|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Section 1** | | | | | | | |
| **5 General Requirements** **ISO/IEC 17029:2019** | | | | | | | |
| **5.1** | **Legal Entity**  Is the validation/verification body a legal entity, or a defined part of a legal entity, that can be held legally responsible for all its validation/verification activities.  **NOTE**: A governmental validation/ verification body is a legal entity on the basis of its governmental status. |  |  |  |  |  |  |
| **5.2** | **Responsibility for validation/ verification statements**  Is the validation/verification body responsible for, and shall retain authority for, its validation/ verification statements. |  |  |  |  |  |  |
| **5.3** | **Management of impartiality** |  | | | | | |
| **5.3.1** | Does Validation/verification activities undertaken impartially. |  |  |  |  |  |  |
| **5.3.2** | Is the validation/verification body responsible for the impartiality of its validation/ verification activities and shall not allow commercial, financial or other pressures to compromise impartiality. |  |  |  |  |  |  |
| **5.3.3** | Is the validation/verification body shall monitor its activities and its relationships to identify threats to its impartiality. This monitoring shall include the relationships of its personnel.  **NOTE 1** While the requirements for impartiality in this document are the same for first-, second- and third-party bodies, the relevant inputs and outcome of the respective risk assessment can differ.  **NOTE 2** The identification of threats to impartiality can include balanced consultation with appropriate interested parties, with no single interest predominating, to advise on matters affecting impartiality including openness and public perception. One way of consultation is by the use of a committee of these interested parties.  **NOTE 3** The programme can make the requirement for consultation with appropriate interested parties to advise on matters affecting impartiality mandatory.  **NOTE 4** A relationship can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding). Such relationships do not necessarily present a validation/ verification body with a threat to impartiality. |  |  |  |  |  |  |
| **5.3.4** | If a threat to impartiality is identified, does its effect eliminated or minimized so that the impartiality is not compromised. |  |  |  |  |  |  |
| **5.3.5** | Does the validation/verification body have top management commitment to impartiality. |  |  |  |  |  |  |
| **5.3.6** | Does the validation/verification body have a publicly available commitment that it understands the importance of impartiality in carrying out its validation/verification activities and manages conflicts of interest and ensures objectivity. |  |  |  |  |  |  |
| **5.3.7** | Are Review (9.6) and decision (9.7) made by personnel different from those who carried out the validation/verification execution (9.5). |  |  |  |  |  |  |
| **5.3.8** | When providing both validation and verification to the same client, Does the validation/verification body consider the potential threat to impartiality (e.g. self-review and familiarity) and shall manage this risk accordingly? |  |  |  |  |  |  |
| **5.3.9** | Does the validation/verification body offer or provide both consultancy and validation/ verification for the same claim from the same client? |  |  |  |  |  |  |
| **5.3.10** | Where the relationship between a body that provides consultancy and the validation/verification body poses an unacceptable threat to the impartiality of the validation/verification body, Does the validation/ verification body provide validation/verification activities to clients who have received consultancy relating to the same claim. This includes potential clients with which the validation/ verification body is pre-engaged. |  |  |  |  |  |  |
| **5.3.11** | Does the validation/verification body’s activities marketed or offered as linked with the activities of any organization that provides consultancy. |  |  |  |  |  |  |
| **5.3.12** | Does the validation/verification body take action when it is made aware of (e.g. via a complaint) inappropriate links with or announcements by any consultancy organization stating or implying that validation/verification would be simpler, easier, faster or less expensive if the validation/verification body were used. |  |  |  |  |  |  |
|  | Does A validation/verification body not state or imply that validation/verification would be simpler, easier, faster or less expensive if a specified consultancy organization were used. |  |  |  |  |  |  |
| **5.3.13** | Does the validation/verification body take action to respond to any threats to its impartiality arising from the actions of other persons, bodies or organizations. This includes the actions of those bodies to which validation/verification activities have been outsourced. |  |  |  |  |  |  |
| **5.4** | **Liability**  Does the validation/verification body able to demonstrate that it has evaluated the risks arising from its validation/verification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its activities in each validation/verification programme and the geographic areas it operates. |  |  |  |  |  |  |
| **6** | **Structural requirements** |  |  |  |  |  |  |
| **6.1** | **Organizational structure and top management** |  |  |  |  |  |  |
| **6.1.1** | Does the validation/verification body organized and managed so as to enable it to maintain the capability to perform its validation/verification activities. |  |  |  |  |  |  |
