

Regulatory Science

What it is and Why it is Important

What is Regulatory Science?

Regulatory science is a field that uses the scientific method to improve the development, review, and oversight of products or tools that require regulatory oversight. Protecting customer safety is one of the core responsibilities of regulatory science. This field of study explores methods and frameworks needed for evaluating the safety, efficacy, and quality of products within regulated industries. **Human services** combine various fields, including law, public policy, data analysis, and risk assessment to inform and guide regulatory decision-making. The goal is to ensure compliance with licensing requirements crucial for maintaining quality standards and safeguarding the well-being of individuals receiving care.

Why is Regulatory Science Important?

Without regulatory science imbedded into human service administration, oversight systems are subject to significant risks and consequences:

Limited Effectiveness: Monitoring is crucial for evaluating the effectiveness and efficiency of human services.

Lack of Accountability: Monitoring plays a vital role in ensuring accountability within human service systems.

Loss of Trust: Inadequate monitoring erodes public trust in human service systems.

Measurement and monitoring systems are regulatory science aids in the development and implementation of evidence-based regulations and policies.

Challenges:

- Unique and diverse landscapes
- Evolving practices and technologies
- Limited resources
- Balancing consistency & flexibility
- Engagement & resistance
- Data management & analysis
- Legal and ethical considerations

A proactive and adaptive approach:

- Fosters collaboration with impacted parties
- Invests in capacity-building efforts
- Leverages technology for efficient data management
- Engages in continuous evaluation and improvement of their oversight strategies

The key is determining an **effective and efficient monitoring system** needed to find the path of least resistance in complying with a given set of rules.

It's not about creating **enough** regulations – it's about finding the **right** regulations using scientific methods!

How Does Regulatory Science Relate to Licensing Systems?

Licensing agencies generate substantial amounts of data that can be analyzed to make informed decisions. Regulators can use regulatory science frameworks to analyze trends, patterns, and performance metrics to identify areas of concern or improvement. Data-driven insights enable regulators to make evidence-based decisions, allocate resources effectively, and prioritize enforcement actions where they are most needed.

What if I Want to Know More?

Regulatory science, specific to human care administration, is relatively new. Innovative methods and strategies are emerging yearly. NARA is committed to advancing the field of regulatory science by building on existing scientific evidence and strategies while working with agencies to develop data-driven and evidence-based licensing and assessment tools. Contact NARA if you are interested in learning more, or if you would like your agency to be a part of this important work.

References | Additional Reading

NARA offers a wide variety of informational and research articles accessible on our webpage inclusive of regulatory science, differential monitoring, as well as key and quality indicators. Please visit: <https://nara.memberclicks.net/key-indicators>



About NARA

The National Association for Regulatory Administration (NARA) is an international professional membership association founded in 1976 dedicated to the protection of the health, safety and well-being of children and adults in day or residential human care facilities through strong licensing and other forms of regulation.

NARA

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Differential Monitoring Focused Measurement Tools

Differential monitoring is a method used to determine the frequency of inspections needed and the scope that will be required based on the setting's licensing history. This method uses weighted risk, licensing indicators, and quality indicators to determine the number and scope of inspections that should be conducted at a licensed setting. **Focused measuring tools** are licensing inspection instruments that increase the effectiveness and efficiency of a regulatory oversight agency without producing recurring operational costs. In other words, focused measurement tools maximize performance while minimizing costs.

There are three basic types of *focused measurement tools* utilized within any differential monitoring approach:

1. **Weighted Risk Assessment** assigns weighted scores to licensing regulations based on the level of risk to persons in care in the event of regulatory noncompliance.
2. **Key Indicator Systems** identify a subset of licensing regulations that statistically predict compliance with the entire set of regulations.
3. **Quality Indicator Systems** identify a subset of licensing regulations and other non-regulatory factors to predict the overall quality of care provided in a licensed setting.

Important dependencies exist when considering differential Monitoring tools:

Full Compliance (100%)	Substantial Compliance (98-99%)
✓ Requires an inspection using <i>all licensing regulations</i> to determine 100% compliance.	✓ Requires <i>weighted risk assessment</i> to determine substantial compliance.
✓ Because all rules are in compliance, a weighted risk assessment is not required	✓ Requires full compliance with all highly weighted rules.
✓ Utilizes <i>key indicators</i> to determine if an inspection requires full or partial expansion.	✓ Utilizes <i>key indicators</i> to determine if an inspection requires full or partial expansion.

