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INSTRUCTION

ON THE CRITERIA AND METHODS OF ACCREDITATION AND SURVEILLANCE OF ENVIRONMENTAL VERIFIERS ACCORDING TO REGULATION 1221/2009 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL

List of amendments

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1. Introduction

- 1.1 According to the Law on National Accreditation of Conformity Assessment Bodies and the Law on Preservation of Environment, the Executive Agency "Bulgarian Accreditation Service" (EA "BAS") provides accreditation of Environmental Verifiers and surveillance in notification of Environmental Verifiers, when they are accredited by Accreditation Body of another EU member-state, according to Regulation 1221/2009 of the European Parliament and Council from 25 November 2009 on the voluntary participation by organizations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) № 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC.
- 1.2 This instruction is intended to clarify the methods and criteria of EA BAS for accreditation of Environmental Verifiers (EV), as well as to provide instructions to EV, which wish to be accredited in this field.
- 1.3 It is applicable for accreditation of legal entities as EVs in compliance with Regulation (EC) № 1221/2009 of the European Parliament and of the Council and Regulation (EC) № 765/2008 of the European Parliament and of the Council.
- 1.4 EA BAS performs accreditation of EV according to the requirements of Regulation (EC) 1221/2009, Regulation (EU) № 2017/1505, EC Guidance, applicable to the accreditation process and BDS EN ISO/IEC 17021-1.
- 1.5 The order for implementation of accreditation procedure of EV is stipulated in BAS QR 2, which is applied jointly with this instruction.

2. Abbreviations

EV Environmental Verifiers

- EMAS Community Eco-Management and Audit Scheme (Regulation (EC) № 1221/2009 of the European Parliament and of the Council from 25 November 2009)
- BAS QR 2 EA BAS Accreditation Procedure
- EA "BAS Executive Agency Bulgarian Accreditation Service
- Regulation (EU) № 1221/2009 of the European Parliament and of the Council from 25 November 2009, Regulation (EU) 2017/1505 on Commission from 28 august 2017 year with amendment of Annexes I, II and III to the Regulation (EU) № 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community Eco- management and audit scheme and Commission Regulation (EU) 2018/2026 of 19 December 2018 amending Annex IV to Regulation (EU) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)

3. Functions of EV

The functions of the EV are specified in Art.18 of Regulation (EC) N $^{\circ}$ 1221/2009. The EV shall verify the following:

a) Fulfillment of all requirements of the Regulation in relation to the initial environmental verification, the policy in the field of environment, the environmental management system, the environmental audit and its results, the management review and the ecological statement or updated ecological statement;

b) Observation of the applicable legal requirements related to environment;

c) Continuous improvement of the ecological results of the organization;

d) Reliability, authenticity and accuracy of the data and information in the ecological statement; updated ecological statement; ecological information, subject to validation.

In addition, the EV shall look up for the application of the reference documents under sectors issued by the Commission according to Art. 46 of Regulation (EC) \mathbb{N}° 1221/2009 on its application, if there are available.

4. Accreditation Process (evaluation methods)

4.1 General conditions

EA BAS provides accreditation to Conformity Assessment Bodies as Environmental Verifiers according to Regulation (EC) № 765/2008.

Application for accreditation is made in the order determined in BAS QR 2 "Accreditation Procedure of EA BAS, as the scope of accreditation is defined according to the Classification of economical activities, as noted in Regulation (EC) № 1893/2006 (NACE Rev.2). The EV presents to the accreditation body evidence of its competence, including knowledge, relevant experience ant technical capabilities corresponding to the applied scope for accreditation.

EA BAS performs accreditation of EVs according to the requirements of Regulation (EC) N $^{\circ}$ 1221/2009, EU guidance, applicable to the accreditation process of EV and BDS EN ISO/IEC 17021-1.

EA BAS carries out an evaluation in compliance with BAS QR 2 - EA BAS Accreditation Procedure. Depending on if the EV is already accredited as an Environmental Management Systems Certification Body, the following actions shall be undertaken:

Environmental Verifiers, which are not accredited as Environmental Management Systems Certification Bodies must demonstrate compliance with the requirements of Regulation (EC) N° 1221/2009 and E_{AC} EN ISO/IEC 17021-1. The accreditation procedure includes preliminary investigation of documents, on-site assessment, and witness of the EV activity.

Environmental Verifiers, which are already accredited as Environmental Management Systems Certification Bodies, must demonstrate conformity with the specific requirements of Regulation (EC) № 1221/2009. The accreditation procedure includes preliminary review of documents, on-site assessment and witness of the EV activity covering at least informational audit according of Regulation (EC) № 1221/2009.

