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CABPUB/54/DTS

2011-07-22

INTERNATIONAL ELECTROTECHNICAL COMMISSION

DRAFT ISO/IEC CONFORMITY ASSESSMENT PUBLICATIONS THROUGH THE IEC CONFORMITY ASSESSMENT BOARD (CAB)

SUBJECT

Launch of ballot on ISO/IEC DTS 17022, Conformity assessment - Requirements and recommendations for the content of a third-party audit report on management systems.

BACKGROUND

CASCO Working Group 33, *Third-party management system audit report*, agreed to process the Technical Specification Draft (TS) 17022 to DIS ballot.

The Draft Technical Specification (DTS) ISO/IEC 17022 in English and French is enclosed hereunder, alongside the CASCO compilation of observed comments.

IEC's weekly closing date being on Friday, the deadline for voting on ISO/IEC DTS 17022 has been determined so as to be as close as possible to the one set for ISO NBs and to the three-month voting deadline generally granted, i.e. 2011-10-14.

Note to IEC NCs: should you have any comments, please use the attached IEC commenting template and please clearly state whether your comments are identical to the ones sent to ISO/CASCO.

ACTION

National Committees are invited to vote on CABPUB/54/DTS using the IEC voting system by **2011-10-14**.

National Committees are strongly encouraged to consult the IECEE, IECQ and IECEx communities in their country when developing their national position on this draft.

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Our ref. CASCO 84/2011

**TO THE MEMBERS OF CASCO AND
ORGANIZATIONS IN LIAISON**

Date 2011-07-06

Launch of ballot on ISO/IEC DTS 17022, *Conformity assessment – Requirements and recommendations for the content of a third-party audit report on management systems*

Dear Sir or Madam,

On behalf of the Convenor of Working Group 33, Mr. Laurent Camberou, we are pleased to inform you that the ballot on ISO/IEC DTS 17022 (Draft Technical Specification) starts on 2011-07-06 with a **closing date on 2011-10-06**.

For your information, please find attached the document in English and French together with the compilation of observed comments received on the PDTS.

We remind you that the voting procedure is managed electronically through the ISO balloting portal. Balloters having access problems should contact the ISO helpdesk at helpdesk@iso.org.

Yours faithfully,

A handwritten signature in black ink that reads 'Sean Mac Curtain'.

Sean Mac Curtain
Head, Conformity Assessment
CASCO Secretary

Enclosures

ISO/IEC

Date: 2011-03-24

ISO/IEC DTS 17022

ISO/IEC CASCO WG 33

Secretariat: CASCO

Conformity assessment — Requirements and recommendations for content of a third-party audit report on management systems

Evaluation de la conformité — Exigences et recommandations pour le contenu d'un rapport d'audit tierce partie de système de management

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

- an ISO/IEC Publicly Available Specification (ISO/IEC PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO/IEC Technical Specification (ISO/IEC TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC TS 17022 was prepared by the ISO *Committee on conformity assessment* (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

Introduction

This Technical Specification contains requirements and recommendations for the content of a third-party management system certification audit report that meets the needs and expectations of interested parties (audit client, certification bodies, accreditation bodies and other potential users).

This Technical Specification has been developed to achieve a basic level of consistency and information in the content of third-party management system certification audit reports, thus increasing the credibility in the work of the audit team and certification process.

Although the audit client is the primary user of the audit report, the content of audit reports are required to satisfy the needs of other interested parties. The following are examples of possible users or other interested parties of the information contained in audit reports:

- Certification Body;
- Accreditation Body;
- Regulatory Authority.

The report is intended to provide the information necessary to satisfy the needs of interested parties.

In this regard an interested party might need to know the following:

- a) if the management system conforms to the specified requirements;
- b) any opportunities for improvement;
- c) any nonconformities and areas of concern;
- d) any strengths and weaknesses;
- e) information for future audit planning;
- f) areas that require follow-up; and
- g) additional information required for a decision regarding certification.

In this Technical Specification, the word "shall" indicates a requirement and the word "should" a recommendation.

Conformity assessment — Requirements and recommendations for content of a third-party audit report on management systems

1 Scope

This International Technical Specification contains requirements and recommendations to be addressed in a third-party management system certification audit report based on the relevant requirements in ISO/IEC 17021.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000 Conformity assessment — *Vocabulary and general principles*

ISO/IEC 17021 Conformity assessment — *Requirements for bodies providing audit and certification of management systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17021 and the following apply.

