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| **Details of the inspection body** |
| Name: |  |
| Address: |       |
| File number: |       |       |  |
| Case number | Phase |  |
| Date of assessment: |       |
| Accreditation process: |  |
| Assessment type[[1]](#endnote-1) : |       |
| Inspection body with several locations: | [ ]  Yes | [ ]  No |
| Name / Address of assessed locations: |

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| Area: | [ ]  Within the permanent facilities | [ ]  On-site | [ ]  Mobile facilities |
| Technical management: |       |
| Deputy:  |       |
| Quality manager: |       |
| Deputy: |       |
| **Details of the assessor** |
| Name: |       |
| Status[[2]](#endnote-2) : | [ ]  LA | [ ]  SA | [ ]  TA | [ ]  TE | [ ]  O |
| **Assessed area** (technical fields of DAkkS, testing fields, sectorspecific requirements, directives/modules) |

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**Notes on usage by the inspection body (blue colored sectors):**

* On the second page only the name and address of the inspection body shall be entered.
* Please enter the following information in the column “Reference documents“:
Where is the implementation of the requirement documented?
(State the specific reference documents, e.g. specification of the document/chapter/section)
Requirements of the standard that are not applicable shall be shall be indicated accordingly.

No further entries shall be made by the inspection body.

**Notes on usage by the assessor (orange colored sectors):**

* The column „Responsible“ indicates the assessor responsible to evaluate a section of the standard.
* The column “Appraisal” and “No of NC” shall be entered by the assessor (evaluation key see final marks).
* The appraisal in the first row of a section of the standard (e.g. 4.1 Impartiality and independence) indicates the overall appraisal after the assessment, including the prior review of documents and records. The appraisal in the first row of a section suffice, if no non-conformity was identified for the relevant section of the standard.

# 4 General requirements

## 4.1 Impartiality and independence

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|  | **SA** |       | [ ]  | [ ]  | [ ]  |       |
| **Result of review of documents and records: [[3]](#endnote-3)** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:[[4]](#endnote-4)** |
| No. | OE[[5]](#endnote-5) | Title / Description | Date / Version |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes:**Review of the correct classification of the type of inspection body by SA necessary** |
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| 4.1.1 | Inspection activities shall be undertaken impartially. |       |  | [ ]  | [ ]  |       |
| 4.1.2 | The inspection body (IB) shall be responsible for the impartiality of its inspection activities and shall not allow commercial, financial or other pressures to compromise impartiality. |       |  | [ ]  | [ ]  |       |
| 4.1.3 | The IB shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present an IB with a risk to impartiality. [🡺Note] |       |  | [ ]  | [ ]  |       |
| 4.1.4 | If a risk to impartiality is identified, the IB shall be able to demonstrate how it eliminates or minimizes such risk. |       |  | [ ]  | [ ]  |       |
| 4.1.5 | The IB shall have top management commitment to impartiality. |       |  | [ ]  | [ ]  |       |
| 4.1.6 | The IB shall be independent to the extent that is required with regard to the conditions under which it performs its services. Depending on these conditions, it shall meet the minimum requirements stipulated in Annex A, as outlined below.1. An IB providing third party inspections shall meet the type A requirements of Clause A.1 (third party IB).
2. An IB providing first party inspections, second party inspections, or both, which forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and which supplies inspection services only to its parent organization (in-house IB) shall meet the type B requirements of Clause A.2.
3. An IB providing first party inspections, second party inspections, or both, which forms an identifiable but not necessarily a separate part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and which supplies inspection services to its parent organization or to other parties, or to both, shall meet the type C requirements of Clause A.3.
 |       |  | [ ]  | [ ]  |       |

## 4.2 Confidentiality

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| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
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| 4.2.1 | The IB shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of inspection activities. The IB shall inform the client, in advance, of the information it intends to place in the public domain. Except for information that the client makes publicly available, or when agreed between the IB and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential. [🡺Note] |       |  | [ ]  | [ ]  |       |
| 4.2.2 | When the IB is required by law or authorized by contractual commitments to release confidential information, the client or individual concerned shall, unless prohibited by law, be notified of the information provided. |       |  | [ ]  | [ ]  |       |
| 4.2.3 | Information about the client obtained from sources other than the client (e.g. complainant, regulators) shall be treated as confidential. |       |  | [ ]  | [ ]  |       |

