

SLOVENSKÁ NÁRODNÁ AKREDITAČNÁ SLUŽBA Karloveská 63, P. O. Box 74, 840 00 Bratislava 4

Statute

ST-08

SNAS COMMISSIONS FOR APPOINTMENT OF ASSESSORS

Approved by: Ing. Štefan Král, PhD. Director

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1 INTRODUCTION

This regulation stipulates the statute and rules of procedure for SNAS Commissions for Appointment of Assessors (hereinafter only as "Commission" or "KVP").

2 ABBREVIATION USED

| AIS | Accreditation Information System |
|------|---|
| E | Expert |
| Ι | SLP inspector |
| IP | Internal regulation |
| KVP | Commission for Appointment of Assessors |
| МК | Quality manager |
| MSA | Methodological Guidelines for Accreditation |
| OCO | Department of Certification Bodies and Assessors |
| OG | Technical guarantee |
| OLIS | Department of Laboratories, Inspection Bodies and SLP |
| Р | Assessor |
| SLP | Good Laboratory Practice |
| TL | Form |
| VI | Lead inspector |
| VP | Lead assessor |

3 RELATED DOCUMENTS

- ISO/IEC 17011 Conformity assessment Requirements for accreditation bodies accrediting conformity assessment bodies IAF MD 8: Application of ISO/IEC 17011 in Medical Device Quality Management Systems (ISO 13485)
- IAF MD 13 Knowledge requirements for accreditation body personnel for information security management systems (ISO/IEC 27001)
- IAF MD 14 Application of ISO/IEC 17011 in Greenhouse Gas Validation and Verification (ISO 14065:2013)
- IAF MD 16Application of ISO/IEC 17011 for the Accreditation of Food Safety
Management Systems (FSMS) Certification Bodies
- IAF MD 20 Generic Competence for AB Assessors: Application to ISO/IEC 17011
- ILAC-G11 ILAC Guidelines on Qualifications and Competence of Assessors and Technical Experts

SNAS Quality Manual

National Programme for Observance of the GLP Principles in SR

- ST-02 SNAS Organization system
- IP-02 Preparation and control of the assessment
- IP-04 SNAS training system

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IP-10Registration of SNAS assessors, inspectors and expertsMSA-05Requirements for SNAS assessors and experts

4 ESTABLISHMENT OF COMMISSIONS FOR APPOINTMENT OF ASSESSORS

A copy of the instrument of establishment of the SNAS Commission for Appointment of Assessors is at

- Department of Laboratories, Inspection Bodies and GLP (hereinafter only as "KVP-OLIS" is in Annex 1,
- Department of Certification Bodies and Verifiers (hereinafter only as "KVP-OCO") is in Annex 3.

5 STATUTE OF COMMISSIONS FOR APPOINTMENT OF ASSESSORS

5.1 SCOPE OF THE COMMISSIONS

- 5.1.1 KVP SNAS are advisory bodies to the Director. They are established by the SNAS Director. They are composed of internal employees of SNAS.
- 5.1.2 KVP members are approved by the Director.
- 5.1.3 The role of KVP is assessing proposals for appointment of VP/P/VI/I and inclusion of experts in the SNAS database on the basis of all submitted relevant documents specified in MSA-05 to make sure that a SNAS assessment can be carried out by competent assessors and experts with objectively affirmed professional competence in line with international standards, regulation of international organizations associating the accreditation bodies, with European directives and SNAS documents.

5.2 TASKS OF THE COMMISSIONS

- 5.2.1 Assess, within the relevant specialization, the submitted proposals for appointment of SNAS lead assessors, assessors, GLP lead inspectors and inspectors and proposals for inclusion of experts in the SNAS database.
- 5.2.2 Prepare the relevant recommendations for appointment of VP/P/VI/I for the Director.
- 5.2.3 Check if the databases of assessors, lead assessors, inspectors, lead inspectors and experts are up-to-date in line with the internally defined requirements for persons involved in the processes of accreditation/attestation activities.
- 5.2.4 On the basis of negative findings from monitoring the activities of VP/P/VI/I/E propose, if needed, at meetings of the Commission take the action/measures needed to ensure competent provision of accreditation/attestation services and check the effectiveness of the implemented corrective actions/measures.
- 5.2.5 Reviewed, once the transition period for revised/updated key documents related to provision of accreditation/attestation services has elapsed, whether the concerned specialists (registered in AIS) were retrained for the new versions.