3.1

nonconformity

non-fulfilment of a requirement

[ISO 9000:2005, definition 3.6.2]

4 Audit report

4.1 Requirements in ISO/IEC 17021

ISO/IEC 17021:2011, 9.1.10.2, states that the audit team leader shall ensure that the audit report is prepared and shall be responsible for its content. The audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made and shall include or refer to the following:

- a) identification of the certification body;
- b) the name and address of the client and the client's management representative;
- c) the type of audit (e.g. initial, surveillance or recertification audit) (see 4.2.2) ;

- d) the audit criteria (see 4.2.3);
- e) the audit objectives (see 4.2.4);
- f) the audit scope, particularly identification of the organizational or functional units or processes audited and the time of the audit (see 4.2.5);
- g) identification of the audit team leader, audit team members and any accompanying persons (see 4.2.6);
- h) the dates and places where the audit activities (onsite or offsite) were conducted (see 4.2.7);
- i) audit findings, evidence and conclusions, consistent with the requirements of the type of audit (see 4.2.8); and
- j) any unresolved issues, if identified (see 4.2.9).

4.2 Requirements and recommendations

4.2.1 General

The requirements and recommendations listed in 4.2.2 to 4.2.10 are not exclusive, meaning that the audit report can include further information.

4.2.2 Type of audit

4.2.2.1 The audit report shall identify the type of audit [e.g. initial (stage 1 and 2), surveillance or recertification audit, and special audits (see ISO/IEC 17021:2011, 9.5, for further information)].

4.2.2.2 The report should indicate, if applicable, it is a joint, combined, or integrated audit.

4.2.3 Audit criteria

4.2.3.1 The audit report shall identify the normative documents of the management systems (e.g. ISO 9001) and any other documents used during the audit against which the management system of the organization is being audited.

4.2.3.2 The audit report shall reference the audit plan and the audit programme.

4.2.3.3 The audit report shall indicate any significant changes that occurred in the client organization during the period under review.

4.2.3.4 The report should document whether the predefined audit criteria are suitable for the situation encountered and the management system audited.

4.2.4 Audit objectives

4.2.4.1 The audit report shall indicate if the audit objectives have been met. (See ISO/IEC 17021:2011, 9.1.2.2.2, for further information).

4.2.4.2 When there are changes to the audit objectives, scope or criteria (e.g. physical locations, organizational units, activities and processes) they shall be recorded.

4.2.4.3 The audit report shall indicate if the audited organization is effectively controlling the use of the certification mark.

4.2.5 Audit scope

4.2.5.1 The audit report shall describe the extent and boundaries of the scope of the audit, such as physical locations, organizational units, activities and processes to be audited including any areas not covered, although within the audit scope.

4.2.5.2 The audit report shall describe any justified exclusions of requirements.

4.2.5.3 The report shall identify the time spent on-site or remote by the audit team.

4.2.5.4 The audit report should indicate any deviation in audit time from the audit plan.

4.2.6 Identification of the audit team

The audit report shall identify the audit team leader, audit team members and any accompanying persons (e.g. guides, observers, translators).

4.2.7 Dates and places of the audit (onsite or offsite)

4.2.7.1 The audit report shall indicate the sites visited and type of activity audited in each site (identifying the requirements that have been audited). The audit report shall distinguish between permanent sites and temporary sites.

4.2.7.2 The audit report shall indicate when access to appropriate persons, locations or information was not possible or denied.

4.2.7.3 The audit report should identify any adverse conditions specifically related to the condition of the sites.

4.2.8 Audit findings, evidence and conclusions

4.2.8.1 The audit report shall include the audit findings indicating the conformity (or not) of the management system in question with the audit criteria.

4.2.8.2 The audit report shall contain or make reference to the nonconformities and areas of concern.

4.2.8.3 The nonconformity shall be a clear detailed record of the finding in order to give the client a proper description of the fact.

4.2.8.4 The nonconformity shall include all necessary references to facilitate determination of an appropriate corrective action. Objective evidence of the nonconformity, (e.g. documents, drawings, test reports, etc.) shall be referenced. Non-documentary evidence (i.e. lack of evidence of competence) shall be referenced. The nonconformity description shall furthermore include the following:

- a) reference to the management system standard requirement;
- b) statement of the non-conformity;
- c) objective evidence on which the non-conformity is based;
- d) reference to the document which has been deviated from (i.e. specification; rule; instruction; drawing; etc.); and
- e) category (major or minor) of nonconformity, when applicable (see ISO/IEC 17021:2011, 9.1.9.6.3, Note, for further information).

4.2.8.5 Where relevant the audit report shall contain any uncertainty or any obstacles encountered during the audit process that may decrease the reliability of the audit conclusions.

4.2.8.6 The report shall address the effectiveness of the management system to ensure the client organization is continually meeting its specified objectives.

