WHO GLOBAL BENCHMARKING TOOL (GBT) FOR EVALUATION OF NATIONAL REGULATORY SYSTEM OF MEDICAL PRODUCTS

LABORATORY TESTING (LT): INDICATORS AND FACT SHEETS

Revision VI version 1
November 2018
**Function:**

<table>
<thead>
<tr>
<th>07- LABORATORY TESTING (LT)</th>
</tr>
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</table>

**Description:**

The laboratory testing regulatory function is intended to ensure that the National Regulatory Authority (NRA) is able to assess the quality of medical products by performing quality tests on them in certain situations. For example, this testing can be a requirement to corroborate manufacturer’s test results as a part of the evaluation for marketing authorization or for a variation to a marketing authorization. Testing can be a requirement for lot release for certain products depending upon national regulations. Testing also may be needed for products for which there has been a complaint or a report or for products that are under investigation due to an adverse event. As part of the market surveillance function, laboratory testing is utilized for checking and confirming the quality of medical products placed on the market and for detecting substandard and falsified medical products. In order to do this product testing, the NRA must have access to suitable laboratories where these tests can be performed.

If a country is able to provide all the resources needed, a laboratory under the responsibility of the NRA or a governmental laboratory represents the best choice. Commonly, this governmental laboratory is a national control laboratory (NCL). As an alternative option, the regulatory system may have access to external laboratories, either inside or outside the country, to perform the required tests on behalf on the NRA. When external laboratories are used, regulatory decisions and actions remain at the discretion of the NRA and the NRA retains accountability.

A well-functioning laboratory for medical products testing is an important resource for the national regulatory system. The staff generally has expertise in different life science disciplines and can help in other regulatory activities, for example, the assessment and review of marketing authorization applications and the review of clinical trial data.

When the regulatory laboratory testing activities are decentralized to one or more internal or external laboratories, the NRA or NCL must ensure that a continuous information exchange mechanism is established so the central authority can issue guidance and the decentralized entity can report back with the information.
needed for making decisions.

<table>
<thead>
<tr>
<th>Indicator:</th>
<th>LT01 Legal provisions, regulations and guidelines required to define the regulatory framework of laboratory testing activities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective:</td>
<td>The objective of this indicator is to ensure that laboratory testing activities are supported by a comprehensive set of legal provisions, regulations and guidelines which provide the necessary mandate to implement all activities related to this regulatory function.</td>
</tr>
<tr>
<td>Category:</td>
<td>01. Legal provisions, regulations and guidelines</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>LT01.01: There are legal provisions to establish a national quality control laboratory (NCL) to perform quality control (QC) testing, and/or to authorize the National Regulatory Authority (NRA) to sub-contract the required testing services.</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>1</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that legal provisions exist and are enacted for establishing a NCL that is responsible for controlling medical products and/or for authorizing the national authority to establish an operational agreement with an independent external laboratory. In the latter case, the independent laboratory may be inside or outside the- country. The assessor should verify that legal provisions exist and are enacted that authorize the NCL to perform QC testing and to issue official results of these tests.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure the existence of legal provisions, regulations or other official government publications that establish the laboratory testing function and that provide the mandate for the responsible entity to actually implement these activities.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Legal provisions for establishing the laboratory testing function through an established NCL and/or authorizing the NRA to have an operational agreement with an independent laboratory. Legal provisions authorizing the NCL to issue official results of the</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review:</td>
</tr>
</tbody>
</table>
1. Legal provisions establishing the laboratory testing function;
2. Regulations or other official government publication establishing the laboratory testing function;
3. Legal provisions authorizing the NCL to perform testing and officially issue results of the same;
4. Regulations or other official government publication establishing NRA’s responsibilities when sub-contracting the required testing services.

**References:**
2. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)

**Framework:** Structure/Foundation/Input

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** There is no legal basis, regulation, or other official government publication establishing an NCL to perform QC testing, authorizing the NRA to sub-contract the required testing services, or authorizing the NCL to issue official results.
- **ONGOING IMPLEMENTATION (OI):** Although there is no legal basis, demonstrable steps have been taken towards establishing one.
- **PARTIALLY IMPLEMENTED (PI):** The legal basis was recently established and implementation is underway.
- **IMPLEMENTED (I):** There is a legal basis authorizing the NRA to establish a national control laboratory that has the duties and responsibilities required to perform this function or to sub-contract the required testing services.

**Limitations and remarks:**
Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

**Sub Indicator:**
**LT01.02: Legal provisions and regulations allow the NRA to recognize and use laboratory testing-related decisions, reports or information from other NRAs or regional and international bodies.**

**Maturity Level:**
1

**Description:**
The assessor should verify that legal provisions and regulations allow the NRA and the NCL to recognize and /or rely on laboratory decisions, data and information from NCLs of other countries or regional and international institutions.

**Objective:**
The objective of this sub-indicator is to ensure that legal provisions and regulations provide the necessary mandate for the NCL to
implement regulatory recognition and/or reliance.

**Requirement:**
Legal provisions and regulations allowing the reliance on and/or recognition of regulatory decisions in the area of laboratory testing.

**Evidence to review:**
The assessor should ask for and review:
1. Legal provisions allow reliance on and/or recognition of other NCL regulatory decisions;
2. Agreements and memoranda of understanding with other NCLs to apply reliance on and/or recognition of regulatory decisions;
3. Documentation providing the rationale and justification for reliance on and/or recognition of other NCL regulatory decisions.
4. Examples of communication with other NCLs;
5. Examples of NRA consideration of decisions, information and data from other NCLs;
6. If legal provisions prevent the NCL from relying on and/or recognizing other NCLs regulatory decisions, examples of any impact this condition may have in the laboratory testing function.

**References:**

**Framework:**
Structure/Foundation/Input

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** There is no evidence of legal provisions or regulations allowing reliance on and/or recognition of other NCL regulatory decisions.
- **ONGOING IMPLEMENTATION (OI):** The NRA is preparing to draft such legal provisions and regulations, but there is no evidence of results from such activities.
- **PARTIALLY IMPLEMENTED (PI):** The legal basis was established recently and is at the implementation stage, so this practice is not consolidated yet.
- **IMPLEMENTED (I):** The NRA has such legal provisions and regulations and also consistently maintains documentation of the results of related activities over time.
- **NA:** When the legal provisions prevent reliance on and/or recognition of other NCL regulatory decisions.

**Limitations and remarks:**
In some countries legal provisions may prevent the NCL from relying on and/or recognizing other NCL regulatory decisions; in this case the sub-indicator may be considered as not applicable.
**Indicator:** LT02 Arrangement for effective organization and good governance.

**Objective:**
The objective of this indicator is to ensure the implementation of effective organization and good governance practices at the entities responsible for laboratory testing activities which, in turn, contribute to effective and efficient functioning of this regulatory function.

**Category:** 02. Organization and governance

**Sub Indicator:** LT02.01: There is a defined organizational structure with clear responsibilities to conduct laboratory testing activities.

**Maturity Level:** 2

**Description:**
The assessor should identify the organization designated to establish, implement or maintain the laboratory testing regulatory function, as well as the specific organizational structure taking on the different relevant activities. Responsibilities, duties and roles of these structures should be clearly defined and documented. If more than one structure is involved, the assessor should check the ways and approaches by which coordination among these structures is taking place. When some of the activities of the NCL can be performed by laboratories of other national or international institutions, these institutions must not have any conflict of interests.

**Objective:**
The objective of this sub-indicator is to ensure effective organization and good governance of laboratory testing of medical products and that these activities are taken over by defined structures with clear roles and responsibilities.

