



**BELARUSIAN STATE CENTRE FOR ACCREDITATION
REPUBLICAN UNITARY ENTERPRISE**

RI SM 7.6-2018

CLASSIFICATION OF FINDINGS

Developed by	Accreditation Management Organization Department
Person responsible for review	Accreditation Department No. 2
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1 SCOPE OF USE

1.1 This operating instruction (hereinafter – the instruction) is a document drawn by the management system of Belarusian State Centre for Accreditation Republican Unitary Enterprise (hereinafter – BSCA) developed in pursuance of clause 7.6 of QM MS with regard to the requirements of clause 7.6 of GOST ISO/IEC 17011, and specifies classification of findings detected in carrying out proficiency testing of conformity assessment bodies (hereinafter – CAB), as well as describes actions of the assessment team applicable to the detected findings.

1.2 The requirements of this instruction must be followed by all staff participating in the process of accreditation.

2 REFERENCES

Herein, references to the following documents were used:

Resolution of the State Committee for Standardization No. 27 dated May 31, 2011 ‘On approval of the Accreditation Rules’, revised by Resolution of the State Committee for Standardization No. 49 dated 19.06.2017 (hereinafter – the Accreditation Rules);

STB ISO 9000 (ISO 9000, IDT) Quality management systems. Fundamentals and vocabulary;

GOST ISO/IEC 17000 (ISO/IEC 17000, IDT) Conformity assessment. Fundamentals and vocabulary;

GOST ISO/IEC 17011 (ISO/IEC 17011, IDT) Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies;

GOST ISO 19011 (ISO/IEC 19011, IDT) Guidelines for auditing management systems;

QM MS Quality manual of BSCA;

DP SM 7 Accreditation process;

DP SM 7.4-01 Sampling procedure for laboratories, inspection bodies, proficiency testing providers;

DP SM 7.4-02 Sampling procedure for certification bodies;

DP SM 7.6. Assessment

Note: The current versions of the referred documents shall be used for the purpose of this instruction. If the reference documents are replaced (amended) then the replacement (amended version) shall apply. If the referred documents are cancelled without replacement then the provisions of the procedure referring to them shall apply in the scope not concerning such references.

3 TERMS AND DEFINITIONS

For the purpose of this instruction, the terms and definitions given in STB ISO 9000, GOST ISO/IEC 17000, GOST ISO/IEC 17011, GOST ISO 19011 shall apply:

Non-conformity: Non-fulfillment of the requirement.

Risk: Influence of uncertainty on the objectives.

Note 1 – Influence means deviation (positive or negative) from the expected status.

Note 2 – Uncertainty means the condition of even partial insufficiency of information relating to understanding or awareness of the event, its consequences or probability.

Note 3 – Risk is often characterized by pointing out potential events and their consequences or combination thereof.

Note 4 – Risk often manifests itself as consequences of the event (including change thereof) and relating probability of occurrence.

Note 5 – The term ‘risk’ is sometimes used when there is probability of negative consequences only.

Comments: Evidence of assessment (documents or actions) for possible improvement upon compliance with the established requirements (criteria).

Corrective action: Action undertaken to eliminate the reason for non-conformity and avoidance of its repeated occurrence.

Correction: Action undertaken to eliminate the detected non-conformity.

4 DESIGNATIONS AND ABBREVIATIONS

For the purpose of this instruction, the following denotations and abbreviations apply:

BSCA, accreditation body	– Belarusian State Centre for Accreditation Republican Unitary Enterprise;
DP	– documented procedure;
AD 1	– Accreditation Department No. 1;
AD 2	– Accreditation Department No. 2;
CBAD	– Certification Bodies Accreditation Department;
ICD	– International Cooperation Department;
AMOD	– Accreditation Management Organization Department;
DELPW	– Department for Economic, Legal and Personnel Work;
CAB	– Conformity assessment body;
OI	– Operating instruction;
MS	– Management system;
TCA	– Technical Commission for Accreditation.

5 LIABILITY AND AUTHORITY

5.1 Team leader is liable for identification and classification of findings based on unbiased evidence and facts detected in the course of competence assessment.

