and efficiency of the conventional assessment process and where possible enhance it and it must support and maintain the integrity of the assessment process. Feasibility of remote assessment activities also depends on the level of confidence between assessor and the Client's personnel.

Short notice assessment:

It may be necessary for CUC to verify whether or not our certification statement that your product or organisation still complies with requirements between regular assessments. For instance to investigate a complaint we have received, or in response to a significant change in your organisation

or product, or as follow up on suspended Clients. To that end we may apply an assessment at short notice. Because the reason of the short notice assessment is normally of a rather urgent or serious nature, it is at the sole discretion of CUC to decide these assessments. We have addressed the matter in our terms of contract. If needed, we may even apply these assessments as unannounced assessment. We must be able to provide you with a clear reason why we want to do a short notice assessment, but that is not open to discussion.

Joint assessment:

A joint assessment is an assessment where two or more conformity assessment bodies cooperate to assess a single auditee. This may concern two or more certification bodies, but could also apply to a scheme owner joining in an assessment. Each assessing party must accept full responsibility for its role in the assessment.

Combined assessment:

It may occur that a Client applies two or more management systems of different disciplines (e.g. quality, environmental, occupational health and safety). When two or more of these disciplines are assessed together in one assessment, this is called a “combined assessment”.

Integrated assessment:

The above Client applying two or more management systems of different disciplines (e.g. quality, environmental, occupational health and safety) may have combined these disciplines into a single management system. An assessment on such a management system is called a “integrated assessment”.

5. Subject of evaluation

The scope of the assessment is stipulated in your Service Agreement for the applicable assessment and is an identification of:

- the product(s), process(es), service(s) or management system(s) for which the certification is granted,
- the applicable certification scheme, and
- the standard(s) and other normative document(s), including their version, to which it is judged that the product(s), process(es), service(s) or management system(s) comply.

You are obliged to inform CUC in case the products, processes, services, units and/or management system that is under the CUC scope are also certified by another certification organisation against the same standard (or applied for certification to another certification organisation).

Where a Client and its subcontractors are assessed by different conformity assessment bodies, the Client and its subcontractors have to assent to the fact that the conformity assessment bodies can exchange information on the operations under their contract.

Changes in subject of evaluation

You are obliged to inform CUC as soon as possible if any changes occur which interfere or might interfere with the requirements as mentioned in the concerned regulations or which indicate a change in the scope of the certificate. This may include but is not limited to changes in ownership, structure,

management or any other change that might impact on your ability to comply with applicable standards.

When you apply for addition of new units, products, processes or services to the scope of your certification, you must apply (in writing) prior to production and/or processing commences, to producing/delivering, processing and/or selling the product, process or service with reference to the certification. You should always apply by means of an application form, so we have a formal registration that we are indeed requested and allowed to perform our services. CUC will evaluate the requested addition and, upon a positive result, add it to the scope of your certification. This evaluation may require a complementary inquiry. The costs of these are not included in the contract and may be charged to you on the basis of real made costs

6. Application for certification

A Client can express interest in CUC assessment services by completing an application form for the specific scheme. This application form can be found on the Control Union Certifications website, or can be requested from CUC by mail or phone. Based on the application form, CUC will calculate the time needed to perform the (distinguished types of) assessments and send you a proposal, outlining the scope and the costs of the services.

Upon return of the signed proposal, we have a valid and legal agreement. CUC will register the project in our information system and allocate you to one of our qualified assessors. This assessor will be responsible for ensuring that the services are conducted in accordance with CUC procedures for the specified scheme. The assessor will probably request you to send in documentation for assessment. You will also be requested to pay down the first instalment of your fee. As long as we have not received that, we will not be able to proceed to the next step, planning your assessment.

During the assessment, the assessor should verify that the scope of the assessment is correct, that all people, products, processes, services, units, etc. are included in the assessment as required by the scheme. If you did not specify this completely in the application form, the assessor may come to the conclusion in the first assessment that the contract that was agreed is (hugely) inadequate to cover all subjects that should have been included. In the worst case he or she may end the assessment and come back for a new appointment after all documentation has been completed. It is therefore very important that you complete the application form in full and truthfully.