**Requirement:** Defined structure and clear responsibilities

**Evidence to review:**
The assessor should ask for and review:
1. Organization chart of the organizations responsible for the implementation of laboratory testing activities along with identification of the particular structures implementing the function.
2. Documentation clarifying roles and responsibilities of the organizational structures implementing laboratory testing activities. This may include administrative decrees, terms of reference, and other relevant documents.
3. Documented contract with laboratories of other national or international institutions, when applicable, establishing responsibilities of each party and stating there is no conflict of interest.
### References:

| Framework: | Structure/Foundation/Input |

### Rating Scale:

<table>
<thead>
<tr>
<th>NOT IMPLEMENTED (NI):</th>
<th>There are no documents available establishing a defined structure with clear responsibilities to conduct laboratory testing activities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONGOING IMPLEMENTATION (OI):</td>
<td>Although there are no approved documents, there is evidence that they are being prepared.</td>
</tr>
<tr>
<td>PARTIALLY IMPLEMENTED (PI):</td>
<td>Such documents were approved recently (e.g. less than one year ago).</td>
</tr>
<tr>
<td>IMPLEMENTED (I):</td>
<td>Such documents were approved some time ago and there has already been a cycle of internal or external audits (with or without accreditation) or a system review.</td>
</tr>
</tbody>
</table>

### Limitations and remarks:

<table>
<thead>
<tr>
<th>Limitations and remarks:</th>
<th>In some countries there may be a centralized NCL; in this case the assessor should look at roles and responsibilities within the structure implementing the laboratory testing function.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Scoring this sub-indicator as &quot;not applicable NA&quot; is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).</td>
</tr>
</tbody>
</table>

### Sub Indicator:

| Sub Indicator: | LT02.02: Documented procedures are implemented to ensure the involvement and contributions of the NCL to support regulatory oversight. |

### Maturity Level:

| Maturity Level: | 3 |

### Description:

| Description: | The assessor should verify the existence of written documentation defining the responsibilities and roles of the NCL for its involvement and contribution to other regulatory functions. Examples of the responsibilities and roles include, but are not limited to, providing technical and scientific input before and after a product receive marketing authorizations (MAs), contributing to clinical trials authorizations, participating in regulatory inspections, performing quality testing on samples collected within the context of the market surveillance programme, detecting substandard and falsified medical products, contributing to analyses of vigilance data, and providing technical advice for national lot release. |

### Objective:

| Objective: | The objective of this sub-indicator is to ensure that standard procedures are implemented for effective involvement and contributions of the NCL in support of other regulatory functions. |

### Requirement:

| Requirement: | Procedures relevant to involvement and contributions of the NCL to other regulatory functions. |
## Evidence to review:

The assessor should ask for and review:
1. Standard procedures and other documentations detailing roles and responsibilities of the NCL with respect to its contribution to other regulatory functions and to regulatory oversight as applicable.
2. Records demonstrating active involvement and contribution of the NCL to other regulatory functions.

### References:

1. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)

### Framework:

Structure/Foundation/Input

### Rating Scale:

- **NOT IMPLEMENTED (NI):** There are no documented procedures or results that demonstrate the NCL involvement in and contributions to other regulatory functions or to regulatory oversight.
- **ONGOING IMPLEMENTATION (OI):** Although there are no approved documents, there is evidence that they are being prepared.
- **PARTIALLY IMPLEMENTED (PI):** Such documents were approved recently (e.g. less than one year ago).
- **IMPLEMENTED (I):** Such documents were approved some time ago (at least one year ago), and there has already been a cycle of internal or external audits (with or without accreditation) or system review.

### Limitations and remarks:

Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

### Indicator:

**LT03 Laboratory activities implemented as per well-established plans and policies according a Quality Management System (QMS)**

### Objective:

The objective of this indicator is to ensure that the laboratory establishes, implements, and maintains a Quality Management System appropriate to the scope of its activities. It is essential to have clear policies and plans in place for effective and reliable laboratory operations. Laboratory policies should cover a range of activities, including calibration and qualification of equipment, validation of testing methods, establishment of reference standards, and performance of testing and retesting. In addition, policies should be in place that cover the establishment, qualification, distribution, and use of reference materials for laboratory testing, including their calibration against international reference materials or standards, when available. The policies should cover the various types of reference materials used in the laboratory, e.g., primary standards, working standards, and official national or international reference preparations.

### Category:

03. Policy and strategic planning
<table>
<thead>
<tr>
<th>Sub Indicator:</th>
<th>LT03.01: Documented and implemented policy for testing exists that is based on the product’s risk.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should identify documented evidence that demonstrates there is a risk-based assessment to support products to be tested and the testing to be done. Market surveillance methodologies, such as field screening technologies, can serve as a basis for prioritizing products for testing in the laboratory.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure efficient use of resources to address products of concern for public health such as substandard and falsified medical products.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Prioritization of testing activities using a risk-based approach.</td>
</tr>
</tbody>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. Documents outlining the information used to support decisions.  
2. Documentation of the criteria used to arrive at decisions, and evidence confirming these are risk-based. |
| References: | 1. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)  
3. WHO good practices for pharmaceutical microbiology laboratories (34) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)  
| Framework: | Structure/Foundation/Input |
| Rating Scale: | NOT IMPLEMENTED (NI): There is no documented evidence that a risk-based testing policy exists  
ONGOING IMPLEMENTATION (OI): Although there are no approved documents, there is evidence that they are being prepared.  
PARTIALLY IMPLEMENTED (PI): Such documents were approved recently (e.g. less than one year ago).  
IMPLEMENTED (I): Such documents were approved some time ago and there has already been a cycle of internal or external audits |
Limitations and remarks:

Testing should be based on the products’ characteristics. The choice of tests and the extent of testing should be based on risk management principles.

Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

<table>
<thead>
<tr>
<th>Sub Indicator:</th>
<th>LT03.02: Documented and implemented policy exists on the validation, verification and transfer of analytical procedures.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
</tbody>
</table>
| Description: | The assessor should verify there is a policy on validation, verification and transfer of analytical procedures, which establishes that all procedures should be validated. This policy should include pharmacopoeial procedures, manufacturer’s procedures, NCL procedures, and other procedures used to support the regulatory oversight function.

The assessor should verify that the NCL is using validated analytical methodologies that ensure reliable results. If validated methods are transferred into the NCL from a manufacturer or any other laboratory, the assessor should verify that the transferred procedure was re-validated, and that supporting documentation is available. The process by which these methodologies were validated should be described, and documentation should identify the validation parameters that were evaluated. The validation parameters should be selected based on the category of analysis. Documentation should also identify the required validation parameters when pharmacopoeial methodologies are used or when methods are transferred.

To evaluate this, the assessor should check and review protocols and reports of test method validations. |
| Objective: | The objective of this sub- indicator is to ensure that policies and procedures that cover test method validation, verification, and transfer are available and will ensure reliability of laboratory test results. |
| Requirement: | Test method validation and verification protocols and reports.
Standard procedures for transfer of validated test methods from the manufacturer or other laboratories. |
| Evidence to review: | The assessor should ask for and review:
1. Policies and procedures for validation and verification of test methods and transfer of validated test methods;
2. List of transferred validated test methods;
3. Examples of documentation of validation or revalidation of transferred test methods;
4. List of validated test methods; |
5. Examples of validation protocols for selected test methods;
6. Examples of validation reports of selected test methods.

References:

1. WHO good manufacturing practices for pharmaceutical products: main principles (51)
   (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)
3. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and
   http://apps.who.int/medicinedocs/en)
4. Quality Management (QM) documents, European Directorate for the Quality of Medicines and Healthcare (EDQM), Council of
5. WHO good practices for pharmaceutical microbiology laboratories (34) (http://digicollection.org/whoqapharm/p/about and
   http://apps.who.int/medicinedocs/en)
6. Validation of analytical procedures, European Directorate for the Quality of Medicines and Healthcare (EDQM), OMCL Network
   of the Council of Europe, PA/PH/. MCL (13) 82 2R (106)
   (https://www.edqm.eu/medias/fichiers/validation_of_analytical_procedures_paphomcl_13_82_2r.pdf)
7. WHO International Reference Preparations Catalogue (103) (http://www.who.int/bloodproducts/catalogue/en/)
8. WHO manual for the establishment of national and other secondary standards for vaccines. WHO/IVB/11.03 (136)
   (http://apps.who.int/iris/bitstream/10665/70669/1/WHO_IVB_11.03_eng.pdf)
9. WHO manual for the preparation of secondary reference materials for in vitro diagnostic assays designed for infectious disease
   nucleic acid or antigen detection: calibration to WHO International Standards (137)
   (http://www.who.int/entity/bloodproducts/norms/SecStandManWHO_TRS_1004_web__Annex_6.pdf?ua=1)

Framework:

Structure/Foundation/Input

Rating Scale:

NOT IMPLEMENTED (NI): There is no documented evidence that a policy on the validation, verification, and transfer of analytical
procedures exist.
ONGOING IMPLEMENTATION (OI): Although there are no approved documents, there is evidence that they are being prepared.
PARTIALLY IMPLEMENTED (PI): Such documents were approved recently (e.g. less than one year ago).
IMPLEMENTED (I): Such documents were approved some time ago (at least one year ago), and there has already been a cycle of
internal or external audits (with or without accreditation) or system review.
Limitations and remarks: In this context, “verification” refers to the verification of compendial procedures, namely, the demonstration of acceptable performance under the conditions in which the procedure is used. Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