# 5 Structural requirements

## 5.1 Administrative requirements

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| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
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| 5.1.1 | The IB shall be a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for all its inspection activities. [🡺Note] |       |  | [ ]  | [ ]  |       |
| 5.1.2 | An IB that is part of a legal entity involved in activities other than inspection shall be identifiable within that entity. |       |  | [ ]  | [ ]  |       |
| 5.1.3 | The IB shall have documentation which describes the activities for which it is competent. |       |  | [ ]  | [ ]  |       |
| 5.1.4 | The IB shall have adequate provision (e.g. insurance or reserves) to cover liabilities arising from its operations. [🡺Note] |       |  | [ ]  | [ ]  |       |
| 5.1.5 | The IB shall have documentation describing the contractual conditions under which it provides the inspection, except when it provides inspection services to the legal entity of which it is a part. |       |  | [ ]  | [ ]  |       |

## 5.2 Organization and management

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| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| 5.2.1 | The IB shall be structured and managed so as to safeguard impartiality. |       |  | [ ]  | [ ]  |       |
| 5.2.2 | The IB shall be organized and managed so as to enable it to maintain the capability to perform its inspection activities. 🡺Note] |       |  | [ ]  | [ ]  |       |
| 5.2.3 | The IB shall define and document the responsibilities and reporting structure of the organization. |       |  | [ ]  | [ ]  |       |
| 5.2.4 | Where the IB forms a part of a legal entity performing other activities, the relationship between these other activities and inspection activities shall be defined. |       |  | [ ]  | [ ]  |       |
| 5.2.5 | The IB shall have available one or more person(s) as technical manager(s) who have overall responsibility to ensure that the inspection activities are carried out in accordance with this International Standard. [🡺Note]The person(s) fulfilling this function shall be technically competent and experienced in the operation of the IB. Where the IB has more than one technical manager, the specific responsibilities of each manager shall be defined and documented. |       |  | [ ]  | [ ]  |       |
| 5.2.6 | The IB shall have one or more named person(s) who will deputize in the absence of any technical manager responsible for ongoing inspection activities. |       |  | [ ]  | [ ]  |       |
| 5.2.7 | The IB shall have a job description or other documentation for each position category within its organization involved in inspection activities. |       |  | [ ]  | [ ]  |       |

# 6 Resource requirements

## 6.1 Personnel

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| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 6.1.1 | The IB shall define and document the competence requirements for all personnel involved in inspection activities, including requirements for education, training, technical knowledge, skills and experience. [🡺Note] |       |  | [ ]  | [ ]  |       |
| 6.1.2 | The IB shall employ, or have contracts with, a sufficient number of persons with the required competencies, including, where needed, the ability to make professional judgements, to perform the type, range and volume of its inspection activities. |       |  | [ ]  | [ ]  |       |
| 6.1.3 | The personnel responsible for inspection shall have appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the inspections to be carried out. They shall also have relevant knowledge of the following:* the technology used for the manufacture of the products inspected, the operation of processes and the delivery of services;
* the way in which products are used, processes are operated and services are delivered;
* any defects which may occur during the use of the product, any failures in the operation of the process and any deficiencies in the delivery of services.

They shall understand the significance of deviations found with regard to the normal use of the products, the operation of the processes and the delivery of services. |       |  | [ ]  | [ ]  |       |
| 6.1.4 | The IB shall make clear to each person their duties, responsibilities and authorities. |       |  | [ ]  | [ ]  |       |
| 6.1.5 | The IB shall have documented procedures for selecting, training, formally authorizing, and monitoring inspectors and other personnel involved in inspection activities. |       |  | [ ]  | [ ]  |       |
| 6.1.6 | The documented procedures for training (see 6.1.5) shall address the following stages:1. an induction period;
2. a mentored working period with experienced inspectors;
3. continuing training to keep pace with developing technology and inspection methods.
 |       |  | [ ]  | [ ]  |       |
| 6.1.7 | The training required shall depend upon the ability, qualifications and experience of each inspector and other personnel involved in inspection activities, and upon the results of monitoring (see 6.1.8). |       |  | [ ]  | [ ]  |       |
| 6.1.8 | Personnel familiar with the inspection methods and procedures shall monitor all inspectors and other personnel involved in inspection activities for satisfactory performance. Results of monitoring shall be used as a means of identifying training needs (see 6.1.7). [🡺Note] |       |  | [ ]  | [ ]  |       |
| 6.1.9 | Each inspector shall be observed on-site, unless there is sufficient supporting evidence that the inspector is continuing to perform competently. [🡺Note] |       |  | [ ]  | [ ]  |       |
| 6.1.10 | The IB shall maintain records of monitoring, education, training, technical knowledge, skills, experience and authorization of each member of its personnel involved in inspection activities. |       |  | [ ]  | [ ]  |       |
| 6.1.11 | The personnel involved in inspection activities shall not be remunerated in a way that influences the results of inspections. |       |  | [ ]  | [ ]  |       |
| 6.1.12 | All personnel of the IB, either internal or external, that could influence the inspection activities shall act impartially. |       |  | [ ]  | [ ]  |       |
| 6.1.13. | All personnel of the IB, including sub-contractors, personnel of external bodies, and individuals acting on the IB's behalf, shall keep confidential all information obtained or created during the performance of the inspection activities, except as required by law. |       |  | [ ]  | [ ]  |       |