| **6.1.2** | Are Validation/verification activities structured and managed so as to safeguard impartiality. |  |  |  |  |  |  |
| **6.1.3** | Does the validation/verification body document its organizational structure, duties, responsibilities and authorities of management and other personnel involved in the validation/ verification activities and any committees. If the validation/verification body is a defined part of a legal entity, the structure shall include the line of authority and the relationship to other parts within the same legal entity. |  |  |  |  |  |  |
| **6.1.4** | Does the validation/verification body identify the top management (board, group of persons, or person) having overall authority and responsibility for each of the following:   1. development of policies and establishment of processes relating to its operations; 2. supervision of the implementation of the policies and processes; 3. ensuring impartiality; 4. supervision of its finances; 5. development of validation/verification activities and requirements; 6. performance of validation/verification activities; 7. decisions and issue of validation/verification statements; 8. delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf; 9. contractual arrangements; 10. personnel competence requirements; 11. responsiveness to complaints and appeals; 12. management system of the validation/verification body;   provision of adequate resources for validation/verification activities. |  |  |  |  |  |  |
| **6.2** | **Operational control** |  |  |  |  |  |  |
| **6.2.1** | Does the validation/verification body have a process for the effective control of validation/ verification activities delivered by entities under its operational control, branch offices, partnerships, agents, franchisees, etc., irrespective of their legal status, relationship or geographical location. |  |  |  |  |  |  |
| **6.2.2** | Does the validation/verification body determine and establish the appropriate level and method of control of activities undertaken. This includes its processes, sectors of validation/verification activities, competence of personnel, lines of management control, reporting and remote access to operations, and records. |  |  |  |  |  |  |
| **6.2.3** | Does the validation/verification body consider the risk that these activities pose to the competence, consistency and impartiality of the validation/verification body. |  |  |  |  |  |  |
| **7** | **Resource requirements** |  |  |  |  |  |  |
| **7.1** | **General**  Does the validation/verification body have access to personnel, facilities, equipment, systems and support services that are necessary to perform its validation/verification activities.  **NOTE** Requirements for personnel, facilities, equipment, systems and support services can be contained in the validation/verification programme. |  |  |  |  |  |  |
| **7.2** | **Personnel** |  |  |  |  |  |  |
| **7.2.1** | Does the validation/verification body have access to a sufficient number of competent persons to perform its validation/verification activities.  **NOTE** Personnel include those persons that are employees, directors and committee members of the body, and any contracted persons that are used by the body to undertake validation/verification activities. |  |  |  |  |  |  |
| **7.2.2** | Does the validation/verification body require all personnel involved in validation/verification activities to enter into a legally enforceable agreement by which the personnel commit themselves to the following:   1. to comply with the processes and instructions of the validation/verification body, including those relating to impartiality and confidentiality; 2. to declare any prior and/or present association on their own part, or on the part of another person or organization with which they have a relationship (e.g. a family member or their employer), with a client of the validation/verification body;   to reveal any situation known to them that can present them or the validation/verification body with a perceived or actual conflict of interest. |  |  |  |  |  |  |
| **7.2.3** | Does the validation/verification body use this information as input into identifying threats to impartiality raised by the activities of such personnel, or by the persons or organizations related to them (see 5.3.3). |  |  |  |  |  |  |
| **7.2.4** | Does all personnel of the validation/verification body, either internal or external, that could influence the validation/verification activities, shall act impartially. |  |  |  |  |  |  |
| **7.2.5** | Within a period specified by the validation/verification body,  Does personnel who have provided consultancy on the claim to be the object of validation/verification not perform validation/ verification activities in relation to their previous involvement.  Does the period long enough to ensure that the threats to impartiality are minimized or eliminated.  **NOTE**  The period can be specified in the programme. |  |  |  |  |  |  |
| **7.2.6** | Does Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the validation/verification body's behalf,keep confidential all information obtained or created during the performance of the body's validation/verification activities. |  |  |  |  |  |  |
| **7.2.7** | Does the validation/verification body communicate to personnel their duties, responsibilities and authorities. |  |  |  |  |  |  |
| **7.3** | **Management process for the competence of personnel** |  |  |  |  |  |  |