<table>
<thead>
<tr>
<th>Sub Indicator:</th>
<th>LT03.03: A policy is in place to establish or qualify all reference standards used in laboratory testing activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify the existence of a national policy for establishment of all reference standards used in laboratory activities. The NCL may set a policy not to develop and establish reference standard materials, and instead, rely on reference standards developed by other entities (e.g. World Health Organization (WHO) or other NCLs). However, in this case, the policy should explain how the reliability of those reference standards that are used is ensured by the laboratory staff. If there is a policy to establish national reference standards, the assessor should review the policy in detail including guidance that it provides related to methodologies and criteria for establishing such national reference standards and for ensuring traceability to international reference standards. In all cases, the policy for establishment or qualification of national reference standards (if any) should be based on relevant WHO guidelines (listed in the reference section) or other internationally accepted standards and practices. In addition, the assessor should verify that a suitable system is in place for using reference standards in the laboratory. In addition, the assessor should verify that the policy includes plans and procedures for replacement or replenishment of reference standards in case the standards have exhausted. Furthermore, if an NCL is supplying national standards to users nationwide (i.e., as a major responsibility), there should be plans and procedures for distribution and monitoring the use of the standards. The reference standards should be identified, recorded and properly stored. An individual or entity within the NCL should be assigned to monitor their use and to verify that they used appropriately.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure that specific policies are in place with respect to establishment and maintenance of reference standard materials. Reliable reference standard materials, in turn, contribute to effective laboratory testing activities.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Policy for establishment or qualification of all reference standards used in laboratory activities.</td>
</tr>
</tbody>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. Policy for establishment or qualification of all reference standards used in laboratory;  
2. Implemented procedures for validation or bridging studies and for implementation and use of control charts;  
3. Examples of reference standards used in the laboratory, if any, along with the documentation supporting qualification (including |
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| References: | 1. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)
5. WHO International Reference Preparations Catalogue (103) (http://www.who.int/bloodproducts/catalogue/en/)
6. WHO manual for the establishment of national and other secondary standards for vaccines. WHO/IVB/11.03 (136) (http://apps.who.int/iris/bitstream/10665/70669/1/WHO_IVB_11.03_eng.pdf)
7. WHO manual for the preparation of secondary reference materials for in vitro diagnostic assays designed for infectious disease nucleic acid or antigen detection: calibration to WHO International Standards (137) (http://www.who.int/entity/bloodproducts/norms/SecStandManWHO_TRS_1004_web_Annex_6.pdf?ua=1) |
| Framework: | Structure/Foundation/Input |
| Rating Scale: | NOT IMPLEMENTED (NI): There is no documented evidence of a policy in place to establish or qualify all reference standards used in the laboratory.
ONGOING IMPLEMENTATION (OI): Although there are no approved documents, there is evidence that they are being prepared.
PARTIALLY IMPLEMENTED (PI): Such documents were approved recently (e.g. less than one year ago).
IMPLEMENTED (I): Such documents were approved some time ago (at least one year ago), and there has already been a cycle of internal or external audits (with or without accreditation) or system review. |
| Limitations and remarks: | |
| Sub Indicator: | LT03.04: Documented and implemented procedures exist for handling atypical or out-of-specification (OOS) results, including a retest policy. |
| Maturity Level: | 2 |
Description: The assessor should verify the existence and implementation of a re-testing policy in case of OOS test results. The policy should initially define OOS and set clear rules to handle these results. The assessor should check the policy and make sure it considers the properties of different test methods including their variabilities and sensitivities (e.g. qualitative or quantitative methods or in vitro or in vivo methods).

The assessor should verify the establishment and implementation of standard procedures for handling events of non-compliance with pre-set specifications. Procedures should provide comprehensive guidance on how to report such non-compliant events and how to communicate and report these cases to supervisors or higher-level officials in the laboratory. In addition, the procedures should provide guidance for notifying the manufacturer and for meeting with its representatives, when necessary. Relevant procedures should cover notification of other departments or entities within the regulatory system. In all cases, assessor should check that a notice of non-compliance authorized by pre-assigned official is issued by the NCL.

The assessor should verify that procedures for the evaluation of test results and decision-making are available and enacted. The assessor should also confirm that relevant procedures provide guidelines on handling appeals against the decisions of the NCL.

Objective: The objective of this sub-indicator is to ensure that specific policies are in place that contribute to effective laboratory testing activities. In particular, a re-testing policy is required to ensure consistency in handling OOS test results.

Requirement: Standard procedures for dealing with and handling events of non-compliance. Re-testing policy is established and implemented. Standard procedures for evaluation of test results and decision-making.

Evidence to review: The assessor should ask for and review:
1. Policy for handling OOS test results.
2. List of OOS test results.
3. Examples of documentation detailing the handling of selected OOS test results.
4. Standard procedures for dealing with and handling events of confirmed non-compliance of test results with pre-set specifications.
5. List of non-compliant events within a particular time interval (e.g. last year).
6. Example records of non-compliant (i.e., OOS) events along with their investigations and final decisions.
7. Standard procedures for evaluation of test results and for decision-making regarding compliance or non-compliance.
8. Example records for which test results were evaluated and for decisions made on compliance or non-compliance (i.e., for specific test methods that are being reviewed by the assessor).
9. Standard procedures for handling appeals against decisions made by the NCL.
10. List of appeals against NCL decisions within a particular time interval (e.g., last year).
11. Example records (i.e., for specific test methods that are being reviewed by the assessor) from selected cases in which the NCL decision was appealed.

**References:**

**Framework:**
Structure/Foundation/Input Process

**Rating Scale:**
- NOT IMPLEMENTED (NI): There is no documented evidence of a policy and procedures in place to handle atypical or OOS results and no evidence for a retesting policy.
- ONGOING IMPLEMENTATION (OI): Although there are no approved documents, there is evidence that they are being prepared.
- PARTIALLY IMPLEMENTED (PI): Such documents were approved recently (e.g. less than one year ago).
- IMPLEMENTED (I): Such documents were approved some time ago (at least one year ago), and there has already been a cycle of internal or external audits (with or without accreditation) or system review.

**Limitations and remarks:**
Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

**Indicator:**
**LT04 Human resources to perform laboratory testing activities.**

**Objective:**
The objective of this indicator is to ensure that all entities within an NRA are adequately resourced with a trained, experienced and skilled workforce that is empowered to fully perform the function of laboratory testing of medical products. This will ensure that medical products testing activities are performed in accordance with international best practices.

The objective of this indicator is to evaluate the human resource capacity of the entities with respect to the number of personnel, the skills and experience of the personnel, and the overall composition the workforce, with the goal of evaluating whether the workforce possesses the specific expertise required to perform the laboratory testing function.

**Category:**
Resources (HR, FR, infrastructure and equipment)

**Sub Indicator:**
**LT04.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform laboratory testing activities**

**Maturity Level:**
3
<table>
<thead>
<tr>
<th>Description:</th>
<th>The assessor should verify that the human resources assigned to perform laboratory testing activities should be sufficient with respect to numbers and competent with respect to the requisite skills, education, experience and training. There should be technical documents and standard operating procedures (SOPs) that provide guidance on the required background for laboratory testing activities and that consider the requirements for educational background, competencies, skills, experience, and training. The assessor should verify that the NRA estimated the number of staff required to effectively and efficiently perform laboratory testing function and that the NRA actually recruited that number. In addition, the assessor should verify that these competency requirements are well-established and maintained by the NRA. Metrics and statistics on the different activities performed as well as performance indicators can be used for estimating the adequacy of the number of the assigned staff. The assessor should also verify that the competency of the assigned staff is built, maintained and improved through recruitment as well as continuous on-the-job training.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure the existing human resources for laboratory testing is sufficient, in terms of numbers, experience, and specific competencies, to perform all the activities along the entire laboratory testing chain.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Sufficient number of competent human resources in charge of laboratory testing activities.</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review: 1. Evidence that the number of staff members involved in each of the documented activities along the entire laboratory testing process flow is adequate. 2. Evidence that the systems and structures are in place to ensure appropriate placement of staff with respect to competence and skills. 3. Evidence that the system and structures have been implemented. The documentation should include the records to verify that the staff competence is appropriate for the job requirements. 4. Evidence that the professional profiles of the human resources engaged in laboratory testing activities are appropriate with respect to education, skills, and expertise, to perform a particular function along the laboratory testing chain. Documentation should include a list of the requisite skills and training for each position. 5. Recruitment plan.</td>
</tr>
</tbody>
</table>
Framework: Structure/Foundation/Input

Rating Scale:  
- NOT IMPLEMENTED (NI): The NRA does not have enough competent staff (i.e., education, training, skills and experience) to perform laboratory testing activities.  
- ONGOING IMPLEMENTATION (OI): The NRA has recently developed a plan to recruit adequate competent staff; however, the plan has not been implemented.  
- PARTIALLY IMPLEMENTED (PI): The NRA has initiated the implementation of the human resources development plan; however, there is need to complete the competency profile.  
- IMPLEMENTED (I): The NRA has a sustained number of competent staff (i.e., education, training, skills and experience) assigned to perform laboratory testing activities.