Be aware that, by signing the contract, you oblige yourself to comply with the following procedures and rules:

- a. You must make available to CUC all documents, samples of products, drawings, specifications and other information required by the CUC assessor, in his or her sole discretion, to complete the assessment programme;
- b. You are obliged to give access to all locations and facilities the CUC assessor, in his or her sole discretion, find necessary. Not providing the required information or access, or intentionally delaying the process, may be interpreted as obstructing the assessment, which may be cause for ending the assessment and, in severe cases, even suspension of the certificate;
- c. Before the assessment may commence, CUC will check whether the payment has been received and any other obligatory requirements by the Client have been fulfilled. If no payment has been received or other obligations have not been met, the assessment will not be carried out. When no payments have been received for a prolonged period of time, following one or more reminders by

- CUC, CUC will consider the decision to suspend the Client. If after 6 months following suspension still no payment has been received, the certificate will be withdrawn, and the Client resigned.;
- d. You must, when so requested, allow and accommodate in the assessments the presence of observers from accreditation bodies, scheme owners, governmental bodies or trainee assessors. You may object against certain people representing these organisations, but you cannot object against these organisations themselves. Meaning that if one of these organisations voice their interest in being present in an assessment at your organisation, you have to comply. Again, refusal to cooperate may be interpreted as obstructing the assessment, which may be cause for ending the assessment and, in severe cases, even suspension of the certificate.
 - e. You have to inform CUC immediately of any changes in your product or organisation that may influence what we have to assess during the assessment and what we declare on the certificate. That may range from additional products to change in key personnel, from adding a new production line to removing a product. You should be aware of a few issues in this: if changes are significant, we may have to adjust the time we have to spend in the assessment and provide you with an adapted contract. Or the addition may be something the current assessor is not qualified for. As a result, we may not be able to perform the assessment at the agreed time, which adds costs. Please be aware that, if you have taken a production line or unit out of service or do not produce a certain product for more than 2 years, we will not be allowed to include that line, unit or product in our statement anymore and we will have to adjust the assessment time and contract accordingly. Please inform us of that also.
 - f. Generally speaking, you cannot refuse an assessment. However, there may be unforeseen circumstances that make it impossible to perform the assessment due to “superior forces” or “force majeure”. This may include inaccessible roads, flooding, fires, explosions, earthquakes, drought, tidal waves, etc. And/or if its access is not safe for the Client and/or assessor due to riot, (civil) war, hostilities, act of terrorism, piracy, rebellion, revolution, insurrection of military or usurped power; but also epidemics, maritime or aviation disasters or failures of utilities companies (such as: providers of telecommunication, internet, gas or electricity services). If such a cause for delay comes to your attention, you have to promptly notify CUC of the Force Majeure event and its cause and likely duration. In such cases CUC will try its outmost to perform the assessment at a later stage or to obtain the required information through alternative means.

7. Planning

Based on the information in the contract, CUC will plan the first assessment and assign the assessment to an assessor based on the information in the application form and offer and rules as set per standard per applicable program. The assigned assessor will be informed, including all relevant information for the assessment and the scope of assessment (area, subprogram, size of project etc.). In large assessments, CUC may decide to appoint an assessment team. Where the assessment requires specific in-depth knowledge and expertise, a technical expert may be contracted by CUC to join in the assessment. And as applicable, translators and interpreters may be part of the team. However, where an expert is allowed to join in the actual assessment on a specific subject, are translators and interpreters only allowed to operate under the direction of an assessor.

The names of all these people are to be mentioned on the assessment plan/communicated to the client by e-mail within 24h before the assesment. In case no reply we consider accepted the team/inspector involved and communicated. In exeptional cases, when we have a short-notice assignement, we do not consider the 24h but we communicate the people assigned as soon as possible. The eventual non-acceptance of the inspection team must be communicated in the shortest possible time and maximum 8h before the inspection.

The assessor or team-leader contacts the Client and makes an appointment for the execution of the assessment within the timeframe specified within the program requirements. If you have changes to report, this is definitely one time to address them. The assessor will also establish the scope and criteria of the assessment in discussion with you. And you may be requested to send relevant documentation prior to the assessment itself. - 8 -

Where applicable, an assessment plan is sent to you in due time before the assessment. This plan is meant to ensure that assessment time is used appropriately and efficiently and that all items that need to be assessed can be assessed within the timeframe of the assessment. It should contain at least:

- a) the assessment objectives;
- b) the assessment criteria;
- c) the assessment scope, including identification of the organisational and functional units or processes to be assessed;
- d) the dates and sites where the on-site assessment activities will be conducted, including visits to temporary sites and remote assessment activities, where appropriate;
- e) the expected duration of on-site assessment activities;
- f) the roles and responsibilities of the assessment team members and accompanying persons, such as observers or interpreters.

Based on the information you should be able to prepare properly for the assessment and to have the applicable people, units and documents available.

If needed, you are allowed to object to the appointment of any particular assessor or technical expert, but you must be able to substantiate such objection. When your objection is valid, CUC will reconstitute the team and appoint another assessor or expert.

8. Assessment

The purpose of the assessment is to provide CUC with sufficient detail to enable an informed certification decision to be made. The assessment takes place against all applicable elements of the standard. For that, CUC will verify product- and process specifications, system plans, registrations, procedures and work instruction, will interview people and cross verify findings with the actual situation.

