Testing Laboratory Quality Assurance Standards

**□ Evaluated Testing Laboratory**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of laboratory |  | Representative | |  |
| Address |  | | | |
| Phone No. |  | Fax No. |  | |
| Type of laboratory | □ food  □ livestock products | □ medicine  □ medical devices  □ cosmetics | | |
| Scope of Work | □ Self-Quality Inspection | □ Import Inspection·Surveillance  or Inspection Orders | | |
| \*Only for Testing Laboratories for foods, etc. and livestock products | | | |
| Evaluation items |  | | | |

**□ Audit Results**

|  |  |  |  |
| --- | --- | --- | --- |
| **Final Results** | □ satisfactory  □ unsatisfactory | **Prerequisite** | **Satisfactory ( )**  **Unsatisfactory ( )** |
| **Total Points** |  |
| **Evaluation Criteria** | **Audit details and findings** | | |
| Management of Organization |  | | |
| Facility/equipment |  | | |
| Testing/ Inspection |  | | |
| Quality assurance |  | | |

**□ Auditors**

|  |  |  |  |
| --- | --- | --- | --- |
| Institution | Title | Name | Signature |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**□ Quality Assurance Evaluation Form**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Audit Parameters** | | | | **Evaluation criteria** | | | |
| **Excellent** | **Good** | **Unsatisfactory** | **N/A** |
| **Ⅰ. Management of Organization** | | | |  | | | |
| 1. **Quality assurance scheme (8 points)** | | | |  | | | |
| Prerequisite | | An individual with the responsibility and authority for the organization and its function shall be appointed as key managerial personnel. | | □ satisfactory □ unsatisfactory | | | |
| A testing manager (one or more persons) shall be appointed. | | □ satisfactory □ unsatisfactory | | | |
| A quality assurance manager (one or more persons) shall be appointed. | | □ satisfactory □ unsatisfactory | | | |
| Deputies of key personnel (testing manager/quality assurance manager) shall be appointed. | | □ satisfactory □ unsatisfactory | | | |
| Responsibilities, authority and assigned tasks, arbitrary decision making procedures of each managerial, technical, and any individual involved in the performance of testing activities shall be set forth. | | □ satisfactory □ unsatisfactory | | | |
| a. The quality assurance managers shall be free from any pressures which might influence judgment. | | | | 1.0 | - | 0 |  |
| b. Laboratory personnel qualifications (education background, major, or past work experiences) shall be fulfilled. | | | | 1.0 | - | 0 |  |
| c. Manger/testing personnel’s authority shall be granted in an appropriate manner as prescribed in procedures. | | | | 1.0 | - | 0 |  |
| d. Adequate number of laboratory personnel who are competent to perform laboratory testing activities shall be available. | | | | 1.0 | - | 0 |  |
| e. In case when a contracted assistant is needed, a procedure and assigned task shall be set forth (if applicable). | | | | 1.0 | - | 0 |  |
| f. The laboratory shall be equipped with proper facilities and equipment to perform laboratory testing. | | | | 1.0 | - | 0 |  |
| g. Key personnel (key managerial personnel, testing manager, quality assurance manager) shall have thorough understanding of quality assurance documents. | | | | 1.0 | - | 0 |  |
| h. A procedure shall be established to set laboratory personnel free from any undue pressures from outside which may affect results of testing activities. | | | | 1.0 | - | 0 |  |
| **2. Education and training (3 points)** | | | |  | | | |
| Prerequisite | | A procedure shall be documented for provision of education and training (including routine training) necessary to carry out testing activities. | | □ satisfactory □ unsatisfactory | | | |
| a. Education and training opportunities shall be available to laboratory personnel. | | | | 1.0 | - | 0 |  |
| b. An annual education/training plan for managerial/testing personnel shall be established, and relevant data shall be recorded and retained. | | | | 1.0 | - | 0 |  |
| c. Any changes made to an education plan shall be documented and properly managed (if applicable). | | | | 1.0 | - | 0 |  |
| 3. **Quality assurance documents (7 points)** | | | |  | | | |
| Prerequisite | Quality assurance documents shall be retained to ensure the accuracy and reliability of test results produced. | | | □ satisfactory □ unsatisfactory | | | |
| a. Any implementation, amendment, or revocation of quality assurance documents shall be approved by an authorized person, and up-to-date documents shall be retained and readily available. | | | | 1.5 | - | 0 |  |