Limitations and remarks:  
Assessment of the adequacy and appropriateness of the number of staff members is quite subjective and should be linked to some process or output indicators. When estimating staff adequacy, the assessor should consider the workload, backlog, and delays in delivery based on established timeframes.  
Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

Sub Indicator: LT04.02: Duties, functions, and responsibilities of the staff in charge of laboratory testing activities are established and updated in the respective job descriptions

Maturity Level: 3

Description: The assessor should verify that procedures are in place to maintain a current and updated structure for managing job descriptions for personnel participating in laboratory testing activities. In addition, job descriptions should address current staff duties, responsibilities and the requisite competencies. A job description with this format and content should be established and implemented for all staff. The management of job descriptions should be supported by a guidance document that provides direction on when and how to update the information and where the information should be kept for easy access. The guidance document should present the appropriate duties and responsibilities that are assigned to each member of the organization involved in laboratory testing activities. Thus, the professional profiles of staff are reflected in their respective roles and responsibilities within the NRA. There should be procedures to guide responsible persons to document that duties, functions and responsibilities are revised and kept up to date. In addition, procedures should be available to guide the keeping and documenting
of up to date work schedules and enforcing the implementation of the documented guidelines and procedures.

| Objective: | The objective of this sub-indicator is to ensure that duties and responsibilities of the staff are clear and well defined, that job descriptions are kept up to date with current duties, functions and responsibilities, and that these activities are adequately documented. |
| Requirement: | Duties, roles and responsibilities of the staff relevant to laboratory testing activities. |
| Evidence to review: | The assessor should ask for and review: 1. Procedures and guidelines that guide placement of staff members within the NRA; 2. The professional profiles of staff (i.e., job descriptions) and documentation that they are related to their current roles and duties; 3. The professional profiles of the external experts and documentation that the profiles provide a composition that is complete and consistent with that prescribed in the legal provisions; 4. Procedures to guide the documentation of up to date duties and work schedules, and to enforce the implementation of the documented guidelines and procedures; 5. Job descriptions for designated staff. |
| Framework: | Structure/Foundation/Input |
| Rating Scale: | NOT IMPLEMENTED (NI): There is no evidence of defined or established duties, functions, responsibilities, respective job descriptions and necessary required competencies. |
| ONGOING IMPLEMENTATION (OI): The NRA has recently drafted or developed the role and responsibilities document but it has not yet been implemented. |
| PARTIALLY IMPLEMENTED (PI): The NRA has initiated implementation of this requirement but it has not been defined or followed for all staff or the roles and responsibilities documents, including staff job descriptions, are not up to date. |
| IMPLEMENTED (I): The NRA has defined and established all required duties, functions, and responsibilities, and respective job descriptions are up-to-date. |

**Limitations and remarks:** Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

**Sub Indicator:** LT04.03: Training plan developed, implemented and updated at least once a year for staff in charge of laboratory testing activities.

**Maturity Level:** 3

**Description:** The assessor should verify that training plans are developed, implemented and updated at least once every year to reflect the current situation by considering education and experience of the staff. The training plan should be complemented with guidelines or similar documents that guide the development and implementation of training plans. The assessor should ensure that induction training for new staff as well as continued on-the-job training for staff is planned and implemented. There should be procedures to approve the training plan and the budget allocated for implementing and updating the training plan. The plans should present clearly defined training goals and should include training in certain topics and skills to address identified deficiencies. Learning objectives, training methods and activities, evidence of learning, and evaluation and assessment of training should be documented. This documentation should confirm that the learning objectives were achieved and were designed to address weaknesses within the entities. Procedures should be in place to ensure that a training plan is developed, implemented and updated at least once every year. The assessor should verify that there is a system in place for monitoring the implementation and effectiveness of the training plan and for documenting the skills acquired in training activities for internal and external experts.

**Objective:** The objective of this sub-indicator is to ensure that a training plan for staff exists, and that it is implemented and updated annually. Through the training plan, NRA can be sure that competency of staff in charge of laboratory testing activities is maintained and enhanced.

**Requirement:** Implementation of training plan

**Evidence to review:** The assessor should ask for and review:
1. Guidelines for development, implementation and annual update (i.e., at least once per year) of the training plan. Guidelines should also provide for a mechanism to measure effectiveness of training.
2. Documentation for the system or structures used to approve the training plan and to evaluate the adequacy of the budget allocated to the training activities.
3. The current or existing staff training plan (or matrix) for staff. The assessor should assess this in relation to the respective individual job descriptions.
4. SOP for developing and maintaining the training plan.
5. Evidence that the NRA has investigated and identified training needs.
6. List of trainings performed.
7. Example records for training activities.

**References:**

**Framework:**
Process

**Rating Scale:**
- NOT IMPLEMENTED (NI): There is no systematic training program including training plan (or matrix).
- ONGOING IMPLEMENTATION (OI): The NRA has recently drafted or developed the training plan but there is no evidence of implementation.
- PARTIALLY IMPLEMENTED (PI): The NRA has developed and initiated the training plan implementation. However, the NRA has not fulfilled all required planned training or has been applying the plan for less than two years.
- IMPLEMENTED (I): The NRA has an updated training plan developed that is supported by adequate records to demonstrate effective plan implementation, including induction training for new staff and routine on-the-job training for recruited staff.

**Limitations and remarks:**
Training plans must be updated regularly; ideally on an annual basis, but not less frequently that once every two years.

Some regulatory functions may include many training activities that are not incorporated in the institutional training programme. Such training normally is offered by invitation. In this case, the assessor should recognize reports from non-routine laboratory testing relevant training not included in the NRA training plan.
Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

<table>
<thead>
<tr>
<th>Sub Indicator:</th>
<th>LT04.04: The NRA generates and maintains records of staff training activities and training effectiveness verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that records of staff training that is performed or organized by the NRA are generated, maintained, regularly updated. This activity should be supported by guidelines that direct the NRA to generate and maintain records of staff training activities. Procedures should be in place to document and propose staff training needs and to allocate a budget for continuous staff capacity building and development. The assessor should check that there is an evaluation or assessment mechanism to verify the quality of learning and to confirm that learning objectives are achieved. Documentation should include an inventory (i.e., soft and/or hard) system that records all impactful and non-impactful trainings and identifies all staff members who participated. A system to measure or estimate impact of trainings should be established.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure that training organized by the NRA or responsible regulatory authority is adequately documented and that the training records are adequately maintained and kept. Staff training records are considered an integral part of staff file and are a tool for measuring and tracking staff competency, development and adequacy.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Training records</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review: 1. Guidelines or similar documents that guide the NRA to generate and maintain records of staff training activities; 2. Evaluations of training effectiveness; 3. The training inventory, and procedures for completing the inventory; 4. Examples of archived records of staff training, and procedures for the archiving system</td>
</tr>
</tbody>
</table>

Framework: Output

Rating Scale:
- NOT IMPLEMENTED (NI): There is no evidence that the NRA generates and maintains records of staff training activities.
- ONGOING IMPLEMENTATION (OI): The NRA has recently initiated plans to generate, document and keep records of staff training activities, however they are not yet followed.
- PARTIALLY IMPLEMENTED (PI): The NRA has recently initiated plans to generate, document and keep records of staff training activities but they are not fully followed for all training activities or they have been established for less than two years.
- IMPLEMENTED (I): The NRA generates and maintains records of staff training activities.

Limitations and remarks:
- The assessor should note that some NRAs out-source training including staff capacity development activities. In this case the assessor should request the identity of the provider, as well as evaluations of the provider. The assessor may request the professional profiles of tutors or resource persons used to offer training. The assessor may also request records covering the archiving systems in place.
- Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

Indicator: LT05 Well maintained and equipped infrastructures for laboratory activities

Objective:
The objective of this indicator is to confirm that buildings and equipment fulfill quality and technical requirements in order to enable adequate performance of the quality testing in the laboratories. For some tests, specific requirements for rooms might be necessary to achieve reliable results.

Category: 06. Resources (HR, FR, infrastructure and equipment)

Sub Indicator: LT05.01: Laboratory facilities are adequate to perform quality testing activities.