4.2.8.7 Management system effectiveness may address:

- a) the suitability of the nature of its activities, products and services;
- b) the activities of the organization within the scope of certification, and the appropriateness for its certification scope;
- c) the analysis, understanding and identification of the needs and expectations of interested parties relevant for the applicable standard;
- d) the objectives of the management system for meeting requirements of interested parties and applicable statutory/regulatory requirements;
- e) the determination and the management of the processes needed to achieve the expected outcomes;
- f) the availability of resources necessary to support the operation and monitoring of these processes;
- g) monitoring and controlling of the defined process characteristics;
- h) the prevention of nonconformities, and the systematic improvement processes to:
 - correct any nonconformities that do occur,
 - analyze the cause of nonconformities and take corrective action to avoid their recurrence, and
 - address customer complaints.
- i) an effective internal audit and management review process; and
- j) monitoring, measurement and continual improvement of the effectiveness of its management system.

4.2.8.8 The audit report may provide comment on the maturity of the management system and may indicate if the management system is fully established in the organization and the level of support that it has from senior and top management.

4.2.8.9 The audit report should indicate risks that may affect, if applicable:

- a) conformance to management systems requirements;
- b) conformance to statutory/regulatory requirements;
- c) performance of the organization's management system(s).

NOTE When describing the identified risks, it can also be important to, if applicable:

- indicate that a significant risk is not being managed;
- indicate that risks have been misrepresented.

4.2.9 Unresolved issues

The audit report shall indicate follow-up of correction and corrective action plans, if any, for the continuity of the audit process.

4.2.10 Disclaimer

4.2.10.1 The audit report shall include a disclaimer statement indicating that auditing is based on a sampling process of the available information and consequently there is an element of uncertainty which may be reflected in the audit findings.

4.2.10.2 The disclaimer shall advise those relying or acting upon the audit results and conclusions to be aware of this uncertainty. The disclaimer shall also advise that audit recommendations are subject to an independent review, prior to a decision concerning the awarding or renewal of certification.

DRAFT

Bibliography

- [1] ISO 9000:2005, *Quality management systems – Fundamentals and vocabulary*
- [2] ISO 9001, *Quality management systems – Requirements*

ISO/CEI TC CASCO/SC N

Date: 2011-03-24

ISO/CEI DTS 17022

ISO/CEI TC CASCO/SC /GT 33

Secrétariat: CASCO

Évaluation de la conformité — Exigences et recommandations pour le contenu d'un rapport d'audit tierce partie de systèmes de management

Conformity assessment — Requirements and recommendations for content of a third-party audit report on management systems

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Avant-propos

L'ISO (Organisation internationale de normalisation) et la CEI (Commission électrotechnique internationale) forment le système spécialisé de la normalisation mondiale. Les organismes nationaux membres de l'ISO ou de la CEI participent au développement de Normes internationales par l'intermédiaire des comités techniques créés par l'organisation concernée afin de s'occuper des domaines particuliers de l'activité technique. Les comités techniques de l'ISO et de la CEI collaborent dans des domaines d'intérêt commun. D'autres organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'ISO et la CEI, participent également aux travaux. Dans le domaine de l'évaluation de la conformité, le comité ISO pour l'évaluation de la conformité (CASCO) est responsable du développement de Normes internationales et de Guides.

Les Normes internationales sont rédigées conformément aux règles données dans les Directives ISO/CEI, Partie 2.

La tâche principale des comités techniques est d'élaborer les Normes internationales. Les projets de Normes internationales adoptés par les comités techniques sont soumis aux comités membres pour vote. Leur publication comme Normes internationales requiert l'approbation de 75 % au moins des comités membres votants.

Dans d'autres circonstances, en particulier lorsqu'il existe une demande urgente du marché, un comité technique peut décider de publier d'autres types de documents normatifs:

- une Spécification publiquement disponible ISO/CEI (ISO/CEI PAS) représente un accord entre les experts dans un groupe de travail ISO et est acceptée pour publication si elle est approuvée par plus de 50 % des membres votants du comité dont relève le groupe de travail;
- une Spécification technique ISO/CEI (ISO/CEI TS) représente un accord entre les membres d'un comité technique et est acceptée pour publication si elle est approuvée par 2/3 des membres votants du comité.

Une ISO/PAS ou ISO/TS fait l'objet d'un examen après trois ans afin de décider si elle est confirmée pour trois nouvelles années, révisée pour devenir une Norme internationale, ou annulée. Lorsqu'une ISO/PAS ou ISO/TS a été confirmée, elle fait l'objet d'un nouvel examen après trois ans qui décidera soit de sa transformation en Norme internationale soit de son annulation.

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L'ISO/CEI TS 17022 a été élaborée par le *comité ISO pour l'évaluation de la conformité* (CASCO).

Le projet a été soumis aux organismes nationaux de l'ISO et de la CEI pour vote et a été approuvé par les deux organisations.

Introduction

La présente Spécification technique contient des exigences et recommandations applicables au contenu d'un rapport d'audit tierce partie de certification de systèmes de management qui répond aux besoins et attentes des parties intéressées (client de l'audit, organismes de certification, organismes d'accréditation et autres utilisateurs potentiels).