The Client must make all required arrangements for the accomplishment of the assessment. You must duly make available to CUC any and all information and documents that CUC finds necessary, including the actions you have taken in response to any complaint. It is your responsibility that this information is correct, complete and reliable. You must also provide CUC (and any authorities rightfully present in the assessment) unobstructed access without prior notification to all areas, premises and units which fall within the scope of certification. And personnel and equipment must be available, so the assessment can be performed effectively. Please be aware that failure to comply with this requirement may result in suspension and even withdrawal of the certificate, upon a decision of CUC at its sole discretion.

CUC may apply any of the assessment types as described in chapter 4. CUC may, if so required for the purpose of verification, have to take samples for analysis, or ask the Client to place samples at its disposal free of charge. The assessor will split the sample in three equal portions and provide the Client with one duplicate. The other two are for the laboratory and for CUC. Verification samples must be analysed by a laboratory that is accredited according to the valid version of ISO/IEC 17025 for the applicable matrix. CUC shall inform the Client as soon as the results are available. If the results of the analyses prove that the applicable regulations are not complied with, the results may cause changes in the certification status or in the scope of the certificate. CUC will not hold any responsibility for the accuracy of the results of the lab analyses.

In a management system assessment, a stage 1 assessment will take place in recertification assessments. The purpose of this stage 1 assessment is to assess the Client's management system documentation, to review the Client's understanding of the requirements, to gather information on the scope of the management system and related statutory and regulatory compliance, to evaluate that the Client is planning and performing internal assessments, to determine the Client's preparedness for the stage 2 assessment and to prepare the details of the stage 2 assessment with the Client. As a result CUC will have gained detailed information to focus its stage 2 assessments purposely in the forthcoming assessment cycle. At least part of the stage 1 assessment should be carried out at the Client's premises.

The assessment will start off with an opening meeting. The aim of the opening meeting is to provide a short explanation of how the assessment activities will be undertaken and to verify a number of prerequisites for the assessment, such as confidentiality and availability of people. If changes in the scope of certification appear that were not mentioned earlier and that will have an impact on the assessment time and/or the contract (e.g. new process/unit, etc.) the assessor will explain that these changes cannot be inspected if they have not been applied for. You may still be given the opportunity to adjust the application at that very moment. Attendance at the opening meeting (and closing meeting) by senior management and key personnel is considered a sign of commitment.

At the end of the assessment a formal closing meeting will be held. The purpose of this meeting is to present the assessment conclusions, including the recommendation regarding certification. Any nonconformities will be presented in such a manner that they are understood, and the timeframe for responding shall be agreed. Keep in mind that "understood" does not necessarily mean that the nonconformities have been accepted by the Client. You will have an opportunity for questions in the closing meeting. Any diverging opinions regarding the assessment findings or conclusions between the assessment team and the Client must be discussed and resolved where possible.

When the assessment lasts for more than one day, every intermediate day will be started by a short opening meeting and closed by a short summary of the day's encounters.

You must ensure that all necessary measures are taken for safety and security of working conditions, sites and installations during the performance of the assessment. You must take all necessary steps to eliminate or remedy any obstructions to or interruptions in the performance of the assessments and inform CUC in advance of any known hazards or dangers, actual or potential, associated with any order or samples or testing including, for example, presence or risk of radiation, toxic or noxious or explosive elements or materials, environmental pollution or poisons. Would the objectivity of the assessment be compromised, the assessor has the right to abort the assessment. Reasons can be for example the interference of accompanying persons or refusal to grant access as requested by the assessor. All costs arising from this will be charged to the Client.

9. Comparable product/process

When the standard production process or a product is unavailable at the time of assessment, for instance with seasonal products, comparable product(s) or process assessment may apply. Where there is no certified production taking place until the assessment, the CUC assessor verifies production with product, process or service that is comparable to the lacking product process or service. Meaning that the product, process or service shall be determined to have comparable processing and risk characteristics. Thereby declaring that the assessed process is the same as the process, which will lead to the respective standard equivalence of the product.

If a certificate was granted based on review of the comparable process, the Client is obliged to inform CUC as soon as processing of that product, process or service commences. The Client should provide unit identification, product name, lot identification and date commenced of certified production process to CUC. This to enable CUC to plan an additional visit to the certified unit if required. Failure to report first processing in case of a comparable assessment may lead to a provisional validity of the certificate, reduction of the scope and ultimately even suspension of the certificate, as applicable. You should be aware that it is the Clients' responsibility to comply with certification requirements.

10. Non-conformities

A nonconformity is a non-fulfilment of a set requirement. So something isn't in place that should be there. Or something is there that should not be there. When an assessor runs into such a non-fulfilment, he or she will address this and discuss this with you. After all, the assessor may be wrong, doesn't see the complete picture or you have addressed the issue in a completely different way. If you are not able to provide satisfactory evidence that the finding is incomplete or incorrect and the requirement is fulfilled, the assessor will issue a nonconformity. Mind you, you might be able to correct the problem on the spot and solve the nonconformity before the assessor leaves the premises. But that does not mean that the nonconformity will disappear; it was found to be a nonconformity and should be registered as such.