## 6.2 Facilities and equipment

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| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
| No. | OE | Title / Description | Date / Version |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 6.2.1 | The IB shall have available, suitable and adequate facilities and equipment to permit all activities associated with the inspection activities to be carried out in a competent and safe manner. [🡺Note] |       |  | [ ]  | [ ]  |       |
| 6.2.2 | The IB shall have rules for the access to, and the use of, specified facilities and equipment used to perform inspections. |       |  | [ ]  | [ ]  |       |
| 6.2.3 | The IB shall ensure the continued suitability of the facilities and the equipment mentioned in 6.2.1 for their intended use. |       |  | [ ]  | [ ]  |       |
| 6.2.4 | All equipment having a significant influence on the results of the inspection shall be defined and, where appropriate, uniquely identified |       |  | [ ]  | [ ]  |       |
| 6.2.5 | All equipment (see 6.2.4) shall be maintained in accordance with documented procedures and instructions. |       |  | [ ]  | [ ]  |       |
| 6.2.6 | Where appropriate, measurement equipment having a significant influence on the results of the inspection shall be calibrated before being put into service, and thereafter calibrated according to an established programme. |       |  | [ ]  | [ ]  |       |
| 6.2.7 | The overall programme of calibration of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the IB are traceable to national or international standards of measurement, where available. Where traceability to national or international standards of measurement is not applicable, the IB shall maintain evidence of correlation or accuracy of inspection results. |       |  | [ ]  | [ ]  |       |
| 6.2.8 | Reference standards of measurement held by the IB shall be used for calibration only and for no other purpose. Reference standards of measurement shall be calibrated providing traceability to a national or international standard of measurement. |       |  | [ ]  | [ ]  |       |
| 6.2.9 | Where relevant, equipment shall be subjected to in-service checks between regular recalibrations. |       |  | [ ]  | [ ]  |       |
| 6.2.10 | Reference materials shall, where possible, be traceable to national or international reference materials, where they exist. |       |  | [ ]  | [ ]  |       |
| 6.2.11 | Where relevant for the outcome of inspection activities, the IB shall have procedures for the following:* selection and approval of suppliers;
* verification of incoming goods and services;
* ensuring appropriate storage facilities.
 |       |  | [ ]  | [ ]  |       |
| 6.2.12 | Where applicable, the condition of stored items shall be assessed at appropriate intervals to detect deterioration. |       |  | [ ]  | [ ]  |       |
| 6.2.13 | If the IB uses computers or automated equipment in connection with inspections, it shall ensure that:1. computer software is adequate for use;

[🡺Note] 1. procedures are established and implemented for protecting the integrity and security of data;
2. computer and automated equipment is maintained in order to ensure proper functioning.
 |       |  | [ ]  | [ ]  |       |
| 6.2.14 | The IB shall have documented procedures for dealing with defective equipment. Defective equipment shall be removed from service by segregation, prominent labeling or marking. The IB shall examine the effect of defects on previous inspections and, when necessary, take appropriate corrective action. |       |  | [ ]  | [ ]  |       |
| 6.2.15 | Relevant information on the equipment, including software, shall be recorded. This shall include identification and, where appropriate, information on calibration and maintenance. |       |  | [ ]  | [ ]  |       |

