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

REGULATORY INSPECTION (RI): INDICATORS AND FACT SHEETS

Revision VI version 1

November 2018
<table>
<thead>
<tr>
<th>Function:</th>
<th>06- REGULATORY INSPECTION (RI)</th>
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</table>
| Description: | Inspection of establishments across the medical product supply chain is an essential regulatory function. The supply chain includes manufacturers, distributors, re-packagers, re-labelers, importers, agents, traders, wholesalers and retailers of medical products. The purpose of regulatory inspections is to ensure that operations at these establishments are carried out in accordance with approved standards, norms, and guidelines and are in compliance with the national medical products legislation and regulations. These, in turn, should be consistent with World Health Organization recommendations and other internationally recognized guidelines. The scope of the function applies to different Good Practices (GXPs) and is not limited to Good Manufacturing Practices (GMPs). Good Distribution Practices and Good Clinical Practices also come under the scope of this function. Good Vigilance Practices are not addressed in this function but are addressed under the vigilance function. National Regulatory Authorities (NRAs) should have the legal mandate to inspect and enforce GXPs throughout the supply chain, to make decisions concerning the issuance, suspension or withdrawal of establishment licenses, and to issue authorizations or certifications for the activities performed by these establishments. Additionally, the NRA should develop policies, regulatory actions and procedures on the handling of medical products with suspected quality defects and medical products identified as substandard and falsified. Commonly, inspectors perform several types of inspections: pre-licensing or post-licensing, pre-approval or post-approval, announced or unannounced, and domestic or overseas inspections. Inspection activities should be conducted based on a risk management approach. Inspections reveal weaknesses and deficiencies, as well as actual or potential errors in the production, quality control, storage or distribution of medical products. Therefore, inspection activities are fundamental for guaranteeing the quality, safety and efficacy of medical products used by the population. An appeal system that is independent of the body that made the initial decision should be available.

The credibility of the inspection depends on the transparency and clarity of the process, on the absence of... |
conflicts of interest, and on the availability of regulations, directives, guidelines and procedures related to the quality management and assurance system of the inspectorate. The system also is highly dependent on the technical competence and integrity of the inspectors. The inspectorate must also ensure confidentiality of the information obtained in the course of its inspection activities.

Networking with other international bodies and NRAs is an important method for acquiring, sharing, and exchanging information relevant to the quality and safety of medical products; in turn, this information contributes to informed science-based decisions. The inspectorate of the NRA should follow uniform procedures incorporating quality system principles.

A general limitation for this function exists in countries where no domestic manufacturing capacities exist. In this case, domestic regulatory inspections based on GMP are not applicable; however Good Distribution Practices would always apply. Similarly, Good Clinical Practices inspections might not apply in countries where no clinical trials are conducted. Even in the absence of a domestic pharmaceutical manufacturer, a GMP inspection function is needed. GMP compliance is always a requirement for granting marketing authorization for a medical product. In this case, GMP compliance can be assured through overseas inspections or desk assessments, which may or may not include verification of documentation. Thus, even if there is no domestic manufacturer, there will be a need for a function which can ensure the GMP compliance of foreign pharmaceutical manufacturers either by physical inspection or desk review (e.g., taking into consideration the GMP certificates from a stringent regulatory authority).

<table>
<thead>
<tr>
<th>Indicator:</th>
<th>RI01 Legal provisions, regulations and guidelines required to define regulatory framework of inspection and enforcement.</th>
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</thead>
<tbody>
<tr>
<td>Objective:</td>
<td>The objective of this indicator is to ensure that regulatory inspection 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. Furthermore, national GXP rules should be consistent with internationally recognized and accepted GXP guidelines such as those from the World Health Organization. The NRA should show evidence that laws, regulations, decrees, agreements, or other mandatory legal provisions are in place regarding inspections that evaluate compliance with best practices and that provide oversight of activities at the establishments.</td>
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</tbody>
</table>
The legal provisions also should provide a mandate to inspect the establishments of marketing authorization holders, manufacturers, importers, exporters, and distributors for compliance with national standards and GXP guidelines.