4.2Preliminary investigation

The purpose of the preliminary investigation is a documental assessment of the EV to be carried out for compliance with the requirements of Regulation (EC) Nº 1221/2009 and the relevant standards and guidance. The EV is necessary to present the documents, specified in item 4.1.1.1 of the Accreditation Procedure BAS QR 2 - BAS QF 2.12 «List of necessary documents, applicable to application for accreditation of Environmental Verifier». The preliminary investigation shall be carried out in the order specified in Accreditation Procedure BAS QR 2.

4.3 Office assessment

The purpose is to verify the implementation of the documented procedures.

During the documental review and office assessment, special attention shall be drawn on the following issues:

- participation of the interested parties and assurance of independence and impartiality;

- competence of the EV;

- review of the contract, including utilization of the competence needed for implementation of verification and validation, determination of the team by the EV;

- verification procedures and records of their application, including preliminary investigation of documentation and visitation to the organisation inclusive of on-site verifications and interviews with the personnel.

4.4 Witness of activity

The purpose is to verify the application of the EV procedures in practice.

For initial accreditation of EV, EA BAS requires the assessor team to attend at least at two witnesses of the EV activity, depending on the applied scope of accreditation. At least one of the witnesses must be covering stage 1 of verification, on-site verification in the organization introduced EMAS and validation of the ecological statement. EV shall plan and propose for witness performed by the EV activities on verification and validation within a term of three months from the date of the office assessment carried out by EA BAS.

One week before the witness is carried out, the EV is necessary to provide, for purpose to prepare for carrying out witnessing, the following additional documents:

- Environmental Policy
- Records from review of contract for the witnessed organization
- Draft of ecological statement (updated ecological statement)
- Plan for verification.

The witness of the on-site verification in the organisation implemented EMAS includes: - opening meeting;

- visitation of the site;
- interviews;
- verification of the legal requirements to the Environmental Management System;
- verification of data, recorded in written and graphic format, etc.;
- verification of the public information;
- closing meeting and presentation of results.

- assessment of corrective actions and validation of ecological statement (on documents).

EA BAS witness how the EV fulfills the requirements of the Regulation and the related Commission guidances, and in particular the following aspects will be followed:

- does the ecological declaration cover adequately all significant aspects and impacts on the environment, applicable for the organization;

- in case of omitted issues – on what basis is it done;

- is there compatibility between the key elements in the whole system, including environmental review, policy, management system and the ecological statement and the information provided for verification and validation;

- the ecological statement and the statements in relation to effectiveness, systems, general and specific aims and programs;

- procedures on determination of the level of accuracy, required by the measurement methods or the quantitively expressed data of effectiveness and for the quality control – in other words item 4.5.1 of ISO 14001.

- relations between the functions of the head office and the sites with implemented EMAS.

- procedures on internal environmental audits, selection and qualification of the personnel, carrying out the audits.

Witness is carried out by lead assessor with competence in the field, where necessarytechnical assessor and expert. The evaluation team in addition provides competence in respect to the organization activity, subject of verification and validation of the environmental statement (NACE rev2).

4.5 Accreditation decision

When reaching decisions related to procedures on accreditation or surveillance of EV, shall be follow the requirements of BAS QR 2 Acreditation Procedure, except of the cases on withdrawal or suspension of accreditation, or cases on reduction of accreditation scope. In these cases the EV is given a hearing by means of participation in Accreditation Commission without the right to vote.

In cases of suspension or withdrawal of accreditation, it is carried out a consultation with the interested parties, including with the environmental verifier. In this case the Accreditation Commission holds a meeting with extended membership with representatives of interested parties (Competent Authority for the Republic of Bulgaria under EMAS, branch organizations, organizations of consumers and organizations on preservation of the environment). The Commission considers and presents to EA BAS all necessary evidence for reaching a decision.

Accreditation is suspended or withdrawn depending on the case, the nature and scope of violation of the legal requirements.

Suspension of accreditation is cancel (accreditation is restored) if EA BAS is provided with satisfactory information that the EV comply the requirements of the Regulation.

4.6 Surveillance of EV

EA "BAS" carries out surveillance of the accredited EVs under the order of BAS QR 2 on intervals not longer than 24 months, by on-site assessmet and other methods, mentioned below, in order to be guaranteed that the EV continues to fulfill the accreditation requirements and to follow the quality of the implemented activities on verification and validation.

The surveillance may be carried out as administrative audit, on-site surveillance in the organizations (witness), by means of questionnaires, review of the validated by the EV ecological statements or updated ecological statements, as well as review of the verification report. The surveillance is proportional of the activity carried out by the environmental verifier.

Witness of the activity is carried out by lead assessor with competence in the field, where necessary- technical assessor and expert. The evaluation team provides competence in respect to the organization, subject of verification and validation of the environmental statement (NACE rev.rev2).