| b. Details and date of enactment, amendment, and revocation of quality assurance documents shall be recorded and retained. | | | | 1.0 | - | 0 |  |
| c. Quality assurance documents shall be periodically reviewed at least once every year to ensure continuing suitability, and the latest modifications made to MFDS’s regulations and policies shall be reflected in the quality assurance documents. | | | | 1.5 | - | 0 |  |
| d. Preventive measures shall be established in advance in case of an error resulting from invalid and/or obsolete quality assurance documents. | | | | 1.5 | - | 0 |  |
| e. Quality assurance documents shall be readily available to key managerial and testing personnel. | | | | 1.5 | - | 0 |  |
| **4. Document and record control (4 points)** | | | |  | | | |
| Prerequisite | The retention period of testing records shall be the same as that of testing reports. | | | □ satisfactory □ unsatisfactory | | | |
| a. When any modification is made to documents or records relating to testing activities, such changes shall be clearly marked, initialed, dated and recorded in detail. | | | | 1.0 | - | 0 |  |
| b. All records and relevant documents shall be legible and easily understandable. | | | | 1.5 | - | 0 |  |
| c. All records shall be held secure and in confidence. | | | | 1.5 | - | 0 |  |
| **5. Purchasing of supplies (1 point)** | | | |  | | | |
| a. A procedure for purchase, reception and storage of laboratory supplies used in testing activities shall be established and followed. | | | | 0.5 | - | 0 |  |
| b. Technical details of laboratory supplies shall be reviewed in prior to purchasing that may affect the reliability of test results. | | | | 0.5 | - | 0 |  |
| **Ⅱ. Facilities and equipment** | | | |  | | | |
| **1. Facilities and environment (3 points)** | | | |  | | | |
| a. The laboratory shall have adequate facilities and environment for testing activities to minimize interference that may affect the reliability of test results. | | | | 0.5 | - | 0 |  |
| b. Where necessary, there shall be effective separation between neighboring areas to prevent cross contamination. | | | | 0.5 | - | 0 |  |
| c. Chemicals, infectious materials, high voltage equipment, etc. shall be separated and stored properly. | | | | 0.5 | - | 0 |  |
| d. Environmental conditions (humidity, air ventilation and lighting) shall be documented and properly maintained. | | | | 1.0 | - | 0 |  |
| e. A testing area shall be designated to prevent interference with test results, and a procedure for control of access and use of the areas shall be established and followed. | | | | 0.5 | - | 0 |  |
| **2. Equipment and apparatus (8 points)** | | | |  | | | |
| Prerequisite | Each item of equipment and apparatus used for testing shall be uniquely identified and its use shall be kept documented. | | | □ satisfactory □ unsatisfactory | | | |
| a. A procedure for calibration and inspection of testing equipment/ apparatus shall be established. | | | | 1.0 | 0.5 | 0 |  |
| b. SOP for testing equipment shall be established. | | | | 1.0 | 0.5 | 0 |  |
| c. A person shall be assigned to be in charge of each testing equipment and apparatus. | | | | 1.0 | - | 0 |  |
| d. Testing equipment shall be regularly inspected and such events shall be recorded. | | | | 2.0 | 1.0 | 0 |  |
| e. When a malfunction of testing equipment is detected, necessary maintenance or repair work shall be performed, and such events shall be documented and retained (if applicable). | | | | 1.0 | - | 0 |  |
| f. Equipment and apparatus used for testing shall be capable of achieving the accuracy required. After each use, equipment and apparatus shall be cleaned, sterilized, and washed thoroughly to maintain its optimal condition. | | | | 1.0 | - | 0 |  |
| g. If a piece of equipment is taken out of service for a long period of time, it shall be isolated to prevent its use or clearly labeled or marked as being out of service. | | | | 1.0 | - | 0 |  |
| **3. Storage facility (2 points)** | | | |  | | | |
| a. Test materials shall be uniquely identified and kept in a place free from any contamination. | | | | 0.5 | - | 0 |  |
| b. A storage facility shall be available to prevent contamination or deterioration of test materials, and to protect their integrity. | | | | 0.5 | - | 0 |  |
| c. Reagents shall be properly stored in a separate place to prevent cross contamination. | | | | 0.5 | - | 0 |  |
| d. Proper protective conditions shall be available in order to protect integrity of test reagents, etc. | | | | 0.5 | - | 0 |  |