La présente Spécification technique a été élaborée dans le but d'obtenir un niveau de base de cohérence et d'information dans le contenu des rapports d'audit tierce partie de certification des systèmes de management et, ainsi, d'améliorer la crédibilité du travail de l'équipe d'audit et du processus de certification.

Bien que le client de l'audit soit le principal utilisateur du rapport d'audit, le contenu du rapport d'audit doit aussi répondre aux besoins d'autres parties intéressées. Les utilisateurs des informations contenues dans le rapport d'audit ou les autres parties intéressées par ces informations peuvent notamment être les suivants :

- organisme de certification ;
- organisme d'accréditation ;
- autorité réglementaire.

Le rapport d'audit vise à fournir les informations nécessaires à la satisfaction des besoins des parties intéressées.

À cet égard, une partie intéressée peut avoir besoin d'être renseignée sur les points suivants :

- a) la conformité ou non-conformité du système de management aux exigences spécifiées ;
- b) toutes opportunités d'amélioration ;
- c) toutes non-conformités et tous points sensibles ;
- d) toutes forces et faiblesses ;
- e) des informations sur la planification de l'audit suivant ;
- f) les domaines qui nécessitent un suivi ; et
- g) toutes informations complémentaires requises pour prendre une décision de certification.

Dans la présente Spécification technique, le verbe « devoir » indique une exigence et la forme verbale « il convient de » précède une recommandation.

Évaluation de la conformité — Exigences et recommandations pour le contenu d'un rapport d'audit tierce partie de systèmes de management

1 Domaine d'application

La présente Spécification technique internationale contient des exigences et recommandations à prendre en compte lors de la rédaction du rapport d'audit tierce partie de certification de systèmes de management, conformément aux exigences pertinentes de l'ISO/CEI 17021.

2 Références normatives

Les documents de référence suivants sont indispensables pour l'application du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

ISO/CEI 17000, *Évaluation de la conformité — Vocabulaire et principes généraux*.

ISO/CEI 17021, *Évaluation de la conformité — Exigences pour les organismes procédant à l'audit et à la certification des systèmes de management*.

3 Termes et définitions

Pour les besoins du présent document, les termes et définitions donnés dans l'ISO/CEI 17000 et l'ISO/CEI 17021 ainsi que les suivants s'appliquent.

3.1

non-conformité

non-satisfaction d'une exigence

[ISO 9000:2005, définition 3.6.2]

4 Rapport d'audit

4.1 Exigences de l'ISO/CEI 17021

Le paragraphe 9.1.10.2 de l'ISO/CEI 17021:2011 spécifie que le responsable de l'équipe d'audit doit s'assurer de la préparation du rapport d'audit et doit être responsable de son contenu. Le rapport d'audit doit fournir un enregistrement précis, concis et clair de l'audit pour permettre de prendre une décision de certification éclairée et doit comporter ou faire référence à ce qui suit :

- a) l'identification de l'organisme de certification ;
- b) le nom et l'adresse du client et de la personne représentant la direction du client ;
- c) le type d'audit (par exemple audit initial, de surveillance ou de renouvellement de la certification) (voir 4.2.2) ;
- d) les critères d'audit (voir 4.2.3) ;
- e) les objectifs de l'audit (voir 4.2.4) ;
- f) le périmètre d'audit, notamment l'identification des unités organisationnelles ou fonctionnelles ou des processus audités, ainsi que la durée de l'audit (voir 4.2.5) ;
- g) l'identification du responsable de l'équipe d'audit, des membres de l'équipe d'audit et, s'il y a lieu, des personnes accompagnantes (voir 4.2.6) ;
- h) les dates et les lieux où les activités d'audit (sur site ou hors site) ont été réalisées (voir 4.2.7) ;
- i) les constats, les preuves et les conclusions de l'audit, correspondant aux exigences du type d'audit (voir 4.2.8) ;
- j) tout problème non résolu, le cas échéant (voir 4.2.9).

4.2 Exigences et recommandations

4.2.1 Généralités

La liste des exigences et recommandations énoncées de 4.2.2 à 4.2.10 n'est pas exhaustive, ce qui signifie que le rapport d'audit peut inclure des informations supplémentaires.

4.2.2 Type d'audit

4.2.2.1 Le rapport d'audit doit identifier le type d'audit [par exemple audit initial (étapes 1 et 2), de surveillance ou de renouvellement de la certification ou audit particulier (pour de plus amples informations, voir le paragraphe 9.5 de l'ISO/CEI 17021:2011)].

4.2.2.2 Le cas échéant, il convient que le rapport indique s'il s'agit d'un audit conjoint, combiné ou intégré.

4.2.3 Critères d'audit

4.2.3.1 Le rapport d'audit doit identifier les documents normatifs des systèmes de management (par exemple, ISO 9001) et tous autres documents utilisés pendant l'audit, en référence auxquels le système de management de l'organisation est audité.