In order to carry out surveillance under Art. 23 of Regulation (EC) № 1221/2009, EA BAS must be notified at - least four weeks before each verification and / or validation of the EV. The notification must include at least the following information:

- Information on the accreditation / license of the EV

- Date and place of the verification and validation;

The information is presented by BAS QF 2.12B. Based on information gathered EA BAS decides what methods of surveillance to take considering the requirement that surveillance should be proportional to the work done by the environmental verifier.

As part of the supervision activities of accredited EV, EA BAS verify also, if they are satisfied the requirements of notification in accordance with Regulation (EC) \mathbb{N}° 1221/2009, when EV operates activity in other Member State.

EA BAS recommend, that the accredited EV must informed their customers, that they are required to allow the supervision in accordance with Article 23(6) of Regulation (EC) N^o 1221/2009 and that the refusal of allowing the supervision can thwarting the registration of organizations.

When after surveillance ascertained and reached decision that:

- the activities of the EV are not satisfactory carried out to guarantee in sufficient degree the fulfillment of the reqirements of Regulation (EC) № 1221/2009.
- the verification and validation by the EV are carried out in violation of one or more requirements of Regulation (EC) № 1221/2009, after consultation with the relevant EV, EA "BAS" prepares a report containing information on implemented surveillance and findings, which is presented to:
- the respective EV;
- the Competent Authority of the member state, in which the organisation is registered or applied for registration.
- In case of disputes and the Forum of Accreditation and Licensing Bodies.

5. Requirements for competence of EV

The requirements for competence of EV are specified in Art. 20 of Regulation EC № 1221/2009.

The scope of accreditation will be defined by the scope of competence of each of the environmental verifiers, proven by the relevant objective evidence on real practical experience regarding the overall functioning of the activity and the technical aspects, which matter to the issues of the environmental field. The activities, for which the environemntal verifiers are assessed are describer by NACE codes, according to Regulation (EC) Nº 1893/2006.

The evidence for competence of each environmental verifier, including competence for carrying out environmental and informational audit for verification of ecological statement, will be assessed during the on-site assessment.

6. Public Register of Environmental Verifiers

According to Art. 17 of the Law on National Accreditation of Conformity Assessment Bodies, EA "BAS" maintains a Public Register of the accredited Environmental Verifiers and monthly notifies the competent authority (The Minister of Environment and Water or authorized by him official) of the introduced amendments.

7. Supervision and notification of EV, which carry out verifications in a memberstate, different from the one, in which they are accredited

7.1 General provisions

EVs accredited or licensed in an EC member-state may carry out activities on verification and validation in any other member state in observation of the requirements of Art. 24 of Regulation (EC) \mathbb{N}° 1221/2009.

According to these requirements EA "BAS" has the obligation to carry out surveillance of EV accredited/licensed by accreditation body/ licensing body of EC member state, carrying out verification and validation activities in the Republic of Bulgaria.

7.2 Notification by the EV

EA BAS shall be notified at least four weeks before each verification and/or validation by the EV on the territory Of the Republic of Bulgaria. The notification shall include at least the following information:

- information on the accreditation/license of the EV (Accreditation Certificate, country, date and scope of accreditation);
- information on the composition and the competence of the auditor team;
- information on how is demonstrated and ensured the knowledge of the Bulgarian legislation;
- information on how the potential language problems are solved;
- date and location of the verification and validation;
- address of the organization subject to verification and validation by EV and verification program;
- draft of ecological statement, subject to verification;
- copy of previous reports of verification and non-conformities, if applicable.

The information shall be presented by means of BAS QF 2.12A – List of necessary documents, applicable to application for notification of Environmental Verifiers.

After receiving this information, EA BAS appoint Lead Assessor and, if necessary, Technical Assessors and / or Experts.

By letter the EV will be notified to the appointed Lead Assessor and Technical Assessors and / or Experts.

Within three (three) days of receipt of the notification letter, the applicant has the right to object once against the designated lead assessor and technical assessors and / or experts.

In the event of a written and reasoned disapproval of the appointed lead assessor or technical assessor or expert, based on objective evidence of the existence of a conflict of interest and / or in terms of de facto incompetence, a new lead assessor or technical assessor / expert is appointed and a new agreement with the EV is being carried out. In the event that the EV does not object in writing within the stipulated term of the letter of agreement, EA BSA accepts that it agrees with the selection of a leading assessor and technical assessors and / or experts.

Lead Assessor and Technical Assessors and / or Experts complete a Declaration of Impartiality and confidentiality.

The lead assessor / assessmant team carries out review of the notification documents, including documents and results of previous notification, if available.

After receiving these documents, EA BAS

EA BAS give notice in writing to EV for the results of the review and the method of supervision, also the connected these costs.

EA BAS must give these information in two weeks period before the begginning of the activites on verification and validation.