## 6.3 Subcontracting

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| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
| No. | OE | Title / Description | Date / Version |
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| 6.3.1 | The IB shall itself normally perform the inspections that it contracts to undertake. Where an IB subcontracts any part of the inspection, it shall ensure and be able to demonstrate that the subcontractor is competent to perform the activities in question and, where applicable, complies with the relevant requirements stipulated in this International Standard or in other relevant conformity assessment standards. [🡺Note 1 to 3] |       |  | [ ]  | [ ]  |       |
| 6.3.2 | The IB shall inform the client of its intention to subcontract any part of the inspection. |       |  | [ ]  | [ ]  |       |
| 6.3.3 | Whenever subcontractors carry out work that forms part of an inspection, the responsibility for any determination of conformity of the inspected item with the requirements shall remain with the IB. |       |  | [ ]  | [ ]  |       |
| 6.3.4 | The IB shall record and retain details of its investigation of the competence of its subcontractors and of their conformity with the applicable requirements of this International Standard or in other relevant conformity assessment standards. The IB shall maintain a register of all subcontractors |       |  | [ ]  | [ ]  |       |

# 7 Process requirements

## 7.1 Inspection methods and procedures

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| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
| No. | OE | Title / Description | Date / Version |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 7.1.1 | The IB shall use the methods and procedures for inspection which are defined in the requirements against which inspection is to be performed. Where these are not defined, the IB shall develop specific methods and procedures to be used (see 7.1.3). The IB shall inform the client if the inspection method proposed by the client is considered to be inappropriate. [🡺Note] |       |  | [ ]  | [ ]  |       |
| 7.1.2 | The IB shall have and shall use adequate documented instructions on inspection planning and on sampling and inspection techniques, where the absence of such instructions could jeopardize the effectiveness of the inspection process. Where applicable, the IB shall have sufficient knowledge of statistical techniques to ensure statistically sound sampling procedures and the correct processing and interpretation of results. |       |  | [ ]  | [ ]  |       |
| 7.1.3 | When the IB has to use inspection methods or procedures which are non-standard, such methods and procedures shall be appropriate and fully documented. [🡺Note] |       |  | [ ]  | [ ]  |       |
| 7.1.4 | All instructions, standards or written procedures, worksheets, check lists and reference data relevant to the work of the IB shall be maintained up-to-date and be readily available to the personnel. |       |  | [ ]  | [ ]  |       |
| 7.1.5 | The IB shall have a contract or work order control system which ensures that:1. work to be undertaken is within its expertise and that the organization has adequate resources to meet the requirements; [🡺Note]
2. the requirements of those seeking the IB's services are adequately defined and that special conditions are understood, so that unambiguous instructions can be issued to personnel performing the duties to be required;
3. work being undertaken is controlled by regular review and corrective action;
4. the requirements of the contract or work order have been met.
 |       |  | [ ]  | [ ]  |       |
| 7.1.6 | When the IB uses information supplied by any other party as part of the inspection process, it shall verify the integrity of such information. |       |  | [ ]  | [ ]  |       |
| 7.1.7 | Observations or data obtained in the course of inspections shall be recorded in a timely manner so as to prevent loss of relevant information. |       |  | [ ]  | [ ]  |       |
| 7.1.8 | Calculations and data transfers shall be subject to appropriate checks. [🡺Note] |       |  | [ ]  | [ ]  |       |
| 7.1.9 | The IB shall have documented instructions for carrying out inspection in a safe manner. |       | [ ]  | [ ]  | [ ]  |       |

## 7.2 Handling inspection items and samples

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| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
| No. | OE | Title / Description | Date / Version |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 7.2.1 | The IB shall ensure items and samples to be inspected are uniquely identified in order to avoid confusion regarding the identity of such items and samples. |       |  | [ ]  | [ ]  |       |
| 7.2.2 | The IB shall establish whether the item to be inspected has been prepared. |       |  | [ ]  | [ ]  |       |
| 7.2.3 | Any apparent abnormalities notified to, or noticed by, the inspector shall be recorded. Where there is any doubt as to the item's suitability for the inspection to be carried out, or where the item does not conform to the description provided, the IB shall contact the client before proceeding. |       |  | [ ]  | [ ]  |       |
| 7.2.4 | The IB shall have documented procedures and appropriate facilities to avoid deterioration or damage to inspection items while under its responsibility. |       |  | [ ]  | [ ]  |       |

