

Regulatory Compliance Scales and Instrument Based Program Monitoring,
Differential Monitoring, and Integrative Monitoring Systems: Alternative
Paradigms for Licensing Decision Making

Richard Fiene PhD

Research Institute for Key Indicators/Penn State University

January 2024

I have written about this topic in posting to this platform but have also posted a great deal on the Medium Platform regarding the importance of the Theory of Regulatory Compliance and bringing substantial compliance to the fore front of regulatory science. This abstract and technical research note will build upon these previous assertions and expand them into some practical applications that can be utilized within regulatory science as it relates to licensing measurement, regulatory compliance scaling, and monitoring systems paradigms.

Regulatory Compliance has been always approached as an all or none phenomenon, whether a rule is in compliance, or it is not. There is no in-between or shades of gray or partial compliance. This worked when the prevailing paradigm was that full regulatory compliance and program quality were a linear relationship. This was the assumption but not empirically verified until the later 1970's-1980's. When this assumption was put to an empirical test, it did not hold up but rather a curvilinear relationship between regulatory compliance and program quality was discovered. This upset the prevailing paradigm and suggested we needed a new approach to addressing the relationship between regulatory compliance and program quality.

It became clear after these findings in the 1970's-80's and then in the 2010's when replication studies were completed that substantial regulatory compliance could not be ignored based upon this new theory of regulatory compliance in which substantial compliance acted as a "sweet spot" of best outcomes or results when comparing regulatory compliance and program quality scores. The nominal metric needed to be revised and more of an ordinal metric was to

be its replacement. Because now it wasn't just being in or out of compliance, but it mattered which rules were in or out of compliance and how they were distributed. This revised application involved aggregate rules and does not apply to individual rule scoring. The studies completed between 1970 and 2010 involved aggregate rules and not individual rules. To determine if the nominal to ordinal metric needs to be revised still needs empirical data to back this change.

The introduction of substantial compliance into the regulatory compliance measurement strategy moved the field from an instrument-based program monitoring into a more differential monitoring approach. With differential monitoring this approach considered which rules and how often reviews should be done. Also, a new Regulatory Compliance Scale was proposed to take into account the importance of substantial compliance based upon the regulatory compliance theory of diminishing returns. As this Regulatory Compliance Scale has evolved within the licensing health and safety field it needs further revision in which program quality can be infused into the decision making related to individual rules. Remember that the original studies were concerned about rules in the aggregate and not individual rules. It has now become apparent that in dealing with the infusion of quality into rule formulation, a return to the individual rule approach makes the most sense.

The next iteration of the Regulatory Compliance Scale will contain the following categories: Exceeding full compliance, Full compliance, Substantial compliance, and Mediocre compliance to adjust for the infusion of the quality element. This differs slightly from the original aggregate rule Regulatory Compliance Scale where the categories were Full compliance, Substantial compliance, Mediocre compliance and Low compliance where only licensing health and safety elements were considered (see the Table below which depicts the regulatory compliance scales and program monitoring systems side by side).

Without the Theory of Regulatory Compliance, differential and integrative monitoring would not be needed because regulatory compliance would have had a linear relationship with program quality and full compliance would have been the ultimate goal. There would have been no need for targeted rule enforcement or reviews because all rules would have had an

equal weight when it came to protecting clients and any individual rule would have predicted overall compliance. But it “just ain’t so” as it is said. The need to make adjustments is brought about by the theory and it has not been the same ever since.

Regulatory Compliance Scales and Program Monitoring Systems

<u>Scoring Level</u>	<u>Individual Rule</u>		<u>Aggregate Rules</u>	<u>Individual Rule</u>
<u>Scale</u>	Instrument based	<u>Scale</u>	Differential	Integrated
7	Full Compliance	7	Full Compliance	Exceeds Compliance
-	---	5	Substantial	Full Compliance
-	---	3	Mediocre	Substantial
1	Out of Compliance	1	Low	Mediocre/Low

The above table attempts to summarize in tabular form the previous paragraphs in describing the relationship between program monitoring and licensing measurement scaling via a proposed regulatory compliance scale. As one can see this moves the paradigm from a nominal to an ordinal measurement rubric and depicts the differences in the measurement focus either at the individual rule or aggregate rules scoring levels. It also considers the significance of substantial compliance given the theory of regulatory compliance in which substantial compliance focus is a “sweet spot” phenomenon as identified in the regulatory science research literature. It is hoped that the regulatory science field takes these paradigm shifts into consideration in moving forward with building licensing decision making systems and how licenses are issued to facilities.

