

Name of FIB Audited:

Audit date :

Name of Inspector:

| ISO/IEC 17020 : 2012 Requirements |   | Judgement |    | Applicable documented procedure item.<br>Please fill in detail such as documented<br>procedure title and control no.<br><br>Remarks |
|-----------------------------------|---|-----------|----|---|
|                                   |   | Yes       | No |   |
| <b>4</b>                          | <b>General requirements</b>   |           |    |   |
| <b>4.1</b>                        | <b>Impartiality and independence</b>  |           |    |   |
| <b>4.1.1</b>                      | Are inspection activities undertaken impartially?   |           |    |   |
| <b>4.1.2</b>                      | Is the inspection body responsible for the impartiality of its inspection activities and doesn't it allow commercial, financial or other pressures to compromise impartiality?  |           |    |   |
| <b>4.1.3</b>                      | Does the inspection body 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 inspection body with a risk to impartiality. |           |    |   |
| <b>Note</b>                       | <i>A relationship that threatens the impartiality of the inspection body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc.</i>                 |           |    |   |

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| <b>4.1.4</b> | If a risk to impartiality is identified, is the inspection body able to demonstrate how it eliminates or minimizes such risk?   |  |  |  |
| <b>4.1.5</b> | Does the inspection body have top management commitment to impartiality?  |  |  |  |
| <b>4.1.6</b> | Is the inspection body independent to the extent that is required with regard to the conditions under which it performs its services? Depending on these conditions, does it meet the minimum requirements stipulated in Annex A, as outlined below?  |  |  |  |
| a)           | Does an inspection body providing third party inspections meet the type A requirements of Clause A.1 (third party inspection body)?   |  |  |  |
| b)           | Does an inspection body 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 inspection body) meet the type B requirements of Clause A.2?                      |  |  |  |
| c)           | Does an inspection body 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, meet the type C requirements of Clause A.3.? |  |  |  |
| <b>4.2</b>   | <b>Confidentiality</b>  |  |  |  |
| <b>4.2.1</b> | Is the inspection body responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of inspection activities? Does the  |  |  |  |

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|              | inspection body 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 inspection body and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and is it regarded as confidential? |  |  |  |
| <b>NOTE</b>  | <i>Legally enforceable commitments can be, for example, contractual agreements.</i>  |  |  |  |
| <b>4.2.2</b> | When the inspection body is required by law or authorized by contractual commitments to release confidential information, is the client or individual concerned, unless prohibited by law, notified of the information provided?   |  |  |  |
| <b>4.2.3</b> | Is information about the client obtained from sources other than the client (e.g. complainant, regulators) treated as confidential?  |  |  |  |
| <b>5</b>     | <b>Structural Requirements</b>   |  |  |  |
| <b>5.1</b>   | <b>Administrative requirements</b>   |  |  |  |
| <b>5.1.1</b> | Is the inspection body a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for all its inspection activities?  |  |  |  |
| <b>Note</b>  | <i>A governmental inspection body is deemed to be a legal entity on the basis of its governmental status.</i>  |  |  |  |
| <b>5.1.2</b> | Is an inspection body that is part of a legal entity involved in activities other than inspection identifiable within that entity?   |  |  |  |
| <b>5.1.3</b> | Does the inspection body have documentation which describes the activities for which it is competent?  |  |  |  |

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| <b>5.1.4</b> | Does the inspection body have adequate provision (e.g. insurance or reserves) to cover liabilities arising from its operations?  |  |  |  |
| <b>NOTE</b>  | <i>The liability can be assumed by the State in accordance with national laws, or by the organization of which the inspection body forms a part.</i>   |  |  |  |
| <b>5.1.5</b> | Does the inspection body 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?               |  |  |  |
| <b>5.2</b>   | <b>Organization and management</b>   |  |  |  |
| <b>5.2.1</b> | Is the inspection body structured and managed so as to safeguard impartiality?   |  |  |  |
| <b>5.2.2</b> | Is the inspection body organized and managed so as to enable it to maintain the capability to perform its inspection activities?   |  |  |  |
| <b>NOTE</b>  | <i>Inspection schemes can require that the inspection body participates in the exchange of technical experience with other inspection bodies in order to maintain this capability.</i>   |  |  |  |
| <b>5.2.3</b> | Does the inspection body define and document the responsibilities and reporting structure of the organization?   |  |  |  |
| <b>5.2.4</b> | Where the inspection body forms a part of a legal entity performing other activities, is the relationship between these other activities and inspection activities defined?  |  |  |  |
| <b>5.2.5</b> | Does the inspection body 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? |  |  |  |