Not all nonconformities are of the same severity. Some are serious, others less. For that reason CUC applies 4 types of nonconformity. Specific schemes may use other grades and also may call them differently. Regarding the Italian National Scheme, the Non-conformities, definition and treatment refers to art.2 and 8 of DM of 07/08/2024

Major nonconformity:

If there is a finding that raises significant doubt that effective process control is in place, or that products, services or the management system will meet specified requirements to the extent that it raises serious doubt that the capability to achieve the intended results is affected, then this is classified as a major nonconformity. This conclusion may also be reached when a number of minor nonconformities associated with the same requirement or issue is found, based on the view that this demonstrates a systemic failure.

Critical nonconformity:

This is a major nonconformity that leads to an immediate and critical failure of the management system or product to comply with the intent of the standard and therefore is a critical breakdown. Because of this critical nature, we will require immediate and robust action from you.

Minor nonconformity:

If there is a non-fulfilment of a requirement, but does not directly affect that products, services or the management system capability to achieve the intended results, this is classified as a minor nonconformity.

Observations:

Some call these Points of Improvement or Opportunity for Improvement. Observations are points that do not constitute a non-fulfilment of a requirement and therefore are technically not nonconformities and there is no absolute need to solve them before a certificate can be issued. However, they have the potential to become a nonconformity if left unattended. For that reason CUC will reassess these elements the next scheduled assessment.

11. Corrections and corrective actions

Nonconformities need to be resolved. Whenever there is an outstanding NC, no positive certification decision can be made and the certificate cannot be issued for the project including concerned units/products; unless otherwise stipulated by the relevant standard. The amount of time that is awarded to you to provide CUC with satisfactory evidence of addressing the issue may differ per scheme. Some make big distinctions between majors and minors, others allow the same amounts of time for both. Therefore the below overview is only a rough guidance, please refer to the scheme specific regulations for the exact timeframes. Please be aware that it is expressly your responsibility to take appropriate remedial action.

Critical:

One thing that all parties agree on is the need for immediate and stern action in case of a critical nonconformity. CUC will require you to take action within 24 hours. We are aware that it is almost always impossible to completely solve the problem within 24 hours. So that is not what we expect. We expect in that 24 hours that you come up with a serious investigation on the root cause of the problem and a valid plan on how to correct the situation soonest. We will also expect you to make measures to ensure that no non-compliant product is placed in the market and that, where necessary, products that already have been placed on the market will be recalled. We strive to provide the Client with an option to redeem himself. However, the situation we find may be so severe, or a specific scheme may require us, to suspend your certificate immediately and only re-instate the certificate after proven satisfactory solving of the issue.

Major:

As said, the amount of time allowed for solving major nonconformities may differ per scheme. CUC normally allows 2 calendar months. For a major nonconformity you are required to actually solve the problem.

Minor:

Some schemes require you to solve a minor nonconformity in 3 calendar months. Others require you to provide the certification body with a valid plan within 3 months and solving of the nonconformity before the next scheduled assessment, which is normally set at around 12 months. This last option is typical for management system assessments: in order to device a proper plan, you must do a root cause assessment, which is quite typical for management system certification. The plan will be assessed and must be accepted by CUC.

Observation:

Since an observation is technically not a nonconformity, we will not require you to provide us with evidence that you addressed the issue seriously and implemented the solution effectively. However, since we will be looking at it again in the next assessment, you might be wise to have a proper look at it yourself.

A proper statement of nonconformity consists of the relevant clause reference to the standard where something isn required from you, a clear description of the found deviation from that requirement and objective evidence that the statement of nonconformity is a valid statement.

If a Client fails to provide CUC with satisfactory evidence that the issue was addressed and the solution effectively implemented within the set amounts of time, we will escalate the nonconformity to the

next higher level. So a minor becomes a major and a major becomes a critical. The timeframes associated with that new grading are applied and you will get an opportunity to still resolve the problem. If you do not, we will start the suspension procedure of your certificate. In many cases that includes informing the scheme owner, who then may make suspension of your certificate public. In order to re-instate the certificate, a full on-site assessment must be performed, the costs of which non-surprisingly will be invoice to the Client. If the Clients still does not resolve the problem after suspension, we will no longer be able to vouch for your credibility and we will withdraw the certificate.

Please be aware that the stated amounts of time refer to the time that you have to investigate the problem, to find a proper solution and to verify and show that this solution actually works. So please, do not start working on solving a nonconformity one week before the deadline, because you may get yourself in serious trouble. Please also be aware that the clock starts ticking on the last day of the assessment, even though the formal report comes in much later. The assessor will leave the nonconformities at your premises at the end of the assessment, including their grading. The nonconformities will also be listed in your Client portal, as is the report.