## 7.3 Inspection records

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|  | **SA + TA** |       | [ ]  | [ ]  | [ ]  |       |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
| No. | OE | Title / Description | Date / Version |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 7.3.1 | The IB shall maintain a record system (see 8.4) to demonstrate the effective fulfilment of the inspection procedures and to enable an evaluation of the inspection. |       |  | [ ]  | [ ]  |       |
| 7.3.2 | The inspection report or certificate shall be internally traceable to the inspector(s) who performed the inspection. |       |  | [ ]  | [ ]  |       |

## 7.4 Inspection reports and inspection certificates

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|  | **SA + TA** |       | [ ]  | [ ]  | [ ]  |       |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
| No. | OE | Title / Description | Date / Version |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 7.4.1 | The work carried out by the IB shall be covered by a retrievable inspection report or inspection certificate. |       |  | [ ]  | [ ]  |       |
| 7.4.2 | Any inspection report/certificate shall include all of the following:1. identification of the issuing body;
2. unique identification and date of issue;
3. date(s) of inspection;
4. identification of the item(s) inspected;
5. signature or other indication of approval, by authorized personnel;
6. a statement of conformity where applicable;
7. the inspection results, except where detailed in accordance with 7.4.3.

[🡺Note] |       |  | [ ]  | [ ]  |       |
| 7.4.3 | An IB shall issue an inspection certificate that does not include the inspection results [see 7.4.2 g)] only when the IB can also produce an inspection report containing the inspection results, and when both the inspection certificate and inspection report are traceable to each other. |       |  | [ ]  | [ ]  |       |
| 7.4.4 | All information listed in 7.4.2 shall be reported correctly, accurately, and clearly. Where the inspection report or inspection certificate contains results supplied by subcontractors, these results shall be clearly identified. |       |  | [ ]  | [ ]  |       |
| 7.4.5 | Corrections or additions to an inspection report or inspection certificate after issue shall be recorded in accordance with the relevant requirements of this subclause (7.4). An amended report or certificate shall identify the report or certificate replaced. |       |  | [ ]  | [ ]  |       |

## 7.5 Complaints and appeals

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|  | **SA** |       | [ ]  | [ ]  | [ ]  |       |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
| No. | OE | Title / Description | Date / Version |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 7.5.1 | The IB shall have a documented process to receive, evaluate and make decisions on complaints and appeals. |       |  | [ ]  | [ ]  |       |
| 7.5.2 | A description of the handling process for complaints and appeals shall be available to any interested party upon request. |       |  | [ ]  | [ ]  |       |
| 7.5.3 | Upon receipt of a complaint, the IB shall confirm whether the complaint relates to inspection activities for which it is responsible and, if so, shall deal with it. |       |  | [ ]  | [ ]  |       |
| 7.5.4 | The IB shall be responsible for all decisions at all levels of the handling process for complaints and appeals. |       |  | [ ]  | [ ]  |       |
| 7.5.5 | Investigation and decision on appeals shall not result in any discriminatory actions. |       |  | [ ]  | [ ]  |       |

## 7.6 Complaints and appeals process

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|  | **SA** |       | [ ]  | [ ]  | [ ]  |       |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 7.6.1 | The handling process for complaints and appeals shall include at least the following elements and methods:1. a description of the process for receiving, validating, investigating the complaint or appeal, and deciding what actions are to be taken in response to it;
2. tracking and recording complaints and appeals, including actions undertaken to resolve them;
3. ensuring that any appropriate action is taken.
 |       |  | [ ]  | [ ]  |       |
| 7.6.2 | The IB receiving the complaint or appeal shall be responsible for gathering and verifying all necessary information to validate the complaint or appeal. |       |  | [ ]  | [ ]  |       |
| 7.6.3 | Whenever possible, the IB shall acknowledge receipt of the complaint or appeal, and shall provide the complainant or appellant with progress reports and the outcome. |       |  | [ ]  | [ ]  |       |
| 7.6.4 | The decision to be communicated to the complainant or appellant shall be made by, or reviewed and approved by, individual(s) not involved in the original inspection activities in question. |       |  | [ ]  | [ ]  |       |
| 7.6.5 | Whenever possible, the IB shall give formal notice of the end of the complaint and appeals handling process to the complainant or appellant. |       |  | [ ]  | [ ]  |       |