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| <b>NOTE</b>  | <i>This person fulfilling this function does not always have the title of technical manager. Are the person(s) fulfilling this function shall be technically competent and experienced in the operation of the inspection body? Where the inspection body has more than one technical manager, are the specific responsibilities of each manager defined and documented?</i> |  |  |  |
| <b>5.2.6</b> | Does the inspection body name one or more person(s) who will deputize in the absence of any technical manager responsible for ongoing inspection activities?   |  |  |  |
| <b>5.2.7</b> | Does the inspection body have a job description or other documentation for each position category within its organization involved in inspection activities?   |  |  |  |
| <b>6</b>     | <b>Resource requirements</b>   |  |  |  |
| <b>6.1</b>   | <b>Personnel</b>   |  |  |  |
| <b>6.1.1</b> | Does the inspection body define and document the competence requirements for all personnel involved in inspection activities, including requirements for education, training, technical knowledge, skills and experience?  |  |  |  |
| <b>Note</b>  | <i>The competence requirements can be part of the job description or other documentation mentioned in 5.2.7.</i>   |  |  |  |
| <b>6.1.2</b> | Does the inspection body employ, or have contracts with, a sufficient number of persons with the required competencies, including, where needed, the ability to make professional judgments, to perform the type, range and volume of its inspection activities?   |  |  |  |
| <b>6.1.3</b> | Do the personnel responsible for inspection have appropriate qualifications, training, experience and a satisfactory knowledge of  |  |  |  |

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|              | the requirements of the inspections to be carried out? Do they 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.                           |  |  |  |
| -            | Do these personnel 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?      |  |  |  |
| <b>6.1.4</b> | Does the inspection body make clear to each person their duties, responsibilities and authorities?  |  |  |  |
| <b>6.1.5</b> | Does the inspection body have documented procedures for selecting, training, formally authorizing, and monitoring inspectors and other personnel involved in inspection activities? |  |  |  |
| <b>6.1.6</b> | Do the documented procedures for training (see 6.1.5) address the following stages?   |  |  |  |
| <b>a)</b>    | an induction period;  |  |  |  |
| <b>b)</b>    | a mentored working period with experienced inspectors;  |  |  |  |
| <b>c)</b>    | continuing training to keep pace with developing technology and inspection methods.   |  |  |  |

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| <b>6.1.7</b>  | Does the training required 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)?   |  |  |  |
| <b>6.1.8</b>  | Do personnel familiar with the inspection methods and procedures monitor all inspectors and other personnel involved in inspection activities for satisfactory performance? Are results of monitoring used as a means of identifying training needs (see 6.1.7)? |  |  |  |
| <b>Note</b>   | <i>Monitoring can include a combination of techniques, such as on-site observations, report reviews, interviews, simulated inspections and other techniques to assess performance, and will depend on the nature of inspection activities.</i>                   |  |  |  |
| <b>6.1.9</b>  | Is each inspector observed on-site, unless there is sufficient supporting evidence that the inspector is continuing to perform competently?  |  |  |  |
| <b>Note</b>   | <i>It is expected that on-site observations are performed in a way that minimizes the disturbance of the inspections, especially from the client's viewpoint.</i>  |  |  |  |
| <b>6.1.10</b> | Does the inspection body maintain records of monitoring, education, training, technical knowledge, skills, experience and authorization of each member of its personnel involved in inspection activities?   |  |  |  |
| <b>6.1.11</b> | Aren't personnel involved in inspection activities remunerated in a way that influences the results of inspections?  |  |  |  |
| <b>6.1.12</b> | Do all personnel of the inspection body, either internal or external, that could influence the inspection activities act impartially?  |  |  |  |
| <b>6.1.13</b> | Do all personnel of the inspection body, including sub-contractors, personnel of external bodies, and individuals acting on the  |  |  |  |