Maturity Level: 3

Description:
The assessor should review the appropriateness and the adequacy of facilities for performing the laboratory testing and other NCL-related activities. The assessor should specifically evaluate and check the adequacy of the laboratory premises, the work...
### Objective:
The objective of this sub-indicator is to confirm the adequacy of laboratory facilities for contributing to effectiveness and reliability of quality testing at the NCL.

### Requirement:
Adequate facilities

### Evidence to review:
The assessor should ask for and review:
1. Evidence for the adequacy of the laboratory premises and facilities, including the work environment and work space;
2. Evidence for the adequacy of the layout of the laboratory premises;
3. Evidence that the assigned biosafety level for the laboratory work is in accordance with WHO recommendations (when applicable).

### References:
2. WHO good manufacturing practices for pharmaceutical products: main principles (51) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)
5. WHO good practices for pharmaceutical microbiology laboratories (34) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)

### Framework:
Structure/Foundation/Input

### Rating Scale:
NOT IMPLEMENTED (NI): Laboratory facilities are not adequate for performing the targeted testing activities.
ONGOING IMPLEMENTATION (OI): The NCL is planning to establish, qualify or upgrade the laboratory facilities in order to be adequate for performing the targeted testing activities, however no evidence of such plans exists.
<table>
<thead>
<tr>
<th>Sub Indicator:</th>
<th>LT05.02: Equipment calibration, qualification and maintenance plans have been defined and implemented and records have been maintained.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should identify the equipment and instruments used in the laboratory and confirm the existence of the relevant operation manuals and SOPs. The assessor should verify the calibration, qualification and maintenance status of laboratory equipment as well as plans and procedures for regular updates. In addition, the assessor should check the log books and records to verify that the equipment is being correctly calibrated, qualified and maintained.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure that calibrated, qualified and well-maintained laboratory equipment is available and contributes to the effectiveness and reliability of laboratory tests.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Calibration, qualification and maintenance of laboratory equipment.</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review: 1. List of laboratory equipment; 2. Operational manuals and SOPs for selected equipment; 3. Log books that record use of selected equipment; 4. Log books that record calibration and maintenance of selected equipment; 5. Plans and procedures for annual equipment calibration; 6. Plans and procedures for annual equipment maintenance; 7. Sample calibration certificates; 8. Sample maintenance records.</td>
</tr>
<tr>
<td>Framework:</td>
<td>Structure/Foundation/Input</td>
</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): There are no plans for equipment calibration, qualification and maintenance. ONGOING IMPLEMENTATION (OI): Although there are no approved documents, there is evidence that they are being prepared. PARTIALLY IMPLEMENTED (PI): Such documents were approved recently (e.g. less than one year ago). IMPLEMENTED (I): The NCL has up-to-date equipment calibration, qualification and maintenance plans and records, which were approved some time ago (at least one year ago), and there has already been a cycle of internal or external audits (with or without accreditation) or system review.</td>
</tr>
<tr>
<td>Limitations and remarks:</td>
<td>Scoring this sub-indicator as &quot;not applicable NA&quot; is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).</td>
</tr>
<tr>
<td>Indicator:</td>
<td>LT06 Procedures established and implemented to perform laboratory testing activities according to Quality Management System.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this indicator is to ensure that a management system is in place to ensure traceability of actions. Standard procedures are an essential element of overall good regulatory practices; importantly, they contribute to consistency, effectiveness and impartiality of the regulatory processes. Written documentation supporting the laboratory quality system should exist, and the regulatory testing laboratory should have procedures in place for the different laboratory testing activities performed. Procedures should be available for receipt, storage and handling of test samples (including retention samples); receipt, handling, and storage of test reagents and materials (including reference standards); performance of different quality tests; notification and issuance of test results; handling of out-of-specification results (including re-testing when necessary); and handling events of non-compliance with pre-set specifications. An auditing system (internal and external) should be established and implemented to assess the performance of the management system of the laboratory testing activities with the objective of promoting on-going improvement.</td>
</tr>
</tbody>
</table>

References:
1. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)
<table>
<thead>
<tr>
<th>Category:</th>
<th>07. Regulatory process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sub Indicator:</td>
<td>LT06.01: There are procedures for receipt, handling, storage and retention of samples.</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that written and enforced standard procedures exist for receipt, handling and storage of medical products samples received for testing. The assessor should evaluate whether special handling procedures (e.g., requirements for storage temperature (i.e., cool or frozen) and humidity or recommendations to protect from light) are considered when required. The assessor should, as well, verify that procedures are providing instructions for storage and handling of retention samples which may be required for re-testing or verification purposes. In addition, the assessor should verify the existence of an identification system to ensure traceability.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure that implemented procedures for ensuring traceability and consistency of laboratory testing activities are available.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Standard procedures for handling and retention of samples under testing.</td>
</tr>
</tbody>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. Standard procedures for receipt, handling, storage and retention of samples received for quality testing.  
2. Example records of the reviewed procedures.  
3. In the case of biological testing samples, verify that procedures for sampling from the manufacturer are available.  
4. Documentation for the identification system used in paper or electronic records to trace samples from receipt to its testing and storage. |
2. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)  
<table>
<thead>
<tr>
<th>Framework:</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): There are no documents for receipt, handling, storage or retention of samples. ONGOING IMPLEMENTATION (OI): Although there are no approved documents, there is evidence that they are being prepared. PARTIALLY IMPLEMENTED (PI): Such documents were approved recently (e.g. less than one year ago). IMPLEMENTED (I): The NCL has all the essential documents, which were approved some time ago (at least one year ago), and there has already been a cycle of internal or external audits (with or without accreditation) or system review.</td>
</tr>
<tr>
<td>Limitations and remarks:</td>
<td>Samples may come from market surveillance or directly from manufacturers. Scoring this sub-indicator as &quot;not applicable NA&quot; is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>LT06.02: There are documented procedures for performing tests in accordance with MA documentation.</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that documented procedures for testing are in accordance with the MA. The assessor should review the procedures by which the NCL staff has access to the MA. Ideally, the NCL staff should be involved in the MA evaluation process (at least with respect to information on pharmaceutical quality).</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure that standard procedures for performing tests are in accordance with the MA in order to ensure consistency of laboratory testing activities.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Standard procedures for testing of medical products as per their MA documentation.</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review: 1. List of SOPs for testing of different medical products; 2. Examples of SOPs for quality testing of selected medical products; 3. Examples of records for testing done according to the SOPs reviewed in item #2 above; 4. Documented evidence that the NCL has access to the QC part of the MA (i.e., when the NCL is part of the NRA); 5. When testing activities are sub-contracted, the contract should reflect that the NCL should have access to the QC part of the MA (including updates), or a verified copy of the QC part of the MA.</td>
</tr>
</tbody>
</table>
### References:
1. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)

### Framework:
Process

### Rating Scale:
- **NOT IMPLEMENTED (NI):** There is no documented evidence that tests are performed in accordance with MA documentation.
- **ONGOING IMPLEMENTATION (OI):** Although there are no approved documents, there is evidence that they are being prepared.
- **PARTIALLY IMPLEMENTED (PI):** Such documents were approved recently (e.g. less than one year ago).
- **IMPLEMENTED (I):** Procedures and records for performing tests in accordance with MA documentation were implemented some time ago (at least one year ago), and there has already been a cycle of internal or external audits (with or without accreditation) or system review.

### Limitations and remarks:
The methods approved in the MA application should ideally be used by the NCL. If not, the assessor should review the NCL justification for deviation from the MA approved testing methods along with the NCL procedure to handle this situation. If the method approved in the MA application is not routinely followed by the NCL because of some limitations in terms of technology or resources or for some other reason, the method included in the MA application should be determinative in the event of OOS test results. This is not only for technical and scientific reasons but also for legislative reasons.

Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

### Sub Indicator:
**LT06.03:** A documented procedure is implemented for notification of test results and for ensuring that test results are issued following a standardized format.

### Maturity Level:
3

### Description:
The assessor should verify that the NCL has established and implemented standard procedures for notifying interested parties (e.g., the manufacturer, the MA holder, and, when necessary, the inspectorate) of the test results. When the NCL is not part of the NRA, the test results should be forwarded to the NRA. Such procedures should provide guidance on issuing the test results in a standardized format containing the information needed to identify the sample, the testing laboratory, the applicant or other source of the sample, the type of tests conducted, the procedures applied, and the relevant specifications.