5.2 Members of the assessment team are liable for correct identification of findings detected by the in the course of the finding assessment procedure, based on unbiased evidence and facts detected in the course of competence assessment.

6 CLASSIFICATION OF FINDINGS

6.1 General provisions

Classification of findings is carried out by the assessment team in the course of competence assessment for the purpose of accreditation, re-accreditation, extending accreditation, surveillance.

Application of this instruction ensures uniform approach to analysis, identification and classification of findings in the course of competence assessment.

6.2 Classification of findings and requirements for CAB

6.2.1 Findings are classified as follows:

Non-conformity: Non-fulfillment of the requirement.

Risk: Potential non-conformities.

Comments: Suggestions for improvement while CAB activity complies with the established requirements (criteria). Comments are not considered as non-conformities.

Description of certain type of findings, actions of the accreditation body and CAB are shown in Annex 1 hereof.

6.2.2 Classification of findings is carried out by the team leader.

Note: The technical expert for accreditation/expert/candidate to the status of the technical expert for accreditation shall agree with the Team leader on correctness of wording of the detected finding, attribution of the non-conformity to the specific requirement of the underlying standard (accreditation scheme), LR, TLR stipulating the activities for accreditation, conformity confirmation, conformity assessment and other sources of non-conformities.

6.2.3 Sources of findings may be the following:

- Documentation not compliant with the requirements of the underlying standard;
- Deviation of the functioning of the management system from the established requirements;

- Technical equipment;
- Insufficient competence of the personnel in conformity assessment activities;
- Feedback from service users, provided by CAB;
- Records (accumulated data and information) obtained in the course of conformity assessment (testing, calibration, certification, etc.);
- Data of CAB MS efficiency analysis;
- Results of previous assessments;
- Existing resources (personnel, equipment, environment, etc.).

6.2.4 Findings may be detected in the course of competence assessment with application of assessment techniques according to the requirements of DP SM 7.4-01, DP SM 7.4-02.

6.2.5 For precise identification of findings by the assessment team, detected facts are analyzed on the basis of specific conditions in which they occurred, identification of findings is based solely on evidence noted by the members of the group during assessment.

6.2.6 The non-conformity shall be:

- identified according to the specific requirement of the underlying standard;
- confirmed by detected fact(s).

6.2.7 Multiple non-conformities to one requirement are considered as one non-conformity.

6.2.8 Recommendations for wording of detected findings are shown in Annex 2 hereof.

6.3 Actions with findings

6.3.1 Actions with findings include the following stages:

- Analysis of all detected findings for the purpose of identification and classification;
- Registration of findings;
- Notifying CAB about findings.

6.3.2 Each finding is discussed at intermediary meetings with members of the assessment team before the final meeting with CAB representatives, to agree the consolidated position of the assessment team.

6.3.3 Identified non-conformity is registered by the Team leader in the non-conformity sheet (Annex 5 of DP SM 7.6) which specifies analysis of reasons, deadlines for corrections (if any), corrective actions and the report on elimination of non-conformities, that may not exceed the deadlines stipulated in the Accreditation Rules.

6.3.4 Risks and comments are registered in the final assessment report (Annex 10 of DP SM 7.6).

6.3.6 In formulating non-conformities and risks, the reference is made to the clause/ subclause of the underlying standard (accreditation scheme), LR, TLR stipulating the activities for accreditation, conformity assessment in relation to which the non-conformity or risk was detected, and/or the respective provisions of CAB MS documents.

6.3.7 The assessment team officially informs the CAB representative about registered findings, and the latter acknowledges the non-conformities by signing the non-conformity sheet and the final assessment report.

6.3.8 Within the established period of time, CAB analyses the reasons for the non-conformities, develops corrective actions/corrections to eliminate the non-conformities, registers results of analysis of reasons for the non-conformities and scheduled corrective actions/corrections in non-conformity sheets, provides completed non-conformity sheets to BSCA for approval by the team leader.

Notes:

1 In eliminating the detected non-conformities, CAB shall strictly adhere to the approved corrective action procedures.

2 Non-conformities are not allowed to be eliminated during assessment, since it may lead to the occurrence of a repeated non-conformity in the course of the following assessment because 'agreed' corrective actions were not duly analyzed.