4.2.3.2 Le rapport d'audit doit référencer le plan d'audit et le programme d'audit.

4.2.3.3 Le rapport d'audit doit indiquer tous changements importants survenus dans l'organisation du client pendant la période soumise à l'examen.

4.2.3.4 Il convient que le rapport indique si les critères d'audit prédéfinis sont adaptés à la situation rencontrée et au système de management audité.

4.2.4 Objectifs de l'audit

4.2.4.1 Le rapport d'audit doit indiquer si les objectifs de l'audit ont été atteints. (Pour de plus amples informations, voir le paragraphe 9.1.2.2.2 de l'ISO/CEI 17021:2011.)

4.2.4.2 Lorsque des modifications sont apportées aux objectifs, au périmètre ou aux critères de l'audit (par exemple sites, unités organisationnelles, activités et processus), ces modifications doivent être enregistrées.

4.2.4.3 Le rapport d'audit doit indiquer si l'organisation auditée contrôle effectivement l'utilisation de la marque de certification.

4.2.5 Périmètre d'audit

4.2.5.1 Le rapport d'audit doit décrire l'étendue et les limites du périmètre d'audit, comme les sites, les unités organisationnelles, les activités et les processus à auditer, y compris, s'il y a lieu, les domaines non couverts bien qu'ils entrent dans le périmètre d'audit.

4.2.5.2 Le cas échéant, le rapport d'audit doit décrire toute exclusion justifiée d'exigences.

4.2.5.3 Le rapport doit identifier le temps passé sur site ou hors site par l'équipe d'audit.

4.2.5.4 Le rapport d'audit doit indiquer tout écart par rapport au temps d'audit prévu dans le plan d'audit.

4.2.6 Identification de l'équipe d'audit

Le rapport d'audit doit identifier le responsable de l'équipe d'audit, les membres de l'équipe d'audit et, s'il y a lieu, les personnes accompagnantes (par exemple guides, observateurs, traducteurs).

4.2.7 Dates et lieux de l'audit (sur site ou hors site)

4.2.7.1 Le rapport d'audit doit indiquer les sites visités et le type d'activité audité sur chaque site (en identifiant les exigences auditées). Le rapport d'audit doit distinguer les sites permanents des sites temporaires.

4.2.7.2 Le rapport d'audit doit mentionner les cas où l'accès à des personnes, lieux ou informations appropriés a été impossible ou refusé.

4.2.7.3 Il convient que le rapport d'audit identifie les éventuelles conditions défavorables spécifiquement liées à l'état des sites.

4.2.8 Constats, preuves et conclusions de l'audit

4.2.8.1 Le rapport d'audit doit inclure les constats d'audit indiquant la conformité (ou non) du système de management en question aux critères d'audit.

4.2.8.2 Le rapport d'audit doit contenir les non-conformités et points sensibles ou une référence à ceux-ci.

4.2.8.3 Les non-conformités doivent être des enregistrements clairs et détaillés des constats de manière à fournir au client une description adéquate des faits.

4.2.8.4 Les non-conformités doivent inclure toutes les références nécessaires permettant de faciliter la détermination d'une action corrective appropriée. Les preuves tangibles de la non-conformité (par exemple documents, plans, rapports d'essai, etc.) doivent être référencées. Les preuves non documentaires (par exemple absence de preuve de compétence) doivent être référencées. La description d'une non-conformité doit également comporter les informations suivantes :

- a) une référence à l'exigence de la norme de système de management ;
- b) un énoncé de la non-conformité ;
- c) les preuves tangibles sur lesquelles repose la non-conformité ;
- d) une référence au document par rapport auquel il a été constaté un écart (c'est-à-dire spécification, règle, instruction, plan, etc.) ;
- e) s'il y a lieu, la catégorie (majeure ou mineure) de la non-conformité (pour de plus amples informations, voir la Note du paragraphe 9.1.9.6.3 de l'ISO/CEI 17021:2011).

4.2.8.5 S'il y a lieu, le rapport d'audit doit contenir les éventuelles incertitudes ou obstacles rencontrés pendant le processus d'audit qui pourraient limiter la fiabilité des conclusions de l'audit.

4.2.8.6 Le rapport d'audit doit traiter de l'efficacité du système de management pour assurer que l'organisation du client répond en permanence à ses objectifs spécifiés.