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|              | inspection body's behalf, keep confidential all information obtained or created during the performance of the inspection activities, except as required by law?  |  |  |  |
| <b>6.2</b>   | <b>Facilities and equipment</b>  |  |  |  |
| <b>6.2.1</b> | Does the inspection body 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?   |  |  |  |
| <b>Note</b>  | <i>The inspection body need not be the owner of the facilities or equipment that it uses. Facilities and equipment can be borrowed, rented, hired, leased or provided by another party (e.g. the manufacturer or installer of the equipment). However, the responsibility for the suitability and the calibration status of the equipment used in inspection, whether owned by the inspection body or not, lies solely with the inspection body.</i> |  |  |  |
| <b>6.2.2</b> | Does the inspection body have rules for the access to, and the use of, specified facilities and equipment used to perform inspections?   |  |  |  |
| <b>6.2.3</b> | Does the inspection body ensure the continued suitability of the facilities and the equipment mentioned in 6.2.1 for their intended use?   |  |  |  |
| <b>6.2.4</b> | Is all equipment having a significant influence on the results of the inspection defined and, where appropriate, uniquely identified?  |  |  |  |
| <b>6.2.5</b> | Is all equipment (see 6.2.4) maintained appropriately in accordance with documented procedures and instructions?   |  |  |  |
| <b>6.2.6</b> | Where appropriate, is all measurement equipment having a significant influence on the results of the inspection calibrated before being put into service, and thereafter calibrated according to an established programme?   |  |  |  |



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| <b>6.2.7</b>  | Is the overall programme of calibration of equipment designed and operated so as to ensure that, wherever applicable, measurements made by the inspection body are traceable to national or international standards of measurement, where available? Where traceability to national or international standards of measurement is not applicable, does the inspection body maintain evidence of correlation or accuracy of inspection results? |  |  |  |
| <b>6.2.8</b>  | Are reference standards of measurement held by the inspection body used for calibration only and for no other purpose? Are reference standards of measurement calibrated so that they provide traceability to a national or international standard of measurement?  |  |  |  |
| <b>6.2.9</b>  | Where relevant, is equipment subjected to in-service checks between regular recalibrations?   |  |  |  |
| <b>6.2.10</b> | Are reference materials, where possible, traceable to national or international reference materials, where they exist?  |  |  |  |
| <b>6.2.11</b> | Where relevant for the outcome of inspection activities, does the inspection body have procedures for the following?  |  |  |  |
| <b>a)</b>     | selection and approval of suppliers;  |  |  |  |
| <b>b)</b>     | verification of incoming goods and services;  |  |  |  |
| <b>c)</b>     | ensuring appropriate storage facilities.  |  |  |  |
| <b>6.2.12</b> | Where applicable, is the condition of stored items assessed at appropriate intervals to detect deterioration?   |  |  |  |
| <b>6.2.13</b> | If the inspection body uses computers or automated equipment in connection with inspections, does it ensure that:   |  |  |  |
| <b>a)</b>     | computer software is adequate for use;  |  |  |  |
| <b>Note</b>   | <i>This can be done by the following:</i>   |  |  |  |
| -             | <i>validation of calculations before use;</i>   |  |  |  |

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| -             | <i>periodic revalidation of related hardware and software;</i>   |  |  |  |
| -             | <i>revalidation whenever changes are made to related hardware or software;</i>   |  |  |  |
| -             | <i>software updates implemented as required</i>  |  |  |  |
| <b>b)</b>     | procedures are established and implemented for protecting the integrity and security of data;  |  |  |  |
| <b>c)</b>     | computer and automated equipment is maintained in order to ensure proper functioning?  |  |  |  |
| <b>6.2.14</b> | Does the inspection body have documented procedures for dealing with defective equipment? Is defective equipment removed from service by segregation, prominent labelling or marking? Does the inspection body examine the effect of defects on previous inspections and, when necessary, take appropriate corrective action?  |  |  |  |
| <b>6.2.15</b> | Is relevant information on the equipment, including software, recorded? This shall include identification and, where appropriate, information on calibration and maintenance.  |  |  |  |
| <b>6.3</b>    | <b>Subcontracting</b>  |  |  |  |
| <b>6.3.1</b>  | Does the inspection body itself normally perform the inspections that it contracts to undertake? Where an inspection body subcontracts any part of the inspection, does it ensure, and is it 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. |  |  |  |
| <b>Note 1</b> | <i>Reasons to subcontract can include the following:</i>   |  |  |  |
| -             | <i>an unforeseen or abnormal overload;</i>   |  |  |  |
| -             | <i>key inspection staff members being incapacitated;</i>   |  |  |  |
| -             | <i>key facilities or items of equipment being temporarily unfit for use;</i>   |  |  |  |

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| -             | <i>part of the contract from the client involving inspection not covered by the inspection body's scope or being beyond the capability or resources of the inspection body.</i>  |  |  |  |
| <b>Note 2</b> | <i>The terms "subcontracting" and "outsourcing" are considered to be synonyms.</i>   |  |  |  |
| <b>Note 3</b> | <i>Where the inspection body engages individuals or employees of other organizations to provide additional resources or expertise, these individuals are not considered to be subcontractors provided they are formally contracted to operate under the inspection body's management system (see 6.1.2).</i>                         |  |  |  |
| <b>6.3.2</b>  | Does the inspection body inform the client of its intention to subcontract any part of the inspection?   |  |  |  |
| <b>6.3.3</b>  | Whenever subcontractors carry out work that forms part of an inspection, does the responsibility for any determination of conformity of the inspected item with the requirements remain with the inspection body?  |  |  |  |
| <b>6.3.4</b>  | Does the inspection body 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?<br>Does the inspection body maintain a register of all subcontractors? |  |  |  |
| <b>7</b>      | <b>Process requirements</b>  |  |  |  |
| <b>7.1</b>    | <b>Inspection methods and procedures</b>   |  |  |  |
| <b>7.1.1</b>  | Does the inspection body 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, does the inspection body develop specific methods and procedures to be used (see 7.1.3)? Does the inspection body inform the client if the    |  |  |  |

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|              | inspection method proposed by the client is considered to be inappropriate?  |  |  |  |
| <b>Note</b>  | <i>The requirements against which the inspection is performed are normally specified in regulations, standards or specifications, inspection schemes or contracts. Specifications can include client or in-house requirements.</i>   |  |  |  |
| <b>7.1.2</b> | Does the inspection body have and 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, does the inspection body have sufficient knowledge of statistical techniques to ensure statistically sound sampling procedures and the correct processing and interpretation of results? |  |  |  |
| <b>7.1.3</b> | When the inspection body has to use inspection methods or procedures which are non-standard, are such methods and procedures appropriate and fully documented?   |  |  |  |
| <b>Note</b>  | A standard inspection method is one that has been published, for example, in international, regional or national standards, or by reputable technical organizations or by co-operation of several inspection bodies or in relevant scientific text or journals. This means that methods developed by any other means, including by the inspection body itself or by the client, are considered to be non-standard methods.                               |  |  |  |
| <b>7.1.4</b> | Are all instructions, standards or written procedures, worksheets, check lists and reference data relevant to the work of the inspection body maintained up-to-date and readily available to the personnel?  |  |  |  |
| <b>7.1.5</b> | Does the inspection body have a contract or work order control system which ensures that:  |  |  |  |

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| <b>a)</b>    | work to be undertaken is within its expertise and that the organization has adequate resources to meet the requirements;  |  |  |  |
| <b>Note</b>  | <i>Resources can include, but are not limited to, facilities, equipment, reference documentation, procedures or human resources.</i>  |  |  |  |
| <b>b)</b>    | the requirements of those seeking the inspection body'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; |  |  |  |
| <b>c)</b>    | work being undertaken is controlled by regular review and corrective action;  |  |  |  |
| <b>d)</b>    | the requirements of the contract or work order have been met?   |  |  |  |
| <b>7.1.6</b> | When the inspection body uses information supplied by any other party as part of the inspection process, does it verify the integrity of such information?  |  |  |  |
| <b>7.1.7</b> | Are observations or data obtained in the course of inspections recorded in a timely manner so as to prevent loss of relevant information?   |  |  |  |
| <b>7.1.8</b> | Are calculations and data transfers subject to appropriate checks?  |  |  |  |
| <b>Note</b>  | <i>Data can include textual material, digital data and anything else that is transferred from one location to another where errors could be introduced.</i>   |  |  |  |
| <b>7.1.9</b> | Does the inspection body have documented instructions for carrying out inspection in a safe manner?   |  |  |  |
| <b>7.2</b>   | <b>Handling inspection items and samples</b>  |  |  |  |

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| 7.2.1 | Does the inspection body 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 | Does the inspection body establish whether the item to be inspected has been prepared?  |  |  |  |
| 7.2.3 | Are any apparent abnormalities notified to, or noticed by, the inspector 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, does the inspection body contact the client before proceeding? |  |  |  |
| 7.2.4 | Does the inspection body have documented procedures and appropriate facilities to avoid deterioration or damage to inspection items while under its responsibility?   |  |  |  |
| 7.3   | <b>Inspection records</b>   |  |  |  |
| 7.3.1 | Does the inspection body 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 | Is the inspection report or certificate internally traceable to the inspector(s) who performed the inspection?  |  |  |  |
| 7.4   | <b>Inspection reports and inspection certificates</b>   |  |  |  |
| 7.4.1 | Is the work carried out by the inspection body covered by a retrievable inspection report or inspection certificate?  |  |  |  |
| 7.4.2 | Does any inspection report/certificate include all of the following?  |  |  |  |
| a)    | identification of the issuing body;   |  |  |  |
| b)    | unique identification and date of issue;  |  |  |  |
| c)    | date(s) of inspection;  |  |  |  |

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| <b>d)</b>    | identification of the item(s) inspected;   |  |  |  |
| <b>e)</b>    | signature or other indication of approval, by authorized personnel;  |  |  |  |
| <b>f)</b>    | a statement of conformity where applicable;  |  |  |  |
| <b>g)</b>    | the inspection results, except where detailed in accordance with 7.4.3.  |  |  |  |
| <b>Note</b>  | <i>Optional elements that can be included in inspection reports or certificates are listed in Annex B.</i>   |  |  |  |
| <b>7.4.3</b> | Does an inspection body issue an inspection certificate that does not include the inspection results [see 7.4.2 g)] only when the inspection body can also produce an inspection report containing the inspection results, and when both the inspection certificate and inspection report are traceable to each other? |  |  |  |
| <b>7.4.4</b> | Are all information listed in 7.4.2 reported correctly, accurately, and clearly? Where the inspection report or inspection certificate contains results supplied by subcontractors, are these results clearly identified?  |  |  |  |
| <b>7.4.5</b> | Are corrections or additions to an inspection report or inspection certificate after issue recorded in accordance with the relevant requirements of this subclause (7.4)? Does an amended report or certificate identify the report or certificate replaced?   |  |  |  |
| <b>7.5</b>   | <b>Complaints and Appeals</b>  |  |  |  |
| <b>7.5.1</b> | Does the inspection body have a documented process to receive, evaluate and make decisions on complaints and appeals?  |  |  |  |
| <b>7.5.2</b> | Is a description of the handling process for complaints and appeals available to any interested party upon request?  |  |  |  |
| <b>7.5.3</b> | Upon receipt of a complaint, does the inspection body confirm whether the complaint relates to inspection activities for which it is responsible and, if so, deal with it?   |  |  |  |

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| 7.5.4 | Is the inspection body responsible for all decisions at all levels of the handling process for complaints and appeals?   |  |  |  |
| 7.5.5 | Don't Investigation and decision on appeals result in any discriminatory actions?  |  |  |  |
| 7.6   | <b>Complaints and appeals process</b>  |  |  |  |
| 7.6.1 | Does the handling process for complaints and appeals include at least the following elements and methods?  |  |  |  |
| a)    | 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;                            |  |  |  |
| b)    | tracking and recording complaints and appeals, including actions undertaken to resolve them;   |  |  |  |
| c)    | ensuring that any appropriate action is taken.   |  |  |  |
| 7.6.2 | Is the inspection body receiving the complaint or appeal responsible for gathering and verifying all necessary information to validate the complaint or appeal?                        |  |  |  |
| 7.6.3 | Whenever possible, does the inspection body acknowledge receipt of the complaint or appeal, and provide the complainant or appellant with progress reports and the outcome?            |  |  |  |
| 7.6.4 | Is the decision to be communicated to the complainant or appellant made by, or reviewed and approved by, individual(s) not involved in the original inspection activities in question? |  |  |  |
| 7.6.5 | Whenever possible, does the inspection body give formal notice of the end of the complaint and appeals handling process to the complainant or appellant?                               |  |  |  |



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| <b>8</b>     | <b>Management system requirements</b>   |  |  |  |
| <b>8.1</b>   | <b>Options</b>  |  |  |  |
| <b>8.1.1</b> | General   |  |  |  |
|              | Does the inspection body 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?   |  |  |  |
| <b>8.1.2</b> | Option A  |  |  |  |
|              | Does the management system of the inspection body 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).   |  |  |  |
| <b>8.1.3</b> | Option B  |  |  |  |
|              | Does an inspection body 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 fulfilment of the requirements of this International Standard, fulfil the management system clause requirements (see 8.2 to 8.8)? |  |  |  |
| <b>8.2</b>   | <b>Management system documentation (Option A)</b>   |  |  |  |

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| <b>8.2.1</b> | Does the inspection body's top management establish, document, and maintain policies and objectives for fulfilment of this International Standard and ensure the policies and objectives are acknowledged and implemented at all levels of the inspection body's organization? |  |  |  |
| <b>8.2.2</b> | Does the top management 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?   |  |  |  |
| <b>8.2.3</b> | Does the inspection body's top management appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that include the following?  |  |  |  |
| <b>a)</b>    | ensuring that processes and procedures needed for the management system are established, implemented and maintained; and   |  |  |  |
| <b>b)</b>    | reporting to top management on the performance of the management system and any need for improvement.  |  |  |  |
| <b>8.2.4</b> | Are all documentation, processes, systems, records, etc. related to the fulfilment of the requirements of this International Standard included, referenced, or linked to documentation of the management system?   |  |  |  |
| <b>8.2.5</b> | Do all personnel involved in inspection activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities?  |  |  |  |
| <b>8.3</b>   | <b>Control of documents (Option A)</b>   |  |  |  |
| <b>8.3.1</b> | Does the inspection body establish procedures to control the documents (internal and external) that relate to the fulfilment of this International Standard?   |  |  |  |

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| <b>8.3.2</b>   | Do the procedures define the controls needed to:   |  |  |  |
| <b>a)</b>      | approve documents for adequacy prior to issue;   |  |  |  |
| <b>b)</b>      | review and update (as necessary) and re-approve documents;   |  |  |  |
| <b>c)</b>      | ensure that changes and the current revision status of documents are identified;   |  |  |  |
| <b>d)</b>      | ensure that relevant versions of applicable documents are available at points of use;  |  |  |  |
| <b>e)</b>      | ensure that documents remain legible and readily identifiable;   |  |  |  |
| <b>f)</b>      | ensure that documents of external origin are identified and their distribution controlled;   |  |  |  |
|                | prevent the unintended use of obsolete documents, and apply suitable identification to them if they are retained for any purpose?  |  |  |  |
| <b>Note</b>    | <i>Documentation can be in any form or type of medium and includes proprietary and in-house developed software.</i>  |  |  |  |
| <b>8.4</b>     | <b>Control of records (Option A)</b>   |  |  |  |
| <b>8.4.1</b>   | Does the inspection body 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?  |  |  |  |
| <b>8.4.2</b>   | Does the inspection body establish procedures for retaining records for a period consistent with its contractual and legal obligations? Is access to these records consistent with the confidentiality arrangements?   |  |  |  |
| <b>8.5</b>     | <b>Management review (Option A)</b>  |  |  |  |
| <b>8.5.1</b>   | General  |  |  |  |
| <b>8.5.1.1</b> | Does the inspection body's top management 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? |  |  |  |

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| <b>8.5.1.2</b> | Are these reviews conducted at least once a year? Alternatively, is a complete review broken up into segments (a rolling review) completed within a 12-month time frame?  |  |  |  |
| <b>8.5.1.3</b> | Are records of reviews maintained?  |  |  |  |
| <b>8.5.2</b>   | Review inputs   |  |  |  |
|                | Does the input to the management review include information related to the following?   |  |  |  |
| <b>a)</b>      | results of internal and external audits;  |  |  |  |
| <b>b)</b>      | feedback from clients and interested parties related to the fulfilment of this International Standard;  |  |  |  |
| <b>c)</b>      | the status of preventive and corrective actions;  |  |  |  |
| <b>d)</b>      | follow-up actions from previous management reviews;   |  |  |  |
| <b>e)</b>      | the fulfilment of objectives;   |  |  |  |
| <b>f)</b>      | changes that could affect the management system;  |  |  |  |
| <b>g)</b>      | appeals and complaints.   |  |  |  |
| <b>8.5.3</b>   | Review outputs  |  |  |  |
|                | Do the outputs from the management review include decisions and actions related to:   |  |  |  |
| <b>a)</b>      | improvement of the effectiveness of the management system and its processes;  |  |  |  |
| <b>b)</b>      | improvement of the inspection body related to the fulfilment of this International Standard;  |  |  |  |
| <b>c)</b>      | resource needs?   |  |  |  |
| <b>8.6</b>     | <b>Internal audits (Option A)</b>   |  |  |  |
| <b>8.6.1</b>   | Does the inspection body 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? |  |  |  |
| <b>Note</b>    | <i>ISO 19011 provides guidelines for conducting internal audits.</i>  |  |  |  |

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| <b>8.6.2</b> | Is an audit programme planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits?   |  |  |  |
| <b>8.6.3</b> | Does the inspection body 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?         |  |  |  |
| <b>8.6.4</b> | Are Internal audits 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. |  |  |  |
| <b>8.6.5</b> | Does the inspection body ensure that:  |  |  |  |
| <b>a)</b>    | internal audits are conducted by qualified personnel knowledgeable in inspection, auditing and the requirements of this International Standard;  |  |  |  |
| <b>b)</b>    | auditors do not audit their own work;  |  |  |  |
| <b>c)</b>    | personnel responsible for the area audited are informed of the outcome of the audit;   |  |  |  |
| <b>d)</b>    | any actions resulting from internal audits are taken in a timely and appropriate manner;   |  |  |  |
| <b>e)</b>    | any opportunities for improvement are identified;  |  |  |  |
| <b>f)</b>    | the results of the audit are documented?   |  |  |  |
| <b>8.7</b>   | <b>Corrective actions (Option A)</b>   |  |  |  |
| <b>8.7.1</b> | Does the inspection body establish procedures for identification and management of nonconformities in its operations?  |  |  |  |
| <b>8.7.2</b> | Does the inspection body also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence?  |  |  |  |
| <b>8.7.3</b> | Are corrective actions appropriate to the impact of the problems encountered?  |  |  |  |
| <b>8.7.4</b> | Do the procedures define requirements for the following?   |  |  |  |

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| <b>a)</b>   | identifying nonconformities;  |  |  |  |
| <b>b)</b>   | determining the causes of nonconformity;  |  |  |  |
| <b>c)</b>   | correcting nonconformities;   |  |  |  |
| <b>d)</b>   | evaluating the need for actions to ensure that nonconformities do not recur;  |  |  |  |
| <b>e)</b>   | determining the actions needed and implementing them in a timely manner;  |  |  |  |
| <b>f)</b>   | recording the results of actions taken;   |  |  |  |
| <b>g)</b>   | reviewing the effectiveness of corrective actions.  |  |  |  |
| <b>8.8</b>  | <b>Preventive actions (Option A)</b>  |  |  |  |
| <b>8.8.1</b>  | Does the inspection body establish procedures for taking preventive actions to eliminate the causes of potential nonconformities?   |  |  |  |
| <b>8.8.2</b>  | Are preventive actions taken appropriate to the probable impact of the potential problems?  |  |  |  |
| <b>8.8.3</b>  | Do the procedures for preventive actions define requirements for the following?   |  |  |  |
| <b>a)</b>   | identifying potential nonconformities and their causes;   |  |  |  |
| <b>b)</b>   | evaluating the need for action to prevent the occurrence of nonconformities;  |  |  |  |
| <b>c)</b>   | determining and implementing the action needed;   |  |  |  |
| <b>d)</b>   | recording the results of actions taken;   |  |  |  |
| <b>e)</b>   | reviewing the effectiveness of the preventive actions taken.  |  |  |  |
| <b>Note</b>   | The procedures for corrective and preventive actions do not necessarily have to be separate.  |  |  |  |
| Annex A (normative) Independence requirements for inspection bodies |   |  |  |  |
| <b>A.1</b>  | Requirements for inspection bodies (Type A)   |  |  |  |
|   | Are the inspection body referred to in 4.1.6a) meet the requirements below?   |  |  |  |
|   | a) The inspection body shall be independent of the parties involved.  |  |  |  |
|   | b) Are the inspection body and its personnel shall not engage in any activities that may conflict with their independence of judgment and integrity in relation to their inspection activities? |  |  |  |

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|  | <p>In particular, are not they engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected?</p>  |  |  |  |
|  | <p>Note 1 This does not preclude exchanging technical information between the client and the inspection body (e.g. explanation of findings, or clarifying requirements or training)</p>   |  |  |  |
|  | <p>Note 2 This does not preclude the purchase, ownership or use of inspected items that are necessary for the operations of the inspection body, or the purchase, ownership or use of the items for personal purposes by the personnel.</p>           |  |  |  |
|  | <p>c) Is not an inspection body be a part of a legal entity that is engaged in design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected ?</p>  |  |  |  |
|  | <p>Note 1 This does not preclude exchanging technical information between the client and any other part of the same legal entity of which the inspection body is a part (e.g. explanation of findings, or clarifying requirements of r training).</p> |  |  |  |
|  | <p>note 2 This does not preclude the purchase, ownership, maintenance or use of inspected items that are necessary for the operations of another part of the same legal entity, or for personal purposes by the personnel.</p>                        |  |  |  |
|  | <p>d) Isn't the inspection body be linked to a separate legal entity engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected by the following?</p>                                   |  |  |  |
|  | <p>1) common ownership, except where the owners have no ability to influence the outcome of an inspection.</p>  |  |  |  |
|  | <p>Example 1 A cooperative type of structure where there are large numbers of stakeholders, but they (individually or as a group) have no ability to influence the outcome of an inspection.</p>  |  |  |  |
|  | <p>Example 2 A holding company consisting of several separate legal entities (sister companies) under a common mother company, where neither the sister companies nor the mother company can influence the outcome of an inspection.</p>              |  |  |  |

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|               | 2) common ownership appointees on the boards or equivalent of the organizations, except where these have functions that have no influence on the outcome of an inspection;  |  |  |  |
|               | Example A bank financing a company insists on an appointee to the board who will overview how the company is managed but will not be involved in any decision-making.   |  |  |  |
|               | 3) directly reporting to the same higher level of management, except where this cannot influence the outcome of an inspection;  |  |  |  |
|               | Note Reporting to the same higher level of management is permitted on matters other than design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected.   |  |  |  |
|               | 4) contractual commitments, or other means that may have an ability to influence the outcome of an inspection.  |  |  |  |
| <b>A.2</b>    | Requirements for inspection bodies (Type B)   |  |  |  |
|               | Are the inspection body referred to in 4.1.6b) meet the requirements below?   |  |  |  |
| <b>a)</b>     | Inspection services shall only be supplied to the organization of which the inspection body forms a part.   |  |  |  |
| <b>b)</b>     | A clear separation of the responsibilities of the inspection personnel from those of the personnel employed in the other functions shall be established by organizational identification and the reporting methods of the inspection body within the parent organization.   |  |  |  |
| <b>c)</b>     | This inspection body and its personnel shall not engage in any activities that may conflict with their independence of judgment and integrity in relation to their inspection activities. In particular, they shall not be engaged in the design, manufacture, supply, installation, use or maintenance of the items inspected. |  |  |  |
| <b>Note 1</b> | <i>This does not preclude exchanging technical information between the inspection body and the other parts of the organization of which the inspection body forms a part, e.g. explanation of findings or clarifying requirements or training.</i>  |  |  |  |



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| <b>Note 2</b> | <i>This does not preclude the purchase, ownership or use of inspected items that are necessary for the operations of the inspection body, or the purchase, ownership, or use of the items for personal purposes by personnel.</i>   |  |  |  |
| <b>A.3</b>    | Requirements for inspection bodies (Type C)   |  |  |  |
|               | Are the inspection body referred to in 4.1.6c) meet the requirements below?   |  |  |  |
| <b>a)</b>     | This inspection body shall provide safeguards within the organization to ensure adequate segregation of responsibilities and accountabilities between inspection and other activities.  |  |  |  |
| <b>b)</b>     | The design/manufacture/supply/installation/servicing/maintenance and the inspection of the same item carried out by a Type C inspection body shall not be undertaken by the same person. An exception to this is where a regulatory requirements explicitly allows an individual person from a Type C inspection body to undertake both the designed/manufacture/supply/installation/servicing/maintenance and the inspection of the same item, as long as this exception does not compromise the inspection results. |  |  |  |
| <b>Note</b>   | <i>Inspections carried out by type C inspection bodies cannot be classified as third party inspections for the same inspection activities because they do not meet the requirements of independence of operations for type A inspection bodies.</i>   |  |  |  |
|               | <b>Annex B (informative) Optional elements of inspection reports and certificates</b>   |  |  |  |
|               | The following optional elements can be included in inspection reports and certificates:   |  |  |  |
| <b>a)</b>     | designation of the document, i.e. as an inspection report or an inspection certificate, as appropriate;   |  |  |  |
| <b>b)</b>     | identification of the client;   |  |  |  |
| <b>Note</b>   | <i>The owner of the inspected item can be mentioned in the report or certificate if the owner is not the client.</i>  |  |  |  |

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| <b>c)</b> | description of the inspection work ordered;  |  |  |  |
| <b>d)</b> | information on what has been omitted from the original scope of work;  |  |  |  |
| <b>e)</b> | identification or brief description of the inspection method(s) and procedure(s) used, mentioning the deviations from, additions to or exclusions from the agreed methods and procedures;                |  |  |  |
| <b>f)</b> | identification of equipment used for measuring/testing;  |  |  |  |
| <b>g)</b> | where applicable, and if not specified in the inspection method or procedure, reference to or description of the sampling method and information on where, when, how and by whom the samples were taken; |  |  |  |
| <b>h)</b> | information on where the inspection was carried out;   |  |  |  |
| <b>i)</b> | information on environmental conditions during the inspection, if relevant;  |  |  |  |
| <b>j)</b> | a statement that the inspection results relate exclusively to the work ordered or the item(s) or the lot inspected;  |  |  |  |
| <b>k)</b> | a statement that the inspection report should not be reproduced, except in full;   |  |  |  |
| <b>l)</b> | the inspector's mark or seal;  |  |  |  |
| <b>m)</b> | names (or unique identification) of the personnel members who have performed the inspection and, in cases when secure electronic authentication is not undertaken, their signature (see also 7.4.2).     |  |  |  |