<table>
<thead>
<tr>
<th>Category:</th>
<th>01. Legal provisions, regulations and guidelines</th>
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</thead>
<tbody>
<tr>
<td>Sub Indicator:</td>
<td>RI01.01: Legal provisions authorize the inspectorate to inspect and enforce Good Practices (GXPs) throughout the supply chain.</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>1</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that current legislation establishes fundamental functions in the regulatory authority that is appointed to verify compliance with laws, regulations, standards and GXPs. These include Good Manufacturing Practices (GMP) for manufacturers, Good Distribution Practices (GDP) for distributors, wholesalers and retailers, and Good Clinical Practices (GCP) for sites where clinical studies are conducted. The assessor should also verify that legislation provides the obligation for manufacturers and marketing authorization (MA) holders to inform the National Regulatory Authority (NRA) of: 1. any safety signal or any quality defect which could impact patient safety of a marketed product, and 2. any marketing or regulatory decisions made in the country of origin or in another country where the product is marketed. In line with these legal provisions, the assessor should review the relevant, approved guidelines that explain the reporting obligations and that describe how, when and what quality defects or safety issues have to be reported. Examples of the types of reports include recall notifications, reports of study results from ongoing or previous studies, and information on supervision of clinical trials. Similar obligations should also be in force for the MA holder for all products marketed in the country. The assessor should ensure the existence and the implementation of a set of enforcement actions in case of non-compliance. The enforcement actions should include, but are not limited to recall, suspension, withdrawal, sanction, and prosecution. The assessor should identify if the law gives the inspectorate the mandate, power and authority that is adequate to implement administrative measures such as suspending or stopping production or supply. To ensure the quality of marketed products, such actions would be required in case of violations of regulatory requirements or detection of confirmed quality defects (i.e., circumstances potentially leading to issuance of a rapid alert).</td>
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<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure that laws, regulations, decrees, agreements, or other mandatory legal provisions have been established that give authority to the inspectorate to inspect establishments (e.g., MA holders, manufacturers, importers, exporters, and distributors) to assess compliance with best practices and to provide oversight of activities. The regulatory authorities should have the mandate to evaluate compliance with national standards and GXP guidelines throughout</td>
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<tr>
<td>Requirement:</td>
<td>Legal provisions, regulations and guidelines</td>
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</tbody>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. Published legal provisions (e.g., laws, acts, executive orders, or regulations) establishing the mandate for the inspectorate to inspect establishments and enforce regulations;  
2. Legal provisions establishing the authority to inspect according to GXP throughout the supply chain. |
| Framework: | Structure/Foundation/Input |
| Rating Scale: |  
NOT IMPLEMENTED (NI): There are no legal provisions for mandating the NRA to inspect and enforce GXP.  
ONGOING IMPLEMENTATION (OI): The NRA is taking steps toward the establishment of legal provisions to allow for regulatory inspections however no formal mandate exists for the regulatory inspection function.  
PARTIALLY IMPLEMENTED (PI): The NRA has the legal provisions to conduct the regulatory inspection activities; however such activities are recently implemented and results associated with this sub-indicator are not yet documented.  
IMPLEMENTED (I): Legal provisions exist for mandating the NRA to inspect and enforce GXP. |
<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>
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<tbody>
<tr>
<td>Sub Indicator:</td>
<td>RI01.02: Legal provisions allow inspectors to enter facilities throughout the supply chain at any reasonable time and in any place.</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>1</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that the legal provisions provide the mandate, the power and the authority for the inspectors to enter establishments throughout the supply chain at any reasonable time and in any place within those facilities. In this context, “any reasonable time” means any time within normal working hours of the establishment that is the subject of the inspection. For example, if the establishment operates during the night, then the legal provisions should ideally authorize the inspectors to have access at that time. On the other side, access to unlicensed or unauthorized establishments or access to establishments outside normal working hours may not be mandated by the respective legal provisions. In such cases, special approvals from judicial departments might be needed.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure that laws, regulations, decrees, agreements, or other mandatory legal provisions regarding inspections are actually providing the necessary mandate to allow inspectors to enter establishments throughout the supply chain at any reasonable time and in any place within those facilities. Such provisions should apply to regulatory inspections that evaluate compliance with best practices and provide other oversight activities. Additionally, these provisions significantly contribute to efficiency and effectiveness of inspection function.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Legal provisions, regulations and guidelines</td>
</tr>
</tbody>
</table>
| Evidence to review:     | The assessor should ask for and review:  
1. Published legal provisions (e.g. laws, acts, executive orders, or regulations)  
2. Examples of inspection records. Assessor should review inspection activities and select examples of records of unannounced or “for cause” inspections that were initiated either as a part of an investigation or in response to a complaint or quality issue. |
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| Framework: | Structure/Foundation/Input |
| Rating Scale: | NOT IMPLEMENTED (NI): There are no legal provisions allowing the inspectors to enter establishments throughout the supply chain at any reasonable time and in any place within the facilities. ONGOING IMPLEMENTATION (OI): The NRA is taking steps toward the establishment of legal provisions to allow inspectors to enter establishments throughout the supply chain at any reasonable time and in any place within the facilities; however, no results yet exist. PARTIALLY IMPLEMENTED (PI): Legal provisions allowing the inspectors to enter establishments throughout the supply chain at any reasonable time and in any place within facilities are recently established; however, the results of this practice are not yet documented. IMPLEMENTED (I): There are legal provisions allowing the inspectors to enter establishments throughout the supply chain at any reasonable time and in any place within the facilities, and documented evidence exists to demonstrate that it happens. |
| 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: | RI01.03: Legal provisions allow inspectors to collect relevant evidence, including samples, during GXP inspections. |
| Maturity Level: | 2 |
| Description: | The assessor should verify that inspectors have the power and authority to collect any important evidence during their inspection and investigation activities. Examples of evidence include copies of documents, photos, videos and samples. As part of compliance verification, the designated inspectors should also be able to collect product samples for testing by the national control laboratory at any phase of the production or supply chain. |
| Objective: | The objective of this sub-indicator is to ensure that the respective laws, regulations, decrees, or other mandatory legal provisions |
allow inspectors to collect relevant evidence, including samples, during GXP inspections. Samples can also be used to check adulteration which might appear during the supply chain.

| Requirement: | Legal provisions, regulations and guidelines |
| Evidence to review: | The assessor should ask for and review:  
1. Published legal provisions (e.g. laws, acts, executive orders, or regulations)  
2. Examples of inspection records. Assessor should review inspection reports and the evidence (e.g., documents or materials) or samples collected during inspection activities.  
3. Records of laboratory results for samples and decisions based on those results. |

| 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)  
5. WHO good manufacturing practices for sterile pharmaceutical products, World Health Organization (WHO) (61) (http://apps.who.int/medicinedocs/en/q/ and http://digicollection.org/whoqapharm/)  
6. WHO guidelines for drafting a site master file, World Health Organization (WHO) (64) (http://apps.who.int/medicinedocs/en/q/ and http://digicollection.org/whoqapharm/)  
10. Guidelines for good clinical practice (GCP) for trials on pharmaceutical products (40) (http://apps.who.int/medicinedocs/en)  


**Framework:** Structure/Foundation/Input

**Rating Scale:**

- **NOT IMPLEMENTED (NI):** There are no legal provisions allowing the inspectors to collect relevant evidence, including samples, during GXP inspections.
- **ONGOING IMPLEMENTATION (OI):** The NRA is taking steps toward the establishment of legal provisions to allow inspectors to collect relevant evidence, including samples, during GXP inspections however this has not yet been carried out.
- **PARTIALLY IMPLEMENTED (PI):** There is evidence that the NRA has the legal basis, elements, and capacity to perform the processes mentioned in the indicator, but the NRA has only limited, recent experience with it.
- **IMPLEMENTED (I):** There are legal provisions allowing the inspectors to collect relevant evidence, including samples, during GXP inspections and the implementation of this activity is documented.

**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:** RI01.04: Updated national GXP regulations, norms or guidelines are mandatory.

**Maturity Level:** 3

**Description:** The assessor should review the GXP regulations and guidelines which should be updated, published and available to all stakeholders. Also, the assessor should verify that the guidance is consistent with World Health Organization (WHO) or other...
internationally recognized guidance. If applicable, differences should be identified. The assessor should verify that the national regulations are mandatory and actually implemented.

**Objective:**

The objective of this sub-indicator is to ensure that national GXP regulations, norms and guidelines are available and their implementation is mandatory for the establishments subjected to regulatory inspections.

**Requirement:**

Legal provisions, regulations and guidelines

**Evidence to review:**

The assessor should ask for and review:

1. Published GXP regulations, norms and guidelines (e.g. GMP, GDP, GCP, and Good Cold Chain Management Practices)
2. Evidence that the guidelines are implemented and enforceable by the NRA.