| **7.3.1** | Does the validation/verification body have a process for managing competence of its personnel involved in the validation/verification activities. |  |  |  |  |  |  |
| **7.3.2** | Does the processes require the validation/verification body:   1. to determine the criteria for the competence of personnel for each function in the validation/ verification process, including at least:    * the ability to apply generic validation/verification concepts (e.g. evidence gathering, risk, misstatements, level of assurance, materiality);    * knowledge about the type and typical content of the client’s claim;    * knowledge of the programme requirements (e.g. competence required for specific validation/ verification process); 2. to identify training needs and provide, as necessary, training on validation/verification processes, requirements, methodologies, activities and other relevant validation/verification programme requirements; 3. to demonstrate that the personnel have the required competence for the duties and responsibilities they undertake; 4. to formally authorize personnel for functions in the validation/verification process; 5. to monitor the performance of the personnel.   **NOTE** Further requirements for competence of personnel can be contained in the validation/verification programme. |  |  |  |  |  |  |
| **7.3.3** | Does the validation/verification body have documented information demonstrating competence of its personnel involved in the validation/verification activities. This includes relevant education, training, experience, performance monitoring, affiliations, and professional status. |  |  |  |  |  |  |
| **7.4** | **Outsourcing**  In the absence of applicable programme prohibitions on outsourcing, Is the validation/verification body may outsource validation /verification activities   1. retain full responsibility for the validation/verification; 2. not outsource the engagement activities (9.3), the decision on the confirmation of the claim and the issue of the statement (9.7); 3. have a legally enforceable agreement, including confidentiality and management of impartiality requirements, with each body that provides outsourced activities; 4. have ensured that the body that provides outsourced activities conforms with the applicable requirements of this document, including competence, impartiality and confidentiality and to any applicable programme requirements; 5. obtain consent from the client to use the organization that provides the outsourced activities.   **NOTE 1** Outsourcing refers to contract arrangements with another organization, including other validation/ verification bodies, to provide validation/verification activities to the validation/verification body.  **NOTE 2** Where the validation/verification body engages individuals or employees of other organizations to provide additional resources or expertise, these individuals or employees do not constitute outsourcing provided they are individually contracted to operate under the validation/verification body’s management system. |  |  |  |  |  |  |
| **8** | **Validation/verification programme**  Does the validation/verification body apply one or more validation/verification programme(s) that are consistent with, and do not exclude the requirements of this document.  **NOTE 1** A validation/verification programme is a set of rules, procedures and management for carrying out validation/verification activities in a specific sector containing the following elements:   * scope of validation/verification; * specific competence criteria for the validation/verification team and body; * process for validation/verification; * evidence gathering activities of validation/verification; * reporting of validation/verification.   **NOTE 2** Annex A specifies the elements than can be included in a validation/verification programme. |  |  |  |  |  |  |
| **9** | **Process requirements** |  |  |  |  |  |  |
| **9.1** | **General**  Does the validation/verification body complete the following process steps as validation/verification activities:   * pre-engagement (9.2); * engagement (9.3); * planning (9.4); * validation/verification execution (9.5); * review (9.6); * decision and issue of the validation/verification statement (9.7); * facts discovered after the issue of the validation/verification statement (9.8); * handling of appeals (9.9); * handling of complaints (9.10);   records (9.11). |  |  |  |  |  |  |
| **9.2** | **Pre-engagement** |  |  |  |  |  |  |
| **9.2.1** | Does the validation/verification body require the client to submit information sufficient to carry out a pre-engagement review, including at least the following:   1. client name and the proposed claim to be validated/verified; 2. locations where the client’s activities are undertaken; 3. the validation/verification programme and associated specified requirements for the validation/ verification; 4. the objectives and scope of the validation/verification; 5. reports, data and any other relevant information; 6. where known at this stage and where applicable, the materiality and the level of assurance;   any other information as required by the validation/verification programme. |  |  |  |  |  |  |