4.2.8.7 L'efficacité du système de management peut porter sur :

- a) la pertinence de la nature de ses activités, produits et services ;
- b) les activités de l'organisation dans le périmètre de certification et l'adéquation de son périmètre de certification ;
- c) l'analyse, la compréhension et l'identification des besoins et attentes des parties intéressées pertinents pour la norme applicable ;
- d) les objectifs du système de management en vue du respect des exigences des parties intéressées et des exigences légales/réglementaires en vigueur ;
- e) la détermination et le management des processus nécessaires pour parvenir aux résultats prévus ;
- f) la disponibilité des ressources nécessaires pour soutenir la mise en œuvre et la surveillance de ces processus ;
- g) la surveillance et le contrôle des caractéristiques des processus définis ;
- h) la prévention des non-conformités et les processus d'amélioration systématique visant à :
 - corriger les non-conformités qui se produisent ;
 - analyser la cause des non-conformités et mener des actions correctives pour éviter leur réapparition ;
 - traiter les réclamations des clients ;
- i) un processus efficace d'audit interne et de revue de direction ;
- j) la surveillance, le mesurage et l'amélioration continue de l'efficacité de son système de management.

4.2.8.8 Le rapport d'audit peut fournir des commentaires sur la maturité du système de management et peut indiquer si le système de management est complètement établi dans l'organisation et le niveau de soutien qu'il reçoit de la direction et de la direction générale.

4.2.8.9 Il convient que le rapport d'audit indique les risques susceptibles d'avoir une incidence, s'il y a lieu, sur :

- a) la conformité aux exigences des systèmes de management ;
- b) la conformité aux exigences légales/réglementaires ;
- c) la performance du ou des systèmes de management de l'organisation.

NOTE Dans le cadre de la description des risques identifiés, il peut aussi être important, s'il y a lieu :

- d'indiquer qu'un risque significatif n'est pas géré ;
- d'indiquer que des risques ont été présentés de manière inexacte.

4.2.9 Problèmes non résolus

Le cas échéant, le rapport d'audit doit indiquer le suivi des actions curatives et des plans d'actions correctives pour la continuité du processus d'audit.

4.2.10 Déclaration de non-responsabilité

4.2.10.1 Le rapport d'audit doit inclure une déclaration de non-responsabilité indiquant que l'audit est fondé sur un processus d'échantillonnage des informations disponibles et que, par conséquent, il existe une part d'incertitude qui peut transparaître dans les constats d'audit.

4.2.10.2 La déclaration de non-responsabilité doit signaler aux personnes qui s'appuient sur les conclusions et résultats de l'audit ou qui agissent en fonction de ceux-ci de bien avoir conscience de cette incertitude. La déclaration de non-responsabilité doit également signaler que les recommandations de l'audit sont soumises à une revue indépendante avant toute décision concernant la délivrance ou le renouvellement de la certification.

Bibliographie

- [1] ISO 9000:2005, *Systèmes de management de la qualité — Principes essentiels et vocabulaire.*
- [2] ISO 9001, *Systèmes de management de la qualité — Exigences.*

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1	2	(3)	4	5	(6)	(7)
MB ¹	Clause No./ Subclause No./ Annex (e.g. 3.1)	Paragraph/ Figure/Table/ Note (e.g. Table 1)	Type of comment ²	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
LP	General		Ge	<p>The text should distinguish between requirements and recommendations. We suggest the main text for requirements an Annex for recommendations</p> <p>The subclauses taken from ISO/IEC 17021 should be in a box.</p>		1. Noted. ISO editor advised to repeat difference between shall/should in the Introduction and repeat the 17021 clause in main text. 17022 develop further requirements and recommendations.
LOZ	Introduction		ge	<p>According to IIOC view the work of this new standard is to be stopped mainly for three reasons:</p> <ul style="list-style-type: none"> • the requirements for audit reports are already addressed by 17021/17021-2 (9.1.10). • If these requirements are not deemed to be adequate, comments should be carried over and used as input into the next systematic review of 17021. • this work will result in proliferation, duplication and overlapping of requirements 	Ditto	2. Noted. NWIP has been adopted and the work will continue.
TI 01	introduction	3 rd paragraph, 2 nd sentence	te	<p>“The following are examples of <u>possible users</u> of the information contained in audit reports.”</p> <p>They are examples of interested parties, so it is better to use “interested party” instead of “possible users”.</p>	The following are examples of <u>parties who have interest on</u> the information contained in audit reports.	3. Agreed to add “ <i>or other interested parties</i> “. Deleted 1 st sentence 4 th paragraph.
LP	4.1.4.1		te	<p>Eliminate key documents. Which documents are key? This is relative.</p>	4.1.4.1 The audit report shall identify the normative documents of the management systems (e.g. ISO 9001) used during the audit against which the management system of the organization is being audited.	4. Agreed to remove "key".