As a final footnote, keep in mind that the Theory of Regulatory Compliance applies to the relationship between regulatory compliance and program quality and does not apply to regulatory compliance in and of itself related to health and safety. When dealing with regulatory compliance, full compliance is the ultimate goal with individual rules and in determining which rules are predictive rules. It is the preferred methodology in order to eliminate false negatives and decreasing false positives in making licensing decisions related to regulatory compliance.

These above concepts all relate to the field of regulatory compliance and how to make informed decisions about licensing, particularly in the context of program monitoring. Here's how they connect:

Regulatory Compliance Scales:

These scales move away from a binary "compliant" or "non-compliant" approach to regulations. Instead, they acknowledge degrees of compliance, recognizing that minor deviations may not be as detrimental as major ones.

They provide a framework for evaluating the severity and frequency of non-compliance, allowing for more nuanced licensing decisions.

Instrument Based Program Monitoring (IBPM):

This is the traditional method of monitoring compliance, relying on standardized instruments and checklists to assess adherence to specific rules.

It's a comprehensive approach, but can be time-consuming and inflexible, potentially leading to over-regulation or missing important aspects of program quality.

Differential Monitoring (DM):

This approach takes into account the risk associated with different regulations, focusing monitoring efforts on areas with the highest potential for harm or non-compliance.

It allows for a more efficient use of resources and can be tailored to the specific needs of each program.

DM often utilizes Regulatory Compliance Scales to determine the severity of non-compliance and guide the level of monitoring needed.

Integrative Monitoring Systems (IMS):

These systems go beyond simply checking compliance and aim to assess the overall quality of a program.

They integrate data from various sources, including IBPM, DM, and other program-specific metrics, to provide a holistic picture of performance.

IMS can inform licensing decisions by considering not only compliance but also program effectiveness in achieving its goals.

Here's a simplified analogy to illustrate the relationships:

Think of regulations as traffic rules.

IBPM is like a police officer checking every car for every violation, regardless of severity.

DM is like a police officer focusing on patrolling areas with high accident rates or known reckless drivers.

Regulatory Compliance Scales are like different levels of fines based on the severity of the traffic violation.

IMS is like a traffic management system that collects data on accidents, traffic flow, and road conditions to optimize traffic flow and safety.

Relationships:

RCS forms the foundation for DM and IMS by providing a way to assess degrees of compliance.

IBPM provides data for RCS and can be incorporated (with adaptations) into DM and IMS.

DM builds on RCS and IBPM by differentiating the intensity of monitoring based on risk and compliance.

IMS is the most comprehensive approach, integrating RCS, IBPM, DM, and additional data sources for a deeper understanding of program performance.

Regulatory Compliance Scales can be used within any of the monitoring approaches to provide a more nuanced assessment of compliance.

IBPM can be a starting point for differential monitoring, providing data on rule compliance to inform risk assessments.

Differential monitoring can be integrated into an integrative monitoring system, along with other data sources, to provide a comprehensive picture of program performance.

Here are some additional points to consider:

The choice of the most appropriate approach will depend on the specific context, such as the type of program being regulated and the available resources.

Implementation of these alternative paradigms requires careful planning and training of regulators and program providers.

Ongoing research and evaluation are needed to refine these approaches and ensure their effectiveness.

Conclusion:

These alternative paradigms offer a more flexible and effective approach to licensing decision-making compared to the traditional IBPM approach. They allow for a better understanding of program strengths and weaknesses, optimize resource allocation, and ultimately lead to better regulatory outcomes.

These concepts offer a shift from traditional "one-size-fits-all" compliance models to more flexible and nuanced approaches that consider risk, program quality, and degrees of

compliance. This can lead to more efficient and effective regulatory systems that support program improvement while protecting public safety.

Ultimately, these concepts offer alternative paradigms for licensing decision-making, moving away from a rigid "one-size-fits-all" approach to a more nuanced and risk-based system that considers both compliance and program quality.