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| **No.** | **Requirement** | **Compliance** | **Quality Management System** (Reference Documents) | **Objective Evidence***(Provide supporting information to prove implementation; describe the observations; note which records were reviewed.)* |
| 5.3.2 |  | **OK****NC****OFI** | **Action** | **Priority** |  |  |
| a) | The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and **procedures** or where thy influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.  |  |  |  |  |  |
| b) | Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations. |  |  |  |  |  |
| 5.3.3 | There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination. |  |  |  |  |  |
| 5.3.4 | Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances. |  |  |  |  |  |
| 5.3.5 | Measures shall be taken to ensure good housekeeping in the laboratory. Special **procedures** shall be prepared where necessary. |  |  |  |  |  |
| **5.4** | **Test and calibration methods and method validation** |
| 5.4.1 | General |
| a) | The laboratory shall use appropriate methods and **procedures** for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data. |  |  |  |  |  |