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2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

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NVL	4.1.4.3		te	The intention of this clause should be clarified: - either it refers to the content of the audit plan (see 4.1.4.2) : the CB and not the team is responsible for drafting the audit plan based on documented motivations and 4.1.4.3 should be deleted - either it refers to the possibility for the team to focus on specific areas, processes and activities, in which case 4.1.4.3 overlaps with 4.1.6.1 and both clauses should be combined		5. Deleted. 4.1.4.3 and added audit programme in 4.1.4.2.
JG	4.1.4.3		te	It is not clear when we can consider "relevant" the explanation about processes and activities focused. It will depend on the audit team thinking.	The clause should be written as a recommendation: <i>The report should document any relevant information about processes and activities that have been focused in the audit</i>	6. See 5.
TI 02	4.1.4.3		Ed	in which <u>areas</u> processes	in which <u>areas</u> ' processes	7. See 5.
JG	4.1.5.2		te	It is too common to find changes in the organizational units and these are not always important for the development of audit. It can also be confusing the term approved, as to who may authorize changes	Delete "organizational units" Delete "have been approved"	8. Not accepted, <i>organizational units</i> come from 17021. Add brackets: "or criteria (eg physical locations, organizational units, activities and processes)" Agreed to delete "have been approved"
TI 03	4.1.5.2		Te	"When changes to the audit objectives, scope or criteria e.g. physical locations, organizational units, activities and processes to be audited <u>have been approved</u> they shall be recorded." Some of those changes require consultation with certification body for approval. It is recommended to	When changes to the audit objectives, scope or criteria e.g. physical locations, organizational units, activities and processes to be audited <u>have been approved, with consultation with certification body as appropriate</u> , they shall be recorded.	9. See 8.

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				describe the matter more precisely.		
JG	4.1.5.3		te	This is not a record for the report. In any type of audit (phase 1, phase 2, etc) the certification body shall record the suitability of equipment at the time of planning. It makes no sense that an audit team assess their eligibility or of other colleagues.	Delete the clause.	10. Accepted.
TI 04	4.1.5.3		te	To harmonize the words with those used in ISO/IEC 17021.	<p>“For a stage 1 audit, <u>the record of audit finding which will be a part of audit report</u> shall indicate the adequacy of the audit team to perform the stage 2 audit.”</p> <p>Or</p> <p>“For a stage 1 audit, <u>the audit finding report</u> shall indicate the adequacy of the audit team to perform the stage 2 audit.”</p>	11. See 10.
JG	4.1.5.4		te	We agree, but considering that the detailed register is just needed when exist some nonconformity (see our comment about clause 4.1.9.1)	<p>Clarify the text in this way:</p> <p><i>The audit report shall indicate if the use of the certification mark has been verified, recording any detailed nonconformity.</i></p>	12. Not accepted. Added "audited" before organization.
TI 15	4.1.6		ed	<p>It is not clear what "the time of the audit" is. The reader of this document might wonder if it is "audit duration" or "audit time".</p> <p>* Since this text is adapted from ISO/IEC 17021, JISC will also make an editorial comment on FDIS 17021 later.</p>	Change "the time of the audit" to "audit duration".	13. Cannot be changed, original 17021 text.
TI 05	4.1.6.4		te	<p>“The audit report shall indicate any deviation in audit time from the audit plan.”</p> <p>This is not based on the requirement in ISO/IEC 17021. Moreover, deviation can be identified from the record of audit time and audit plan. This should be recommendation but not requirement.</p>	Change "shall" to "may".	14. Changed into recommendation "should".

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LOZ	4.1.8.1			With regard the current draft, our specific comments are: 4.1.8.1 <i>"the audit report shall identify any adverse conditions specifically related to the conditions of the sites"</i> . Too broad. Such comments should be applicable only to the scope of the audit / assessment criteria. Such a requirement is obligating the assessment team to make comments outside of the audit scope and beyond their area(s) of competence.	Ditto	15. Second sentence separated, and turned into recommendation.
JG	4.1.8.1		te	Regarding to <i>"The audit report shall identify any adverse conditions specifically related to the condition of sites"</i> we think that is difficult to objectify what are adverse conditions.	Delete the sentence.	16. Not accepted, see 15.
LP	4.1.8.1		te	The audit report shall distinguish between permanent sites from temporary sites	4.1.8.1 The audit report shall indicate the sites visited and type of activity audited in each site (identifying the requirements that have been audited). The audit report shall distinguish between permanent sites from temporary sites. The audit report shall identify any adverse conditions specifically related to the condition of the sites	17. See 15. 2 nd sentence incorporated.
TI 06	4.1.8.1	2 nd sentence	Te	<u>"The audit report shall identify any adverse conditions specifically related to the condition of the sites."</u> "Adverse conditions" may include conditions those not related with conformance. To limit those affect conformance, the word "conditions" should be replaced with "findings".	The audit report shall identify any <u>findings</u> specifically related to the sites.	18. Not accepted, see 15.
JG)	4.1.9.1		te	We agree, but this requirement should be redacted in the same way that in ISO IEC DIS 17021-2 (9.1.9.6.1): <i>"9.1.9.6.1 Audit findings summarizing conformity and detailing nonconformity and its supporting audit evidence shall be recorded and reported to enable an informed certification decision to be made or the certification to be maintained"</i>	The17022 clause could be redacted: <i>4.1.9.1 The audit report shall indicate the summarized conformity and detailed nonconformity of the management system in question with the audit criteria</i>	19. Partial agreed, replaced the word "indicate" by "include the audit findings indicating".