There are a number of elements you need to keep in mind and address when solving a nonconformity. What we require from you is:

Correction

A correction is an action to eliminate the detected nonconformity. For instance, if there is a requirement that your production facility needs to be tiled, and it was found that some tiles were missing, than the correction is that you replace the missing tiles. A correction can be made in conjunction with a corrective action.

Corrective action

A corrective action is an action to eliminate the cause of a detected nonconformity or other undesirable situation and thus prevents recurrence of the same problem. If for instance in the above example the reason for the tiles to fall off is that the brick wall is damp, than you may replace the tiles as a correction, but chances are that the tiles will fall off again shortly. In order to prevent the tiles from falling off, you need to remedy the damp wall. That is what is known as a corrective action. Be aware that there can be more than one cause for a nonconformity.

Root cause analysis

In order to find out what an effective corrective action is for the found problem, you need to perform a root cause analysis: try and get to the root of the problem. You need to identify the factors that resulted in the nature, the magnitude, the location, and/or the timing of the nonconformity. To be effective, you should perform the root cause analysis systematically. There are several techniques to do perform a root cause analysis, but one that may be useful to you is the "5 whys" method. It basically requires you to repeat the question "Why?" five times (or as many more or less as is reasonable). Each answer forms the basis of the next question. For example:

Problem: The vehicle will not start. (the problem)

Why? - The battery is dead. (First why)

Why? - The alternator is not functioning. (Second why)

Why? - The alternator belt has broken. (Third why)

Why? - The alternator belt was well beyond its useful service life and not replaced. (Fourth why)

Why? - The vehicle was not maintained according to the recommended service schedule. (Fifth why, a root cause)

Not all problems have a single root cause. If you wish to uncover multiple root causes, the method must be repeated asking a different sequence of questions each time.

When you know the root cause of the problem, you also know what to solve so this problem will not recur.

Extent analysis

Knowing what the root of the problem was, is one. It is another thing to make sure that the same problem does not occur or has the potential to occur elsewhere as well. So you should ask yourself: are there other places where I need to address this same problem.

Implementation

Finding the root cause is a good thing and so is planning strong corrections and corrective actions. But those still do not solve the problem. What we will want to know is whether you actually implemented the corrections and corrective actions and that these were indeed effective. When submitting your evidence to close the nonconformity, you need to provide evidence of effective implementation as well.

For each and every nonconformity you need to provide evidence of the correction and its implementation. Not all schemes require you to take corrective action and to do the associated root cause and extent analysis. Those are typically related to management system certification. Which makes sense, management system certification are much more about procedures and interactions within an organisation, where product certification is about specified characteristics of that product. Therefore it is much more essential to find the root cause and extent in management system certification than it is in product certification. Be aware though that product certification schemes tend to incorporate an increasing number of management system elements, so corrective actions and their related activities become more and more relevant for all types of certification. Besides, taking corrective actions and doing the root cause and extent analyses is a sensible thing to do. If not for the benefit of the certification body, than definitely for the cost-effectiveness of your business.

12. Report

The assessor will record assessment findings in a report, summarising conformity and detailing nonconformity, including its supporting evidence. The report will state the findings with all certification requirements. This report and the evidence submitted by the Client for solving of nonconformities is reviewed by CUC. This includes a review that the procedure was followed correctly by CUC, for instance that a qualified assessor was used and the valid version of the standard and its supporting documents was applied. After an assessment has taken place, CUC will provide you with the report or its summary, at least conforming to the specific program requirements. The Client has the right to respond to the content of the report.

13. Issuance of a certification

CUC will take the following aspects into consideration:

- the information provided by the Client in the application;
- an impartial review of the assessment findings and conclusions as being sufficient with respect to the certification requirements and the scope of certification;
- any registered nonconformities and the effectiveness of their identified causes, corrections and corrective actions as submitted by the Client;

- any other relevant information, for instance public information or comments on the assessment report from the Client.

After this review, CUC will make a certification decision. This may result in granting or maintaining of certification, expanding or reducing the scope of certification or renewing, suspending, restoring, or withdrawing of certification. We will inform the Client of the same. Might the decision be negative, than the Client has the right of appeal against the decision. When CUC is satisfied that the Client meets all the certification requirements, we will issue a certificate. This certificate and the report always remain the property of CUC and may only be copied or reproduced for the benefit of a third party if it clearly contains the word "copy". Since the certificate and report remain our property, CUC has the right to request you to return any certificates, for instance in case of withdrawal of the certificate or termination of the Service Agreement.

The Certificate will remain valid until its expiry date, unless it is proven that the management system and/or products of the Client no longer meet the requirements and a new certification decision is made. The validity of the certificate will also expire upon termination of the Service Agreement regarding this assessment between CUC and the Client.

Be aware that CUC is required to inform any stakeholder of the status of your certificate upon request.