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Risk Assessment



Risk Assessment Tools are licensing inspection instruments that identify licensing rules where violations pose a greater risk to children. This approach focuses on identifying and monitoring those rules that place children at greater risk of injury or death if violations or citations occur. This is done by assigning a weight to each rule to distinguish levels of regulatory compliance. Utilizing risk assessment tools assists in building consistent compliance and improving overall consumer protection across all relevant domains.

How risk assessment tools work?

The selection of these regulations may be informed by various methods, including an internal process that seeks agreement among licensing staff and other experts, a review of research and resources, the solicitation of feedback from providers and other stakeholders, work with an external consultant, or the use of a statistical methodology to determine which regulations are most critical to protecting children from injury or death.

Maintains a research-based risk-assessment focus, including both immediate and cumulative risks.

Inspections and technical assistance are focused on high-risk rules.

Agency's enforcement continuum is applied systematically to avert or abate priority risks.

Focusing on high-risk rules

- Implement a differential monitoring policy,
- guide case management such as targeted technical assistance or witnessed visits,
- determine enforcement actions based on categories of violations, and
- assist families in better understanding the potential impact of noncompliance on their child's care.

supports licensing agency

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Key Indicator Systems for Licensing

What are Licensing Indicator Systems?

Key indicators are inspection items within the differential monitoring approach that statistically predicts overall regulatory compliance. They are an efficient metric for determining the overall regulatory compliance of a facility in a summary fashion. A Licensing Indicator System includes a shortened version of a more comprehensive licensing inspection instrument designed to measure compliance with a smaller number of rules, while predicting high compliance with all the rules. This system integrates statistical information, such as economic, social and environmental factors, to be able to provide reliable information on an organization's level of compliance.

How Do Key Indicators Systems Work?

Key Indicator Systems identify a subset of core rules from an existing full set of regulations that statistically predicts compliance with the entire set. When a key indicator is found out of compliance, a full or partial expansion is needed. To develop a key indicator system as part of the any differential monitoring system, the agency must have:

- 1 An established comprehensive set of regulations covering all areas health and safety
- 2 instrument long enough to be considered reliable in determining full compliance.
- 3 Enough historical data to understand each licensee patterns of compliance.

***To use an abbreviated inspection, independent of a risk assessment, licensees must first demonstrate a history of 100% compliance.*

Indicator systems lead to cost efficiency and overall effectiveness. Rather than a one size fits all system, state agencies use an indicator system to reward high-compliance programs with abbreviated monitoring visits, allowing more resources to focus on facilities with a history of non-compliance with more frequent visits and comprehensive technical assistance.

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Quality Indicator Systems for Licensing

What are Quality Indicator Systems?

Quality indicators are measures that provide information regarding programming within the differential monitoring approach that statistically predicts program quality. Indicators are identified from various delivery systems and quality initiatives such as licensing, QRIS, quality scales, accreditation, and professional development. The quality indicators use the Key Indicator Methodology and therefore have predictive value when it comes to determining overall quality while using a shortened version of a more comprehensive quality inspection instrument designed to measure compliance with a smaller number of requirements, while predicting high compliance with all the requirements.

How Do Quality Indicators Systems Work?

The Early Childhood Education Quality Indicators Scale (ECEQIS) uses evidence-based data already available to track and measure a program's performance. They identify a subset of core components from an existing assessment system that statistically predicts compliance with the entire set. When a key indicator is found out of compliance, a full or partial expansion is needed. All scoring and scaling utilize observation, record review and interviewing if necessary. The scale is organized into two parts: 1) Record Review and 2) Observations.

✓ Measures indicators from all major initiatives in the related field.

✓ Provides an effective and efficient means for assessing the overall quality of programs in a respective jurisdiction

✓ Specialized by selecting specific program quality indicators.

While Quality Indicator Systems have been exclusively validated in early learning programs, the methodology may be used in other licensing systems as well.

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