5.3 COMMISSION MEMBERS

KVP members include all heads of SNAS departments and technical guarantees (ST-02, Annex 3) at respective departments through a balanced representation:

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- KVP-OLIS accreditation in the areas of testing, calibration, inspection and observance of GLP principles,
- KVP-OCO accreditation in the area of certification of persons, products, management systems, environmental verification and verification of greenhouse gas emissions.

The list of the KVP-OLIS members is in Annex 2 and of KVP-OCO members in Annex 4.

6 RULES OF PROCEDURE FOR COMMISSIONS FOR APPOINTMENT OF ASSESSORS

6.1 **RIGHTS AND RESPONSIBILITIES OF KVP MEMBERS**

KVP Chair:

- Sets the date of the meeting,
- Manages the course of deliberations,
- Is responsible for the KVP's activities,
- Approves the minutes from deliberations.

In the absence of the Chair, his / her rights and duties carries Deputy chair.

KVP members:

- Attend KVP deliberations. Connection via teleconference, videoconference or written opinion on the deliberations of the program is deemed to be present at the meeting,
- Give their opinion of completeness and up-to-datedness of the submitted documentation related to qualifications, trainings, experience, records from monitoring of every SNAS assessor/ lead assessor/GLP inspector/ lead inspector/expert and objective confirmation of the professional competence of an assessor/inspector/expert,
- Give their opinion of whether the adopted corrective actions/measures to remedy negative findings are sufficient (See 5.2, point 4),
- Participate in preparation of relevant recommendations for the SNAS Director,
- Consistently observe confidentiality of all confidential information that they learned during the deliberations and assessment,
- Carry out their activities impartially, objectively, impartially, consistently and observe the required scope of the assessment,
- Notify their absence from deliberations to the KVP secretary in advance.

KVP secretary:

- Is not an ordinary member of the commission and has no voting right,
- Cooperates with the chair in drafting the program for deliberations,
- Prepares supporting materials for deliberations,
- Produces the minutes from the deliberations.

6.2 **DELIBERATIONS OF THE COMMISSIONS**

- 6.2.1 The dates of KVP meetings are set by its chair as needed,
- 6.2.2 The KVP **deliberations program** is set by the chair in cooperation with the secretary on the basis of the proposals from the technical guarantees for appointment of SNAS assessors/lead assessors and GLP inspectors/lead inspectors and proposals for inclusion of experts in the SNAS database from respective departments,

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- 6.2.3 **Criteria for assessment** of the submitted proposals are in MSA-05. The criteria for GLP inspectors/lead inspectors are in the National Programme for Observance of the GLP Principles in SR.
- 6.2.4 KVP has a quorum if the chair/deputy chair and at least two members are present,
- 6.2.5 Persons such as case officers, lead assessors, relevant external experts can be invited to the deliberations if needed,
- 6.2.6 The secretary produces **minutes in AIS** from each KVP deliberations that are approved by the Commission chair.
- 6.2.7 **The outcome of** KVP **deliberations** are resolutions under which the KVP may:
 - Return the proposal to the submitter if no relevant supporting documents have been submitted to include the concerned person into the SNAS database or to grant the person the proposed status,
 - Withdraw the candidate/VP/P/VI/I/E if the candidate fails/has ceased to meet the requirements for a SNAS worker to be involved in the accreditation/attestation process,
 - Suspend the concerned person's activities in the position of a VP/P/VI/I/E, if the
 person temporarily fails to meet the criteria (such as not having been retrained for
 a new accreditation standard),
 - Include in AIS those VP/P/VI/I/E who have met the criteria stipulated in MSA 05,
- 6.2.8 The Director, upon KVP's recommendation, officially approves the VP/P/VI/I status by granting a SNAS VP/P certificate or by granting an appointment decree for VI/I SLP.