| **4. Safety control of laboratory and facilities (5 points)** | | | |  | | | |
| a. Harmful chemical substances, high pressure gas and hazardous substances, etc. shall be used and stored in compliance with pertinent regulations. | | | | 1.0 | - | 0 |  |
| b. Precautionary and preventive action plans for laboratory safety accidents shall be established and necessary equipment and facilities (shower, fire extinguisher, etc.) for laboratory safety shall be readily available. | | | | 1.0 | - | 0 |  |
| c. A procedure for laboratory safety management shall be retained and followed. | | | | 1.0 | - | 0 |  |
| d. Protective gears to prevent laboratory personnel from any potential harm shall be provided and used in testing activities. | | | | 1.0 | - | 0 |  |
| e. An annual education for laboratory safety shall be provided. | | | | 1.0 | - | 0 |  |
| **5. Waste control (2 points)** | | | |  | | | |
| a. Adequate facilities shall be available to process chemical waste. | | | | 1.0 | - | 0 |  |
| b. Any activities involving waste collection, storage, handling, and transportation shall be performed in compliance with pertinent regulations of waste control. | | | | 1.0 | - | 0 |  |
| **Ⅲ. Testing and inspection** | | | |  | | | |
| **1. Handling of test materials (3 points)** | | | |  | | | |
| Prerequisite | | | Each test material shall be uniquely identified upon receipt. | □ satisfactory □ unsatisfactory | | | |
| a. Test materials shall be properly transported (only applicable when the sampling process is involved). | | | | 0.5 | - | 0 |  |
| b. The details, condition and amount of test materials shall be confirmed upon receipt. | | | | 0.5 | - | 0 |  |
| c. A procedure for handling test materials shall be documented and followed. | | | | 0.5 | - | 0 |  |
| d. Test materials shall be kept from any contamination or damages and details of storage, disposal and return of test materials shall be all documented. | | | | 1.0 | - | 0 |  |
| e. A procedure shall be established for test materials with abnormalities or departures from normal conditions and specifications, and such test materials shall be handled in compliance with the procedure. | | | | 0.5 | - | 0 |  |
| **2. Reagents and materials (7 points)** | | | |  | | | |
| Prerequisite | | | A procedure to identify and manage reagents (including kits), mediums, reference materials (including standard solutions), etc. shall be established and a testing person shall be assigned to perform the task. | □ satisfactory □ unsatisfactory | | | |
| a. Verification of reference materials (including standard solutions) used in testing activities shall be conducted periodically. (Verification of reference materials within its expiration dating may be exempted) (“Not applicable” is only an appropriate answer for medical device testing laboratories). | | | | 1.5 | 0.5 | 0 |  |
| b. Name, purity, concentration, storage condition, and expiration date of reagents, mediums, and reference materials shall be legibly labeled and managed (“Not applicable” is only an appropriate answer for medical device testing laboratories). | | | | 1.5 | 0.5 | 0 |  |
| c. Solutions made shall be labeled legibly with name of reagent, manufacturer, manufacturing date, method, and expiration date. | | | | 1.0 | - | 0 |  |
| d. Deteriorated or expired reagents shall be processed in accordance with pertinent procedures (“Not applicable” is only an appropriate answer for medical device testing laboratories). | | | | 0.5 |  |  |  |
| e. In-house made microorganism mediums shall be checked and managed periodically. | | | | 1.5 | - | 0 |  |
| f. Distilled water used in making reagents for testing activities shall be managed (“Not applicable” is only an appropriate answer for medical device testing laboratories). | | | | 1.0 | - | 0 |  |
| **3. Testing/inspection activities and control of records(10 points)** | | | |  | | | |
| Prerequisite | | | Testing and inspection methods shall be in compliance with pertinent regulations. | □ satisfactory □ unsatisfactory | | | |
| A procedure for documentation and management of testing basic data shall be established and basic data shall include the following;  Name of reagents, name of testing manager/testing personnel, date of testing (including completing date), testing scopes, testing material identification number, name of test methods used or quality assurance document number, analytical (measurement) conditions, analytical (measurement) equipment and its management number, reference material management number and records of standard solution production, amount of test material collection, a procedure for making test sample solution and its final volume, measurement values for test materials, reference materials and test sample solutions, calculation and final results, results of blank test (if necessary), recovery rate (if necessary), LOD or LOQ (if necessary) | □ satisfactory □ unsatisfactory | | | |