# 8 Management system requirements

## 8.1 Options

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|  | **SA** |       | [ ]  | [ ]  | [ ]  |       |
|  | [ ]  | Option A | General management system requirements (according to 8.2 up to 8.8) |
|  | [ ]  | Option B | Management system requirements in accordance with ISO 9001 (according 8.2 up to 8.8)***Note:*** *In the case* *that option B was chosen, the assessors have to assess and to review the implementation of the requirements according to clauses 8.2 to 8.8.* |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| **8.1.1** | **General** |       |  | [ ]  | [ ]  |       |
|  | The IB shall establish and maintain a management system that is capable of achieving the consistent fulfilment of the requirements of this International Standard in accordance with either Option A or Option B. |       |  | [ ]  | [ ]  |       |
| **8.1.2** | **Option A**The management system of the IB shall address the following:* management system documentation (e.g. manual, policies, definition of responsibilities, see 8.2);
* control of documents (see 8.3);
* control of records (see 8.4);
* management review (see 8.5);
* internal audit (see 8.6);
* corrective actions (see 8.7);
* preventive actions (see 8.8);
* complaints and appeals (see 7.5 and 7.6).
 |       |  | [ ]  | [ ]  |       |
| **8.1.3** | **Option B**An IB that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent ful-filment of the requirements of this International Standard, fulfils the management system clause requirements (see 8.2 to 8.8). |       |  | [ ]  | [ ]  |       |

## 8.2 Management system documentation (Option A)

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|  | **SA** |       | [ ]  | [ ]  | [ ]  |       |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
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| **Result of assessment:** Findings / justification of findings / sectorspecific features / notes: |
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| 8.2.1 | The IB's top management shall establish, document, and maintain policies and objectives for fulfilment of this International Standard and shall ensure the policies and objectives are acknowledged and implemented at all levels of the IB's organization. |       |  | [ ]  | [ ]  |       |
| 8.2.2 | The top management shall provide evidence of its commitment to the development and implementation of the management system and its effectiveness in achieving consistent fulfilment of this International Standard. |       |  | [ ]  | [ ]  |       |
| 8.2.3 | The IB's top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that include the following:1. ensuring that processes and procedures needed for the management system are established, implemented and maintained; and
2. reporting to top management on the performance of the management system and any need for improvement.
 |       |  | [ ]  | [ ]  |       |
| 8.2.4 | All documentation, processes, systems, records, etc. related to the fulfilment of the requirements of this International Standard shall be included, referenced, or linked to documentation of the management system. |       |  | [ ]  | [ ]  |       |
| 8.2.5 | All personnel involved in inspection activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities. |       |  | [ ]  | [ ]  |       |

## 8.3 Control of documents (Option A)

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|  | **SA** |       | [ ]  | [ ]  | [ ]  |       |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD during the assessment:** |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 8.3.1 | The IB shall establish procedures to control the documents (internal and external) that relate to the fulfilment of this International Standard. |       |  | [ ]  | [ ]  |       |
| 8.3.2 | The procedures shall define the controls needed to:1. approve documents for adequacy prior to issue;
2. review and update (as necessary) and reapprove documents;
3. ensure that changes and the current revision status of documents are identified;
4. ensure that relevant versions of applicable documents are available at points of use;
5. ensure that documents remain legible and readily identifiable;
6. ensure that documents of external origin are identified and their distribution controlled;
7. prevent the unintended use of obsolete documents, and apply suitable identification to them if they are retained for any purpose.

[🡺Note] |       |  | [ ]  | [ ]  |       |

## 8.4 Control of records (Option A)

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|  | SA + TA |       | [ ]  | [ ]  | [ ]  |       |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 8.4.1 | The IB shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this International Standard. |       |  | [ ]  | [ ]  |       |
| 8.4.2 | The IB shall establish procedures for retaining records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements. |       |  | [ ]  | [ ]  |       |