Might you request us to provide you with more than one issue of the certificate, than we provide you with such it clearly containing the word "copy". CUC has the right to charge a fee for providing copies of certificates.

CUC will endeavour to renew the certificate within the timeframe indicated in the applicable standards or after a change of scope, provided that the Client remains in conformity with applicable requirements and regulations, the Client contract is continued and financial obligations are fulfilled.

14. Suspension of a certificate

If the Client fails to submit evidence of adequate and effective measures being taken and implemented on registered nonconformities within the agreed period of time, the certificate may be suspended. Or it has been found that the Client makes incorrect use of the certificate and/or the logo or mark and this has not been remedied to the satisfaction of CUC. Or the Client does not comply with financial obligations. Or the Client has placed products on the market in an unsafe or nonconforming condition.

CUC will inform the Client in writing of the suspension, stating at least the commencement date, duration and justification of the suspension and the options and terms for appeal. Suspension will be postponed for the period the appeal is under consideration, until a final decision has been made. The suspension will not commence until 10 days after notification at the earliest and the term of suspension is maximum 3 months.

Upon receiving notice of suspension of its certification, the Client must immediately discontinue all use of advertising materials/declarations that contain a reference to certification, as instructed by CUC, and revise all advertising materials accordingly when the scope of certification has been reduced. You are not allowed to make any reference to certification whilst being suspended. In case the Client has attached a mark directly to the product, it will refrain from bringing this product on the market whilst under suspension.

CUC is obliged in many cases to inform the scheme owner of suspension of the certificate. CUC also expressly reserves the right to publish suspensions.

At the end of the suspension period, an assessment will be carried out to determine whether the indicated conditions for reinstating the certificate have been fulfilled. Upon compliance with these conditions the suspension shall be lifted and the Client will be notified of the certificate reinstatement. However, if the conditions are not fulfilled the Certificate shall be withdrawn.

All costs incurred by CUC in suspending and reinstating a certificate will be charged to the Client.

15. Withdrawal of a certificate

The certificate may be withdrawn if the Client deliberately, at the sole discretion of CUC, fails to comply with provisions of the Service Agreement or when the Client remains in breach with set requirements during suspension. The certificate may also be withdrawn upon termination of the Service Agreement. CUC will inform the Client in writing of such withdrawal, stating at least the commencement date, justification of the withdrawal and the options and terms for appeal. Withdrawal will be postponed for the period the appeal is under consideration, until a final decision has been made. The withdrawal will not commence until 10 days after notification at the earliest.

Upon receiving notice of withdrawal of its certification, the Client must immediately discontinue all use of advertising materials/declarations that contain a reference to certification, as instructed by CUC, and revise all advertising materials accordingly when the scope of certification has been reduced. You are not allowed to make any reference to certification anymore. In case the Client has attached a mark directly to the product, it will refrain from bringing this product on the market. The Client is also required to return the certificate to CUC.

In cases of withdrawal, no reimbursement of assessment fees will be given and withdrawal of the certificate is published by CUC and notified to the appropriate accreditation body and/or scheme owner, if any.

16. Resignation of a certificate

The Client may request cancellation of the certificate and the Service Agreement. CUC will examine whether or not the Client has fulfilled its financial obligations and inform the Client in writing on the procedure of resignation. Resignation will not commence until 10 days after notification at the earliest.

From the date of resignation of the Client contract, the certificate becomes invalid and the Client is required to return the certificate. In the event of invalidity of a certificate, CUC has the right to notify buyers, assessment bodies, competent authorities and other third parties concerned.

17. Extension and reduction of certification scope

In order to extend or reduce the scope of a certificate to cover additional sites or products, or to remove sites or products that no longer apply, the Client must complete a new application form or give notice through the Client portal. The application procedure as mentioned in chapter 6 will be followed and an assessment will be carried out. The cost of extending or reducing the scope of certification will be based on the nature and programme of work.

Following a successful assessment, an amended certificate will be issued.

18. Reference to certificate and certification mark or logo

Upon issuance of a certificate, CUC may authorise the Client to use a designated certification mark or logo. A Client's right to use any such mark is contingent on maintaining a valid certificate in respect of the certified management system or products and compliance with the scheme governing the use of the mark. A Client who has been authorised to use the mark of an accrediting body must also comply with the rules governing the mark of that body. However, the Client is not obliged to make use of such authorisation.

The use of indications that refer to the certified production method or to CUC is only allowed after the concerned certificate has been issued. The use of marks and logos will be evaluated during the assessment against the program specific requirements.

You must be very aware that in case of management system certification, no mark, logo or statement of certification may be used on a product or product packaging or in any other way that may be interpreted as denoting product conformity.

