Regulatory Science
What it is and Why it is Important

nara
Consumer Protection Through Prevention

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.

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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%)

✔ Requires an inspection using *all licensing regulations* to determine 100% compliance.

✔ Because all rules are in compliance, a weighted risk assessment is not required

✔ Utilizes *key indicators* to determine if an inspection requires full or partial expansion.

Substantial Compliance (98-99%)

✔ Requires *weighted risk assessment* to determine substantial compliance.

✔ Requires full compliance with all highly weighted rules.

✔ Utilizes *key indicators* 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   supports licensing agency

- 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.

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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 An 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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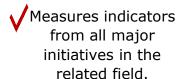Fredericksburg, VA 22405
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Quality Indicator Systems for Licensing

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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Why NARA?

The National Association for Regulatory Administration (NARA) has been developing and refining measurement tools for over 30 years. NARA's professional services and educational curricula have been used by dozens of states and provinces for program-specific research, training, and customized technical assistance for child day and residential care settings, care settings for older adults, and care settings for persons with mental illness and intellectual disabilities. Our methods are time-tested and proven to maximize agency performance without sacrificing the health and safety of persons in care.

NARA's licensing professionals are experts in the field of regulatory administration. Importantly, each member of the NARA team has real-world experience in the administration of state licensing programs, human development and education, civil law, and/or information systems. We understand the fiscal and operational obstacles faced by state and local governments and have the collective expertise to meet and overcome those obstacles.

Who Benefits?

In addition to helping inform choices regarding the allocation of public resources and assess whether programs are working, licensing indicator systems benefit:

• *Regulatory agencies*: Can spend more time providing technical assistance and/or monitoring programs with compliance issues

• *Providers*: Are rewarded for high compliance with shortened inspections and time for technical assistance

• *Public*: Can provide assurance that strong regulatory practices are occurring

• *Advocacy community*: Gain confidence that every person in care is protected through valid and reliable prevention strategies.

National Impact

NARA's Key Indicators and Risk Assessment methodologies have had a national impact. For example:

• *Stepping Stones to Caring for Our Children* used the Risk Assessment methodology in its development.

• *Caring for Our Children Basics* used Risk Assessment and Key Indicators along with other sources in its development.

• *The National Early Childhood Program Accreditation (NECPA)* system research base is drawn from the Risk Assessment and Key Indicator methodologies.

• *Head Start Key Indicator (HSKI-C)* was developed using the Key Indicator

Why Choose NARA?

Professionals at the National Association for Regulatory Administration (NARA) have been researching, developing and refining focused measurement tools for more than 40 years.

NARA has assisted dozens of states and provinces in creating program-specific research, training and customized technical assistance for a wide variety of human care settings including child care, foster care, residential care, older adult care and persons with intellectual disabilities.

NARA's consultants have the experience and expertise to provide agencies with resources to implement Key Indicator Systems. They work with states to analyze licensing compliance data, update and develop policies and procedures, and train staff to implement Key Indicator protocols. Our consultants have worked in regulatory systems as regulators, licensees, administrators, researchers and subject matter experts in specialized disciplines.

NARA specializes in assisting leadership make informed and equity-based recommendations by providing outside perspective and expertise to frame problems, analyzing data, and providing assessment.

NARA's methods are time-tested and proven to maximize agency performance without sacrificing the health and safety of persons in care. NARA's approach to the differential monitoring approach and the risk assessment and key indicator methodologies is grounded in regulatory science focusing squarely on Fiene's theory of regulatory compliance which clearly demonstrates the efficacy of the risk assessment and key indicator methodologies as being the most cost effective and efficient ways to do differential monitoring.

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The following pages list the schedule of services and estimated number of hours required for each stage of targeted measurement tool development.

** All Numbers are and may vary from one project to another, based on a variety of factors unique to that department, such as the current system, resources available, and the quality and condition of data, to name a few.

Item	Description	Estimated Number of Service Hours			
		Risk Assessment	Key Indicator	Quality Indicator	Differential Monitoring
Planning and Background Discussion	Meeting with NARA to determine the client's objectives, review the data available for tabulation and analysis, and determine the short and long-term goals of the project.	30	40	50	50
Focus Groups	Develop, organize and conduct focus groups.	50	50	100	50
Data Collection	Collection of data based on client's data storage mechanisms; identification and selection of representative sample as needed.	Varies greatly based on client's objectives, comprehensive licensing tools, and availability of data Range: 220 - 350 hours			
Data Analysis	Tabulation of data and qualitative/quantitative analysis to generate desired system.				
Development of Indicator Work Tools and Instruction Manual	Development of work tools to be used by client during inspections; creation of "System Instruction Manual" for line staff and management.	50	50	50	50
On-site/Virtual Staff Training	Training sessions for line staff and management in the use of the system, work tools, and instruction manual.	Varies greatly based on scope and number of users Range: 50-100 hours per session			
Policy Development	Development of client-specific policy and creation of explanatory material for public dissemination	125	125	150	100
On-site/Virtual Stakeholder Meetings	Coordination of meetings with stakeholders, including advocacy agencies, providers, consumers, and legislative liaisons	50	50	100	50
Pilot, Test and Validation	Implement identified system. Post pilot evaluation.	125	125	150	100
Full Implementation, Final Evaluation and Future Analysis	Plan for long-term system maintenance, including data collection and recalculation of core elements. Develop methodology for applying system to other licensing programs.	200	200	250	200
Post Project Evaluation	Evaluate the impact of approach on key outcomes.	150	150	200	125

Task	Months																							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Planning	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Stakeholder Meetings	X	X													X	X								
Data Collection		X	X	X																				
Data Analysis				X	X																			
Policy Development	X	X	X	X	X										X	X								
Work Tools & Manual		X	X	X	X	X									X	X								
Staff Training						X	X									X								
Pilot Test & Validation							X	X	X	X	X	X	X	X	X	X								
Full Implementation, Final Eval., Future Analysis & Application																	X	X	X	X	X	X	X	X
Post Project Evaluation																								X