## 8.5 Management review (Option A)

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|  | **SA** (If no SA used: LA) |       | [ ]  | [ ]  | [ ]  |       |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| **8.5.1** | **General** |       |  | [ ]  | [ ]  |       |
| 8.5.1.1 | The IB's top management shall establish procedures to review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this International Standard. |       |  | [ ]  | [ ]  |       |
| 8.5.1.2 | These reviews shall be conducted at least once a year. Alternatively, a complete review broken up into segments (a rolling review) shall be completed within a 12-month time frame. |       |  | [ ]  | [ ]  |       |
| 8.5.1.3 | Records of reviews shall be maintained. |       |  | [ ]  | [ ]  |       |
| **8.5.2** | **Review inputs**The input to the management review shall include information related to the following:1. results of internal and external audits;
2. feedback from clients and interested parties related to the fulfilment of this International Standard;
3. the status of preventive and corrective actions;
4. follow-up actions from previous management reviews;
5. the fulfilment of objectives;
6. changes that could affect the management system;
7. appeals and complaints.
 |       |  | [ ]  | [ ]  |       |
| **8.5.3** | **Review outputs**The outputs from the management review shall include decisions and actions related to:1. improvement of the effectiveness of the management system and its processes;
2. improvement of the IB related to the fulfilment of this International Standard;
3. resource needs.
 |       |  | [ ]  | [ ]  |       |

## 8.6 Internal Audits (Option A)

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|  | **SA** (If no SA used: LA) |       | [ ]  | [ ]  | [ ]  |       |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 8.6.1 | The IB shall establish procedures for internal audits to verify that it fulfils the requirements of this International Standard and that the management system is effectively implemented and maintained. [🡺Note] |       |  | [ ]  | [ ]  |       |
| 8.6.2 | An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits. |       |  | [ ]  | [ ]  |       |
| 8.6.3 | The IB shall conduct periodic internal audits covering all procedures in a planned and systematic manner, in order to verify that the management system is implemented and is effective. |       |  | [ ]  | [ ]  |       |
| 8.6.4 | Internal audits shall be performed at least once every 12 months. The frequency of internal audits may be adjusted depending on the demonstrable effectiveness of the management system and its proven stability. |       |  | [ ]  | [ ]  |       |
| 8.6.5 | The IB shall ensure that:1. internal audits are conducted by qualified personnel knowledgeable in inspection, auditing and the requirements of this International Standard;
2. auditors do not audit their own work;
3. personnel responsible for the area audited are informed of the outcome of the audit;
4. any actions resulting from internal audits are taken in a timely and appropriate manner;
5. any opportunities for improvement are identified;
6. the results of the audit are documented.
 |       |  | [ ]  | [ ]  |       |

## 8.7 Corrective actions (Option A)

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|  | **SA + TA** |       | [ ]  | [ ]  | [ ]  |       |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 8.7.1 | The IB shall establish procedures for identification and management of nonconformities in its operations. |       |  | [ ]  | [ ]  |       |
| 8.7.2 | The IB shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. |       |  | [ ]  | [ ]  |       |
| 8.7.3 | Corrective actions shall be appropriate to the impact of the problems encountered. |       |  | [ ]  | [ ]  |       |
| 8.7.4 | The procedures shall define requirements for the following:1. identifying nonconformities;
2. determining the causes of nonconformity;
3. correcting nonconformities;
4. evaluating the need for actions to ensure that nonconformities do not recur;
5. determining the actions needed and implementing them in a timely manner;
6. recording the results of actions taken;
7. reviewing the effectiveness of corrective actions.
 |       |  | [ ]  | [ ]  |       |

## 8.8 Preventive actions (Option A)

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|  | **SA + TA** |       | [ ]  | [ ]  | [ ]  |       |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |  |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| 8.8.1 | The IB shall establish procedures for taking preventive actions to eliminate the causes of potential nonconformities. |       |  | [ ]  | [ ]  |       |
| 8.8.2 | Preventive actions taken shall be appropriate to the probable impact of the potential problems. |       |  | [ ]  | [ ]  |       |
| 8.8.3 | The procedures for preventive actions shall define requirements for the following:1. identifying potential nonconformities and their causes;
2. evaluating the need for action to prevent the occurrence of nonconformities;
3. determining and implementing the action needed;
4. recording the results of actions taken;
5. reviewing the effectiveness of the preventive actions taken.