When making reference to and making use of the certificate and marks or logos, the following applies:

- It is not allowed to make any misleading statement regarding the status of certification;
- It is not allowed to suggest that certification relates to activities, units, products etc. that fall outside of the scope of certification;
- Certificates, marks and logos must be represented in their entirety, including frames;
- Logos may only be represented in their intended colours or in black and white;
- It is not allowed to place the logo on testing reports of laboratories or calibration reports or certificates;
- If a Client after withdrawal or resignation of a certificate keeps using logos or other expressions that give rise to the suggestion that certification still commences, CUC may take legal action;
- CUC expressly reserves the right to publish any unlawful use of its logos and certificates;

CUC will take suitable action, at the expense of the Client, to deal with incorrect, unlawful or misleading references to certification or use of certificates and certification marks. These may include legal action and/or publication of the transgression. Incorrect, unlawful or misleading use of such a mark or logo is considered a critical nonconformity with certification requirements and will most likely result in immediate suspension of certification.

19. Transfer of a certificate

The transfer of certification is the recognition of an existing and valid management system certification, granted by one certification body, by another certification body, for the purpose of issuing its own certification. However, multiple certification, (concurrent certification by more than one certification body), does not fall under this definition. Where the accepting certification body is accredited for the scope to be transferred, the former CB must also be accredited by an IAF MLA signatory.

Prior to a transfer a documentation review, normally including a visit of the prospective Client, is performed. The site visit is mandatory if no contact can be made with the former certification body. The review will cover the ability of CUC to perform the assessment within its accredited scope, the reasons for a transfer, the existence of a valid accredited certification, consideration of the last certification or recertification assessment reports, subsequent surveillance reports and any outstanding nonconformities, including any other available, relevant documentation regarding the

certification process. If the last certification, recertification or subsequent surveillance assessment reports are not made available or if the surveillance assessment is overdue then a transfer of certification cannot apply. Also complaints received and action taken, the stage in the current certification cycle and any current engagement by the organisation with regulatory bodies in respect of legal compliance will be considered.

Any open non-conformities given by the previous certification body must be evaluated and closed before CUC can make a positive certification decision.

If no further outstanding or potential problems are identified by the pre-transfer review a certification may be issued following the normal decision making process. The programme of on-going surveillance will be based on the previous certification regime unless CUC has conducted an initial or recertification assessment as a result of the review.

If you chose to transfer from one certification body to another, you would be wise to consider the on-going validity of your certification. You should make sure that your agreement with your former certification body is not cancelled before you have gained your new certificate. Otherwise you may end up not holding a certificate at all for a period of time. You should also make sure your new certification body receives all applicable information regarding your last certification, including the last report and any outstanding nonconformities and issues.

20. Complaints, claims and appeals

Although CUC is obliged to do its utmost to provide its Clients with correct services, it may happen that one or more of the service aspects are not to the Client's satisfaction. In those cases the Client may decide to file an appeal, complaint or claim against CUC.

An **appeal** is a formal notification of disagreement with a (certification) decision within a certification process, or request by the provider of the object of conformity assessment to CUC for reconsideration of a decision it has made relating to that object.

A **complaint** is a formal expression of dissatisfaction, other than appeal, by any person or organisation regarding a CUC employee's behaviour, CUC methodology, or work executed under contractual responsibility of CUC by a critical office or subcontractor. Where the dissatisfaction relates to a (certification) decision within a certification process of CUC, this must be submitted as an appeal, not a complaint.

A **claim** is a formal request for a financial or legal settlement, not to be considered as complaints or appeals. Claims are resolved by the financial and / or legal departments. Elements crucial to CUC's procedures, are mentioned in this section.

If you wish to file a complaint or appeal, you can make use of the form in Annex I.

Appeal

Clients wishing to submit an appeal to CUC against a (certification) decision, or request to reconsider a (certification) decision it has made, are requested to specify the nature of the appeal as detailed as possible ("who, what, where, when"), to describe the subject matter clearly and to provide any objective evidence to support each element or aspect of the appeal, if applicable.

An appeal must be submitted in writing. CUC will only accept appeals in English or Dutch, unless otherwise agreed in writing. Appeals must be received by CUC within 6 (six) weeks after the (certification) decision was issued and must be submitted to the office of CUC in the Netherlands. If the Client fails to do so, or if the appeal is insufficiently substantiated or incomplete, CUC may reject the appeal and will not assume responsibility for such an appeal. CUC will inform the appellant of the same.

CUC will appoint two members of staff to investigate the appeal. All personnel engaged in the appeals-handling process, including those in review, approval and decision-making, must be different from those who carried out the assessment and made the certification decision. Any member of staff, including those acting in a managerial capacity, who have provided consultancy for the Client in question, or have been employed by that Client, within two years prior to submission of the appeal, shall not be involved in the review or approval of the resolution of the appeal for that Client.