6.3.9 The assessment team is liable for control over fulfillment of corrective actions in accordance with DP SM 7.6.

6.3.10 The results of competence assessment and the findings detected by the assessment team are analyzed by TCA members and taken into account when setting frequency of periodical competence assessment within the accreditation cycle in accordance with the requirements of Chapter 8 of the Accreditation Rules, DP SM 7.

7 RECORD MANAGEMENT

No records subject to storage are made as a result of this instruction.

Description of finding categories

Finding	Classification criteria	Actions of the accreditation body	Actions of CAB
1	2	3	4
Non-conformity	Findings: - relating to technical activity of CAB, make a direct influence on results of CAB activities; - non-conformities in CAB management system; - violations of CAB obligations in compliance with the accreditation scope, unjustified use of references to accreditation, accreditation mark.	According to the Accreditation Rules, presence of one or more non-conformities to the requirements of the underlying standard, technical requirements of regulations (documents), methodologies in the accreditation scope that may influence unbiased and competent attitude in performance of work within the declared accreditation scope, may be the ground for suspension or withdrawal of the accreditation certificate for full or partial accreditation scope. Establishment and agreement of the deadline for presentation of corrections (if necessary), analysis of reasons that lead to occurrence of non-conformities, corrective actions for their elimination, and the report on fulfillment of corrective actions with unbiased evidence before deadlines stipulated in the Accreditation Rules. If it is impossible to eliminate non-conformities based on documented evidence – carrying out additional on-site assessment. <u>For the accredited CAB:</u> In cases when detected non-conformities cannot be eliminated by means of development and fulfillment of corrective actions – withdrawal of the accreditation certificate for CAB. <u>For the applicant:</u> In cases when detected non-conformities cannot be eliminated by means of development and fulfillment of corrective actions – denial of accreditation.	Correction (if necessary), analysis of reasons and development of corrective actions, agreement of corrections/corrective actions with AD, provision of the report on fulfillment of corrective actions with unbiased evidence before deadlines agreed upon with AD in accordance with the Accreditation Rules.

1	2	3	4
Risks	Potential non-conformities (detection of facts that may lead to non-conformities)	Assessment of risk elimination/ mitigation is carried out during the following assessment.	In case of risk detection, CAB shall demonstrate how it eliminates or mitigates such risk. Evidence of elimination / mitigation shall be presented during the following assessment.
Comments	Possible areas for improvement in case of compliance with the established requirements (criteria)	Assessment of undertaken actions for analysis and implementation of areas for improvement is carried out during the following on-site assessment.	It is recommended to react to comments (carry out analysis of areas for improvement and, if necessary, develop and implement measures for improvement)

Recommendations for wording of findings

1 Drawing wordings of non-conformities

When drawing wordings of non-conformities, the following shall be stated:

- Reference to the specific requirement of the research, testing, inspection, calibration, certification process methodology, procedures of the Quality Manual and other MS document, procedural or other document to which the detected non-conformity relates.
- In case of non-conformities relating to the equipment used by CAB, its registration (factory) number and the document of metrological usability (certificate, calibration report) shall be stated.
- In case of non-conformities relating to manufacturing conditions and environment, the reference to the specific requirement of the research, testing, calibration methodology, established fact, required parameter (e.g.: temperature ($15 \pm 0,5$)°C, humidity 85%)) shall be stated.
- In case of non-conformities relating to CAB management systems, the reference to the requirement documented in CAB MS documents shall be stated.
- Reference to the program and sequence number of audit, full name of the auditor in case of internal audit carried out by the personnel not possessing the required qualification.
- Reference to the report and certificate of analysis of the management system by the management in case of absence of established input data, non-compliance with the deadlines for meetings, failure to take the necessary decisions based upon analysis results.

Wording of non-conformities shall not contain corrective actions and comments.

2 Wording of risks

Wording of risks shall include the reference to the source being the reason for risk and the threat itself.

3 Wording of comments

Wording of comments shall include suggestions of the assessment team for the areas where improvements are possible, yet no specific solutions.

Amendments registration sheet

Amendment No.	Amendment enforcement date	No. of amendment notification, date of approval	Amended item	Signature of amending person	Printed name of amending person
1	2	3	4	5	6