**References:**

7. WHO good manufacturing practices for pharmaceutical products: main principles (51) (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)
10. WHO good manufacturing practices for sterile pharmaceutical products, World Health Organization (WHO) (61)
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<tr>
<th>Framework:</th>
<th>Structure/Foundation/Input</th>
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<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): National GXP guidelines do not exist or are not mandatory. ONGOING IMPLEMENTATION (OI): The NRA is taking steps towards establishment of national GXP guidelines however none of these guidelines (e.g., GMP, GDP, and GCP) is yet established. PARTIALLY IMPLEMENTED (PI): Some national GXP guidelines (e.g., GMP, GDP or GCP) are established while others are not. IMPLEMENTED (I): National GXP regulations, norms and guidelines exist and are mandatory.</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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<tr>
<td>Sub Indicator:</td>
<td>RI01.05: Legal provisions and regulations allow the recognition of and/or reliance on foreign NRA inspections and enforcement actions based on well-defined criteria.</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>1</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should review the legal provisions and regulations which should be available and published and verify that the guidance allows for the recognition of and/or reliance on foreign NRA inspections and enforcement actions based on well-defined criteria. While the criteria may vary significantly, the assessor must ensure the criteria are clear and supported by an appropriate rationale.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure that laws, regulations, or other mandatory legal provisions are actually providing the mandate for the recognition of and/or reliance on foreign NRA inspections and enforcement actions based on well-defined criteria.</td>
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<tr>
<td>Requirement:</td>
<td>Legal provisions, regulations and guidelines</td>
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</table>
| Evidence to review: | The assessor should ask for and review:  
1. Published legal provisions and regulations for recognition and/or reliance.  
2. Examples of records demonstrating recognition of and/or reliance on foreign NRA inspections and enforcement actions. |
| Framework: | Structure/Foundation/Input |
| Rating Scale: | NOT IMPLEMENTED (NI): There are no legal provisions or regulations allowing the recognition of and/or reliance on foreign NRA inspections and enforcement actions.  
ONGOING IMPLEMENTATION (OI): The NRA is taking steps toward the establishment of legal provisions and regulations allowing the recognition of and/or reliance on foreign NRA inspections and enforcement actions however this has not yet been carried out in practice.  
PARTIALLY IMPLEMENTED (PI): Legal provisions or regulations allowing the recognition of and/or reliance on foreign NRA inspections and enforcement actions are recently established, but there is only limited, recent experience (less than two years) with the implementation of the same.  
IMPLEMENTED (I): There are legal provisions or regulations allowing the recognition of and/or reliance on foreign NRA inspections and enforcement actions. |
Limitations and remarks: In some countries neither recognition nor reliance are permitted. In this case, the assessor can score the sub-indicator as NOT APPLICABLE if evidence is provided to show effective and efficient regulatory inspection function without recognition or reliance.

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<thead>
<tr>
<th>Indicator:</th>
<th>RI02 Arrangement for effective organization and good governance.</th>
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<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 entities in charge of establishments licensing activities, which in turn contributes to effective and efficient functioning of the regulatory inspection activities.</td>
</tr>
<tr>
<td>Category:</td>
<td>2. Organization and good governance</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>RI02.01: There is a defined organizational structure with clear responsibilities to conduct regulatory inspection 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 regulatory inspection 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 among these structures takes place.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure effective organization and good governance of regulatory inspection activities and to ensure that these activities are taken over by defined structures with clear roles and responsibilities.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Roles and responsibilities of the structures in charge of establishments 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 inspection activities along with identification of the particular structures implementing the function. 2. Documentation clarifying roles and responsibilities of the organizational structures implementing inspection activities. This may include administrative decrees, terms of reference, and other relevant documents. 3. Documentation identifying established mechanisms of coordination (e.g., committees, internal and work-sharing) among</td>
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organizational structures, if any, which take part in regulatory inspection activities.

**References:**


**Framework:**

Structure/Foundation/Input

**Rating Scale:**

- NOT IMPLEMENTED (NI): There is no defined organizational structure in charge of regulatory inspection activities.
- ONGOING IMPLEMENTATION (OI): A mandate to establish a structure in charge of regulatory inspection activities is available however the structure itself is not yet established.
- PARTIALLY IMPLEMENTED (PI): A structure in charge of regulatory inspection 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 organizational structure in charge of regulatory inspection 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:**

RI02.02: Documented procedures and mechanisms are implemented to ensure the involvement and communication among all stakeholders relevant to regulatory inspection activities.

**Maturity Level:**

3
Description: The assessor should verify that documented procedures and mechanisms are implemented to ensure the involvement and communication among different entities and departments relevant to regulatory inspection activities. These entities may be inside or outside the NRA (e.g. National Control Laboratory, NRA departments involved in vigilance or MA activities, police, customs authorities, judicial offices, professional associations, manufacturers, and other industrial organizations). 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: Agreements, memoranda of understanding and procedures for ensuring involvement of and communication among stakeholders relevant to regulatory inspection function.

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. Examples of records of communication and collaborations providing evidence for implementation of the above-mentioned procedures.
3. Documented evidence for regular formal and official communications and meetings among above mentioned key players. Assessor should verify that these are systematic and well-established processes.
4. Documentation for paths of communication and reporting.
5. Platforms for information sharing and exchange.

References:

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<th>Structure/Foundation/Input</th>
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<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): There are no information exchange procedures or mechanisms among different stakeholders of the regulatory inspection 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 or mechanism and it is at the early 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 regulatory inspection function and between the central authority and the decentralized entities.</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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<tr>
<td>Indicator:</td>
<td>RI03 Human resources to perform regulatory inspection activities.</td>
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<tr>
<td>Objective:</td>
<td>The objective of this indicator is to ensure to that all entities within an NRA are adequately resourced with a trained, experienced and skilled workforce that is empowered to fully perform the regulatory inspection function. This will ensure that regulatory inspection activities are performed in accordance with international best practices.</td>
</tr>
<tr>
<td>Category:</td>
<td>06. Resources (HR, FR, infrastructure and equipment)</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>RI03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform regulatory inspection activities</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
<tr>
<td><strong>Description:</strong></td>
<td>The assessor should verify that the human resources assigned to perform regulatory inspection 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 regulatory inspection 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 regulatory inspection 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.</td>
</tr>
<tr>
<td><strong>Objective:</strong></td>
<td>The objective of this sub-indicator is to ensure the existing human resources for regulatory inspection is sufficient, in terms of numbers, experience, and specific competencies, to perform all the activities along the entire regulatory inspection chain.</td>
</tr>
<tr>
<td><strong>Requirement:</strong></td>
<td>Sufficient number of competent human resources in charge of regulatory inspection activities.</td>
</tr>
<tr>
<td><strong>Evidence to review:</strong></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 regulatory inspection 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 regulatory inspection activities are appropriate with respect to education, skills, and expertise, to perform a particular function along the regulatory inspection chain. Documentation should include a list of the requisite skills and training for each position. 5. Recruitment plan.</td>
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<thead>
<tr>
<th>Framework:</th>
<th>Process</th>
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| Rating Scale: | NOT IMPLEMENTED (NI): The NRA does not have enough competent staff (i.e., education, training, skills and experience) to perform regulatory inspection 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 regulatory inspection 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: | RI03.02: Duties, functions, and responsibilities of the staff in charge of regulatory inspection 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 regulatory inspection 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. When inspection activities are subcontracted, liability of third party inspectors should be clearly defined in an agreement or contract. 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 regulatory inspection 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.