7 **RELATED FORMS**

| TL 35: | Certificate of lead assessor/assessor | |
|--------|---------------------------------------|-----|
| | | · • |

TL 36: Appointment decree for lead inspector/inspector

8 ANNEXES

- Annex 1: Instrument of establishment of KVP-OLIS
- Annex 2: List of KVP-OLIS members
- Annex 3: Instrument of establishment of KVP-OCO
- Annex 4: List of KVP-OCO members

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INSTRUMENT OF ESTALISHMENT OF KVP-OLIS



ZRIAĎOVACIA LISTINA

Dňom 01.06.2013 zriaďujem

KOMISIU SNAS NA VYMENOVANIE POSUDZOVATEĽOV

NA ODBORE LABORATÓRIÍ, INŠPEKČNÝCH ORGÁNOV A SLP

ako poradný orgán riaditeľa SNAS na posudzovanie návrhov na vymenovanie vedúcich posudzovateľov, posudzovateľov SNAS, vedúcich inšpektorov a inšpektorov SLP.

Vymenovanie vedúcich posudzovateľov a posudzovateľov SNAS, vedúcich inšpektorov a inšpektorov SLP môže byť vykonané len na základe kladného odporúčania Komisie SNAS na vymenovanie posudzovateľov (KVP).

Zoznam členov Komisie (KVP) schval'uje riaditeľ SNAS.

Poslanie a pôsobnosť Komisie (KVP) určuje jej štatút.

Pôsobiskom Komisie (KVP) je sídlo SNAS v Bratislave.

Mgr. Martin Senčák riaditeľ

V Bratislave 01.06.2013

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LIST OF KVP-OLIS MEMBERS

| RNDr. Lívia Kijovská, PhD. | Chair |
|----------------------------|--------------|
| Ing. Stanislav Musil, CSc. | Deputy Chair |
| Ing. Jana Pašková | Member |
| Ing. Kvetoslava Foríšeková | Member |
| Ing. Stanislav Mikušínec | Member |
| Mgr. Zuzana Tunegová | Member |
| Ing. Jaromír Durný | Member |
| Ing. Henrieta Bóriková | Member |
| Ing. Janka Szabová | Member |
| PHDr. Mesíková Ivona, PhD. | Secretary |

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INSTRUMENT OF ESTABLISHMENT OF KVP-OCO



ZRIAĎOVACIA LISTINA

Dňom 01.06.2013 zriaďujem

KOMISIU SNAS NA VYMENOVANIE POSUDZOVATEĽOV

NA ODBORE CERTIFIKAČNÝCH ORGÁNOV A OVEROVATEĽOV

ako poradný orgán riaditeľa SNAS na posudzovanie návrhov na vymenovanie vedúcich posudzovateľov a posudzovateľov SNAS.

Vymenovanie vedúcich posudzovateľov a posudzovateľov SNAS môže byť vykonané len na základe kladného odporúčania Komisie SNAS na vymenovanie posudzovateľov (KVP).

Zoznam členov Komisie (KVP) schvaľuje riaditeľ SNAS.

Poslanie a pôsobnosť Komisie (KVP) určuje jej štatút.

Pôsobiskom Komisie (KVP) je sídlo SNAS v Bratislave.

V Bratislave 01.06.2013

Mgr. Martin Senčák

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LIST OF KVP-OCO MEMBERS

| Ing. Gizela Pelechová | Chair |
|----------------------------|--------------|
| Ing. Renáta Kuťková | Deputy Chair |
| Ing. Pavol Kothaj | Member |
| Ing. Jana Vašková | Member |
| Ing. Alena Trabalková | Member |
| PHDr. Mesíková Ivona, PhD. | Secretary |

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