### Objective:
The objective of this sub-indicator is to ensure the implementation of standard procedures for notification of test results and for issuing test results following a standardized format. These procedures will ensure consistency of laboratory testing activities.
<table>
<thead>
<tr>
<th>Requirement:</th>
<th>Standard procedures for following a standardized format for laboratory test results.</th>
</tr>
</thead>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. Standard procedures for notification and issuance of test results;  
2. List of issued test results within a specified time (e.g., last year);  
3. Documentation of examples of decision-making process;  
4. Examples of issued test results;  
5. Examples of records showing implementation of the reviewed procedures;  
6. Examples of test results forwarded to the NRA when the NCL is not part of the NRA. |
2. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en) |
| Framework: | Process |
| Rating Scale: | NOT IMPLEMENTED (NI): There is no documented evidence for a procedure for notification of test results or for ensuring that test results are issued following standardized format.  
ONGOING IMPLEMENTATION (OI): Although there are no approved documents, there is evidence that they are being prepared.  
PARTIALLY IMPLEMENTED (PI): Such documents were approved recently (e.g. less than one year ago).  
IMPLEMENTED (I): Procedures and records are in place for notification of test results and for ensuring that results are issued following standardized format. |
| Limitations and remarks: | Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs). |
| Sub Indicator: | LT06.04: There are appropriate procedures for obtaining and handling of all materials required for testing. |
| Maturity Level: | 3 |
| Description: | The assessor should verify the existence and implementation of standard procedures for procuring, receiving, storing and handling of all materials, including reference materials, required for quality testing. The procedures should ensure a regular and adequate supply of the required materials and standards. The assessor should verify that all reagents used in the NCL are of assured quality |
and labelled accordingly (e.g., preparation date, expiry date, specifications, storage conditions, and identity of tests in which they are used).

**Objective:** The objective of this sub-indicator is to ensure the implementation of standard procedures for procuring and handling of all materials required for testing. These procedures will ensure consistency of laboratory testing activities.

**Requirement:** Standard procedures for procuring and handling of materials required for laboratory testing.

**Evidence to review:**
1. Standard procedures for purchase, receipt, storage, handling, and use of all materials required for testing;
2. Examples of records for the reviewed procedures;
3. List of materials required for different quality tests;
4. List of suppliers of materials required for testing.

**References:**
1. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)

**Framework:** Process

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** There is no documented evidence of procedures for procuring and handling of all materials required for testing.
- **ONGOING IMPLEMENTATION (OI):** Although there are no approved documents, there is evidence that they are being prepared.
- **PARTIALLY IMPLEMENTED (PI):** Such documents were approved recently (e.g. less than one year ago).
- **IMPLEMENTED (I):** Documented procedures for procuring and handling of all materials required for testing are implemented some time ago.

**Limitations and remarks:** Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

**Sub Indicator:** LT06.05: Staff has access to reference documents, including pharmacopoeias, textbooks and operational manuals.

**Maturity Level:** 3
<table>
<thead>
<tr>
<th>Description:</th>
<th>The assessor should verify that the laboratory staff has access to all documentation required for quality testing including, but not limited to, pharmacopoeias, textbooks, operational manuals, scientific publications, and publications of the WHO Technical Report Series. The assessor should also verify that the most updated version of each document is available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure that staff has access to the documentation required for testing. Access to these documents will contribute to effective operations of the different laboratory activities.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Staff access to the necessary documentation for performing different laboratory activities.</td>
</tr>
</tbody>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. Documentation of the information resources available to laboratory staff;  
2. Evidence that current and updated versions are available to laboratory staff;  
3. List of the scientific publications for which the NCL has subscriptions.;  
4. Procedures describing access to documents and location. |
| References:     | 1. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)  
3. WHO Expert Committee on Biological Standardization (ECBS), Vaccine-specific standardization (135) (https://www.who.int/biologicals/vaccines/en/) |
| Framework:      | Process |
| Rating Scale:   | NOT IMPLEMENTED (NI): There are no documents establishing access to reference documents, including pharmacopoeias, textbooks and operational manuals.  
ONGOING IMPLEMENTATION (OI): Although there are no approved documents, there is evidence that they are being prepared.  
PARTIALLY IMPLEMENTED (PI): Such a document was approved recently (e.g. less than one year ago).  
IMPLEMENTED (I): The NCL has demonstrated access to the essential documents, and has had access for some time (at least one year), and there has already been a cycle of internal or external audits (with or without accreditation) or system review. |
<p>| Limitations and remarks: | Scoring this sub-indicator as &quot;not applicable NA&quot; is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs). |</p>
<table>
<thead>
<tr>
<th>Indicator:</th>
<th>LT07 Mechanism exists to promote transparency, accountability and communication.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective:</strong></td>
<td>The objective of this indicator is to ensure that mechanisms are in place that promote effective communication of laboratory testing activities and related information within the NRA and NCL, that promote transparency and outreach to the public, and that establish milestones that encourage accountability of the NRA and NCL to its mandate. Additionally, these activities contribute to mutual understanding and involvement of all stakeholders relevant to laboratory testing activities. Consequently, confidence in the regulatory system is raised.</td>
</tr>
<tr>
<td><strong>Category:</strong></td>
<td>08. Transparency, accountability and communication</td>
</tr>
<tr>
<td><strong>Sub Indicator:</strong></td>
<td>LT07.01: Laboratory testing activities are appropriately communicated to the public community.</td>
</tr>
<tr>
<td><strong>Maturity Level:</strong></td>
<td>4</td>
</tr>
<tr>
<td><strong>Description:</strong></td>
<td>The assessor should verify that different laboratory testing activities and findings are appropriately communicated to the public community. This may be done through an annual report of the NCL or through other regular publications. In addition, the assessor should confirm that, when needed in the event of public health issues and concerns, immediate and rapid communications to the public community are done to inform them about the status of the issues of concern. Such communications will help avoid any misunderstandings.</td>
</tr>
<tr>
<td><strong>Objective:</strong></td>
<td>The objective of this sub-indicator is to ensure transparency to the public community. This transparency will contribute to accountability of the NRA and NCL, promote consistency in activities undertaken, and increase the public trust and confidence in the regulatory system.</td>
</tr>
<tr>
<td><strong>Requirement:</strong></td>
<td>Outreach and communication of laboratory testing activities to the public community.</td>
</tr>
</tbody>
</table>
| **Evidence to review:** | The assessor should ask for and review:  
1. Documentation of communication and any outreach to the public community regarding laboratory testing activities and findings.  
2. Evidence for public communications from website |
<p>| <strong>References:</strong> | 1. Good regulatory practices: guidelines for national regulatory authorities for medical products (112) |</p>
<table>
<thead>
<tr>
<th>Framework:</th>
<th>Output</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): Laboratory testing activity reports are not publicly available. ONGOING IMPLEMENTATION (OI): The NRA established a procedure or mechanism by which laboratory testing activities could be publicly available, however, this is not yet implemented. PARTIALLY IMPLEMENTED (PI): There is evidence that the NRA has the elements (i.e., procedures, documentation, management systems, and other relevant information) and the capacity to perform the processes mentioned in the indicator; however, it has only limited experience or a limited number of documented events. IMPLEMENTED (I): Laboratory testing activity reports are regularly and consistently published and publicly available.</td>
</tr>
<tr>
<td>Limitations and remarks:</td>
<td>In some countries, these public communications may be done through the NRA. Scoring this sub-indicator as &quot;not applicable NA&quot; is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).</td>
</tr>
<tr>
<td>Indicator:</td>
<td>LT08 Mechanism in place to monitor regulatory performance and output.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this indicator is to ensure that mechanisms are in place to track regulatory effectiveness of laboratory testing activities, to measure relevant advancements in the programme, and to establish, implement and regularly verify performance indicators. The NRA or NCL should monitor and analyze laboratory results. These analyses are essential to monitor the quality of medical products for each specific product and manufacturer, to detect trends in non-compliance, and to detect shifts in results towards the specified upper or lower confidence limits.</td>
</tr>
<tr>
<td>Category:</td>
<td>09. Monitoring progress and assessing outcomes &amp; impact</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>LT08.01: There is an updated database of all medical products batches that have undergone quality testing.</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>4</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that a database (electronic or paper based) of all medical products batches tested is established and maintained. The database should include comprehensive information about these medical products batches including name, batch number, manufacturer, tests conducted, test results, and any other relevant information.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure the establishment of a database (electronic or paper based) of all medical products batches that have undergone quality testing by the NCL. This database is essential for storing, consolidating and analyzing information for these batches, including test results and test details (e.g., methods, analysts, reagents, and equipment). Thus, tracing of relevant regulatory testing activities and decisions for the sake of institutional memory is ensured. Furthermore, analyses of the data would contribute to optimization of regulatory performance.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>An updated database of medical products batches tested for quality by the NCL.</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review: 1. Database (electronic and/or paper based) of medical products batches tested for quality by the NCL.</td>
</tr>
<tr>
<td>Framework:</td>
<td>Output</td>
</tr>
<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): There are no updated databases of all medical products batches that have undergone quality testing. ONGOING IMPLEMENTATION (OI): Although there are no databases, there is evidence that they are being prepared. PARTIALLY IMPLEMENTED (PI): Such databases were established recently (e.g. less than one year ago). IMPLEMENTED (I): The NCL has updated databases, which were established some time ago (at least one year ago), and there has already been a cycle of internal or external audits (with or without accreditation) or system review.</td>
</tr>
<tr>
<td>Limitations and remarks:</td>
<td>Scoring this sub-indicator as &quot;not applicable NA&quot; is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>LT08.02: Monitoring and trend analyses are carried out for laboratory testing results data of reference materials and medical products.</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that quality of all reference materials and working standards that are used in routine testing are under control through use of control charts, and also that they are regularly monitored through periodic testing against established references (e.g. international, regional or national standards). Test results of the laboratory should be monitored using trend analyses to identify any trends (positive or negative) or deviations from their mean values. When required, confidence intervals could be reconsidered. When necessary, new replacement reference materials may be required when trend analyses reveal a problem with a current reference. The assessor should check the knowledge and understanding of the laboratory staff of basic statistical concepts and inference including, for example, the theory of probability and methods for detection of data trends.</td>
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<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure reliability and consistency of laboratory testing activities. Performance of reference materials should be monitored, and their test results should be evaluated using trend analyses. Laboratory test results of medical products should also be monitored using trend analyses.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Monitoring and trend analyses of laboratory result data of reference materials and medical products.</td>
</tr>
<tr>
<td>Framework:</td>
<td>Process</td>
</tr>
<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): There are no monitoring and trend analyses of laboratory testing data of reference materials and medical products. ONGOING IMPLEMENTATION (OI): Although there are no monitoring and trend analyses of laboratory testing data of reference materials and medical products, the NCL is taking some actions to develop and formalize these procedures. PARTIALLY IMPLEMENTED (PI): There are monitoring and trend analyses of laboratory testing data of reference materials and medical products however these are recently implemented (e.g., less than two years ago). IMPLEMENTED (I): There are monitoring and trend analyses of laboratory testing data of reference materials and medical products.</td>
</tr>
</tbody>
</table>
products, and these have been consistently implemented over a relatively long period of time (e.g. more than two years).