[🡺Note] |       |  | [ ]  | [ ]  |       |

# Further issues of the assessment

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| --- | --- | --- | --- | --- |
| **Additional requirements** | **Responsible** | **Reference documents** | **Appraisal** | **No. of** |
|  |  | **for the implementation** | **1** | **2** | **3** | **NC** |
| * **Use of the accreditation symbol /References to the accreditation**
 | **SA** (If no SA used: LA) |       | [ ]  | [ ]  | [ ]  |       |
| Compliance with the rule 71 SD 0 011 on the use of the accreditation symbol in inspection reports, business letters, offers, letterhead, websites, other documents and advertising media as well as on other cross references to the accreditation **(Not applicable for the assessment for initial accreditation)** |
| **Result of review of documents and records:** | [ ]  | [ ]  | [ ]  |       |

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| Findings / justification of findings / specifics / notes: |
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| **Objective evidence / Reviewed documents (OE/RD) during the assessment:** |
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| **Result of assessment:** Findings / justification of findings / sectorspecific provisions / notes: |
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| * Is the inspection body notified for the assessed scope in the frame of EU directives/modules or is the notification requested?
 | **SA + TA** |       |  |
| [ ]  Yes | [ ]  No |
| * Implementation of additional requirements according to relevant directives/modules (taking into account EA 2/17, Decision No. 768/2008/EC)
 | **SA + TA** |       | [ ]  | [ ]  | [ ]  |       |
| [ ]  Yes | [ ]  No | [ ]  Not applicable | **If the answer is "Yes" or "No", please note the next line!** |

|  |  |
| --- | --- |
| Remarks: | *If the previous question was answered in the affirmative, this field must explicitly address the implementation of the essential directive-specific requirements by the inspection body with reference to the applicable articles of the directive (corresponding to article R 17 of decision 768/2008/EC) (e.g. independence, subcontracting, participation in the coordination group, notification obligations to the notifying authority).* |

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| * Fulfilment of imposed conditions and implementation of the corrective actions from the previous assessment
 | **SA + TA** |  |
| [ ]  Yes | [ ]  No | [ ]  Not applicable |

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| Remarks: |

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| **The specific requirements of the applicable rules of ILAC and EA were considered during the assessment.** |

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| **Preliminary assessment of documents and records completed on:** |       |

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| **No. of non-conformities:** | Non critical: |  | Critical: |  |

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| **Reductions of the scope of accreditation (indication of inspection methods):**  |

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| --- |
| **Summary, remarks and improvement potential** |
| Existing accreditations, certifications, notifications, approvals and recognitions • recognitions • correct classification of the type of inspection body including changes • competence of personnel, and appropriateness of spatial infrastructure and equipment • meeting additional requirements • overall impression with respect to inspection body’s strengths and areas requiring improvement to appraise the appropriateness and effectiveness of the quality system including improvement potential • final evaluation • key aspects/consideration for the following assessment, if applicable |

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| **Recommendation on accreditation:**[[6]](#endnote-6)), [[7]](#endnote-7)) | [ ]  **Yes** | [ ]  **No**  |
| Place: |       | Date: |       | Signed *Assessor Name:* |  [[8]](#endnote-8) |

|  |  |
| --- | --- |
| **Report reviewed by the case manager:** |  |
| Place: |       | Date: |       | Signed *Case manager:* |  |

Note: The assessor does not confirm the complete correctness of the reference documents of the conformity assessment body.

\* Grading of fulfilment the requirements of a section of the standard to be entered by the assessor:

1 **No** non-conformity

2 **Non critical** non-conformity

3 **Critical** non-conformity

\*\* NC = Non-conformity

1. Under assessment type, the assessment technique is to be indicated, whereby several assessment types can be used in the context of an assessment. Please select the applicable element or combination of elements from the following options to indicate the type of assessment:

On-site assessment / Remote assessment / Witness audit (on-site) / Witness audit (remote) / Witness examination / Document review / Other assessment activity (please specify if necessary) [↑](#endnote-ref-1)
2. Status in the assessment team: LA=Lead Assessor; SA=System Assessor; TA=Technical Assessor; TE=Technical expert; O=Observer [↑](#endnote-ref-2)
3. Only if the review of documents and records reveals that an assessment cannot be performed, the assessor prepares
a separate partial assessment report/checklist for the review of documents and records according to this form. [↑](#endnote-ref-3)
4. As an alternative to entering the OE/RD here, the separate form provided for this purpose can be used. [↑](#endnote-ref-4)
5. “Objective evidence” are to be distinguished from „Reviewed documents“ by marking with a cross „x“. [↑](#endnote-ref-5)
6. In the closing meeting the laboratory was informed about the preliminary result of the assessment, non-conformity reports
were handed over, if applicable. [↑](#endnote-ref-6)
7. Subject to a sufficient correction of non-conformities [↑](#endnote-ref-7)
8. This report was prepared personally by on . [↑](#endnote-ref-8)