| All records obtained during testing activities shall be documented clearly and stored in such a way that they are readily retrievable to prevent damage and loss. | □ satisfactory □ unsatisfactory | | | |
| A records management system shall be established to store and retain all records of testing activities, including changes in test results. | □ satisfactory □ unsatisfactory | | | |
| In the circumstances where hand writing is necessary for particular test scopes, including testing on microorganism, photographs, lab notebooks and other relevant information that demonstrate the process or results of testing activities shall be documented and retained. | □ satisfactory □ unsatisfactory | | | |
| a. Testing activities shall be documented and conducted in accordance with procedures and regulations | | | | 2.0 | - | 0 |  |
| b. Reagents, reference materials, and equipment used in testing activities shall be appropriate for the intended use. | | | | 2.0 | - | 0 |  |
| c. Test results shall be accurately recorded. | | | | 1.0 | - | 0 |  |
| d. The laboratory shall have procedures to protect and back-up records of electronic documents (including raw data) and to prevent unauthorized access to or amendment of these records. | | | | 1.0 | - | 0 |  |
| f. When using all or part of the output from analytical**·** measurement equipment as raw data, the output shall be labeled with a unique identification number, name of testing personnel, date of testing, etc. in the margin. | | | | 1.0 | - | 0 |  |
| g. When a computerized on-line system is used for processing, recording, transmitting and storing test data, the laboratory shall ensure that software used shall be suitably validated as being adequate for use. (When the laboratory uses the LIMS, laboratory information management system, provided by the Ministry of Food and Drug Safety of Korea to record and store test data, such conditions may be exempted) | | | | 1.0 | - | 0 |  |
| **4. Reporting of testing and inspection results (7 points)** | | | |  | | | |
| prerequisite | | | Upon completion of testing, testing personnel shall report the results in a test report. | □ satisfactory □ unsatisfactory | | | |
| Test reports shall be designed to minimize the possibility of misunderstanding and misuse. |
| a. Upon completion of testing, testing personnel shall confirm whether the testing was carried out properly in accordance with pertinent regulations and procedures. | | | | 3.0 | 1.0 | 0 |  |
| b. When an abnormality in test results occurs, appropriate measures shall be taken and details shall be recorded (if applicable). | | | | 1.5 | - | 0 |  |
| c. In case when conditions that may influence the reliability of test results occur repeatedly, details and preventive measures shall be recorded in detail (if applicable). | | | | 1.5 | - | 0 |  |
| **Ⅳ. Quality assurance** | | | |  | | | |
| **1. Quality assurance activities (5 points)** | | | |  | | | |
| prerequisite | | | The laboratory shall prepare documented quality assurance procedures and perform testing activities in accordance with the quality assurance procedures. | □ satisfactory □ unsatisfactory | | | |
| a. Quality assurance activities shall be conducted by a quality assurance manager or quality assurance personnel who are independent of the testing activities to be conducted. | | | | 5.0 | 3.0 | 0 |  |
| **2. Internal audit (5 points)** | | | |  | | | |
| prerequisite | | | The laboratory shall conduct an internal audit at least once every year. | □ satisfactory □ unsatisfactory | | | |
| a. An annual plan for internal audits shall be established. | | | | 1.0 | - | 0 |  |
| b. An internal audit shall be conducted as required by the schedule and its findings shall be reported and retained. | | | | 1.0 | - | 0 |  |
| c. When internal audit findings show the need for corrective actions, the corrective actions taken and verification review, including cause analysis, shall be reported to key managerial personnel and relevant data shall be retained. | | | | 2.0 | - | 0 |  |
| d. Corrective actions including cause analysis shall be taken when key managerial personnel order a follow-up action and relevant data shall be retained and managed. | | | | 1.0 | - | 0 |  |
| **3. Corrective actions and follow-up activities (4points)** | | | |  | | | |
| prerequisite | | | The laboratory shall establish corrective action procedures for each of the following events;  1) In the event that nonconforming work or departures from the quality assurance scheme included within the quality assurance scheme have been identified  2) In the event that there has been a warning from an administrative government body  3) In the event that an objection has been arisen regarding appropriateness of test methods used  4) Internal audit findings of nonconforming work (if applicable) | □ satisfactory □ unsatisfactory | | | |
| a. The laboratory shall take corrective actions for nonconforming works as follows (if applicable).  1) Evaluation of the significance of the nonconforming work shall be conducted.  2) Laboratory personnel shall decide whether to resume testing after reviewing the results of corrective actions including cause analysis. | | | | 2.0 | - | 0 |  |
| b. When a corrective action has been taken, verification of such activity shall be done and relevant records shall be documented and retained. | | | | 2.0 | - | 0 |  |
| 4. **Proficiency Testing (5 points)** | | | |  | | | |
| prerequisite | | | Testing personnel shall participate in intra- and inter-laboratory proficiency testing programs, including the ones conducted by the Mister of the MFDS at least once every other year. | □ satisfactory □ unsatisfactory | | | |
| a. An annual plan of proficiency testing programs shall be established and conducted accordingly. | | | | 2.0 | - | 0 |  |
| b. Complete reports of results obtained as the records output of intra- and inter-laboratory proficiency testing programs shall be reported, evaluated, retained and maintained. | | | | 2.0 | - | 0 |  |
| c. When it deems to have corrective actions, results shall be documented and retained in accordance with corrective action procedures (if applicable). | | | | 1.0 | - | 0 |  |
| **5. Estimation and review of measurement uncertainty (3points)** | | | |  | | | |
| a. The laboratory shall establish a procedure in regarding with estimation of measurement uncertainty. | | | | 1.0 | - | 0 |  |
| b. Measurement uncertainty method and procedure shall comply with international standards or equivalent. | | | | 0.5 | - | 0 |  |
| c. Key equipment shall be used when estimating measurement uncertainty and continually maintained. | | | | 0.5 | - | 0 |  |
| d. All sources of measurement uncertainty shall be appropriately reviewed. | | | | 0.5 | - | 0 |  |
| e. When there has been a departure from the standards and specification or a request by a relevant government body or a client, measurement uncertainty shall be estimated and reported (if applicable). | | | | 0.5 | - | 0 |  |
| **6. Traceability (4 points)** | | | |  | | | |
| a. The laboratory shall establish procedures to maintain traceability. | | | | 1.0 | - | 0 |  |
| b. An annual calibration plan for traceability maintenance shall be established and followed, and records of such events shall be maintained. | | | | 1.0 | - | 0 |  |
| c. The laboratory shall use adequate methods to obtain traceability. | | | | 1.0 | - | 0 |  |
| d. Test results shall be traceable to the International system of units (the SI). When it is set forth in a regulation, traceability is not required. | | | | 1.0 | - | 0 |  |
| **7. Verification and validation of test methods (4 points)** | | | |  | | | |
| a. The laboratory shall establish a procedure to verify and validate test methods. | | | | 1.0 | - | 0 |  |
| b. Test methods used in testing activities shall be verified and validated. | | | | 1.5 | - | 0 |  |
| c. Verification and validation of test methods which utilize analytical equipment shall be conducted with the use of certified reference materials (CRM), reference materials (RM), or equivalent reference materials. | | | | 1.0 | - | 0 |  |
| d. Laboratory personnel shall keep all instructions, standards, and reference data relevant to testing activities up-to-date, and be aware of amendments made to regulations periodically. | | | | 0.5 | - | 0 |  |
| **<Point conversion>** | | | |  | | | |
| **Total points earned** | | | |  | | | |
| **Difference in total points and total points earned** | | | |  | | | |
| **Converted points : {total points earned / (100 – difference in total points and total points earned) } x 100** | | | |  | | | |