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

LICENSING ESTABLISHMENTS (LI): INDICATORS AND FACT SHEETS

Revision VI version 1
November 2018
### Function: 05- LICENSING ESTABLISHMENTS (LI)

**Description:**

In order to protect public health, licensing activities are of outstanding importance and are considered fundamental, together with inspections activities, for guaranteeing the quality, safety and efficacy of medical products used within or exported out of the country. The National Regulatory Authority (NRA) is responsible for coordinating licensing activities and should be supported by published and readily available legal provisions, regulations and guidelines which ensure that licensing of facilities throughout the supply chain is based on compliance with Good Practices (GXP) and that the NRA is empowered to issue, suspend or revoke licenses for premises and establishments.

Premises, facilities, establishments and companies throughout the supply chain should possess a license to operate issued by the NRA. These facilities include, but are not limited to, manufacturers, distributors, wholesalers, importers, exporters and retailers. The process of issuing licenses should be based on the implementation of and compliance with quality standards of GXP. An inspection for confirmation of compliance with GXP is required in order to grant or re-grant a license or approval of a substantial modification.

An updated list or database of all licensed facilities should be published and publicly available.

The GXPs considered most relevant for this function are good manufacturing practices and good distribution practices, including good cold chain management practices. Good clinical practices and good vigilance practices, which are generally excluded from this function, are addressed, however, in other functions.

A general limitation to this function occurs when there is no domestic manufacturing of medical products. In this case, the function cannot apply to manufacturers, because none exist in the country. Nevertheless, the function will always apply to distribution practices, including wholesaling. Another general limitation applies to those countries that depend on the regulatory inspection function, without licensing, to ensure compliance to GXPs at the premises, facilities, establishments and companies throughout the supply chain. In the latter case, the whole function might not apply; however, the assessor of this establishment licensing function should
liaise with the assessor of the regulatory inspection function to verify that proper and appropriate controls are in place despite the absence of any licensing activities in the country.

<table>
<thead>
<tr>
<th>Indicator:</th>
<th>LI01 Legal provisions, regulations and guidelines required to define framework for licensing activities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective:</td>
<td>The objective of this indicator is to ensure that licensing 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. There should be a legal basis to establish the licensing system for the facilities throughout the supply chain and to authorize the responsible entities to take the necessary actions. The legislation should also provide a mandate that allows for adequate and proportional sanctions, penalties and prosecutions for violations of the applicable legislation. (Please refer to regulatory inspection function for further information on the regulatory enforcement and compliance activities).</td>
</tr>
<tr>
<td>Category:</td>
<td>01. Legal provisions, regulations and guidelines</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>LI01.01: There are legal provisions for licensing of facilities throughout the supply chain and based on Good Practices (GXPs) compliance.</td>
</tr>
<tr>
<td>MATURITY LEVEL:</td>
<td>1</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that legislation establishes fundamental functions in the regulatory authority appointed to license different type of facilities across the supply chain (e.g., manufacturer, re-packer, re-labeller, distributor, wholesaler and retailer). The assessor should ensure that, for the purpose of being licensed, legal provisions require the responsible entity to conduct a GXP inspection prior to taking related decision.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure the existence of legislation that requires premises, facilities, establishments and companies throughout the supply chain (including, but not limited to, manufactures, distributors, wholesalers, importers, exporters and retailers) hold a license to operate that is issued by the National Regulatory Authority (NRA).</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Legal provisions, regulations and guidelines for licensing facilities</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review: 1. Published legal provisions establishing the licensing of facilities throughout the supply chain; 2. Relevant public information available from the website, official bulletins or other legal publications;</td>
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<tr>
<td>3.</td>
<td>Legal provisions authorizing the NRA to conduct GXP inspections;</td>
</tr>
<tr>
<td>4.</td>
<td>Guidelines, procedures, forms, and instructions for applicants;</td>
</tr>
<tr>
<td>5.</td>
<td>Guidance to applicants defining the circumstances that would warrant an application for a new license or for renewal, expansion, or modification to an existing license.</td>
</tr>
</tbody>
</table>

**References:**


**Framework:**

Structure/Foundation/Input

**Rating Scale:**

NOT IMPLEMENTED (NI): There is no legal basis for the indicator.

ONGOING IMPLEMENTATION (OI): The NRA is preparing to establish a legal basis for this requirement, but there is no evidence of any results from those preparations.

PARTIALLY IMPLEMENTED (PI): The legal basis was established recently (less than one year ago) and it is at the implementation stage, so this practice is not yet consolidated.

IMPLEMENTED (I): The NRA has legal provisions in place requiring premises, facilities, establishments and companies throughout the supply chain including, but not limited to, manufactures, distributors, wholesalers, importers, exporters and retailers, to hold a license to operate issued by the NRA.
### Limitations and remarks:
A general limitation to this function occurs when there is no domestic manufacturing of medical products. In this case, the function cannot apply to manufacturers, because none exist in the country. Nevertheless, the function will always apply to distribution, including wholesaling, practices. Another general limitation applies to those countries that depend on the regulatory inspection function, without licensing, to ensure compliance to GXP at the premises, facilities, establishments and companies throughout the supply chain. In the latter case, the whole function might not apply; however, the assessor of this establishment licensing function should liaise with the assessor of the regulatory inspection function to verify that proper and appropriate controls are in place despite the absence of any licensing activities in the country.

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

### Sub Indicator:
LI01.02: There are legal provisions to empower the NRA to issue, suspend or revoke licenses for establishments.

### MATURITY LEVEL:
1

### Description:
The assessor should verify existing legislation establishes a requirement for compliance with and respect for the quality standards of GxPs on the part of manufacturers of pharmaceutical products and for the quality standards of Good Distribution Practice on the part of wholesale companies. Compliance with these quality standards is essential for ensuring that licensing establishments meet the requirements recommended by the World Health Organization (WHO) to safeguard the quality, safety, and effectiveness of their products. The NRA must verify a manufacturer’s adherence to Good Manufacturing Practices before and after production starts. Therefore, it is imperative that the NRA is empowered by legislation to both issue licenses to such establishments and to suspend them when critical risks associated with lack of compliance with GXP are identified.

The assessor should confirm the existence of laws, decrees and provisions related to licensing and verify that the legislation empowers the NRA to suspend or revoke licenses for establishments.

### Objective:
The objective of this sub-indicator is to ensure that legislation empowers the NRA to not only issue licenses, but also to suspend or revoke licenses for establishments.

### Requirement:
Legal provisions, regulations and guidelines on issuance, suspension, withdrawal or cancellation of licenses.

### Evidence to review:
The assessor should ask for and review:
1. Legal provisions authorizing the NRA to suspend or revoke a license in case requirements are not met;
2. Relevant public information available from the website, official bulletins, or other legal publications.
## Framework:

**Structure/Foundation/Input**

## Rating Scale:

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOT IMPLEMENTED (NI)</strong></td>
<td>There are no legal provisions empowering the NRA to issue licenses and to suspend or halt production.</td>
</tr>
<tr>
<td><strong>ONGOING IMPLEMENTATION (OI)</strong></td>
<td>The NRA is preparing to establish a legal basis for this indicator, but there is no evidence of any results from such activities.</td>
</tr>
<tr>
<td><strong>PARTIALLY IMPLEMENTED (PI)</strong></td>
<td>The legal basis was established recently (less than one year ago) and it is at the implementation stage, so this practice is not yet consolidated; or the NRA carries out these actions, but legal provisions do not explicitly empower it to do so.</td>
</tr>
<tr>
<td><strong>IMPLEMENTED (I)</strong></td>
<td>The NRA has the legal bases and also consistently maintains documentation of the results of related activities over time. The legal provisions explicitly indicate that the NRA grants licenses and may revoke them or apply health sanctions, as the case may be, for any noncompliance it finds. There is evidence that the NRA is following through on these actions.</td>
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</table>

## Limitations and remarks:

In some cases, license revocation is not the responsibility of the NRA. Instead, other institutions may have that responsibility (e.g., police authorities). In any case, the inspectors should have the authority to halt production.

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

## Sub Indicator:

**LI01.03**: There are legal provisions that require that the NRA to be informed, for the purpose of notification or approval, in case post-licensure changes or variations are made.

## MATURITY LEVEL:

3

## Description:

The assessor should verify the existence of legal provisions that require a responsible person from the establishment inform the NRA for notification or approval of any changes or variations to the conditions under which the initial license was issued. This
provision applies to any change or variation which may affect the quality, safety or efficacy of medical products. Establishments may make changes at their facilities (e.g. introduce a new manufacturing line or new product). However, because such changes may create new risk factors that might impact the quality, safety, or efficacy of the products being manufactured, the NRA must assess the situation to decide whether to approve such changes and include them in the corresponding manufacturing license.

**Objective:**

The objective of this sub-indicator is to ensure that legal provisions or regulations provide the necessary mandate for the NRA to require that a responsible person from the establishment inform the NRA, for purpose of notification or approval, of any changes or variations to the conditions under which the initial license was issued.

**Requirement:**

Legal provisions, regulations and guidelines on post-licensure changes or variations

**Evidence to review:**

The assessor should ask for and review:
1. Published legal provisions regarding the obligation to report changes or variations to the original license;
2. Relevant published guidelines, procedures, forms, and instructions for applicants;
3. Evidence of approved and rejected amendments.

**References:**


**Framework:**

Structure/Foundation/Input

**Rating Scale:**

NOT IMPLEMENTED (NI): There is no legal basis for the indicator.
ONGOING IMPLEMENTATION (OI): The NRA is preparing to establish the legal basis, but there is no evidence of results associated with such activities.
PARTIALLY IMPLEMENTED (PI): The legal basis was established recently, and it is at the implementation stage, so this practice is not yet consolidated.
IMPLEMENTED (I): The NRA has such legal bases and also consistently maintains documentation of the results of related activities over time. There is a legal provision requiring notification, and there are records that both license holders and the NRA are adhering to this legal provision.

**Limitations and remarks:**

The following may not be found on the website:
1. The legal bases mandating the reporting of changes that would affect the original license;
2. Evidence of changes or variations approved and rejected by the NRA.

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

**Sub Indicator:**

LI01.04: There are guidelines on the procedures to apply for a license and on content and format of the license application.

**MATURITY LEVEL:**

3

**Description:**

The assessor should verify the existence of published guidance that specifies the content of the application, the forms that are required, and the procedures to follow when submitting a license application. In order to ensure proper interpretation and complete compliance, it is important to verify that:
1. the instructions regarding the content and format of license application are clear;
2. the instructions that describe the procedure to follow when submitting an application license are clear;
3. the NRA has evidence, preferably public, that states that the guidelines are to be followed;
4. the requirements state that products at the stage of research and development also are included;
5. The guidelines clearly establish that the licensing requirements apply to domestic, foreign, public, and private manufacturers, distributors, wholesalers, importers, exporters and retailers;
6. the NRA applies these requirements consistently, and has documentary evidence, preferably public, to demonstrate this.

Furthermore, the assessor should verify the guidelines are available, intelligible, and properly communicated to the target audience. For these communications, a push rather than a pull approach should be employed.

**Objective:**

The objective of this sub-indicator is to ensure that guidelines for submitting an application for a license are available to those governed by the regulations. These guidelines should address the content of the application and its format. Availability of such guidelines will contribute to proficiency in all aspects of GXP covered by the legislation and to proper interpretation and implementation of the guidelines. Availability of guidelines also will help the NRA to be consistent in application of this
**Requirement:**
Guidelines on content and format of the application and on procedure to follow when submitting a license application.

**Evidence to review:**
The assessor should ask for and review:
1. Published guidelines for licensing applications, including instructions or guidelines for applicants.
2. Evidence that administrative instructions exist and that they are all available to establishments applying for licenses.
3. Official requirements for the submission of licensing applications;
4. Documented evidence from the NRA demonstrating that this indicator is implemented (if no publicly-available evidence is available)

**References:**

**Framework:**
Structure/Foundation/Input

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** There are no guidelines for the content and format of the license application.
- **ONGOING IMPLEMENTATION (OI):** The NRA is preparing to establish such guidelines, but there is no evidence of results associated with such activities, or the guidelines are available within the NRA however they are not available, intelligible or communicated to the target audience.
- **PARTIALLY IMPLEMENTED (PI):** The guidelines were established recently and it is at the early implementation stage, so this practice is not yet consolidated.
- **IMPLEMENTED (I):** The NRA has guidelines for producers on the content of the application and its format, and on the procedures to follow when submitting an application for a production license in accordance with WHO standards. The NRA also consistently maintains documentation of the results of related activities over time.
<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>Sub Indicator:</td>
<td>LI01.05: There are legal provisions that require manufacturers to inform the NRA about the appointed qualified and authorized person for the purpose of acknowledgment or approval.</td>
</tr>
<tr>
<td>MATURITY LEVEL:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that legal provisions or regulations exist to obligate the manufacturer to designate a qualified and authorized person.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure the existence of legal provisions or regulations that provide necessary mandate to the NRA to obligate the manufacturers to designate a qualified and authorized person.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Legal provisions, regulations and guidelines on the qualified and authorized person</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review: 1. Legal provisions or regulations authorizing the NRA to approve or acknowledge the qualified and authorized person appointed by the manufacturer;</td>
</tr>
<tr>
<td>Framework:</td>
<td>Structure/Foundation/Input</td>
</tr>
<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): There is no legal basis for the indicator. ONGOING IMPLEMENTATION (OI): The NRA is preparing to establish a legal basis for this requirement, but there is no evidence of</td>
</tr>
</tbody>
</table>
any results from those preparations.

PARTIALLY IMPLEMENTED (PI): The legal basis was established recently (less than one year ago) and it is at the implementation stage, so this practice is not yet consolidated.

IMPLEMENTED (I): The NRA has legal provisions in place requiring manufacturers to designate a qualified and authorized person and to inform the NRA of this for notification and approval purposes.

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).

<table>
<thead>
<tr>
<th>Indicator:</th>
<th>LI02 Arrangement for effective organization and good governance.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective:</td>
<td>The objective of this indicator is to ensure the implementation of effective organization and good governance practices at the organizational structures in charge of establishment licensing activities.</td>
</tr>
<tr>
<td>Category:</td>
<td>02. Organization and governance</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>LI02.01: There is a defined structure with clear responsibilities to conduct establishments licensing activities.</td>
</tr>
<tr>
<td>MATURITY LEVEL:</td>
<td>2</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should identify the organization designated to establish, implement or maintain the licensing regulatory function, as well as the specific organizational structures 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 between these structures is taking place.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure effective organization and good governance of establishment licensing activities and to ensure that these licensing activities are taken over by defined organizational structures with clear roles and responsibilities.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Roles and responsibilities of the structures in charge of establishment licensing activities.</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review: 1. Organization chart of the organization responsible for the implementation of licensing activities along with identification of the specific structures implementing the function.</td>
</tr>
</tbody>
</table>
2. Documentation clarifying roles and responsibilities of the organizational structures implementing licensing activities. This may include administrative decrees, terms of reference, or other relevant documents

**References:**

**Framework:** Structure/Foundation/Input

**Rating Scale:**
- NOT IMPLEMENTED (NI): There is no defined structure in charge of establishment licensing activities.
- ONGOING IMPLEMENTATION (OI): A mandate to establish a structure in charge of licensing activities is available however the structure itself is not yet established.
- PARTIALLY IMPLEMENTED (PI): Structure in charge of licensing activities is newly established and mandated however the regular work and practice of this structure is not yet consolidated.
- IMPLEMENTED (I): There is a defined structure in charge of establishment licensing activities with clear and well-documented roles and responsibilities.

**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:** LI02.02: Documented procedures and mechanisms are implemented to ensure the involvement and communication between all stakeholders relevant to establishments licensing activities.

**Maturity Level:** 3

**Description:** The assessor should verify that documented procedures and mechanisms are implemented to ensure the involvement and communication between different entities and departments relevant to licensing activities. These entities may be inside or outside the NRA (e.g., laboratory, inspection and enforcement departments, police authorities, and professional associations). In case of a decentralized establishment licensing function, an information exchange system, mechanism or platform must be
established and used so that appropriate communication between the central and peripheral structures is ensured. As one example, the decentralized entity can receive requests or guidance from the central authority and report back to it. The availability of such communication mechanisms will also encourage consistency among different peripheral structures.

**Objective:**

The objective of this sub-indicator is to ensure the existence and implementation of documented procedures and mechanisms to guide the involvement and communication among the different entities and departments. These activities will encourage appropriate organization and good governance of the function.

**Requirement:**

Organization and governance

**Evidence to review:**

The assessor should ask for and review:
1. Guidelines or standard operating procedures (SOPs) that are related to external and internal communications;
2. Documentation of paths of communication and reporting;
3. Platforms for information sharing and exchange.

**References:**


**Framework:**

Structure/Foundation/Input

**Rating Scale:**

NOT IMPLEMENTED (NI): There are no information exchange procedures or mechanisms among different stakeholders of the licensing function or between the central authority and the decentralized entities.

ONGOING IMPLEMENTATION (OI): The NRA is developing an information exchange mechanism, but it is not yet ready, or exchanges are being conducted without an established methodology.
PARTIALLY IMPLEMENTED (PI): The NRA recently established an information exchange procedure and mechanism and it is at the implementation stage, so this practice is not yet consolidated.

IMPLEMENTED (I): There are established, implemented and maintained information exchange procedures and mechanisms among different stakeholders of the licensing function and between the central authority and the decentralized entities.

**Limitations and remarks:**

The scope of this sub-indicator is not confined only to routine activities, but also applies, most importantly, to regulatory decisions and actions.

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

**Indicator:** LI03 Human resources to perform licensing 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 licensing function. This will ensure that medical products licensing processes or 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 licensing function.

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

**Sub Indicator:** LI03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform licensing activities

**Maturity Level:** 3

**Description:**

The assessor should verify that the human resources assigned to perform licensing 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 SOPs that provide guidance on the required background for licensing 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 licensing 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.

**Objective:**
The objective of this sub-indicator is to ensure the existing human resources for licensing is sufficient, in terms of numbers, experience, and specific competencies, to perform all the activities along the entire licensing chain.

**Requirement:**
Sufficient number of competent human resources in charge of licensing activities.

**Evidence to review:**
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 licensing 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 licensing activities are appropriate with respect to education, skills, and expertise, to perform a particular function along the licensing chain. Documentation should include a list of the requisite skills and training for each position.
5. Recruitment plan.

**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)

**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 licensing 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 licensing 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:
**LI03.02: Duties, functions, and responsibilities of the staff in charge of licensing 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 licensing 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 licensing 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 licensing activities.

### Evidence to review:
The assessor should ask for and review:
1. Procedure 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.

References:

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: LI03.03: Training plan developed, implemented and updated at least once a year for staff in charge of licensing 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 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.

The assessor should verify that inspectors in charge of Good Manufacturing Practices inspections associated with manufacturer licensing activities receive a minimum of ten (10) training days per year as recommended by the WHO and Pharmaceutical Inspection Cooperation Scheme guidelines.

**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 licensing 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 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.
<table>
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<th>References:</th>
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<tr>
<th>Framework:</th>
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<td>Process</td>
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<th>Rating Scale:</th>
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</thead>
</table>
| 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 planed 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. |

<table>
<thead>
<tr>
<th>Limitations and remarks:</th>
</tr>
</thead>
</table>
| 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 licensing-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>LI03.04: 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>
</tbody>
</table>

**Description:**
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.

**Objective:**
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.

**Requirement:**
Training records

**Evidence to review:**
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.

**References:**
### 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:

LI04 Procedures established and implemented to perform licensing activities.

#### Objective:

The objective of this indicator is to ensure that the NRA, when supported by appropriate mandates, effective organization and governance, and essential resources, is actually able to perform the licensing activities. These activities are performed through standard procedures and work instructions in order to ensure consistency, effectiveness, efficiency, impartiality and proportionality of the activities.

There should be written procedures that define how relevant data are routinely shared among key personnel engaged in licensing activities and on how any actions taken are reviewed for appropriateness. Documented evidence to be assessed include procedures for review and sharing of relevant data between key players, for review of reports of notifications, investigations, data analyses, and committee meetings, and for taking appropriate actions.

#### Category:

Regulatory process
<table>
<thead>
<tr>
<th>Sub Indicator:</th>
<th><strong>LI04.01:</strong> Procedures for assessment of applications for licensing activities, including license issuance, renewal, modification or revocation, are established and documented.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MATURITY LEVEL:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that different phases of licensing activities, including application receiving, screening, processing, assessing, and decision-making (e.g., issue, renew, amend, modify, suspend or revoke) are well established and documented. With particular emphasis on license renewals, amendments and modifications, the relevant procedures and mechanisms should ideally be based on Quality Risk Management principles. When applicable, the validity of the establishment license should be stated in the respective certificate in order to clarify status and to avoid misunderstandings.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure consistency and standardization of licensing activities through established and documented procedures and mechanisms that are complemented with the necessary tools.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Regulatory process</td>
</tr>
</tbody>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. SOPs, checklists and records for different licensing activities (e.g. issuance, renewal, modification, and revocation);  
2. Evaluation reports provided by the NRA and other documented evidence of decisions that were based on the procedures. |
| Framework:     | Process                                                                                                                                                                                          |
### Rating Scale:

<table>
<thead>
<tr>
<th>Rating Scale</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT IMPLEMENTED (NI)</td>
<td>There are no procedures for making decisions on license issuance, renewal, modification, or revocation.</td>
</tr>
<tr>
<td>ONGOING IMPLEMENTATION (OI)</td>
<td>The NRA is preparing procedures for making decisions on licensing activities, but they are not completed so there is no evidence of results from such activities.</td>
</tr>
<tr>
<td>PARTIALLY IMPLEMENTED (PI)</td>
<td>Procedures for different licensing activities are newly established and at the implementation stage, so this practice is not yet consolidated.</td>
</tr>
<tr>
<td>IMPLEMENTED (I)</td>
<td>The NRA has procedures for making decisions on license issuance, renewal, modification, or revocation; the NRA applies the procedures consistently, and reliably maintains documentation of the results of related activities over time.</td>
</tr>
</tbody>
</table>

### Limitations and remarks:

In some countries, license renewal might not be applicable. Rather the license is maintained based on regular inspections for compliance with GXPs. In this case, the requirement to document license renewals will not apply provided the assessor confirms the proper implementation of regular regulatory inspections.

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

### Sub Indicator:

**LI04.02: Inspection is required for granting or re-granting a license or approval of a substantial modification.**

### Maturity Level:

3

### Description:

The assessor should verify the existence and implementation of standard procedures for the inspection process that is required before granting or re-granting a license or approval of a substantial modification. The inspection should be carried out in accordance with the official guidelines and in accordance with a formal inspection plan.

### Objective:

The objective of this sub-indicator is to ensure that the inspectorate has established procedures and other mechanisms to consistently perform inspections before granting or re-granting a license or an approval of a substantial modification. Also, the objective is to ensure consistency of licensing and inspection procedures and to ensure regulatory compliance of establishments. These activities will promote the ultimate goal of protecting public health.

### Requirement:

Regulatory process

### Evidence to review:

- The assessor should ask for and review:
  1. Procedures for the inspection process.
  2. SOPs, checklists and records for different licensing activities (e.g. issuance, renewal, modification, or revocation.
  3. Examples of inspection reports done prior to license issuance, renewal, amendment or revocation.
4. Procedures for the NRA to conduct GXP inspections.

## References:


## Framework:

| Process |

## Rating Scale:

| NOT IMPLEMENTED (NI): License issuances and renewals and approvals of substantial modification are never made in conjunction with GXP inspections. |
| ONGOING IMPLEMENTATION (OI): License issuances and renewals and approvals of substantial modification are sometimes made in conjunction with GXP inspections. |
| PARTIALLY IMPLEMENTED (PI): License issuances and renewals and approvals of substantial modification have been made in conjunction with GXP inspections for a short time (less than one year) so this practice is not yet consolidated. |
| IMPLEMENTED (I): License issuances and renewal and approvals of substantial modification are always made in conjunction with GXP inspections. |

## Limitations and remarks:

In some cases, a license or approval of a substantial modification may be granted without inspection. However, these should be seen as exceptional situations and need to be justified, well described and compatible with guidelines. Also, these activities are tightly linked to transparency.

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>LI04.03: There are clearly defined timelines for the assessment of applications.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MATURITY LEVEL:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that clear timelines have been defined for the different steps in the licensing process as well as for the different types of license applications, including new applications and applications for license renewals or modifications. These timelines should be clear and understandable to the target audience. The assessor should review examples of the processing of different applications and ensure that a proper monitoring system is in place to verify adherence to the stated timelines.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure the existence and implementation of standard procedures for defining clear timelines for the processing of license applications.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Regulatory process</td>
</tr>
</tbody>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. Records of license processing that cover the steps from initial application up to issuance of final decision. Assessor review should focus on timelines.  
2. Records from the timelines tracking system, if available. |
| References:   |                                                                                   |
| Framework:    | Process                                                                          |
| Rating Scale: | NOT IMPLEMENTED (NI): There are no timelines for different licensing activities.  
ONGOING IMPLEMENTATION (OI): The NRA is drafting timelines for different licensing activities however these are not yet implemented and no results are yet achieved.  
PARTIALLY IMPLEMENTED (PI): The NRA recently established timelines for different licensing activities so this practice is not yet consolidated.  
IMPLEMENTED (I): There are clear timelines, which are tracked, for different licensing activities. |
<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>Sub Indicator:</th>
<th><strong>LI04.04:</strong> The same criteria are used for the licensing of domestic, public and private establishments regardless of ownership.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MATURITY LEVEL:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that the conduct of licensing activities and application of the relevant standards, procedures, and GXPs is consistent and unbiased regardless of the source of production (e.g., domestic or foreign, public or private sector).</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure consistent and unbiased conduct of licensing activities and application of relevant standards, procedures and GXPs.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Regulatory process</td>
</tr>
</tbody>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. SOPs or similar documents that ensure that the same licensing criteria are used regardless of ownership of the establishment (e.g., domestic, foreign, public or private).  
2. Sample licensing records for establishments from different ownership categories (e.g., domestic, foreign, public or private). |
| Framework: | Process |
| Rating Scale: | NOT IMPLEMENTED (NI): The NRA does not apply the same licensing criteria for domestic, public and private establishments, including for products at the research and development stage. |
| 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: | LI05 Mechanism in place to monitor regulatory performance and output. |

| Objective: | The objective of this indicator is to ensure the existence and implementation of a system or mechanism for monitoring regulatory performance and output and for using that information to estimate the effectiveness and efficiency of the licensing function. |

| Category: | 09. Monitoring progress and assessing outcomes and impact |

| Sub Indicator: | LI05.01: A database is established and regularly updated that includes all licensing applications received, approved, refused, suspended or withdrawn, along with the essential documentation for each application. |

| MATURITY LEVEL: | 4 |

| Description: | The assessor should verify that, within the NRA, there is a database of all the applications received, approved, refused, suspended or withdrawn. The database should also include the essential documentation for each application. At a minimum, documentation should include the applications received and records of assessments done, and regulatory decisions made. |

<p>| Objective: | The objective of this sub-indicator is to ensure consistency and traceability of licensing activities through the establishment and maintenance of a database of all the applications received, approved, refused, suspended or withdrawn, along with the essential documentation for each application. |</p>
<table>
<thead>
<tr>
<th>Requirement:</th>
<th>Monitoring progress and assessing outcomes and impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review:</td>
</tr>
<tr>
<td></td>
<td>1. The NRA internal database of the licensing applications along with the regulatory decisions made for each application (i.e., approved, rejected, denied, withdrawn, cancelled, or suspended).</td>
</tr>
<tr>
<td>Framework:</td>
<td>Output</td>
</tr>
<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): There is no internal database of licensing applications along with their regulatory decisions (i.e., approved, rejected, denied, withdrawn, cancelled, or suspended).</td>
</tr>
<tr>
<td></td>
<td>ONGOING IMPLEMENTATION (OI): The NRA is working on the establishment of an internal database of licensing applications along with their regulatory decisions (i.e., approved, rejected, denied, withdrawn, cancelled, or suspended) however the database is not yet established.</td>
</tr>
<tr>
<td></td>
<td>PARTIALLY IMPLEMENTED (PI): The NRA has recently established an internal database of licensing applications along with their regulatory decisions (i.e., approved, rejected, denied, withdrawn, cancelled, or suspended) however the outputs and outcomes of this practice are not yet documented.</td>
</tr>
<tr>
<td></td>
<td>IMPLEMENTED (I): There is an implemented internal database of licensing applications along with their regulatory decisions (i.e., approved, rejected, denied, withdrawn, cancelled, or suspended).</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>
</tbody>
</table>
### Sub Indicator: LI05.02: Performance indicators for licensing activities are established and implemented

<table>
<thead>
<tr>
<th>MATURITY LEVEL:</th>
<th>4</th>
</tr>
</thead>
</table>

#### Description:

The assessor should verify the existence and implementation of performance indicators for different activities included under the licensing functions. Specifically, the system should define key performance indicators (KPIs) along the entire licensing 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.

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 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 licensing chain. Additionally, the objective is to ensure that KPIs are actually contributing to monitoring of regulatory performance, to measuring effectiveness of licensing regulatory activities, and to making any necessary adjustments or optimizations.

#### Requirement:

KPIs for licensing 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 licensing activity chain.
2. Evidence that the performance indicators have been established and implemented, and that the members of staff involved in the licensing function are aware of the indicators and the guidelines and SOPs used for monitoring and evaluating their performance.
3. The current performance indicators for licensing 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 licensing activities.
- **ONGOING IMPLEMENTATION (OI):** The NRA has recently drafted KPIs for licensing activities but they have not yet been reported.
- **PARTIALLY IMPLEMENTED (PI):** The NRA has developed KPIs for licensing activities and has been applying them for less than two years or they have not covered all critical steps.
- **IMPLEMENTED (I):** The NRA has established and implemented KPIs for licensing 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 licensing 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>LI06 Mechanism exists to promote transparency, accountability and communication.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective:</td>
<td>The objective of this indicator is to ensure that mechanisms are in place that promote effective communication inside and outside the NRA, that promote transparency and outreach to the public, and that establish milestones that encourage accountability of the NRA to its mandate. Additionally, these contribute to mutual understanding and involvement of all stakeholders relevant to licensing activities. Consequently, confidence in the regulatory system is raised.</td>
</tr>
<tr>
<td>Category:</td>
<td>08. Transparency, accountability and communication</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>LI06.01: An updated list or database of all licensing applications, along with the regulatory decision for each, is regularly published and publicly available.</td>
</tr>
<tr>
<td>MATURITY LEVEL:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify the availability of a well-established mechanism or procedure to promote transparency, accountability and communication of licensing activities. The assessor should check the availability of an updated and complete list or database of licensed facilities throughout the supply chain, along with the regulatory decision for each application (i.e., whether the license was granted or not). The assessor should determine whether the list or database is published and can be accessed by the public. As a minimal requirement, the list or database of all manufacturing licenses approved should be publicly available on the NRA website or the official government record of each country. The list or database should be maintained and regularly updated. This information supports decision-making on other regulatory activities within the NRA and provides transparency for the general public on the status of the NRAs licensing activities. The publication of negative decisions (i.e. applications which were not granted or approved) is encouraged; however, priority should go to approved applications.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to build confidence and accountability of the licensing process via enhanced transparency.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Transparency, accountability and communication</td>
</tr>
</tbody>
</table>
### Evidence to review:
The assessor should ask for and review:
1. Databases of establishments licensed by the NRA containing information on licenses that were approved, withdrawn, canceled, or suspended;
2. Latest publicly available list of licensed establishments.

### References:

### Framework:
Output

### Rating Scale:
- **NOT IMPLEMENTED (NI):** There is no publicly available list or database of all establishment licenses along with their regulatory actions.
- **ONGOING IMPLEMENTATION (OI):** The NRA is preparing to establish a database on licensed establishments, but there is no evidence of results from such activities.
- **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):** There is a publicly available list or database of all establishment licenses along with their regulatory actions.

### Limitations and remarks:
The legal provisions may not allow publication of the establishments that have been sanctioned or suspended.

### Sub Indicator:
LI06.02: Inspection reports or summaries (or excerpts) relevant to licensing activities are published and publicly available.

### MATURITY LEVEL:
4
**Description:**
For inspections relevant to licensing activities, the assessor should verify that reports of inspections performed are available for the general public. The information which can be shared with the public varies according to the national legislation. In some countries, full inspection reports, redacted or non-redacted, might be published. In other countries, only inspection summaries or excerpts might be publicly available.

**Objective:**
The objective of this sub-indicator is to build confidence and accountability in the licensing entity via enhanced transparency through publication of the licensing-related inspection data.

**Requirement:**
Transparency, accountability and communication

**Evidence to review:**
The assessor should ask for and review:
1. Procedures and processes for publishing the list of inspections performed;
2. List of inspections performed;
3. Examples of actual published Inspection reports or summaries (or excerpts)

**References:**

**Framework:**
Output

**Rating Scale:**
- NOT IMPLEMENTED (NI): Licensing relevant inspection reports or summaries (or excerpts) are not publicly available.
- ONGOING IMPLEMENTATION (OI): The NRA established a procedure or mechanism by which licensing-relevant inspection reports or summaries (or excerpts) could be publicly available, however, this is not yet implemented.
- PARTIALLY IMPLEMENTED (PI): Licensing-related inspection reports or summaries are publicly available, but only upon request (i.e., using a pull rather than push publication mechanism).
**IMPLEMENTED (I):** Licensing relevant inspection report or summaries (or excerpts) are regularly and consistently published and publicly available.

**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).