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TI 07	4.1.9.3	3 rd bullet	Te	The part "as well as the statutory and regulatory requirements" is duplicated with the 4 th bullet, and should be deleted.	the analysis, understanding and identification of the needs and expectations of interested parties, as well as the statutory and regulatory requirements, relevant for the applicable standard;	20. Accepted.
TI 08	4.1.9.3	7 th bullet	ed	Delete "for them".	Delete "for them".	21. Accepted, and changed to "process characteristics.
LOZ	4.1.9.8			4.1.9.8 third bullet - <i>record of how the finding was identified</i> " Why? Suggest that this bullet is deleted.	Ditto	22. Agreed change to: "objective evidence on which the non-conformity is based" and changed 2 nd bullet from "description of what has been found" to "statement of the non-conformity"
JG	4.1.9.8	Third item	te	The item "record of how the finding was identified" do not provides relevant information. The way for identify findings is always by documental review and personal interview.	Delete third item	23. Not accepted, see 22.
TI 09	4.1.9.8	2 nd sentence	ed	"Objective evidence of the nonconformity, (e.g. documents, drawings, test reports, etc.) <u>should</u> be referenced." Reference to the objective evidence should be requirement.	Change "should" to "shall".	24. Accepted.
TI 10	4.1.9.8	3 rd sentence	Ed	Non-documentary evidence (i.e. lack of evidence of competence shall be referenced).	Non-documentary evidence (i.e. lack of evidence of competence) shall be referenced.	25. Accepted.
TI 11	4.1.9.9		ed	4.1.9.9 is skipped.	Adjust clause number according.	26. Noted. The structure of clause 4 was reviewed.

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TI 12	4.1.9.10		te	"Risks that might affect" includes nonconformity in principle. Therefore, the sentence should be more precise to indicate the intention of this recommendation.	The audit report may indicate risks that <u>can be reduced more effectively</u> .	27. Not accepted, it does not mean the same
TI 13	4.1.9.11		te	4.1.9.11 is additional explanation to 4.1.9.10. Therefore, it should be described as note to 4.1.9.10.	Change 4.1.9.11 to Note of 4.1.9.10	28. Accepted.
JG	4.1.10.1		te	Should be clarified that this refers to corrective actions arising from the audit	Add "corrective": The audit report shall indicate follow-up corrective action plans, if any, for the continuity of the audit process	29. Accepted, also added "correction".
JG	4.1.11		te	The confidential character of the audit report is determined by the contractual documents between certification body and client, but we think that including any statement about this in the audit report it is not necessary neither adds value.	Delete the clause	30. Accepted.
JG	4.1.12	Last sentence	te	The requirement from ISO 17021 regarding to the independent review of audit report prior to a certification decision, makes reference to certification and recertification decisions, but that standard allow to maintain a client's certification based on a positive conclusion by the audit team leader without further independent review.	Delete the last sentence	31. Not accepted, deleted "maintenance" and changed it to "renewal of certification"
LOZ	4.1.13			4.1.13. Don't understand. This whole para is poorly written and needs re-drafting.	Ditto	32. Clause deleted.
JG	4.1.13		te	The sampling criteria are a part of the audit methodology and sometimes this information hardly can be defined in the audit report.	Do not set any additional requirements of ISO 17021	33. Noted, see 32
TI 14	4.1.13		te	ISO/IEC 17021 doesn't require any specific method of sampling. Therefore, 4.1.13 should be recommendation instead of requirement. In addition, "which means that an auditor is unable to verify that the process is working" is inappropriate for international standard.	The audit report <u>should</u> indicate the relevance of audit samples e.g. if audit samples are taken at different stages, <u>the relation of those sample taken</u> .	34. See 32.
HS	4	New Note	te	The requirements and recommendations listed under 4.1.1 to 4.1.10 are not exclusive.	Add the following Note under 4: Note The requirements and recommendations	35. Accepted, see 4.2.1.

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					listed under 4.1.1 to 4.1.10 are not exclusive, meaning that the audit report can include further information.	
LP	bibliography		te	To have into account the documents issued by the ISO 9001 Auditing Practices Group and IAF.		36. Not accepted.

Initials WG members:

HS – Hinrich Schaub, ASI Austria
 JG - José Antonio Gómez Martínez, AENOR Spain
 LOZ - Leonardo Omodeo Zorini, IIOC
 LP – Luisa F. Pallares, ICONTEC Colombia
 NVL - Nicole Vanlaethem, NBN Belgium
 TI – Takeo Iwamoto, JISC Japan

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