As the results of notification could be having an effects to process on verification and validation, EA BAS recommend on EV to announces the result of notification to its customers.

7.3 Surveillance

The manner for implementation of surveillance depends on the complexity and completeness of the information received in the notification and, if applicable, the results from previous surveillances. For each specific case, EA "BAS" determines the methodology of the surveillance, as includes some or all of the following activities:

- witness of the EV activity on verification and validation of ecological statement;

- review of the validated by the EV ecological statements or updated ecological statements;

- review of the verification report.

The first surveillance of EV includes mandatory witness of the activities of verification and validation of the ecological statement.

Witness of the activity is carried out by lead assessor with competence in the field, where necessary- technical assessor and expert. In addition the evaluation team provides competence in respect to the organization activity, subject of verification and validation of the environmental statement (NACE rev2).

During the observation of the EV activity, EA BAS assessors will focus their attention on the correctness of implementation of the verification activities and knowledge of the national legislation in terms of environment and good understanding of the working language, in which is implemented the audit of verification and validation of the ecological statement.

In subsequent surveillances, when enough confidence is accumulated in the EV activity, EA BAS may carry out only verification of the verification reports.

In case that during the surveillance is ascertained that the quality of work of the environmental verifier does not comply with the requirements of the Regulation, EA BAS decide to recommend that the competent authority do not register the organization, EA BAS documents the results in surveillance report and sends them to:

- the respective EV;

- the Accreditation Body, which has accredited the respective EV or the licensing body which issued the license;

- the competent authority, to which the relevant organisation intends to apply for registration, or which has registerred the relevant organisation;

- in case of disputes – to the Forum of Accreditation and Licensing Bodies.

7.4 Non-discrimination measures

EA "BAS" does not set out any additional conditions which may obstruct the EV to carry out activities on the territory of the Republic of Bulgaria, as well as does not use the notification procedure to impede the EV activity on the territory of the country.

In the event of difficulties in the implementation of surveillance of EV on the part of EA BAS, in the noted period for verification and validation, EA BAS motivatedly informs the EV and agrees on a period acceptable for both parties.

7.5 Consequences of failure to comply with the notification procedure

When EA BAS becomes aware that verification or validation activities are to be conducted, or already have been conducted, without notification, EA BAS remind the environmental verifier about the requirements of Regulation (EC) No 1221/2009 regarding notification in the specific country

Where the requested information according Article 24 (1) of the Regulation (E C) $N^{\rm o}_{\rm 1221/2009}$

(p.7.2 of these instruction) is not provided in due time, EA BAS inform be written EV for not respecting the term for notification.

In case, that necessary information, that is essential to perform a satisfactory supervision of the verification or validation activity (for example time and place of the verification and validation, address and contact details of the organization accreditation or licence details, composition and competence of verification team, knowledge of legal requirements relating to the environment and knowledge of the official language of the Member State where the verification or validation should take place), has not been received, EA BAS can ask additional information before to accept notification

EA BAS inform the environmental verifier that it considers the notification as unsatisfactory, that a satisfactory supervision is therefore not possible and that if the verification or validation take place before complementing the missing information and EA BAS will recommend the competent body not to register the organisation.

If EA BAS considers that the missing information does not preclude satisfactory supervision of the environmental verifier, EA BAS consider the notification as satisfactory for the execution of the supervisory activities, and request the environmental verifier to provide the missing information at a later stage.

EA BAS inform by written EV of this decision in a timely manner and, prior to the verification or validation.

8. Prices of the services on accreditation and surveillance in notification of EV

The prices for the services of initial accreditation, surveillance, re-accreditation depend on the applied scope of accreditation according to the Classification of economical activities, as noted in Regulation (EC) Nº 1893/2006 (NACE Rev.2).

The fees for surveillance in notification of EVs which carry out verifications in a member state, different from the one in which they obtained accreditation, are are charged and are proportional of the expenditures made for verification of the information of the notification and implementation of a surveillance of EV.

The price and manner of payment of the services on accreditation and notification are indicated in Price list of accreditation services BAS QR 8.

9. Duration of assessments

The duration and scope of assessment is determined according to BAS QI 2 "Instruction on determination of the duration of on-site assessment. Factors of influence".

10. Applicable documents

BAS QR 2	Accreditation Procedure	

BAS QR 3 Rules of Accreditation Commission

- BAS QR 8 Price list of EA "BAS" accreditation services
- BAS QI 2 Instruction on determination of the duration of on-site assessment. Factors of influence
- BAS QF 2.12 List of necessary documents, applicable to Application for Accreditation of Environmental Verifiers
- BAS QF 2.12A List of necessary documents, applicable to Application for notification of Environmental Verifier, accredited by a National Accreditation Body of EU member state
- BAS QF 2.12B Application for notification of the Environmental Verifier, accredited from BAS