<p>| 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 regulatory inspection 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 any 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. |</p>
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<th>Framework:</th>
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<tr>
<td>Rating Scale:</td>
<td>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.</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>RI03.03: Training plan developed, implemented and updated at least once a year for staff in charge of regulatory inspection activities.</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>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</td>
</tr>
</tbody>
</table>
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 GMP inspections receive a minimum of ten (10) training days per year as recommended by the WHO and Pharmaceutical Inspection Cooperation Scheme guidelines. Furthermore, the NRA should establish the minimum number of days that an inspector must spend on inspections in order to retain competence.

| 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 regulatory inspection 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.  
8. Documentation of the number of training days per inspector as well as average number of training days for staff.  
9. Number of days spent on site for inspections per inspector as well as average number of days spent on inspection. |

<table>
<thead>
<tr>
<th>Framework:</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rating Scale:</td>
<td>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.</td>
</tr>
<tr>
<td>Limitations and remarks:</td>
<td>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 regulatory inspection-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).</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>RI03.04: The NRA generates and maintains records of staff training activities and training effectiveness verification.</td>
</tr>
<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</td>
</tr>
</tbody>
</table>
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: | RI04 Procedures established and implemented to perform inspection and enforcement.

Objective: | The objective of this indicator is to ensure the NRA or Inspectorate is supported by appropriate mandates, effective organization and governance, and essential resources. The regulatory inspection activities should be implemented through standard procedures and work instructions in order to ensure consistency, effectiveness, efficiency, impartiality and proportionality of the activities.  
The NRA should have established a system which allows the regular review of quality aspects of the authorized products on the market, and which includes processes to review and share relevant data between key players and to take appropriate action.

Category: | 07. Regulatory process

Sub Indicator: | RI04.01: The different inspection activities, including inspection preparation, conduct and reporting, are documented for GXP inspections.

Maturity Level: | 3

Description: | The assessor should verify the existence of procedures for efficiently working on planning, preparing, conducting, reporting and monitoring of activities for GXP inspections performed throughout the supply chain. The assessor should also confirm the
existence of documented procedures and resources to enable regulatory GXP inspections to be carried out in accordance with official guidelines and national legislation and in accordance with a formal inspection plan. All relevant instructions, standards, written procedures, worksheets, check lists and reference data should be maintained up-to-date and be readily available to staff. As part of inspection processes and procedures, the assessor should verify that inspection reports are prepared in accordance with applicable national or other requirements. In addition, the assessor should verify that reports are prepared in approved format and signed and dated by the relevant inspector. Ideally, the report should follow a standard format which in, turn, is in compliance with the relevant WHO guidelines or other internationally recognized and accepted guidelines.

**Objective:**

The objective of this sub-indicator is to ensure that all pre-inspection, inspection and post-inspection activities are well-documented and follow written procedures. These activities include inspection planning, preparation (e.g., inspection announcement and designation of inspectors), conduct (e.g., opening meeting and evidence collection), and reporting (e.g., classification of findings, closing meeting, conclusions and recommendations). These procedures enable the regulatory inspections of manufacturing and distribution operations to be carried out in accordance with official guidelines and national legislation and in accordance with a formal inspection plan. Following these procedures will also ensure consistency, effectiveness, impartiality and proportionality of practices.

**Requirement:**

Regulatory process

**Evidence to review:**

The assessor should ask for and review:
1. SOPs and procedures for planning, conducting, and monitoring of GXP inspections, as well as records for performance of these activities;
2. GXP inspection reports and documentation of processes for inspection review and follow-up. The inspection process should be analyzed on a regular basis.;
3. Instructions, worksheets, check lists and reference data relevant to the different inspection activities.

**References:**

Framework: Process

Rating Scale:
- NOT IMPLEMENTED (NI): There is no documentation for the different inspection activities that evaluate compliance with GXP, including inspection preparation, conduct and reporting.
- ONGOING IMPLEMENTATION (OI): The NRA is preparing to establish the procedures along with the associated documentation for the different inspection activities that check compliance with GXP, including inspection preparation, conduct and reporting; however these are not yet established.
- PARTIALLY IMPLEMENTED (PI): There is evidence that the NRA has the capacity to conduct the inspections mentioned in the indicator, with procedures and documentation in place; however, experience is limited or recent and therefore the relevant records are limited.
- IMPLEMENTED (I): The NRA has established procedures for the different inspection activities that check compliance with GXP, including inspection preparation, conduct and reporting, and the NRA consistently maintains documentation of the results of related activities over time.

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: RI04.02: Regulatory inspection follow-up, decision-making (including certification) and enforcement activities are documented.

Maturity Level: 3

Description: The assessor should check the availability and implementation of procedures related to following up after the inspection, making of regulatory decisions (including certifications) and initiating enforcement actions. There should be written guidance, e.g., on how to follow up on identified deficiencies. The assessor should review documented evidence that actions were initiated when needed, e.g. with regard to product MAs or establishment licenses. The assessor should review examples of inspection reports, with special...
attention to findings and observations from the inspection and to deficiencies, recommendations, summaries and conclusions. The assessor should check and verify that relevant regulatory actions were taken to enforce compliance with GXP. Assessor should review that any corrective or preventive actions taken as a result of audits (or other reports of non-conformities) are implemented and documented, and that effectiveness of the actions is verified. The assessor should also verify the existence of internal procedures or mechanisms to ensure that GXP certifications (where applicable) are properly issued. Evidence that a system is in place for GXP certification should also be reviewed.

| Objective: | The objective of this sub-indicator is to ensure the availability and implementation of procedures related to following up after the regulatory inspections, making of regulatory decisions (including certifications) and initiating enforcement actions. Assessor should review evidence that actions were initiated, when needed, e.g., with regard to product MAs or establishment licenses. Such documentation would in turn contribute to consistency and effectiveness of the regulatory inspection function. |
| Requirement: | Regulatory process |
| Evidence to review: | The assessor should ask for and review: 1. SOPs for GXP follow up 2. SOPs for GXP certification 3. SOPs for GXP enforcement 4. Examples of GXP certificates 5. Examples of GXP enforcement records. |

References:

<table>
<thead>
<tr>
<th>Framework:</th>
<th>Process</th>
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</thead>
</table>
| Rating Scale: | NOT IMPLEMENTED (NI): There is no documentation of the regulatory inspection follow up, decision-making (including certification) or enforcement activities.  
ONGOING IMPLEMENTATION (OI): The NRA is preparing to establish procedures along with the associated documentation for regulatory inspection follow up, decision-making (including certification) and enforcement activities.  
PARTIALLY IMPLEMENTED (PI): There is evidence that the NRA has established the documentation relevant to regulatory inspection follow up, decision-making (including certification) and enforcement activities; however NRA experience with these activities is only recent or limited.  
IMPLEMENTED (I): The NRA demonstrates that all the regulatory inspection follow up, decision-making (including certification) and enforcement activities are in place, and that the NRA consistently maintains documentation of the results of related activities over time. |
| 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: | RI04.03: Inspection planning is based on quality risk management (QRM). |
| Maturity Level: | 3 |
| Description: | The assessor should verify the existence and implementation of QRM throughout the process of inspection planning. The scope of QRM includes:  
• Planning of routine GXP inspections by the inspectorates;  
• Inspections of Investigational Medicinal Product manufacturers;  
• Follow-up activities, such as assigning a new risk rating to the site following the receipt of new information about the site or its products. This normally occurs between inspections. Examples of the types of new information might include information on quality defects, product recalls, market surveillance or product testing.  
This review process requires a complete knowledge of the GXP compliance status. New sites should not be rated for their initial inspection in accordance with QRM principles, because the inspectorate in question probably will not have the necessary and complete knowledge about the site or products. Thus, QRM should not normally be applied until a full inspection has occurred.  
Important questions to be answered during the process of preparing for an inspection include: |
1. The focus, depth, site and the duration of the inspection;
2. The required number of inspectors to be assigned;
3. Identification of any specific competency or expertise required on the inspection team.

Applying QRM principles require the collection of relevant data during inspection preparation, and these data (e.g. vigilance, laboratory, and previous inspection data) are fundamental for risk-based planning.

The preparation requires the inspectors to consider the following items before making their recommendations:
1. Specific areas in which deficiencies were identified during the most recent inspection at the site;
2. Specific areas that were not inspected in recent inspections;
3. Any new information that may relate to the site, for example, new quality defect reports, MA variation applications affecting the site, product recall actions, non-conforming results from market surveillance testing, or any other general indicators of non-compliance (e.g., a failure to implement a MA variation on time).

Ideally, a meaningful and robust inspection plan based on QRM should be developed in conjunction with data from other regulatory departments (e.g. vigilance data, quality control data, or market surveillance data).

### Objective:

The objective of this sub-indicator is to ensure that planning of the frequency and scope of inspections is based on QRM for enhancement of the inspection programme effectiveness and efficiency. QRM is a methodology based upon the concept of rating sites on the basis of an estimated risk that they may pose to patients, consumers, animals and users of medicines. The Inspectorates should prioritize sites for inspection when planning the frequency and scope of GXP inspections.

### Requirement:

Regulatory process

### Evidence to review:

The assessor should ask for and review:
1. Procedures describing methodology for developing annual (i.e., routine) inspection plans along with examples of completed plans;
2. Documentation of GXP inspection plan review process along with any updates to the inspection plans (e.g., updates based on access to additional information).

### References:


Framework: Process

Rating Scale: NOT IMPLEMENTED (NI): There is no evidence of activities or documentation for this indicator.
ONGOING IMPLEMENTATION (OI): The NRA is preparing to establish procedures to plan inspections based on risk management but no results yet exist.
PARTIALLY IMPLEMENTED (PI): There is evidence that the NRA has procedures to plan inspections based on risk management, as well as the capacity to perform the procedures mentioned in the indicator; however NRA experience with this is only recent or limited. If inspection planning has only recently been established, the rating should be PI.
IMPLEMENTED (I): The NRA demonstrates all the aforementioned elements and also consistently maintains documentation of the results of related activities over time.

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: RI04.04: Multi-disciplinary teams are used to ensure proper expertise for inspection of specific medical products.
<table>
<thead>
<tr>
<th>Maturity Level:</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description:</strong></td>
<td>The assessor should verify the existence and implementation of a system for defining the composition of the inspection team. The composition of the inspection team should be based on the skills and experience required for the type of inspection being performed. A lead inspector should be designated. This lead inspector has the responsibility to coordinate the entire inspection process (i.e., from the planning up to the evaluation of the corrective measures) in active collaboration with the other members of the inspection team. Assessor should note that a follow-up inspection would trigger a new inspection process. Sub-contracted personnel or experts may be employed as part of an inspection team to assist or to advise in a technical capacity; however, the team should normally be led by a GMP lead inspector. Sub-contracted personnel should be bound by the requirements of the quality system and there should be a written contractual agreement between the parties. Organizations, experts or other persons to whom inspection activities are contracted, should be free from any commercial or financial pressures which might affect their freedom to act. They should follow defined ethics rules to avoid conflict of interests. Senior management of the Pharmaceutical Inspectorate should ensure that these outside persons are appropriately qualified and experienced and that they are independent of any organizations which they might be asked to inspect. In case of specialized or highly sophisticated products (e.g. vaccines or advanced therapy medicinal products), experts may be asked to join the inspection team. However, it is important that designation of the necessary experts be based on QRM in order to ensure consistency, effectiveness, impartiality and proportionality of inspection process. The number of members of the inspection team is another aspect which should be considered for optimal work of the team throughout the inspection process.</td>
</tr>
</tbody>
</table>

| Objective: | The objective of this sub-indicator is to ensure that optimal human resources are available for and involved in regulatory inspections. Optimal composition of inspection teams contributes to effective and efficient implementation of the function. |