CUC will endeavour to seek a timely resolution of the appeal and will take any subsequent action needed to resolve the appeal. It will give the appellant formal notice of the outcome and the end of the appeals handling process and the motivation of the decision in writing within 3 (three) months after receipt of the appeal. CUC will record the appeal, its outcome and any action undertaken to resolve it, including any established correction and corrective action.

Submission, investigation and decision on appeals may under no circumstances result in discriminatory actions against the appellant.

Complaint

Clients wishing to submit a complaint to CUC are requested to specify the nature of the complaint as detailed as possible (“who, what, where, when”), to describe the subject matter clearly and to provide any objective evidence to support each element or aspect of the complaint, if applicable.

In order to avoid misinterpretation and the appearance of self-favouritism from the side of CUC, complaints must always be submitted in writing. Only complaints in English or Dutch will be accepted, unless otherwise agreed in writing. Complaints must be received by CUC within 6 (six) weeks after the event that gave rise to the complaint at the applicable office of CUC. Complaints that are insufficiently substantiated or incomplete may be deemed inadmissible by CUC and rejected. CUC will inform the complainant of the same.

CUC will decide upon the admissibility of the complaint. CUC will appoint two members of staff to investigate the complaint. All personnel engaged in the complaints handling process, including those in review, approval and decision making, shall be different from those who carried out the assessment and made the certification decision. Any member of staff, including those acting in a managerial capacity, who have provided consultancy for the Client in question, or been employed by that Client, within two years prior to submission of the complaint, shall not be involved in the review or approval of the resolution of the complaint for that Client.

The appointed members of staff will gather and verify all necessary information (as far as possible), including a root cause analysis, and propose how to proceed, including corrections and corrective actions where applicable. CUC will endeavour to seek a timely resolution of the complaint and will take any subsequent action needed to resolve the complaint. If the complaint relates to a Client certified for a management system, examination of the complaint must also consider the effectiveness of the certified management system.

CUC will endeavour to seek a timely resolution of the complaint and will take any subsequent action needed to resolve the complaint. CUC will give the complainant formal notice of the outcome and the end of the complaint handling process and the motivation of the decision in writing within 3 (three) months after receipt of the complaint. CUC will record the complaint, its outcome and any action undertaken to resolve it in ICU under unique identification, including any established correction and corrective action.

Complaints about a certified Client that have passed through the complaints handling process must be addressed to that certified Client by CUC within an appropriate timeframe. If this is requested by the complainant, the anonymity of the complainant must be retained. And CUC must determine, together with the certified Client and the complainant, whether and, if so to what extent, the subject of the complaint and its resolution will be made public.

Submission, investigation and decision on complaints may under no circumstances result in discriminatory actions against the complainant.

If CUC decides and substantiates that CUC or any of its employees, officers, agents or subcontractors was not to be blamed to the extent specified in the complaint, all costs and expenses may be charged to the complainant.

CUC will endeavour to settle any complaint amicably. Where no amicable settlement is reached, all disputes which may arise between CUC and the Client shall be brought before the competent court of jurisdiction in Italy, which shall have exclusive jurisdiction on the matter, unless the parties agree in writing between themselves upon another competent court.

Claims

The liability CUC in respect of any claims for loss, damage or expense of whatsoever nature and howsoever arising in respect of any breach of contract and/or any failure to exercise due skill and care by CUC shall in no circumstances exceed a total aggregate sum equal to 10 (ten) times the amount of the fee or commission payable for the specific services required under the applicable contract with CUC. CUC will not be held liable for any claims for indirect or consequential loss including loss of profit and/or loss of future business and/or loss of production and/or cancellation of contracts entered into by the Client.

The Client shall hold CUC harmless and shall indemnify CUC as a result of damages suffered by CUC due to the Client not observing the standard's requirements and/or national and international governmental laws and regulations.

Annex I: Complaint / Appeal Registration Form

An appeal is a formal notification of disagreement with a (certification) decision within a certification process, or request by the provider of the object of conformity assessment to CUC for reconsideration of a decision it has made relating to that object.

A complaint is a formal expression of dissatisfaction, other than appeal, by any person or organisation regarding a CUC employee’s behaviour, CUC methodology, or work executed under contractual responsibility of CUC by a critical office or subcontractor, where a response is expected.

A concern is an expression of dissatisfaction or concern by any person or organisation regarding a Client certified by CUC, which is not sufficiently substantiated to be classified as a complaint and where a response is expected.

Date	
Your Organisations name	
Your personal name	
Your address	
Telephone	
Fax	
e-mail	
Type (cross out what is not applicable)	Complaint Appeal
Description PLEASE DESCRIBE YOUR COMPLAINT/APPEAL AS MUCH AS POSSIBLE (“WHO, WHAT, WHERE, WHEN”) AND PROVIDE ANY NECESSARY DOCUMENTATION IF APPLICABLE	

Evidence

PLEASE SPECIFY THE EVIDENCE FOR YOUR COMPLAINT/APPEAL.