| **9.2.2** | Does the validation/verification body conduct a pre-engagement review of the information received from the client to ensure that:   1. an applicable programme exists or a programme is to be established; 2. the claim is understood (e.g. context, content and complexity); 3. the objectives and scope of the validation/verification have been agreed with the client; 4. the specified requirements against which the claim will be validated/verified have been identified and are suitable; 5. where applicable, the materiality and level of assurance have been agreed; 6. the process for validation/verification activities can be achieved (e.g. evidence gathering activities, evaluation of gathered evidences); 7. the validation/verification duration can be estimated; 8. the validation/verification body has identified and has access to the resources and competences that are required to undertake the validation/verification;   the time frame for the planned validation/verification can be proposed. |  |  |  |  |  |  |
| **9.2.3** | Following the pre-engagement review of the submitted information by the client, Does the validation/ verification body either accept or decline to perform validation/verification. |  |  |  |  |  |  |
| **9.3** | **Engagement** |  |  |  |  |  |  |
| **9.3.1** | Does the validation/verification body have an agreement with each client for the provision of validation/verification activities in accordance with the relevant requirements of this document and the requirements specified in the applicable validation/verification programme:   1. for second- and third-party validation/verification activities, a legally enforceable agreement (e.g. a contract);   for first party validation/ verification activities, an internal agreement such as service level agreement, internal contract, statement of work, or other enforceable internal agreement. |  |  |  |  |  |  |
| **9.3.2** | Does the validation/verification body ensure its agreement requires that the client complies at least with the following:   1. validation/verification requirements; 2. making all necessary arrangements for the conduct of the validation/verification, including provisions for examining documentation and access to all relevant processes, areas, records, and personnel; 3. where applicable, making provisions to accommodate observers;   complying with the rules of the validation/verification body for reference to validation/verification or use of marks (10.3). |  |  |  |  |  |  |
| **9.3.3** | Does the agreement confirm that the client engages the validation/verification body to undertake validation/verification activities, including the specification of:   1. the items listed in 9.2.2;   the specific requirements for the validation/verification activity, including any additional relevant requirements set by a programme or standard. |  |  |  |  |  |  |
| **9.3.4** | Does the validation/verification body take responsibility for any inputs that it accepts to take into account as part of its validation/verification activities, including those that have been generated by the client or other external parties. |  |  |  |  |  |  |
| **9.4** | **Planning** |  |  |  |  |  |  |
| **9.4.1** | Does the validation/verification body undertake the following planning activities taking into account the requirements specified in the applicable validation/verification programme before undertaking the validation/verification activities:   1. assign competent resources to undertake the activities; 2. determine the validation/verification activities based on the understanding of the claim; 3. assess the risk of a material misstatement regarding the claim; 4. confirm the timing and access arrangements with the client; 5. determine evidence-gathering activities needed to complete the validation/verification in accordance with the specified requirements and consistent with the results of b) and c); 6. prepare an evidence-gathering plan, taking into account c) and any measures that the client has in place to control sources of potential errors, omissions and misrepresentations; 7. prepare a validation/verification plan (9.4.2) considering the evidence-gathering plan as an input.   **NOTE 1** Preparation of an evidence-gathering plan and a validation/verification plan can be an iterative process.  **NOTE 2** In some programmes, the evidence-gathering plan is called “sampling plan”.  **NOTE 3** Other parameters that can be specified by programmes to be considered during planning are materiality or level of assurance.  **NOTE 4** The level of assurance is used to determine the depth of detail that a validation/verification body designs into their validation/verification plan and evidence-gathering plan to determine if there are any material errors, omissions, or misrepresentations. |  |  |  |  |  |  |
| **9.4.2** | Does the validation/verification body develop a validation/verification plan that describes activities and schedules, and that includes the following:   1. objectives and scope of validation/verification; 2. identification of the validation/verification team members and their roles and responsibilities in the team (e.g. team leader, observer); 3. time frame and duration of validation/verification activities;   specified requirements. |  |  |  |  |  |  |
| **9.4.3** | Does the validation/verification body inform the client of the names and roles of the team members with sufficient notice for any objection to the appointment of a team member to be made. |  |  |  |  |  |  |
| **9.4.4** | Does the validation/verification body communicate to the client the validation/verification plan. |  |  |  |  |  |  |
| **9.5** | **Validation/verification execution** |  |  |  |  |  |  |