<table>
<thead>
<tr>
<th>Limitations and remarks:</th>
<th>Scoring this sub-indicator as &quot;not applicable NA&quot; is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sub Indicator:</strong></td>
<td><strong>LT08.03: Regular participation in proficiency schemes, collaborative studies and inter-laboratory comparisons.</strong></td>
</tr>
<tr>
<td><strong>Maturity Level:</strong></td>
<td>4</td>
</tr>
<tr>
<td><strong>Description:</strong></td>
<td>The assessor should verify that the technical competency of the NCL is periodically monitored to confirm consistency and reliability of test results. The monitoring may be conducted in various ways, including: performance evaluation systems, collaborative studies, and inter-laboratory comparisons. The assessor should verify that the NCL participates in proficiency schemes or collaborative studies organized by WHO, the European Directorate for the Quality of Medicines and HealthCare, the National Institute for Biological Standards and Control, or other institutions. Participation allows the NCL to compare its own performance to an international benchmark. The assessor should check dates of participation, scope of study, the product tested, and coordinating institution. In addition, the assessor should ascertain the number of collaborative studies in which laboratory participated, the specific tests evaluated, and whether or not the NCL had appropriate performance.</td>
</tr>
<tr>
<td><strong>Objective:</strong></td>
<td>The objective of this sub-indicator is to ensure that NCL participation in proficiency schemes, collaborative studies and inter-laboratory comparisons contributes to regulatory harmonization and networking. These, in turn, lead to improvements in the effectiveness and efficiency of the regulatory function.</td>
</tr>
<tr>
<td><strong>Requirement:</strong></td>
<td>Participation in proficiency schemes, collaborative studies and inter-laboratory comparisons.</td>
</tr>
</tbody>
</table>
| **Evidence to review:**  | The assessor should ask for and review:  
  1. Records of participation in proficiency schemes, collaborative studies and inter-laboratory comparisons.  
  2. Records of performance during participation in proficiency schemes, collaborative studies and inter-laboratory comparisons. |
| **References:**          | 1. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)  
<table>
<thead>
<tr>
<th>Framework:</th>
<th>Output</th>
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</thead>
<tbody>
<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): There are no documents establishing regular participation in international proficiency schemes, collaborative studies and inter-laboratory comparisons. ONGOING IMPLEMENTATION (OI): At least some monitoring has been done with results that warrant actions for improvement. PARTIALLY IMPLEMENTED (PI): At least some monitoring has been done with acceptable results. Or, if there are decentralized activities, most of the laboratories involved have demonstrated acceptable results in at least one evaluation. IMPLEMENTED (I): Laboratory has participated in several studies to monitor performance. For these studies, acceptable results were obtained, demonstrating the technical competency of the NCL (including all laboratories when the activities are decentralized).</td>
</tr>
<tr>
<td>Limitations and remarks:</td>
<td>When results from participation in proficiency studies are not satisfactory the NCL should show evidence of corrective actions and preventive actions. Scoring this sub-indicator as &quot;not applicable NA&quot; is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>LT08.04: Performance indicators for laboratory testing activities are established and implemented</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>4</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify the existence and implementation of performance indicators for different activities included under the laboratory testing functions. Specifically, the system should define key performance indicators (KPIs) along the entire laboratory testing activity chain and all indicators should be adequately justified. For the purpose of clarity and consistency, established KPIs should be supported with guidelines for monitoring and maintenance of the KPIs. The guidelines in turn should be supported by SOPs and tools that define the procedures to be used for monitoring and evaluating the performance indicators and that define procedures and timelines for reviewing and revising the indicators. Examples of performance indicators for activities included under the laboratory access and testing function include, but are not limited to: number of product batches tested, number of tests performed, number of non-compliant events, mean time for performing different quality tests, and other relevant parameters. Established KPIs might be qualitative, quantitative or combination of both. In general, quantitative indicators are preferred to avoid bias or misinterpretation. However, qualitative indicators are also accepted. Qualitative indicators may or may not include scoring or scaling to render them semi-quantitative and thus more informative. The assessor should ensure that indicators are</td>
</tr>
</tbody>
</table>
measured on a regular basis to monitor progress and advancement.

In addition, the assessor should verify measured indicators are analyzed to identify trends or abnormalities. Justifications for any identified abnormalities should be provided; when necessary, process optimizations should be introduced to avoid recurrence.

**Objective:**
The objective of this sub-indicator is to ensure that a system, mechanism, or procedure exists to require the NRA to establish performance indicators along the entire laboratory testing chain. Additionally, the objective is to ensure that KPIs are actually contributing to monitoring of regulatory performance, to measuring effectiveness of laboratory testing regulatory activities, and to making any necessary adjustments or optimizations.

**Requirement:**
KPIs for laboratory testing activities

**Evidence to review:**
The assessor should ask for and review:
1. Documents supporting the system, mechanism, or procedure compelling the NRA to establish and implement performance indicators along the entire laboratory testing activity chain.
2. Evidence that the performance indicators have been established and implemented, and that the members of staff involved in the laboratory testing function are aware of the indicators and the guidelines and SOPs used for monitoring and evaluating their performance.
3. The current performance indicators for laboratory testing activities
4. Analyses of the measured indicators along with the investigations done to identify trends or abnormalities.
5. Documentation for follow-up of any observed abnormalities, including justifications for any identified abnormalities as well as any process optimizations introduced to avoid recurrence.

**References:**

**Framework:**
Output

**Rating Scale:**
NOT IMPLEMENTED (NI): There are no KPIs for laboratory testing activities.
ONGOING IMPLEMENTATION (OI): The NRA has recently drafted KPIs for laboratory testing activities but they have not yet been reported.
PARTIALLY IMPLEMENTED (PI): The NRA has developed KPIs for laboratory testing activities and has been applying them for less than two year or they have not covered all critical steps.
IMPLEMENTED (I): The NRA has established and implemented KPIs for laboratory testing activities. The indicators are reviewed regularly, and appropriate actions are taken, and decisions made.

Limitations and remarks:
When they refer to outcomes, indicators may be ambiguous and difficult to interpret, as outcomes are the result of many factors that are difficult to disentangle. When they refer to processes, indicators are often too specific, as they may focus on a particular intervention or condition or they may quickly become outdated as business models develop.

Different methodologies are used to measure the NRAs performance on laboratory testing activities. In this case, the assessor should verify that adequate supporting documents are available. The assessor should consider that developed performance indicators should be Specific, Measurable, Achievable, Realistic, and Time-bound (i.e., “SMART”).

Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

<table>
<thead>
<tr>
<th>Indicator:</th>
<th>LT09 Measures for occupational health and safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective:</td>
<td>The objective of this indicator is to ensure that safety issues to protect staff and the environment are considered of critical importance. Laboratory work is linked to specific risks because of the use of chemical, radiological and biological materials.</td>
</tr>
<tr>
<td>Category:</td>
<td>03. Policy and strategic planning</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>LT09.01: A laboratory hazardous substances list exists and documented procedures for storage, handling and disposal of these substances are implemented.</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that lists of hazardous substances used in the laboratories are available. In addition, the assessor should determine if standard procedures for storing, labelling, handling and disposal of hazardous substances are available and implemented.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure that hazardous laboratory substances are carefully handled and adversely affect neither the health of the laboratory staff nor the environment.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>List of hazardous substances and standard procedures for handling them.</td>
</tr>
</tbody>
</table>
### Evidence to review:

The assessor should ask for and review:
1. List of hazardous substances used in the laboratory;
2. Standard procedures for the storage, handling and disposal for hazardous substances used in the laboratory;
3. Standard procedures for waste management and final disposal according national regulations;
4. Examples of records for each of the reviewed procedures.

### References:

1. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)
2. WHO good manufacturing practices for pharmaceutical products: main principles (51) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)

### Framework:

Process

### Rating Scale:

- **NOT IMPLEMENTED (NI):** There is no list of hazardous substances used in the laboratory and no documented procedure for storage, handling and disposal of these substances.
- **ONGOING IMPLEMENTATION (OI):** Although there are no approved documents, there is evidence that they are being prepared.
- **PARTIALLY IMPLEMENTED (PI):** Such documents were approved recently (e.g. less than one year ago).
- **IMPLEMENTED (I):** The NCL has a list of laboratory hazardous substances used in the laboratory and documented procedures for storage, handling and disposal of these substances. These have been in place for at least one year, and there has already been a cycle of internal or external audits (with or without accreditation) or system review.

### Limitations and remarks:

Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

### Sub Indicator:

LT09.02: A laboratory safety programme exists and a designated person is responsible for its management.

### Maturity Level:

4

### Description:

The assessor should confirm that a laboratory safety programme is established and that a staff member (or a group of staff members) is responsible for managing all aspects within that safety programme. The programme should provide comprehensive guidance with general and specific instructions on occupational safety in the laboratory. Specific attention should be given to protection from microbiological materials such as live bacteria and viruses. In addition, the assessor should confirm that the
<table>
<thead>
<tr>
<th><strong>Laboratory Safety</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>The objective of this sub-indicator is to ensure that a laboratory safety programme exists. Hazardous laboratory activities should adversely affect neither the environment nor the health of the laboratory staff.</td>
</tr>
<tr>
<td>Requirement:</td>
</tr>
<tr>
<td>Establishment of a laboratory safety programme and designation of qualified staff for its management</td>
</tr>
<tr>
<td>Evidence to review:</td>
</tr>
</tbody>
</table>
| The assessor should ask for and review:  
1. Policies and procedures for the laboratory safety programme;  
2. Evidence that staff has been designated to manage the laboratory safety programme;  
3. Examples of documented communications of the laboratory safety programme to all laboratory staff;  
4. Examples of laboratory staff training records covering the handling of hazardous substances and spills, and the protection of staff from exposure to chemical substances. |
| References: |
| Framework: Structure/Foundation/Input |
| Rating Scale: |
| NOT IMPLEMENTED (NI): There is no laboratory safety programme.  
ONGOING IMPLEMENTATION (OI): Although there are no approved documents, there is evidence that they are being prepared.  
PARTIALLY IMPLEMENTED (PI): Such documents were approved recently (e.g. less than one year ago).  
IMPLEMENTED (I): The NCL has a laboratory safety programme, which was approved and implemented some time ago (at least one year ago), and there has already been a cycle of internal or external audits (with or without accreditation) or system review. |
| Limitations and remarks: |
| Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs). |
| Sub Indicator: |
| LT09.03: Staff immunization requirements are defined, implemented and monitored. |
| Maturity Level: 4 |
| Description: The assessor should verify that immunization programs for laboratory staff are defined, implemented and monitored. Staff compliance with the predefined immunization requirements should be verified prior to permitting access to designated work areas or use of designated equipment. |
### Objective:
The objective of this sub-indicator is to ensure that requirements for staff immunization are defined, implemented and monitored.

#### Requirement:
Laboratory staff immunization programme is established, implemented and monitored.

#### Evidence to review:
The assessor should ask for and review:
1. Immunization requirements, if any, for staff from different laboratory work areas
2. Examples of health records for selected staff;
3. Documentation of regular monitoring of staff immunization programme;
4. Examples of antibody titer measurement records for selected staff.

#### References:
1. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)

#### Framework:
Structure/Foundation/Input

#### Rating Scale:
- NOT IMPLEMENTED (NI): There are no defined staff immunization requirements.
- ONGOING IMPLEMENTATION (OI): Although there are no defined requirements, there is evidence that they are being prepared.
- PARTIALLY IMPLEMENTED (PI): Such requirements were approved recently (e.g. less than one year ago).
- IMPLEMENTED (I): The NCL has defined staff immunization requirements, and there is documented evidence for implementation and monitoring. The program has been in place for some time ago (at least one year), and there has already been a cycle of internal or external audits (with or without accreditation) or system review.

#### Limitations and remarks:

#### Indicator:
LT10 Measures for good management of outsourced laboratory activities

**Objective:**
The objective of this indicator is to ensure that an NRA or NCL that is outsourcing laboratory testing activities has the following processes in place: an established, formal evaluation process for identifying qualified laboratories; a decision-making process for issuing, renewing or rescinding contracts for laboratory services; established and implemented procedures for managing...
outsourced activities; and procedures for handling communication exchanges.

Category: 07. Regulatory process

Sub Indicator: LT10.01: Documented procedures are implemented for managing outsourced QC activities.

Maturity Level: 3

Description: The assessor should verify the existence and implementation of standard procedures for managing all outsourced testing activities. The assessor should check these procedures and confirm that they are providing comprehensive guidance on implementation and management of quality agreements between the NCL (i.e., contract giver) and the independent laboratory or organization (i.e., contract acceptor). In addition, the procedures should provide guidance on the selection of contract acceptor, on the pathways of communication with clear roles and responsibilities (e.g., sourcing of materials required for testing including reference materials) and on a programme for regular audits (internal or external) of the contract acceptor by the NCL. The assessor should verify that the information exchange is handled in a confidential manner and that a system is in place to ensure there are no conflicts of interest.

Objective: The objective of this sub-indicator is to ensure that outsourcing and sub-contracting is well controlled by the responsible NRA in order to ensure reliability of the outsourced test results.

Requirement: Standard procedures for managing outsourced testing activities.

Evidence to review:

1. Standard procedures for managing outsourced testing activities;
2. Documentation of quality audits (internal or external) and other evidence that demonstrates that defined criteria have been met before accepting the sub-contracting laboratory;
3. Quality agreements between the NCL and the independent laboratory or organization;
4. Evidence from quality audits (internal or external) that confirm the sub-contracting laboratory has a QMS in place;
5. Documents that demonstrate that confidentiality agreements and declarations of Interests have been signed;
6. Examples of records of communication (including notifications) between both parties.

References:

1. WHO good practices for pharmaceutical quality control laboratories (35) (http://digicollection.org/whoqapharm/p/about and
<table>
<thead>
<tr>
<th>Framework:</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): There are no documented procedures implemented for managing outsourced QC activities. ONGOING IMPLEMENTATION (OI): Although there are no approved documents, there is evidence that they are being prepared. PARTIALLY IMPLEMENTED (PI): Such documents were approved recently (e.g. less than one year ago). IMPLEMENTED (I): The NCL has implemented documented procedures for managing outsourced QC activities. These procedures were approved some time ago (at least one year ago), and there has already been a cycle of internal or external audits (with or without accreditation) or system review.</td>
</tr>
<tr>
<td>Limitations and remarks:</td>
<td>Scoring this sub-indicator as &quot;not applicable NA&quot; is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).</td>
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</tbody>
</table>