| Requirement: | Regulatory process |

<table>
<thead>
<tr>
<th>Evidence to review:</th>
<th>The assessor should ask for and review:</th>
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</thead>
<tbody>
<tr>
<td>1. Procedures for team inspections</td>
<td></td>
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<tr>
<td>2. Examples of inspection plans, including nominations for inspection teams.</td>
<td></td>
</tr>
<tr>
<td>3. Examples of inspection records.</td>
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</tbody>
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<tbody>
<tr>
<td>2. Quality systems requirements for national good manufacturing practice inspectorates. In: WHO Expert Committee on</td>
<td></td>
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<tr>
<td>Framework:</td>
<td>Process</td>
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</tr>
<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): The NRA does not use multi-disciplinary teams for inspection of specific medical products. ONGOING IMPLEMENTATION (OI): The NRA is taking steps to use multi-disciplinary teams for inspection of specific medical products but no results are yet available. PARTIALLY IMPLEMENTED (PI): The NRA recently established the practice of using multi-disciplinary teams for inspection of specific medical products however results of such practice are not yet documented. IMPLEMENTED (I): The NRA regularly and consistently uses multi-disciplinary teams for inspection of specific medical products.</td>
</tr>
<tr>
<td>Limitations and remarks:</td>
<td>In order to ensure the access to certain specific expertise, the inspection team may include experts from the quality control laboratory or reviewers or other personnel external to the NRA. However, there is still a need for all members of the inspection team to be qualified as inspectors with at least a minimum of inspection training (e.g., techniques for asking questions or writing observations). 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>RI04.05: Inspection findings and observations are categorized according to QRM.</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
</tbody>
</table>
| Description: | The assessor should verify the existence and implementation of a quality system that covers the different inspection processes. The assessor should also verify that inspection findings and observations are categorized according to QRM following a systematic process consistent with WHO or other internationally-recognized guidelines (e.g., observations should be classified as critical, }
**Objective:**
The objective of this sub-indicator is to ensure that QRM considerations include reporting and are not limited to inspection planning, preparation and conduct. Use of QRM for the reporting process would significantly contribute to efficiency and effectiveness of the inspection process, including the categorization of the findings and observations.

**Requirement:**
Regulatory process

**Evidence to review:**
The assessor should ask for and review:
1. Procedures for categorization of findings, including categorization criteria
2. Examples of reviews of inspection reports
3. Examples of findings reviews and categorizations. These should be compared to categorization procedures and criteria.

**References:**
## Framework: Process

### Rating Scale:

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT IMPLEMENTED (NI)</td>
<td>Inspection findings and observations are not categorized according to QRM.</td>
</tr>
<tr>
<td>ONGOING IMPLEMENTATION (OI)</td>
<td>The NRA is taking steps to categorize inspection findings and observations according to QRM, but no results are yet available.</td>
</tr>
<tr>
<td>PARTIALLY IMPLEMENTED (PI)</td>
<td>The NRA recently established the practice to categorize findings and observations according to QRM; however results of such practice are not yet documented.</td>
</tr>
<tr>
<td>IMPLEMENTED (I)</td>
<td>Inspection findings and observations are categorized according to QRM.</td>
</tr>
</tbody>
</table>

### Limitations and remarks:

As per WHO guidelines (WHO Technical Report Series 996, annex 4, Guidance on good manufacturing practices: inspection report), a “critical” deficiency may be defined as an observation that has produced, or may result in a significant risk of producing, a product that is harmful to the user. A “major” deficiency may be defined as a non-critical observation that:

- a) has produced or may produce a product that does not comply with its MA and/or prequalification application (including variations);
- b) indicates a major deviation from the GMP guide;
- c) indicates a failure to carry out satisfactory procedures for release of batches;
- d) indicates a failure of the person responsible for quality assurance or quality control to fulfill his or her duties; or
- e) consists of several other deficiencies, none of which on its own may be major, but which together may represent a major deficiency and should be explained and reported as such.

A deficiency may be classified as “other” if it cannot be classified as either critical or major but indicates a departure from GMP. A deficiency may be classified as “other” either because it is judged as minor or because there is insufficient information to classify it as “major” or “critical.”

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

### Sub Indicator:

RI04.06: The same criteria are used for the inspection of domestic, foreign, public and private facilities regardless of the ownership.

### Maturity Level:

3

### Description:

The assessor should check that the same criteria are applied equally for all establishments, domestic, foreign, public, or private, regardless of ownership. In this case, the relevant criteria include regulatory requirements and actual inspection and enforcement actions. In the evaluation of this sub-indicator, the assessor is asked to perform a systematic review and comparison of inspection processes as applied to different types of facilities.

### Objective:

The objective of this sub-indicator is to ensure that regulatory requirements are applied equally for all inspections (i.e., domestic,
<table>
<thead>
<tr>
<th>Requirement:</th>
<th>Regulatory process</th>
</tr>
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</table>
| Evidence to review: | The assessor should ask for and review:  
1. Examples of inspection processes and reports from domestic, foreign, public, or private facilities. Assessor should review these to confirm that there are no differences in application of regulatory requirements, regardless of ownership. |
| Framework: | Process |
| Rating Scale: | NOT IMPLEMENTED (NI): There is no evidence that the inspectorate uses the same criteria for the inspection of domestic, foreign, public and private establishments regardless the ownership.  
ONGOING IMPLEMENTATION (OI): The NRA is working on ensuring that the same criteria are used for the inspection of domestic, foreign, public and private establishments regardless the ownership; however, no yet results are yet available.  
PARTIALLY IMPLEMENTED (PI): There is evidence that the NRA uses the same criteria for the inspection of domestic, foreign, public and private establishments regardless the ownership; however, it has only limited or recent experience with it.  
IMPLEMENTED (I): There is evidence that the NRA uses the same criteria for the inspection of domestic, foreign, public and private establishments regardless the ownership; and also consistently maintains documentation of the results of related activities over time. |
**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><strong>Indicator:</strong></th>
<th>RI05 Mechanism in place to monitor regulatory performance and output.</th>
</tr>
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<tbody>
<tr>
<td><strong>Objective:</strong></td>
<td>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 regulatory inspection function.</td>
</tr>
<tr>
<td><strong>Category:</strong></td>
<td>09. Monitoring progress and assessing outcomes &amp; impact</td>
</tr>
<tr>
<td><strong>Sub Indicator:</strong></td>
<td>RI05.01: A database is established and regularly updated of all establishments which may be subject to inspection, along with their relevant regulatory decisions (certifications and/or enforcement activities).</td>
</tr>
<tr>
<td><strong>Maturity Level:</strong></td>
<td>4</td>
</tr>
<tr>
<td><strong>Description:</strong></td>
<td>The assessor should verify the existence of an updated database of all facilities and premises subject to regulatory inspections throughout the supply chain. Clinical trial sites should also be included. The database should be comprehensive and should contain essential information for the inspected facility, as well as information from previous inspections (e.g., general information, conclusions, and relevant regulatory decisions such as certification or enforcement actions). Furthermore, the assessor should verify that the database is regularly updated in accordance with well-established procedures and mechanisms.</td>
</tr>
<tr>
<td><strong>Objective:</strong></td>
<td>The objective of this sub-indicator is to ensure consistency and traceability of regulatory inspection activities through the establishment and maintenance of a database of all the inspected establishments along with the regulatory decisions associated with each establishment (e.g., certifications and enforcement actions).</td>
</tr>
<tr>
<td><strong>Requirement:</strong></td>
<td>Monitoring progress and assessing outcomes and impact</td>
</tr>
</tbody>
</table>
| **Evidence to review:** | The assessor should ask for and review:  
1. Database of inspected facilities showing inventory of facilities along with regulatory decisions. |

### Framework:
- Output

### Rating Scale:
- **NOT IMPLEMENTED (NI):** There is no list or database of all establishments that are subject to inspection along with their regulatory actions (certification and/or enforcement).
- **ONGOING IMPLEMENTATION (OI):** The NRA is preparing to establish a database, 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 list or database of all establishments that are subject to inspection along with their regulatory actions (certification and/or enforcement). Also, this list or database is regularly updated.