| **9.5.1** | Does the validation/verification body perform the validation/verification execution activities in accordance with the validation/verification plan. |  |  |  |  |  |  |
| **9.5.2** | Does the validation/verification plan revised as necessary during the validation/verification execution activities. |  |  |  |  |  |  |
| **9.5.3** | Does any revisions to the validation/verification plan internally documented, including the reasons, and communicated to the client. |  |  |  |  |  |  |
| **9.5.4** | Does the body undertake the following activities:   1. collection of sufficient objective evidence on original data/information, ensuring its traceability through the data/information management process, any further analysis and calculation; 2. identification of misstatements and consideration of their materiality;   assessment of conformity with specified requirements, taking into account the validation/ verification programme. |  |  |  |  |  |  |
| **9.5.5** | Does the validation/verification body prepare the following:   1. a conclusion on the outcome of the activities in 9.5.4; 2. a draft validation/verification statement; 3. a report, if applicable.   **NOTE** The report can be a separate document or can be included in a document containing the draft validation/verification statement. |  |  |  |  |  |  |
| **9.6** | **Review** |  |  |  |  |  |  |
| **9.6.1** | Does the validation/verification body undertake review activities. |  |  |  |  |  |  |
| **9.6.2** | Does the review carried out by persons who have not been involved in the validation/ verification execution.  **NOTE** A programme can specify further limitations, e.g. requiring the review to be made by persons who have not been involved in particular validation/verification planning activities. |  |  |  |  |  |  |
| **9.6.3** | Does the review confirm:   1. that all validation/verification activities have been completed in accordance with the agreement and the programme; 2. sufficiency and appropriateness of evidence to support the decision;   whether significant findings have been identified, resolved, and documented. |  |  |  |  |  |  |
| **9.6.4** | Does the reviewer communicate with the validation/verification team when the need for clarification arises. The validation/verification team shall address concerns raised by the reviewer. |  |  |  |  |  |  |
| **9.6.5** | Does the review have available all records of the validation/verification activities as specified in 9.11. |  |  |  |  |  |  |
| **9.7** | **Decision and issue of the validation/verification statement** |  |  |  |  |  |  |
| **9.7.1** | **Decision** |  |  |  |  |  |  |
| **9.7.1.1** | Upon completion of the validation/verification review, Does the validation/verification body make the decision on whether or not to confirm the claim. |  |  |  |  |  |  |
| **9.7.1.2** | Does the decision shall be made by persons who have not been involved in the validation/verification execution.  **NOTE** A programme can specify further limitations, e.g. requiring the decision to be made by persons who have not been involved in particular validation/verification planning activities. |  |  |  |  |  |  |
| **9.7.1.3** | Based on this decision, a validation/verification statement is issued or not issued according to the programme requirements. |  |  |  |  |  |  |
| **9.7.1.4** | When the validation/verification body is not issuing a validation/verification statement, Does the validation/verification body inform the client. |  |  |  |  |  |  |
| **9.7.2** | **Issue of the validation/verification statement**  When the validation/verification body issues a validation/verification statement, (9.7.1) Does the statement :   1. state the client’s name; 2. identify whether it is a validation statement or a verification statement; 3. refer to the claim, including date or period which the claim covers; 4. include the type of the validation/verification body in relation to the statement in question (i.e. first party, second party or third party); 5. include the name and address of the validation/verification body (if symbols, e.g. accreditation symbol, are included, they shall not be misleading or ambiguous); 6. describe the objectives and scope of the validation/verification; 7. describe whether the data and information supporting the claim were hypothetical, projected and/ or historical in nature; 8. include a reference to the validation/verification programme and associated specified requirements; 9. include the decision made about the claim, including the fulfilment of any programme related requirements (e.g. materiality or level of assurance); 10. indicate the date and the unique identification of the statement;   include any findings, that have not been addressed prior to the issue of the validation/verification statement, if required by the programme. |  |  |  |  |  |  |
| **9.8** | **Facts discovered after the issue of the validation/verification statement** |  |  |  |  |  |  |
| **9.8.1** | If new facts or information that could materially affect the validation/verification statement are discovered after the issue date, Does the validation/verification body:   1. communicate the matter as soon as practicable to the client and, if required, the programme owner; 2. take appropriate action, including the following: 3. discuss the matter with the client;   consider if the validation/ verification statement requires revision or withdrawal. |  |  |  |  |  |  |
| **9.8.2** | If the validation/verification statement requires revision, Does the validation/ verification body implement processes to issue a new statement including specification of the reasons for the revision. These can include repeating relevant steps of the validation/verification process. |  |  |  |  |  |  |
| **9.8.3** | Does the validation/verification body may also communicate to other interested parties the fact that reliance of the original statement can now be compromised given the new facts or information. |  |  |  |  |  |  |
| **9.9** | **Handling of appeals** |  |  |  |  |  |  |
| **9.9.1** | Does the validation/verification body have a documented process to receive, evaluate and make decisions on appeals. |  |  |  |  |  |  |
| **9.9.2** | Does the process for handling appeals include at least the following:   1. a description of the process for receiving, investigating, substantiating the appeal, and deciding what actions are to be taken in response; 2. tracking and recording the appeal, including the actions to resolve it;   ensure appropriate action is taken. |  |  |  |  |  |  |
| **9.9.3** | Does the validation/verification body receiving the appeal responsible for gathering all necessary information to determine whether the appeal is substantiated. |  |  |  |  |  |  |
| **9.9.4** | Does the validation/verification body acknowledge receipt of the appeal, and provide the appellant with the outcome and, if applicable, progress reports. |  |  |  |  |  |  |
| **9.9.5** | A description of the process for handling appeals available to any interested party. |  |  |  |  |  |  |
| **9.9.6** | Does the responsible for all decisions during the process for handling appeals. |  |  |  |  |  |  |
| **9.9.7** | Does Investigation and decision on appeals not result in any discriminatory actions. |  |  |  |  |  |  |
| **9.9.8** | Does the decision on the appeal made by, or reviewed and approved by, individuals not involved in the decision which is the subject of the appeal in question. |  |  |  |  |  |  |
| **9.10** | **Handling of complaints** |  |  |  |  |  |  |
| **9.10.1** | Does the validation/verification body have a documented process to receive, evaluate and resolve complaints. |  |  |  |  |  |  |
| **9.10.2** | Does the process for handling complaints include at least the following:   1. a description of the process for receiving, substantiating, investigating the complaint, and deciding what actions are to be taken in response; 2. tracking and recording the complaint, including the actions undertaken to resolve it;   ensuring appropriate action is taken. |  |  |  |  |  |  |
| **9.10.3** | Does the validation/verification body receiving the complaint responsible for gathering all necessary information to determine whether the complaint is substantiated. |  |  |  |  |  |  |
| **9.10.4** | Whenever possible, Does the validation/ verification body acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports. |  |  |  |  |  |  |
| **9.10.5** | Is a description of the process for handling complaints available to any interested party. |  |  |  |  |  |  |
| **9.10.6** | Upon receipt of a complaint, Does the body confirm whether the complaint relates to its validation/verification activities and, if so, resolve the complaint. |  |  |  |  |  |  |
| **9.10.7** | Does Investigation and resolution of complaints not result in any discriminatory actions. |  |  |  |  |  |  |
| **9.10.8** | Does the resolution of complaints shall be made by, or reviewed and approved by, individuals not involved in the complaint in question. Where resources do not permit this, any alternative approach shall not compromise impartiality. |  |  |  |  |  |  |
| **9.11** | **Records** |  |  |  |  |  |  |
| **9.11.1** | Does the validation/verification body maintain and manage records of its validation/verification activities including:   1. information submitted during pre-engagement and scopes of validation/verification; 2. justification for how validation/verification duration is determined; 3. any revisions to the validation/verification planning activities; 4. demonstration that the validation/verification activities have been carried out in accordance with the requirements of this document and the validation/verification programme including findings and information on material or non-material misstatements; 5. evaluation, selection and monitoring of performance of bodies providing outsourced activities; 6. evidence to support conclusions and the decisions; 7. validation/verification statements;   complaints and appeals, and any subsequent correction or corrective actions. |  |  |  |  |  |  |
| **9.11.2** | Does the validation/verification body maintain validation/verification records securely and confidentially, including during their transport, transmission, or transfer. |  |  |  |  |  |  |
| **9.11.3** | Does the validation/verification body retain validation/verification records in accordance with the programme, contractual, and other management system requirements.  **NOTE** ISO 15489-1 defines the concepts and principles from which approaches to the creation, capture and management of records are developed. |  |  |  |  |  |  |
| **10** | **Information requirements** |  |  |  |  |  |  |
| **10.1** | **Publicly available information** |  |  |  |  |  |  |
| **10.1.1** | Does the validation/verification body ensure the following information is made publicly available:   1. information about the validation/verification process; 2. commitment to impartiality; 3. list of validation/verification activities the validation/ verification body provides, including reference to applicable programmes;   complaints and appeals process. |  |  |  |  |  |  |