### Limitations and remarks:
- Some facilities may be subject to inspection without being licensed by the NRA (e.g. clinical trial sites). Although these sites may not be licensed by the NRA, ideally, they are licensed by another governmental institution. Integration and communication within the government is critical in the latter situation.
- Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

### Sub Indicator:
- **RI05.02:** Inspection reports are well-archived and easily retrieved.

### Maturity Level:
- 3
<table>
<thead>
<tr>
<th>Description:</th>
<th>The assessor should verify that reports of inspections are well-archived and easily retrieved. The assessor should review how all the information collected during the inspection process is managed and how inspection reports are registered and archived (e.g., in paper or electronic formats).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure that a mechanism or procedure is in place for defining a standard format for inspection reports and for setting up an archival system which is secure and can be reached only by authorized, competent personnel. Reports should be easily, securely, effectively and efficiently retrieved.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Monitoring progress and assessing outcomes and impact</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>The assessor should ask for and review: 1. SOPs for archiving and retrieval of inspection reports 2. Evidence for adequate space and suitability of the archive system 3. Documentation of the time needed to retrieve inspection reports.</td>
</tr>
<tr>
<td>Framework:</td>
<td>Output</td>
</tr>
</tbody>
</table>
| Rating Scale: | NOT IMPLEMENTED (NI): Inspection reports are not properly archived and not easily retrieved.  
ONGOING IMPLEMENTATION (OI): The NRA is in the process of establishing an inspection archival system.  
PARTIALLY IMPLEMENTED (PI): Inspection report archival system is recently established; however, consolidated documentation over time (at least two years) is not yet available.  
IMPLEMENTED (I): Inspection reports are properly archived and easily retrieved. |
| 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: | RI05.03: Inspection reports are subjected to a regular and robust review by experts other than the designated inspection team. |
| Maturity Level: | 4 |
| Description: | The assessor should check the existence of a process for systematic review of each inspection report by a group of experts other than the designated inspectors who performed the inspection and wrote the report. The reviewing experts or committee may be internal or external provided that the necessary confidentiality and declaration of interest measures are followed as indicated in the transparency and communication indicator. The review process should be technically efficient, thorough and deep. |
| Objective: | The objective of this sub-indicator is to ensure the existence of a systematic review of each individual inspection report by a group of experts other than the designated inspectors who performed the inspection and wrote the report. This enhances objectivity and fairness and reduces bias. |
| Requirement: | Regulatory process |
| Evidence to review: | The assessor should ask for and review:  
1. SOPs for review of GXP inspection reports  
2. Examples of records of the review of GXP inspection reports. |
### Framework:
Process

### Rating Scale:

- **NOT IMPLEMENTED (NI):** Inspection reports are not subjected to a regular and robust review by experts other than the designated inspection team.
- **ONGOING IMPLEMENTATION (OI):** The NRA is in the process of establishing a regular and robust review by experts other than the designated inspection team; however, such a mechanism or process is not yet established.
- **PARTIALLY IMPLEMENTED (PI):** The NRA recently established a process for regular and robust review by experts other than the designated inspection team; however, it is at the implementation stage, so this practice is not yet consolidated.
- **IMPLEMENTED (I):** Inspection reports are subjected to a regular and robust review by experts other than the designated inspection team.

### 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:
RI05.04: Inspection data and outcomes are systematically evaluated or interpreted.

### Maturity Level:
4

### Description:
The assessor should confirm that inspection reports and data, including inspection findings and outcomes, are collectively reviewed, analyzed, evaluated and interpreted in a systematic way to identify gaps, strengths, and trends. The output of this systematic review and analysis represents the body of inspection metrics. The availability of these inspection metrics enables the NRA to identify relevant guidelines that require developing or updating, to set up and amend inspection plans and resources, and to re-structure the format of inspection process.
### Objective:
The objective of this sub-indicator is to ensure that a system is in place for checking and confirming the effectiveness of the regulatory inspection programme through the systematic review, analysis, evaluation and interpretation of the inspection reports.

### Requirement:
Monitoring progress and assessing outcomes and impact

### Evidence to review:
The assessor should ask for and review:
1. Documentation of available inspection data and analyses of outcomes (i.e., inspection metrics).
2. Documentation showing frequency of data analysis and review.

### References:

### Framework:
Output

### Rating Scale:
- **NOT IMPLEMENTED (NI):** Inspection data are not systematically evaluated and interpreted.
- **ONGOING IMPLEMENTATION (OI):** The NRA is in the process of establishing a system for inspection data evaluation and interpretation.
- **PARTIALLY IMPLEMENTED (PI):** The NRA recently established a system for evaluation and interpretation of inspection data; however, consolidated documentation over a time (at least two years) is not yet available.
- **IMPLEMENTED (I):** Inspection data are systematically evaluated and interpreted.
<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>RI05.05: Performance indicators for regulatory inspection 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 regulatory inspection functions. Specifically, the system should define key performance indicators (KPIs) along the entire regulatory inspection 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.</td>
</tr>
<tr>
<td>Objective:</td>
<td>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 regulatory inspection chain. Additionally, the objective is to ensure that KPIs are actually contributing to monitoring of regulatory performance, to measuring effectiveness of regulatory inspection regulatory activities, and to making any necessary adjustments or optimizations.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>KPIs for regulatory inspection activities</td>
</tr>
<tr>
<td>Evidence to review:</td>
<td>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 regulatory inspection activity chain. 2. Evidence that the performance indicators have been established and implemented, and that the members of staff involved in the regulatory inspection function are aware of the indicators and the guidelines and SOPs used for monitoring and evaluating</td>
</tr>
</tbody>
</table>
their performance.
3. The current performance indicators for regulatory inspection 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 regulatory inspection activities.
ONGOING IMPLEMENTATION (OI): The NRA has recently drafted KPIs for regulatory inspection activities but they have not yet been reported.
**PARTIALLY IMPLEMENTED (PI):** The NRA has developed KPIs for regulatory inspection 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 regulatory inspection 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 regulatory inspection 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>RI06 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 communication within and outside the NRA, that promote transparency and outreach to the public, and that establish milestones that reflect the accountability of the NRA to its mandate. Additionally, these contribute to mutual understanding and involvement of all stakeholders relevant to regulatory inspection 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>RI06.01: The list of inspectors is publicly available and the identity of the designated team for each inspection is communicated to the relevant institutions subject to inspections.</td>
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<tr>
<td><strong>Maturity Level:</strong></td>
<td>4</td>
</tr>
<tr>
<td><strong>Description:</strong></td>
<td>The assessor should verify that a proper mechanism is available, enacted and used, together with internal procedures, to ensure that information related to the list and identity of the inspectors is publicly available. The assessor should also verify that the identity of the designated team for each inspection is provided to the institutions that are being inspected. The communications regarding information of designated inspectors may be done via public communication aids (e.g., website or national bulletin) or,</td>
</tr>
<tr>
<td><strong>Objective:</strong></td>
<td>The objective of this sub-indicator is to ensure confidence building and accountability of the licensing structure via enhanced transparency, specifically, a mechanism to ensure the list and identity of inspectors is publicly available.</td>
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<tr>
<td>---</td>
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<tr>
<td><strong>Requirement:</strong></td>
<td>Transparency, accountability and communication</td>
</tr>
</tbody>
</table>
| **Evidence to review:** | The assessor should ask for and review:  
1. Procedures and processes for publishing the list of inspectors.  
2. Documents comparing the current NRA list of inspectors to the publicly available list of inspectors.  
3. Procedures and processes for communicating the identity of the designated team for each inspection to the relevant institution subject to inspection.  
4. Examples of inspection notifications, letters of designation or similar communications using another mechanism. |
6. PIC/S Pre-Accession Procedure, related documents, PIC/S Audit Checklist (138) |
| **Framework:** | Output |
| **Rating Scale:** | NOT IMPLEMENTED (NI): The NRA is not notifying the inspectee of the designated inspection team and the list of the inspectors is not published |
### Sub Indicator: RI06.02