| **10.2** | **Other information to be available** |  |  |  |  |  |  |
| **10.2.1** | Does the validation/verification body maintain and, upon request, provide clear, traceable, and accurate information about its activities and the sectors in which it operates. |  |  |  |  |  |  |
| **10.2.2** | Unless otherwise specified in the programme, Does the validation/verification body provide, upon request, the status of a given validation/verification statement. |  |  |  |  |  |  |
| **10.2.3** | Does the validation/verification body shall provide information and update clients on the following:   1. the applicable validation/verification programmes and any changes; 2. the fees for the validation/verification activity; 3. the validation/verification body’s requirements for the client to: 4. comply with the validation/verification programme; 5. make all necessary arrangements for the conduct of the validation/verification activities; 6. make provisions, where applicable, to accommodate the presence of observers (e.g. accreditation assessors or trainee validator/verifier);   its policy governing any statement that the client is authorized to use when making reference to its validation/ verification statement in communication of any kind in line with the requirements in 10.3. |  |  |  |  |  |  |
| **10.3** | **Reference to validation/verification and use of marks** |  |  |  |  |  |  |
| **10.3.1** | Does a validation/verification body have rules governing any reference to validation/verification or use of its marks that it authorizes its clients to use.  Does these rules ensure, among other things, traceability back to the validation/verification body and to the validation/verification statement issued. |  |  |  |  |  |  |
| **10.3.2** | This reference or marks shall be used only in relation to the claim which has been validated/ verified and shall not be misleading with regards to product certification. |  |  |  |  |  |  |
| **10.4** | **Confidentiality** |  |  |  |  |  |  |
| **10.4.1** | Does the validation/verification body responsible, through legally enforceable agreements, for the management of all information obtained or created during the performance of validation/ verification activities. |  |  |  |  |  |  |
| **10.4.2** | Does the validation/verification body inform the client, in advance, of the information it intends to place in the public domain. |  |  |  |  |  |  |
| **10.4.3** | Except for information that the client makes publicly available, or when agreed between the validation/verification body and the client, Does all other information is considered proprietary information and regarded as confidential. |  |  |  |  |  |  |
| **10.4.4** | When the validation/verification body is required by law or authorized by contractual arrangements to release confidential information, Does the client or individual concerned shall, unless prohibited by law, be notified of the information released. |  |  |  |  |  |  |
| **10.4.5** | Does Information about the client obtained from sources other than the client (e.g. complainant, regulatory authority) confidential between the client and the validation/verification body. The provider (source) of this information shall be confidential to the body and shall not be shared with the client, unless agreed by the source. |  |  |  |  |  |  |
| **11** | **Management system requirements** |  |  |  |  |  |  |
| **11.1** | **General** |  |  |  |  |  |  |
| **11.1.1** | Does the validation/verification body establish, document, implement and maintain a management system to support and demonstrate the consistent achievement of the requirements of this document. |  |  |  |  |  |  |
| **11.1.2** | Does the management system of the validation/verification body include at least the following:   * policies and responsibilities; * management review (11.2); * internal audits (11.3); * corrective actions (11.4); * actions to address risks and opportunities (11.5);   documented information (11.6). |  |  |  |  |  |  |
| **11.1.3** | Does validation/verification body can meet 11.1.2 by establishing and maintaining a quality management system, in accordance with the requirements of ISO 9001. Does This quality management system support and demonstrate the consistent fulfilment of the requirements of this document. |  |  |  |  |  |  |
| **11.2** | **Management review** |  |  |  |  |  |  |
| **11.2.1** | Does the validation/verification body's management 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 document. |  |  |  |  |  |  |
| **11.2.2** | Does the inputs to management review recorded and include information related to the following:   1. changes in internal and external issues that are relevant to the validation/verification body; 2. fulfilment of objectives; 3. suitability of policies and procedures; 4. status of actions from previous management reviews; 5. outcome of recent internal audits; 6. corrective actions; 7. assessments by external bodies; 8. changes in the volume and type of the work or in the range of validation/verification body's activities; 9. client and personnel feedback; 10. complaints and appeals; 11. effectiveness of any implemented improvements; 12. adequacy of resources; 13. results of risk analysis;   other relevant factors, such as monitoring activities and training. |  |  |  |  |  |  |
| **11.2.3** | Does the outputs from the management review record all decisions and actions related to at least:   1. the effectiveness of the management system and its processes; 2. improvement of the validation/verification body's activities related to the fulfilment of the requirements of this document; 3. provision of required resources;   any need for change. |  |  |  |  |  |  |
| **11.3** | **Internal audits** |  |  |  |  |  |  |
| **11.3.1** | Does the validation/verification body conduct internal audits at planned intervals to provide information on whether the management system:   1. conforms to:  * the validation/verification body’s own requirements for its management system, including the validation/verification activities; * the requirements of this document;   is effectively implemented and maintained. |  |  |  |  |  |  |
| **11.3.2** | Does the validation/verification body :   1. plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the validation/verification body's activities concerned, changes affecting the validation/verification body and the results of previous audits; 2. define the audit criteria and scope for each audit; 3. ensure that the results of the audits are reported to relevant personnel; 4. implement appropriate correction and corrective actions without undue delay; 5. retain records as evidence of the implementation of the audit programme and the audit results.   **NOTE** ISO 19011 provides guidance for internal audits. |  |  |  |  |  |  |
| **11.3.3** | Does the validation/verification body ensure that its internal auditors do not audit their own work. |  |  |  |  |  |  |
| **11.4** | **Corrective action** |  |  |  |  |  |  |
|  | Does the validation/verification body establish processes for identification and management of nonconformities in its activities. Does the validation/verification body also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the impact of the problems encountered. Doess processes define requirements for:   1. identifying nonconformities (e.g. from valid complaints and internal audits); 2. determining the causes of nonconformity; 3. correcting nonconformities; 4. evaluating the need for actions to ensure that nonconformities do not recur; 5. determining and implementing in a timely manner, the actions needed; 6. recording the results of actions taken;   reviewing the effectiveness of corrective actions. |  |  |  |  |  |  |
| **11.5** | **Actions to address risks and opportunities** |  |  |  |  |  |  |
| **11.5.1** | Does the validation/verification body consider the risks and opportunities associated with the validation/verification activities in order to:   1. give assurance that the management system achieves its intended results; 2. enhance opportunities to achieve the programme and objectives of the validation/verification body; 3. prevent, or reduce, undesired impacts and potential failures in the validation/verification body's activities;   achieve improvement. |  |  |  |  |  |  |
| **11.5.2** | Does the validation/verification body plan:   1. actions to address these risks and opportunities; 2. how to integrate and implement these actions into its management system; 3. how to evaluate the effectiveness of these actions.   **NOTE** Although this document specifies that the validation/verification body plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Validation/verification bodies can decide whether or not to develop a more extensive risk management methodology than is required by this document (e.g. through the application of other guidance or standards). |  |  |  |  |  |  |
| **11.5.3** | Are actions taken to address risks and opportunities proportional to the potential impact on the validation/verification statement.  **NOTE 1** Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.  **NOTE 2** Opportunities can lead to expanding the scope of the validation/verification body's activities, addressing new clients, using new technology and other possibilities to address clients' needs. |  |  |  |  |  |  |
| **11.6** | **Documented information** |  |  |  |  |  |  |
| **11.6.1** | Does the validation/verification body control documented information required by the management system and by this document to ensure that it is:   1. available and suitable for use, where and when it is needed, and   adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). |  |  |  |  |  |  |
| **11.6.2** | For the control of documented information, the validation/verification body shall address the following activities, as applicable:   1. distribution, access, retrieval and use; 2. storage and preservation, including preservation of legibility; 3. control of changes (e.g. version control);   retention and disposition. |  |  |  |  |  |  |
| **11.6.3** | Does Documented information of external origin determined by the validation/verification body to be necessary for the planning and operation of the management system be identified as appropriate and shall be controlled. |  |  |  |  |  |  |
| **11.6.4** | Does the documented information retained as evidence of conformity protected from unintended alterations.  **NOTE 1** Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.  **NOTE 2** Documented information refers to processes, procedures, records, data, statements and other information required by this document. |  |  |  |  |  |  |

**For internal use only**

|  |  |  |
| --- | --- | --- |
| **Validation/Verification body** |  | **Acc. No.** |
| **Type of Visit** | **Document and Record Review/Pre-Assessment/ Initial Assessment / Surveillance / Re-Assessment** | |
| **Name of the Assessor** |  | |
| **Date** |  | |