The updated list or database of all inspected facilities along their regulatory decisions, actions and enforcement activities, is regularly published and publicly available.

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<tr>
<th>Maturity Level</th>
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</thead>
<tbody>
<tr>
<td><strong>Description:</strong></td>
<td></td>
</tr>
</tbody>
</table>

The assessor should verify that a well-established system is in place to ensure that information related to inspections performed is available to the general public. This information includes a list of inspections performed, along with the following information for each inspection: conclusions, regulatory decisions, regulatory actions and enforcement actions (e.g., recalls, production suspensions, license suspensions or revocations, sanctions, or prosecutions). In addition, the assessor should make sure that urgent regulatory decisions (e.g., those related to quality, safety or efficacy of a medical product) and enforcement actions affecting the public health are immediately communicated to the public to ensure high level of public health protection.

| Objective: |

The objective of this sub-indicator is to build confidence and accountability of the licensing structure via enhanced transparency through making the information related to regulatory inspections available for the general public.

| Requirement: |

Transparency, accountability and communication

| Evidence to review: |

The assessor should ask for and review:
1. Latest publicly available list or database of inspected facilities along with their conclusions, regulatory decisions, regulatory actions and enforcements.
2. Earlier publicly available list of inspected facilities.

| References: |


Framework: Output
Rating Scale:
- **NOT IMPLEMENTED (NI):** There is no publicly available list or database of all inspections performed along with their conclusions, regulatory decisions, regulatory actions and enforcements.
- **ONGOING IMPLEMENTATION (OI):** The NRA is preparing to establish a publicly available list or database of all inspections performed along with their conclusions, regulatory decisions, regulatory actions and enforcements, 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 inspections performed along with their conclusions, regulatory decisions, regulatory actions and enforcements.

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: **RI06.03: Inspection metrics are regularly published and publicly available.**

Maturity Level: 4
Description: The assessor should check that a well-established and regularly updated system or mechanism is available to communicate to the
The available quality metrics can be used as input in inspection models, but also can be used to predict possible drug shortages, to determine inspection schedules for a manufacturer, or to optimize the format of inspection processes. Some examples of possible inspection metrics include: total number inspections, relative proportion of each type of inspection (e.g., routine, cause-triggered, new product, new license, innovative pharma, or generics), number in each category of findings (i.e., critical, major or other), number of inspection findings for each inspection type, average number of findings reported for each type of inspection, average number of inspection findings over time, and the number of selected frequently occurring observations. Inspection metrics are always dependent on inspectorate mandate and activities planned. The above examples do not represent an exhaustive list of the possible metrics. Rather, other inspection metrics may be adopted based on multiple factors which include the objective, the relevance, and the ease of measurements.

**Objective:**
The objective of this sub-indicator is to ensure confidence building and accountability of the licensing structure via enhanced transparency provided by a system or mechanism in place to inform the general public of inspection metrics.

**Requirement:**
Transparency, accountability and communication

**Evidence to review:**
The assessor should ask for and review:
1. Procedures and processes addressing inspections metrics
2. Procedures and processes for publishing the inspection metrics and performance
3. Published inspection metrics.

**References:**
### Framework:
Output

### Rating Scale:
- **NOT IMPLEMENTED (NI):** Inspection metrics are not regularly published or publicly available.
- **ONGOING IMPLEMENTATION (OI):** The NRA is preparing to establish publicly available inspection metrics, 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):** Inspection metrics are not regularly 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).

### Sub Indicator:
**RI06.04: Information on inspections conducted is regularly published and publicly available in accordance with national confidentiality requirements.**

### Maturity Level:
4

### Description:
The assessor should check that the regulatory inspections performed, and reports for those inspections, are available for the general public. The information that may be shared with the public varies according to the national legislations. In some countries, full inspection reports (redacted or non-redacted) may be published. In other countries, only inspection summaries (or excerpts) may be publicly available. Both approaches are accepted; however, the earlier one is encouraged. It should be noted that publication of inspection reports or summaries would significantly contribute to regulatory reliance and recognition in the area of regulatory inspection.

### Objective:
The objective of this sub-indicator is to build confidence and accountability of the licensing structure via enhanced transparency through public availability of information on inspections performed and reports from those inspections.

### 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. The list of inspections performed
3. Examples of actual published Inspection reports or summaries (or excerpts).

### References:


### Framework:

Output

### Rating Scale:

NOT IMPLEMENTED (NI): Inspection reports or summaries (or excerpts) are not publicly available.

ONGOING IMPLEMENTATION (OI): The NRA established a procedure or mechanism by which relevant inspection reports or summaries (or excerpts) could be publicly available; however, this is not yet implemented.

PARTIALLY IMPLEMENTED (PI): Inspection reports or summaries are publicly available, but only upon request (i.e. pull rather than push mechanism).

IMPLEMENTED (I): Inspection reports or summaries (or excerpts) are regularly and consistently published and publicly available.

### Limitations and remarks: