Regulatory Science Selected Abstracts

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Regulatory Science and Compliance Measurement Selected Research Abstracts

Date: May 16, 2025

Subject: Review of Regulatory Science and Compliance Measurement Concepts based on Provided Research Abstracts Source Material

Purpose: This briefing document summarizes the main themes and most important ideas presented in the Research Abstracts provided source material concerning regulatory science and the measurement of regulatory compliance.

Key Themes:

Defining Regulatory Science: Regulatory science is a broad, multi-disciplinary field focused on the scientific methods used by regulatory agencies to protect the public, particularly in the context of medical products and other regulated entities.

Challenges in Regulatory Compliance Measurement: Traditional regulatory compliance measurement relies on a nominal or binary scale (in-compliance or out-of-compliance), which presents significant challenges for statistical analysis and distinguishing between levels of performance.

Shift from Nominal to Ordinal Measurement: There is a push to move regulatory compliance measurement from a nominal to an ordinal scale to provide more nuanced assessment and better distinguish between levels of compliance and quality.

Substantial Compliance: The concept of "substantial compliance" is identified as a key area of focus in regulatory science research, representing a "sweet spot" in compliance levels.

Metrics and Tools for Measurement: Several specific metrics and tools are discussed for measuring and analyzing regulatory compliance, including the Confusion Matrix (reframed as the Uncertainty-Certainty Matrix - UCM), Risk Assessment Matrices (RAM), Regulatory Compliance Scales (RCS), and Key Indicators.

Differential Monitoring: Differential or targeted monitoring, which tailors' inspection frequency and depth based on risk and compliance history, is presented as an evolution from traditional comprehensive reviews.
Relationship between Regulatory Compliance and Program Quality: The source material highlights the distinct data distributions found in regulatory compliance (skewed) and program quality (more normally distributed) and explores the potential for integrating these two areas of measurement.

Validation and Reliability: The importance of validating measurement tools and decisions, including standards validation and measures validation, is emphasized, particularly in the context of regulatory compliance systems.

Most Important Ideas and Facts:

Definition of Regulatory Science: "regulatory science is a broad term concerning drug and other product regulations, regulatory standards, law and procedures across many disciplines. It is a systematized body of knowledge (practiced by FDA and similar regulatory agencies world-wide) comprising public protection-oriented medical product regulations, policy and decisions using scientific methods employing empirical and causal..." This definition underscores the scientific basis and public protection focus of the field.

Nominal Nature of Licensing Data: "The reason for selecting this matrix is the nature of licensing data, it is binary or nominal in measurement. Either a rule/regulation is in-compliance or out of compliance." This is a foundational problem addressed throughout the sources.

The "Sweet Spot" of Substantial Compliance: "*substantial compliance focus is a "sweet spot" phenomenon as identified in the regulatory* science research literature." This suggests that aiming for perfect compliance across all rules may not be the most effective or realistic goal.

Regulatory Compliance Scale (RCS): The RCS is proposed as a new metric to address the limitations of nominal measurement by categorizing compliance into distinct "buckets": full (100%, 0 violations), substantial (99-98%, 1-2 violations), mediocre (97-90%, 3-9 violations), and low/non-optimal (89% or lower, 10+ violations).

The Uncertainty-Certainty Matrix (UCM): The UCM, adapted from the Confusion Matrix, is presented as a fundamental tool for analyzing the accuracy of licensing decisions by comparing the inspector's decision to the actual state of compliance. Its formula is given as: "$UCM = \ll A \times D \gg - \ll B \times C \gg \div \sqrt{\ll W \times X \times Y \times Z \gg}$". A coefficient closer to 1 indicates certainty (agreement), closer to -1 indicates uncertainty (disagreement), and closer to 0 indicates randomness.

Risk Assessment Matrices (RAM): RAMs, typically 3x3 matrices, are used to assess the probability and severity of a negative outcome, driving decisions about the frequency of monitoring visits in differential monitoring.

Key Indicators: Key indicators are specific rules or regulations that are particularly predictive of overall compliance or risk, used to inform "what is reviewed" in differential monitoring.

Differential Monitoring Logic: The source material describes how risk assessment drives "how frequent" visits are in differential monitoring, while key indicators drive "what is reviewed." A 2x2 matrix illustrates the relationship between differential monitoring, key indicators, weighting, and risk assessment rules.

Data Distribution Differences: "It is obvious when one observes the PQ as versus the RC data distributions that the RC data distributions are much more skewed, medians and means are significantly different, and kurtosis values are much higher which means that the data contain several outliers." This highlights the statistical challenges of working with regulatory compliance data compared to program quality data.

Validation in Data Analysis: "Although this plan is geared to dealing with risk assessment indicators, the overall plan is applicable to any data analysis plan in general. The validation phase is not followed through in many monitoring systems, especially when it comes to licensing or regulatory compliance systems." This points to a critical gap in current regulatory practices.

The Uncertainty-Certainty Risk Predictor Pyramid Model: This proposed 3D model combines the UCM (as the base, representing decision reliability) and the RAM (as the sides, representing rule validity) to illustrate how different risk levels should correlate with the certainty of licensing decisions, with the highest risk rules requiring the highest degree of certainty.

Quotes of Note:
"Either a rule/regulation is in-compliance or out of compliance. Presently most jurisdictions deal with regulatory compliance measurement in this nominal level or binary level. There is to be no gray area..."

"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." (referring to the focus on substantial compliance and other concepts)
"In this separate development and implementation, risk assessment has driven the "how frequent" visits in a differential monitoring approach while key indicators have driven "what is reviewed" when it comes to rules/regulations/standards."

"The theory of regulatory compliance has another application when it comes to regulatory compliance measurement in helping to move the licensing field from a nominal based measurement strategy to one of ordinal based measurement. The new measurement strategy is the Regulatory Compliance Scale (RCS)..."

"The basic premise of the UCM is that individual decision-making matches reality."

Conclusion:

The provided Research Abstracts source material presents a compelling case for evolving regulatory science, particularly in the area of compliance measurement. It highlights the limitations of traditional nominal measurement and advocates for the adoption of more nuanced approaches like ordinal scaling, the Regulatory Compliance Scale, and metrics like the Uncertainty-Certainty Matrix. The emphasis on substantial compliance, differential monitoring based on risk and key indicators, and the critical need for validation underscores a move towards more efficient, effective, and potentially more accurate regulatory practices. The data presented also highlights the inherent statistical challenges of working with regulatory compliance data and the need for appropriate analytical methods.

The Holy Grail of Regulatory Science: Finding the "Right Rules" with the Theory of Regulatory Compliance

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September 2024

The theory of regulatory compliance has appeared in a series of articles in the *Journal of Regulatory Science* and its spin off methodologies in other journals, *Child Care Quarterly, Child and Youth Forum, International Journal of Child Care and Education Policy, and Early Childhood Research Quarterly.* The theory has had a large impact on the human services industry, in particular the early care and education field. The purpose of this article is to reach a larger audience that may be representative of some of the other regulatory areas in the physical sciences, medical sciences and the economic sciences.

The organization of this article will first deal with the theory itself, explaining it in simple, non-mathematical terms and its implications for public policy and licensing decision making. Then we will delve into the implications and spin off methodologies of the theory, such as differential monitoring, risk assessment rule formulation, key predictor rules, the uncertainty-certainty matrix, ceiling effect, dichotomization of skewed licensing data distributions, and selecting rules that have a differential positive impact on client outcomes.

Regulatory science is a relatively new science appearing on the scene in the past 20 years. Regulatory compliance and the licensing of programs, industries, etc. has been around for quite some time. The first licensing law was passed over 100 years ago governing orphanages in

Pennsylvania. But as is clearly evident the science behind licensing and regulatory compliance lagged by many decades. Licensing grew at a slow pace in the human services during the twentieth century and it was not until the late 1960's to early 1970's that human services began to really expand and grow in terms of the number of programs driven by the Great Society programs such as Head Start. Prior to the 1960s-70s, human services was more of a cottage type industry with program monitoring done via case notes and anecdotal records. This all changed in the 1980s when an instrument-based program monitoring approach was introduced and empirical evidence was introduced into the equation of monitoring and assessing safety and quality of services for clients. Other industries grew in a corresponding way with most of the growth in later portions of the previous century. The pharmaceutical industry is a perfect example of this. In fact, regulatory science has really grown out of this need to regulate the pharmacological industry. The Food and Drug Administration (FDA) is the leading federal agency in pursuing the expansion and dissemination of regulatory science with the establishment of national centers across the USA.

The FDA defines regulatory science in the following terms: regulatory science is a broad term concerning drug and other product regulations, regulatory standards, law and procedures across many disciplines. It is a systematized body of knowledge (practiced by FDA and similar regulatory agencies world-wide) comprising public protection-oriented medical product regulations, policy and decisions using scientific methods employing empirical and causal evidence utilized in the evaluation and approval of all the products that FDA regulates.

The growth of regulatory science has been uneven and the emphases have been somewhat disjointed. My thesis in this article will be drawn from the human services industry which

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places a great deal of emphasis on facility reviews and inspections. The pharmacological industry has placed a great deal of emphasis on random clinical trials of drug efficacy and quality control related to medical devices. The two industries have continued along these two tracks in a parallel fashion since the fruition of the regulatory science field. It is hoped that through this article, intersections can be found in which the two industries can share and communicate more effectively in order to move regulatory science forward in a coordinated way. This is typical of the early stages of scientific theory in a field in which parallel avenues of thought are developed and it is only later in scientific progress that intersections are discovered related to these particular pathways.

Let me provide some historical context to the theory and how it has evolved over the past several decades based upon empirical evidence. The original standard paradigm when it came to regulatory compliance and its relationship to program quality was that there is a linear relationship between the two components of regulatory compliance and quality. As one goes up, the other goes up in a corresponding way. From a public policy standpoint this made a great deal of sense. Any licensing agency wants to see increased quality of services based upon their rules, regulations, and standards. I will only be addressing the human services, in particular early care and education programs, that is where all the research has been done. In future, it will be necessary to determine if what is being described in the human services industry related to facility reviews, applies to industries outside of this domain, such as hospitals, restaurants, housing, etc .

The problem with this standard paradigm was that it was not based on empirical evidence but rather on expert opinion and anecdotal evidence, and there were no well-designed studies that

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looked at the relationship between regulatory compliance and program quality in any of the human services. Fast forward to the 1970's as the number of early care and education programs were increasing dramatically because of the influx of federal dollars as part of the Great Society and the creation of Head Start and a major expansion of child care in the United States. It became clear that the standard paradigm which included doing case studies as their major means for data collection and program monitoring was not going to be a viable measurement strategy. This ushered in a new form of program monitoring and data collection called Instrument-based Program Monitoring which utilized checklists, tools, and instruments for their data collection and licensing measurement.

Another thing that happened in the movement from qualitative to quantitative measurement was that larger studies could be done to evaluate the relationship between regulatory compliance and program quality. Finally, there would be a chance to collect scientific data on this relationship and prove the linear relationship between regulatory compliance and program quality. When these studies were done, sure enough, low levels of regulatory compliance which essentially means rule or regulatory violations are being found and comparing these data to the overall quality of the respective programs there was a direct linear relationship and that continued to be so right up to substantial regulatory compliance which means being 98-99% in compliance with all rules and regulations. However, then a very interesting change occurred in moving from substantial regulatory compliance to full (100%) regulatory compliance in which the respective programs did not follow the linear relationship and there was a plateauing or a ceiling effect in which it was difficult to distinguish the quality of programs that were in substantial vs full regulatory compliance. It was in some cases in subsequent studies (2010's)

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which replicated these initial studies in the 1970's where the relationship followed more of a diminishing returns type of curve. Not always but definitely a ceiling effect was always observed in the data.

These results obviously upset the proverbial public policy apple cart and the standard paradigm which was based upon a linear model and that licenses should only be issued to those programs that were in full regulatory compliance, no exceptions. The data did not support this claim nor the public policy. Substantial regulatory compliance was clearly demonstrating that these programs were providing the same level of quality care as those programs that were in full regulatory compliance and in some cases were doing an even better job of providing quality care. This is the major finding of the theory of regulatory compliance demonstrating these diminishing returns and/or ceiling effect and introduces substantial regulatory compliance as a licensing decision point rather than relying only on full 100% regulatory compliance. The original paradigm still holds in that regulatory compliance is very accurate in distinguishing between low and higher quality, but it is not as accurate when it comes to distinguishing quality at the substantial regulatory compliance and the full regulatory compliance levels.

The following figure/graphic (Figure 1) depicts the relationship between regulatory compliance levels and program quality scores. This graphic is a summary depiction of the various studies that have been completed starting in the 1970's through to the 2010's in looking at this relationship. The graphic also shows the relationship to several other concepts that will be addressed in this article, dealing with differential and integrative monitoring, key indicator predictor rules, risk assessment rules, nominal data, and dichotomization of data. All these additional concepts will be dealt with in the following sections of this article.

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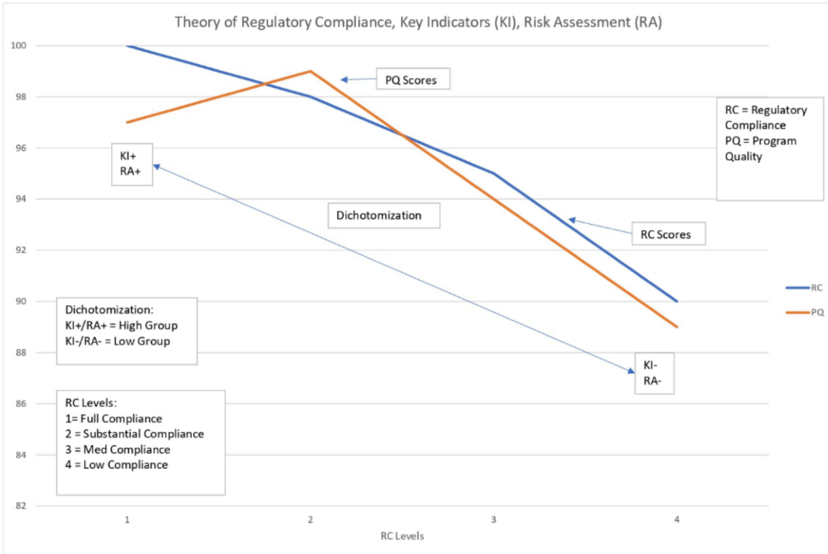

Figure 1: Theory of Regulatory Compliance

Let's turn our attention to some of the spin off methodologies and approaches from the theory of regulatory compliance. The first one to consider is differential monitoring because it is the most significant in altering the licensing landscape in how programs are monitored, reviewed, and inspected. Differential monitoring is about focused reviews rather than a one size fits all approach which again was predominant in the standard uniform program monitoring paradigm. Because the theory of regulatory compliance introduced the importance of substantial regulatory compliance into the new and revised paradigm when it comes to program monitoring, it ushered in more targeted inspections or reviews which focused on key predictor rules or rules that placed clients at particular risk, more so than other rules and regulations. The Uniform Monitoring Approach, One Size Fits All, was supplemented by a more targeted and focused monitoring approach, Differential Monitoring. There was also part of this new

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paradigm the notion of reviewing programs less often but that was removed from the differential monitoring approach because all the research into program monitoring indicated that just reviewing the program more frequently brought about more positive change in regulatory compliance and quality.

In Figure 2, the differential monitoring approach is depicted along with the definitions of each of the methodologies which are part of the approach. Risk assessment is one of the methodologies which is part of the differential monitoring approach. It focuses on those specific rules and regulations which place clients/children at greatest risk of morbidity or mortality. These are the rules that deal with supervision, hazardous materials being in locked cabinets, etc. Generally, jurisdictions/states/provinces can identify these rules through an empirical weighting approach where a Likert Scale is used to weight each rule or regulation on the basis of this morbidity and mortality dimension. The Likert Scales used in most jurisdictions utilize a 1 - 10 Likert Scale where 1 = little risk for morbidity or mortality if the specific rule or regulation is out of compliance; while a 10 = high risk for morbidity or mortality if the specific rule or regulation is out of compliance. Those rules that are determined to be highly weighted are part of the risk assessment rules and are to be measured in every differential monitoring focused review or inspection. There are no exceptions to this.

Key indicator predictor rules is the other methodology which is part of the differential monitoring approach. Key indicator or predictor rules statistically predict overall regulatory compliance and are a very efficient metric for determining the overall regulatory compliance of a facility but in a summary, targeted, and focused fashion without having to do a comprehensive inspection in looking at all the rules and regulations.

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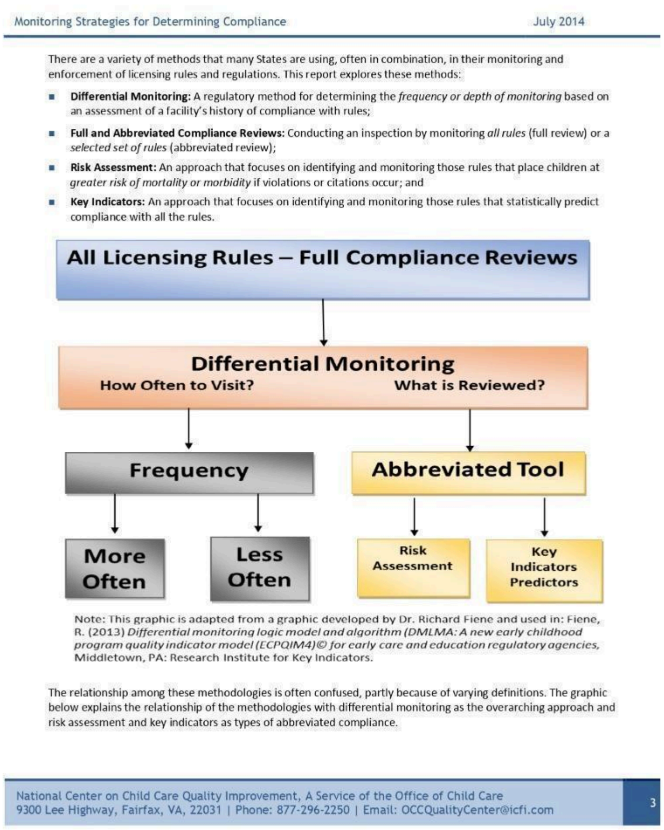
Using the combined methodologies of key indicator predictor rules and risk assessment rules makes the differential monitoring approach the most effective and efficient program monitoring system because it focuses on those rules where clients/children may be injured while at the same time predicting overall regulatory compliance with all the rules. It is the perfect balance of effectiveness and efficiency. It helps us to identify the so-called "right rules" which is the ultimate goal of regulatory science.


Monitoring Strategies for Determining Compliance July 2014

There are a variety of methods that many States are using, often in combination, in their monitoring and enforcement of licensing rules and regulations. This report explores these methods:

- **Differential Monitoring:** A regulatory method for determining the *frequency or depth of monitoring* based on an assessment of a facility's history of compliance with rules;
- **Full and Abbreviated Compliance Reviews:** Conducting an inspection by monitoring *all rules* (full review) or a *selected set of rules* (abbreviated review);
- **Risk Assessment:** An approach that focuses on identifying and monitoring those rules that place children at *greater risk of mortality or morbidity* if violations or citations occur; and
- **Key Indicators:** An approach that focuses on identifying and monitoring those rules that statistically predict compliance with all the rules.

Note: This graphic is adapted from a graphic developed by Dr. Richard Fiene and used in: Fiene, R. (2013) *Differential monitoring logic model and algorithm (DMLMA: A new early childhood program quality indicator model (ECPQIM4)© for early care and education regulatory agencies,* Middletown, PA: Research Institute for Key Indicators.

The relationship among these methodologies is often confused, partly because of varying definitions. The graphic below explains the relationship of the methodologies with differential monitoring as the overarching approach and risk assessment and key indicators as types of abbreviated compliance.

National Center on Child Care Quality Improvement, A Service of the Office of Child Care
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Figure 2: Regulatory Compliance's Differential Monitoring Approaches

This is the highly recommended way to utilize differential monitoring, but many jurisdictions, states, and provinces use either the risk assessment or the key indicator methodologies, few are utilizing both. Hopefully this will change as the regulatory science field matures over the upcoming decades.

Another way of looking at the regulatory compliance's differential monitoring approaches is with the following 2 x 2 logic model matrix (Table 1) which depicts how differential monitoring, key indicators, risk assessment and weighting of rules all inter-relate. This logic model matrix may be of more use for scientists and researchers while figure 2 above is more useful for licensing policy analysts. Weighting of rules demonstrates its key role in the development of key indicators and risk assessment methods within a differential monitoring approach. This is not as self-evident when viewing Figure 2. The logic model matrix also depicts the relationship between comprehensive reviews and differential monitoring/focused reviews that are more abbreviated.

Table 1: Relationship of Key Indicators and Risk Assessment and Weighting in Differential Monitoring Matrix			Key Indicators	Key Indicators
			Yes	No
			Differential Monitoring	Uniform Monitoring
Weighting	Yes	Differential Monitoring	***Substantial Regulatory Compliance***	***Risk Assessment***
Weighting	No	Uniform Monitoring	***Full Regulatory Compliance***	***Comprehensive Review***

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Let's move from the theory, program monitoring approaches and methodologies to the actual measurement of licensing data. Licensing data are at the nominal measurement level. This is important which will be pointed out shortly in the specific approach being taken here. The approach we will take is to use the Confusion Matrix, which is a well-known metric in the decision-making computer research literature and refocus it for regulatory science within the context of the definition of regulatory compliance and licensing measurement. It will also deal with the policy implications of this particular metric. It is being proposed that this new Uncertainty-Certainty Matrix (UCM) is a fundamental building block to licensing decision making. The 2 x 2 matrix has been written about a great deal in the development of the various methodologies described above and is the center piece for determining key indicator predictor rules, but it is also a core conceptual framework in licensing measurement and ultimately in program monitoring and reviews.

The reason for selecting this matrix is the nature of licensing data, it is binary or nominal in measurement. Either a rule/regulation is in-compliance or out of compliance. Presently most jurisdictions deal with regulatory compliance measurement in this nominal level or binary level. There is to be no gray area, this is a clear distinction in making a licensing decision about regulatory compliance. The UCM also takes the concept of Inter-Rater Reliability (IRR) a step further in introducing an uncertainty dimension that is very important in licensing decision making which is not as critical when calculating IRR. It is moving from an individual metric to a group metric involving regulatory compliance with rules.

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The key pieces to the UCM are the following: the decision (D) regarding regulatory compliance and actual state (S) of regulatory compliance. Plus (+) = In-compliance or Minus (-) = Out of compliance. So, let's build the matrix in the following table (Table 2):

Table 2: Uncertainty-Certainty Matrix (UCM) Regulatory Compliance Logic Model

UCM Matrix Logic		Decision (D) Regarding	Regulatory Compliance
		(+) In Compliance	(-) Not In Compliance
Actual State (S) of	(+) In Compliance	Agreement	Disagreement
Compliance	(-) Not In Compliance	Disagreement	Agreement

The above UCM matrix demonstrates when agreement and disagreement occur which establishes a level of certainty (Agreement Cells) or uncertainty (Disagreement Cells). In a perfect world, there would only be agreements and no disagreements between the decisions made about regulatory compliance and the actual state of regulatory compliance. But from empirical evidence, this is not the case based upon reliability testing done in the licensing research field in which a decision is made regarding regulatory compliance with a specific rule or regulation and then that is verified by a second observer who generally is considered the measurement standard.

Disagreements raise concerns in general, but the disagreements are of two types: false positives and false negatives. A false positive is when a decision is made that a rule/regulation is out of compliance when it is in compliance. Not a good thing but its twin disagreement is worse where with false negatives it is decided that a rule/regulation is in compliance when it is out of compliance. False negatives need to be avoided because they place clients at extreme risk, more so than a false positive. False positives should also be avoided but it is more important to deal with the false negatives first before addressing the false positives.

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The next logical question after dealing with the measurement issues of licensing data and the fact that it is measured nominally is how best to deal with a data distribution which is severely skewed. In Figure 1, dichotomization was introduced in the graphic in depicting the differences between high and low regulatory compliance. As presented above in attempting to eliminate false negatives and reduce false positives, the same can be done by dichotomizing the licensing data distribution in order to accentuate the differences between low regulatory compliance and substantial + full regulatory compliance. Dichotomization of data is generally not recommended from a statistical point of view but because of the nature of licensing data being measured at the nominal level and being so severely skewed, it is warranted.

Regulatory Compliance has always been 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/non-linear 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 as mentioned earlier in this article.

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

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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's and 2010's 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 consider 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

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compliance, Mediocre compliance, and Low compliance where only licensing health and safety elements were considered (see the Table 3 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.

Table 3: Regulatory Compliance Scales and Program Monitoring Systems

Scoring Level	**Individual Rule**		**Aggregate Rules**	**Individual Rule**
Scale	**Instrument based**	***Scale***	**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. So, this creates an interesting caveat in that the theory of regulatory compliance predicts a non-linear relationship between regulatory compliance and quality but a linear relationship when dealing with regulatory compliance and the safety of clients.

So, what are the takeaways from the theory of regulatory compliance and its implications for regulatory science.

1) The theory of regulatory compliance has ushered in a new paradigm demonstrating the importance of substantial compliance and putting it on equal footing with full 100% regulatory compliance. The theory has also demonstrated the importance of weighting rules in order to determine their differential impact on client outcomes and in enhancing the regulatory compliance scoring distribution.

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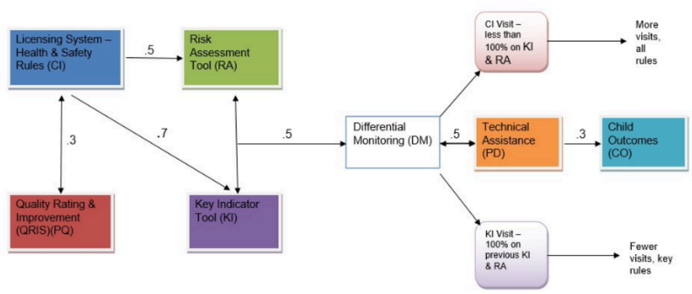
2) Regulatory compliance will not get us to quality on its own, rules and regulations need an infusion of quality so there is the need to balance regulatory compliance and quality standards in any future promulgation of rules and regulations.

3) How does all this fit together? An Early Childhood Program Quality/Regulatory Compliance Improvement and Indicator Model has been proposed to build off the results of the theory of regulatory compliance and to build a robust program monitoring system that both differentiates and integrates. See the following Figure 3 which provides a logic model for how the model would play out.



$$\sum CI \times \sum PQ \Rightarrow \sum RA + \sum KI \Rightarrow \sum DM + \sum PD \Rightarrow CO$$

1

Figure 3: Regulatory Compliance Improvement and Indicator Model

4) All the studies and research presented in this article are from the human services area. It will be interesting to see if other industries in the medical, scientific, and economic (banking, transportation, housing) arenas demonstrate the same type of relationship between regulatory compliance in their respective industries and sets of rules and regulations and the ultimate quality of the products they produce.

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5) The ceiling effect, diminishing returns, plateauing all depict a curvilinear relationship rather than a linear relationship. As additional studies are completed, this relationship needs to be fine-tuned. Hopefully moving from a nominal measurement strategy to one that is more ordinally based via the Regulatory Compliance Scale will help to fine-tune that relationship.
6) The idiosyncratic nature of licensing data distributions needs to be dealt with statistically because of severe skewness in the data which limits the analytical frames that can be used. Various weighting schemes (equal interval weighting and relative weighting) are being attempted in order to build in more variance in the data and the infusion of more quality standards into rule formulation should help.
7) *The theory of regulatory compliance has led us on a quest to find the "right rules" via regulatory science. It is all about following the empirical data wherever it leads rather than a more political approach which involves over-regulation or deregulation. The methods presented in this paper will hopefully guide regulatory scientists on this future quest. It is about data utilization and using the risk assessment and key indicator methodologies in order to identify these "right rules" that keep clients safe and promote overall quality of setting. We can no longer utilize a "One Size Fits All" paradigm and assume that all rules/regulations are created equally and administered equally. The empirical evidence does not support this approach.*
8) Hopefully, this article has given the reader the necessary background to understand this new paradigm for licensing measurement and monitoring systems with all its intricacies and foibles, and its applications to other industries.

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Introducing the Ceiling Effect/Diminishing Returns, Regulatory Compliance Scale, and the Quality Indicators Scale to Regulatory Science

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The purpose of this short paper/public policy commentary is to introduce three relatively new, recently validated concepts to regulatory science. The first of the concepts (ceiling effect) is one that I have written about a good deal in previous policy commentaries when addressing the theory of regulatory compliance (Fiene, 2019). The other two (regulatory compliance and quality indicator scales (Fiene, 2022, 2023b; NARA, 2023)) have been validated more recently so they are relatively new, but I think will have a similar impact on the regulatory science field based upon the research interest generated worldwide.

The "Ceiling Effect" is a more user-friendly term for the theory of regulatory compliance diminishing returns. I have found in recent webinars and presentations that the notion of a ceiling effect resonates with other regulatory science researchers more so than the theory of regulatory compliance diminishing returns. Scientists can wrap their heads around the ceiling effect much easier than the theory, so I am going to use this new term rather than the older. However, they do mean the same thing, same result, just different terminology. It is similar to what happened with "inferential inspections" (earlier term) and "differential monitoring" (present terminology) (Fiene, 2023a). Same concept, just different terms.

The "ceiling effect" is the same relationship between regulatory compliance and program quality. As regulatory compliance increases from substantial compliance to full 100% compliance, program quality shows either no improvement or diminished improvement over the same course. This is the essence of the theory of regulatory compliance diminishing returns (Fiene, 2019, 2023a, 2023b; NARA, 2023). No change here.

The second concept I want to introduce is the regulatory compliance scale (Fiene, 2022) which appears from recent studies to be a better metric in measuring regulatory compliance than just counting the number of violations that a program has related to their respective rules, regulations, or standards. So how does the regulatory compliance scale work. It essentially puts violations into buckets of regulatory compliance as follows: full compliance (100%) or no violations; substantial compliance (99-98%) or 1-2 violations; mediocre compliance (97-90%) or 3-9 violations; and lastly low/non-optimal compliance (89% or lower) or 10+ violations. Why buckets, because logically it works, it is the way we think about regulatory compliance. It is a discrete rather than continuous metric and logically fits into these four categories. This is based upon 50 years of research into regulatory compliance data distributions and when the data are moved from frequency counts of violation data into these buckets/categories, the math works very well in identifying the better performing programs.

The last concept to be introduced deals with quality indicators which have been proposed as part of a differential monitoring paradigm but not utilized and validated in specific jurisdictions. Well, that has changed now with a major study completed in the Province of Saskatchewan which has clearly demonstrated in a valid and reliable fashion how quality indicators can be used effectively and efficiently when compared to other program quality scales and regulatory compliance data (NARA, 2023).

All these above results (Fiene, 2023b; NARA, 2023) were part of this Province of Saskatchewan five-year project, and they are all in the early care and education domain, but I think that the results are pertinent to any industry governed by regulatory science principles. One needs to change the content obviously, but the metrics and methodology would hold up because of their base in solid scientific principles of instrument and research design.

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Importance of the Theory of Regulatory Compliance

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Introduction

Regulatory compliance refers to the process by which individuals, organizations, or entities adhere to and fulfill the requirements set forth by relevant laws, regulations, and industry standards. It involves ensuring that policies, procedures, and practices align with the specific legal and regulatory frameworks applicable to a particular industry or jurisdiction. Compliance involves actively identifying and understanding the relevant regulations, establishing internal controls and processes to meet those requirements, and consistently monitoring and reviewing operations to ensure ongoing adherence. It encompasses various aspects, such as legal, financial, operational, and ethical considerations, and aims to ensure that organizations operate within the boundaries of the law, maintain ethical standards, and fulfill their responsibilities to stakeholders, customers, and the public.

The theory of regulatory compliance provides a framework for understanding the underlying principles and concepts that guide the compliance process. It encompasses several key elements that shape the approach to achieving and maintaining compliance. Here is an overview of the theory of regulatory compliance:

1. Legal and Regulatory Environment: The theory recognizes that regulatory compliance is rooted in the legal and regulatory landscape. It acknowledges the importance of identifying and understanding applicable laws, regulations, and standards that govern an industry or jurisdiction.
2. Risk Management: The theory emphasizes the proactive identification, assessment, and management of risks associated with non-compliance. It highlights the need to establish robust risk management processes to mitigate legal, financial, operational, and reputational risks.
3. Policies and Procedures: Effective compliance requires the development and implementation of comprehensive policies and procedures. The theory underscores the significance of clear, well-documented, and communicated policies that guide employees in adhering to regulatory requirements.
4. Internal Controls: The theory emphasizes the establishment of internal controls to ensure compliance. This involves designing and implementing systems, processes, and

checks that monitor and mitigate risks, detect and prevent non-compliance, and promote accountability.

5. Training and Awareness: Recognizing the role of individuals in compliance, the theory highlights the importance of training programs and awareness initiatives. It emphasizes educating employees about applicable regulations, ethical standards, and the organization's compliance obligations.
6. Monitoring and Auditing: The theory acknowledges the need for ongoing monitoring and auditing to assess compliance effectiveness. Regular internal audits, reviews, and assessments help identify gaps, weaknesses, and areas for improvement, ensuring continuous compliance efforts.
7. Reporting and Documentation: The theory stresses the significance of accurate and timely reporting of compliance activities. It underscores the need to maintain proper documentation, records, and evidence of compliance processes, actions taken, and outcomes achieved.
8. Compliance Culture: The theory recognizes that compliance is not solely a set of rules and processes but also a cultural mindset. It highlights the importance of fostering a culture of compliance within an organization, where integrity, ethics, and adherence to regulations are valued and embedded in the organizational DNA.
9. Accountability and Enforcement: The theory acknowledges that compliance requires accountability for non-compliance. It recognizes the role of regulatory bodies, internal enforcement mechanisms, and disciplinary actions in promoting compliance and deterring violations.
10. Continuous Improvement: Finally, the theory emphasizes the need for continuous improvement in compliance efforts. It encourages organizations to learn from past experiences, adapt to evolving regulations, embrace emerging best practices, and strive for excellence in their compliance initiatives.

By understanding and applying the theory of regulatory compliance, organizations can establish a solid foundation for effective compliance management, minimize risks, and uphold legal and ethical standards in their operations.

Ensuring Legal and Ethical Practices

Compliance with laws and regulations is a fundamental aspect of the theory of regulatory compliance. It recognizes that adherence to legal and regulatory requirements is crucial for organizations to operate within the boundaries set by governing bodies and to fulfill their obligations to stakeholders. Here are key points related to compliance with laws and regulations in the context of the theory of regulatory compliance:

11. Understanding Applicable Laws: The theory emphasizes the importance of identifying and comprehending the specific laws and regulations that pertain to an organization's

industry, jurisdiction, and operational activities. This involves staying updated with changes in regulations and interpreting their implications for the organization.

12. Regulatory Research and Analysis: Organizations need to conduct thorough research and analysis to determine how laws and regulations apply to their operations. This includes examining regulatory frameworks, guidance documents, legal precedents, and industry-specific requirements.
13. Compliance Obligations: The theory recognizes that compliance obligations vary based on the nature of the organization's activities. It stresses the need to determine the specific requirements, obligations, and standards that the organization must meet to ensure legal and regulatory compliance.
14. Compliance Program Development: To achieve compliance, the theory highlights the importance of developing a comprehensive compliance program tailored to the organization's needs. This involves establishing policies, procedures, and controls that align with legal and regulatory requirements.
15. Regulatory Reporting and Filings: Compliance entails fulfilling reporting obligations to regulatory authorities. The theory emphasizes the significance of timely and accurate reporting, including financial statements, disclosures, permits, licenses, certifications, and other regulatory filings.
16. Compliance Monitoring and Auditing: The theory underscores the need for ongoing monitoring and auditing of compliance efforts. Regular reviews help identify potential compliance gaps, assess the effectiveness of controls, and ensure corrective actions are taken to address non-compliance.
17. Compliance Documentation: Documentation plays a critical role in compliance. The theory highlights the importance of maintaining accurate and comprehensive records of compliance activities, including policies, procedures, training materials, audit reports, incident reports, and evidence of compliance.
18. Compliance Risk Assessment: Organizations should conduct compliance risk assessments to identify and evaluate potential risks associated with non-compliance. This allows for the implementation of risk mitigation strategies, such as internal controls, training programs, and monitoring systems.
19. Enforcement and Consequences: The theory acknowledges that non-compliance can lead to legal and financial consequences. It emphasizes the need for organizations to understand the potential penalties, fines, sanctions, and reputational damage that can result from violations of laws and regulations.
20. Regulatory Engagement and Communication: Organizations should actively engage with regulatory authorities and maintain open lines of communication. The theory emphasizes the importance of understanding regulatory expectations, seeking guidance when needed, and participating in industry consultations.

By emphasizing compliance with laws and regulations, the theory of regulatory compliance aims to ensure that organizations operate within legal boundaries, mitigate risks, protect stakeholders, and maintain a strong ethical foundation in their operations.

Protection of Consumers and Public Interest

Protection of consumers and the public interest is a fundamental objective of regulatory compliance. Regulatory compliance refers to the adherence of individuals, organizations, or businesses to laws, regulations, and guidelines set forth by governing bodies or regulatory authorities. It aims to ensure that entities operate in a manner that safeguards the interests of consumers and the general public.

The theory behind regulatory compliance is rooted in the belief that certain industries or activities require oversight and regulation to prevent harm, ensure fair competition, and maintain public trust. By establishing rules and standards, regulatory bodies seek to create a level playing field, promote transparency, and protect the well-being of consumers.
Key principles and considerations associated with regulatory compliance for the protection of consumers and public interest include:

21. Consumer Protection: Regulatory compliance frameworks typically include provisions to safeguard consumers from fraudulent, deceptive, or unfair practices. This involves regulations related to product safety, labeling, advertising, pricing, warranties, and consumer rights.
22. Public Health and Safety: Compliance regulations often address public health and safety concerns. For instance, in the pharmaceutical industry, compliance with drug safety regulations ensures that medications meet quality standards and do not pose unreasonable risks to patients.
23. Market Integrity: Regulatory compliance helps maintain the integrity of markets by prohibiting anti-competitive behavior, ensuring fair trading practices, and preventing market manipulation or insider trading. These regulations promote fair competition and protect consumers from monopolistic practices.
24. Data Protection and Privacy: With the increasing prevalence of data-driven technologies, regulatory compliance frameworks emphasize the protection of personal information and privacy rights. Regulations like the European Union's General Data Protection Regulation (GDPR) aim to safeguard consumer data and establish guidelines for its lawful collection, storage, and use.
25. Financial Stability: Regulatory compliance plays a crucial role in the financial sector to prevent fraud, money laundering, and unethical practices that can destabilize markets or harm consumers. Regulations impose standards for capital adequacy, risk management, disclosure, and consumer financial protection.

26. Ethical Considerations: Compliance regulations often incorporate ethical considerations to ensure responsible and ethical behavior by individuals and organizations. This may involve guidelines on corporate governance, social responsibility, environmental sustainability, or labor practices.

To ensure effective regulatory compliance, regulatory bodies conduct inspections, audits, and enforcement actions. Non-compliance can result in penalties, fines, or legal actions against the offending parties. Moreover, compliance management systems, internal controls, and self-regulatory mechanisms are employed by organizations to proactively adhere to regulatory requirements and promote a culture of compliance.

Overall, the theory of regulatory compliance revolves around the idea that by setting and enforcing rules, regulators can protect consumers, preserve public interest, and maintain the stability and fairness of various sectors in society.

Financial Stability and Risk Management

Financial stability and risk management are critical components of regulatory compliance. The theory of regulatory compliance emphasizes the importance of establishing and enforcing regulations to ensure the stability and integrity of financial systems, protect consumers, and mitigate systemic risks.

Here are some key aspects of the theory of regulatory compliance related to financial stability and risk management:

27. Prudential Regulation: Prudential regulation focuses on ensuring the soundness and stability of financial institutions, such as banks, insurance companies, and investment firms. Regulatory compliance frameworks impose requirements related to capital adequacy, risk management, liquidity, and asset quality to prevent excessive risk-taking and protect the financial system from disruptions.
28. Systemic Risk Mitigation: Regulatory compliance measures aim to identify and mitigate systemic risks that can have widespread adverse effects on the financial system. This includes regulations on risk concentration, interconnectedness, and exposure limits to prevent the domino effect of failures and contagion across institutions.
29. Risk Assessment and Monitoring: Regulatory compliance frameworks often require financial institutions to conduct thorough risk assessments and implement robust risk management practices. This involves identifying, measuring, and monitoring various types of risks, including credit risk, market risk, liquidity risk, and operational risk. Compliance regulations may prescribe specific methodologies, reporting requirements, and stress testing to ensure that risks are adequately identified and managed.

30. Transparency and Disclosure: Regulatory compliance promotes transparency in financial markets by requiring financial institutions to provide accurate and timely disclosure of relevant information to investors, regulators, and the public. This includes financial reporting, disclosures of risk exposures, and information about the institution's financial health. Transparent reporting helps stakeholders make informed decisions, enhances market efficiency, and fosters trust in the financial system.
31. Consumer Financial Protection: Regulatory compliance frameworks incorporate measures to protect consumers in financial transactions. This includes regulations on fair lending practices, disclosure requirements for financial products and services, and regulations against abusive or predatory practices. These regulations aim to ensure that consumers are treated fairly, have access to transparent information, and are protected from fraudulent or deceptive practices.
32. Regulatory Oversight and Enforcement: Regulatory compliance is reinforced by regulatory bodies that oversee financial institutions, enforce compliance, and impose penalties for non-compliance. These regulatory authorities monitor institutions' compliance with regulations, conduct audits and examinations, and take enforcement actions when violations are identified. Such oversight ensures accountability and promotes a culture of compliance within the financial industry.

By adhering to regulatory compliance requirements, financial institutions are expected to minimize risks, enhance stability, and maintain the confidence of investors and the public. Compliance management systems, internal controls, and risk management frameworks are utilized by financial institutions to meet regulatory obligations and proactively manage risks.

Overall, the theory of regulatory compliance underscores the role of regulations in promoting financial stability, mitigating risks, protecting consumers, and maintaining the integrity of financial systems. Compliance with these regulations helps build a resilient financial sector that can withstand shocks and contribute to overall economic stability.

Preserving Competitive Market Environment

Preserving a competitive market environment is essential for fostering innovation, encouraging efficiency, and benefiting consumers. The theory of regulatory compliance is closely linked to this objective, as it involves establishing and enforcing rules and regulations that promote fair competition and prevent anti-competitive practices.

The theory of regulatory compliance is based on the idea that regulatory frameworks can help create a level playing field for all market participants. By setting clear rules and standards, regulators aim to ensure that businesses operate within the bounds of fair competition. Compliance with these regulations helps prevent monopolistic behavior, collusion, price-fixing, and other practices that could harm competition.

Here are a few key principles related to preserving a competitive market environment and the theory of regulatory compliance:

33. Anti-Trust Laws: Anti-trust laws are designed to promote competition by preventing the abuse of market power. They prohibit practices such as monopolies, cartels, price-fixing, and mergers that may substantially lessen competition. Regulators enforce these laws to preserve a competitive landscape and protect consumer interests.
34. Market Entry and Exit: Regulatory frameworks should facilitate the entry of new businesses into the market while allowing existing ones to exit if they are unable to compete effectively. Barriers to entry, such as excessive licensing requirements or unfair regulations, can hinder competition. Regulatory compliance should aim to reduce these barriers and ensure fair access for all participants.
35. Consumer Protection: A competitive market environment should prioritize consumer welfare. Regulatory compliance plays a crucial role in safeguarding consumer interests by ensuring transparency, fair pricing, quality standards, and adequate information disclosure. Consumer protection laws and regulations address issues such as misleading advertising, product safety, and fair dispute resolution mechanisms.
36. Enforcement and Monitoring: Regulatory agencies are responsible for enforcing compliance with regulations. They monitor market activities, investigate potential violations, and take appropriate enforcement actions when necessary. Effective enforcement requires sufficient resources, expertise, and collaboration among regulators, ensuring a level playing field for all participants.
37. International Cooperation: In a globalized economy, preserving a competitive market environment requires international cooperation. Collaboration between regulatory authorities across jurisdictions can help address cross-border anti-competitive practices, harmonize regulatory standards, and promote fair competition in the global marketplace.

Overall, the theory of regulatory compliance supports the notion that well-designed and effectively enforced regulations can foster a competitive market environment. By promoting fair competition, preventing anti-competitive practices, and protecting consumer interests, regulatory compliance contributes to a healthy and vibrant marketplace.

Establishing Trust and Credibility

Establishing trust and credibility is crucial for regulatory compliance efforts. The theory of regulatory compliance recognizes that trust is essential in fostering cooperation between regulatory authorities, businesses, and other stakeholders. Trust is built when regulations are transparent, consistently enforced, and perceived as fair and unbiased.

Here are some key aspects of establishing trust and credibility in the context of regulatory compliance:

38. Transparency: Transparency is a fundamental principle in regulatory compliance. Regulations and their enforcement processes should be clearly communicated and accessible to all stakeholders. Openness helps build trust by ensuring that the rules are known and understood by businesses and individuals, reducing uncertainty and promoting voluntary compliance.
39. Consistency: Consistency in applying regulations is critical for building trust. Regulators should strive to enforce regulations uniformly and without favoritism or discrimination. Consistent enforcement establishes a level playing field, fostering trust among market participants who know that everyone is subject to the same rules.
40. Accountability: Regulatory authorities should be accountable for their actions. This includes being transparent about decision-making processes, justifying regulatory actions, and providing avenues for recourse and appeal. Accountability mechanisms help prevent abuse of regulatory power and build trust by demonstrating fairness and impartiality.
41. Collaboration and Engagement: Regulatory compliance efforts benefit from collaboration and engagement with various stakeholders. This includes businesses, industry associations, consumer groups, and experts. Involving stakeholders in the regulatory process helps ensure that regulations are practical, effective, and well-understood. Collaboration also enhances trust by incorporating diverse perspectives and building consensus.
42. Risk-Based Approach: A risk-based approach to regulation can contribute to trust and credibility. It involves assessing risks, prioritizing enforcement efforts based on the potential harm to the public or the market, and proportionately allocating regulatory resources. This approach demonstrates that regulatory actions are driven by objective evaluations and the need to address significant risks, enhancing trust in the regulatory system.
43. Continuous Improvement: Regulatory compliance should be a dynamic and evolving process. Regular evaluation and improvement of regulations and enforcement mechanisms are essential for maintaining trust and credibility. Regulators should engage in periodic reviews, solicit feedback from stakeholders, and adapt regulations to changing market dynamics and emerging challenges.
44. Effective Communication: Clear and effective communication is vital for establishing trust. Regulators should communicate expectations, obligations, and changes in regulations in a timely and accessible manner. Communication channels should be open to addressing queries, providing guidance, and clarifying regulatory requirements, fostering trust by ensuring transparency and promoting compliance.

In summary, trust and credibility are foundational elements of successful regulatory compliance. By promoting transparency, consistency, accountability, collaboration, and effective communication, regulatory authorities can establish a trusted regulatory framework that fosters compliance and cooperation among stakeholders.

Penalties and Consequences of Non-Compliance

Regulatory compliance refers to the act of adhering to laws, regulations, guidelines, and standards set forth by governing bodies or regulatory agencies. Non-compliance occurs when individuals, organizations, or businesses fail to meet these requirements. The penalties and consequences of non-compliance can vary depending on the specific regulations and jurisdictions involved. Here are some common penalties and consequences:

45. Fines and Monetary Penalties: Regulatory agencies often have the authority to impose fines and monetary penalties for non-compliance. The amount of the penalty may vary depending on the severity of the violation and the regulatory framework in place. These fines can be substantial and can significantly impact the finances of non-compliant entities.
46. Legal Proceedings and Lawsuits: Non-compliance may lead to legal action, including lawsuits filed by affected parties or regulatory bodies. This can result in costly litigation, potential damages, and a tarnished reputation.
47. License Revocation or Suspension: Certain industries and professions require licenses or permits to operate legally. Non-compliance can lead to the revocation or suspension of these licenses, effectively shutting down the business or preventing individuals from practicing their profession.
48. Regulatory Audits and Inspections: Regulatory agencies may conduct audits and inspections to assess compliance. Non-compliant entities may face increased scrutiny, additional audits, or more frequent inspections, leading to disruption of operations and additional costs.
49. Reputational Damage: Non-compliance can harm an organization's reputation, leading to loss of customer trust, decreased sales, and difficulty attracting new customers. Negative publicity and media attention can have long-lasting effects on brand value and perception.
50. Corrective Actions and Remediation Costs: In many cases, non-compliant entities are required to take corrective actions to address the violations. This may involve implementing new policies, procedures, or systems, as well as investing in training and education. The costs associated with these remediation efforts can be significant.
51. Criminal Charges and Penalties: In cases of serious non-compliance, intentional violations, or fraudulent activities, criminal charges may be pursued. This can result in fines, imprisonment, or both, depending on the severity of the offense.

The theory of regulatory compliance seeks to understand why individuals or organizations choose to comply or not comply with regulations. Factors influencing compliance behavior include perceived legitimacy of regulations, trust in regulatory agencies, the presence of effective enforcement mechanisms, and the perceived costs and benefits of compliance. The theory emphasizes the importance of clear communication, consistent enforcement, and proportionate penalties to achieve higher compliance rates.

Compliance Programs and Frameworks

Compliance programs and frameworks are designed to help organizations establish and maintain a culture of regulatory compliance. They provide a structured approach to understanding and meeting regulatory requirements, mitigating risks, and promoting ethical behavior. Additionally, compliance programs help organizations detect and address non-compliance issues promptly and effectively.

Here are some common compliance programs and frameworks:

52. Compliance Management System (CMS): A CMS is a comprehensive framework that encompasses policies, procedures, processes, and controls to manage compliance within an organization. It includes elements such as risk assessment, compliance training, monitoring and auditing, incident reporting, and corrective action planning.
53. ISO 19600: This international standard provides guidelines for establishing, implementing, evaluating, and improving a compliance management system. It emphasizes a risk-based approach to compliance and provides a framework for organizations to identify, analyze, and address their compliance obligations effectively.
54. COSO Framework: The Committee of Sponsoring Organizations of the Treadway Commission (COSO) developed a framework that focuses on internal controls and risk management. While not specifically geared towards compliance, it provides a solid foundation for managing compliance risks within an organization.
55. Federal Sentencing Guidelines (FSG): The U.S. Federal Sentencing Guidelines provide guidance for organizations on establishing effective compliance programs. They outline specific factors that organizations should consider when developing compliance programs, such as conducting risk assessments, implementing training and communication programs, and monitoring compliance.
56. Principle-Based Approach: The principle-based approach to compliance focuses on establishing a set of core principles and values that guide an organization's compliance efforts. It emphasizes ethical conduct, integrity, and accountability as the foundation for compliance programs. This approach encourages employees to make ethical decisions and act in accordance with the organization's values.

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The theory of regulatory compliance explores the factors that influence compliance behavior and the effectiveness of compliance programs. It recognizes that compliance is not solely driven by the fear of penalties but also by factors such as organizational culture, perceived legitimacy of regulations, and the presence of strong internal controls. The theory suggests that effective compliance programs should:

57. Clearly communicate regulatory requirements and expectations to employees and stakeholders.
58. Foster a culture of compliance by promoting ethical behavior, accountability, and integrity.
59. Provide training and education to employees to enhance their understanding of compliance obligations.
60. Implement monitoring and auditing mechanisms to detect and address non-compliance promptly.
61. Establish strong internal controls and risk management processes to mitigate compliance risks.
62. Encourage reporting of potential compliance issues and provide channels for anonymous reporting.
63. Continuously evaluate and improve the compliance program based on feedback and changes in regulations.

By understanding the theory of regulatory compliance and implementing effective compliance programs, organizations can enhance their ability to meet regulatory requirements, manage risks, and uphold ethical standards.

Role of Technology in Regulatory Compliance and monitoring and reporting tools

Technology plays a crucial role in regulatory compliance by providing tools and systems that help organizations monitor and report their adherence to regulatory requirements. Here are some key ways technology supports regulatory compliance:

64. Automation and Workflow Management: Technology enables the automation of various compliance processes, such as data collection, analysis, and reporting. Workflow management systems help streamline compliance tasks by providing clear processes and guidelines, ensuring consistent and efficient execution.
65. Data Management and Analysis: Compliance often involves handling large volumes of data. Technology solutions, such as data management systems and analytics tools, facilitate the collection, storage, organization, and analysis of data for compliance purposes. These systems can identify patterns, anomalies, and trends in the data, helping organizations detect and address compliance risks.

66. Monitoring and Surveillance: Technology enables real-time monitoring and surveillance of activities, transactions, and communications to identify potential compliance violations. Advanced monitoring tools use algorithms and machine learning techniques to detect suspicious behavior, fraud, market manipulation, or any non-compliant activities.
67. Reporting and Documentation: Compliance requires accurate and timely reporting to regulatory authorities. Technology offers reporting tools that help automate the creation of regulatory reports, ensuring the required information is captured, organized, and submitted in the appropriate format. These tools often include templates, data mapping capabilities, and integration with existing systems.
68. Audit Trail and Documentation Management: Technology allows organizations to maintain a comprehensive audit trail and documentation of compliance activities. Digital systems enable the secure storage, retrieval, and tracking of compliance-related documents, making it easier to demonstrate compliance during audits or investigations.
69. Risk Assessment and Compliance Monitoring: Technology supports risk assessment processes by providing tools for identifying, assessing, and prioritizing compliance risks. Compliance monitoring tools can continuously track regulatory changes and updates, ensuring organizations stay informed and adapt their compliance programs accordingly.
70. Training and Education: Technology can be utilized to deliver compliance training and educational materials to employees and stakeholders. Online learning platforms, webinars, and interactive modules can provide accessible and engaging compliance training programs, ensuring widespread understanding of regulatory requirements and promoting a culture of compliance.

Overall, technology plays a vital role in enhancing the efficiency, accuracy, and effectiveness of regulatory compliance efforts. By leveraging technology, organizations can better manage compliance requirements, mitigate risks, and ensure adherence to regulations in an increasingly complex regulatory landscape.

Conclusion Recap of the importance of the theory of regulatory compliance

The theory of regulatory compliance is of great importance in various domains, particularly in legal and business contexts. It refers to the set of rules, regulations, and standards that individuals, organizations, and industries must follow to ensure compliance with applicable laws and regulations.

Here are some key points highlighting the importance of the theory of regulatory compliance:

71. Legal Compliance: Regulatory compliance ensures that individuals and organizations adhere to laws and regulations set forth by governing bodies. This helps maintain law and order in society and promotes fairness, transparency, and accountability.

72. Risk Mitigation: Compliance measures help identify and mitigate potential risks associated with non-compliance. By following regulations, organizations can minimize legal, financial, reputational, and operational risks. Compliance frameworks often include risk assessment and management components, enabling proactive risk mitigation.
73. Consumer Protection: Compliance regulations often aim to protect consumers' rights and interests. Compliance with consumer protection laws ensures fair business practices, prevents fraud, and enhances consumer trust in products and services.
74. Data Privacy and Security: In the digital age, data privacy and security have become crucial concerns. Regulatory compliance frameworks, such as the General Data Protection Regulation (GDPR), enforce strict guidelines for handling personal data. Compliance helps safeguard sensitive information, maintain privacy, and prevent data breaches.
75. Ethical Standards: Compliance extends beyond legal obligations and encompasses ethical standards. It encourages organizations to adopt ethical business practices, such as fair competition, anti-corruption measures, and environmental sustainability. Compliance frameworks often incorporate ethical guidelines to promote responsible conduct.
76. Industry Standards: Many industries have specific regulatory compliance requirements tailored to their unique characteristics and risks. Compliance with industry-specific regulations ensures safety, quality, and standardization within the sector. Examples include regulations in healthcare, finance, energy, and manufacturing.
77. Reputation and Trust: Compliance with regulations builds a positive reputation for individuals and organizations. It demonstrates commitment to legal and ethical standards, fostering trust among customers, investors, and other stakeholders. A strong reputation for compliance can lead to increased business opportunities and competitive advantage.
78. Legal Consequences: Non-compliance with regulatory requirements can have severe legal consequences, including fines, penalties, sanctions, and legal liabilities. Violations can result in damaged reputation, loss of business licenses, and even criminal charges. Compliance helps organizations avoid legal pitfalls and maintain a good standing with regulatory authorities.
79. Global Business Landscape: With increasing globalization, organizations often need to navigate complex regulatory frameworks across multiple jurisdictions. Understanding and complying with international regulations is essential for expanding businesses, facilitating international trade, and avoiding legal disputes.
80. Continuous Improvement: The theory of regulatory compliance emphasizes the need for continuous improvement. Compliance programs encourage regular monitoring, self-assessment, and adaptability to evolving regulations. This fosters a culture of compliance and enables organizations to stay up to date with changing legal requirements.

In summary, the theory of regulatory compliance plays a vital role in promoting legality, ethical conduct, risk management, and trust in various domains. It ensures adherence to laws, protects consumers, mitigates risks, and helps organizations thrive in a complex regulatory landscape.

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Contact Hour Pilot Study Validation Design: Taking Group Size, Exposure Time, & Space/Distance Into Consideration (v7)

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The purpose of this paper is to validate the key parameters for testing out the Contact Hour (CH) methodology in a series of facilities to determine its efficacy. The pilot validation study will determine if this CH methodology has any merit in being able to measure regulatory compliance with adult-child ratios. Since monitoring of facilities will not be occurring during the COVID19 pandemic are there ways to measure the research question in the previous sentence. Yes there is and it is based upon the Contact Hour (CH) methodology and involves asking the following six questions (The six questions should be asked of each grouping that is defined by a classroom or a well-defined group within each classroom tied to a specific adult-child ratio.):

1. **When does your first teaching staff arrive or when does your facility open (TO1)?**
2. **When does your last teaching staff leave or when does your facility close (TO2)?**
3. **Number of teaching/caregiving staff (TA)?**
4. **Number of children on your maximum enrollment day (NC)?**
5. **When does your last child arrive (TH1)?**
6. **When does your first child leave (TH2)?**

After getting the answers to these questions, the following formulae can be used to determine contact hours (CH) based upon the relationship between when the children arrive and leave (TH) and how long the facility is open (TO):

$$(1)\ CH = ((NC\ (TO + TH))\ /\ 2)\ /\ TA;$$

$$(2)\ CH = (NC \times TO)\ /\ TA;$$

$$(3)\ CH = ((NC \times TO)\ /\ 2)\ /\ TA;$$

$$(4)\ CH = (NC^2)\ /\ TA$$

Where: CH = Contact Hours; NC = Number of Children; TO = Total number of hours the facility is open (TO2 - TO1); TA = Total number of teaching staff, and TH = Total number of hours at full enrollment (TH2 - TH1).

By knowing the number of contact hours (CH) it will be possible to rank order the exposure time of adults with children. Theoretically, this metric could then be used to determine that the greater contact hours is correlated with the increased non-regulatory compliance with adult-child ratios as determined in the below table on page 2.

Table 1: Contact Hour (CH) Conversion Table (RS Model(1.0)) (Fiene, 2020©)

Taking into Account Exposure Time and Density

Group Size, Staff Child Ratio, Number of Children and Staff

<------------------- *Adult-Child Ratios (Relatively Weighted Contact Hours)* --------------->

NC	CH	1:1	2:1	3:1	4:1	5:1	6:1	7:1	8:1	9:1	10:1	11:1	12:1	13:1	14:1	15:1
1	8	**8**	8	8	8	8	8	8	8	8	8	8	8	8	8	8
2	16	**8**	**16**	16	16	16	16	16	16	16	16	16	16	16	16	16
3	24	**8**	12	**24**	24	24	24	24	24	24	24	24	24	24	24	24
4	32	**8**	**16**	16	**32**	32	32	32	32	32	32	32	32	32	32	32
5	40	**8**	13	20	20	**40**	40	40	40	40	40	40	40	40	40	40
6	48	**8**	**16**	**24**	24	24	**48**	48	48	48	48	48	48	48	48	48
7	56	**8**	14	19	28	28	28	**56**	56	56	56	56	56	56	56	56
8	64	**8**	**16**	21	**32**	32	32	32	**64**	64	64	64	64	64	64	64
9	72	**8**	14	**24**	24	36	36	36	36	**72**	72	72	72	72	72	72
10	80	**8**	**16**	20	27	**40**	40	40	40	40	**80**	80	80	80	80	80
11	88	**8**	15	22	29	29	44	44	44	44	44	**88**	88	88	88	88
12	96	**8**	**16**	**24**	**32**	32	**48**	48	48	48	48	48	**96**	96	96	96
13	104	**8**	15	21	26	35	35	52	52	52	52	52	52	**104**	104	104
14	112	**8**	**16**	22	28	37	37	**56**	56	56	56	56	56	56	**112**	112
15	120	**8**	15	**24**	30	**40**	40	40	60	60	60	60	60	60	60	**120**
16	128	**8**	**16**	21	**32**	32	43	43	**64**	64	64	64	64	64	64	64
17	136	**8**	15	23	27	34	45	45	45	68	68	68	68	68	68	68
18	144	**8**	**16**	**24**	29	36	**48**	48	48	**72**	72	72	72	72	72	72
19	152	**8**	15	22	30	38	38	51	51	51	76	76	76	76	76	76
20	160	**8**	**16**	23	**32**	**40**	40	53	53	53	**80**	80	80	80	80	80
21	168	**8**	15	**24**	28	34	42	**56**	56	56	56	84	84	84	84	84
22	176	**8**	**16**	22	29	35	44	44	59	59	59	**88**	88	88	88	88
23	184	**8**	15	23	31	37	46	46	61	61	61	61	92	92	92	92
24	192	**8**	**16**	**24**	**32**	38	**48**	48	**64**	64	64	64	**96**	96	96	96
25	200	**8**	15	22	29	**40**	40	50	50	67	67	67	67	100	100	100
26	208	**8**	**16**	23	30	35	42	52	52	69	69	69	69	**104**	104	104
27	216	**8**	15	**24**	31	36	43	54	54	**72**	72	72	72	72	108	108
28	224	**8**	**16**	22	**32**	37	45	**56**	56	56	75	75	75	75	**112**	112
29	232	**8**	15	23	29	39	46	46	58	58	77	77	77	77	77	116
30	240	**8**	**16**	**24**	30	**40**	**48**	48	60	60	80	80	80	80	80	**120**

This table is based upon the assumptions that the child care is 8 hours in length (TO) and that the full enrollment is present for the full 8 hours (TH). This is unlikely to ever occur but it gives us a reference point to measure adult child contact hours in the most efficient manner. Based upon the relationship between TO and TH based upon the algorithms, select from one of the formulae from the previous page (formulae 1 - 4) to determine how well the actual Relatively Weighted Contact Hours (RWCH) match with this table. If the RWCH exceed the respective RWCH in this table, then the facility would be over ratio on ACR standards, in other words, they would be overpopulated.

(RS Model = 1.0)

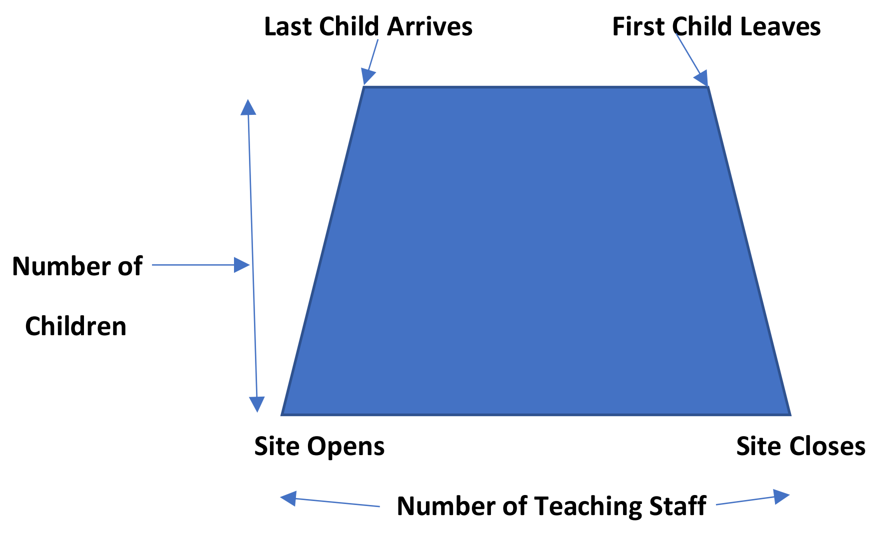
(TT Model = 0.5)

Sample/Data Collection Methods

Child care attendance data was explored and collected in partnership with the Washington State Department of Children, Youth, and Families (DCYF). A convenient sample of center and school age providers was initially identified through the use the state subsidy electronic payment system. All providers who accept Working Connections Child Care subsidies are required to use and track child attendance using an electronic attendance system. Providers may use and electronic sign in and out system provided by the state or opt to use another system. For this validation process, the sample was identified from the attendance tracking system provided and operated by DCYF and was inclusive of providers who use the system to track attendance of both subsidy and private pay children. The search resulted in approximately 100 providers within the State of Washington who have opted to use the electronic check-in system for all children regardless of payment type.

The sample was prioritized by identifying a single week since the Covid-19 outbreak began and from there the highest attendance day for that week was chosen for each provider. From this narrowed data set, it was determined the exact time the last child for the chosen day checked in, when the first child left, how many children were in attendance that day and the regular operating hours of the center or school age program. Because the attendance tracking system does not also track staffing attendance, it was necessary to contact each provider by phone in order to gather data inclusive of when the first staff arrived and when the last staff left and the total staff working that day. All responses were voluntary. Additionally, providers confirmed operating hours (many had been temporarily adjusted due to lowered demand during the gubernatorial stay at home order). Finally, providers reported if a child or staff member had tested positive for Covid-19. Of the 100 phone calls, the final sample was inclusive of 88 licensed providers statewide. Twelve providers either did not answer the call or opted to not answer the questions.

Figure 1: Contact Hour Diagram Paradigm and Schematic



The above diagram (Figure 1) depicts how the number of staff and children help to construct the contact hour formula. Depending on when the children arrive and leave could change the shape from a trapezoid to a rectangle or square or triangle. Please see the following potential density distributions which could impact these changes in the above contact hour diagram (Figure 1).

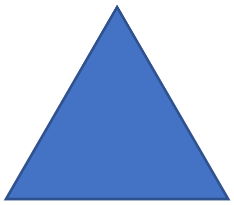
Potential Density Distributions
Taking into Account Number of Children, Staff, and Exposure Time

Here are some basic key relationships or elements related to the Contact Hour (CH) methodology.

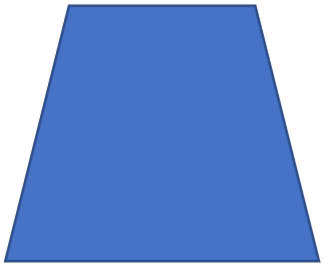
- RWCH = ACR
- CH = GS = NC
- NC and CH are highly correlated
- ACR and GS are static, not dynamic
- CH makes them dynamic by making them 2-D by adding in Time (T)
- ΣACR = GS
- GS = total number of children NC
- ACR = children / adult

ACR = Adult Child Ratio, GS = Group Size, RWCH = Relatively Weighted Contact Hours, NC = Number of Children.

<u>Possible Density Displays of Contact Hours (Horizontal Axis = Time (T); Vertical Axis = NC):</u>



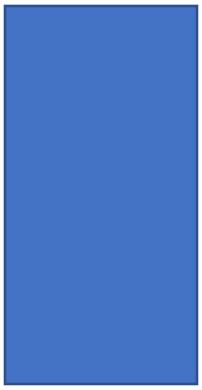
This density distribution should result in the lowest CH but probably not very likely to occur. Essentially what would happen is that full enrollment would be a single point which means that the last child arrives when the first child is leaving. Very unlikely but possible. (TT Model Reference(0.5))



This density distribution is probably the most likely scenario when it comes to CH in which the children gradually, albeit rather steeply, arrive at the facility and also leave the facility gradually. They don't all show up at the same time nor leave at the same time. However, the arriving and leaving will be a rather close time frame. (TT Model)

This scenario is unlikely but is used as the reference point for CH because it provides the most efficient model. This is where all the children arrive and leave at the same time. Very unlikely, but I guess it could happen. The important element here is its efficiency in that all contact hours are covered, so although a lesser amount of CH is not as efficient it does demonstrate compliance with ACR and GS which is one of the purposes of CH. As the bottom two distributions will demonstrate, CHs above this level would either depict a program that is open for an extended time or where there are too many children present and the facility is out of compliance with GS and/or ACR. (RS Model Reference(1.0))

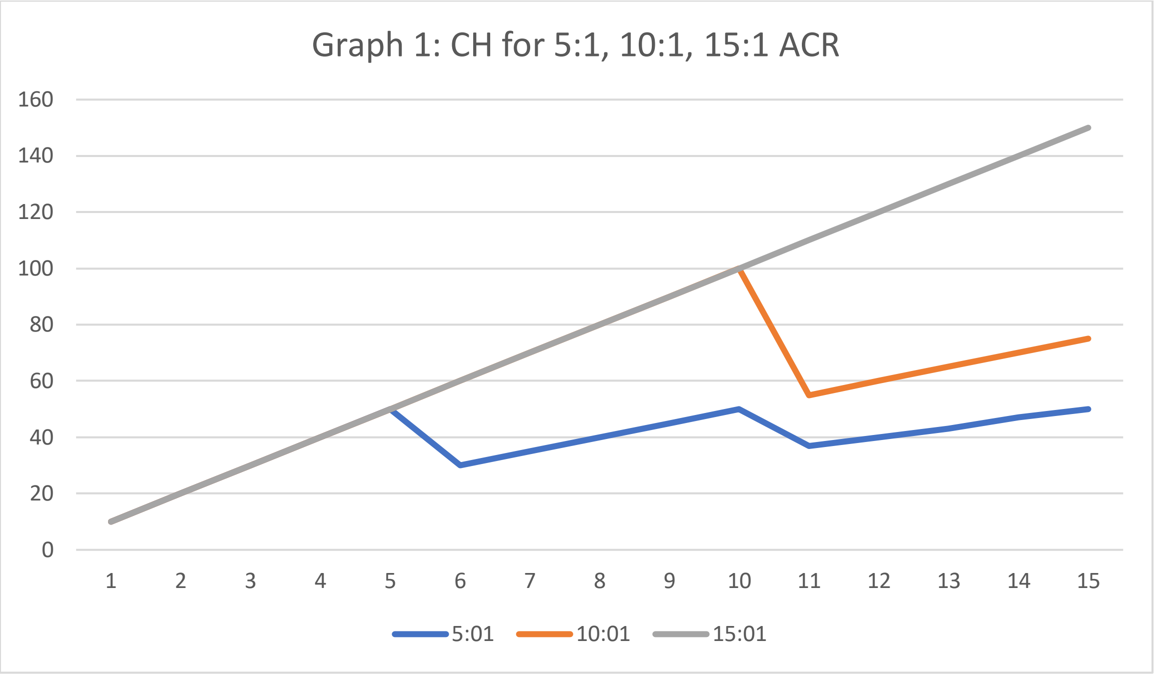
This distribution would indicate that the facility is open for an extended time and exceeds the number of total CH as depicted in the reference square standard. Although not out of compliance with GS or ACR, this could become a determining factor when looking at the potential overall exposure of adults and children when we are concerned about the spread of an infectious diseases, such as what happened with COVID19. Are facilities that high CH because of a scenario distribution of this type more prone to the spread of infectious diseases? (RS Model)



This depiction clearly indicates a very high CH and non-compliance with ACR and GS. This is the reason for designing the CH methodology which was to determine these levels of regulatory compliance as its focus. (RS Model)

There is some overlap in the RWCH (Table 1 on page 2) in moving across the various levels, that occurs because of the change in group size (GS) where an overall group size (GS) could influence the overall CH by increasing NC.

The below graph (Graph 1) depicts the contact hours (CH) for three different adult to child ratios (ACR) 5:1, 10:1 and 15:1 to demonstrate the relationship between CH & ACR as the number of children (NC) increases. CH is along the vertical axis, with NC along the horizontal axis.



This graphic (Graph 1) depicts how with the addition of staff, the CH drop off accordingly.

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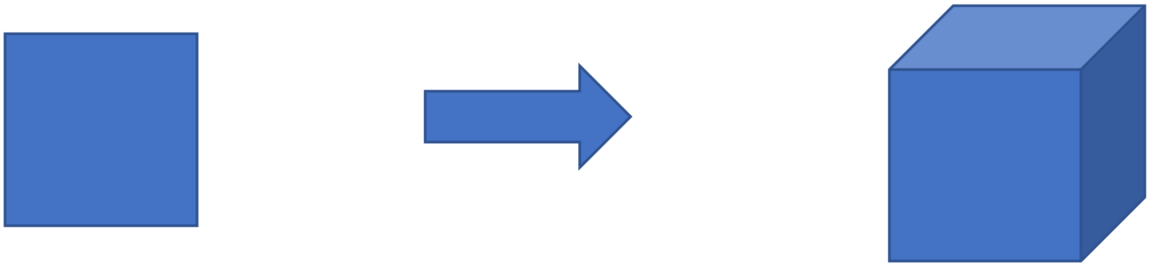
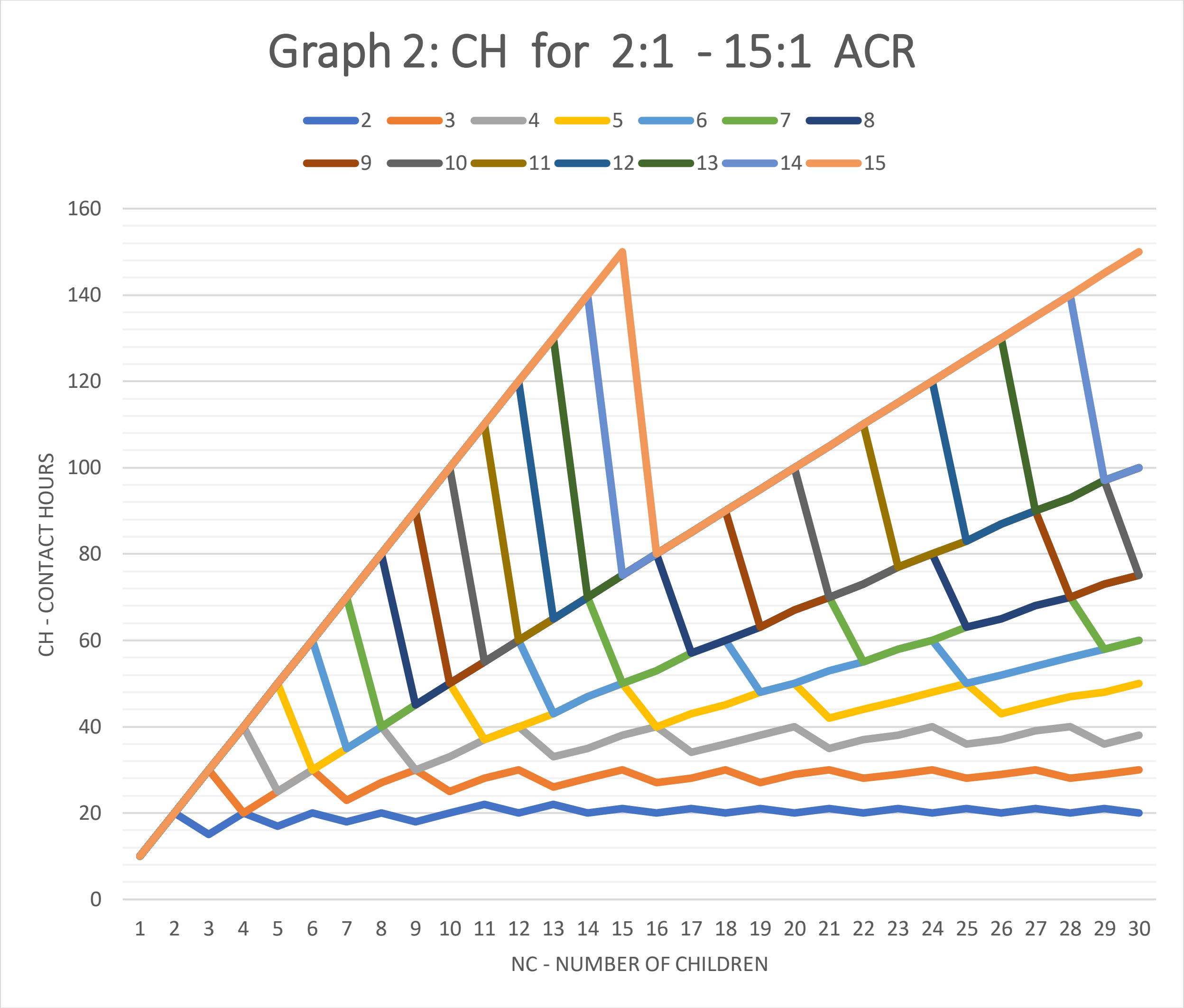
A possible extension or the next level to the CH methodology is to move from 2-D to 3-D and make the CH block format rather than area format. It could be used to describe the trilemma of accessibility, affordability and quality more fully. It could be a means for determining the unit cost at a much finer level and could then be used to make more informed decisions about the real cost of services.

Or another way of moving to 3-D is to include the square footage of the classroom or facility which would then provide a space metric along with time exposure and density metrics.



The move from 2-D (GS, ACR) to 3-D (GS, ACR, Quality or SQFT) and its potential impacts on the density distributions. Utilizing SQFT as a distancing/space dimension does help to mitigate the increased CH.

The following graph (Graph 2) depicts the Contact Hours (CH) for all the various Adult-Child ratios (ACR) in the Table on page 2 of this paper and how CH change with the number of children (NC).



From the above graph (Graph 2) it clearly shows how CHs vary with the number of children present. Please note the various slopes of the respective lines for each of the ACRs. As can be seen, once the lines begin to fluctuate, the CHs are entering into a zone of higher rate of exposure based on the ACRs. This demonstrates that the lower the ratio the more stable the CH line.

This is a listing of the algorithms for determining which formula (1-4 from page 1) & which model (RS or TT) to use in order to calculate the Contact Hours (CH). NC = Number of Children; TO = Total number of hours facility is open; TH = Total number of hours at full enrollment; TA = Total number of adult staff:

If TO = TH = NC, then (NC x TO)/TA = CH (RS Model)

If TH < TO, then ((NC (TO + TH))/2)/TA = CH; or If TH = 0, then ((NC x TO)/2)/TA = CH (TT Model)

If TO = TH < NC, then (NC x TH)/TA = CH (RS Model)

If TO = TH > NC, then (NC x TO)/TA = CH (RS Model)

Based upon the Washington State data, the Contact Hour methodology was validated in being able to act as a screener with those programs that would have exceeded the required staff child ratios. As can be seen through the data the more contact hours a staff person has with more children increases the probability of infection rates; when educators spend less time with lower amounts of children there is a lower chance of infection and vice versa. These data demonstrate how this methodology was used to assist in predicting appropriate child to adult ratios during an outbreak or pandemic by identifying safety thresholds of adult child ratios in licensed early learning facilities. The following spreadsheet plays out several scenarios with the actual data from Washington State early learning sites. For individuals interested in using the below spreadsheet in their respective jurisdiction, please contact the authors for the actual templates[1].

This provides evidence to support the use of this methodology in determining staff child ratio virtually as well as identifying when those ratios allow for in-person inspections or indicate when it is more appropriate to conduct virtual inspections. The authors do want to caution licensing administrators in that the results from this methodology is not to substitute for on-site observations when they are possible. It is intended as a screening tool to determine in a very overarching way how to target limited observational visits. The methodology is based upon statistical probabilities which have demonstrated in this pilot study to be highly reliable and valid but they are not full proof. So with any programs where there is any doubt, the agency should follow up with a direct observational inspection. Finally, agencies may want to consider using medical and geographical outbreak data in conjunction with this methodology to refine the results given the unique nature of the various infectious diseases.

In using the actual data from Washington State in the following spreadsheet, please note that the potential spread of the virus is mitigated the most greatly in the results in Green while Yellow and Red provide less mitigation and begin to place the adults and children at greater risk. Examples are provided for both the RS (1.0) and TT (0.5) Models

As a footnote to this study, a follow-up is to introduce distance/spacing via square footage (SQFT) to the Contact Hour formula. The results indicate a significant mitigation effect on increased Contact Hours when the available square footage is increased. This addition will be used in future studies to ascertain its relative impact on the Contact Hour formulas as indicated in the following revision.

CH2 = (((NC (TO + TH)) / 2) / TA) / (SQFT);

CH2 = ((NC x TO) / TA) / (SQFT);

CH2 = (((NC x TO) / 2) / TA) / (SQFT);

CH2 = ((NC^2) / TA) / (SQFT)

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[1] Richard Fiene, Ph.D., Research Psychologist, Research Institute for Key Indicators and Affiliate Professor, Prevention Research Center, Penn State University. rjf8@psu.edu; http://prevention.psu.edu/people/fiene-richard

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Enhanced Dichotomization Model for Generating Licensing Key Indicators Technical Research Note

Richard Fiene, Ph.D.

The Pennsylvania State University, Research Institute for Key Indicators, & National Association for Regulatory Administration

December 2019

The licensing key indicator methodology has been evolving over the past decade in making it more sensitive to the selection process of the specific rules to be included as key indicators. Some of the enhancements can occur because of state licensing data systems being able to provide population data rather than having to select sample data. Because of the nominal nature of licensing data and the severe skewness of the data distributions, non-parametric statistical approaches need to be employed in the analysis of the data.

A key component in the analysis of the licensing data distributions is to dichotomization of the data which is generally not warranted but is acceptable with very skewed data distributions. The dichotomization that has been most successful is a H25/M50/L25 distribution in which H25 represents the High Group of regulatory compliance, M50 which represents the Mediocre or Middle Group of regulatory compliance, L25 which represents the Lowest Group of regulatory compliance. In the past, the methodology allowed for full and substantial compliance within the High Group. This decision is no longer recommended. Rather, in order to decrease the number of False Negatives, it is now recommended that only Full (100%) regulatory compliance is used in defining the High Group. This eliminates the possibility of False Negatives.

By making this above change and in using the full distribution of licensing data, it enhances the results for generating the licensing key indicator rules. For additional information on this modeling please see:

Fiene, Richard (2018), "ECPQIM National Data Base", Mendeley Data, V1.
http://dx.doi.org/10.17632/kzk6xssx4d.1

This data base provides the detailed ECPQIM data distributions for the above changes. The enhancements increase the phi coefficients and reliability in either moving or not moving from abbreviated inspections to full comprehensive inspections. This data base also contains clear demonstrations of the efficacy of the ECPQIM – Early Childhood Program Quality Improvement and Indicator Model as a vehicle for improving early care and education programs.

For additional information regarding the Fiene Licensing Key Indicator Methodology, please go to http://RIKInstitute.com

So Which Is Better: Differential Monitoring & Abbreviated Inspections or Comprehensive Inspections?
Technical Research Note #98

Richard Fiene, Ph.D.

March 2020

During 2019 and 2020, several validation studies have been or are being completed in the states of Washington, Indiana, and in the Province of Saskatchewan. These validation studies are determining if the key indicator and risk assessment methodologies are valid approaches to conducting abbreviated inspections in comparison to more comprehensive inspections in which all rules are assessed. These abbreviated inspections are a form of differential or targeted monitoring. This technical research note focuses on the empirical evidence to determine the efficacy of these approaches, are they better than doing comprehensive reviews when it comes to health and safety outcomes.

When the key indicator and risk assessment methods were originally proposed in the 1980's, an outcome validation study was completed in Pennsylvania during 1985 – 1987 by Kontos and Fiene to determine what impact those methods had on children's development. In that original study, it was determined that the Child Development Program Evaluation Indicator Checklist (CDPEIC) was more effective and efficient in predicting child development outcomes than the more comprehensive Child Development Program Evaluation. In fact, the CDPEIC and the accompanying Caregiver Observation Scale (COFAS) were as effective and more efficient than the ECERS – Early Childhood Environmental Rating Scale in that study.

Fast forward to 2019 – 2020, in the province of Saskatchewan, Canada, and a similar study was undertaken but in this case the outcomes were more based upon health and safety rather than child development developmental outcomes. In this case, again the key indicator and risk assessment tool was both a more effective and efficient model over the more comprehensive inspection approach giving credence to utilizing differential monitoring with abbreviated inspections.

In both of the above validation studies involving either child development assessment outcomes or health & safety outcomes, a 16 to 28% increase in effectiveness was observed in the outcome data. In the abbreviated or targeted inspections, 33% of the total rules or less are used to make the determination of regulatory compliance. It is like having the best of both worlds when it comes to effectiveness (16 – 28% increase in outcomes) and in efficiency (66% fewer rules being used). These studies help to validate the use of differential monitoring as a viable alternative to the more comprehensive one-size-fits-all monitoring reviews.

Effectiveness and Efficiency Relationship Leading to Cost Benefit

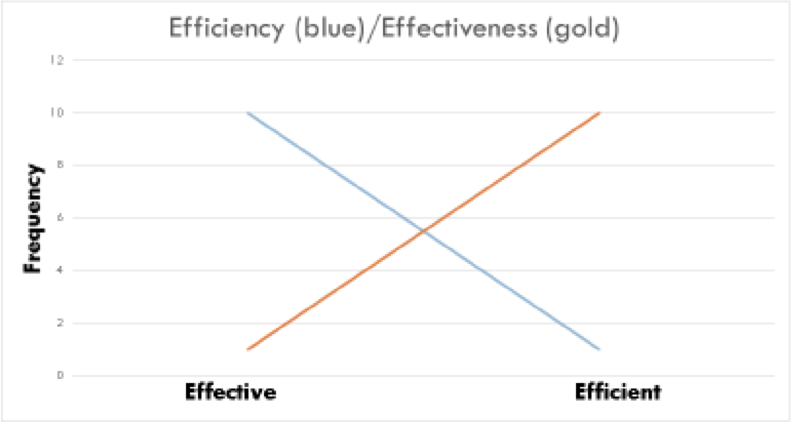
Richard Fiene, Ph.D.

March 2019

In management science and economic theory in general, the relationship between effectiveness and efficiency has been delineated in terms of two mutually exclusive processes in which you have one but not the other. This brief technical research note will outline an approach which mirrors the relationship in economics between supply and demand and how effectiveness and efficiency can be thought of as images of each other giving way to cost benefit analysis in order to have the proper balance between the two.

The proposed relationship between effectiveness and efficiency is that as one increases the other decreases in a corresponding and proportionate way as depicted in the graphic below. This relationship is drawn from my work in regulatory compliance/licensing systems in comparing data collected in comprehensive licensing reviews and abbreviated licensing reviews where only a select group of rules/regulations are measured. When comprehensive reviews are completed these reviews tend to be more effective but not very efficient use of resources. When abbreviated reviews are completed these reviews tend to be more efficient but are not as effective if too few rules are measured for compliance.

Effectiveness & Efficiency Relationship



Effectiveness deals with the quality of outputs while efficiency deals with input of resources expended. The Theory of Regulatory Compliance is finding the right balance between effectiveness and efficiency in the above graphic. Where is the balanced "sweet" spot of inputs to produce high quality outputs. As one can see where the effectiveness line is at the highest point and efficiency is at the lowest point, this is a very costly system that is totally out of balance. But the same is true where efficiency is at the highest point and effectiveness is at the lowest point, this is a very cheap system that is totally out of balance producing low quality. The key to this relationship and the theory of regulatory compliance is finding that middle ground where effectiveness and efficiency are balanced and produce the best results for cost and quality and leads us directly to cost benefit analysis.

Richard Fiene, Ph.D., RFiene@RIKInstitute.com, http://RIKInstitute.com

Research Institute for Key Indicators (RIKIllc) Technical Research Note #70.

A Treatise on Essential Early Care and Education

Richard Fiene, Ph.D.

January 2021

After being in the early care and education (ECE) field for approximately a half century, I want to propose a radical departure from how we have designed our ECE systems. Many national organizations have been suggesting that we take this time because of the COVID19 pandemic and rethink how we want to bring ECE back online building a newer and better system. We do have a unique opportunity to do this since we have lost approximately 25% of ECE as of this writing. However, I am sure what I am about to suggest is not what many of my ECE colleagues had in mind.

It is ironic because what I am proposing is very similar to an idea I had and even proposed to a federal agency practically 50 years ago. It starts with rank ordering the need of ECE and thinking of offering ECE only on an essential basis. By essential I mean for those parent(s) who only really need and want to have ECE services. For those who do not, let's pay them a stipend to stay at home with their child(ren). And this can be either mom or dad. I have not had the opportunity to run the numbers, but I am guessing that my suggestion of providing stay at home stipends could be paid for by the reduction in total need for ECE services since we would definitely see a reduction in the total need for ECE as it relates to out-of-home care. So this could be a cost neutral program.

So rather than trying to replace the 25% we have lost in ECE programs and replacing them with a higher quality version, let's totally think outside-the-box and ask parents if they really want those services or would they prefer to stay at home and raise their children in their own homes. The remaining 75% of ECE programs still will need a quality booster-shot because by best estimates prior to the COVID19 pandemic, only 10% of ECE programs were of a high-quality level.

I know that this is a radical departure from our present thinking both within the ECE advocacy community and I am sure within political circles, but maybe this is exactly the type of proposal we need to reinvent ECE. I know this is not going to be a popular idea but I want to get us thinking more broadly because the thinking so far appears to be centered on fixing an already broken system but mostly staying within the confines of that broken system. Let's really reinvent ourselves and ask parents what they want and need rather than ECE "experts" trying to make this decision for them.

The Evolution of Differential Monitoring With the Risk Assessment and Key Indicator Methodologies

Richard Fiene, Ph.D.

Research Institute for Key Indicators (RIKIllc)

The Pennsylvania State University

National Association for Regulatory Administration (NARA)

December 2018

The use of differential monitoring by states and Canadian Provinces has evolved very interestingly over the past decade into two parallel approaches which help to inform other interested jurisdictions as they consider a differential monitoring approach.

Differential monitoring is a more targeted or abbreviated form of monitoring facilities or programs based upon "what is reviewed/depth of the review" and "how often/frequent do we review". Two specific methodologies have been used by states to design and implement a differential monitoring approach: risk assessment and key indicators.

It was originally conceived that risk assessment and key indicator methodologies would be used in tandem and not used separately. Over the past decade, a real dichotomy has developed in which risk assessment has developed very independently of key indicators and risk assessment has become the predominant methodology used, while the key indicator methodology has lagged behind in development and implementation.

In this separate development and implementation, risk assessment has driven the "how frequent" visits in a differential monitoring approach while key indicators has driven "what is reviewed" when it comes to rules/regulations/standards.

The other development with both methodologies are the data matrices developed to analyze the data and to make decisions about frequency and depth of reviews. For risk assessment, the standard matrix used is a 3 x 3 matrix similar to the one presented below.

Risk Assessment with Probability along the vertical axis and Risk along the horizontal axis

A	**B**	**C**
D	**E**	**F**
G	**H**	**I**

In the above 3 x 3 Risk Assessment Matrix, (A) indicates a very high risk rule/regulation/standard with a high likelihood that it will occur, while (I) indicates a very low or no risk rule/regulation/standard with a low likelihood that it will occur. (B) through (H) indicate various degrees of risk and probability based upon their position within the Matrix.

The decision making relationship of more frequent visits to the facility or program is made on the following algorithm:

If I > E + F + H > B + C + D + G > A, than more frequent reviews are completed

Just as Risk Assessment utilizes a 3 x 3 Matrix, Key Indicators utilizes a 2 x 2 Matrix in order to analyze the data and make decisions about what is reviewed. Below is an example of a 2 x 2 Matrix that has been used.

Key Indicator with Compliance/Non-Compliance listed vertically and High vs Low Grouping listed hortizontally

A	**B**
C	**D**

In the above 2 x 2 Key Indicator Matrix, (A) indicates a rule/regulation/standard that is in compliance and in the high compliant group, while (D) indicates a rule/regulation/standard that in out of compliance and in the low compliant group. (B) and (C) indicate false positives and negatives.

The decision making relationship of more rules to be reviewed is made on the following algorithm:

If A + D > B + C, than a more comprehensive review is completed

Given the interest in utilizing differential monitoring for doing monitoring review, having this decade's long review of how the risk assessment and key indicator methodologies have evolved is an important consideration.

Is it still possible to combine the risk assessment and key indicator methodologies? It is by combining the 3 x 3 and 2 x 2 Matrices above where the focus of utilizing the Key Indicator methodology is (I) cell of the 3 x 3 Matrix. It is only here that the Key Indicator methodology can be used when combined with the Risk Assessment methodology.

Key Indicator and Risk Assessment Methodologies Used in Tandem

A	**B**	**C**
D	**E**	**F**
G	**H**	**Only Use Key Indicators here**

By utilizing the two methodologies in tandem, both frequency of reviews and what is reviewed are dealt with at the same time which makes the differential monitoring approach more effective and efficient.

Richard Fiene, Ph.D., Psychologist, Research Institute for Key Indicators (RIKIllc); Professor of Psychology (ret), Penn State University; and Senior Research Consultant, National Association for Regulatory Administration (NARA).

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RIKI Technical Research Note on the Licensing Key Indicator Predictor Methodology Threshold Updates, Regulatory Compliance, False Positives & Negatives, Data Dichotomization, and Licensing Measurement

April 2021

The purpose of this technical research note is to provide the latest updates to the Key Indicator Predictor Methodology and associated measurement issues, such as eliminating or reducing false positives and negatives, the use of data dichotomization with regulatory compliance frequency distributions.

It has always been recommended that a data dichotomization model be employed in distinguishing between the highly regulatory compliant from the low levels of regulatory compliance. The suggested model was 25/50/25 in which the top 25% constituted the highly compliant group, the middle 50% constituted the substantial – mid range compliant group, and the bottom 25% constituted the low compliant group. This was different from what had been done in the past in which fully compliant (100%) facilities were compared with those facilities who had any violations of regulatory compliance. It was found that by utilizing the 25/50/25 model a clearer distinction could be made between the high and low compliant groups. Generally, the top 25% are those facilities that are in full (100%) compliance, with the middle 50% are those facilities that have regulatory non-compliance ranging from 1 – 10 violations. The bottom 25% are those facilities that have regulatory non-compliance of greater than 10 violations. In this dichotomization model, the middle 50% are not used in the calculations, only the top and bottom 25%.

The dichotomization model described in the above paragraph has worked very well in producing licensing key indicator predictor rules by eliminating false negatives and decreasing false positives in the resultant 2 x 2 Key Indicator Predictor Matrix. The Fiene Coefficients for the licensing key indicator predictor rules have been more stable and robust by utilizing this model. It was made possible because of the increasing sample sizes selected for analyses and in some cases where population data were available. Also, the overall level of full compliance in states/provinces has increased over time and that has been a contributing factor as well in eliminating false negatives. False positives have been decreased because of the same factors but will never be eliminated because of the nature of the data distribution being highly positive skewed. Because of this distribution, there will always be false positives identified in the analyses. But that is the lesser of two evils: a rule being in compliance although it is present in the low regulatory compliant group.

However, are there ways to mitigate the impact of false positives. Based upon results from the *Early Childhood Program Quality Improvement & Indicator Model Data Base (ECPQI2MDB)* maintained at the Research Institute for Key Indicators/Penn State, there appears to be several adjustments that can be made so that the impact of false positives is not as pronounce as it has been in the past. The first adjustment that can be made is to increase the sample size so that additional non-compliance is identified. This is difficult at times because the nature of licensing or regulatory compliance data trends towards very high compliance for most facilities with little non-compliant facilities. It is the nature of a regulatory compliance or licensing program; these are basic health and safety rules which have had a history of substantial to full compliance with the majority of the rules. The data are extremely positively skewed. There is little variance in the data. So, increasing the sample size should help on all these accounts. In addition to increasing the sample size, an additional methodology was developed in order to increase the variance in licensing/regulatory compliance data by weighting rules/regulations based upon the risk children are placed in because of non-compliance. This proposal makes a great deal of sense but its application in reality hasn't played out as intended. What most jurisdictions do in implementing the risk assessment methodology is to identify the most heavily weighted rules but then to deal with these rules as high risk rules and not using the weights assigned to them for aggregating regulatory compliance scores. The use of the methodology in this way is very effective in identifying the specific rules based upon risk, but does little to nothing in increasing the variance in the regulatory compliance data distribution. The data distribution remains severely positively skewed.

Another way to mitigate the impact of false positives is to increase the data dichotomization of the data distribution but this is recommended only with the increase sample size. If it is done without an increased sample size, the resultant Fiene Coefficients for the licensing key indicator predictor rules will be less robust and stable. For example, the data dichotomization model of 25/50/25 could be increased to a 10/80/10 model which should help in decreasing the false positives in the analyses.   But this is cautionary, for example, in going to a 5/90/5 model could again make the resultant Fiene Coefficients for the licensing key indicator predictor rules less robust and stable. The sample size needs to be very large or the full population needs to be measured in order to do these analyses and co-balance the increased data dichotomization because the cell sizes will be decreasing significantly. The following 2 x 2 matrix will depict these relationships for generating the Licensing Key Indicator Predictor Fiene Coefficients (FC).

Licensing Key Indicator Predictor Fiene Coefficient (FC) Table

Individual Rules/Groups ->	High Compliant (Top 25%)	Low Compliant (Bottom 25%)
Rule In Compliance	FC (++)	FP (+)
Rule Out of Compliance	FN (-)	FC (--)

((FC (++) + (FC (--)) > ((FN (-)) + (FP (+))

where FC = Fiene Coefficient which results in Licensing Key Indicator Predictor Rules (FC = .25 or >);

FN (-) = False Negative; FP (+) = False Positive

The cells represented by the Fiene Coefficients should always be larger than the False Positive and Negative results in the above table. With the above dichotomization 25/50/25 model and high levels of full 100% regulatory compliance, false negatives can be eliminated and by increasing the sample size, false positives will be decreased but never fully eliminated. Full 100% regulatory compliance increased levels will help to eliminate false negatives, but it will also increase the chances of false positives. There is a delicate balance with confounding the increased sample sizes (false positives will decrease) and increased levels of full 100% regulatory compliance (false positives will increase).   This will take a bit of adjusting to get this balancing just right.

By utilizing the *ECPQI2MDB* it has demonstrated that the above-mentioned dichotomization models may be difficult to hit the percentages exactly. The actual models may be more heavily weighted in the percent for the high group as versus the low because of the regulatory compliance data distribution being highly positive skewed as mentioned earlier. This may have an impact on the Fiene Coefficients (FC) for licensing key indicator predictor rules but it will not impact the actual selection of the licensing key indicators – they will remain the same, just the FCs will change.

One last footnote on the relationship between regulatory compliance and program quality. This relationship has been addressed several times over the past four decades in the regulatory science and human services regulatory administration fields; but it needs to be re-emphasized as it relates to this discussion about licensing measurement. Regulatory compliance and program quality are linear and non-random in moving from low regulatory compliance to mid-substantial regulatory compliance as with low program quality to mid program quality. However, when one moves from substantial regulatory compliance to full 100% regulatory compliance the relationship with program quality is more non-linear and random.

The Public Policy Implications of the Regulatory Compliance Theory of Diminishing Returns, Regulatory Compliance Scaling, and the Program Quality Scoring Matrix along with Integrative Monitoring

Richard Fiene PhD

Research Institute for Key Indicators/Penn State

March 2023

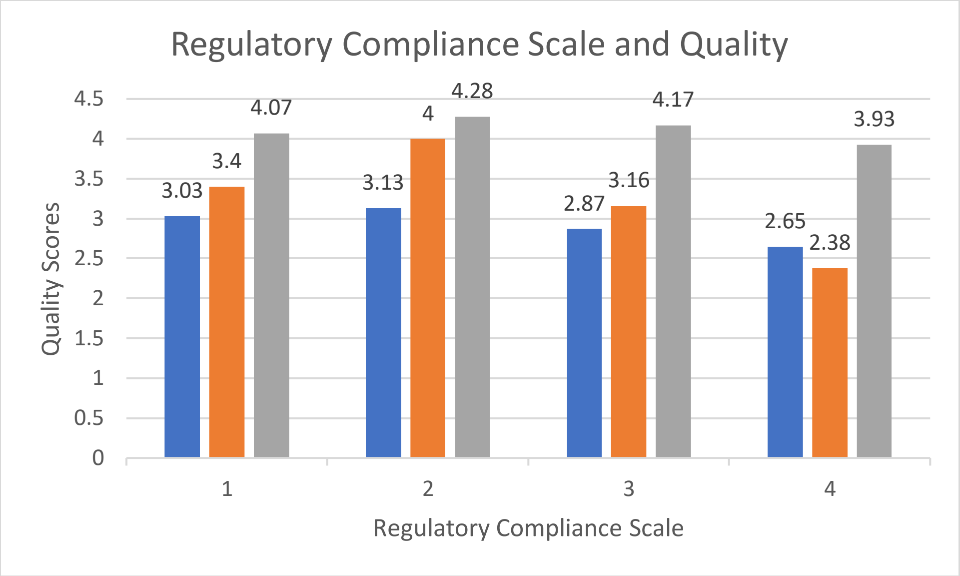
This technical research note/abstract provides a data matrix (below table) depicting the relationship between regulatory compliance and program quality. The data clearly demonstrate the regulatory compliance theory of diminishing returns which depicts the ceiling or plateau effect in this relationship between regulatory compliance data and program quality data. It also shows the difficulty one will have in distinguishing program quality differences at the full and high regulatory compliance levels but the ease in distinguishing program quality between low regulatory compliance and high regulatory compliance levels.

This abstract unifies several separately developed regulatory compliance metrics and concepts by combining them into a single technical research note. The Regulatory Compliance Theory of Diminishing Returns (2019), The Regulatory Compliance Scale (2022), Integrative Monitoring (2023), and the Ten Principles of Regulatory Compliance Measurement (2023) have all been presented separately (all these papers are available for the interested reader on ***SSRN (***https://www.ssrn.com/index.cfm/en/***) or the Journal of Regulatory Science (***https://regsci-ojs-tamu.tdl.org/regsci/***)***). This abstract shows how they are all related and their importance in moving forward with regulatory compliance measurement in the future. The four jurisdiction's (US National, Southern State, Western State, Canada) final reports are available at https://www.naralicensing.org/key-indicators for the interested reader.

Relationship of Regulatory Compliance Scale and Program Quality in Four Jurisdictions Matrix

Reg Comp Scale	US National	Southern State	Western State	Canada
Full	3.03 (75)	3.40 (15)	4.07 (82)	37.4 (44)
High	3.13 (135)	4.00 (20)	4.28 (69)	38.5 (33)
Mid	2.87 (143)	3.16 (32)	4.17 (163)	29.1 (36)
Low	2.65 (28)	2.38 (2)	3.93 (71)	-----------
Significance	***p* < .001**	***p* < .05**	***p* < .001**	***p* < .01**

Legend:
US National = CLASS-IS scores
Southern State and Western State = ECERS-R scores
Canada = Canadian Program Quality Tool scores
One-way ANOVA was performed on the data in each jurisdiction.
Regulatory Compliance Scale (Reg Comp Scale (RCS)):
Full = 0 violations (100% regulatory compliance with all rules/regulations)
High = 1-2 violations
Mid = 3-9 violations
Low = 10+ violations
The number in parentheses is the number of programs assessed in each jurisdiction.



Legend:
1 = Full; 2 = High; 3 = Mid; 4 = Low.
Blue = US National; Orange = Southern State; Gray = Western State. Canada was left off because of different scaling.

The above data matrix display is important for the early care and education (ECE) field because it demonstrates the relationship between licensing via regulatory compliance data measurement and program quality scores via CLASS, ERS, and the Canadian Quality Tool. The CLASS and ERS are well grounded ECE program quality tools while the Canadian Quality Tool is a new addition to the field.

The data displayed show that a ceiling or plateau effect (quality scores did not change significantly as was generally the case with lower levels of regulatory compliance) occurred in all four jurisdictions when the regulatory compliance levels or the absence of rule/regulatory violations were compared to program quality scores as one moves from high regulatory compliance to full regulatory compliance (0 violations or 100% regulatory compliance with all rules). From a public policy point of view, it would lead us to believe that licensing is not the best avenue to program quality and that another intervention, such as Quality Rating and Improvement Systems (QRIS), would be necessary to enhance quality programming. What regulatory compliance and licensing does do is prevent harm and keep children in healthy and safe environments (please go to https://rikinstitute.com for examples to support this claim). So, from a public policy point of view, licensing is accomplishing its goals. But don't expect licensing to address quality programming. For that to occur, either we need to continue our present system of licensing and Quality Initiatives, such as QRIS, as an add on; or infuse quality into the rules and regulations which has been suggested via a new form program monitoring called: integrative monitoring.

There are some other takeaways from the above data matrix that are significant contributions to the regulatory compliance measurement research literature, such as, how skewed the data are. Focus more on the number of programs rather than their quality scores for each of the Regulatory Compliance Scale levels. You will notice that most programs in each of the jurisdictions are either in full or high regulatory compliance and that there are few programs at the low end of the regulatory compliance scale. There is an unusually very high percentage of programs at full compliance. This also contributes to a lack of variance in the upper end of the regulatory compliance scale which can be problematic as indicated in the previous paragraph in distinguishing between the quality levels of programs.

The importance of these four studies and the summary matrix above is to provide a context in how licensing and regulatory compliance data should be used in making public policy decisions, for example: is it more effective and efficient to require high or substantial regulatory compliance than full regulatory compliance with all rules and regulations to be granted a full license to operate? It appears prudent to continue with the US emphasis on QRIS as an add on quality initiative, especially in states where rules/regulations are at a minimal level. In Canada their emphasis has been more in line with an integrative monitoring approach in which quality elements are built in or infused within the rules and regulations themselves. This approach appears to work in a similar fashion and is an effective public policy initiative. Either approach appears to be an effective modality to increasing program quality; but are both equally efficient.

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Full versus Substantial Regulatory Compliance

Richard Fiene PhD

Research Institute for Key Indicators/Penn State University

December 2023

This research abstract builds off several other research abstracts/notes in this series on regulatory compliance. It will attempt to take a more overview approach than the more technical and methodological approaches utilized in previous posts.

There is an important distinction when it comes to regulatory compliance related to levels of compliance: Full or 100% regulatory compliance with no violations and substantial regulatory compliance where there may be 1-2 violations of low-risk rules/regulations. The goal of any licensing or regulatory system is to have programs meet all rules/regulations/standards. This has been an important focus of all licensing/regulatory agencies throughout the US, Canada and the world.

But this goal needs to be altered a bit based upon several research studies conducted by this author over several decades in which full regulatory compliance does not equate with a high-quality program. While this empirical result may change our thinking about the relationship related to full regulatory compliance and substantial regulatory compliance which appears to be more related to program quality, it does not alter the need for full regulatory compliance in making predictions of overall regulatory compliance in the selection of key predictor rules. In order to eliminate false negatives in licensing decision making, full regulatory compliance is critical as a continuous goal.

Substantial regulatory compliance turned out to be an important discovery related to the theory of regulatory compliance where programs at this level demonstrated a higher level of program quality than those programs that were in full 100% regulatory compliance. It had been assumed up until the introduction of the theory of regulatory compliance that full regulatory compliance equated to high program quality. Since then, substantial regulatory compliance and the issuance of licenses based upon substantial rather than full regulatory compliance is a sound public policy approach.

However, when utilizing the key indicator methodology for identifying predictor rules, full regulatory compliance is still the paradigm that needs to be employed. It is the only safeguard to decrease and/or eliminate false negatives in which additional regulatory non-compliance could occur when full regulatory compliance is attained with the key indicator tool.

The overall key element is that substantial compliance does not replace full compliance in license decision making. It is predominant when it comes to the theory of regulatory compliance but has a back seat when it comes to identifying predictor rules unless an adjustment is made to the 2 x 2 Key Indicator Matrix which has been addressed in previous posts. The use of substantial compliance is also a key measurement component of the Regulatory Compliance Scale which has been introduced as an alternative to licensing violation data. However, full compliance will remain as the goal of any key indicator predictor rule method.

In conclusion, full compliance equates to a healthy and safe environment, but it does not necessarily mean it is of the highest quality. Within a regulatory compliance schema, substantial compliance appears more related to program quality. Risk assessment rules are always in compliance in either one of these scenarios.

Child Injuries in Childcare Centers: Example from an Eastern State

Richard Fiene PhD

Research Institute for Key Indicators Data Laboratory/Penn State University

November 2023

This technical research abstract will provide a glimpse at a larger study involving an eastern state with exploring the relationship between child injuries in childcare centers and other regulatory compliance and demographic characteristics. Regulatory compliance does not have many empirical demonstrations of outcome studies in determining if children are healthier and safer in childcare centers. This abstract will attempt to begin to provide some guidance related to this question.

The key variables in this study are the following: child injuries, complaints, program size, and regulatory compliance. Child injuries are the outcome variable, what we are trying to impact. Complaints, program size and regulatory compliance are the independent variables that were collected by the respective state where this study is being conducted. The number of programs in this abstract is 200. The final study will involve over 400 programs. However, the results in reviewing the first 200 programs are so statistically significant that it warranted sharing the results to date.

The results show some very interesting relationships. For example, and this should not be overly surprising, there is not a very strong relationship between child injuries and overall regulatory compliance. When you think about overall regulatory compliance, some rules could influence upon child injuries directly, such as overall supervision, group size, staff child ratios and the overall safety of the childcare center, but when you think of the other rules that make up regulatory compliance involving structural, or record compliance not so direct a relationship. However, it is this more targeted rule identification that does have an effect, and this is very evident when one begins to look at the series of complaints and its relationship to child injuries ($r = .20$; $p < .005$).

The strongest predictor of child injuries is not regulatory in nature but more demographic related to the size of the program. Child injuries generally occur in larger childcare centers rather than in smaller centers ($r = .41$; $p < .0001$). So, it appears that we really want to pay attention to the size of the childcare center, especially if the program has an enrollment of over 100 children.

This brief abstract is presented in the interest of attempting to get additional empirical evidence in the research literature related to regulatory compliance outcomes. So far in this study, it is demonstrating that overall regulatory compliance is not significantly related to preventing child injuries, but specific, targeted rules appear too, such as supervision and staff child ratios. This is consistent with the theory of regulatory compliance in which it is finding the deep-rooted cause structure when it comes to regulatory compliance rather than a more generic regulatory compliance level. This pilot study is being expanded to include all the childcare centers in the particular state and to expand the study to other jurisdictions to determine if these same relationships hold up under greater scrutiny.

Relationship of Key Indicators and Risk Assessment/Weighting in Differential Monitoring

Richard Fiene PhD

Penn State Prevention Research Center

September 2024

This research abstract will provide a 2 x 2 Matrix Logic Model depicting the relationship amongst key indicators, weighting, risk assessment and differential monitoring. This has been written about and depicted in different modalities but this presentation gets at the underlying structure of how these methodologies all fit together and support each other from a program monitoring perspective.

The starting point is the differential monitoring approach where the key indicators and risk assessment methodologies are the key components of this approach. What sometimes gets lost in utilizing this approach is the deep structure used around weighting of rules and regulations. The weighting process is and has always been a key element of the key indicator and risk assessment methodologies. Through weighting, a more robust scoring system which accounts for the idiosyncrasies of regulatory compliance databases is accounted for based upon the theory of regulatory compliance (Fiene, 2019).   It also provides a means for identifying rules that place clients at greatest risk for mortality or morbidity. Weighting is obviously a driver for both these methodologies by introducing the necessary variance in the regulatory compliance database.

But at the same time, weighting may have contributed to a certain amount of confusion regarding the differences between key indicator and risk assessment rules where in the licensing research literature the lines are not as clearly drawn. In the quest to select the most salient rules (Fiene, 2024) sometimes risk and prediction get confused in their use for differential monitoring. The purpose of this research abstract and presenting this new 2 x 2 matrix is hopefully to clear up some of this confusion.

Key indicator and risk assessment rules are the key components of a differential monitoring systems approach that has been demonstrated to be both cost effective and efficient in conducting licensing inspections. But, exactly, how do these methodologies complement each other? The following 2 x 2 matrix will provide some guidance in thinking about these relationships and clear up confusion in how they can be used in tandem or alone.

Probably the starting point is addressing program monitoring that involves a uniform approach in which all rules are assessed and dealt with in an equal manner versus a differential monitoring approach in which selected rules are assessed and dealt with in a more focused program review. In the regulatory science research literature, key indicator and risk assessment rules are generally proposed as the most cost effective and efficient methods for a differential monitoring approach. Are there better methods? Of course, but as of this writing, key indicator and risk assessment methods appear as the most likely candidates and will continue until the regulatory science has progressed to the point to empirically propose better renditions of these methods.

The below matrix: *Relationship of Key Indicators and Risk Assessment and Weighting in Differential Monitoring* depicts how this relationship plays out. Let's take a closer look at the various cells of the matrix and what it all means. To start with, the opposite of differential monitoring is uniform monitoring where all rules are reviewed via a comprehensive instrument, (the bottom right cell). Differential monitoring is either done via key indicators or risk assessment but pay close attention to the importance of how weighting of rules/regulations plays in this process. Weighting is required when a differential monitoring approach employs a substantial regulatory compliance scale based upon the theory of regulatory compliance (the top left cell); but it is not required, although recommended, when a full 100% regulatory compliance scale is used (the bottom left cell). If weighting is utilized but key indicators are not, then the resultant method is a risk assessment rule/regulation method, (the top right cell). This is an effective method but not as efficient & effective when both risk assessment and key indicators are utilized together in tandem.

<table>
<tr><td colspan="3" rowspan="3">Relationship of Key Indicators and Risk Assessment and Weighting in Differential Monitoring Matrix</td><td>Key Indicators</td><td>Key Indicators</td></tr>
<tr><td>Yes</td><td>No</td></tr>
<tr><td>Differential Monitoring</td><td></td></tr>
<tr><td>Weighting</td><td>Yes</td><td>Differential Monitoring</td><td>Substantial Regulatory Compliance</td><td>Risk Assessment</td></tr>
<tr><td>Weighting</td><td>No</td><td></td><td>Full Regulatory Compliance</td><td>Comprehensive Review</td></tr>
</table>

Hopefully, the above 2 x 2 matrix provides a clearer logic model for licensing researchers, regulatory scientists, and licensing administrators in demonstrating the relationship between differential monitoring, key indicators, weighting, and risk assessment rules. It should then lead to better understanding and decision making in which method to use and when it is appropriate to do so. Also, it is hoped that the importance of weighting is demonstrated in this model as well as the impact of the theory of regulatory compliance and its influence on differential monitoring by introducing substantial regulatory compliance in licensing decision making. Please consult the National Association for Regulatory Administration's webpage on Differential Monitoring and Key Indicators (https://www.naralicensing.org/key-indicators) for additional information and resources related to this discussion, especially regulatory science and theory.

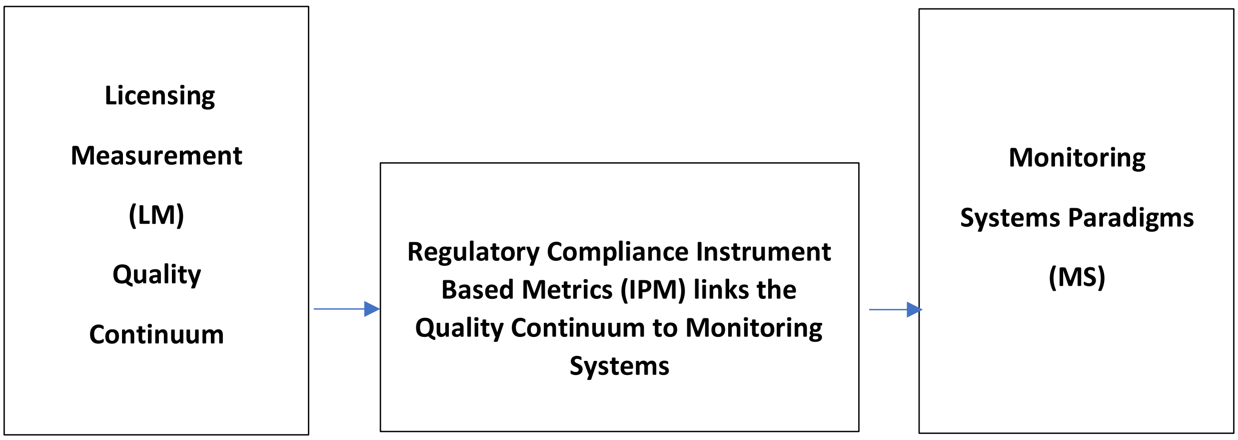
References:

Fiene, R. (2019). A treatise on theory of regulatory compliance, ***Journal of Regulatory Science, 7, no. 1, 1-3.*** https://doi.org/10.21423/JRS-V07FIENE

Fiene, R. (2024). The Holy Grail of Regulatory Science: Finding the Right Rules with the Theory of Regulatory Compliance, ***American Scientist***, accept for publication, August 2, 2024.

Relationship Amongst Regulatory Compliance Metrics, Monitoring Paradigms, and Licensing Measurement Quality Continuum Graphic and Matrix

The below graphic presents the relationship amongst regulatory compliance metrics, monitoring systems paradigms, and the licensing measurement quality continuum. It demonstrates the inter-relationships amongst the three areas. Refer to the Matrix for the details to each area and refer to ***Licensing Measurement and Monitoring Systems: Regulatory science applied to human services Regulatory Administration ehandbook (Fiene, 2023)*** for additional details regarding this overall model.



The above graphic shows the linkages while the below matrix shows how significant the "*Ceiling Effect*" is in impacting the monitoring systems paradigms. When it comes to licensing measurement influences, the "*Ceiling Effect"* probably is the most significant influence on licensing and regulatory compliance data distributions when it comes to skewed data, the ease between identifying high versus low performers, and the difficulty in distinguishing between high and full regulatory compliance providers when it comes to program quality differences.

Matrix: Comparing Regulatory Compliance, Quality, and Monitoring Systems Paradigms

Licensing Measurement Quality Continuum -->	Regulatory Compliance Instrument Based Metrics -->	Monitoring Systems Paradigms
Ceiling Effect	*Ceiling Effect*	Substantial versus monolithic
Do no harm versus do good	Ease between high and low	Do things well vs do no harm
Nominal versus ordinal	Nominal measurement	100 – 0 versus 100 or 0
Structural vs process quality	Moving nominal to ordinal	Program quality vs compliance
Full versus partial compliance	Difficulty between full and high	One size fits all vs differential
Risk versus performance	False negatives	Strength based versus deficit
Rules versus indicators	Dichotomization	Rules are equal vs not equal
Gatekeeper versus enabler	Lack of reliability and validity	QRIS versus licensing
Open versus closed system	Skewed data	Linear versus non-linear
Hard versus soft data	Lack of variance	Formative versus summative

The Implications in Regulatory Compliance Measurement When Moving from Nominal to Ordinal Scaling

Richard Fiene, Ph.D.

May 2018

The purpose of this paper is to provide an alternate paradigm for regulatory compliance measurement in moving from a nominal to an ordinal scale measurement strategy. Regulatory compliance measurement is dominated by a nominal scale measurement system in which rules are either in compliance or out of compliance. There are no gradients for measurement within the present licensing measurement paradigm. It is very absolute. Either a rule is in full compliance to the letter of the law or the essence of the regulation or it is not. An alternate paradigm borrowing from accreditation and other program quality systems is to establish an ordinal scale measurement system which takes various gradients of compliance into account. With this alternate paradigm, it offers an opportunity to begin to introduce a quality element into the measurement schema. It also allows to take into consideration both risk and prevalence data which are important in rank ordering specific rules.

So how would this look from a licensing decision making vantage point. Presently, in licensing measurement, licensing decisions are made at the rule level in which each rule is either in or out of compliance in the prevailing paradigm. Licensing summaries with corrective actions are generated from the regulatory compliance review. It is a nominal measurement system being based upon Yes/No responses. The alternate measurement paradigm I am suggesting in this paper is one that is more ordinal in nature where we expand the Yes/No response to include gradients of the particular rule. In the next paragraph, I provide an example of a rule that could be measured in moving from a nominal to ordinal scale measurement schema.

Rather than only measuring a rule in an all or none fashion, this alternate paradigm provides a more relative mode of measurement at an ordinal level. For example, with a professional development or training rule in a particular state which requires, let's say, 6 hours of training for each staff person. Rather than having this only be 6 hours in compliance and anything less than this is out of compliance, let's have this rule be on a relative gradient in which any amount of hours above the 6 hours falls into a program quality level and anything less than the 6 hours falls out of compliance but at a more severe level depending on how far below the 6 hours and how many staff do not meet the requirement (prevalence). Also throw in a specific weight which adds in a risk factor and we have a paradigm that is more relative rather than absolute in nature.

From a math modeling perspective, the 1 or 0 format for a Yes or No response becomes -2, -1, 0, +1, +2 format. This is more similar to what is used in accreditation systems where 0 equals Compliance and -1 and -2 equals various levels of Non-Compliance in terms of severity and/or prevalence. The +1 and +2 levels equal value added to the Compliance level by introducing a Quality Indicator. This new formatting builds upon the compliance vs non-compliance dichotomy (C/NC) but now adds a quality indicator (QI) element. By adding this quality element, we may be able to eliminate or at least lessen the non-linear relationship between regulatory compliance with rules and program quality scores as measured by the

Environmental Rating Scales (ERS) and CLASS which is the essence of the Theory of Regulatory Compliance (TRC). It could potentially make this a more linear relationship by not having the data as skewed as it has been in the past.

By employing this alternate paradigm, it is a first demonstration of the use of the Key Indicator Methodology in both licensing and quality domains. The Key Indicator Methodology has been utilized a great deal in licensing but in few instances in the program quality domain. For example, over the past five years, I have worked with approximately 10 states in designing Licensing Key Indicators but only one state with Quality Key Indicators from their QRIS – Quality Rating and Improvement System. This new paradigm would combine the use in both. It also takes advantage of the full ECPQI2M – Early Childhood Program Quality Improvement and Indicator Model by blending regulatory compliance with program quality standards.

A major implication in moving from a nominal to an ordinal regulatory compliance measurement system is that it presents the possibility of combining licensing and quality rating and improvement systems into one system via the Key Indicator Methodology. By having licensing indicators and now quality indicators that could be both measured by licensing inspectors, there would be no need to have two separate systems but rather one that applies to everyone and becomes mandated rather than voluntary. It could help to balance both effectiveness and efficiency by only including those standards and rules that statistically predict regulatory compliance and quality and balancing risk assessment by adding high risk rules.

I will continue to develop this scale measurement paradigm shift in future papers but wanted to get this idea out to the regulatory administration field for consideration and debate. This will be a very controversial proposal since state regulatory agencies have spent a great deal of resources on developing free standing QRIS which build upon licensing systems. This alternate paradigm builds off my Theory of Regulatory Compliance's key element of relative vs absolute measurement and linear vs non-linear relationships. Look for additional information about this on my website RIKI Institute Blog - https://rikinstitute.com/blog/.

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Uniform, Differential, and Integrated Program Monitoring

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May 2024

This technical research paper demonstrates the key similarities and differences amongst uniform, differential, and integrated monitoring. The similarities and differences will be depicted in the following table. The table depicts how each monitoring approach addresses the specific key element presented. Explanations are provided after the summary table. It builds off several other papers* that dealt with regulatory compliance paradigms and the relationship between regulatory compliance and program quality; but this paper deals more specifically with program monitoring systems that are being utilized within the human services.

Program Monitoring System's Key Elements Comparison

Key Element	Uniform	Differential	Integrated
1Risk	Absolute	Relative	Relative
2Rules	Equal	Not equal	Not the focus
3Quality Standards	Not the focus	Not the focus	Focus
4Measurement	Nominal	Nominal	Ordinal
5Approach	Everyone gets same	Based on need	Open ended
6Weights	None	Equal or Relative	Balance
7Philosophy	Do no harm	Do no harm	Do things well
8Data distribution	Linear	Non-linear	Linear
9Risk/Performance	Risk	Risk	Performance
10Scaling	100 or 0	100 or 0	100 - 0
11Function	Gatekeeper	Gatekeeper	Enabler
12Quality	Structural	Structural	Process
13Compliance	Full	Substantial	Full/Substantial

1. Risk is defined in a uniform monitoring system with all rules at an equal risk level. In differential monitoring, risk changes to be more relative in that certain rules are more of a concern than others. In an integrated monitoring system with the influx of quality elements, risk is relative also because of this added dimension.
2. Rules are either created equally, which is the case with uniform monitoring systems, or they are not equal in differential monitoring systems where weights are employed to demonstrate the relative risk of specific rules. In integrated monitoring systems, rules are replaced with standards and specific health and safety rules are not the focus.
3. Quality standards are the focal point of integrated monitoring systems but not so with uniform and differential monitoring systems which emphasize health and safety rules.

4. Measurement at both the uniform and differential monitoring systems levels are nominal in which either a rule is in or out of compliance. Integrated monitoring systems which deal with program quality are generally at an ordinal, Likert level of measurement.
5. The approach of each of the monitoring systems varies from everyone gets-the- same for uniform monitoring systems to based-on-need for differential monitoring systems, and more open ended for integrated monitoring systems where both compliance and quality are equally important.
6. Weights are not an issue with uniform monitoring systems because all rules are dealt with equally and therefore are dealt with as strictly violation data with an equal weight. With differential monitoring systems that is not the case and is the focal point in this approach where weights can be either equally applied with a Likert Scale with an equal interval or relatively applied with the Fibonacci Sequence. Integrated monitoring systems have a more balanced approach dependent upon the balance of compliance and quality.
7. Philosophy for the uniform and differential monitoring systems deals more with rules and "do no harm" while integrated monitoring systems focus on quality and "doing good" or best practices.
8. Data distributions are linear when dealing with uniform and integrated monitoring systems, but differential monitoring systems have clearly demonstrated a non-linear data distribution based upon the theory of regulatory compliance**.
9. Risk/Performance plays out with risk being predominant with uniform and differential monitoring systems but performance being predominant with integrated monitoring systems where quality is central.
10. Scaling is at a nominal level in both uniform and differential monitoring systems where measurement is based upon either being in or out of compliance with rules (100 or 0). Integrated monitoring systems are at an ordinal level where various levels of quality are being assessed (100 – 0).
11. Function of the approach is either as gatekeeper at both the uniform and differential monitoring systems levels and as an enabler at the integrated monitoring systems where it is more of an open system rather than a closed system which is based upon licensing. Open systems are represented by voluntary systems dealing with quality standards.
12. Quality at the uniform and differential monitoring systems is more structural than process-oriented, as with integrated monitoring systems. In legal terms, it is the difference between soft data in the case of process-oriented quality as versus hard data in the case of structural quality.
13. Compliance needs to be fully or 100% compliant in uniform monitoring systems, which is not the case in differential monitoring systems where substantial regulatory compliance is sufficient based upon the results of the theory of regulatory compliance**. With integrated monitoring systems there is more of a balancing act between full and substantial compliance levels.

Hopefully, this clarifies how the various program monitoring systems used within the human services are similar and different. This paper should be read with the other technical research papers dealing with regulatory compliance and program quality paradigms which enhance upon these above stated elements.

References:

***Regulatory Compliance Monitoring Paradigms and the Relationship of Regulatory Compliance/Licensing with Program Quality: A Policy Commentary, Fiene, 2023.** (https://doi.org/10.21423/JRS-V10A239).

****Treatise on Regulatory Compliance, Fiene, 2019. Journal of Regulatory Science https://doi.org/10.21423/jrs-v07fiene**

Could the Fibonacci Sequence be Superior to the Equal Interval Weighting for Risk Assessment?

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Risk assessment (RA) has generally used a 3 x 3 matrix similar to the one depicted in Table 1 below where an equal interval weighting was utilized in describing the nine cells that constituted the 3 x 3 matrix. The matrix considers the risk levels and compares that to the probability of the actual risk occurring, so there were nine possibilities (1 – 9).

Table 1: RA Likert Absolute Equal Interval Weighting

Uniform Risk		**Risk Levels**		
		High	**Medium**	**Low**
Probability of Occurring	**High**	9	6	3
	Medium	8	5	2
	Low	7	4	1

More recently, a proposed change has been suggested to utilize the Fibonacci Sequence in place of the equal interval weighting. There is a great deal of merit in considering this because the Fibonacci Sequence has an interesting effect in introducing a differential risk function rather than a more uniform risk as is the case with equal interval weighting as depicted in table 1. In table 2, it is clear the Fibonacci Sequence has a tremendous impact on the increasing value of the various risk/probability cells within the 3 x 3 matrix. It mirrors the increasing risk, which considers the risk already present in the previous cell and then increases it by the next numeric increase. This increase changes markedly as the risk/probability goes up by a factor of over 10 at the highest risk level. The nine cells range from 1 – 100 rather than 1 - 9.

Table 2: RA Relative Weighting: The Fibonacci Sequence

Differential Risk		**Risk Levels**		
		High	**Medium**	**Low**
Probability of Occurring	**High**	100	13	3
	Medium	40	8	2
	Low	20	5	1

The above sequence is not an exact Fibonacci Sequence and modifies the cell results at the high-risk levels to accentuate this level. A potential proposal is depicted in table 3 in how this could play out with the weighting of rules/regulations related to the health and safety of clients and their relative risk of mortality and/or morbidity because of non-compliance with such rules/regulations either directly or indirectly.

Table 3: RA Relative Weighting: The Fibonacci Sequence Proposal

Differential Risk		**Risk Levels**		
		Direct (Causality)		**Indirect (Correlation)**
		Mortality	**Morbidity**	**Mortality/Morbidity**
		High	Medium	Low
Probability of Occurring	High	100	13	3
	Medium	40	8	2
	Low	20	5	1

This proposal needs to be tested and compared to the more prevalent equal interval weighting approach to see if it is a better predictor in identifying the risk level of rules and regulations when it comes to health and safety.

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Rule Risk Assessment with Independent Likert Equal Interval Weighting and Group Modified Fibonacci Sequential Relative Weighting

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September 2024

Rule risk assessment is a critical component in differential monitoring and ultimately in the identification of key indicator rules. In fact, it is required when substantial regulatory compliance is used in identifying high regulatory compliant groups and is highly recommended even when full regulatory compliance is used for the same purpose. The predominant paradigm used in rule risk assessment has been an equal interval weighting approach via independent surveys. However, more recently, a relative weighting approach has been introduced as an alternative to equal interval weighting which employs a group consensus approach. This research abstract will compare the two approaches and the results from 4 states/provinces that have utilized the two approaches to determine their advantages and disadvantages.

Let's start with why a risk assessment approach was needed with rules. Two major reasons: 1) Based upon the theory of regulatory compliance (Fiene, 2019) it was determined that all rules were not created nor monitored equally. There are certain rules that place clients at increased risk of mortality or morbidity if non-compliance is present. In order to determine which rules placed clients at greater risk, a weighting approach was proposed to assign a specific weight to each rule. 2) There was a need to introduce more variance in the data distribution of regulatory compliance rather than having frequency counts of violation data. Regulatory compliance data are severely skewed with very little variance. The majority of programs are either in full or substantial regulatory compliance. The addition of weights to frequency counts increased the variance in the data distributions.

A 3 x 3 Risk Assessment Matrix (RAM) is used for both equal interval weighting and relative weighting (see Tables 1 and 2). The RAM assesses risk level and the probability of the rule being out of compliance and causing a negative outcome for the client. Both risk level and probability are measured on a 1 - 9 weighted scale when they are combined together in Table 1 for a Likert equal interval weighting; and are measured on a 1 - 100 weighted scale when they are combined together in Table 2 for relative weighting.

Table 1: RAM Likert Equal Interval Weighting Approach

Uniform Risk			Risk Levels	
		High	Medium	Low
Probability of	High	9	6	3
Occurring	Medium	8	5	2
	Low	7	4	1

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Table 2: RAM Relative Weighting Approach Utilizing a Modified Fibonacci Sequence

Differential Risk			Risk Levels	
		High	Medium	Low
Probability of	High	100	13	3
Occurring	Medium	40	8	2
	Low	20	5	1

As one can clearly see, there are dramatically different weights that were assigned based on the matrices in Tables 1 & 2. The two matrix model approaches were tested side by side in four Jurisdictions (states/provinces) to determine their effectiveness. The relative weighting matrix model approach (Table 2) was much more effective at introducing additional variance in rule risk differentiation that is consistent with regulatory compliance theory.

Table 3 below provides the results from the four states/provinces (Jurisdictions 1 - 4) that utilized either a Likert equal interval weighting (Jurisdictions 1-2) or a Modified Fibonacci relative weighting approach (Jurisdictions 3-4). It clearly depicts how the relative weighting is more normally distributed (Jurisdiction 3) or evenly distributed (Jurisdiction 4) than the equal interval weighting approach (Jurisdictions 1 & 2). The results are all presented in the percent of rules that were either high risk rules (weights 7-9 or 20-100), medium risk rules (weights 4-6 or 5-13), or low risk rules (weights 1-3).

Table 3: RAM Results for Equal Interval and Relative Weighting Approaches in Four Jurisdictions - States/Provinces

	Jurisdiction 1	Jurisdiction 2	Jurisdiction 3	Jurisdiction 4
Risk Levels	Equal	Equal	Relative	Relative
High	67%	43%	30%	30%
Medium	27%	30%	40%	34%
Low	8%	27%	30%	35%

There isn't a right or wrong here, just that the results from utilizing equal interval vs relative weighting are different. Having a more normally distributed or evenly distributed risk level from a statistical point of view is positive but having a skewed data distribution where there are more heavily weighted risk rules is positive when one is looking at the risk assessment rules in general. So, I leave this decision about which to use to the regulatory scientists, licensing researchers, and licensing administrators & policy makers. I just wanted to share the results so far in the field.

It will also be necessary to conduct validation studies to determine the impact of both approaches and I am sure this will impact a final decision about which approach to select. It will be interesting to see how risk rules that are more normally distributed or evenly distributed impact the overall regulatory compliance data distribution and the selection thresholds for the high and low regulatory compliance groups which will have an impact on the selection of key indicator rules. Just as weighted risk assessment is much more effective than utilizing frequency count violation data in determining risk level and key indicator rules; it will be interesting to see if relative weighting has the same advantage over equal interval weighting.

Reference:

Fiene, R. (2019). A treatise on theory of regulatory compliance, ***Journal of Regulatory Science, 7, no. 1, 1-3.***
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What is the Relationship between Regulatory Compliance and Complaints in a Human Services Licensing System? RIKIllc Technical Research Note

Richard Fiene, Ph.D.

January 2019

Within licensing measurement and the validation of licensing systems it is particularly difficult to have specific outcome metrics that can be measured within a human services licensing system. The purpose of this technical research note is to propose a potential solution to this problem.

Probably the most accurate measures of licensing outcomes focuses on improvements in the health and safety of clients within human services licensed facilities, such as: fewer injuries (safety) or higher levels of immunizations (health). Another measure related to client satisfaction is the number of complaints reported about a licensed facility by clients and the general public. The advantage of using complaints is that this form of monitoring is generally always part of an overall licensing system. In other words, the state/provincial licensing agency is already collecting these data. It is just a matter of utilizing these data in comparing the number of complaints to overall regulatory compliance.

The author had the opportunity to have access to these data, complaint and regulatory compliance data in a mid-Western state which will be reported within this technical research note. There are few empirical demonstrations of this relationship within the licensing research literature. The following results are based upon a very large sample of family child care homes (N = 2000+) over a full year of licensing reviews.

The results of comparing the number of complaints and the respective regulatory compliance levels proved to show a rather significant relationship ($r = .47$; $p < .0001$). This result is the first step in attempting to understand this relationship as well as developing a methodology and analysis schema since directionality (e.g., did the complaint occur before or after the regulatory compliance data collection?) can play a key role in the relationship (this will be developed more fully in a future technical research note). The focus of this research note was to determine if any relationship existed between regulatory compliance and complaint data and if it is worth pursuing.

It appears that looking more closely at the relationship between complaint and regulatory compliance data is warranted. It may provide another means of validating the fourth level of validation studies as proposed by Zellman and Fiene's OPRE Research Brief (*Zellman, G. L. & Fiene, R. (2012). Validation of Quality Rating and Improvement Systems for Early Care and Education and School-Age Care, Research-to-Policy, Research-to-Practice Brief OPRE 2012-29. Washington, DC: Office of Planning, Research and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services)* in which four approaches to validation are delineated for Quality Rating and Improvement Systems (QRIS). This author has taken this framework and applied it to licensing systems (*Fiene (2014). Validation of Georgia's Core Rule Monitoring System, Georgia Department of Early Care and Learning*) and more recently proposed as the framework for Washington State's Research Agenda (*Stevens & Fiene (2018). Validation of the Washington State's Licensing and Monitoring System, Washington Department of Children, Youth, and Families*).

For additional information regarding the above studies, the interested reader should go to http://RIKInstitute.com.

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Some Technical Considerations in Using Complaint Data and Regulatory Compliance Data: RIKIllc Technical Research Note #66

Richard Fiene, Ph.D.

January 2019

As promised in RIKIllc Technical Research Note #65, this Note will provide details on the methodology and analytical considerations when using complaint and regulatory compliance data together. As pointed out in the previous technical research note, using complaint data as a potential outcome appears to have merit and should be explored in greater detail. However, with that said there are some parameters that the methodology has that should be explored in order to make the analyses more meaningful.

When looking at regulatory compliance and complaint data there are four possibilities: 1) the facility is in full compliance and has no complaints; 2) the facility is in full compliance but has complaint(s); 3) the facility has some non-compliance and has no complaints; and 4) the facility has some non-compliance and has complaint(s). These four possibilities can be depicted in the following 2 x 2 matrix:

Complaints	***Regulatory Compliance Full (0)***	***Regulatory Compliance Non-Compliance (1)***
No (0)	***00 = Full & No Cell C = Expected***	***10 = Non-Compliance & No Cell B = False Positive***
Yes (1)	***01 = Full & Yes Cell A = False Negative***	***11 = Non-Compliance & Yes Cell D = Expected***

In the above 2 x 2 matrix, we would want to see cell C and cell D as the predominant cells and cell A and B as the less dominant cells, especially cell A because this represents a false negative result.

However, there are a couple of limitations to the above matrix that need to be taken into account. One, are the complaints substantiated or not. Any complaint must be substantiated to be counted in the model. If it is unsubstantiated, than it is not counted in the matrix. Two, there is the problem with directionality that needs to be addressed. For example, does the complaint occur before or after the full inspection in order to determine regulatory compliance. The 2 x 2 matrix and the modeling for these analyses is based on the complaint occurring after the full inspection and that is the reason for cell A being labeled a false negative. If the directionality is reversed and the full inspection occurs after a complaint, cell A is no longer a false negative.

Regulatory Compliance, Licensing, and Monitoring Measurement Principles: Rule Compliance Versus Rule Performance

Richard Fiene, Ph.D.

January 2021

The purpose of this short paper is to delineate the parameters of regulatory compliance, licensing and monitoring measurement principles (throughout this paper the term "regulatory compliance" will be used to encompass these principles). Regulatory compliance is very unique when it comes to measuring it because it is very different from other measurement systems and this impacts how one uses various statistical analyses. In this paper, the limitations of the measurement system will be highlighted with potential solutions that have been devised over the past several decades. Hopefully this paper will add to the measurement and statistical analysis licensing research literature. It is meant for those agency staff who are responsible for designing regulatory compliance, licensing and monitoring systems. Its focus is the human services but the basic principles can be applied to any standards-based system that is based upon a compliance or performance model.

The organization of this paper is as follows. First, let's introduce what is included when we talk about measurement principles for regulatory compliance, licensing and monitoring systems. Second, provide examples that should be familiar to most individuals who have been involved in the human services, in particular the early care and education field. Third, what are the limitations of these various systems that have been identified in the research literature. Fourth, what are some potential solutions to these limitations. And, fifth, what are the next steps and where do we go to build reliable and valid measurement systems dealing with regulatory compliance, licensing, and program monitoring as these relate to the human services delivery system.

So, what is included in this approach. I can be any rule, regulation, or standard based measurement system. Generally, these systems are focused on a nominally based system, sometimes they will be ordinally based. By a nominally based system, either the facility being assessed is in compliance with a particular set of rules, regulations, or standards or it is not. In an ordinally based system, a facility may attain a score on a Likert scale, such as 1 through 5 where 1 is non-optimal and 5 is excellent. These types of measurement scales involve a performance component and are not limited to more of a compliance focus as is the case with a nominally based system. These distinctions are important as one will see later in this paper when it comes to the selection of the appropriate statistics to measure data distributions and the subsequent analyses that can be undertaken.

What are examples of these types of systems? For nominally based systems, just about all the licensing systems in the USA, Canada and beyond employ this type of measurement strategy. As has been said in the previous paragraph, either there is compliance or there is not. It is very black or white, there are not shades of gray. For ordinally based systems, these systems are a bit more diverse. Accreditation, Quality Rating and Improvement Systems (QRIS), the new Head Start Grantee Performance Management System (GPMS), the Environmental Rating Scales, and the CLASS are all examples of ordinally based systems based upon a Likert type measurement system. There are many others, but as a research psychologist whose total career (50 years) has been spent in early care and education, this has been the focus of my research.

The limitations of the above systems are numerous and, in some ways, are difficult to find solutions. In the past, these measurement systems have focused more on the descriptive aspects of data distributions rather than attempting to be predictive or inferential. The first major limitation of the data from regulatory compliance systems is the fact that the data distribution is markedly skewed. What does skew data mean? Most data distributions are normally distributed with very few occurrences at the extremes with the majority of the cases in the middle section of the measurement scale. IQ is an example of a normally distributed data distribution. In a skew data distribution, the majority of data are at one end of the data distribution, either at the positive end or the negative end of the distribution. With regulatory compliance data, it is at the positive end with the majority of facilities being in full or 100% compliance with the rules. Very few of the facilities are at the negative end of the distribution.

What is the big deal? The big deal is that statistically we are limited in what we can do with the data analyses because the data are not normally distributed which is an assumption when selecting certain statistical tests. Basically, we need to employ non-parametric statistical analyses to deal with the data. The other real limitation is in the data distribution itself. It is very difficult to distinguish between high and mediocre facilities. It is very easy to distinguish between high and low performing facilities because of the variance between the high performing facilities and the low performing facilities. However, that is not the case between high and mediocre preforming facilities. Since the majority of facilities are either in full or substantial compliance with the rules, they are all co-mingled in a very tight band with little data variance. This makes it very difficult to distinguish differences in the facilities. And this only occurs with regulatory compliance data distributions. As will be pointed later in this paper, this is not the case with the second measurement system to be addressed dealing with ordinal measurement systems.

There is also a confounding factor in the regulatory compliance data distributions which has been termed the theory of regulatory compliance or the law of regulatory compliance diminishing returns. In this theory/law, when regulatory compliance data are compared to program quality data, a non-linear relationship occurs where either the facilities scoring at the substantial compliance level score better than the fully compliant facilities or there is a plateau effect and there is no significant difference between the two groups: substantial or fully compliant facilities when they are measured on a program quality scale. From a public policy stand point, this result really complicates how best to promulgate compliance with rules. This result has been found repeatedly in early care and education programs as well as in other human service delivery systems. It is conjectured that the same result will be found in any regulatory compliance system.

Another limitation of regulatory compliance data is the fact that it is measured at a nominal level. There is no interval scale of measurement and usually not even an ordinal level of measurement. As mentioned above, either a facility is in compliance or not. From a statistical analytical view, again this limits what can be done with the data. In fact, it is probably one of the barriers for researchers who would like to conduct analyses on these data but are concerned about the robustness of the data and their resulting distributions.

Let's turn our attention to potential solutions to the above limitations in dealing with regulatory compliance data.

One potential solution and this is based upon the theory of regulatory compliance in which substantial compliance is the threshold for a facility to be issued a license or certificate of compliance. When this public policy determination is allowed, it opens up a couple of alternate strategies for program monitoring and licensing reviews. Because of the theory of regulatory compliance/law of regulatory compliance diminishing returns, abbreviated or targeted monitoring reviews are possible, differential monitoring or inferential monitoring as it has been documented in the literature. This research literature on differential monitoring has been dominated by two approaches: licensing key indicators and weighted risk assessments.

A second solution to the above limitations deals with how we handle the data distribution. Generally, it is not suggested to dichotomize data distributions. However, when the data distribution is significantly skewed as it is with regulatory compliance, it is an appropriate adjustment to the data. By essentially having two groups, those facilities that are in full compliance and those facilities that are not in full compliance with the rules. In some cases, the fully compliant group can be combined with those facilities that are in substantial compliance but this should only be employed when there are not sufficient fully compliant facilities which is hardly never the case since population data and not sampled data are available from most jurisdictions. When data samples were drawn and the total number of facilities were much smaller, substantial compliant facilities were used as part of the grouping strategy. The problem in including them was that it increased the false negative results. With them not being included, it is possible to decrease and eliminate false negatives. An additional methodological twist is also to eliminate and not use the substantial compliant facilities at all in the subsequent analyses which again helps to accentuate the difference scores between the two groups of highly compliant and low compliant scoring facilities.

The next steps for building valid and reliable regulatory compliance systems are drawing upon what has been learned from more ordinally based measurement systems and applying this measurement structure to regulatory compliance systems. As such, the move would be away from a strict nominally based measurement to more ordinal in which more of a program quality element is built into each rule. By utilizing this paradigm shift, additional variance should be built into the measurement structure. So rather than having a Yes/No result, there would be a gradual Likert type (1-5) scale built in to measure "rule performance" rather than "rule compliance" where a "1" indicates non-compliance or a violation of the specific rule. A "5" would indicate excellent performance as it relates to the specific rule. A "3" would indicate compliance with the specific rule meeting the specifics of the rule but not exceeding it in any way.

This paradigm shift has led to the creation of Quality Rating and Improvement Systems (QRIS) throughout the USA because of a frustration to move licensing systems to more quality focused. The suggestion being made here is to make this movement based upon the very recent developments in designing such systems as is the case with Head Start monitoring. Head Start GPMS is developing an innovative Likert based ordinal system which incorporates compliance and performance into their monitoring system. Other jurisdictions can learn from this development. It is not being suggested as a replacement for QRIS or accreditation or ERS/CLASS assessments but as a more seamless transition from licensing to these various assessments. As indicated by the theory of regulatory compliance and the law of regulatory compliance diminishing returns, this relationship between licensing and program quality is not linear. By having this monitoring system approach in place, it may be able to reintroduce more of a linear relationship between licensing and program quality.

Regulatory Compliance Monitoring Paradigms and the Relationship of Regulatory Compliance/Licensing with Program Quality

Richard Fiene, PhD

May 2022

This paper will deal with two key issues within regulatory science that need to be dealt with by licensing researchers and regulatory scientists: 1) Program monitoring paradigms; 2) Relationship of regulatory compliance/licensing and program quality. The examples drawn are from early care and education but the key elements and implications can be applied to any field of study related to regulatory science that involves rules/regulations/standards. For the purposes of this paper "rules" will be used to describe or refer to "rules/regulations/standards".

Program Monitoring Paradigms:

This section of the paper provides some key elements to two potential regulatory compliance monitoring paradigms (Differential/Relative versus Absolute/Full) for regulatory science based upon the Regulatory Compliance Theory of Diminishing Returns (Fiene, 2019).

As one will see, there is a need within regulatory science to get at the key measurement issues and essence of what is meant by regulatory compliance. There are some general principles that need to be dealt with such as the differences between individual rules and rules in the aggregate. Rules in the aggregate are not equal to the sum of all rules because all rules are not created nor administered equally. And all rules are to be adhered to, but there are certain rules that are more important than others and need to be adhered to all the time. Less important rules can be in substantial compliance most of the time but important rules must be in full compliance all of the time.

Rules are everywhere. They are part of the human services landscape, economics, banking, sports, religion, transportation, housing, etc... Wherever one looks we are governed by rules in one form or another. The key is determining an effective and efficient modality for negotiating the path of least resistance in complying with a given set of rules. It is never about more or less rules, it is about which rules are really productive and which are not. Too many rules stifle creativity, but too few rules lead to chaos. Determining the balance of rules is the goal and solution of any regulatory science paradigm.

Differential/Relative versus Absolute/Full Regulatory Compliance Paradigms: this is an important key organizational element in how standards/rules/regulations are viewed when it comes to compliance. For example, in an absolute/full approach to regulatory compliance either a standard/rule/regulation is in full compliance or not in full compliance. There is no middle ground. It is black or white, no shades of gray as are the cases in a differential/relative paradigm. It is 100% or zero. In defining and viewing these two paradigms, this dichotomy is the organizational key element for this paper. In a differential/relative regulatory compliance paradigm full compliance is not required and emphasis on substantial regulatory compliance becomes the norm.

Based upon this distinction between differential/relative and absolute/full regulatory compliance paradigms, what are some of the implications in utilizing these two respective approaches. Listed below are the basic implications of the two approaches on program monitoring systems listing the differential/relative versus the absolute/full regulatory compliance paradigms.

There are ten basic implications that will be addressed: 1) Substantial versus Monolithic. 2) Differential Monitoring versus One size fits all monitoring. 3) “Not all standards are created equal” versus “All standards are created equal”. 4) “Do things well” versus “Do no harm”. 5) Strength based versus Deficit based. 6) Formative versus Summative. 7) Program Quality versus Program Compliance. 8) 100-0 scoring versus 100 or 0 scoring. 9) QRIS versus Licensing. 10) Non-Linear versus Linear.

First: Substantial versus Monolithic: in monolithic regulatory compliance monitoring systems, it is one size fits all, everyone gets the same type of review (this is addressed in the next key element below) and is more typical of an absolute paradigm orientation. In a substantial regulatory compliance monitoring system, programs are monitored on the basis of their past compliance history and this is more typical of a relative paradigm orientation. Those with high compliance may have fewer and more abbreviated visits/reviews while those with low compliance have more comprehensive visits/reviews.

Second: Differential Monitoring versus One Size Fits All Monitoring: in differential monitoring (Differential/Relative Paradigm), more targeted or focused visits are utilized spending more time and resources with those problem programs and less time and resources with those programs that are exceptional. In the One Size Fits All Monitoring (Absolute/Full Paradigm), all programs get the same type/level of review/visit regardless of past performance.

Third: “Not all standards are created equal” versus “All standards are created equal”: when looking at standards/rules/regulations it is clear that certain ones have more of an impact on outcomes than others. For example, not having a form signed versus having proper supervision of clients demonstrates this difference. It could be argued that supervision is much more important to the health and safety of clients than if a form isn’t signed by a loved one. In a differential/relative paradigm, all standards are not created nor administered equally; while in an absolute/full paradigm of regulatory compliance, the standards are considered created equally and administered equally.

Fourth: “Do things well” versus “Do no harm” (this element is dealt with in the second component to this paper below as well): “doing things well” (Differential/Relative Paradigm) focuses on quality of services rather than “doing no harm” (Absolute/Full Paradigm) which focuses on health and safety. Both are important in any regulatory compliance monitoring system but a balance between the two needs to be found. Erring on one side of the equation or the other is not in the best interest of client outcomes. "Doing no harm" focus is on the "least common denominator" – the design and implementation of a monitoring system from the perspective of focusing on only 5% of the non-optimal programs ("doing no harm") rather than the 95% of the programs that are "doing things well".

Fifth: Strength based versus Deficit based: in a strength-based monitoring system, one looks at the glass as “half full” rather than as “half empty” (deficit-based monitoring system). Emphasis is on what the programs are doing correctly rather than their non-compliance with standards. A strength-based system is non-punitive and is not interested in catching programs not doing well. It is about exemplars, about excellent models where everyone is brought up to a new higher level of quality care.

Sixth: Formative versus Summative: differential/relative regulatory compliance monitoring systems are formative in nature where there is an emphasis on constant quality improvement and getting better. In absolute/full regulatory compliance monitoring systems, the emphasis is on being the gate-keeper (more about the gate-keeper function in the next section on regulatory compliance/licensing and program quality) and making sure that decisions can be made to either grant or deny a license to operate. It is about keeping non-optimal programs from operating.

Seventh: Program Quality versus Program Compliance: (this element is dealt with in greater detail in the second component of this paper) differential/relative regulatory compliance monitoring systems focus is on program quality and quality improvement while in absolute/full regulatory compliance monitoring systems the focus in on program compliance with rules/regulations with the emphasis on full, 100% compliance.

Eight: 100 – 0 scoring versus 100 or 0 scoring: in a differential/relative regulatory compliance monitoring system, a 100 through zero (0) scoring can be used where there are gradients in the scoring, such as partial compliance scores. In an absolute/full regulatory compliance monitoring system, a 100% or zero (0) scoring is used demonstrating that either the standard/rule/regulation is fully complied with or not complied with at all (the differences between nominal and ordinal measurement is dealt with in the next section on regulatory compliance/licensing and program quality).

Ninth: QRIS versus Licensing: examples of a differential/relative regulatory compliance monitoring system would be QRIS – Quality Rating and Improvement Systems. Absolute/full regulatory compliance systems would be state licensing systems. Many programs talk about the punitive aspects of the present human services licensing and monitoring system and its lack of focus on the program quality aspects in local programs. One should not be surprised by this because in any regulatory compliance system the focus is on "doing no harm" rather than "doing things well". It has been and continues to be the focus of licensing and regulations in the USA. The reason QRIS - Quality Rating and Improvement Systems developed in early care and education was to focus more on "doing things well" rather than "doing no harm".

Tenth: Non-Linear versus Linear: the assumption in both differential/relative and absolute/full regulatory compliance monitoring systems is that the data are linear in nature which means that as compliance with standards/rules/regulations increases, positive outcomes for clients increases as well. The problem is the empirical data does not support this conclusion. It appears from the data that the relationship is more non-linear where there is a plateau effect with regulatory compliance in which client outcomes increase until substantial compliance is reached but doesn't continue to increase beyond this level. There appears to be a "sweet spot" or balancing of key standards/rules/regulations that predict client outcomes more effectively than 100% or full compliance with all standards/rules/regulations – this is the essence of the Theory of Regulatory Compliance – substantial compliance with all standards or full compliance with a select group of standards that predict overall substantial compliance and/or positive client outcomes.

As the regulatory administration field continues to think about the appropriate monitoring systems to be designed and implemented, the above structure should help in thinking through what these systems' key elements should be. Both paradigms are important, in particular contexts, but a proper balance between the two is probably the best approach in designing regulatory compliance monitoring systems.

Regulatory Compliance/Licensing and Quality

This part of the paper will delineate the differences between regulatory compliance and quality. It will provide the essential principles and elements that clearly demonstrate the differences and their potential impact on program monitoring. Obviously, there is some overlap between this section and the above section dealing with regulatory compliance monitoring paradigms. When we think about regulatory compliance, we are discussing licensing systems. When we think about quality, we are discussing Quality Rating and Improvement Systems (QRIS), accreditation, professional development, or one of the myriad quality assessment tools, such as the Classroom Assessment Scoring System (CLASS) or Environment Rating Scales (ERS's). All these systems have been designed to help improve the health and safety of programs (licensing) to building more environmental quality (ERS), positive interactions amongst teachers and children (CLASS), enhancing quality standards (QRIS, accreditation), or enhancing teacher skills (professional development).

There are eight basic principles or elements to be presented (they are presented in a binary fashion demonstrating differences): 1) "Do no harm" versus "Do good". 2) Closed system versus Open system. 3) Standards/Rules versus Indicators. 4) Nominal versus Ordinal measurement. 5) Full versus Partial compliance. 6) Ceiling effect versus No Ceiling effect. 7) Gatekeeper versus Enabler. 8) Risk versus Performance.

First: Let's start with the first principal element building off what was discussed in the above section, "Do No Harm" versus "Do Good". In licensing, the philosophy is to do no harm, its emphasis is on prevention, to reduce risk to children in a particular setting. There is a good deal of emphasis on health and safety and not so much on developmentally appropriate programming. In the quality systems, such as QRIS, accreditation, professional development, Environmental Rating Scales, CLASS, the philosophy is to do good, its emphasis is looking at all the positive aspects of a setting. There is a good deal of emphasis on improving the programming that the children are exposed to or increasing the skill set of teachers, or improving the overall environment or interaction that children are exposed to.

Second: Closed system versus Open system. Licensing is basically a closed system. It has an upper limit with full compliance (100%) with all standards/rules/regulations. The goal is to have all programs fully comply with all rules. However, the value of this assumption has been challenged over the years with the introduction of the Regulatory Compliance Theory of Diminishing Returns. With quality systems, they have a tendency to be more open and far reaching where attaining a perfect score is very difficult to come by. The majority of programs are more normally distributed where with licensing rules the majority of programs are skewed positively in either substantial or full compliance. It is far more difficult to distinguish between the really best programs and the mediocre programs within licensing but more successful in quality systems.

Third: Standards/Rules/Regulations versus Indicators/Best Practices. Licensing systems are based around specific standards/rules/regulations that either are in compliance or out of compliance. It is either a program is in compliance or out of compliance with the specific rule. With quality systems, there is more emphasis on indicators or best practices that are measured a bit more broadly and deal more with process than structure which is the case with licensing. It is the difference between hard and soft data as many legal counsels term it. There is greater flexibility in quality systems.

Fourth: Nominal versus Ordinal measurement. Licensing systems are nominally based measurement systems. Either you are in compliance or out of compliance. Nothing in-between. It is either a yes or no response for each rule. No maybe or partial compliance. With quality systems, they are generally measured on an ordinal level or a Likert scale. They may run from 1 to 3, or 1 to 5, or 1 to 7. There is more chances for variability in the data than in licensing which has 1 or 0 response. This increases the robustness of the data distribution with ordinal measurement.

Fifth: Full or None versus Gradients or Gray Area. Building off of the fourth element, licensing scoring is either full or not. As suggested in the above elements, there is no in-between category, no gradient or gray area. This is definitely not the case with quality systems in which there are gradients and substantial gray areas. Each best practice can be measured on a Likert scale with subtle gradients in improving the overall practice.

Sixth: Ceiling effect versus No Ceiling. With licensing there is definitely a ceiling effect because of the emphasis on full 100% compliance with all rules. That is the goal of a licensing program, to have full compliance. With quality systems, it is more open ended in which the sky is not a limit. Programs have many ways to attain excellence.

Seventh: Gatekeeper versus Enabler: Licensing has always been called a gatekeeper system. It is the entry way to providing care, to providing services. It is a mandatory system in which all programs need to be licensed to operate. In Quality systems, these are voluntary systems. A program chooses to participate, there is no mandate to participate. It is more enabling for programs building upon successes. There are enhancements in many cases.

Eight: Risk versus Performance: Licensing systems are based upon mitigating or reducing risks to children when in out of home care. Quality systems are based upon performance and excellence where this is rewarded in their particular scoring by the addition of a new Star level or a Digital Badge or an Accreditation Certificate.

There has been a great deal of discussion in the early care and education field about the relationship between licensing, accreditation, QRIS, professional development, and technical assistance. It is important as we continue this discussion to pay attention to the key elements and principles in how licensing and these quality systems are the same and different in their emphases and goals, and about the implications of particular program monitoring paradigms. For other regulatory systems, the same model can be applied positioning compliance and quality as a continuum one building off of the other.

<u>Reference:</u>

Fiene, R. (2019). A treatise on Regulatory Compliance. *Journal of Regulatory Science*, Volume 7, 2019. https://doi.org/10.21423/jrs-v07fiene

Regulatory Compliance (RC) and Program Quality (PQ) Data Distributions

Richard Fiene, Ph.D.

July 2019

This report will provide the data distributions for a series of regulatory compliance (RC) and program quality (PQ) studies which show dramatically different frequencies and centralized statistics. The regulatory compliance data distributions have some very important limitations that will be noted as well as some potential adjustments that can be made to the data sets to make statistical analyses more meaningful. These data distributions are from the USA and Canada.

For purposes of reading the following Table 1, a Legend is provided:
Data Set = the study that the data are drawn from.
Sites = the number of sites in the particular study.
mean = the average of the scores.
sd = standard deviation.
p0 = the average score at the 0 percentile.
p25 = the average score at the 25th percentile.
p50 = the average score at the 50th percentile or the median.
p75 = the average score at the 75th percentile.
p100 = the average score at the 100th percentile.

Table 1

Data Set	Sites	mean	sd	p0	p25	p50	p75	p100	PQ or RC
ECERS total score	209	4.24	0.94	1.86	3.52	4.27	4.98	6.29	PQ
FDCRS total score	163	3.97	0.86	1.71	3.36	4.03	4.62	5.54	PQ
ECERS and FDCRS totals	372	4.12	0.91	1.71	3.43	4.12	4.79	6.29	PQ
ECERS prek	48	4.15	0.74	2.56	3.6	4.15	4.65	5.56	PQ
ECERS preschool	102	3.42	0.86	1.86	2.82	3.26	4.02	5.97	PQ
ITERS	91	2.72	1.14	1.27	1.87	2.34	3.19	5.97	PQ
FDCRS	146	2.49	0.8	1.21	1.87	2.42	2.93	4.58	PQ
CCC RC	104	5.51	5.26	0	2	4	8	25	RC
FCC RC	147	5.85	5.71	0	2	4	8.5	33	RC
CCC RC	482	7.44	6.78	0	2	6	11	38	RC
FDC RC	500	3.52	4.05	0	0	2	5	34	RC
CI Total Violations	422	3.33	3.77	0	1	2	5	24	RC – PQ
CLASS ES	384	5.89	0.36	4.38	5.69	5.91	6.12	6.91	PQ
CLASS CO	384	5.45	0.49	3.07	5.18	5.48	5.77	6.56	PQ
CLASS IS	384	2.98	0.7	1.12	2.5	2.95	3.37	5.74	PQ
CLASS TOTAL OF THREE SCALES	384	14.33	1.32	8.87	13.52	14.33	15.11	17.99	PQ
ECERS Average	362	4.52	1.05	1.49	3.95	4.58	5.25	7	PQ
FDCRS Average	207	4.5	1	1.86	3.83	4.66	5.31	6.71	PQ
CCC RC	585	5.3	5.33	0	2	4	8	51	RC

QRIS	585	2.78	1.24	0	2	3	4	4	PQ
FDC RC	2486	2.27	3.42	0	0	1	3	34	RC
FDC PQ	2486	1.35	1.26	0	0	1	2	4	PQ
CCC RC	199	7.77	8.62	0	3	6	10	61	RC
CCC RC	199	6.69	10.32	0	1	4	8	98	RC
CCC RC	199	6.77	7.91	0	1.5	4	8.5	57	RC
QRIS	199	1.06	1.32	0	0	1	2	4	PQ
CCC RC	199	7.08	6.96	0	2.33	5.67	9.84	52	RC
QRIS	381	2.55	0.93	0	2	3	3	4	PQ
CCC RC	1399	1.13	2.1	0	0	0	1	20	RC
CCC RC	153	5.28	5.97	0	1	3	6	32	RC
FDC RC	82	3.52	4.36	0	0	2	4	21	RC

It is obvious when one observes the PQ as versus the RC data distributions that the RC data distributions are much more skewed, medians and means are significantly different, and kurtosis values are much higher which means that the data contain several outliers. These data distributions are provided for researchers who may be assessing regulatory compliance (RC) data for the first time. There are certain limitations of these data which are not present in more parametric data distributions which are more characteristic of program quality (PQ) data.

To deal with the level of skewness of RC data, weighted risk assessments have been suggested in order to introduce additional variance into the data distributions. Also, dichotomization of data has been used successfully with very skewed data distributions as well. One of the problems with very skewed data distributions is that it is very difficult to distinguish between high performing providers and mediocre preforming providers. Skewed data distributions provide no limitations in distinguishing low preforming providers from their more successful providers.

Regulatory Compliance and Quality: How are They Different?

Richard Fiene, Ph.D.

June 2021

This technical research note will delineate the differences between regulatory compliance and quality. It will provide the essential principles and elements that clearly demonstrate the differences and their potential impact on program monitoring.

When we think about regulatory compliance, we are discussing licensing systems. When we think about quality, we are discussing Quality Rating and Improvement Systems (QRIS), accreditation, professional development, or one of the myriad quality assessment tools, such as the CLASS or ERS's. All these systems have been designed to help improve the health and safety of programs (licensing) to building more environmental quality (ERS), positive interactions amongst teachers and children (CLASS), enhancing quality standards (QRIS, accreditation), or enhancing teacher skills (professional development).

There are eight basic principles or elements to be presented (they are presented in a binary fashion demonstrating differences):

1) Do no harm versus Do good.

2) Closed system versus Open system.

3) Standards/Rules versus Indicators.

4) Nominal versus Ordinal measurement.

5) Full versus Partial compliance.

6) Ceiling effect versus No Ceiling effect.

7) Gatekeeper versus Enabler.

8) Risk versus Performance.

First: Let's start with the first principal element, Do No Harm versus Do Good. In licensing, the philosophy is to do no harm, its emphasis is on prevention, to reduce risk to children in a particular setting. There is a good deal of emphasis on health and safety and not so much on developmentally appropriate programming.

In the quality systems, such as QRIS, accreditation, professional development, ERS, CLASS, the philosophy is to do good, its emphasis is looking at all the positive aspects of a setting. There is a good deal of emphasis on improving the programming that the children are exposed to or increasing the skill set of teachers, or improving the overall environment or interaction that children are exposed to.

Second: Closed system versus Open system. Licensing is basically a closed system. It has an upper limit with full compliance (100%) with all standards/rules/regulations. The goal is to have all programs fully comply with all rules. However, the value of this assumption has been challenged over the years with the introduction of the Regulatory Compliance Theory of Diminishing Returns.

With quality systems, they have a tendency to be more open and far reaching where attaining a perfect score is very difficult to come by. The majority of programs are more normally distributed where with licensing rules the majority of programs are skewed positively in either substantial or full compliance. It is far more difficult to distinguish between the really best programs and the mediocre programs within licensing but more successful in quality systems.

Third: Standards/Rules/Regulations versus Indicators/Best Practices. Licensing systems are based around specific standards/rules/regulations that either are in compliance or out of compliance. It is either a program is in compliance or out of compliance with the specific rule.

With quality systems, there is more emphasis on indicators or best practices that are measured a bit more broadly and deal more with process than structure which is the case with licensing. It is the difference between hard and soft data as many legal counsels term it. There is greater flexibility in quality systems.

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Seventh: Gatekeeper versus Enabler: Licensing has always been called a gatekeeper system. It is the entry way to providing care, to providing services. It is a mandatory system in which all programs need to be licensed to operate.

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Eight: Risk versus Performance: Licensing systems are based upon mitigating or reducing risks to children when in out of home care.

Quality systems are based upon performance and excellence where this is rewarded in their particular scoring by the addition of a new Star level or a Digital Badge or an Accreditation Certificate.

There has been a great deal of discussion in the early care and education field about the relationship between licensing, accreditation, QRIS, professional development, and technical assistance. It is important as we continue this discussion to pay attention to the key elements and principles in how licensing and these quality systems are the same and different in their emphases and goals.

Regulatory Compliance, Licensing, and Monitoring Measurement Principles: Rule Compliance Versus Rule Performance

Richard Fiene, Ph.D.

January 2021

The purpose of this short paper is to delineate the parameters of regulatory compliance, licensing and monitoring measurement principles (throughout this paper the term "regulatory compliance" will be used to encompass these principles). Regulatory compliance is very unique when it comes to measuring it because it is very different from other measurement systems and this impacts how one uses various statistical analyses. In this paper, the limitations of the measurement system will be highlighted with potential solutions that have been devised over the past several decades. Hopefully this paper will add to the measurement and statistical analysis licensing research literature. It is meant for those agency staff who are responsible for designing regulatory compliance, licensing and monitoring systems. Its focus is the human services but the basic principles can be applied to any standards-based system that is based upon a compliance or performance model.

The organization of this paper is as follows. First, let's introduce what is included when we talk about measurement principles for regulatory compliance, licensing and monitoring systems. Second, provide examples that should be familiar to most individuals who have been involved in the human services, in particular the early care and education field. Third, what are the limitations of these various systems that have been identified in the research literature. Fourth, what are some potential solutions to these limitations. And, fifth, what are the next steps and where do we go to build reliable and valid measurement systems dealing with regulatory compliance, licensing, and program monitoring as these relate to the human services delivery system.

So, what is included in this approach. I can be any rule, regulation, or standard based measurement system. Generally, these systems are focused on a nominally based system, sometimes they will be ordinally based. By a nominally based system, either the facility being assessed is in compliance with a particular set of rules, regulations, or standards or it is not. In an ordinally based system, a facility may attain a score on a Likert scale, such as 1 through 5 where 1 is non-optimal and 5 is excellent. These types of measurement scales involve a performance component and are not limited to more of a compliance focus as is the case with a nominally based system. These distinctions are important as one will see later in this paper when it comes to the selection of the appropriate statistics to measure data distributions and the subsequent analyses that can be undertaken.

What are examples of these types of systems? For nominally based systems, just about all the licensing systems in the USA, Canada and beyond employ this type of measurement strategy. As has been said in the previous paragraph, either there is compliance or there is not. It is very black or white, there are not shades of gray. For ordinally based systems, these systems are a bit more diverse. Accreditation, Quality Rating and Improvement Systems (QRIS), the new Head Start Grantee Performance Management System (GPMS), the Environmental Rating Scales, and the CLASS are all examples of ordinally based systems based upon a Likert type measurement system. There are many others, but as

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a research psychologist whose total career (50 years) has been spent in early care and education, this has been the focus of my research.

The limitations of the above systems are numerous and, in some ways, are difficult to find solutions. In the past, these measurement systems have focused more on the descriptive aspects of data distributions rather than attempting to be predictive or inferential. The first major limitation of the data from regulatory compliance systems is the fact that the data distribution is markedly skewed. What does skew data mean? Most data distributions are normally distributed with very few occurrences at the extremes with the majority of the cases in the middle section of the measurement scale. IQ is an example of a normally distributed data distribution. In a skew data distribution, the majority of data are at one end of the data distribution, either at the positive end or the negative end of the distribution. With regulatory compliance data, it is at the positive end with the majority of facilities being in full or 100% compliance with the rules. Very few of the facilities are at the negative end of the distribution.

What is the big deal? The big deal is that statistically we are limited in what we can do with the data analyses because the data are not normally distributed which is an assumption when selecting certain statistical tests. Basically, we need to employ non-parametric statistical analyses to deal with the data. The other real limitation is in the data distribution itself. It is very difficult to distinguish between high and mediocre facilities. It is very easy to distinguish between high and low performing facilities because of the variance between the high performing facilities and the low performing facilities. However, that is not the case between high and mediocre preforming facilities. Since the majority of facilities are either in full or substantial compliance with the rules, they are all co-mingled in a very tight band with little data variance. This makes it very difficult to distinguish differences in the facilities. And this only occurs with regulatory compliance data distributions. As will be pointed later in this paper, this is not the case with the second measurement system to be addressed dealing with ordinal measurement systems.

There is also a confounding factor in the regulatory compliance data distributions which has been termed the theory of regulatory compliance or the law of regulatory compliance diminishing returns. In this theory/law, when regulatory compliance data are compared to program quality data, a non-linear relationship occurs where either the facilities scoring at the substantial compliance level score better than the fully compliant facilities or there is a plateau effect and there is no significant difference between the two groups: substantial or fully compliant facilities when they are measured on a program quality scale. From a public policy stand point, this result really complicates how best to promulgate compliance with rules. This result has been found repeatedly in early care and education programs as well as in other human service delivery systems. It is conjectured that the same result will be found in any regulatory compliance system.

Another limitation of regulatory compliance data is the fact that it is measured at a nominal level. There is no interval scale of measurement and usually not even an ordinal level of measurement. As mentioned above, either a facility is in compliance or not. From a statistical analytical view, again this limits what can be done with the data. In fact, it is probably one of the barriers for researchers who would like to conduct analyses on these data but are concerned about the robustness of the data and their resulting distributions.

Let's turn our attention to potential solutions to the above limitations in dealing with regulatory compliance data.

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One potential solution and this is based upon the theory of regulatory compliance in which substantial compliance is the threshold for a facility to be issued a license or certificate of compliance. When this public policy determination is allowed, it opens up a couple of alternate strategies for program monitoring and licensing reviews. Because of the theory of regulatory compliance/law of regulatory compliance diminishing returns, abbreviated or targeted monitoring reviews are possible, differential monitoring or inferential monitoring as it has been documented in the literature. This research literature on differential monitoring has been dominated by two approaches: licensing key indicators and weighted risk assessments.

A second solution to the above limitations deals with how we handle the data distribution. Generally, it is not suggested to dichotomize data distributions. However, when the data distribution is significantly skewed as it is with regulatory compliance, it is an appropriate adjustment to the data. By essentially having two groups, those facilities that are in full compliance and those facilities that are not in full compliance with the rules. In some cases, the fully compliant group can be combined with those facilities that are in substantial compliance but this should only be employed when there are not sufficient fully compliant facilities which is hardly never the case since population data and not sampled data are available from most jurisdictions. When data samples were drawn and the total number of facilities were much smaller, substantial compliant facilities were used as part of the grouping strategy. The problem in including them was that it increased the false negative results. With them not being included, it is possible to decrease and eliminate false negatives. An additional methodological twist is also to eliminate and not use the substantial compliant facilities at all in the subsequent analyses which again helps to accentuate the difference scores between the two groups of highly compliant and low compliant scoring facilities.

The next steps for building valid and reliable regulatory compliance systems are drawing upon what has been learned from more ordinally based measurement systems and applying this measurement structure to regulatory compliance systems. As such, the move would be away from a strict nominally based measurement to more ordinal in which more of a program quality element is built into each rule. By utilizing this paradigm shift, additional variance should be built into the measurement structure. So rather than having a Yes/No result, there would be a gradual Likert type (1-5) scale built in to measure "rule performance" rather than "rule compliance" where a "1" indicates non-compliance or a violation of the specific rule. A "5" would indicate excellent performance as it relates to the specific rule. A "3" would indicate compliance with the specific rule meeting the specifics of the rule but not exceeding it in any way.

This paradigm shift has led to the creation of Quality Rating and Improvement Systems (QRIS) throughout the USA because of a frustration to move licensing systems to more quality focused. The suggestion being made here is to make this movement based upon the very recent developments in designing such systems as is the case with Head Start monitoring. Head Start GPMS is developing an innovative Likert based ordinal system which incorporates compliance and performance into their monitoring system. Other jurisdictions can learn from this development. It is not being suggested as a replacement for QRIS or accreditation or ERS/CLASS assessments but as a more seamless transition from licensing to these various assessments. As indicated by the theory of regulatory compliance and the law of regulatory compliance diminishing returns, this relationship between licensing and program quality is not linear. By having this monitoring system approach in place, it may be able to reintroduce more of a linear relationship between licensing and program quality.

Regulatory Compliance Scale, Key Indicators, Risk Assessment, Differential Monitoring, and Program Quality

Richard Fiene PhD

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May 2025

This research abstract will expand the Regulatory Compliance Scale (RCS) conceptually to demonstrate how it relates to the key indicator and risk assessment methodologies as well as the infusion of program quality into rule development (Fiene, 2025a). The RCS has been pilot tested and demonstrated to be a viable alternative for measuring regulatory compliance with rules/regulations in the human services (Fiene, 2023, 2025b). The RCS moves regulatory compliance from a nominal based measurement strategy to an ordinal based measurement strategy. This change helps to enhance its statistical modeling capabilities which will mirror how more program quality systems operate: accreditation systems, such as the National Association for the Education of Young Children (NAEYC, 2025) and other program quality scales: the Environmental Rating Scales (Harms, Clifford, & Cryer , 2023). It also aligns more closely with the theory of regulatory compliance (Fiene, 2019, 2022) in which a quality infusion component has been added to rule development and implementation.

To depict this relationship of regulatory compliance, key indicators, risk assessment, and program quality, the below table (Table 1: Regulatory Compliance Scale Plus) does a side-by-side comparison of these components. The first column shows how key indicators would play out at both the licensing and quality levels. The second column presents the regulatory compliance scale and shows how the infusion of quality builds upon full regulatory compliance. The third column shows how risk assessment interfaces with the regulatory compliance scale in which low risk rules (weights = 1-3) would be generally at a substantial compliance level with medium risk rules (weights = 4-6) being at a partial compliance level and lastly high-risk rules (weights = 7-9) being at a low compliance level. The fourth column suggests when differential monitoring (DM), in which targeted or abbreviated inspections are utilized focusing on key risk indicator rules, can be used in place of a comprehensive review (CR) when all rules are assessed. In studies (Fiene, 2025c), it has been demonstrated that key indicator rules predict either full or substantial compliance with all rules and are generally of a low overall risk; while risk assessment rules, especially those determined to be high risk rules, are usually always in compliance.

Recently, the Regulatory Compliance Scale and the risk assessment methodology have been combined with the Uncertainty-Certainty Matrix (UCM) in making licensing decisions (Fiene, 2025d). This combinatory effort has resulted in a more robust measurement strategy that helps to support moving from a nominal to ordinal measurement strategy. The UCM is used in determining the accuracy of each rule’s regulatory compliance which enhances the reliability of the Regulatory Compliance Scale (RCSplus).

The purpose of this research abstract is to demonstrate the interface amongst the various methodologies (key indicators and risk assessment) utilized within a differential monitoring approach in making licensing decisions (Fiene, 2025a), as well as showing how the key indicator methodology can be used for both licensing as well as quality indicator development (Fiene, 2022, 2023).

Table 1: Regulatory Compliance Scale Plus (RCSplus)

Key Indicators	Regulatory Compliance Scale	Risk Assessment	Differential Monitoring
Quality Indicators	7+ = Exceeds Compliance		Yes
Licensing Indicators	7 = Full Compliance		Yes
Licensing Indicators	5 = Substantial Compliance	Low Risk (1-3)	Yes
	3 = Partial Compliance	Medium Risk (4-6)	No
	1 = Low Compliance	High Risk (7-9)	No

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Development of a Regulatory Compliance Scale

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April 2025

The purpose of this paper is to provide an alternate paradigm for regulatory compliance measurement in moving from a nominal to an ordinal scale measurement strategy and to introduce a new licensing/regulatory compliance metric: the Regulatory Compliance Scale. Regulatory compliance measurement is dominated by a nominal scale measurement system in which rules are either in compliance or out of compliance. There are no gradients for measurement within the present licensing measurement paradigm. It is very absolute. Either a rule is in full compliance to the letter of the law or the essence of the regulation or it is not. An alternate paradigm borrowing from accreditation and other program quality systems is to establish an ordinal scale measurement system which takes various gradients of compliance into account. With this alternate paradigm, it offers an opportunity to begin to introduce a quality element into the measurement schema. It also allows us to take into consideration both risk and prevalence data which are important in rank ordering specific rules.

So how would this look from a licensing decision making vantage point. Presently, in licensing measurement, licensing decisions are made at the rule level in which each rule is either in or out of compliance in the prevailing paradigm. Licensing summaries with corrective actions are generated from the regulatory compliance review. It is a nominal measurement system being based upon Yes/No responses. The alternate measurement paradigm I am suggesting in this paper is one that is more ordinal in nature where we expand the Yes/No response to include gradients of the particular rule. In the next paragraph, I provide an example of a rule that could be measured in moving from a nominal to ordinal scale measurement schema.

Rather than only measuring a rule in an all or none fashion, this alternate paradigm provides a more relative mode of measurement at an ordinal level. For example, with a professional development or training rule in a particular state which requires, let's say, 6 hours of training for each staff person. Rather than having this only be 6 hours in compliance and anything less than this is out of compliance, let's have this rule be on a relative gradient in which any amount of hours above the 6 hours falls into a program quality level and anything less than the 6 hours falls out of compliance but at a more severe level depending on how far below the 6 hours and how many staff do not meet the requirement (prevalence). Also throw in a specific weight which adds in a risk factor, and we have a paradigm that is more relative rather than absolute in nature.

From a math modeling perspective, the 1 or 0 format for a Yes or No response becomes -2, -1, 0, +1, +2 format. This is more similar to what is used in accreditation systems where 0 equals Compliance and -1 and -2 equals various levels of Non-Compliance in terms of severity and/or prevalence. The +1 and +2 levels equal value added to the Compliance level by introducing a Quality Indicator. This new formatting builds upon the compliance vs non-compliance dichotomy (C/NC) but now adds a quality indicator (QI) element. By adding this quality element, we may be able to eliminate or at least lessen the non-linear relationship between regulatory compliance with rules and program quality scores as measured by the Environmental Rating Scales (ERS) and CLASS which is the essence of the Theory of Regulatory Compliance (TRC). It could potentially make this a more linear relationship by not having the data as skewed as it has been in the past.

By employing this alternate paradigm, it is a first demonstration of the use of the Key Indicator Methodology in both licensing and quality domains. The Key Indicator Methodology has been utilized a great deal in licensing but in few instances in the program quality domain. For example, over the past five years, I have worked with approximately 10 states in designing Licensing Key Indicators but only one state with Quality Key Indicators from their QRIS – Quality Rating and Improvement System. This new paradigm would combine the use in both. It also takes advantage of the full ECPQI2M – Early Childhood Program Quality Improvement and Indicator Model by blending regulatory compliance with program quality standards.

A major implication in moving from a nominal to an ordinal regulatory compliance measurement system is that it presents the possibility of combining licensing and quality rating and improvement systems into one system via the Key Indicator Methodology. By having licensing indicators and now quality indicators that could both be measured by licensing inspectors, there would be no need to have two separate systems but rather one that applies to everyone and becomes mandated rather than voluntary. It could help to balance both effectiveness and efficiency by only including those standards and rules that statistically predict regulatory compliance and quality and balancing risk assessment by adding high risk rules.

I will continue to develop this scale measurement paradigm shift in future papers but wanted to get this idea out to the regulatory administration field for consideration and debate. This will be a very controversial proposal since state regulatory agencies have spent a great deal of resources on developing free standing QRIS which build upon licensing systems. This alternate paradigm builds off the Theory of Regulatory Compliance's key element of relative vs absolute measurement and linear vs non-linear relationships (Fiene, 2022). Look for additional information about this on RIKI Institute Blog - https://rikinstitute.com/blog/.

Introduction to the Regulatory Compliance Scale

The theory of regulatory compliance has been proven in multiple studies over the past four decades and has been utilized extensively in the creation of differential monitoring and its spin off methodologies of risk assessment and key indicators (Fiene, 2025). In fact, differential monitoring would not have been possible without the theory of regulatory compliance because the paradigm which it replaced, one of one-size-fits-all monitoring or uniform monitoring would have predominated. However, with the theory of regulatory compliance which introduced the importance of substantial regulatory compliance and the search for the right rules/regulations that made a difference in client's lives, rather than emphasizing more or less regulations or rules.

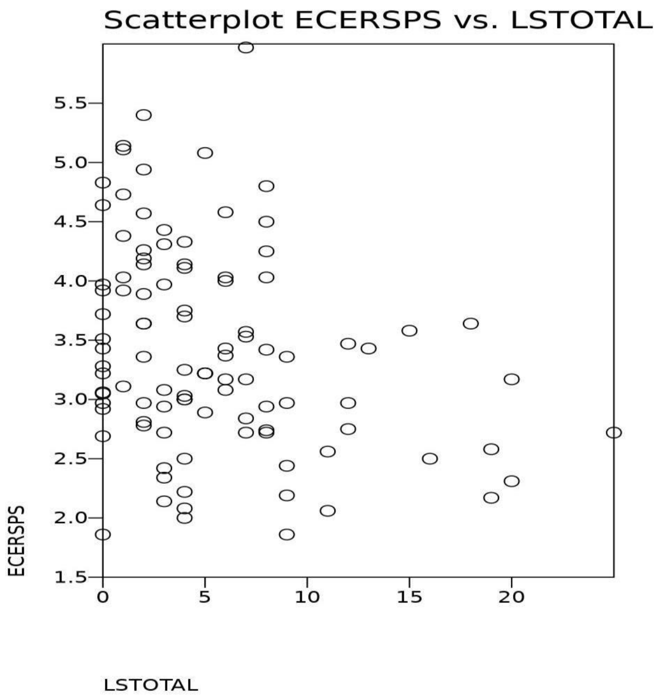
The theory of regulatory compliance has another application when it comes to regulatory compliance measurement in helping to move the licensing field from a nominal based measurement strategy to one of ordinal based measurement. The new measurement strategy is the Regulatory Compliance Scale (RCS) and it is depicted in the following table.

RCS	***Compliance***	***Risk***	***Model***	***Model***
Scale	***Level***	***Level***	***Violations***	***Weights***
7 = A	**Full**	**None**	**0**	**0**
5 = B	**Substantial**	**Low**	**1-3**	**1-3**
3 = C	**Medium**	**Medium**	**4-9**	**4-6**
1 = D	**Low**	**High**	**10+**	**7+**

The above table needs some explanation. The first column is the proposed ordinal scale similar to other scales utilized in the program quality measurement research literature on a 1 – 7 Likert Scale where 7 = Full Regulatory Compliance, 5 = Substantial Regulatory Compliance, 3 = Medium Regulatory Compliance, and 1 = Low Regulatory Compliance. It could also be thought of as an Alpha Scale of A – D as well. The next column has the compliance levels that run from full 100% regulatory compliance to low regulatory compliance. The third column depicts the risk level from none to high which corresponds with the compliance levels. The next two columns depict two models, one unweighted and one in which the rules are weighted with corresponding weights. These models are based upon the two prevailing approaches to rank ordering rules or regulations in the research literature.

The following figures will depict how the scale was conceived based upon empirical evidence in the various studies supporting the theory of regulatory compliance.

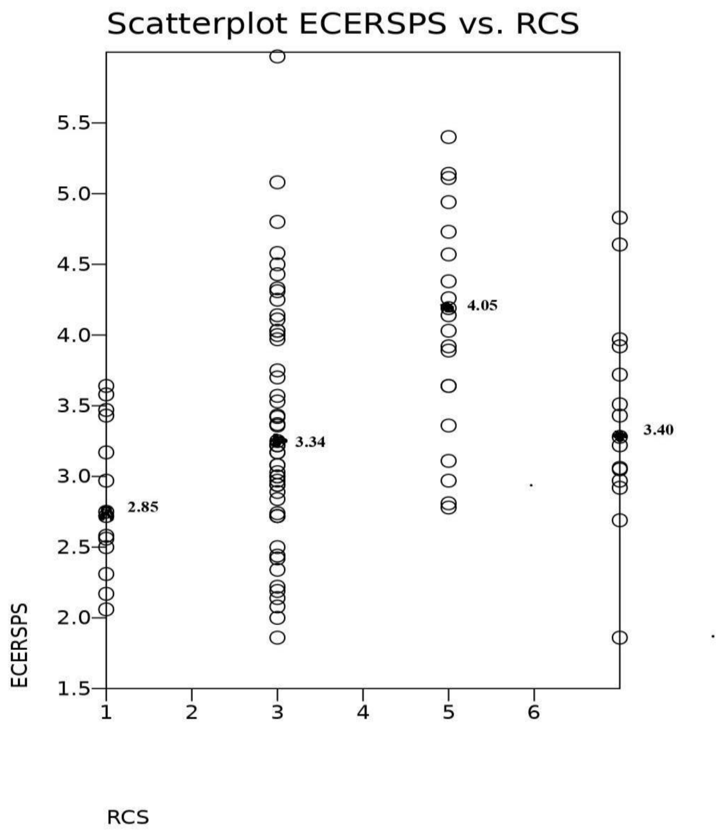
The first figure shows the actual individual violation data of the programs compared to their corresponding ECERS scores. There is not a significant relationship between the two as depicted in the graphic.



The following figure below depicts what occurs when the individual violation data are grouped according to the theory of regulatory compliance in which a substantial compliance category is introduced, and the data are moved from a nominally based metric to an ordinally based metric of full, substantial, medium, and low regulatory compliance categories. This grouping more clearly reflects the theory of regulatory compliance. It also clearly demonstrates the ceiling effect which is an outcome of the theory of regulatory compliance in which substantial and full regulatory compliance levels are basically equivalent when quality is taken into account. Or at the extreme level which is depicted here where full regulatory compliance quality scores are actually lower than the substantial regulatory compliance quality scores. A footnote about the figures and the scaling: the scales for the first figure are on a lower to higher progression but the higher LSTOTAL represents higher non-compliance where the second figure is also based upon lower to higher but the higher scores represent increased quality and increased regulatory compliance.

So, in reading the change from left to right, these two figures are reversed images of each other. This is just a quirk of the scaling and not a mistake in the plotting of data.

The RCS has been pilot tested in both the non-weighted and weighted models and based upon these studies it appears to be more effective in distinguishing quality amongst the various categories rather than utilizing violation count data. This would be a significant improvement when it comes to licensing measurement. Of course, additional replication studies need to be completed before it would be recommended as a new Scale to be used for making licensing decisions.



The above figure is dramatically different than the prevailing paradigm which predicts a linear relationship between regulatory compliance and quality which is the paradigm of a uniform monitoring approach. The above results clearly indicate a reconsideration with the introduction of substantial regulatory compliance as an important contributor to overall quality if not the most important contributor to quality. As stated above, these findings have been replicated in several studies conducted over the past several decades.

This would be a major paradigm shift in moving from individual violation data counts to an ordinal scale metric but it does warrant additional research. The problem with individual violation data is that it doesn't take into account the relative risk of the individual rule which could place clients at increased risk of morbidity or mortality. Risk assessment has worked really well when coupled with key indicators in the differential monitoring approach and it appears to be an asset in the development of a Regulatory Compliance Scale (RCS).

Regulatory Compliance Scale Studies

The Regulatory Compliance Scale (RCS) was introduced several years ago and has been used in a couple of validation studies for differential monitoring and regulatory compliance's ceiling effect phenomenon. RCS buckets or thresholds were statistically generated based upon these studies, but it is time to validate those buckets and thresholds to determine if they are really the best model in creating a regulatory compliance scale. Since proposing the RCS, there has been a great deal of interest from jurisdictions in particular from Asian and African nations. Additional statistically based trials were conducted, and this brief report is the compilation of those trials over the past year.

The data used are from several jurisdictions that are part of the international database maintained at the Research Institute for Key Indicators Data Laboratory at Penn State University focusing on program quality scores and rule violation frequency data. These data from the respective databases were recoded into various thresholds to determine the best model. The jurisdictions were all licensing agencies in the US and Canada geographically dispersed where both regulatory compliance and program quality data was obtained from a sample of early care and education programs.

Methodology

The following methodology was used starting with the original RCS buckets/thresholds of Full, Substantial, Medium, and Low regulatory compliance:

RCS Models used for analyses

RCS				**Models**			
		Original	***1***	***2***	***3***	***4***	***5***
	Full	100	100	100	100	100	100
Scaling	***Substantial***	99-98	99-97	99-97	99-98	99-98	99-97
	Medium	97-90	96-90	96-93	97-95	97-85	96-85
	Low	89>	89>	92>	94>	84>	84>

Five alternate models were used to compare the results to the original RCS. The numbers indicate the number of violations subtract from a perfect score of 100. Full regulatory compliance indicates no violations and a score of 100 on the scale. The next bucket of 99-98 indicates that there were 1 or 2 regulatory compliance violations which resulted in a 99-98 score on the scale. This logic continues with each of the models.

The scale score was determined in the following manner: Full Regulatory Compliance = 7; Substantial Regulatory Compliance = 5; Medium Regulatory Compliance = 3; and Low Regulatory Compliance =1. This rubric is how the original RCS scaling was done on a Likert type scale similar to other ECE program quality scales, such as the Environmental Rating Scales.

Results

The following results are correlations amongst the respective RCS Models from Table above compared to the respective jurisdictions program quality tool (Quality1-3): ERS or CLASS Tools.

RCS Model Results compared to Quality Scales

RCS results	Models	Quality1	Quality2	Quality3
Jurisdiction1	**RCS0**	**.26***	**.39***	**.39***
	RCS3	.21	.32*	.33*
	RCS5	.20	.36*	.33*
Jurisdiction2	**RCS0**	**.76****	**.46****	**---**
	RCS3	.12	-.07	---
	RCS5	.18	-.02	---
	RCSF1	.55**	.29*	---
	RCSF2	.63**	.34	---
Jurisdiction3	RCS0	.19	.18	.16
	RCS3	**.21**	**.21**	**.15**
	RCS5	.18	.16	.07
	RCSF1	.17	.17	.10
	RCSF2	.18	.18	.19
Jurisdiction4	RCS0	.24*	---	---
	RCS3	.28*	---	---
	RCS5	**.30***	**---**	**---**
	RCSF1	.21	---	---
	RCSF2	.29*	---	---
Jurisdiction5	RCS0	.06	-.02	.07
	RCS3	.06	-.01	.05
	RCS5	**.08**	**.00**	**.09**
	RCSF1	.00	-.03	.05
	RCSF2	.05	-.03	.05

*Statistically significant .05 level;

**Statistically significant .01 level.

In the above table starting under Jurisdiction2, two new models were introduced based upon the Fibonacci Sequence (Fibonacci1 = RCSF1; Fibonacci2 = RCSF2) and their model structure is in the following Table. The reason for doing this is that the Fibonacci Sequence introduces additional variation into the scaling process.

RCS Fibonacci Models

RCS Fibonacci			**Models**	
		Original	***Fibonacci1***	***Fibonacci2***
	Full	100	100	100
Scaling	***Substantial***	99-98	40	90
	Medium	97-90	20	20
	Low	89>	13	13

A second series of analyses were completed in comparing the RCS models with program quality (Quality1) by running ANOVAs with the RCS models as the independent variable and program quality as the dependent variable. The reason for doing this was the nature of the data distribution in which there was a ceiling effect phenomenon identified which would have had an impact on the correlations in table above. All results are significant at $p < .05$ level with the exception of Jurisdiction2.

ANOVAs Comparing the RCS Models with Program Quality

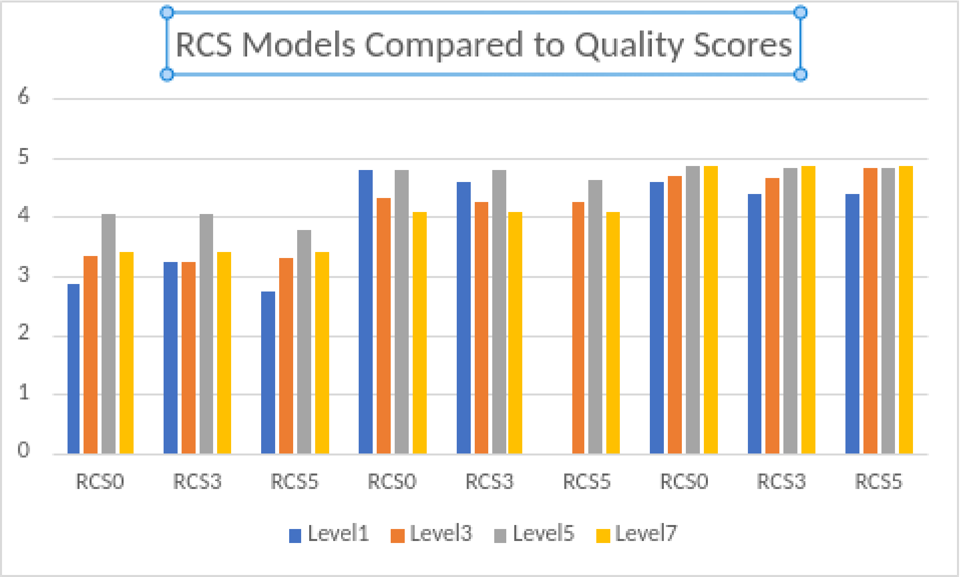
Jurisdictions	**Model**	**Level 1**	**Level 3**	**Level 5**	**Level 7**
Jurisdiction1	**RCS0**	**2.85**	**3.34**	**4.05**	**3.40**
	RCS3	3.24	3.23	4.05	3.40
	RCS5	2.73	3.32	3.77	3.40
Jurisdiction2	RCS0	4.81	4.31	4.80	4.10
	RCS3	**4.59**	**4.25**	**4.80**	**4.10**
	RCS5	---	4.26	4.64	4.10
Jurisdiction3	RCS0	4.59	4.68	4.86	4.87
	RCS3	**4.38**	**4.67**	**4.83**	**4.87**
	RCS5	4.38	4.83	4.83	4.87
Jurisdiction4	RCS0	37.81	37.01	44.28	41.96
	RCS3	36.57	38.60	44.28	41.96
	RCS5	**33.46**	**36.53**	**43.10**	**41.96**
Jurisdiction5	RCS0	3.93	4.17	4.28	4.07
	RCS3	4.02	4.24	4.28	4.07
	RCS5	**3.75**	**4.13**	**4.26**	**4.07**

Discussion

Based upon the above results, it appears that the original RCS model proposed in 2021 is still the best model to be used, although the Fibonacci Sequence model is a close second in some of the jurisdictions. This model will need further exploration in determining its efficacy as a replacement or enhancement to the original RCS Model.

The bottom line is that the original RCS Model is as good as any and no other model is consistently better than all the rest. The RCS Model does have a slight edge over Regulatory Compliance Violation RCV frequency counts in some jurisdictions but not in others. It is much easier to interpret the relationship between quality and the RCS models than it is to interpret the results from the quality scores and the RCV data distribution. So, the recommendation would be for licensing agencies to think about using this new scaling technique in one of its model formats to determine its efficacy. Pairing up RCS and RCV data side by side by licensing agencies would be important studies to determine which approach is the better approach.

The below graphic depicts the relationship between the RCS Models (0, 3, 5) when compared to the quality scores (1-6) clearly showing the ceiling effect and diminishing returns effect phenomenon so typical of regulatory compliance data when compared to program quality. These graphs are from the first three jurisdictions (1, 2, 3) from the above tables.



Additional Analyses Comparing the 11 Studies

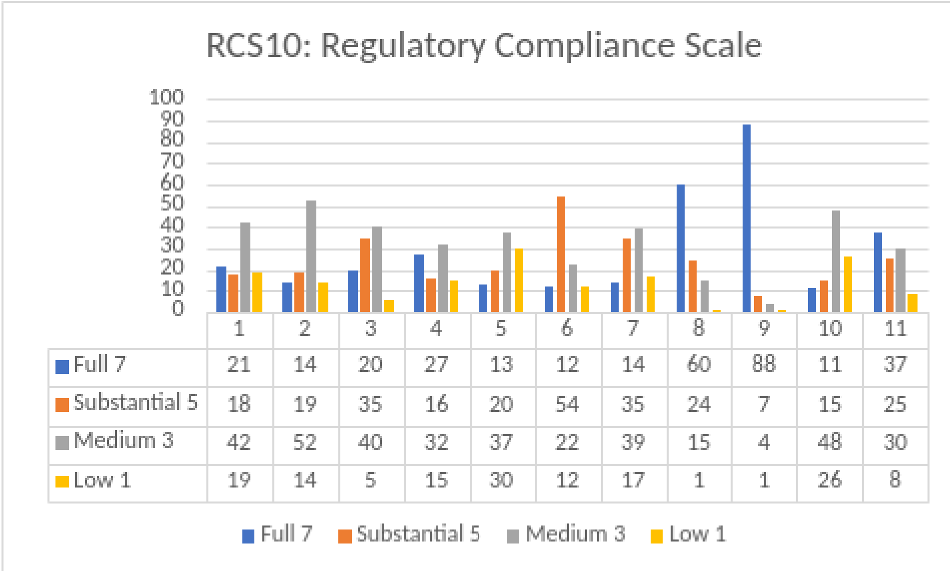
This section provides the results from 11 studies from 10 states and Canadian Provinces in which the proposed new Regulatory Compliance Scale (RCS) was utilized as a byproduct of a differential monitoring implementation or validation study. These studies were undertaken over a decade long period (2013-2023).

The RCS was based upon the following rubric: Full Regulatory Compliance (100%) or no violations = 7; Substantial Regulatory Compliance (99-98) or 1-2 violations = 5; Medium Regulatory Compliance (97-90) or 3-10 violations =3; and Low Regulatory Compliance (89 or less) or 11 or more violations = 1.

These are the results from these 10 jurisdictions which are presented in the following Table (all results are presented as percents of programs that fell into the scaling 1-7). Under the Studies, the number of the specific study is provided, followed by the sample size, followed by if it is in the USA (US) or Canada (CA).

RCS Scale			**RCS Scaling**		
Studies	**7=Full**	**5=Substantial**	**3=Medium**	**1=Low**	**Comments**
1-403-US	21%	18%	***42%***	19%	***High Med NC***
2-104-US	14%	19%	***52%***	14%	***High Med NC***
3-422-US	***20%***	***35%***	***40%***	***5%***	***OK***
4-219-CA	***27%***	***16%***	***32%***	***15%***	***OK***
5-60-CA	13%	20%	***37%***	***30%***	***High NC/Low C***
6-585-US	***12%***	***54%***	***22%***	***12%***	***OK***
7-255-US	***14%***	***35%***	***39%***	***17%***	***OK***
8-1399-US	***60%***	24%	15%	***1%***	***Low NC/High C***
9-2116-US	***88%***	7%	4%	***1%***	***Low NC/High C***
10-482-US	11%	15%	*48%*	*26%*	***High NC/Low C***
11-3070-US	***37%***	***25%***	***30%***	***8%***	***OK***

In looking at the results, it is preferrable to have most of the programs at either a full or substantial regulatory compliance level (7 or 5) and to have fewer programs at the medium or low regulatory compliance level (3 or 1). But in those jurisdictions where there are higher percentages of programs at the medium or low levels of regulatory compliance, it could be that their enforcement of rules and regulations is more stringent. This potential result needs further investigation to get to the root cause of these differences because there is a good deal of variation across the jurisdictions as is evident from the above table.



	1	2	3	4	5	6	7	8	9	10	11
Full 7	21	14	20	27	13	12	14	60	88	11	37
Substantial 5	18	19	35	16	20	54	35	24	7	15	25
Medium 3	42	52	40	32	37	22	39	15	4	48	30
Low 1	19	14	5	15	30	12	17	1	1	26	8

Based upon the above studies and results, the regulatory compliance scale (Fiene, 2022) which appears from recent studies to be a better metric in measuring regulatory compliance than just counting the number of violations that a program has related to their respective rules, regulations, or standards. So how does the regulatory compliance scale work. It essentially puts violations into buckets of regulatory compliance as follows: full compliance (100%) or no violations; substantial compliance (99-98%) or 1-2 violations; mediocre compliance (97-90%) or 3-9 violations; and lastly low/non-optimal compliance (89% or lower) or 10+ violations. Why buckets, because logically it works, it is the way we think about regulatory compliance. It is a discrete rather than continuous metric and logically fits into these four categories. This is based upon 50 years of research into regulatory compliance data distributions and when the data are moved from frequency counts of violation data into these buckets/categories, the math works very well in identifying the better performing programs.

Regulatory Compliance Scale Extensions

Depicted below is a regulatory compliance grid model showing the relationship between regulatory compliance (RC) and program quality (PQ).

An explanation of the below chart will demonstrate how regulatory compliance and program quality in human service facilities interact. The horizontal blue axis depicts the various levels of regulatory compliance while the vertical green axis depicts the various levels of program quality of facilities. It ranges from 1-5 or low to high for each axis. The red "**X's**" represents the relationship that has been identified in the research literature based upon the theory of regulatory compliance in which there is either a plateau effect or a downturn in quality as regulatory compliance increases. The one italicized "***X***" is an outlier that has also been identified in the research literature in which some (it does not happen often) low compliant programs really are at a high-quality level.

It is proposed in order to mitigate the plateau effect with regulatory compliance and program quality standards because regulatory compliance data distributions are severely skewed which means that many programs that have questionable quality are being included in the full (100%) compliance domain. When regulatory compliance standards are increased in their quality components this will lead to a higher level of overall quality as depicted in the "**XX**" cell all the way on the lower right. It also helps to mi gate the severe skewness in the regulatory compliance data distribution. The data distribution does not approximate a normally distributed curve which is the case with the program quality data distribution.

Regulatory Compliance x Program Quality Grid Model

PQ/RC ->	**1 Low**	**2 Med**	**3 Substantial**	**4 Full 100%**	**5QualityAdditions**
1 Low	**XXX**				
2		**XX**			
3 Med			**XX**	**XXX**	
4			**XX**	**X**	
5 High	***X***				**XX**

By utilizing this model, it helps to deal more directly in taking a non-linear relationship and making it linear again when comparing regulatory compliance with program quality. This model provides a theoretical approach supporting what many state licensing administrators are thinking from a policy standpoint: add more quality to health and safety rules/regulations. This grid/matrix also depicts the three regulatory compliance models: Linear, Non-linear, and Stepped.

Here is another potential extension of the Regulatory Compliance Scale using the ECPQIM DB – Early Childhood Program Quality Improvement and Indicator Model Data Base, it is possible to propose developing and using a Regulatory Compliance Scoring System and Scale (RC3S). This new proposed RC3S could be used by state human service agencies to grade facilities as is done in the restaurant arena. Presently, in the human service field, licenses are issued with a Certificate of Compliance but generally it does not indicate what the regulatory compliance level is at. This new proposal would alleviate this problem by providing a scale for depicting the level of regulatory compliance.

The ECPQIM DB is an international data base consisting of a myriad group of data sets drawn from around the USA and Canada. It has been in the making over 40 years as of this writing, so its stability and generalizability have been demonstrated. What follows is the chart depicting the RC3S.

Regulatory Compliance Scoring System and Scale (RC3S)

Color	Non-Compliance Level	Regulatory Compliance Level
Blue	**0**	**Full Compliance**
Green	**1-2**	**Substantial Compliance**
Yellow	**3-6**	**Mid-Range Compliance**
Orange	**7-9**	**Low Compliance**
Red	**10-15+**	**Very Low Compliance**

It is evident from the above chart that the color go from blue to red which indicates an increasing risk of non-compliance and a lower level of overall regulatory compliance, which is not a good thing in the licensing field. Non-compliance levels indicate the number of rules or regulations or standards that are not complied with. And lastly, the regulatory compliance level indicates the movement from full (100% regulatory compliance with all rules) to very low compliance with rules. These ranges for the scaling are based on 40 years of research in understanding and plotting the data distributions around the world related to regulatory compliance in the human services. These results have consistently appeared over this 4-decade time period and show no signs of changing at this point.

Regulatory Compliance Scaling for Decision Making

There is a lack of empirical demonstrations of regulatory compliance decision making. In the past, I have used the methodologies of key indicators, risk assessment and the resultant differential monitoring techniques of how often and what should be reviewed for decision making. What has not been addressed is decision making based upon comprehensive reviews when all regulations are assessed. This section addresses how empirical evidence taken from the past 40+ years of establishing and researching a national database for regulatory compliance can help lead us to a new scaling of regulatory compliance decision making.

In analyzing regulatory compliance data, it becomes perfectly clear that the data have very little variance and are terribly skewed in which the majority of programs are in either full or substantial compliance with all the respective regulations. Only a small handful of programs fall into the category of being in low compliance with all the regulations.

The proposed scaling has three major decision points attached to regulatory compliance scores. Either programs are in full or substantial compliance, in low compliance or somewhere in the middle. Full or substantial regulatory compliance is 100% or 99-98% in regulatory compliance. Low regulatory compliance is less than 90% and mid-regulatory compliance is between 97%-90%. These ranges may seem exceptionally ght but based upon the national database on regulatory compliance that I maintain at the Research Institute for Key Indicators (RIKILLC) these are the ranges that have formed over the past 40 years. These data ranges should not come as a surprise because we are talking about regulatory compliance with health and safety standards. These are not quality standards; these are basic protections for clients. The data are not normally distributed, not even close as is found in quality tools and standards.

What would a **Regulatory Compliance Decision-Making Scale** look like:

Data	Level	Decision
100-98%	*Full/Substantial*	*License*
97-90%	*Mid-Range*	*Provisional*
89% or less	*Low*	*No-License*

States/Provinces/Jurisdictions may want to adjust these levels, and the scaling based upon their actual data distribution. For example, I have found certain jurisdictions to have very unusually skewed data distributions which means that these ranges need to be ghten even more. If the data distribution is not as skewed as the above scale, then these ranges may need to be more forgiving.

This regulatory compliance decision making scale does not take into account if abbreviated methodologies are used, such as risk assessment or key indicator models that are used in a differential monitoring approach. The above scale is to be used if a jurisdiction decides not to use a differential monitoring approach and wants to measure regulatory compliance with all regulations and complete comprehensive reviews.

Conclusion

The Theory of Regulatory Compliance (Fiene, 2019) and bringing substantial compliance to the fore front of regulatory science has been written about a great deal. This paper builds upon these previous assertions and expands 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. This paper has introduced the Regulatory Compliance Scale which is a departure in how best to measure regulatory compliance. This new scale along with the proposed Uncertainty-Certainty Matrix (Fiene, 2025b) provides a robust licensing measurement and program monitoring strategy. This paper provides the last piece of a differential monitoring approach that includes instrument-based program monitoring, key indicators, risk assessment, and the uncertainty-certainty matrix.

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

Scoring Level	**Individual Rule**		**Aggregate Rules**	**Individual Rule**
Scale	**Instrument based**	***Scale***	**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.

These alternative paradigms offer a more flexible and effective approach to licensing decisionmaking 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.

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Regulatory Compliance, Regulatory Compliance Scale, and Program Quality Data Distributions

Richard Fiene PhD

Research Institute for Key Indicators/Penn State University

February 2024

This research abstract will depict the differences in regulatory compliance violation (RSV) data, regulatory compliance scale (RCS) data, and program quality (PQ) data distributions. This is an important distinction amongst the three data sets to determine how best to make licensing decisions. A series of previous research abstracts and technical research notes will be compared with the latest research on the newly proposed regulatory compliance scales (RCS).

The 2018 technical research note provides descriptive statistics for regulatory compliance and program quality data. It clearly demonstrates how the two data sets are very different from each other and the issues for measurement when it comes to regulatory compliance data.

The 2019 technical research note provides basic characteristics of the data distributions for many of the databases in the RIKI/PSU Early Childhood Program Quality Improvement and Indicator Model's international Database.

The 2024 research abstract presents the regulatory compliance scale and its relationship to program quality scores and regulatory compliance violation data. In this abstract, several RCS models are introduced in which various thresholds are used in the RSV data in determining the RCS levels. What is clear from the abstract is that the RCS models provide a clearer picture of the overall data distribution over the use of the RSV data display. This is graphically displayed in the abstract.

The three papers show the progression made over time in attempting to better analyze regulatory compliance data distributions. The major issue with RSV data is that the data distribution is severely skewed with the majority of the scores being at the full or substantial regulatory compliance levels. This is not the case with PQ data distributions which are more normally distributed. The RCS data distributions help to smooth out the skewness to a certain degree in moving the RSV nominally measured data to an ordinally measured data distribution. This helps in making the data more understandable, for example, the one thing that jumps out is the ceiling effect in moving from substantial to full regulatory compliance which is not as clear in the RSV data distribution.

The three papers follow here:

Regulatory Compliance Skewness

Richard Fiene, Ph.D.

June 2018

In dealing with regulatory compliance data distributions, one is always impressed with the skewness of the data distribution. This is a major disadvantage of working with these data distributions because it eliminates utilizing parametric statistics. These short comings have been dealt with in the past by using non-parametric statistics, the dichotomization of data distributions, moving from a nominal to ordinal scaling, and risk assessment/weighting. These adjustments have been successful in helping to analyze the data but are not ideal and will never approach a normally distributed curve. However, that is not the intent of regulatory compliance data, the data distribution should demonstrate a good deal of skewness because these data are demonstrating protections for clients and not quality services. One would not want the data to be normally distributed.

This short paper/technical research note delineates the state of the art with an international regulatory compliance data base that has been created over the past 40 years at the Research Institute for Key Indicators (RIKILLC). In it, I provide basic descriptive statistics to demonstrate to other researchers the nature of the data distributions so that they can be aware of the shortcomings of the data when it comes to statistical analyses. I have employed various scaling methods to help with the skewness of the data but it still does not approximate normally distributed data. This will be self-evident in the data displays.

	KI	PQ	RC	PQ 1-5	RC 1-5
Mean	1.68	3.42	5.51	2.96	3.48
SD	1.61	0.86	5.26	0.90	1.43
Sum	175	348	573	302	362
Variance	3.61	0.74	27.63	0.81	2.06
Range	6.00	4.11	25.00	4.00	4.00
Minimum	0	1.86	0	1.00	1.00
Maximum	6.00	5.97	25.00	5.00	5.00
SE Mean	0.16	0.09	0.52	0.09	0.14
Kurtosis	0.073	-0.134	2.112	-0.388	-1.097
Skewness	0.898	0.467	1.468	0.327	-0.494

Legend:

KI = Key Indicators

PQ = Program Quality (ERS Scale)

RC = Regulatory Compliance (State Comprehensive Review Checklist)

PQ 1-5 = Program Quality using 1-5 scale

RC 1-5 = Regulatory Compliance using 1-5 scale (1 = Low RC; 2-4 = Med Level RC; 5 = High/Substantial RC)

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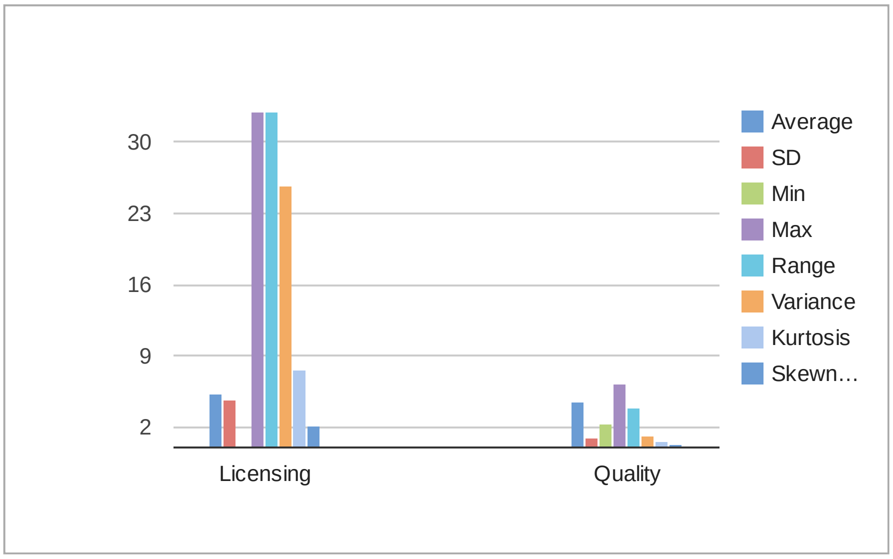
This display presents descriptive statistics for licensing and quality studies averaged from several states and national data
The data are displayed in both chart and graphic forms.
It clearly demonstrates the differences between licensing and quality data in which licensing data are much more skewed

Licensing and Quality Descriptive Statistics

	Average	SD	Min	Max	Range	Variance	Kurtosis	Skewnes	Programs
Licensin	5.35	4.76	0	33	33	25.66	7.72	2.22	3452
Quality	4.58	1.07	2.32	6.33	4.01	1.17	0.67	0.26	1371



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Regulatory Compliance (RC) and Program Quality (PQ) Data Distributions

Richard Fiene, Ph.D.

July 2019

This report will provide the data distributions for a series of regulatory compliance (RC) and program quality (PQ) studies which show dramatically different frequencies and centralized statistics. The regulatory compliance data distributions have some very important limitations that will be noted as well as some potential adjustments that can be made to the data sets to make statistical analyses more meaningful. These data distributions are from the USA and Canada.

For purposes of reading the following Table 1, a Legend is provided:
Data Set = the study that the data are drawn from.
Sites = the number of sites in the particular study.
mean = the average of the scores.
sd = standard deviation.
p0 = the average score at the 0 percentile.
p25 = the average score at the 25th percentile.
p50 = the average score at the 50th percentile or the median.
p75 = the average score at the 75th percentile.
p100 = the average score at the 100th percentile.

Table 1

Data Set	Sites	mean	sd	p0	p25	p50	p75	p100	PQ or RC
ECERS total score	209	4.24	0.94	1.86	3.52	4.27	4.98	6.29	PQ
FDCRS total score	163	3.97	0.86	1.71	3.36	4.03	4.62	5.54	PQ
ECERS and FDCRS totals	372	4.12	0.91	1.71	3.43	4.12	4.79	6.29	PQ
ECERS prek	48	4.15	0.74	2.56	3.6	4.15	4.65	5.56	PQ
ECERS preschool	102	3.42	0.86	1.86	2.82	3.26	4.02	5.97	PQ
ITERS	91	2.72	1.14	1.27	1.87	2.34	3.19	5.97	PQ
FDCRS	146	2.49	0.8	1.21	1.87	2.42	2.93	4.58	PQ
CCC RC	104	5.51	5.26	0	2	4	8	25	RC
FCC RC	147	5.85	5.71	0	2	4	8.5	33	RC
CCC RC	482	7.44	6.78	0	2	6	11	38	RC
FDC RC	500	3.52	4.05	0	0	2	5	34	RC
CI Total Violations	422	3.33	3.77	0	1	2	5	24	RC – PQ
CLASS ES	384	5.89	0.36	4.38	5.69	5.91	6.12	6.91	PQ
CLASS CO	384	5.45	0.49	3.07	5.18	5.48	5.77	6.56	PQ
CLASS IS	384	2.98	0.7	1.12	2.5	2.95	3.37	5.74	PQ
CLASS TOTAL OF THREE SCALES	384	14.33	1.32	8.87	13.52	14.33	15.11	17.99	PQ
ECERS Average	362	4.52	1.05	1.49	3.95	4.58	5.25	7	PQ
FDCRS Average	207	4.5	1	1.86	3.83	4.66	5.31	6.71	PQ
CCC RC	585	5.3	5.33	0	2	4	8	51	RC

QRIS	585	2.78	1.24	0	2	3	4	4	PQ
FDC RC	2486	2.27	3.42	0	0	1	3	34	RC
FDC PQ	2486	1.35	1.26	0	0	1	2	4	PQ
CCC RC	199	7.77	8.62	0	3	6	10	61	RC
CCC RC	199	6.69	10.32	0	1	4	8	98	RC
CCC RC	199	6.77	7.91	0	1.5	4	8.5	57	RC
QRIS	199	1.06	1.32	0	0	1	2	4	PQ
CCC RC	199	7.08	6.96	0	2.33	5.67	9.84	52	RC
QRIS	381	2.55	0.93	0	2	3	3	4	PQ
CCC RC	1399	1.13	2.1	0	0	0	1	20	RC
CCC RC	153	5.28	5.97	0	1	3	6	32	RC
FDC RC	82	3.52	4.36	0	0	2	4	21	RC

It is obvious when one observes the PQ as versus the RC data distributions that the RC data distributions are much more skewed, medians and means are significantly different, and kurtosis values are much higher which means that the data contain several outliers. These data distributions are provided for researchers who may be assessing regulatory compliance (RC) data for the first time. There are certain limitations of these data which are not present in more parametric data distributions which are more characteristic of program quality (PQ) data.

To deal with the level of skewness of RC data, weighted risk assessments have been suggested in order to introduce additional variance into the data distributions. Also, dichotomization of data has been used successfully with very skewed data distributions as well. One of the problems with very skewed data distributions is that it is very difficult to distinguish between high performing providers and mediocre preforming providers. Skewed data distributions provide no limitations in distinguishing low preforming providers from their more successful providers.

Regulatory Compliance Scale Trials and Tribulations (Enhanced Version)

Richard Fiene PhD

Research Institute for Key Indicators Data Lab/Penn State University

January 2024

The Regulatory Compliance Scale (RCS) was introduced several years ago and has been used in a couple of validation studies for differential monitoring and regulatory compliance's ceiling effect phenomenon. RCS buckets or thresholds were statistically generated based upon these studies, but it is time to validate those buckets and thresholds to determine if they are really the best model in creating a regulatory compliance scale. Since proposing the RCS, there has been a great deal of interest from jurisdictions in particular from Asian and African nations. Additional statistically based trials were conducted, and this brief report is the compilation of those trials over the past year.

The data used are from several jurisdictions that are part of the international database maintained at the Research Institute for Key Indicators Data Laboratory at Penn State University focusing on program quality scores and rule violation frequency data. These data from the respective databases were recoded into various thresholds to determine the best model. The jurisdictions were all licensing agencies in the US and Canada geographically dispersed where both regulatory compliance and program quality data was obtained from a sample of early care and education programs.

METHODOLOGY

The following methodology was used starting with the original RCS buckets/thresholds of Full, Substantial, Medium, and Low regulatory compliance:

Table 1: RCS Models used for analyses

RCS				**Models**			
		Original	***1***	***2***	***3***	***4***	***5***
	Full	100	100	100	100	100	100
Scaling	***Substantial***	99-98	99-97	99-97	99-98	99-98	99-97
	Medium	97-90	96-90	96-93	97-95	97-85	96-85
	Low	89>	89>	92>	94>	84>	84>

Five alternate models were used to compare the results to the original RCS. The numbers indicate the number of violations subtract from a perfect score of 100. Full regulatory compliance indicates no violations and a score of 100 on the scale. The next bucket of 99-98 indicates that there were 1 or 2

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regulatory compliance violations which resulted in a 99-98 score on the scale. This logic continues with each of the models.

The scale score was determined in the following manner: Full Regulatory Compliance = 7; Substantial Regulatory Compliance = 5; Medium Regulatory Compliance = 3; and Low Regulatory Compliance =1. This rubric is how the original RCS scaling was done on a Likert type scale similar to other ECE program quality scales, such as the Environmental Rating Scales.

RESULTS

The following results are correlations amongst the respective RCS Models from Table 1 compared to the respective jurisdictions program quality tool (Quality1-3): ERS or CLASS Tools.

Table 2: RCS Model Results compared to Quality Scales

RCS results	Models	Quality1	Quality2	Quality3
Jurisdiction1	**RCS0**	**.26***	**.39***	**.39***
	RCS3	.21	.32*	.33*
	RCS5	.20	.36*	.33*
Jurisdiction2	**RCS0**	**.76****	**.46****	**---**
	RCS3	.12	-.07	---
	RCS5	.18	-.02	---
	RCSF1	.55**	.29*	---
	RCSF2	.63**	.34	---
Jurisdiction3	RCS0	.19	.18	.16
	RCS3	**.21**	**.21**	**.15**
	RCS5	.18	.16	.07
	RCSF1	.17	.17	.10
	RCSF2	.18	.18	.19
Jurisdiction4	RCS0	.24*	---	---
	RCS3	.28*	---	---
	RCS5	**.30***	**---**	**---**
	RCSF1	.21	---	---
	RCSF2	.29*	---	---
Jurisdiction5	RCS0	.06	-.02	.07
	RCS3	.06	-.01	.05
	RCS5	**.08**	**.00**	**.09**
	RCSF1	.00	-.03	.05
	RCSF2	.05	-.03	.05

*Statistically significant .05 level;

**Statistically significant .01 level.

In the above table starting under Jurisdiction2, two new models were introduced based upon the Fibonacci Sequence (Fibonacci1 = RCSF1; Fibonacci2 = RCSF2) and their model structure is in the following Table 3. The reason for doing this is that the Fibonacci Sequence introduces additional variation into the scaling process.

Table 3: RCS Fibonacci Models

RCS Fibonacci			Models	
		Original	***Fibonacci1***	***Fibonacci2***
	Full	100	100	100
Scaling	***Substantial***	99-98	40	90
	Medium	97-90	20	20
	Low	89>	13	13

A second series of analyses were completed in comparing the RCS models with program quality (Quality1) by running ANOVAs with the RCS models as the independent variable and program quality as the dependent variable (Table 4). The reason for doing this was the nature of the data distribution in which there was a ceiling effect phenomenon identified which would have had an impact on the correlations in Table 2 above. All results are significant at $p < .05$ level with the exception of Jurisdiction2.

Table 4: ANOVAs Comparing the RCS Models with Program Quality

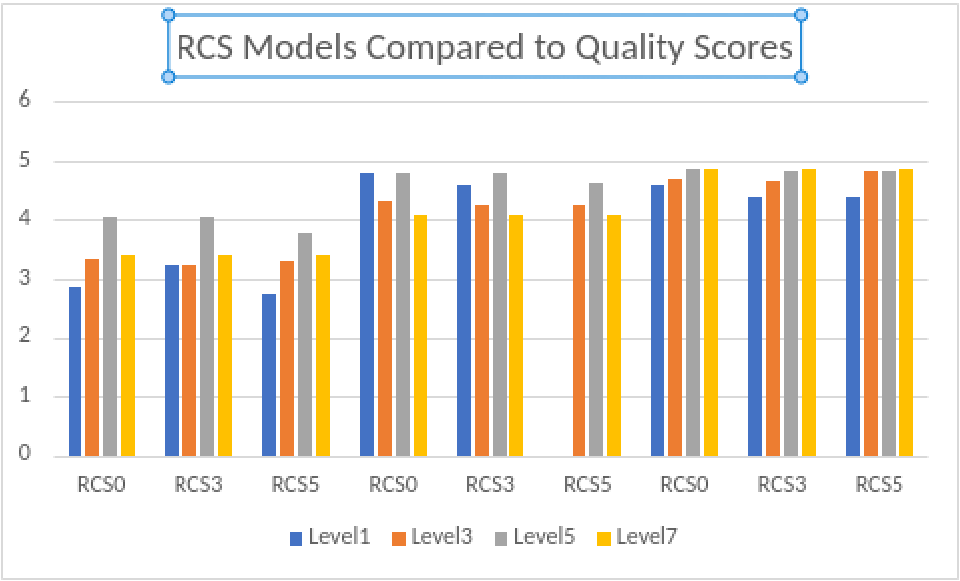
Jurisdictions	Model	Level 1	Level 3	Level 5	Level 7
Jurisdiction1	**RCS0**	**2.85**	**3.34**	**4.05**	**3.40**
	RCS3	3.24	3.23	4.05	3.40
	RCS5	2.73	3.32	3.77	3.40
Jurisdiction2	RCS0	4.81	4.31	4.80	4.10
	RCS3	**4.59**	**4.25**	**4.80**	**4.10**
	RCS5	---	4.26	4.64	4.10
Jurisdiction3	RCS0	4.59	4.68	4.86	4.87
	RCS3	**4.38**	**4.67**	**4.83**	**4.87**
	RCS5	4.38	4.83	4.83	4.87
Jurisdiction4	RCS0	37.81	37.01	44.28	41.96
	RCS3	36.57	38.60	44.28	41.96
	RCS5	**33.46**	**36.53**	**43.10**	**41.96**
Jurisdiction5	RCS0	3.93	4.17	4.28	4.07
	RCS3	4.02	4.24	4.28	4.07
	RCS5	**3.75**	**4.13**	**4.26**	**4.07**

DISCUSSION

Based upon the above results, it appears that the original RCS model proposed in 2021 is still the best model to be used, although the Fibonacci Sequence model is a close second in some of the jurisdictions. This model will need further exploration in determining its efficacy as a replacement or enhancement to the original RCS Model.

The bottom line is that the original RCS Model is as good as any and no other model is consistently better than all the rest. The RCS Model does have a slight edge over Regulatory Compliance Violation RCV frequency counts in some jurisdictions but not in others. It is much easier to interpret the relationship between quality and the RCS models than it is to interpret the results from the quality scores and the RCV data distribution. So, the recommendation would be for licensing agencies to think in terms of using this new scaling technique in one of its model formats in order to determine its efficacy. Pairing up RCS and RCV data side by side by licensing agencies would be important studies to determine which approach is the better approach.

The below graphic depicts the relationship between the RCS Models (0, 3, 5) when compared to the quality scores (1-6) clearly showing the ceiling effect and diminishing returns effect phenomenon so typical of regulatory compliance data when compared to program quality. These graphs are from the first three jurisdictions (1, 2, 3) from the above tables.



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The below appendices present graphic displays of moving from nominal RCV to ordinal RSC measurement which really captures the differences in how the data are displayed and the ease in which viewing the data becomes in making such a move. Also, basic descriptive statistics are displayed to clearly demonstrate the differences in the various RCS Models.

Comparison of Regulatory Compliance Metric Principles, Paradigms, and Continuum of Quality Matrix

Principles	***Paradigms***	***Quality Continuum***
Lack of variance	Substantial vs monolithic	Hard vs soft data
Ceiling effect	**One size fits all vs differential**	**Full vs partial compliance**
Difficulty between full and high	Rules are equal vs not equal	Rules vs indicators
Nominal measurement	**Do things well vs do no harm**	**Do no harm vs do good**
Moving nominal to ordinal	**Strength based vs deficit**	Open vs closed system
Dichotomization	Formative vs summative	**Structural vs process quality**
Lack of reliability and validity	**Program quality vs compliance**	**Risk vs performance**
Skewed data	**100-0 vs 100 or 0**	**Nominal vs ordinal**
Ease between high and low	QRIS vs licensing	Gatekeeper vs enabler
False negatives	Linear vs non-linear	**Ceiling effect**

Legend:

Principles = Regulatory compliance measurement key principles of instrument design.

Paradigms = Regulatory compliance major paradigms: Absolute vs relative compliance.

Quality Continuum = Regulatory compliance and program quality continuum.

Bold faced = Common concepts in the principles & elements, there is overlapping.

Fiene, 2023

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The Holy Grail of Regulatory Science: Identifying the "Right Rules"

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August 2024

Regulatory science has made tremendous strides in the past 20-30 years in developing as a science. This has been particularly evident in the pharmaceutical area led by the industry and the FDA. The focus on establishing the science and clinical trials has been very robust. However, there has been one area where it has been difficult to ascertain within regulatory compliance the identification of specific rules/regulations that may be having a differential positive impact on outcomes for clients from a safety and quality perspective.

However, if we look to other industries that are equally regulated, such as the human services, there has been a great deal of experimentation with doing just that, finding if there are rules that have a differential positive impact on outcomes for clients, in other words, identifying the "Right Rules" or as the title implies, the "Holy Grail of Regulatory Science". Regulatory science is about rules and regulations and determining how well they improve overall safety and quality of products produced or services provided. This can be any type of product or service in any industry. Rules are everywhere. We are not just talking about drugs and medical devices although these have led the way in the regulatory science arena. There are rules for banking, finance, transportation, restaurants, power plants, child care centers, personal care homes, assisted living, hospitals, etc., the list goes on and on.

The area that needs to be looked at a bit more closely to see if some of the methodologies and metrics developed there have broader applicability is the human services arena, in particular early care and education. There does not appear to be a similar avenue of inquiry in the other industries but they may be able to learn from the latest developments in the human services and early care and education/child care. The specific methodologies or metrics being referred to are the risk assessment and key indicator methodologies being developed in order to determine overall safety and quality concerns for children in early care and education settings. Risk assessment is what its name suggests, rules that place clients at increased risk of mortality or morbidity. Key indicators are rules that statistically predict overall regulatory compliance and quality.

When risk assessment and key indicators are used in tandem, the resultant approach points us in the direction of attempting to find the "right rules" that both statistically predict overall safety and quality while also protecting clients at the same time. This is exactly what regulatory science is all about. These two methodologies and the resultant differential monitoring approach puts us on a trajectory of the most cost effective and efficient way of achieving the goal of regulatory science or as the title suggests, "The Holy Grail" of regulatory science.

The regulatory science field has had great success via clinical trials to find what drugs and medical devices are safe and improve the overall quality of life for patients. Could the above approach help to improve on these initial successes to produce even better results related to the specific rules that need additional emphasis and selection while others may eventually fall away? This will take a good deal of experimentation to see if these methodologies and approach from the human services has more broad-based applicability or not.

Why search for the "right rules"? Why not just look at the rules in the aggregate? Because of the theory of regulatory compliance and the ceiling or diminishing returns effect where substantial regulatory compliance is significantly more effective when compared with quality than full regulatory compliance. So, it makes sense to identify individual rules which may have an increased differential positive impact on client outcomes. It appears that there is a non-linear relationship between regulatory compliance and quality but there still remains a linear relationship between regulatory compliance and safety. This is an interesting dual relationship when it comes to regulatory compliance. At least this is what has been found in the human services, in particular, early care and education. The question for the future is: Does it apply to other regulatory science arenas, such as: banking, financing, pharmaceuticals, etc. Are there specific rules related to these industries that have an increased differential positive impact on client outcomes? What are the "right rules" for these industries, the regulatory science "Holy Grail"?!

If the above risk assessment and key indicator methodologies are of interest, please check out the following website (Research Institute for Key Indicators Data Laboratory associated with the Penn State Prevention Research Center (link is listed below)) for additional information and details on how to use the methodologies. The methodologies are open course and in the public domain in the best interests of open science.

https://rikinstitute.com

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The Relationship between Early Care & Education Quality Initiatives and Regulatory Compliance: RIKIllc Technical Research Note #67

Richard Fiene, Ph.D.

February 2019

Over the past couple of decades there has been many early care and education initiatives, such as Quality Rating and Improvement Systems (QRIS), Professional Development, Training, Technical Assistance, Accreditation, and Pre-K programs to just name a few. Validation and evaluation studies have begun to appear in the research literature, but in these studies there has been few empirical demonstrations of the relationship between these various quality initiatives and their impact on regulatory compliance or a comparison to their respective regulatory compliance. This brief technical research note will provide examples of these comparisons taken from the Early Childhood Program Quality Improvement and Indicator Model (ECPQI2M) Data Base maintained at the Research Institute for Key Indicators (RIKIllc).

I have written about this back in 2014 (Fiene, 2014) in how the various quality initiatives were having a positive impact on the early care and education delivery system but at that point regulatory compliance data were not available. Today, in 2019, with many changes and developments in state data systems, this is no longer the case. Now it is possible to explore the relationships between data from the various quality initiatives and licensing. Several states in multiple service delivery systems have provided replicable findings in which I feel comfortable reporting out about the relationships across the data systems.

What we now know is that there is a positive and statistically significant relationship between regulatory compliance and moving up the QRIS Quality Levels. In other words, facilities have higher compliance in the higher QRIS Quality Levels and lower compliance in the lower QRIS Levels or if they do not participate in their state's respective QRIS ($F = 5.047 – 8.694$; $p < .0001$).

Other quality initiatives, such as being accredited, shows higher compliance with licensing rules than those facilities that are not accredited ($t = 2.799 - 3.853$; $p < .005 - .0001$).

This is a very important result clearly demonstrating the positive relationship between regulatory compliance and quality initiatives. I have some additional state data sets that I will add to the ECPQI2M data base and will continue to analyze these relationships.

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Risk Assessment Indicator Data Analysis Plan Notes

Richard Fiene, PhD

May 2022

In any data analysis plan there are two phases to the plan: 1) The initial data collection and analysis and 2) The validation of the data and its use to make certain that how the data are used is appropriate. Although this plan is geared to dealing with risk assessment indicators, the overall plan is applicable to any data analysis plan in general. The validation phase is not followed through in many monitoring systems, especially when it comes to licensing or regulatory compliance systems. It is hoped that this will change as the field moves forward with the building blocks of regulatory science.

Initial Data Collection Phase

There are several items to consider in developing the initial risk assessment indicator analysis plan. The first is to identify those indicators where outcome (O) or results data are available. By having both the risk assessment indicator (R) (process data) available and the outcome/results (O) available it will be able to determine if there is any type of relationship between the two. This has occurred for approximately 5 risk indicators already dealing with staff turnover, fiscal accountability, compliance history, complaints, etc. In the data plan, these correlations would constitute the first level of analyses. It would be more exploratory in nature to see where the relationships are.

Once the significant relationships are identified via the correlational analyses, the second step would be to either conduct a factor analysis or a regression analysis. This will be dependent upon the sample size and the number of risk indicators identified in step 1. If there are sufficient observations path analyses could also be done.

O = Outcomes or Results ***F = Factors***

R = Risk Assessment Indicators

Correlational Analyses:

	R1	R2	R3	R4	Rn....
O1					
O2....					

Factor Analyses:

F1 = R1 + R2 + R3 + Rn….

F2 = R4 + R5 + R6 + Rn….

F1 + F2 + Fn….

Regression Analyses:

O1 = R1 + R2 + R3 + Rn….

Lastly, the database can be an excel spreadsheet, csv formatted for SPSS processing. There would be outcome variables followed by the risk assessment indicators along the horizontal axis with grantees along the vertical axis.

<u>Validation Data Phase</u>

The validation data phase has four validations that can be performed

1. Standards Validation
2. Measures Validation
3. Outputs Validation
4. Outcomes Validation.

1. Standards Validation: with this validation the specific risk assessment indicators would be compared to the agreed upon research standards (Std) that have been accepted in the research literature as the go to standards. For example, in child care licensing the agreed upon standards in the field are the *Caring for Our Children* (CFOC) national health and safety standards. Specific rules would be compared to CFOC to determine how well they size up side by side. These analyses would be more qualitative than quantitative involving a content analysis to see where there is agreement and gaps in the standards. This could be done on a standard by standard basis or looking at the standards as a whole and expressed as a percent.

R1 x Std; R2 x Std; R3 x Std; Rn x Stdn, etc.....

2. Measures Validation: with this validation the key element is the reliability of the measuring tool. If there are sufficient data, a Cronbach Alpha could be generated to determine the stability of the tool. If there are not sufficient data to perform this level of analysis, then random portions of the the tool can be compared with other portions of the tool to determine consistency. Or lastly, the scores on the risk assessment tool can be compared to decisions being made on the basis of the scores to determine consistency. For example, in the licensing research literature this is done when comparing licensing key indicator tools with comprehensive tool data collection and the respective licensing decision being made to conduct a full versus abbreviated inspection. Or in the care of risk assessment tools, where scores on the risk assessment tools are compared to the licensing decision making. If reliability analysis is not used via Cronbach Alpha, then correlational analyses would be appropriate, and possibly factor analyses.

3. Output Validation: with this validation comparisons are made between the target variable and a more standardized quality element in the research literature, such as licensing or Quality Rating and Improvement Systems (QRIS). With the case of risk assessment indicators and what is the ultimate grantee's success potentially looking at scores with the risk assessment indicators and comparing it to CLASS scores may be appropriate to validate. Correlational analyses would most likely be used here.

4. Outcome Validation: this is generally the most difficult validation study to perform because it involves obtaining specific outcome data either from the program (compliance histories) and the clients within the program, such as health & safety information (immunization status) or developmental outcomes (child development progress). This can be very labor intensive in order to collect these data. With risk assessment indicators it would be a deep dive into compliance histories dealing with injury data and developmental data and comparing it with the specific risk assessment indicators to determine if there are a specific group of risk assessment indicators that always statistically predict when grantees will perform less well when these risk assessment indicators occur. Regression analysis or potentially path analysis would most likely be used here.

Classification Matrix & Sensitivity Analysis for Validating Licensing Key indicator Systems (Fiene, 2017)

	1	*2*	*3*	*5*	*7*	*8*	*10*	*Comments*
A	**1**	**1**	**1**	**0**	**0**	**1**	**1**	**Perfect**
B	**.52**	**.52**	**.52**	**.48**	**.48**	**.52**	**.04**	**Random**
C	**.71**	**.96**	**.94**	**.04**	**.29**	**.84**	**.70**	**False (-)**
D	**.94**	**.78**	**.71**	**.22**	**.06**	**.81**	**.70**	**False (+)**
E	**---**	**0**	**0**	**1**	**---**	**0**	**---**	**False +100%**
F	**0**	**0**	**0**	**1**	**1**	**0**	**-1**	**False+-100**
H	**.45**	**.46**	**.40**	**.54**	**.55**	**.46**	**-.08**	**Random**

Measures:

1 = Sensitivity ***TPR = TP / (TP + FN)***
2 = Specificity ***SPC = TN / (FP + TN)***
3 = Precision ***PPV = TP / (TP + FP)***
5 = False Positive ***FPR = FP / (FP + TN)***
7 = False Negative ***FNR = FN / (FN + TP)***
8 = Accuracy ***ACC = (TP +TN) (P + N)***
10 = Correlation ***((TP)(TN)) - ((FP)(FN)) / SQRT((TP + FP)(TP + FN)(TN + FP)(TN + FN))***

PP = Predicted Positive = CI+
PN = Predicted Negaive = CI-
TP= True Positive = KI+
TN = True Negative =KI-

	TRUE POSITIVE (TP)(KI+)	***TRUE NEGATIVE (TN)(KI-)***
PREDICTED POSITIVE (PP)(CI+)	***++***	***+-***
PREDICTED NEGATIVE (PN)(CI-)	***-+***	***--***

CI+/CI-/KI+/KI-

A = 25/0/0/25 – Perfect match between CI and KI.
B = 13/12/12/13 – Random matching between CI and KI.
C = 17/7/1/25 – KI+ x CI- (False-)
D = 17/1/7/25 – KI- x CI+ (False+)
E = 0/0/50/0 – KI- x CI+ unlikely
F = 0/25/25/0 - False + & - 100% unlikely
H = 20/24/30/26 – Random matching between CI and KI.

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A Theory on the Relationship With Professional Development, Program Quality and Regulatory Compliance Predicting Early Childhood Outcomes

Richard Fiene, Ph.D.

July 2019

This abstract is the compilation of 50 years of research into early childhood professional development, program quality indicators and regulatory compliance and their respective impact on early childhood outcomes. Professional development, program quality and regulatory compliance all have impacts on early childhood outcomes (ECO) but if we put them all in the same equation, what are their relative impact on outcomes. That is the purpose of this abstract. Based upon results from the Research Institute for Key indicators (RIKI) Early Childhood Program Quality Improvement and Indicators Model (ECPQIM) data base, it is now possible to ascertain their relative weights.

For purposes of this abstract, professional development (PD) includes any training, coaching or technical assistance which focuses on teaching staff. Program quality (PQ) includes Quality Rating and Improvement Systems (QRIS) standards and their respective observational evaluations (ERS, CLASS). Regulatory compliance (RC) includes licensing health and safety rules and regulations as promulgated and enforced by state agencies. In the past, these systems have been dealt with in silos and there has been very little attempts at combining them in any fashion. One of the results of the ECPQIM data base was and is to attempt combining these various systems into a unified equation or algorithm.

Based on the results of the ECPQIM data base results, the following equation/algorithm can depict this unified relationship:

$$ECO = \Sigma\ (.50PD + .30PQ + .20RC)$$

In this relationship, the largest impact comes from the PD system, followed by the PQ system and lastly by the RC system. The implications of this relationship are that states may want to reconsider how they are allocating resources based upon this above equation/algorithm. This is a controversial proposal but one that should be considered since it is driven by empirical evidence into the relative impact over the past 50 years of research related to professional development, program quality and regulatory compliance as they relate to early childhood outcomes.

The Ten Principles of Regulatory Compliance Measurement

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March 2023

Abstract

This paper will outline ten principles of regulatory compliance measurement that have been gleaned from 50 years of research into regulatory and licensing databases. For the purposes of this paper, regulatory compliance is to be used interchangeably with licensing and regulatory science. The source of the data is from many jurisdictions in both the United States and Canada. A sampling of these data is displayed on Mendeley Data. These ten principles have been found repeatedly in the various data sets from the jurisdictions that have been analyzed over the past 50 years.

The ten principles to be addressed are the following:

Lack of Variance in data distributions. Data tightly grouped at high compliance levels.

Ceiling/Plateau Effect in data distributions.

Difficulty distinguishing levels of quality between full and substantial compliance.

Nominal measurement level: Either In-Compliance or Out-of-Compliance.

Attempting to move to ordinal measurement level when quality is included.

Dichotomization of data is warranted because of the data distribution.

Problem with false negatives and positives, especially false negatives.

Lack of reliability and validity testing.

Ease in distinguishing levels of quality between low and substantial compliance.

Skewed Data. Majority of programs in substantial or full regulatory compliance.

The first principle deals with the lack of Variance in data distributions. Data are found to be tightly grouped at high compliance levels (upper 90% level). This will lead to another principle addressed later in this paper dealing with skewness of the data distribution. In fact, the majority of scores are at a full regulatory compliance level, in other words, 100% in compliance with all rules and regulations. This led to variance statistics showing little movement and the majority of programs being in very close proximity. This makes for difficult statistical analyses when there is little variance in the data set.

The second principle is finding a ceiling or plateau effect in data distributions. It was like there was a diminishing returns effect as one moves from substantial regulatory compliance (upper 90%+) to full regulatory compliance (100%) with all rules and regulations. This was especially true when one compares the regulatory compliance levels with program quality scores on those same programs which is addressed more in the next principle.

The third principle is the difficulty distinguishing levels of quality between full and substantial compliance. This principle builds off of the previous principle dealing with a ceiling or plateau effect. Because so much of the data, as much as 70-80% of programs, are grouped so tightly at the substantial and high levels of regulatory compliance when one begins to go beyond regulatory compliance and begin to look at quality there is a great deal of difficulty distinguishing levels of quality. In other words, the full regulatory compliant level programs are not necessarily the highest quality programs.

The fourth principle is the fact that rules and regulations are measured at a nominal measurement level: the rules and regulations are either In-Compliance or Out-of-Compliance. The rule or regulation is measured at a "Yes" or "No" level or a "1" or "0" level. There are no in-between measures, no ordinal measurement going on. Either you got it, or you don't. It is black or white, no shades of gray. It is just the nature of measurement when it comes to rules and regulations which are very different in other measurement systems. The data are very discrete and not continuous. They are frequency counts and not a ruler type of measurement. One will not find an interval level of measurement in any regulatory science data distribution.

A fifth principle is attempting to move to an ordinal measurement level when quality is included. This principle builds off of the previous principle in which in some cases it has been suggested to add a quality component to particular rules or regulations. This is an interesting development and moves the philosophy from one of "Do no harm" to one of "Do things well". It will be interesting to see how much this concept moves forward and changes a basic tenet in the regulatory science field which is more based upon health & safety, gatekeeper, hard data, risk aversion, and deficit based.

The sixth principle of regulatory compliance measurement is the ability to dichotomize the data can be warranted because of the data distribution. Data dichotomization is generally not recommended because it accentuates differences in a data set. However, given the nature of regulatory compliance measurement being at a nominal level, fitting into a bucket format, the lack of variance, and the skewness of the data distribution all lead to the ability to dichotomization of the data set.

The seventh principle has to do with the problem with false negatives and positives, especially false negatives. Because of the data being measured in a nominal In-Compliance vs Out-of-Compliance dichotomy it can lead to false negatives in which In-Compliance decisions are made that in reality are not In-Compliance. False positives are a problem as well but not as much of a problem as false negatives. In false positives, Out-of-Compliance may be determined when in reality the rule or regulation is actually In-Compliance. This is not a good scenario for the provider of services, but it potentially doesn't harm the client as much as when a false negative occurs.

The eighth principle is the lack of reliability and validity testing. This principle builds from the previous principle in that there are very few examples of scientific testing of instrumentation and the administration of protocols to make certain that everything is running as it should. Because of this, it leads to the above problem of false positives and negatives. All jurisdictions need to build in regular reliability and validity testing to ascertain that the final decision making is within the ranges that are acceptable.

The ninth principle is the ease in distinguishing levels of quality between low and substantial compliance. The one result that has been consistent over the years is the ability to see differences in programs that score low on regulatory compliance versus those that are at a substantial or high compliant level. From a licensing or regulatory administration point of view this is a real plus in being able to be an effective gatekeeper and keeping non-optimal programs out of service. But as indicated in the third principle this advantage is short-lived as one moves up the regulatory compliance scale to substantial and finally to full regulatory compliance. When one gets to these levels it becomes increasingly difficult to distinguish differences in quality in those programs that are in substantial regulatory compliance versus those that are in full regulatory compliance. It appears that the regulatory compliance theory of diminishing returns is rearing its plateau/ceiling effect. The policy implications are immense since the assumption is that there is a linear relationship between program quality and regulatory compliance. How do we more effectively deal with this non-linear relationship in formulating public policy regarding licensing decision making?

And the final tenth principle is that regulatory compliance data are always skewed data. The majority of programs are in substantial or full regulatory compliance. And in many cases, this can be rather severe. There generally is a long tail which contains some low regulatory compliant programs, but these are usually few in number. The data distribution just does not approach a normally distributed curve as we see in many other examples of social science data distributions.

It is important as the regulatory science field moves forward that we remain cognizant of the limitations of regulatory compliance measurement. There are some severe limitations that need to be addressed (e.g., skewed data, lack of variance in data, ceiling effect, nominal metrics) and mitigated (e.g., data dichotomization) or it will continue to lead to problems in our analyses (e.g., false positives and negatives).

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The Regulatory Compliance Matrices: Risk, Compliance, and Licensing Decision Making

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February 2024

Several forms of matrices have been used in describing the parameters of regulatory compliance, such as for risk assessment, compliance patterns, and decision making along an uncertainty-certainty rubric. This research abstract will distill this thinking into one approach in attempting to standardize the various approaches into a 2x2 matrix approach. Most of the other approaches utilize a 2x2 format except for the risk assessment matrix (RAM)(3x3) but that will also be put into the same 2x2 format.

Table 1: Risk Assessment Matrix based upon Risk/Severity and Probability of Happening

Risk Assessment (RAM)		Risk/Severity	Risk/Severity
		High	Low
Probability	High	4	2
Probability	Low	3	1

Table 1 provides the 2x2 logic to the matrix in how risk assessment would be determined based upon the potential risk/severity of a particular rule/regulation and its potential or probability of being out of compliance. This new 2x2 matrix transitions from a 3x3 matrix with the same horizontal and vertical axis's but now it is much more streamlined and consistent with the other matrices used to describe the parameters within regulatory compliance. Obviously, the higher the number, the greater the risk and the greater the potential of it occurring. The lower the number, the lower the risk and the lower the potential of it occurring. The resulting rules from RAM are ones that are to be reviewed every time an inspection is done, no exceptions.

Table 2: Uncertainty-Certainty Matrix (UCM) regarding Compliance and Decision Making

UCM Matrix Logic		Decision Regarding	Compliance
		In Compliance	Not in Compliance
Actual State of	In Compliance	Agreement	Disagreement
Compliance	Not In Compliance	Disagreement	Agreement

The above UCM matrix demonstrates when agreement and disagreement occur which establishes a level of certainty (Agreement Cells) or uncertainty (Disagreement Cells). In a perfect world, there would only be agreements and no disagreements between the decisions made about regulatory compliance and the actual state of regulatory compliance. But from experience, this is not the case based upon reliability testing done in the licensing research field in which a decision is made regarding regulatory compliance with a specific rule or regulation and then that is verified by a second observer who generally is considered the measurement standard.

Disagreements raise concerns in general, but the disagreements are of two types: false positives and false negatives. A false positive is when a decision is made that a rule/regulation is out of compliance when it is in compliance. Not a good thing but its twin disagreement is worse where with false negatives it is decided that a rule/regulation is complying when it is out of compliance. False negatives need to be avoided because they place clients at extreme risk, more so than a false positive. False positives should also be avoided but it is more important to deal with the false negatives first before addressing the false positives.

Table 3: Key Indicator Compliance based upon History and Individual Reviews

Indicator Compliance (KIM)		Compliance History	
		High Group	Low Group
Individual Review	In Compliance	Medium	Low-False Positive
	Not In Compliance	High-False Negative	Medium

Key indicators are statistical predictor rules which statistically predict overall regulatory compliance. They are the efficient driver of the theory of regulatory compliance where risk assessment rules are the effectiveness driver of the theory. Key indicator rules can be used as focused inspections as if the full set of rules were applied. This is not the case with risk assessment rules because risk assessment rules do not predict, they ensure that the most risk-based rules are always reviewed. Key indicator rules are the predictor rules.

But even though key indicator rules are statistical predictor rules, there are specific cautions with their application. For example, in doing focused reviews, false negatives need to be eliminated or at least reduced substantially. Having false negatives creates a highly negative outcome where the key indicators say that everything is ok when they are not, there are other areas of non-compliance. False positives can also occur (this is where the key indicators say things are not ok when they really are ok, there are no other areas of non-compliance), these are not as critical as the false negatives but should be minimized as best as possible. Key indicator rules are generally of medium non-compliance and medium risk value. They are not like risk assessment rules which are always heavily risk aversive and have very low non-compliance rates. The risk is high, but non-compliance is low.

The hope here is to begin to standardize the parameters, logic, and rubrics for measurement related to risk, compliance, and decision making in licensing. By moving to a 2x2 matrix format it should provide some consistency in doing this moving forward.

This research abstract will provide a glimpse at the major theories of regulatory compliance:

1. Responsive regulation (Ayers & Braithwaite, 1992)

This theory argues that regulation should be responsive to the needs of both regulators and those who are regulated. It suggests that regulators should use a variety of tools, including persuasion, negotiation, and enforcement, to achieve compliance. The goal is to create a system of regulation that is both effective and fair.

2. Socio-economic theory of regulatory compliance (Sutinen & Kuperan, 1999)

This theory argues that regulatory compliance is influenced by a variety of factors, including economic incentives, social norms, and the perceived legitimacy of the regulator. The theory suggests that regulators should design regulations that take these factors into account.

3. Diminishing returns theory of regulatory compliance (Fiene, 2019)

This theory argues that there is a diminishing relationship between the level of regulatory effort and the level of compliance. The theory suggests that regulators should focus their efforts on the most important areas of risk and avoid over-regulation.

Authors of the theories:

Responsive regulation: Ian Ayres and John Braithwaite

Socio-economic theory of regulatory compliance: Jon G. Sutinen and Kuperan Viswanathan

Diminishing returns theory of regulatory compliance: Richard Fiene

These theories have been influential in shaping our understanding of regulatory compliance and how to achieve it. They have been used to develop a variety of regulatory approaches, including risk-based regulation, performance-based regulation, and collaborative regulation.

It is important to note that these theories are not mutually exclusive. In fact, they can be complementary. For example, responsive regulation can be used to implement socio-economic theory and diminishing returns theory.

Regulators should consider all of these theories when designing and implementing regulatory programs. The best approach will vary depending on the specific context.

Here is additional information about Regulatory Compliance Theory of Diminishing Returns (TRC+):

The Regulatory Compliance Theory of Diminishing Returns (TRC+) is a fascinating concept that challenges the traditional "more regulation is better" approach to public policy. It suggests that there's a sweet spot for compliance, where increasing efforts beyond that point yield less and less benefit in terms of program quality and public safety.

The Regulatory Compliance Theory of Diminishing Returns (TRC+) challenges the traditional assumption that 100% compliance with regulations is always the best goal for achieving desired outcomes in public policy. Instead, it posits that substantial, not full, compliance is the most effective and efficient approach, yielding similar positive outcomes while requiring fewer resources.

Overall, the Regulatory Compliance Theory of Diminishing Returns offers a valuable new perspective on the complex relationship between regulation and program quality. While further research is needed to fully understand its implications, it has the potential to inform more effective and efficient regulatory approaches in various public policy domains.

Here are some key points about the theory:

The theory proposes that the relationship between regulatory compliance and program quality isn't linear, but rather follows a diminishing returns curve. This means that while initial compliance efforts can significantly improve program quality, the impact of additional efforts becomes progressively smaller, eventually reaching a point where further increases in compliance bring negligible or even negative returns.

As compliance efforts increase, the incremental benefits in terms of program quality or public safety diminish at a faster rate. This means that, beyond a certain point, investing more resources to achieve perfect compliance won't significantly improve outcomes.

The theory is based on research in various areas, including early childhood education, adult care, and environmental protection. These studies have shown that programs with substantial compliance (around 80-90%) tend to achieve similar quality and safety standards as those with 100% compliance, while spending less on monitoring and enforcement.

Key elements:

Regulatory Compliance Key Indicator Matrix (RCKIM): This tool helps assess program compliance based on two key factors: 1) substantial compliance: meeting core regulatory requirements, and 2) full compliance: meeting all regulatory requirements, even minor ones.

Regulatory Compliance Scaling (RCS): This concept emphasizes that the optimal level of compliance effort can vary depending on the specific context and program goals.

Program Quality Scoring Matrix (PQSM): This framework helps evaluate program quality by considering multiple dimensions, not just compliance.

Substantial, not full, compliance: TRC+ argues that focusing on achieving a high level of compliance, not necessarily 100%, is more effective and efficient. This is because:

Full compliance can be costly and impractical to achieve, especially in complex systems with nuanced regulations.

The marginal benefit of further compliance improvements often diminishes as the system already reaches a high level of adherence.

Risk assessment and key indicators: TRC+ emphasizes the importance of risk-based approaches to compliance. This involves identifying areas with higher risks and focusing resources on those areas, rather than a blanket approach. Key performance indicators (KPIs) can be used to track progress and measure the effectiveness of compliance efforts.

Regulatory compliance scaling: TRC+ proposes a framework called "regulatory compliance scaling" (RCS) that categorizes programs based on their compliance level and risk profile. This allows for targeted interventions and monitoring strategies, ensuring resources are allocated efficiently.

Program quality scoring matrix: TRC+ utilizes a scoring matrix to assess program quality based on various factors, not just compliance. This helps in understanding the broader impact of regulatory efforts and identifying areas for improvement beyond just ticking compliance boxes.

Implications:

Shifting focus from full compliance to substantial compliance: TRC+ suggests that focusing solely on achieving 100% compliance might not be the most effective or efficient approach. Instead, ensuring substantial compliance with core regulations may be sufficient to achieve good program quality and public safety, while freeing up resources for other areas.

More targeted and risk-based monitoring: The theory suggests that monitoring efforts should be more targeted towards programs with lower compliance, rather than applying a one-size-fits-all approach.

Promoting innovation and flexibility: By acknowledging the limitations of strict compliance, TRC+ encourages policymakers to consider more flexible and innovative approaches to regulation that allow programs to adapt and improve.

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Shifting focus: TRC+ encourages a shift from punitive, compliance-driven approaches to more collaborative, risk-based strategies. This can lead to better relationships between regulators and regulated entities.

Resource optimization: By focusing on areas with the highest potential impact, TRC+ can help optimize resource allocation and achieve better outcomes with less effort.

Data-driven decision making: TRC+ emphasizes the use of data and KPIs to inform decision-making about regulatory interventions and monitoring. This can lead to more evidence-based and effective policies.

Risk-based approach: Resources can be prioritized based on the potential risks associated with non-compliance in different areas. This allows for more efficient allocation of resources and better targeting of interventions.

Innovation in monitoring: The TRC+ encourages exploring alternative monitoring approaches that go beyond traditional inspections and checklists. This could include data-driven methods, self-assessment tools, and collaborative partnerships between regulators and regulated entities.

Criticisms:

Lack of empirical evidence: While the theory has been supported by some research in human service programs, it's still relatively new and lacks extensive empirical validation across diverse contexts.

Potential for abuse: Some critics argue that focusing on substantial compliance could be used as a justification for lowering regulatory standards or reducing oversight, potentially compromising public safety.

Difficulty in measuring program quality: Critics argue that measuring program quality beyond compliance can be subjective and challenging.

Potential for regulatory capture: Concerns exist that focusing on substantial compliance might lead to leniency and reduced enforcement, potentially undermining the effectiveness of regulations.

Limited applicability: Some argue that TRC+ might not be suitable for all types of regulations, particularly those dealing with high-risk activities.

Data limitations: Some argue that the evidence base for the TRC+ is limited to specific sectors and may not be generalizable to all areas of regulation.

Implementation challenges: Shifting away from a "zero-tolerance" approach to compliance can be difficult, requiring changes in regulatory culture and potentially facing resistance from stakeholders.

Risk of under-compliance: Critics worry that focusing on substantial compliance could lead to some entities falling below acceptable standards.

In conclusion, the regulatory compliance theory of diminishing returns offers a valuable framework for thinking about regulatory effectiveness and resource allocation. By focusing on substantial compliance, risk assessment, and program quality, it can help to achieve better outcomes with fewer resources. However, it's important to carefully consider the limitations and potential challenges of this approach before applying it to specific policy contexts.

The TRC+ is a valuable theory that provides a new perspective on regulatory compliance. While it doesn't advocate abandoning regulations altogether, it encourages policymakers to consider a more nuanced and efficient approach that balances the costs and benefits of achieving different levels of compliance.

Here are some additional resources you might find helpful:

TRC+: Regulatory Compliance Theory of Diminishing Returns:
https://nara.memberclicks.net/assets/docs/KeyIndicators/Fiene%20TRC%20JRS%207%202019.pdf

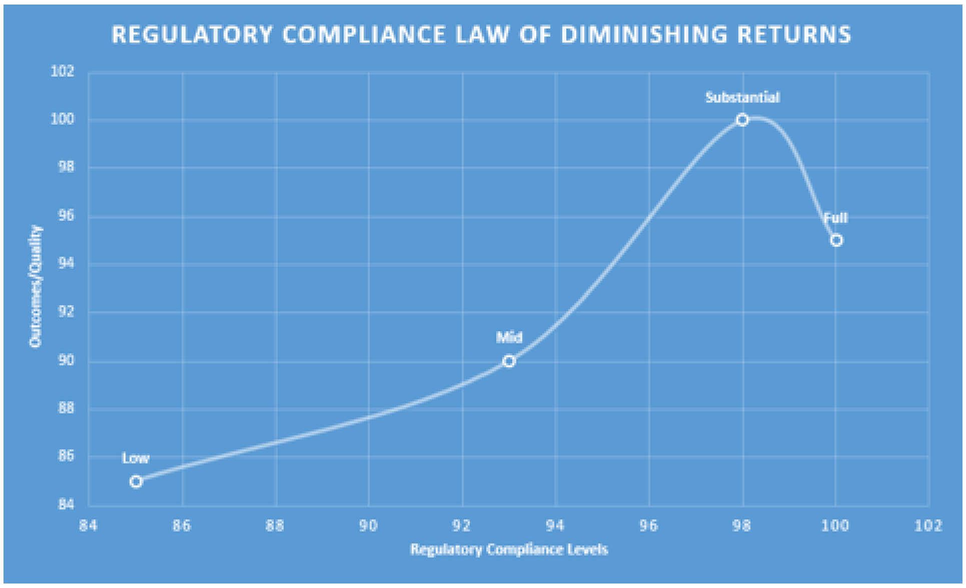
The Public Policy Implications of the Regulatory Compliance Theory of Diminishing Returns:
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4391924

The Relationship between the Theory of Regulatory Compliance and the Fiene Coefficients

Richard Fiene PhD

October 2023

This paper will formalize the logical relationship between the theory of regulatory compliance and the Fiene Coefficients as demonstrated by key predictor rules and risk assessment rules. The relationship between the theory and the coefficients has been implicated in previous research but it is clear now from a public policy and research perspective that it is in everyone's best interest to move substantial regulatory compliance to the identification of key risk predictor rules. It is the only way to develop more effective and efficient program monitoring systems, not only in the human services but throughout regulatory science.



The above graph depicts the relationship between regulatory compliance and program quality that has been demonstrated in repeated studies over the past decade. It clearly shows how moving from substantial to full regulatory compliance does not produce an equal increase in quality. In fact, in the studies to date, either quality dropped off as depicted in the graphic or it plateaued out and showed no statistically significant increase. This is problematic from a public policy standpoint which requires full regulatory compliance with all rules. It just is not an effective or efficient approach. A more effective and efficient approach would be one of finding the rules that are predictor rules and those rules which place children/clients at greatest risk of harm. An approach that balances "Do No Harm" along with "Do Good". This is depicted more clearly in the next graphic.

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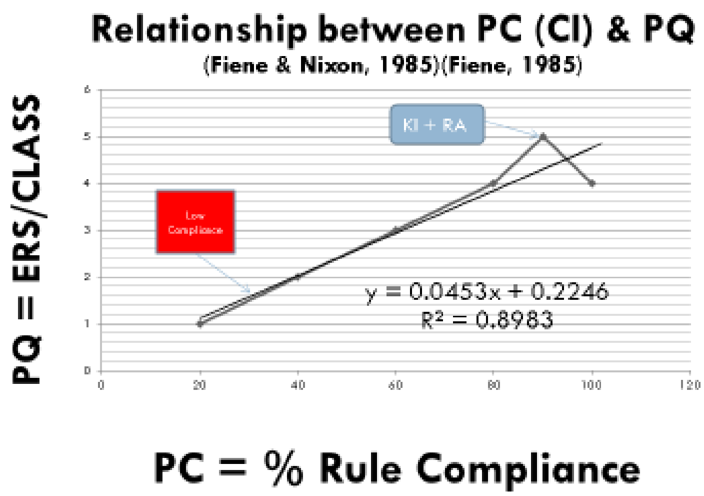

The above graph builds upon the previous graphic in providing additional detail about the relationship between regulatory compliance and program quality and at the same time where risk assessment and key indicator predictor rules can come into play. The next group of figures will provide displays of the risk assessment methodology and the key indicator predictor methodology providing key decision points related to licensing decisions and how rules get included as key indicator predictor rules. The figure below presents the risk assessment matrix that is used in determining the relative risk of particular rules as well the key licensing decisions made from these determinations.

Risk Assessment Matrix (RAM)

Risk Assessment (RA) Matrix Revised

	Levels	High	Medium	Low
Risk/Severity	Immediate	9	8	7
	Short-term	6	5	4
	Long-term	3	2	1
			Probability	
	Regulatory Compliance (RC): # of Rules out of compliance and in compliance	8+ rules out of compliance. 92 or less regulatory compliance.	3-7 rules out of compliance. 93 – 97 regulatory compliance.	2 or fewer rules out of compliance. 98 – 99 regulatory compliance.

*Regulatory Compliance (RC)(Prevalence/Probability/History + Risk/Severity Level)

Tier 1 = ((RC = 93 – 97) + (Low Risk)); ((98 – 99) + (Low Risk)) = Tier 1

Tier 2 = (RC = 92 or less) + (Low Risk) = Tier 2

Tier 3 = ((RC = 93 – 97) + (Medium Risk)); ((98 – 99) + (Medium Risk)) = Tier 3

Tier 4 = (RC = (92 or less) + (Medium Risk)) = Tier 4; ((93 -97) +(High Risk)) = Tier 4; ((98 – 99) + (High Risk)); ((92 or less) + (High Risk)) = Tier 4+

Using RAM to make licensing decisions

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Key Indicator Formula Matrix

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Use data from this matrix in the formula on the next slide in order to determine the phi coefficients.

	Providers In Compliance with specific standard	*Programs Out Of Compliance with specific standard*	*Row Total*
High Group = top 25%	*A*	*B*	*Y*
Low Group = bottom 25%	C	D	Z
Column Total	*W*	*X*	Grand Total

The above figure provides the key indicator formula matrix in designing how the data will be organized for analysis in determining which rules are predictive of overall regulatory compliance. The below figure presents the expected results from the matrix.

Key Indicator Matrix Expectations

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- **A + D > B + C**
- **A + D** = 100% is the best expectation possible.
- If **C** has a large percentage of hits, it increases the chances of other areas of non-compliance (False positives).
- If **B** has a large percentage of hits, the predictive validity drops off considerably (False negatives). This can be eliminated by using 100% compliance for the High Group.

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Key Indicator Statistical Methodology

$$\phi = (A)(D) - (B)(C) \div \sqrt{(W)(X)(Y)(Z)}$$

A = High Group + Programs in Compliance on Specific Compliance Measure.
B = High Group + Programs out of Compliance on Specific Compliance Measure.
C = Low Group + Programs in Compliance on Specific Compliance Measure.
D = Low Group + Programs out of Compliance on Specific Compliance Measure.

W = Total Number of Programs in Compliance on Specific Compliance Measure.
X = Total Number of Programs out of Compliance on Specific Compliance Measure.
Y = Total Number of Programs in High Group.
Z = Total Number of Programs in Low Group.

The above figure provides the formula for generating the Fiene Coefficient for Key Indicator Predictor Rules. It takes the data from the key indicator formula matrix and generates those specific rules that meet the key indicator matrix expectations. The below figure provides the algorithm for generating the key indicator predictor rules.

Theory of Regulatory Compliance Algorithm (Fiene KIS Algorithm)

- 1) ΣR = C
- 2) Review C history x 3 yrs
- 3) NC + C = CI
- 4) If CI = 100 -> KI
- 5) If KI > 0 -> CI or if C < 100 -> CI
- 6) If RA (NC% > 0) -> CI
- 7) KI + RA = DM
- 8) KI = ((A)(D)) - ((B)(E)) / sqrt ((W)(X)(Y)(Z))
- 9) RA = ΣR1 + ΣR2 + ΣR3 + ….. ΣRn / N
- 10) (TRC = 99%) + (φ = 100%)
- 11) (CI < 100) + (CIPQ = 100) -> KI (10% CI) + RA (10-20% CI) + KIQP (5-10% of CIPQ) -> OU

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Legend:

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- R = Rules/Regulations/Standards
- C = Compliance with Rules/Regulations/Standards
- NC = Non-Compliance with Rules/Regulations/Standards
- CI = Comprehensive Instrument for determining Compliance
- ϕ = Null
- KI = Key Indicators; KI >= .26+ Include; KI <= .25 Null, do not include
- RA = Risk Assessment
- ΣR1 = Specific Rule on Likert Risk Assessment Scale (1-8; 1 = low risk, 8 = high risk)
- N = Number of Stakeholders
- DM = Differential Monitoring
- TRC = Theory of Regulatory Compliance

These two figures on this page provide the legends for the key indicator predictor algorithm presented on the previous page. It provides the definitions of each of the terms utilized in the previous figures presented in this paper.

Legend (cont)

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- CIPQ = Comprehensive Instrument Program Quality
- KIPQ = Key Indicators Program Quality
- OU = Outcomes
- A = High Group + Programs in Compliance on Specific Compliance Measure (R1...Rn).
- B = High Group + Programs out of Compliance on Specific Compliance Measure (R1...Rn).
- E= Low Group + Programs in Compliance on Specific Compliance Measure (R1...Rn).
- D = Low Group + Programs out of Compliance on Specific Compliance Measure (R1...Rn).
- W = Total Number of Programs in Compliance on Specific Compliance Measure (R1...Rn).
- X = Total Number of Programs out of Compliance on Specific Compliance Measure (R1...Rn).
- Y = Total Number of Programs in High Group (ΣR = 98+).
- Z = Total Number of Programs in Low Group (ΣR <= 97).
- High Group = Top 25% of Programs in Compliance with all Compliance Measures (ΣR).
- Low Group = Bottom 25% of Programs in Compliance with all Compliance Measures (ΣR).

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Theory of Regulatory Compliance, Regulatory Compliance Scale, and Differential Monitoring

Richard Fiene PhD

Penn State Edna Bennett Pierce Prevention Research Center

June 2024

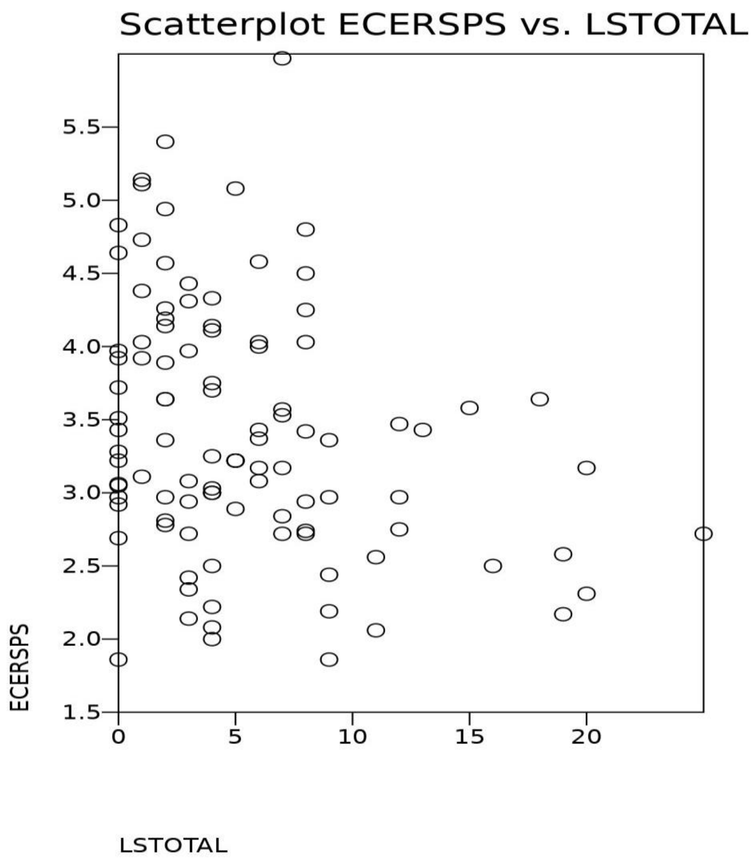
The theory of regulatory compliance has been proven in multiple studies over the past four decades and has been utilized extensively in the creation of differential monitoring and its spin off methodologies of risk assessment and key indicators. In fact, differential monitoring would not have been possible without the theory of regulatory compliance because the paradigm which it replaced, one of one-size-fits-all monitoring or uniform monitoring would have predominated. However, with the theory of regulatory compliance which introduced the importance of substantial regulatory compliance and the search for the right rules/regulations that made a difference in client's lives, rather than emphasizing more or less regulations or rules.

The theory of regulatory compliance has another application when it comes to regulatory compliance measurement in helping to move the licensing field from a nominal based measurement strategy to one of ordinal based measurement. The new measurement strategy is the Regulatory Compliance Scale (RCS) and it is depicted in the following table.

RCS	***Compliance***	***Risk***	***Model***	***Model***
Scale	***Level***	***Level***	***Violations***	***Weights***
7 = A	**Full**	**None**	**0**	**0**
5 = B	**Substantial**	**Low**	**1-3**	**1-3**
3 = C	**Medium**	**Medium**	**4-9**	**4-6**
1 = D	**Low**	**High**	**10+**	**7+**

The above table needs some explanation. The first column is the proposed ordinal scale similar to other scales utilized in the program quality measurement research literature on a 1 – 7 Likert Scale where 7 = Full Regulatory Compliance, 5 = Substantial Regulatory Compliance, 3 = Medium Regulatory Compliance, and 1 = Low Regulatory Compliance. It could also be thought of as an Alpha Scale of A – D as well. The next column has the compliance levels that run from full 100% regulatory compliance to low regulatory compliance. The third column depicts the risk level from none to high which corresponds with the compliance levels. The next two columns depict two models, one unweighted and one in which the rules are weighted with corresponding weights. These models are based upon the two prevailing approaches to rank ordering rules or regulations in the research literature.

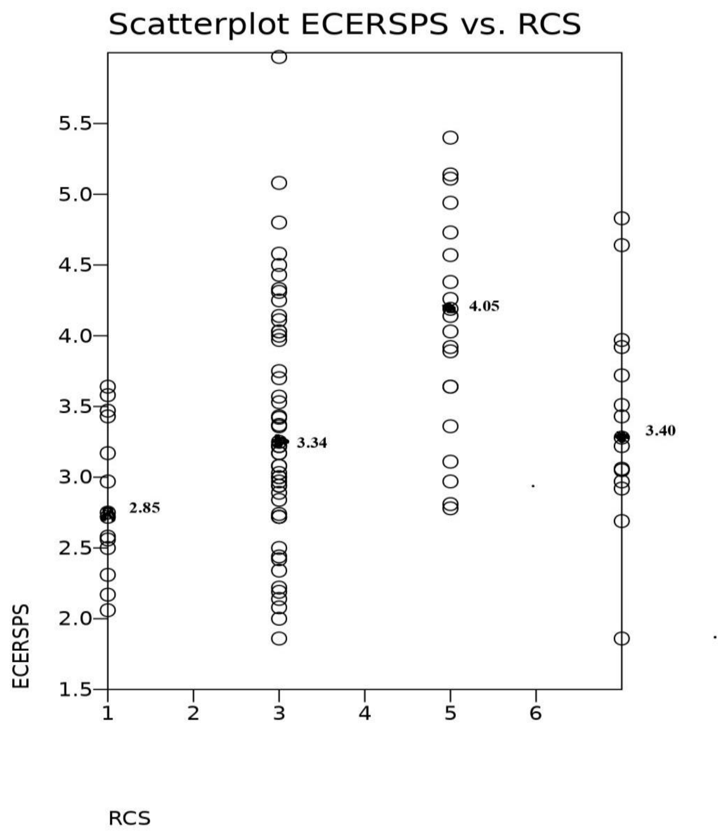
The following figures will depict how the scale was conceived based upon empirical evidence in the various studies supporting the theory of regulatory compliance. The first figure shows the actual individual violation data of the programs compared to their corresponding ECERS scores. There is not a significant relationship between the two as depicted in the graphic.



The following figure below depicts what occurs when the individual violation data are grouped according to the theory of regulatory compliance in which a substantial compliance category is introduced and the data are moved from a nominally based metric to an ordinally based metric of full, substantial, medium, and low regulatory compliance categories. This grouping more clearly reflects the theory of regulatory compliance. It also clearly demonstrates the ceiling effect which is an outcome of the theory of regulatory compliance in which substantial and full regulatory compliance levels are basically equivalent when quality is taken into account. Or at the extreme level which is depicted here where full regulatory compliance quality scores are actually lower than the substantial regulatory compliance quality scores. A footnote about the figures and the scaling: the scales for the first figure are on a lower to higher progression but the higher LSTOTAL represents higher non-compliance where the second figure is also based upon lower to higher but the higher scores represent increased quality and increased regulatory compliance.

So, in reading the change from left to right, they two figures are reversed images of each other. This is just a quirk of the scaling and not a mistake in the plotting of data.

The RCS has been pilot tested in both the non-weighted and weighted models and based upon the these studies it appears to be more effective in distinguishing quality amongst the various categories rather than utilizing violation count data. This would be a significant improvement when it comes to licensing measurement. Of course, additional replication studies need to be completed before it would be recommended as a new Scale to be used for making licensing decisions.



The above figure is dramatically different than the prevailing paradigm which predicts a linear relationship between regulatory compliance and quality which is the paradigm of a uniform monitoring approach. The above results clearly indicate a reconsideration with the introduction of substantial regulatory compliance as an important contributor to overall quality if not the most important contributor to quality. As stated above, these findings have been replicated in several studies conducted over the past several decades.

This would be a major paradigm shift in moving from individual violation data counts to an ordinal scale metric but it does warrant additional research. The problem with individual violation data is that it doesn't take into account the relative risk of the individual rule which could place clients at increased risk of morbidity or mortality. Risk assessment has worked really well when coupled with key indicators in the differential monitoring approach and it appears to be an asset in the development of a Regulatory Compliance Scale (RCS).

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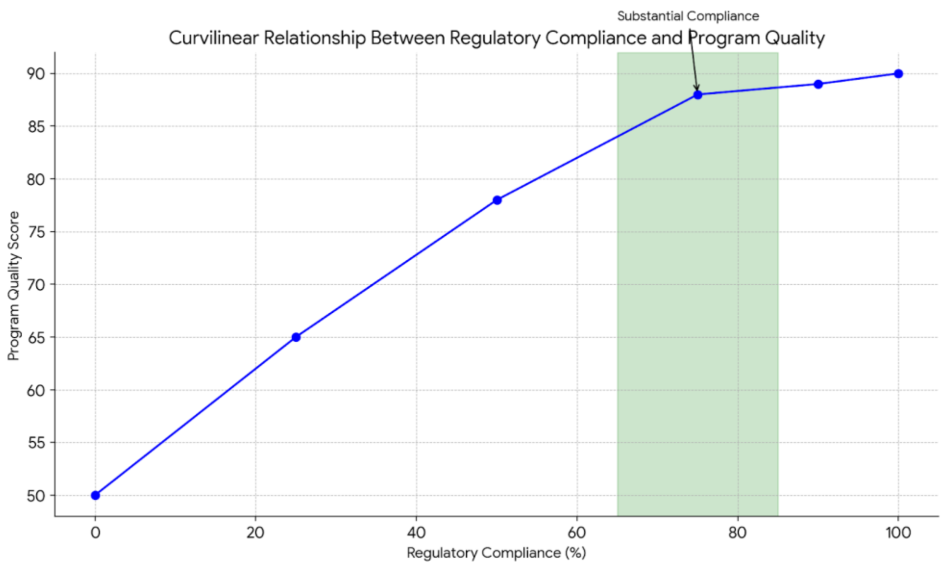
TRC+: Regulatory Compliance Theory of Diminishing Returns

Richard Fiene PhD

Research Institute for Key Indicators/Penn State University

January 2024

This research abstract will update the relationship between regulatory compliance and program quality (depicted in the below graph) using three equations listed below which deal with a simple linear model at the low compliance range, a threshold model at the midpoint compliance range, and a diminishing returns model at the higher compliance range. A fourth model is also proposed which places more emphasis on the program quality side of the equation going beyond compliance levels.



1. Simple Linear Model (Low Compliance Range):

For the lower end of the compliance spectrum, where achieving basic rules leads to improved quality, a simple linear model might be applicable:

Program Quality = a * Regulatory Compliance + b

This assumes a direct positive relationship between compliance (measured as 0-100%) and quality, represented by the slope "a" and baseline quality "b" when no compliance exists.

2. Threshold Model:

Another approach is to introduce a threshold level of compliance, below which there's minimal quality improvement, but exceeding it leads to rapid quality gains:

Program Quality = f(Regulatory Compliance - Threshold)

Here, "f" is a function (potentially non-linear) representing the quality increase based on exceeding the threshold level.

3. Diminishing Returns Model:

The theory emphasizes a "plateau effect" for high compliance levels, where further compliance improvements yield minimal quality gains. This can be captured through models like:

Program Quality = max(Quality_max , min (Regulatory Compliance, Quality_max))

Here, "Quality_max" represents the upper limit of achievable quality, and the equation ensures quality doesn't exceed this limit regardless of compliance exceeding it.

These three equations should help to fine tune the analyses related to TRC+: Regulatory Compliance Theory of Diminishing Returns. A fourth model is also proposed which expands the theory called the Multivariate Model:

4. Multivariate Model:

The theory acknowledges numerous factors influencing the relationship, including program type, regulatory agency, and implementation effectiveness. These can be incorporated into more complex, multivariate models, like:

Program Quality = f1(Regulatory Compliance, Program Type, Agency Effectiveness) + f2(Compliance Implementation)

This example utilizes various functions ("f1", "f2") to account for diverse influences on program quality, going beyond just compliance levels.

Remember, these are just conceptual examples, and the specific equation will depend on the context and chosen factors for analysis. It's crucial to consider the specific research questions and limitations of each model approach when interpreting the results.

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Relationship of the Theory of Regulatory Compliance, Key Indicators, & Risk Assessment Rules with Weights and Compliance Data

Richard Fiene, Ph.D.

April 2019

There is a relationship between general regulatory compliance levels, weights and how these work within the risk assessment and key indicator differential monitoring approaches. What generally happens is that there are high compliance levels with high risk assessment/weighted rules and with moderate weighted rules and low compliance levels with more low weighted rules which led to the Theory of Regulatory Compliance and an emphasis on substantial regulatory compliance. This is a general pattern and there are exceptions to every rule. Please see the chart below which depicts this relationship.

The reason for pointing this relationship out is for policy makers and researchers to be cognizant of these relationships and to be alert for when certain rules do not follow this pattern. Regulatory compliance data are very quirky data and because of its non-parametric characteristics can be difficult to analyze. I know that these results and relationships may seem self-evident, but they need emphasis because it is easy to overlook the obvious and to miss "the forest in looking at the trees".

Compliance	Weights	Approach	Violation of Approach
High	High	Risk Assessment Rules	Low Compliance with Rule
High - Medium	Medium	Key Indicator Rules	False Negatives
Medium	Low	Substantial Compliance	100% Compliance with all Rules

Let's walk through this chart.

High compliance means being in compliance with all or a substantial number of rules, but always keep in mind that when we are discussing regulatory compliance, being in high compliance means 100% - 99% in compliance with all rules. This is a very high standard and most programs can achieve these levels.

Medium compliance is still rather high regulatory compliance (98% - 97%) and is generally considered a high enough level for issuing a full license with a brief plan of correction. This is a level that is considered legally to be in substantial compliance with all rules. This regulatory result of substantial compliance led to the Theory of Regulatory Compliance and the public policy suggestion that substantial and not full (100%) regulatory compliance is in the best interests of clients. Low regulatory compliance, although not part of the chart above, happens very rarely. Programs that do not meet basic health and safety rules are issued cease and desist orders and are put out of business.

High weights are rules that place clients at greatest risk and should never be out of compliance. These are the Risk Assessment Rules that are always reviewed when a licensing inspection is completed, either when a full or abbreviated/differential monitoring visit is conducted. A licensing inspector does not want to leave a facility without having checked these rules.

Medium weights are rules that are very important but do not place clients at greatest risk. They generally add to the well-being of the client but will not jeopardize their health or safety. Generally, but not always, we find these rules as part of a licensing key indicator abbreviated inspection in a differential monitoring visit. For whatever, reason, facilities in high compliance generally have these in compliance and facilities in low compliance generally have these out of compliance or not in compliance. These are our predictor rules that statistically predict overall regulatory compliance.

Low weights are rules that do not have a real risk impact on the client. They are generally paper oriented rules, record keeping type rules. A lot of times they make it into the Key Indicator Rule list because it has to do with attention to detail and at times this will distinguish a high performing provider from one that is not doing as well. However, it can also have the opposite effect and these rules can "muddy the waters" when it comes to distinguishing between really high performing facilities and facilities that are just mediocre by contributing to data distributions that are highly skewed and difficult to find the "best of the best". Licensing researchers and policymakers need to pay attention to this dichotomy.

Risk assessment rules are those rules which have been identified as the most critical in providing the safeguards for clients when in out of home facilities. These rules are very heavily weighted and usually always in compliance. A violation of this approach is finding low compliance with specific risk assessment rules. These rules constitute approximately 10-20% of all rules.

Key indicator rules are those rules which statistically predict overall compliance with all rules. There is a small number of key indicator rules that are identified, generally less than 10% of all rules. These rules are in the mid-range when it comes to their weights or risk factor. And the rules are generally in high to substantial compliance. A violation of this approach is finding a facility in compliance with the key indicator rules but finding other rules out of compliance or the facility in the low group. (Please go to the following website for additional information http://RIKInstitute.com)

Substantial compliance is when the majority of the rules are in compliance with only a couple/few rules being out of compliance which are generally low weighted rules, such as paper driven rules. These rules are in the low-range when it comes to their weights or risk factor. Nice to have in place in being able to say we have "crossed every 't' and dotted every 'i'" but not critical in protecting the health, safety and well-being of the client. A violation of substantial compliance would be requiring full (100%) compliance with all rules.

This short RIKI Technical Research Note (#71) provides some additional guidance and interpretation of how particular patterns of licensing data impact and relate to each other. It is provided because of the nuances of regulatory compliance/licensing data which have limitations from an analytical perspective (Please see the RIKINotes blog on the RIKInstitute.com website).

Here is another way of looking at the chart presented on page 1 which incorporates all the elements elaborated in the chart: **Compliance, Weights, Approach, and Violation of the Approach (V).**

			Weights	
		High Risk	**Medium Risk**	**Low Risk**
Non-	**High NC**	**VRA**	**False Negative**	**TRC**
Compliance	**Medium NC**		**Key Indicators**	
(NC)	**Low NC**	**Risk Assessment**	**False Positive**	**VTRC**

VRA = Violation of Risk Assessment; VTRC = Violation of Theory of Regulatory Compliance.

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Theory of Regulatory Compliance Models

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August 2018

Three models are presented here which depict the theory of regulatory compliance as it has evolved over the past four decades. Initially, it was thought that there was a linear relationship between regulatory compliance and program quality as depicted in the first line graph below (see Figure 1). As compliance increased a corresponding increase in quality would be seen in the respective programs.

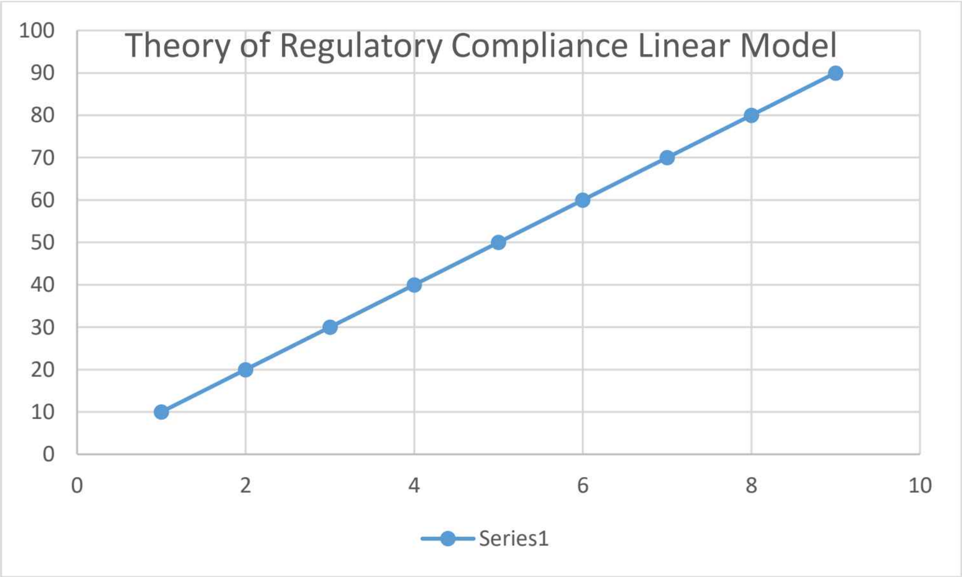

Figure 1

This initial graphic needed to be modified because of various studies conducted in order to confirm this regulatory compliance theory. It was discovered that at the lower ends of regulatory compliance there still was a linear relationship between compliance and quality. However, as the compliance scores continued to increase to a substantial level of compliance and then finally to full (100%) compliance with all rules, there was a corresponding drop off in quality as depicted in the second line graph below (see Figure 2).

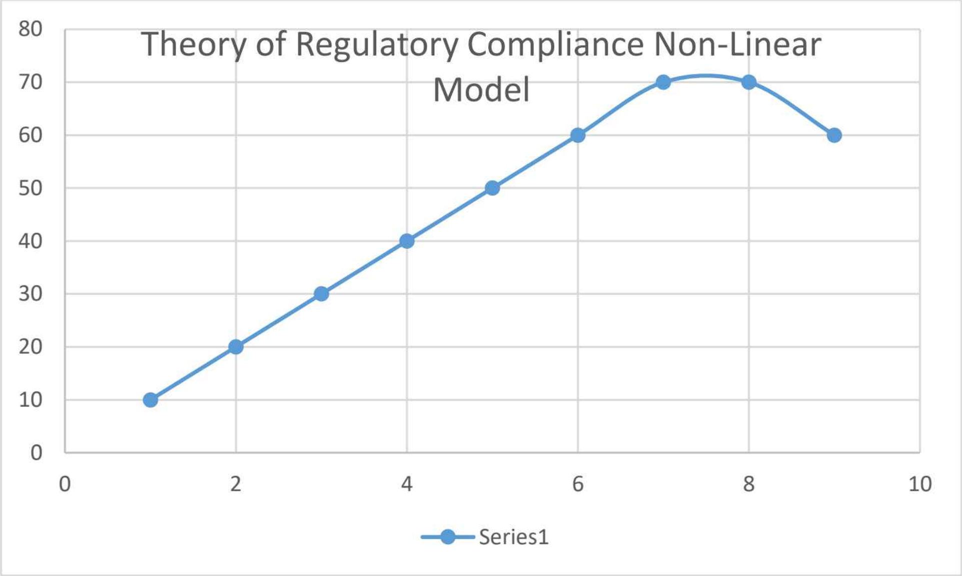

Figure 2

This Non-Linear Model has worked well in explaining the Theory of Regulatory Compliance and the studies conducted for the past three decades. However, the most recent studies related to the theory appear to be better explained by the latest proposed model in Figure 3 which suggests using a Stepped or Tiered Model rather than a Non-Linear Model. The Stepped/Tiered Model appears to explain more fully how certain less important rules can be significant predictors of overall compliance and quality.

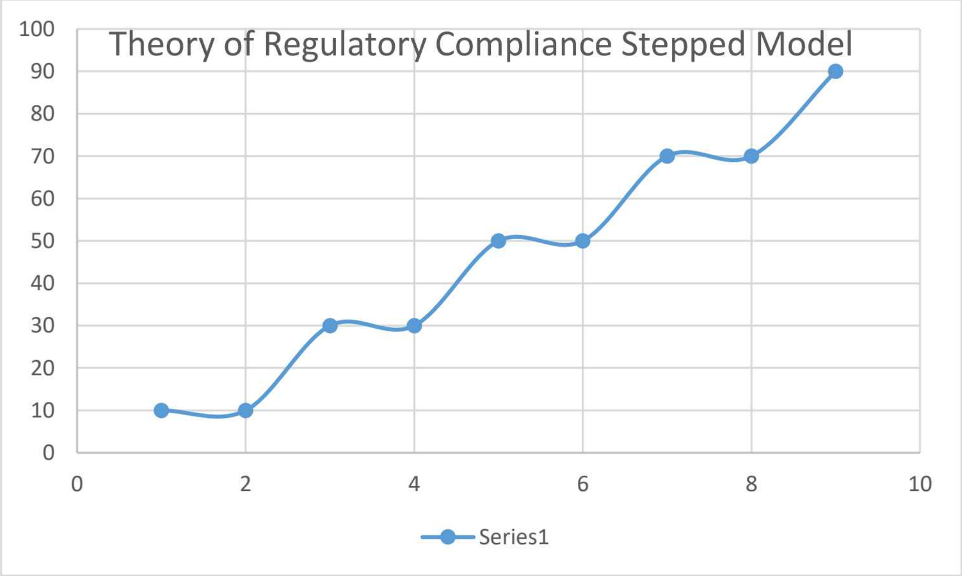

Figure 3

This last model (Stepped/Tiered) has more flexibility in looking at the full regulatory field in attempting to find the "predictor" or right rules that should be selected as key indicators. It is about identifying those key indicator rules that move the needle from one step/tier to the next rather than focusing on the plateau. So rather than having just one plateau, this model suggests that there are several plateaus/tiers.

Mathematically, the three models appear as the following:

1) $PQ = a\,(PC) + b$ ***(Linear)***
2) $PQ = a\,(PC)^b$ ***(Non-Linear)***
3) $PQ = a + ((b - a) / (1 + (PC / b)^b))$ ***(Stepped/Tiered)***

Where PQ = Program Quality; PC = Regulatory Program Compliance; a and b are regulatory constants

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The Twin Pillars of Regulatory Compliance: Reduction of Risk and Increase in Compliance

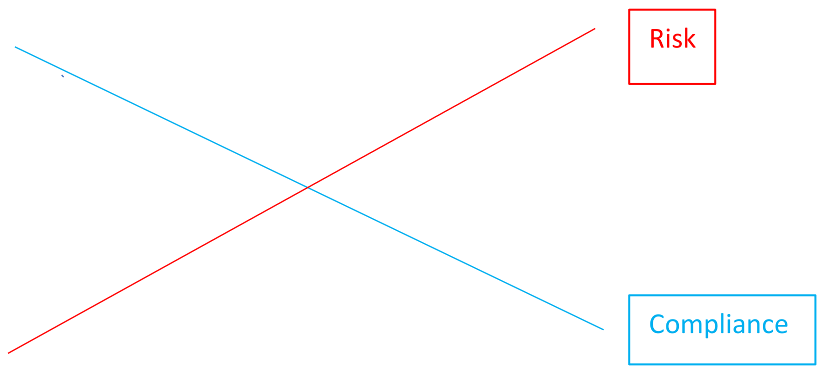
Richard Fiene PhD

Research Institute for Key Indicators Data Lab/Penn State University

February 2024

This research abstract will highlight how the reduction of risk and the increase in compliance are the twin pillars of regulatory compliance. As one can see from figure 1 below these two pillars of risk and compliance are not independent of each other but rather inter-dependent. As one increases, the other decreases and vice versa.

Figure 1: Relationship Between Risk Reduction and Compliance



The above Figure 1 depicts the proposed relationship between the pillars of regulatory compliance: risk reduction and increased compliance. It depicts a relationship similar to more well-known relationships such as the economic supply and demand relationship or the management effectiveness and efficiency relationship. Rules and regulations are promulgated to ensure that clients are in a safe environment. Their purpose is to protect individuals and to "do no harm". Risk is reduced when regulatory compliance is high, and risk is high when regulatory compliance is low with rules and regulations. Risk and compliance do not operate independent of each other but are related in this way.

The essence of this relationship is determining what has been called "the sweet spot" phenomenon where risk and compliance reach an equilibrium which is somewhere at the crisscrossing of the risk and compliance lines. The reason for suggesting "the sweet spot" is based upon the theory of regulatory compliance in which substantial compliance with rules/regulations is equivalent with full compliance with rules/regulations when you compare regulatory compliance scores with quality scores. The ultimate goal of rules and regulations is to "do no harm" but it is also "to do good" which emphasizes a quality element. This is a paradigm shift from previous thinking in which full compliance was the ultimate goal which means 100% regulatory compliance with all rules and regulations. However, the

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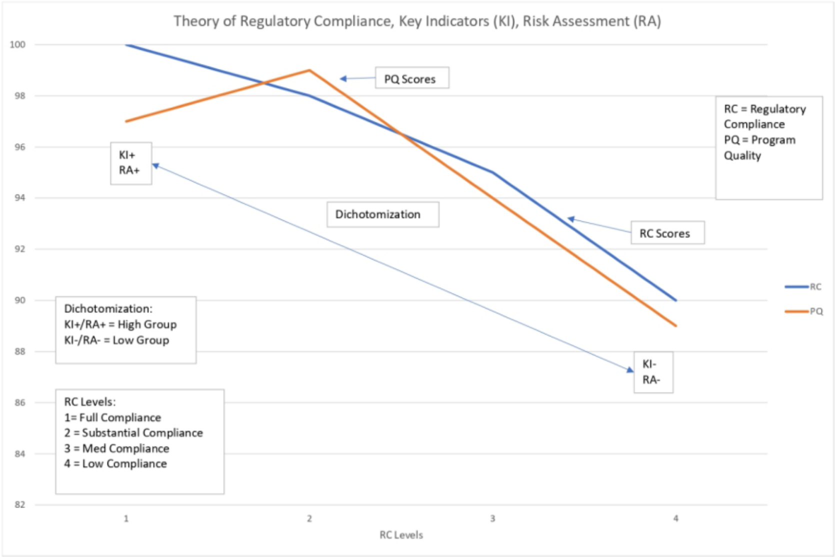
theory of regulatory compliance just does not support this policy edict. It is more beneficial to also include substantial compliance along with full compliance when making licensing decisions regarding who should be entering respective industries and who should not.

Figure 2 below depicts the theory of regulatory compliance and the relationship between quality and regulatory compliance. It also demonstrates how through data dichotomization; risk assessment and key indicator statistical methodologies can be employed to determine the targeted rules that place clients at greatest risk and those rules that statistically predict overall regulatory compliance. This approach gets us to "the sweet spot" identified in figure 1 where risk and compliance crisscross. Without the theory of regulatory compliance, figure 1 would be dealt with very differently in that high compliance and low risk would be the ultimate goal alone. It still is the ultimate goal but with the additional "sweet spot" which reflects substantial compliance with all rules and regulations.

Figure 2: Theory of Regulatory Compliance



Hopefully, this research abstract helps to further delineate how the intricacies of risk and compliance play out in regulatory compliance. Another way of looking at this is through the vantage point of the regulatory compliance scale in which levels 7 and 5 would be acceptable while levels 3 and 1 would not because compliance would be too low and risk too high. Also, an additional way of looking at this is through the effectiveness and efficiency relationship in which the "sweet spot" represents the balance point between effectiveness and efficiency. Utilizing this "sweet spot" phenomenon is the most cost effective and efficient approach to attaining regulatory compliance. The older paradigm of requiring a "one size fits all" full compliance approach is not as cost effective and efficient.

The Uncertainty-Certainty Matrix for Licensing Decision Making, Validation, Reliability, and Differential Monitoring Studies

Richard Fiene PhD

Penn State Edna Bennett Pierce Prevention Research Center

April 2024

This research abstract will take the Confusion Matrix which is a well-known metric in the decision-making research literature and refocus it on regulatory science within the context of the definition of regulatory compliance and licensing measurement. It will also deal with the policy implications of this particular metric. In this abstract, it is proposed that the Uncertainty-Certainty Matrix (UCM) is a fundamental building block to licensing decision making. The 2 x 2 matrix has been written about in several posts in this blog and is the center piece for determining key indicator rules, but it is also a core conceptual framework in licensing measurement and ultimately in program monitoring and reviews.

The reason for selecting this matrix is the nature of licensing data, it is binary or nominal in measurement. Either a rule/regulation is in compliance or out of compliance. Presently most jurisdictions deal with regulatory compliance measurement in this nominal level or binary level. There is to be no gray area, this is a clear distinction in making a licensing decision about regulatory compliance. The UCM also takes the concept of Inter-Rater Reliability (IRR) a step further in introducing an uncertainty dimension that is very important in licensing decision making which is not as critical when calculating IRR. It is moving from an individual metric to a group metric (See Figures 1 & 2) involving regulatory compliance with rules.

The key pieces to the UCM are the following: the decision (D) regarding regulatory compliance and actual state (S) of regulatory compliance. Plus (+) = In-compliance or Minus (-) = Out of compliance. So, let's build the matrix:

Table 1: Uncertainty-Certainty Matrix (UCM) Logic Model

UCM Matrix Logic		**Decision (D) Regarding**	**Regulatory Compliance**
		(+) In Compliance	(-) Not In Compliance
Actual State (S) of	(+) In Compliance	Agreement	Disagreement
Compliance	(-) Not In Compliance	Disagreement	Agreement

The above UCM matrix demonstrates when agreement and disagreement occur which establishes a level of certainty (Agreement Cells) or uncertainty (Disagreement Cells). In a perfect world, there would only be agreements and no disagreements between the decisions made about regulatory compliance and the actual state of regulatory compliance. But from experience, this is not the case based upon reliability testing done in the licensing research field in which a decision is made regarding regulatory compliance with a specific rule or regulation and then that is verified by a second observer who generally is considered the measurement standard.

Disagreements raise concerns in general, but the disagreements are of two types: false positives and false negatives. A false positive is when a decision is made that a rule/regulation is out of compliance when it is in compliance. Not a good thing but its twin disagreement is worse where with false negatives it is decided that a rule/regulation is in compliance when it is out of compliance. False negatives need to be avoided because they place clients at extreme risk, more so than a false positive. False positives should also be avoided but it is more important to deal with the false negatives first before addressing the false positives.

Let's look at this from a mathematical point of view in the following matrix. In order to better understand the above relationships and determine when ameliorative action needs to occur to shore up the differences between the agreements and disagreements, it is easier to do this mathematically than trying to eyeball it.

Table 2: Uncertainty-Certainty Matrix (UCM) Math Model

UCM Matrix Math Model		**Decision (D) Regarding**	**Regulatory Compliance**	**Totals**
		(+) In Compliance	(-) Not In Compliance	
Actual State (S)	(+) In Compliance	A	B	Y
Of Compliance	(-) Not In Compliance	C	D	Z
Totals		W	X	

Formulae based upon above: Agreements = (A)(D); Disagreements = (B)(C); Randomness = sqrt ((W)(X)(Y)(Z))

UCM Coefficient = ((A)(D)) - ((B)(C)) / sqrt ((W)(X)(Y)(Z)) in which a coefficient closer to 1 indicates agreement (certainty) and a coefficient closer to –1 indicates disagreement (uncertainty). A coefficient closer to 0 indicates randomness. Obviously, we want to see (A)(D) being predominant and very little in (B)(C) which are false positives and negatives where decisions and the actual state of regulatory compliance are not matching. If (WXYZ) is predominant then there is just randomness in the data. Also, not an intended result.

The reason for even suggesting this matrix is the high level of dissatisfaction with the levels of reliability in the results of program monitoring reviews as suggested earlier. If it were not so high, it would not be an issue; but with it being so high the field of licensing needs to take a proactive role in determining the best possible way to deal with increasing inter-rater reliability among licensing inspectors. Hopefully, this organizational schema via the UCM Matrix will help to think through this process related to licensing measurement and monitoring systems.

$$UCM = \ll A \times D \gg - \ll B \times C \gg \div \sqrt{} \ll W \times X \times Y \times Z \gg$$

The above formula provides a means to calculate when action needs to be taken based upon the respective UCM coefficients. A UCM coefficient from +.25 to +1.00 is in the acceptable range; +.24 to -.24 is due to randomness and needs to be addressed with additional inter-rater reliability training; -.25 to –1.00 indicates a severe disagreement problem that needs to be addressed both in reliability training and a full review of the targeted rules/regulations to determine if the specific rule needs additional clarification.

Table 3: Uncertainty-Certainty Matrix (UCM) Licensing Decision Coefficient Ranges

UCM Coefficient	**Licensing Decision**
+.25 to +1.00	Acceptable, No Action Needed, In or Out of Regulatory Compliance Verified through mostly Agreements. (Generally, 90% of cases)
+.24 to -.24	Random, Agreements + Disagreements, Needs Reliability Training. (Generally, 5% of cases)
-.25 to –1.00	Unacceptable, Mostly Disagreements, Needs Training & Rule/Regulation Revision. (Generally, 5% of cases)

Figure 1: Kappa Coefficient

Observed agreement

$$\kappa = \frac{p_o - p_e}{1 - p_e}$$

Expected agreement if random judgment

Figure 2: Uncertainty-Certainty Coefficient

$$\phi = \frac{ad - bc}{\sqrt{(a+b)(c+d)(a+c)(b+d)}}$$

$$\phi = \sqrt{\frac{\chi^2}{n}}$$

Let’s provide an example of how this could work. A standard/rule/regulation that is common is the following:

Do all caregivers/teachers and children wash their hands often, especially before eating and after using the bathroom or changing diapers?

This is obviously an observation item where the licensing staff would observe in a sample of classrooms in a child care center for a set period of time. During their observations, there were several opportunities where the necessary behavior was required, and the staff complied with the rule and washed their hands. So, on the surface this specific rule was in compliance and there would appear to be full compliance with this rule based upon the observation.

A second scenario is where the observation is made, and the licensing staff observes the child care staff not washing their hands on several occasions. Then this specific rule would be out of compliance, and it would be duly noted by the licensing staff. These two scenarios establish a certain level of certainty during this observation session. However, there are other outcomes, for example, possibly one of the classrooms that was not observed had the opposite finding than what was observed in these particular classrooms. If data were being aggregated and a specific percentage was to be used the final decision about this rule could be different. Now we are getting into the uncertainty cells of the matrix where a false positive or negative could be the result. The licensing staff records the rule as being in compliance when in reality it is not = false negative or the rule is recorded as being out of compliance when in reality it is in compliance = false positive.

Another example which involves either Random Clinical Trials (RCT) or the use of abbreviated inspections (AI) and the results from these two interventions. The decision making in both RCT and AI is basically the same. We want to make sure that the results match reality. Every time an abbreviated review is done the following four regulatory compliance results should occur based upon the UCM matrix: 1) no additional random non-compliance is found; 2) there are no false negatives (abbreviated review finds no non-compliance but in reality there is); 3) when there is non-compliance found in abbreviated inspections, other related non-compliance is found; and 4) lastly the level of false positives (abbreviated review finds non-compliance but in reality there are no other related non-compliances) is kept to a minimum. This last result based upon copious research is that it is difficult to obtain but as the regulatory science moves forward hopefully this will become more manageable.

Hopefully these above examples provided some context for how the Uncertainty-Certainty Matrix (UCM) can be used in making specific licensing decisions based upon the regulatory compliance results.

Uncertainty-Certainty Matrix for Validation and Reliability Studies

The purpose of this part of this research abstract is to explore the possibility of utilizing the Uncertainty-Certainty Matrix (UCM) in validation and reliability studies in licensing decision making. The UCM has been proposed for use in licensing decision making but this would be an extension of this thinking to studies that involve validating licensing decisions such as when key indicators are used in comparison with comprehensive reviews of rules, and in reliability studies to determine individual inspector bias in regulatory compliance.

The basic premise of the UCM is that individual decision-making matches reality. When it comes to regulatory compliance decision making a 2 x 2 matrix can be drawn with the possible outcomes as is indicated in the following table (Table 4).

Table 4

UCM Matrix Logic		**Decision Regarding**	**Regulatory Compliance**
		(+) In Compliance	(-) Not In Compliance
Actual State of	(+) In Compliance	Agreement (++)	Disagreement (+-)
Compliance	(-) Not In Compliance	Disagreement (-+)	Agreement (--)

In using this table, the hope is that the decision regarding regulatory compliance matches the actual state of compliance where the coefficient is as close to +1.0 as possible, in other words, perfect agreement. So, the agreement cells are heavily weighted.   We do not want to see all the cells, both agreement and disagreement cells, equally weighted. That would indicate a random response rate and a coefficient close to 0.0.

But there is another possibility which involves bias on the part of the licensing inspector in which they have certain biases or tendencies when it comes to making regulatory compliance decisions about individual rules. So, it is possible that decisions made regarding regulatory compliance could be either overall (+) positive In-Compliance or (-) negative Not-In-Compliance when in reality the actual state of compliance is more random.

When this occurs, the coefficient falls off the range category and is not between 0 and +/-1.0 because there is no variance detected in the data. It is always biased either positively or negatively.

The UCM can be used for both reliability and validity testing as suggested in the above. Just look for different results. For validity, false positives and negatives should either be eliminated or reduced as well as possible and the remaining results should show the typical diagonal pattern as indicated by the agreement cells.

For reliability, the same pattern should be observed as in the validity testing above but there is an additional test in which bias is tested for. Bias will be ascertained if the patterns in the results indicate a horizontal or vertical pattern in the data with little or no diagonal indication. Bias can be found at the individual inspector level as well as at the standard level or the actual state of compliance.

In both reliability and validity testing, random results in which each of the cells are equally filled is not a desirable result either.

The following tables 5-10 depict the above relationships with results highlighted in red:

Table 5

Valid & Reliable Results	(+) In Compliance	(-) Not In Compliance
(+) In Compliance	Agreement (++)	Disagreement (+-)
(-) Not In Compliance	Disagreement (-+)	Agreement (--)

Table 6

Random Results	(+) In Compliance	(-) Not In Compliance
(+) In Compliance	Agreement (++)	Disagreement (+-)
(-) Not In Compliance	Disagreement (-+)	Agreement (--)

Table 7

Positive Bias Results Individual	(+) In Compliance	(-) Not In Compliance
(+) In Compliance	Agreement (++)	Disagreement (+-)
(-) Not In Compliance	Disagreement (-+)	Agreement (--)

Table 8

Negative Bias Results Individual	(+) In Compliance	(-) Not In Compliance
(+) In Compliance	Agreement (++)	Disagreement (+-)
(-) Not In Compliance	Disagreement (-+)	Agreement (--)

Table 9

Positive Bias Results Standard	(+) In Compliance	(-) Not In Compliance
(+) In Compliance	Agreement (++)	Disagreement (+-)
(-) Not In Compliance	Disagreement (-+)	Agreement (--)

Table 10

Negative Bias Results Standard	(+) In Compliance	(-) Not In Compliance
(+) In Compliance	Agreement (++)	Disagreement (+-)
(-) Not In Compliance	Disagreement (-+)	Agreement (--)

Tables 5 – 10 demonstrate the different results based upon individual response rates when making regulatory compliance decisions about rules. Table 5 is what needs to be attained and tables 6 – 10 need to be avoided. Only in table 5 are false negatives and positives eliminated or avoided. In tables 6 – 10, false negatives and/or false positives are introduced which is not desirable when making validity or reliability decisions.

Table 6 results clearly indicate that a great deal of randomness has been introduced in the regulatory compliance decision making in which the individual licensing inspector decisions do not match reality. Tables 7 and 8, demonstrate bias in the decision-making process either positively (inspector always indicates in compliance) or negatively (inspector always indicates out of compliance). It is also possible that the standard being used has bias built into it, this is less likely but is still a possibility. The results in Tables 9 and 10 demonstrate where this could happen.

All these scenarios need to be avoided and should be monitored by agency staff to determine if there are patterns in how facilities are being monitored.

Uncertainty-Certainty Matrix for Differential Monitoring Studies

The purpose of this part of the research abstract is to explore the possibility of utilizing the Uncertainty-Certainty Matrix (UCM) not only in validation and reliability studies in licensing decision making but also with differential monitoring studies. The UCM has been proposed for use in licensing decision making but this would be an extension of this thinking to studies that involve validating licensing decisions such as when key indicators are used in comparison with comprehensive reviews of rules, and in the development of risk rules as part of the risk assessment methodology. This new Differential Monitoring 2x2 Matrix can also be used to depict the relationship between full and substantial regulatory compliance and the nature of rulemaking.

The basic premise of the DMM: Differential Monitoring Matrix is similar to the original thinking with the UCM but there are some changes in the formatting of the various cells in the matrix (see Table 11). When it comes to regulatory compliance decision making a 2 x 2 matrix can be drawn with the possible outcomes as is indicated in Table 11 where each individual rule is either in (+) or out (-) of compliance. Also, there is the introduction of a high regulatory compliant group (+) and a low regulatory compliant group (-) which is different from the original UCM.

Table 11

DMM Matrix	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

By utilizing the format of Table 11, several key components of differential monitoring can be highlighted, such as key indicators and risk assessment rules, as well as the relationship between full and substantial regulatory compliance.

Regulatory compliance is grouped into a high group (+), generally this means that there is either full or substantial regulatory compliance with all rules. The low group (-) usually has 10 or more regulatory compliance violations. Individual rules being in (+) or out (-) of regulatory compliance is self-explanatory.

Tables 12-18 below will demonstrate the following relationships:

Table 12 depicts the key indicator relationship between individual rules and the high/low groups as indicated in red. In this table, the individual rule is in compliance with the high group and is out of compliance with the low group. This result occurs on a very general basis and should have a .50 coefficient or higher with a p value of less than .0001.

Table 13 depicts what most rules look like in the 2x2 DMM. Most rules are always in full compliance since they are standards for basic health and safety for individuals. This is especially the case with rules that have been weighted as high-risk rules. Generally, one never sees non-compliance with these rules. There will be a substantial number of false positives (+-) found with high-risk rules but that is a good thing.

Table 14 depicts what happens when full compliance is used as the only criterion for the high group. Notice that the cell right below (++) is eliminated (-+). This is highly recommended since it eliminates false negatives (-+) from occurring in the high group. As will be seen in Table 5, when substantial compliance is used as part of the high group sorting, false negatives are re-introduced. If possible, this should be avoided, however in some cases because of the regulatory compliance data distribution it is not always possible where not enough full compliant programs are present.

Table 15 depicts what occurs when substantial compliance is used as part of determining the high group. False negatives can be reintroduced into the matrix which needs to be either eliminated or reduced as best as possible. If substantial compliance needs to be used in determining the high group, then there is a mathematical adjustment that can be made which will impact the equation and essentially eliminate false negatives mathematically (see the research note at the end of this research abstract).

Table 16 depicts what happens if the individual rule is particularly difficult to comply with. Both the high performers as well as the low performers are out of compliance with the rule.

Table 17 depicts a situation where the programs are predominantly in a low group with few at full or substantial regulatory compliance which is indicative of poor performing programs. Very honestly, this is generally not seen in the research literature, but it is a possibility and one to be in tune with.

Table 18 depicts a terrible individual rule which predicts just the opposite of what we are trying to do with programs. Obviously, this rule would need to be rewritten so that it fits with the essence of regulatory compliance in helping to protect individuals.

The following tables 12-18 will depict the above relationships with results highlighted in red:

Table 12

Key Indicators	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

Table 13

Risk Rules	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

Table 14

Full Compliance	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance		(--)

Table 15

Substantial Compliance	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

Table 16

Very Difficult Rule	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

Table 17

Poor Performing Programs	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

Table 18

Terrible Rule	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

Tables 12 – 18 demonstrate the different results based on the relationship between individual regulatory compliance and if a program is either a high performer or a low performer. These tables are provided as guidance for understanding the essence of differential monitoring and regulatory compliance which has various nuances when it comes to data distributions. This research abstract hopefully can be used as a guide in determining from a data utilization point of view how to make important regulatory compliance policy decisions, such as: which rules are excellent key indicator rules, which are performing as high risk rules, importance of full compliance, what to do when substantial compliance needs to be employed, are there difficult rules to comply with, how well are our programs performing, and do we have less than optimal rules that are in need of revision.

<u>Research Note:</u>

Over the past decade in doing research on the Regulatory Compliance Key Indicator Metric (RCKIm) it has become very clear that false negatives needed to be controlled for because of their potential to increase morbidity and mortality. When dealing with regulatory compliance and full compliance as the threshold for the high grouping variable in the 2 x 2 Regulatory Compliance Key Indicator Matrix (RCKIm) (see matrix below in Table 19), false negatives could be either eliminated or reduced to the point of no concern.

However, if substantial compliance rather than full compliance is used as the threshold for the high grouping variable in the 2 x 2 Regulatory Compliance Key Indicator Matrix (RCKIm) this becomes a problem again. There is the need to introduce a weighting factor. In utilizing the RCKIm, the following equation/algorithm is used to produce the Fiene Coefficient (FC):

FC = ((A)(D)) – ((B)(C)) / sqrt (WXYZ)

This RCKIm needs to be revised/updated to the following to consider the need to again eliminate false negatives being generated by the results of the equation/algorithm; this can be accomplished by cubing B:

FC* = ((A)(D)) – ((B^3)(C)) / sqrt (WXYZ)

By this simple adjustment to cube (B = False Negatives) it will basically eliminate the use of any results in which a false negative occurs when substantial compliance is determined. The table below (Table 19) displays the variables of the Regulatory Compliance Key Indicator Matrix (RCKIm).

Table 19: RCKIm	High RC Group	RC Low Group	
KI In Compliance	A	B^3	Y
KI Violations	C	D	Z
Totals	W	X	

In the above examples, FC can be used when the High RC Group is at full regulatory compliance, but FC* needs to be used when the High RC Group is including substantial as well as full regulatory compliance. By using both equations/algorithms, it better deals with the results of the Regulatory Compliance Theory of Diminishing Returns.

The results should clearly show that only positive (+) coefficients will become Regulatory Compliance Key Indicators versus those rules that do not show any relationship to overall regulatory compliance (0), but now the negative (-) coefficients will more clearly show when any false negatives appear and clearly not include them as Regulatory Compliance Key Indicators. This is a major improvement in the Regulatory Compliance Key Indicator methodology which clearly demonstrates the differences in the results. It provides a gateway in regulatory compliance data distributions where substantial regulatory compliance is heavily present while full regulatory compliance is not. This could become a problem as the regulatory science field moves forward with the use of the Regulatory Compliance Theory of Diminishing Returns.

Uncertainty-Certainty Matrix for Validation and Reliability Studies

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April 2024

The purpose of this research abstract is to explore the possibility of utilizing the Uncertainty-Certainty Matrix (UCM) in validation and reliability studies in licensing decision making. The UCM has been proposed for use in licensing decision making but this would be an extension of this thinking to studies that involve validating licensing decisions such as when key indicators are used in comparison with comprehensive reviews of rules, and in reliability studies to determine individual inspector bias in regulatory compliance.

The basic premise of the UCM is that individual decision-making matches reality. When it comes to regulatory compliance decision making a 2 x 2 matrix can be drawn with the possible outcomes as is indicated in the following table (Table 1).

Table 1

UCM Matrix Logic		**Decision Regarding**	**Regulatory Compliance**
		(+) In Compliance	(-) Not In Compliance
Actual State of	(+) In Compliance	Agreement (++)	Disagreement (+-)
Compliance	(-) Not In Compliance	Disagreement (-+)	Agreement (--)

In using this table, the hope is that the decision regarding regulatory compliance matches the actual state of compliance where the coefficient is as close to +1.0 as possible, in other words, perfect agreement. So, the agreement cells are heavily weighted. We do not want to see all the cells, both agreement and disagreement cells, equally weighted. That would indicate a random response rate and a coefficient close to 0.0.

But there is another possibility which involves bias on the part of the licensing inspector in which they have certain biases or tendencies when it comes to making regulatory compliance decisions about individual rules. So, it is possible that decisions made regarding regulatory compliance could be either overall (+) positive In-Compliance or (-) negative Not-In-Compliance when in reality the actual state of compliance is more random.

When this occurs, the coefficient falls off the range category and is not between 0 and +/-1.0 because there is no variance detected in the data. It is always biased either positively or negatively.

The UCM can be used for both reliability and validity testing as suggested in the above. Just look for different results. For validity, false positives and negatives should either be eliminated or reduced as well as possible and the remaining results should show the typical diagonal pattern as indicated by the agreement cells.

For reliability, the same pattern should be observed as in the validity testing above but there is an additional test in which bias is tested for. Bias will be ascertained if the patterns in the results indicate a horizontal or vertical pattern in the data with little or no diagonal indication. Bias can be found at the individual inspector level as well as at the standard level or the actual state of compliance.

In both reliability and validity testing, random results in which each of the cells are equally filled is not a desirable result either.

The following tables 2-7 depict the above relationships with results highlighted in red:

Table 2

Valid & Reliable Results	(+) In Compliance	(-) Not In Compliance
(+) In Compliance	Agreement (++)	Disagreement (+-)
(-) Not In Compliance	Disagreement (-+)	Agreement (--)

Table 3

Random Results	(+) In Compliance	(-) Not In Compliance
(+) In Compliance	Agreement (++)	Disagreement (+-)
(-) Not In Compliance	Disagreement (-+)	Agreement (--)

Table 4

Positive Bias Results Individual	(+) In Compliance	(-) Not In Compliance
(+) In Compliance	Agreement (++)	Disagreement (+-)
(-) Not In Compliance	Disagreement (-+)	Agreement (--)

Table 5

Negative Bias Results Individual	(+) In Compliance	(-) Not In Compliance
(+) In Compliance	Agreement (++)	Disagreement (+-)
(-) Not In Compliance	Disagreement (-+)	Agreement (--)

Table 6

Positive Bias Results Standard	(+) In Compliance	(-) Not In Compliance
(+) In Compliance	Agreement (++)	Disagreement (+-)
(-) Not In Compliance	Disagreement (-+)	Agreement (--)

Table 7

Negative Bias Results Standard	(+) In Compliance	(-) Not In Compliance
(+) In Compliance	Agreement (++)	Disagreement (+-)
(-) Not In Compliance	Disagreement (-+)	Agreement (--)

Tables 2 – 7 demonstrate the different results based upon individual response rates when making regulatory compliance decisions about rules. Table 2 is what needs to be attained and tables 3 – 7 need to be avoided. Only in table 2 are false negatives and positives eliminated or avoided. In tables 3 – 7, false negatives and/or false positives are introduced which is not desirable when making validity or reliability decisions.

Table 3 results clearly indicate that a great deal of randomness has been introduced in the regulatory compliance decision making in which the individual licensing inspector decisions do not match reality. Tables 4 and 5, demonstrate bias in the decision-making process either positively (inspector always indicates in compliance) or negatively (inspector always indicates out of compliance). It is also possible that the standard being used has bias built into it, this is less likely but is still a possibility. The results in Tables 6 and 7 demonstrate where this could happen.

All these scenarios need to be avoided and should be monitored by agency staff to determine if there are patterns in how facilities are being monitored.

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UCM Matrix: Uncertain-Certainty Matrix

Certain	***UnCertain***	***UnCertain***	***Certain***
A	**B**	**C**	**D**
50	0	0	50
25	25	25	25
0	50	50	0
50	50	0	0
0	50	0	50

Random	***Random***	***Random***	***Random***	***Certain***
A+B	**A+C**	**B+D**	**C+D**	**A*D**
50	50	50	50	2500
50	50	50	50	625
50	50	50	50	0
100	50	50	0	0
50	0	100	50	0

UnCertain	***Random***	***Random***	***+/-***	***+/0/-***	***Matrix***	
B*C	**SUM**	**SQRT**	**SUB**	**PHI**	**Result**	
0	6250000	2500	2500	1	**Certain**	
625	6250000	2500	0	0	**Random**	
2500	6250000	2500	-2500	-1	**Uncertain**	
0	0	0	0	0	**Null: Bias**	**Positive**
0	0	0	0	0	**Null: Bias**	**Negative**

Formula:

$$\phi = \frac{ad - bc}{\sqrt{(a+b)(c+d)(a+c)(b+d)}}$$

$$\phi = \sqrt{\frac{\chi^2}{n}}$$

UCM Matrix Math Model		**Decision Regarding**	**Regulatory Compliance**	**Totals**
		(+) In Compliance	(-) Not In Compliance	
Actual State	(+) In Compliance	A	B	Y
Of Compliance	(-) Not In Compliance	C	D	Z
Totals		W	X	

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Random Matrix		Decision Regarding	Regulatory Compliance
		(+) In Compliance	(-) Not In Compliance
Actual State of	(+) In Compliance	25	25
Compliance	(-) Not In Compliance	25	25

Certain Matrix		Decision Regarding	Regulatory Compliance
		(+) In Compliance	(-) Not In Compliance
Actual State of	(+) In Compliance	50	0
Compliance	(-) Not In Compliance	0	50

Uncertain Matrix		Decision Regarding	Regulatory Compliance
		(+) In Compliance	(-) Not In Compliance
Actual State of	(+) In Compliance	0	50
Compliance	(-) Not In Compliance	50	0

Positive Bias		Decision Regarding	Regulatory Compliance
		(+) In Compliance	(-) Not In Compliance
Actual State of	(+) In Compliance	50	50
Compliance	(-) Not In Compliance	0	0

Negative Bias		Decision Regarding	Regulatory Compliance
		(+) In Compliance	(-) Not In Compliance
Actual State of	(+) In Compliance	0	50
Compliance	(-) Not In Compliance	0	50

Uncertainty-Certainty Risk Predictor Pyramid Proposal

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May 2025

This proposal will combine two methodologies that are utilized in the human services regulatory science field to monitor program's regulatory compliance dealing with predicting overall compliance with all rules/regulations and the relative risk to clients if noncompliance is determined in specific rules/regulations (Fiene, 2025a,b).

This paper builds off the Uncertainty-Certainty Matrix (UCM) (Fiene, 2025c) and the Regulatory Compliance Scale (RCS) (Fiene, 2025d). It attempts to combine these tools into an enhanced model that suggests reducing uncertainty as the potential risk of harm increases. This model utilizes the 2x2 matrix proposed to explain the UCM and the 3x3 matrix which explains the relative risk continuum involving risk and prevalence (Risk Assessment Matrix (RAM))(Fiene, 2019, 2022). Both these matrices are depicted below in Table 1: UCM Logic Model and Chart 1: Risk Assessment Matrix (RAM).

The table and chart need some explanation in and of themselves and then how they will be combined together in a three-dimensional model: the Uncertainty-Certainty Risk Predictor Pyramid Model.

The UCM is a licensing decision making model in which individual inspector decisions are measured against a standard in the licensing field, an expert. It is then determined if the decision being made by the individual inspector in the field is actually accurate. The individual inspector decision goes along the horizontal axis while the actual state of compliance (expert) goes along the vertical axis. The matrix shows what the potential results can be in that there is agreement between the decision regarding regulatory compliance and the actual state of compliance. This is the desired result; it is a true positive result. Also, a determination could be made that there is non-compliance and this is the actual state of compliance. Again, this would be a desired agreement although the result of non-compliance is not what you want to see but it is still a desired result from a decision-making perspective; it is a true negative result.

The other two cells where there are disagreements are not results one wants to see when it comes to decision making. These two cells fall into a false positive and a false negative which is diametrically opposed to the true positive and true negative cells addressed in the previous paragraph. False positives occur when the inspector determines that there is a rule violation when in reality there is not. Not a good situation but it does not place clients at additional risk which occurs with the false negative. In the false negative the inspector determines that the rule is in compliance when in reality it is not. Now, this does place clients at additional risk because there really is a rule violation but the inspector has determined that the facility/program is in compliance with the rule.

Table 1. Uncertainty-Certainty Matrix (UCM) Logic Model.

UCM Matrix Logic		**Decision (D) Regarding**	**Regulatory Compliance**
		(+) In Compliance	(-) Not In Compliance
Actual State (S) of	(+) In Compliance	**Agreement**	*Disagreement*
Compliance	(-) Not In Compliance	*Disagreement*	**Agreement**

Now let's turn our attention to Chart 1 which deals with a risk assessment matrix (RAM). This matrix measures the relative risk of a rule violation along with the prevalence of the rule being out of compliance. Risk is on the vertical axis while prevalence is on the horizontal axis. The matrix has 9 levels with 1 being low risk and low prevalence while 9 is a high risk and high prevalence rule. These are highlighted with a color coding to enhance this change in the matrix cells from green (low risk) to yellow (medium risk) to red (high risk).

Chart 1 – Risk Assessment Matrix

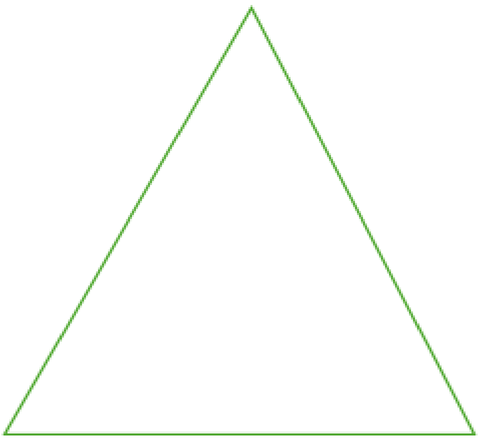
		Probability/	Prevalence		
	Levels	High	Medium	Low	Weights
Risk/	High	*9*	*8*	*7*	*7-8*
Severity	Medium	*6*	*5*	*4*	*4-6*
	Low	*3*	*2*	*1*	*1-3*
	# of Rules	*8 or more*	*3-7*	*2 or fewer*	

Having dealt with the reliability of the decision making via UCM and the validity of the rule being at a particular risk level (RAM), what would this pyramid model: Uncertainty-Certainty Risk Predictor Pyramid look like in combining the two matrices? As I said, it is a three-dimensional model with the UCM as the base and the RAM as the sides moving up to the top of the pyramid from low risk to high risk (See the below graphic: Figure 1).

The pyramid starts at its base with very low risk rules/regulations where if false negatives were to occur it would not adversely affect clients. It then begins to move up the pyramid with increasing risk and with less tolerance for making errors. For example, false positives are the next level followed by true negatives. Still not great outcomes but situations where either clients are not at increased risk or the licensing decision making is accurate even though the result is not compliant rules. The top of the pyramid, the pinnacle, are the greatest risk rules and this is where only true positives should be occurring. It is at this level where we do not want to have errant licensing decision making in which regulatory compliance is not correct.

The reason for proposing this new model is to add to the theoretical foundations of regulatory science and to build a series of tools that can be used at a practical level in regulatory compliance, monitoring and decision making. Hopefully this latest model will join an ever growing series of methods and approaches that should enhance the regulatory science field, such as differential monitoring, key indicators for licensing and quality, risk assessment, uncertainty-certainty matrix, regulatory compliance scale, and the early childhood program quality improvement and indicator model.

Figure 1: Uncertainty-Certainty Risk Predictor Pyramid Model



True Positives and Highest Risk

True Negatives and Medium Risk

False Positives and Low-Medium Risk

False Negatives and Very Low Risk

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Validation of Relative Weighting in Two Jurisdiction

Richard Fiene PhD

Penn State Prevention Research Center

November 2024

This brief technical research abstract will delineate the validation study completed to determine the efficacy of utilizing a relative weighting methodology as versus the more typical violation driven scoring protocol in licensing data distributions from two jurisdictions. The abstract will contain the basic statistical parameters of the two distributions. The programs being used in this study are all early care and education programs.

Relative weighting has emerged as an alternative to using straight licensing violation data for identifying regulatory compliance data distributions. This was necessary given the concerns about false positive and false negatives which may appear in a high regulatory compliant grouping when substantial compliance is used to make that determination. When full regulatory compliance is used, this concern is mitigated since the high group is always identified as being in full (100%) regulatory compliance. Not only is relative weighting different from straight violation counts but it is slightly different from the equal interval weighting approach used by most jurisdictions when they utilize a weighting methodology. Relative weighting introduces a more robust weighting scale with greater variability in which the equal interval weighting scale of 1 – 9 is replaced by a relative weighting scale of 1 - 100. The differences between these two weighting approaches has been described in previous technical research abstracts (please see the following website (ResearchGate.net) for these abstracts ResearchGate).

Both jurisdictions are state licensing agencies from the Western part of the USA. One jurisdiction (JRS1) is more stringent in making licensing decisions revolving around full regulatory compliance with the majority of programs having zero violations. The second jurisdiction (JRS2) is a bit less stringent in making licensing decisions and appears to employ more of a substantial regulatory compliance decision making process with less than 25% of programs having zero violations.

The first Jurisdiction (JRS1) demonstrated a highly compliant sample of programs in which the range of violations was between 0 and 13 with the vast majority (91%) having 0 violations. This is a very skewed (7.21) data distribution with an extremely spiked kurtosis (72.45). The mean

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number of violations was only 0.22 which is extremely low for a state licensing agency. The sample size consisted of 752 programs.

When relative weighting was utilized with JRS1 programs, violation data ranged from 0 to 332. The data distribution was still skewed (6.80) and demonstrated a still high spiked kurtosis (53.02). The mean weight was 6.20 and variance increased from 0.82 to 985.24. Using relative weighting clearly helped in introducing variance into the data distribution. From these two respective data distributions, a highly compliant and a low compliant groups were determined. The high compliant group contained 90% of the programs while the low compliant group contained only 0.1% of the programs in viewing the violation count data. Essentially this data distribution was not a workable distribution that could be used for data analysis for determining key indicators. When relative weighting was utilized, the high compliant group also contained 90% of the programs but the low compliant group now contained 5% of the programs. This is not ideal but did make for a workable distribution that could be used for data analysis for determining key indicators.

The second jurisdiction (JRS2) was more typical of a substantial regulatory compliance data distribution in which full regulatory compliance was significant but not the dominant data structure in which the range of violations was between 0 and 54 with 27% having 0 violations. The data distribution was also skewed (2.23) and it had a spiked kurtosis (7.23), but not near what JRS1 was showing. The mean number of violations was 5.88 which is more in line with averages in other licensing agency jurisdictions. The sample size consisted of 723 programs.

When relative weighting was utilized with JRS2 programs, violation data ranged from 0 to 594. The data distribution was still skewed (2.03) and demonstrated a spiked kurtosis (4.09) but these metrics were not extreme. The mean weight was 70.93 and variance increased from 42.84 to 9829.87. Using relative weighting clearly helped in introducing variance into the data distribution but it was not needed as much as it was in JRS1. From these two respective data distributions, a highly compliant and a low compliant groups were determined. The high compliant group contained 15% of the programs while the low compliant group contained 20% of the programs in viewing the violation count data. This data distribution was a workable distribution that could be used for data analysis for determining key indicators, but we wanted to see the impact of relative weighting on the violation data distribution. When relative weighting was utilized, the high compliant group contained 27% of the programs and the low compliant group now contained 55% of the programs. This is ideal in making for a more workable distribution that could be used for data analysis for determining key indicators, but the violation count data distribution could still be used if only programs with 0 violations (15%) were used as the high group.

It is clear from this validation study that relative weighting of rules and the resultant changes in the data distribution are highly desirable with violation count data distributions in which the distribution is severely skewed and has very little variance in the data. Relative weighting provides a more workable data distribution that can be used for further analyses related to differential monitoring, in particular in generating key indicator rules.

With a less skewed data distribution with more of a substantial regulatory compliance emphasis, relative weighting is very helpful but not essential. The original data distribution based upon violation data counts can be used for determining high and low group compliance but only if the high group has full regulatory compliance with those programs that have no regulatory violations.

So, the takeaway from the validation study is to utilize relative weighting when a state licensing agency has fewer rules to weight, where the data distribution is severely skewed, and with very little variance in the data distribution with the majority of the programs being in full 100% regulatory compliance.

With those state licensing agencies where substantial compliance is emphasized rather than full regulatory compliance with a less skewed data distribution and sufficient variance in the data, relative weighting will add robustness to the further analyses involving key indicators but it is not necessary as is the case with the above.

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Risk Assessment and Licensing Decision Making Matrices: Taking into Consideration Rule Severity and Regulatory Compliance Prevalence Data

Sonya Stevens, Ed.D. & Richard Fiene, Ph.D.

June 2019

This short paper combines the use of risk assessment and licensing decision making matrices. In the past, risk assessment matrices have been used to determine the frequency of monitoring and licensing visits and scope of reviews based upon individual rule severity, risk factors, or both. Notably, these data were lacking because they had not been aggregated to determine what type of licensing decisions should be made based upon prevalence, probability, or regulatory compliance history data. The approach described here is a proposed solution to that problem.

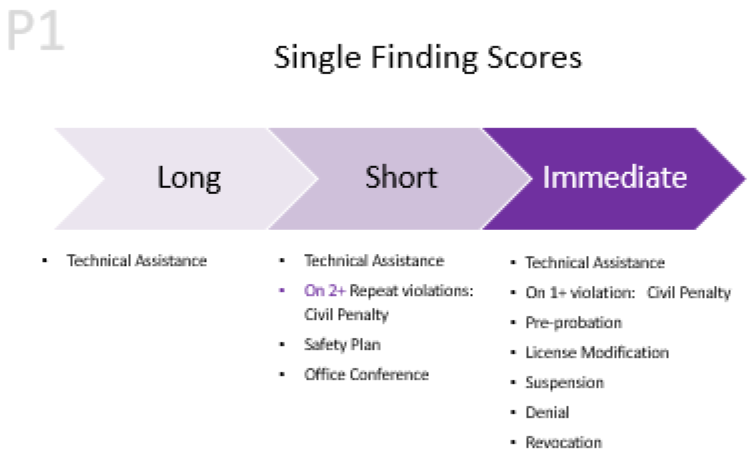
Washington State's HB 1661 (2017) redefined the department's facility licensing compliance agreement (FLCA) process. One feature of this new process is to allow licensed providers to appeal violations noted on the FLCA that do not involve "health and safety standards.[1]" To determine what licensing rules are and are not "health and safety standards" under the new definition, the department worked with community and industry stakeholders, and sought extensive public input, to assignment weights to licensing regulations. These weights were based on each regulation's risk of harm to children. A rule designed to protect against the lowest risk of harm was assigned a "1" and a rule designed to protect against the highest risk of harm was assigned an "8". Weights of "2" through "7" were determined accordingly. These weights were then grouped into three different categories based on risk:

- **Weights 8, 7 and some 6 = immediate concern**
- **Weights 4, 5 and most 6 = short term concern**
- **Weights 1, 2, and 3 = long term concern**

Using the new risk categories, the department developed a two-prong approach that considers both the risk of harm to children at the time a violation is monitored (single findings) and the risk of harm to children arising from violations noted for a given provider over a four year period (historical or overall findings). Used together, the department will assess the single findings and the historical findings to determine appropriate licensing actions, ranging from offering technical assistance to summarily suspending and revoking a child care license. In addition, the department will also note how many times a provider violates the *same* rule, with the severity of a licensing action increasing each time. For example, a violation within the short term concern category could be subject to a civil penalty when violated the second (or potentially the 3rd) time in a four-year period. Whereas, a violation in the immediate concern category could be subject to a civil penalty or more severe action upon the first violation. (See Graphic for Step 1).

[1] Washington law governing child care and early learning defines "health and safety standards" to mean "rules or requirements developed by the department to protect the health and safety of children against substantial risk of bodily injury, illness, or death." RCW 43.216.395(2)(b).

Step 1:



A more difficult task is assigning initial thresholds for the overall finding score. It is this second step (Step 2) where we need to consider probability and severity side by side as depicted in Chart 1 below which is generally considered the standard Risk Assessment Matrix in the licensing research literature:

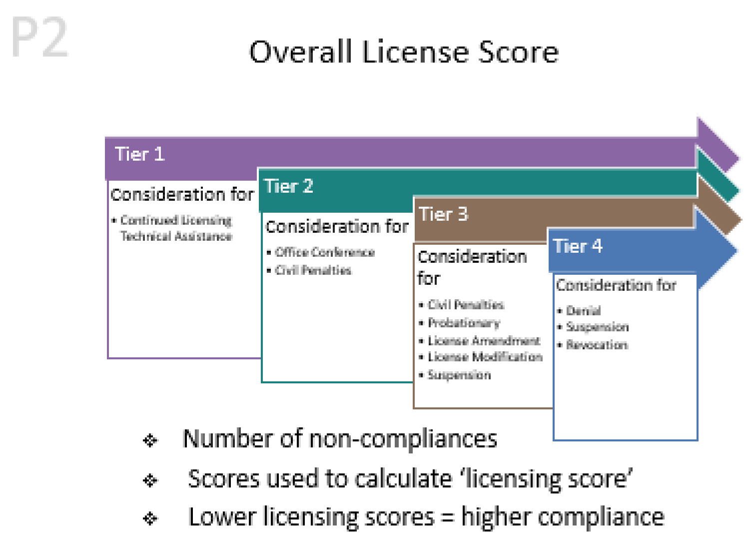
Step 2:

Chart 1 – Risk Assessment Matrix

		Probability/	Prevalence		
	Levels	**High**	**Medium**	**Low**	**Weights**
Risk/	**High**	***9***	***8***	***7***	***7-8***
Severity	**Medium**	***6***	***5***	***4***	***4-6***
	Low	***3***	***2***	***1***	***1-3***
	# of Rules	***8 or more***	***3-7***	***2 or fewer***	

The next step (Step 3) is to build in licensing decisions using a graduated Tiered Level system as depicted in the following figure. In many jurisdictions, a graduated Tiered Level system is used to make determinations related to monitoring visits (frequency and scope) and not necessarily for licensing decisions.

Step 3:



Step 4 involves combining steps 1 and 2 into a revised risk assessment matrix as depicted in the following chart:

Step 4:

Risk Assessment (RA) Matrix Revised

	Levels	High	Medium	Low
Risk/Severity	**Immediate**	**9**	**8**	**7**
	Short-term	**6**	**5**	**4**
	Long-term	**3**	**2**	**1**
			Probability	
	Regulatory Compliance (RC): # of Rules out of compliance and In compliance	**8+ rules out of compliance. 92 or less regulatory compliance.**	**3-7 rules out of compliance. 93 – 97 regulatory compliance.**	**2 or fewer rules out of compliance. 98 – 99 regulatory compliance.**

The last step (Step 5) is to take steps 3 and 4 and combine them together into the following charts which will provide guidance for making licensing decisions about individual programs based upon regulatory compliance prevalence, probability, and history as well as rule risk/severity data.

Step 5:

Licensing Decision Making Matrix*

Tier 1 = (1 – 2) RA Matrix Score

Tier 2 = (3) RA Matrix Score
Tier 3 = (4 – 5) RA Matrix Score

Tier 4 = (6 – 9) RA Matrix Score

***Regulatory Compliance (RC)(Prevalence/Probability/History + Risk/Severity Level)**

Tier 1 = ((RC = 93 – 97) + (Low Risk)); ((98 – 99) + (Low Risk)) = Tier 1

Tier 2 = (RC = 92 or less) + (Low Risk) = Tier 2

Tier 3 = ((RC = 93 – 97) + (Medium Risk)); ((98 – 99) + (Medium Risk)) = Tier 3

Tier 4 = (RC = (92 or less) + (Medium Risk)) = Tier 4; ((93 -97) +(High Risk)) = Tier 4; ((98 – 99) + (High Risk)); ((92 or less) + (High Risk)) = Tier 4+

The following algorithms should be followed in moving from the Risk Assessment Matrix (RAM) (Step 4) to the Licensing Decision Making Matrix (Step 5):

1) Σ (Yr1 RC + Yr2 RC + Yr3 RC + Yr4 RC).
2) Identify all rules by high, medium, low, no risk levels. HR, MR, LR, NULL.
3) HR = Tier4.
4) Σ NC Total/# of Years = Average NC.
5) Σ NC by RCH, RCM, and RCL.
6) LR + RCL or LR + RCM = Tier 1.
7) LR + RCH = Tier 2.
8) MR + RCL or MR + RCM = Tier 3.
9) MR + RCH or HR + RCM or HR + RCL = Tier 4.
   HR + RCH = Tier 4+.

Risk Level:
HR = High Risk (7-8 weights)
MR = Medium Risk (4-6 weights)
LR = Low Risk (1-3 weights)
Prevalence Level:
RCH = High Non Compliance (NC) (8+) or Low Regulatory Compliance (RC) (92 or less)
RCM = Medium Non Compliance (3-7) or Medium Regulatory Compliance (93-97)
RCL = Low Non Compliance (1-2) or High Regulatory Compliance (98-99)

Risk Assessment Matrix (RAM) for the State of Washington

Richard Fiene, Ph.D.

May 2019

Risk Assessment Matrices (RAM) are potential decision making tools developed as part of the weighting/risk assessment methodology for licensing and regulatory compliance. Most matrices have two major foci, risk/severity and prevalence/probability components. Each is rank ordered from low to medium to high risk/severity or prevalence/probability. To date there has not been much empirical data used to determine the various levels of low, medium and high that has been shared in the research literature. I am hoping to change this with this short paper.

The data drawn for this paper is taken from the National Licensing, Differential Monitoring, Key Indicator and Risk Assessment Data Base maintained at the Research Institute for Key Indicators (RIKIllc). This data base has been in existence for over 40 years and contains data from many states, provinces and national programs.

In order to determine the relative risk level of specific rules/regulations, generally a weighting system is used where a group of stakeholders in a specific state make assessments to the potential risk for clients if a specific rule is out of compliance. Usually the weighting scale is a Likert type scale going from low risk (1) to high risk (8). Medium risk usually is around a 4.

Prevalence/probability data are not as well determined in the literature and focuses more on the individual rule. However, for the purposes of this paper, I want to use prevalence/probability data drawn from regulatory compliance histories and move beyond individual rules so that the Risk Assessment Matrix (RAM) can be used more effectively for making monitoring decisions. Regulatory compliance histories will provide an overall picture of how well the program has complied with rules over time. The number of rules in Chart 1 are rules that are out of compliance in any monitoring review conducted. Based upon the National Licensing, Differential Monitoring, Key Indicator and Risk Assessment Data Base, these are the averages across jurisdictions and have become the standard thresholds for determining low, medium and high regulatory compliance.

Chart 1 – Risk Assessment Matrix

		Probability/	**Prevalence**		
	Levels	**High**	**Medium**	**Low**	**Weights**
Risk/	**High**	***9***	***8***	***7***	***7-8***
Severity	**Medium**	***6***	***5***	***4***	***4-6***
	Low	***3***	***2***	***1***	***1-3***
	# of Rules	***8 or more***	***3-7***	***2 or fewer***	

The resulting numeric scale from 1-9 provides a rank ordering when Severity/Risk and Prevalence/Probability are cross-referenced. In this rank ordering 9 = High Risk/Severity (Weight = 7-8) and High Prevalence/Probability (8 rules or more are out of compliance) while a 1 = Low Risk/Severity (Weight = 1-3) and Low Prevalence/Probability (2 rules or fewer are out of compliance). A 5 = Medium Risk/Severity (Weight = 4-6) and Medium Prevalence/Probability (3-7 rules are out of compliance).

Utilizing the data from the above Chart 1, a Monitoring Decision Making Matrix (MD2M) can be constructed for the various Licensing Tiers which will assist in determining further targeted monitoring as depicted in Chart 2 below.

Chart 2 – Monitoring Decision Making Matrix

Tier 1	**1,2**	**Potentially eligible for abbreviated reviews & differential monitoring + Technical Assistance (TA) being available.**
Tier 2/3	**3,4,5,6**	**Comprehensive review + required TA + potentially more frequent reviews.**
Tier 4	**7,8,9**	**Comprehensive review + required TA + Potential Sanctions that could lead to licensing revocation.**

Chart 2 takes the data from Chart 1 and transposes the 1-9 Severity/Prevalence data (column 2) to a Tiered Decision Making Scale (Column 1) regarding targeted monitoring and technical assistance (column 3). This chart could be taken further and decisions regarding the status of the license could be made such as Tier 1 would result in a full license, Tier 2/3 would result in a provisional license, and Tier 4 would result in the removal of a license.

In the past, these decisions were generally driven by general guidance with a lack of data driving the decisions. By utilizing data from the National Licensing, Differential Monitoring, Key Indicator and Risk Assessment Data Base it is now possible to make these decisions more objective and data driven. Also, the focus of RAM's in the past has been at the individual rule/regulation level for both risk/severity and prevalence/probability. This presentation moves this level of analysis to a broader focus which looks at the program in general by incorporating regulatory compliance histories in determining prevalence/probability data.

Weighting of Rules Comparing Mean, Median and Mode

Richard Fiene PhD

Penn State Prevention Research Center

September 2024

Weighting of rules is a general occurrence in the human service regulatory administration and licensing field. This is done via an Equal Interval Likert Weighting Scale technique using licensing staff, experts, providers, parents and advocates to do the rank ordering via individual surveys (generally 100 surveys from a representative sample of these various groups are used to do a weighting consensus). These data are then aggregated to determine the average weight for a particular rule or regulation. The question before us is to determine if utilizing the mean, median, or mode will influence this average score. The answer to this question has not been put to the test so this research abstract will provide an analysis taken from a jurisdiction in which this Equal Interval Likert Weighting Scale technique has been done[1].

The following table provides a side-by-side comparison of the mean, median, and mode results for a series of rules/regulations from a jurisdiction that the author has worked with for several years and had the best overall data for doing this type of analysis (144 individual surveys were analyzed). Please keep in mind that this jurisdiction has very minimal rules and the overall health and safety risks that were being measured were at a high level. This is not the case in some other jurisdictions in which the author has worked but the key here is the comparison amongst the scores for the mean, median and model related to the weighting consensus data. The scaling was on a 1 – 8 scale with 8 being high risk and 1 being low risk of mortality or morbidity if non-compliance was determined probable. The research question is whether one approach is more accurate than the others.

Rule Weighting Utilizing the Mean, Mode, and Median for Central Tendency

Item	Mean	Mode	Median
1	7.04	8	8
2	7.06	8	8
3	6.21	8	7
4	7.51	8	8
5	7.64	8	8
6	6.70	8	7

7	6.12	6	6
8	6.71	8	7
9	7.19	8	8
10	7.38	8	8
11	5.40	6	6
12	6.60	8	7
13	6.81	8	7
14	7.04	8	7
15	7.40	8	8
16	7.41	8	8
17	6.76	8	7
18	7.31	8	8
19	7.41	8	8
20	7.42	8	8
21	7.36	8	8
22	6.56	8	7
23	7.48	8	8
24	7.59	8	8
25	7.36	8	8
26	7.12	8	8
27	7.14	8	8
28	7.08	8	8
29	6.97	8	8
30	7.15	8	8
31	7.17	8	8
32	7.16	8	8
33	7.19	8	8
34	7.50	8	8
35	6.56	8	7
36	6.45	8	7
37	7.36	8	8
38	7.09	8	8
39	7.19	8	8
40	7.24	8	8
41	5.47	8	6
42	7.83	8	8
43	5.35	8	6
44	7.63	8	8
45	5.83	8	6
46	7.68	8	8
47	7.19	8	8

48	7.15	8	8
49	7.49	8	8
50	7.06	8	8
51	6.87	8	8
52	6.72	8	7
53	7.21	8	8
54	7.30	8	8
55	6.97	8	8
56	6.08	8	7
57	7.77	8	8
58	6.68	8	8
59	6.74	8	7

From the above, because of the high-risk nature of the rules, there is relatively little variance in the data especially when one compares the mode and median. The mean shows a bit more variance but not significantly. However, with this particular set of rules, the mean was selected as the metric to use. The data clearly demonstrate the risk value of the rules by all being heavily weighted with all metrics of mean, mode, and median. This would be expected and was confirmed.

In future studies, it will be interesting to utilize this same type of analyses with Relative Weighting in place of the Equal Interval Likert Weighting Scale. Relative Weighting, which is on a 1 – 100 scale, introduces a bit more variance into the data distribution and is a group consensus process rather than an individual process with little to no group interaction and consensus. The consensus comes from the measures of central tendency statistically and not having individuals come together to reach group consensus before assigning a weight. Relative Weighting is dynamically very different from Equal Interval Likert Weighting in how weights are determined and applied.

Note:

1. **Fiende & Kroh, (2000). Licensing Measurement and Program Monitoring Systems. *National Association for Regulatory Administration's Licensing Curriculum, Chapter 11.* Fredericksburg, Virginia.**

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Regulatory Compliance, Quality, QRIS, and Head Start Data Distributions

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May 2025

This research abstract will address the various data distributions that we find in the Child Care and Early Education field, such as licensing/regulatory compliance, Head Start, Quality Rating and Improvement Systems (QRIS), and program quality (ERS, CLASS). This is a topic that is dealt with at the micro level a great deal in micro studies that are done but there are not many instances in which the various data distributions are dealt with at the macro level in comparing how these distributions are very different. These above data distributions will be dealt with in the sequence that they are listed above since the distributions move from more skewed data to more normally distributed data (see Fiene's Regulatory Compliance & Program Quality Spectrum idea for how these systems fit together and build upon one another).

Licensing/regulatory compliance data distributions when it comes to the number of violations that may occur in a licensing review or inspection when plotted demonstrate how skewed the data are. Licensing represents basic health and safety rules/regulations/standards that all programs who are licensed must follow, so it makes sense that these programs demonstrate a high level of regulatory compliance with these rules. When one looks at licensing data that is exactly the case with the majority of programs being in full or substantial compliance. It is unusual to see a high degree of low regulatory compliance. It just doesn't happen when it comes to licensing. Paying attention to full 100% regulatory compliance is important because it generally indicates a pattern in the enforcement efforts in a particular jurisdiction. If one finds a high degree of full 100% regulatory compliance, a weaker enforcement strategy is probably occurring while not seeing a high full 100% regulatory compliance level would indicate a stronger enforcement strategy. Also, another consideration with skewed licensing/regulatory compliance data is the need to dichotomize the data into buckets for analyses similar to a Regulatory Compliance Scale (RCS) which utilizes a 1-7 Likert type scale which is more similar to what is found in program quality tools or a QRIS system. It has been found that utilizing a RCS enhances the ability to utilize these data statistically than to use frequency violation counts at a nominal measurement level.

The second data distribution to deal with in this sequence is Head Start. The Head Start Performance Standards (HSPS) go a bit more in depth and move beyond basic health and safety and delve into quality programming. Their data distribution is not as skewed as the licensing/regulatory compliance data distribution but there is definitely some skewness to the data distribution. This is typical to see when standards become more stringent or the enforcement of those standards become more stringent. Either way it will see the full 100% regulatory compliance levels drop off and substantial compliance become a major player.

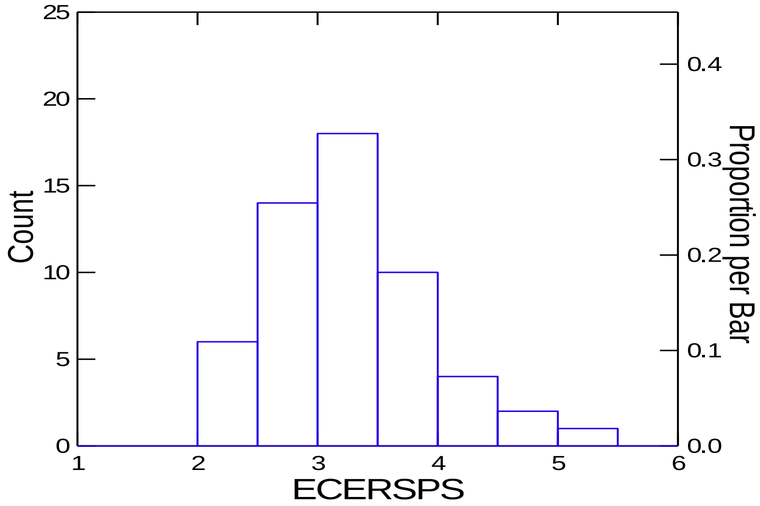
The third data distribution deals with QRIS: Quality Rating and Improvement Systems which have been employed as a supplemental set of standards to build off of licensing/regulatory compliance to enhance child care and early education (CCEE) services. It is a way of infusing quality into the overall CCEE delivery system. The data distribution systems observed here are a bit different and it will be interesting to see what happens over time if these data distributions change over time but in the past these distributions were more U-shaped (bimodal) rather than skewed or normally distributed. The reason for this is more how the QRIS systems were introduced policy wise rather than their theoretical structure. When CCEE programs were allowed to participate in their respective jurisdiction's QRIS, if they were accredited they were grandfathered into the system at the highest level. And then you had all the programs that were licensed and just beginning the process which placed them at the other end of the continuum. Very few programs fell in the middle because it was the beginning of the respective QRISs. It would be interesting to see if this data distribution still holds or not.

The fourth and final data distribution deals with program quality tools, such as the CLASS and ERS which have been employed a great deal in the CCEE research literature and in particular in QRIS (ERS) and Head Start (CLASS). The data distributions for these tools are always normally distributed and show no data skewness in their distribution. The kurtosis is a bit different with the CLASS showing a higher level of kurtosis than the ERS tools when compared side by side. This data distribution is very desirable from a statistical point of view but is not always attainable with the CCEE research literature as demonstrated by the classification in this research abstract when looking at other CCEE systems: Licensing, Head Start, and QRIS. Take a look at the slides that are appended to this abstract to get a better visualization of these differing distributions.

Several slides taken from presentations and webinars are included/appended to this abstract to help depict the above relationships and provide examples of the data distributions. All the slides have notes attached to them to give further explanation of the particular graphic.

ECERS Child Care Distribution

18



This slide clearly demonstrates the lower scores on the ECERS for child care/preschool programs (Georgia term for child care). There is not as much variation or dispersion in the data set as should be with an assessment tool that is generally normally distributed.

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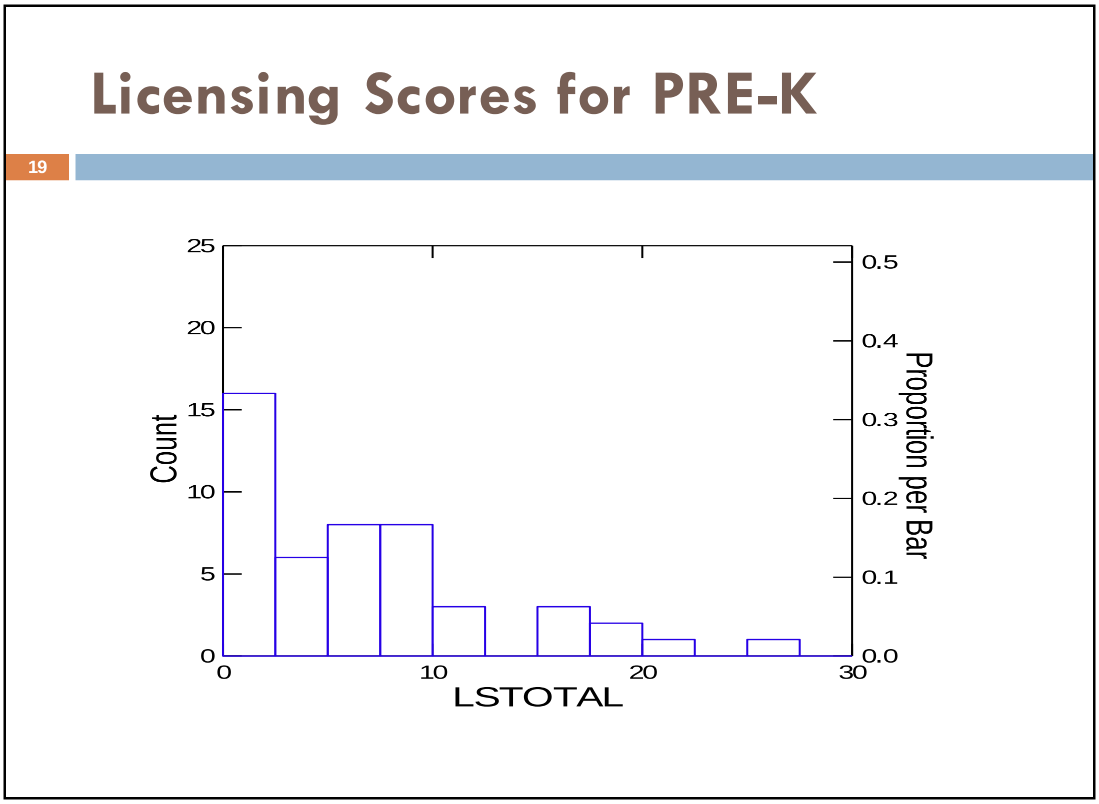
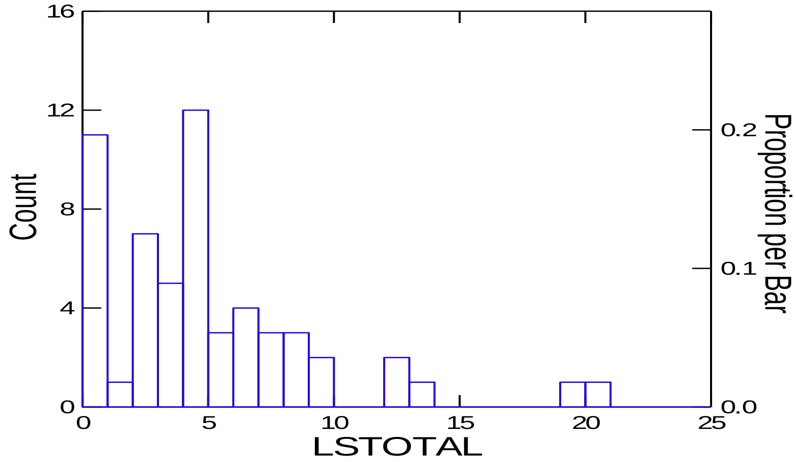


This slide clearly demonstrates the greater variance in the licensing data base with the Pre-K programs. Also note the large number of fully compliant programs.

Licensing Scores for Child Care

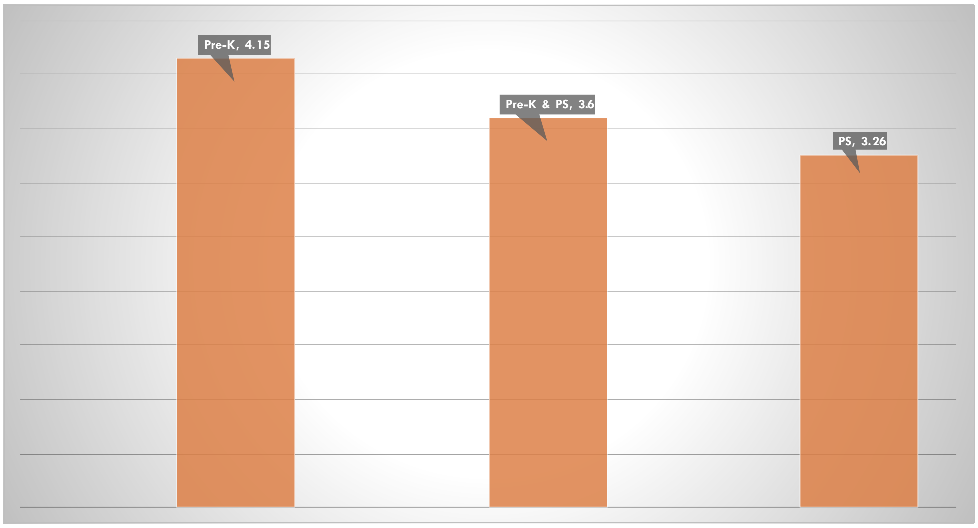
20



This slide shows how extremely skewed the licensing score data are with child care/preschool programs. Skewed data present many problems by introducing mediocre programs along side highly functioning programs when data are dichotomized. This is addressed more fully in later slides.

Impact of Pre-K on ECERS Scores

22



This graphic shows the impact that a high quality program such as Pre-K can have on all classrooms in a program. Not only do the Pre-K classrooms benefit but there is a spill over effect to those classrooms in the same building. The child care/preschool only (PS) child care programs had the lowest average scores on the ECERS.

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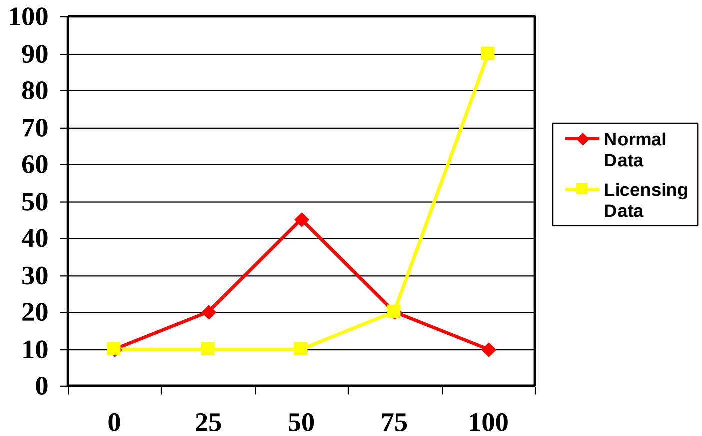
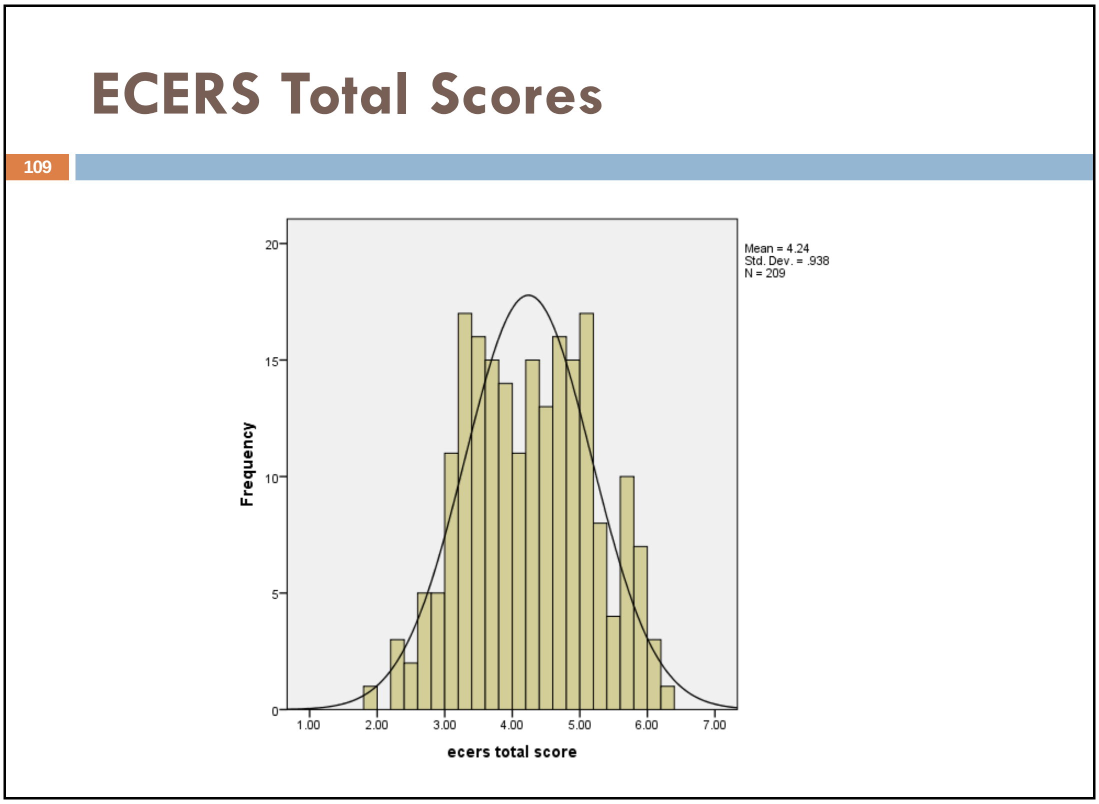
Normal & Skewed Data

108



The data distributions for normally and skewed data sets. PQ data such as ERS are more normally distributed while licensing data are more skewed. This is a very important distinction because skewed data provides more challenges both statistically and from a policy stand point. These challenges will be explained in the subsequent slides.



ECERS data show a more normally distributed curve than what one finds with licensing data.

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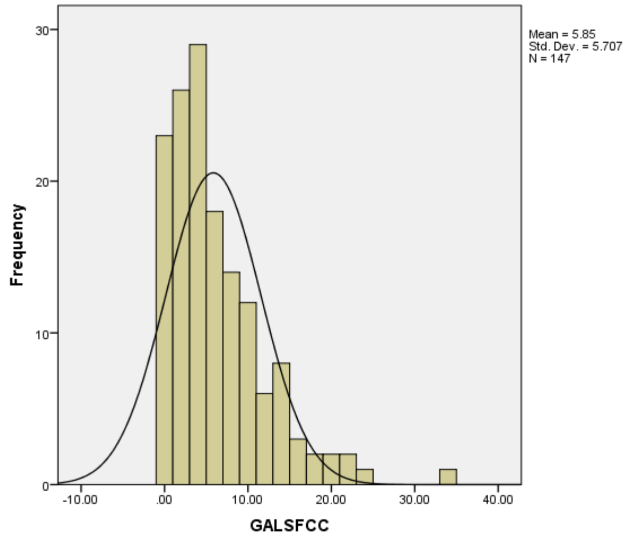
State's Family CC Home Licensing

110



A state's family child care home licensing data which depicts the classic skewness of data always present in licensing data in general.

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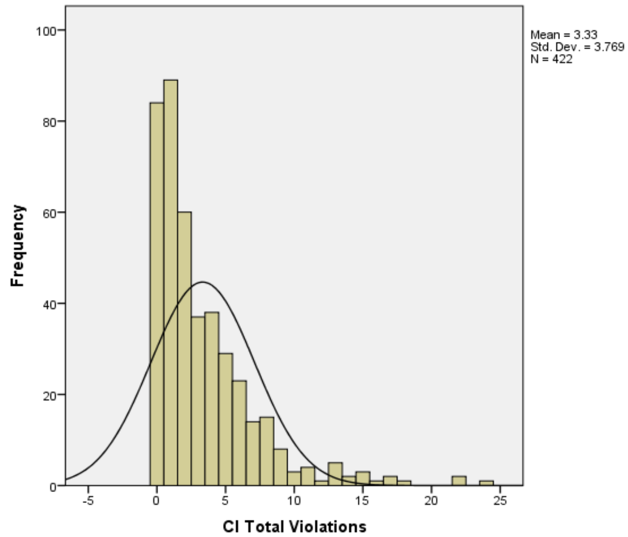
Head Start Performance Standards

111



This graphic shows how even HSPS – Head Start Performance Standards compliance data are skewed in a similar fashion as state licensing data.

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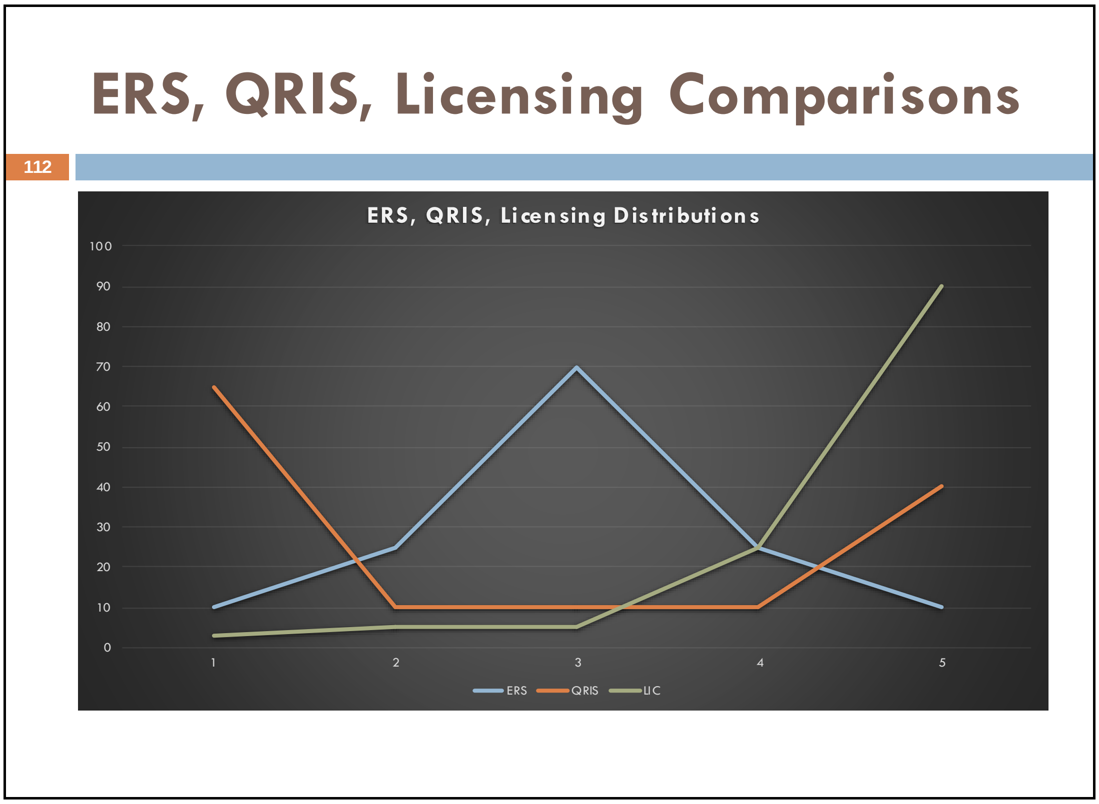


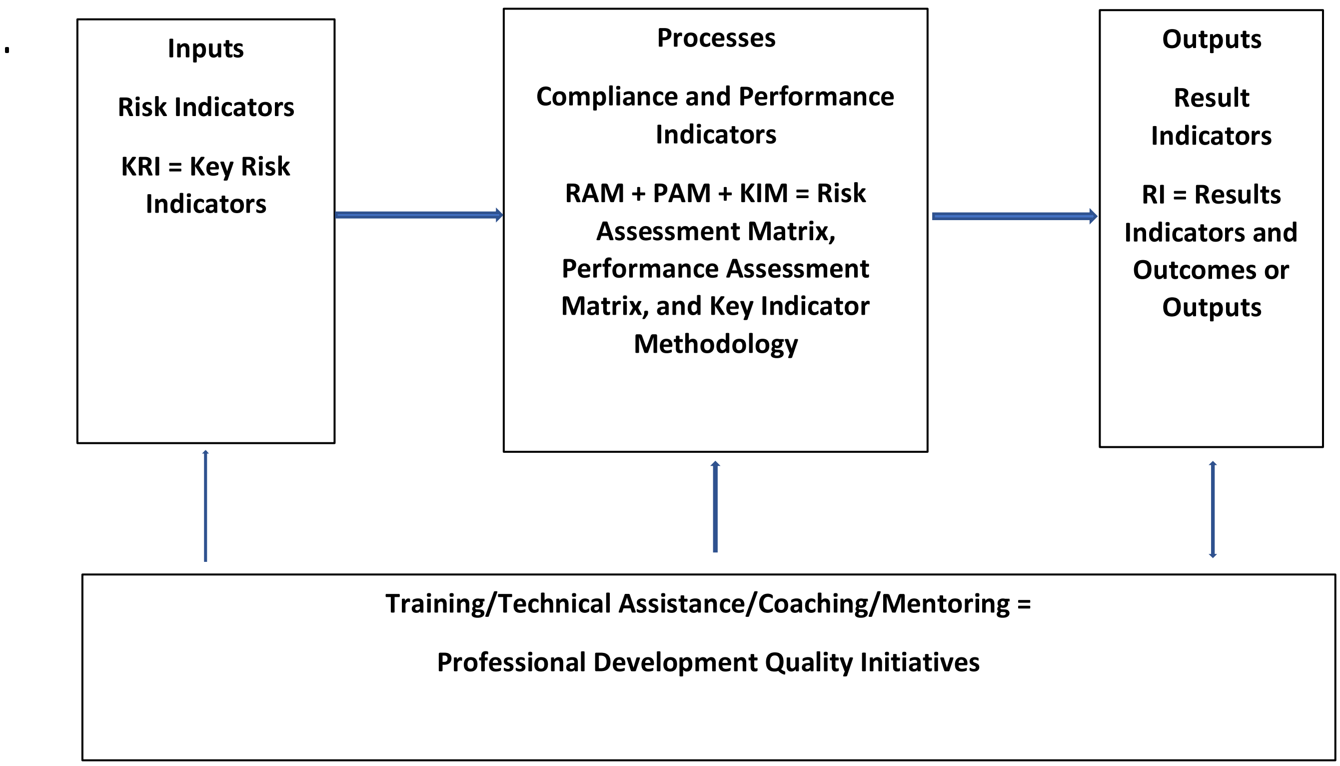
The graph depicts the potential data distributions found in ERS, QRIS, and Licensing scoring systems. The data distribution that is preferred is the normally distributed ERS data example. Both the QRIS and licensing data distributions lend themselves to dichotomization of the data. There are two potential enhancements that may help to reduce the need for dichotomization of the data through the introduction of quality standards within rules/regulations as proposed in the beginning slides of this presentation and the newly proposed Regulatory Compliance Scale also introduced in the earlier slides. Both help to more normally distribute the regulatory compliance data set and reduce the skewness of the data distribution.

ECPQIM5: Early Childhood Program Quality Improvement/Indicator Model Version 5 Technical Research Note

Richard Fiene, Ph.D.

April 2022

The purpose of this brief technical research note is to introduce the latest version of the Early Childhood Program Quality Improvement/Indicator Model (Version 5). This latest version takes into account the previous versions of the ECPQIMs and incorporates the latest monitoring research into the model.



The above figure depicts the relationships of risk indicators to compliance and performance indicators to outcome/result indicators. It also demonstrates the importance of quality initiatives such as professional development systems engaged in training, technical assistance, coaching, and mentoring of teachers. ECPQIM5 has taken all the best components from previous versions and has combined it in this present Version Five.

Another way of thinking about the relationships is to think in terms of a typical information system that involves inputs, processes, and outputs. ECPQIM2 was organized in this fashion while the other versions of ECPQIM were organized more according to the dictates of a logic model.

The best example of this version of the model is the Head Start Grantee Performance Management System (GPMS) that is under development and revision as we speak. There has been a great deal of interest in developing similar models in various state and Canadian Provinces. Head Start appears to have the lead in developing this state-of-the-art program monitoring system.

The other thing to notice with ECPQIM5 is the balance of compliance and performance indicators. This can occur with a deliberate effort to build in best practices or promising practices or through the use of other quality initiatives from Quality Rating and Improvement Systems, Accreditation Systems, or Professional Development Systems. And it is with the constant tie ins to professional development that really increases the strength of this latest version of ECPQIM5.

Also, the addition of Risk Indicators is an important design consideration which should have been introduced much earlier. It has been present in licensing and compliance but it is a critical element that will help to either make or break a program monitoring system. It helps to get programs off on a good start and not behind the eight ball.

As with any program monitoring system it is attempting to find the critical paths of those agencies that are successful and those that are struggling. It is through the use of validation studies to determine what the appropriate paths are statistically so that the proper balance of key indicators can be put in place to produce the greatest outputs/outcomes/results.

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The Future of QRIS: A Controversial Opinion

Richard Fiene PhD

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May 2025

With the latest developments in regulatory science, in particular the proposal to infuse quality into rule/regulation development because of the theory of regulatory compliance's ceiling effect and diminishing return when regulatory compliance is correlated with program quality, are we at a point of re-evaluating the need for QRIS: Quality Rating and Improvement Systems? QRIS grew out of the frustrations of child care and early education (CCEE) advocates 30-40 years ago when licensing was not moving in a positive direction to quality. A new quality initiative had to be introduced to enhance the level of CCEE services, QRIS was born.

QRIS's across the country have been a very successful intervention which has helped to enhance the overall quality of CCEE services nationally. I am not questioning if they have been successful or not because based upon the research evidence they have been. The reason I am even suggesting any change is based more on what has been occurring in licensing in the movement to infuse quality into the regulatory compliance licensing system. Thirty-forty years ago, the licensing field wasn't ready for anything close to suggesting a quality component, but today, again based upon the research evidence that has built up over the past 30-40 years, infusing quality into rules/regulations may be a more cost effective and efficient and more equitable approach opening a voluntary QRIS system to everyone.

I know this is controversial and some may see it as CCEE heresy, but I have always been driven by research evidence and data and how to utilize those data for building the most effective and efficient monitoring systems. So, I am wondering if QRIS has done its job and we should be realigning resources to support the quality infusion of rules/regulations. If this transition were to be embraced, obviously it would take years to make the changes, but the system change would be cost neutral with funding shifting from QRIS to licensing and quality staff shifting to licensing positions.

Hopefully CCEE leaders will take a step back and look at the infrastructure of our CCEE delivery systems and determine if this is a more effective and efficient approach. I hope individuals look at it as they have when I proposed in the past the use of developmental play patterns to determine staff child ratios, such as herding behaviors of toddlers; or utilizing the key indicator and risk assessment methodologies for building a new accreditation system: NECPA; or when I suggested a trapezoid mathematical model for measuring compliance with staff child ratios and potential infectious disease patterns during the COVID pandemic; or when I first proposed the theory of regulatory compliance and the ceiling effect/diminishing returns when regulatory compliance was correlated with program quality, I know that was a major public policy shift in accepting substantial compliance for issuing full licenses to facilities; or most recently in proposing a regulatory compliance scale to be used in making licensing decisions based upon a certainty-uncertainty matrix which helps to identify inspector bias; and finally, proposing the use of weighting/ranking because I suggested that rules/regulations are not created nor administered equally and that their differential impact on children should be measured.

So, let's continue on a path of utilizing the empirical data we collect to build the most effective and efficient CCEE systems. Many of my ideas have been controversial but the bottom line for me has always been to build program monitoring systems based upon regulatory science. It is all about "*Show me the data*!!"

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The CCEE Regulatory Compliance and Program Quality Spectrum

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May 2025

This research abstract will introduce a new idea related to depicting regulatory compliance and program quality's linear relationship called the Regulatory Compliance Program Quality Spectrum. This new spectrum idea has grown out of research conducted by the author over the past five decades in describing and maintaining data distributions from licensing, quality, accreditation, quality rating and improvement systems, state rules/regulations, and national standards. This analysis has led to this spectrum idea as an interesting way of depicting how the various systems build upon each other and how they interrelate (see Figure 1).

Figure 1: Regulatory Compliance Program Quality Spectrum

<RC--x--------x---------x--------x-----x----------x---------x-------x-------x-------------x----------x-PQ>

CI KIM CFOCB KIM SS HSPS QRIS PQI CLASS ERS

RAM RAMRW CFOC

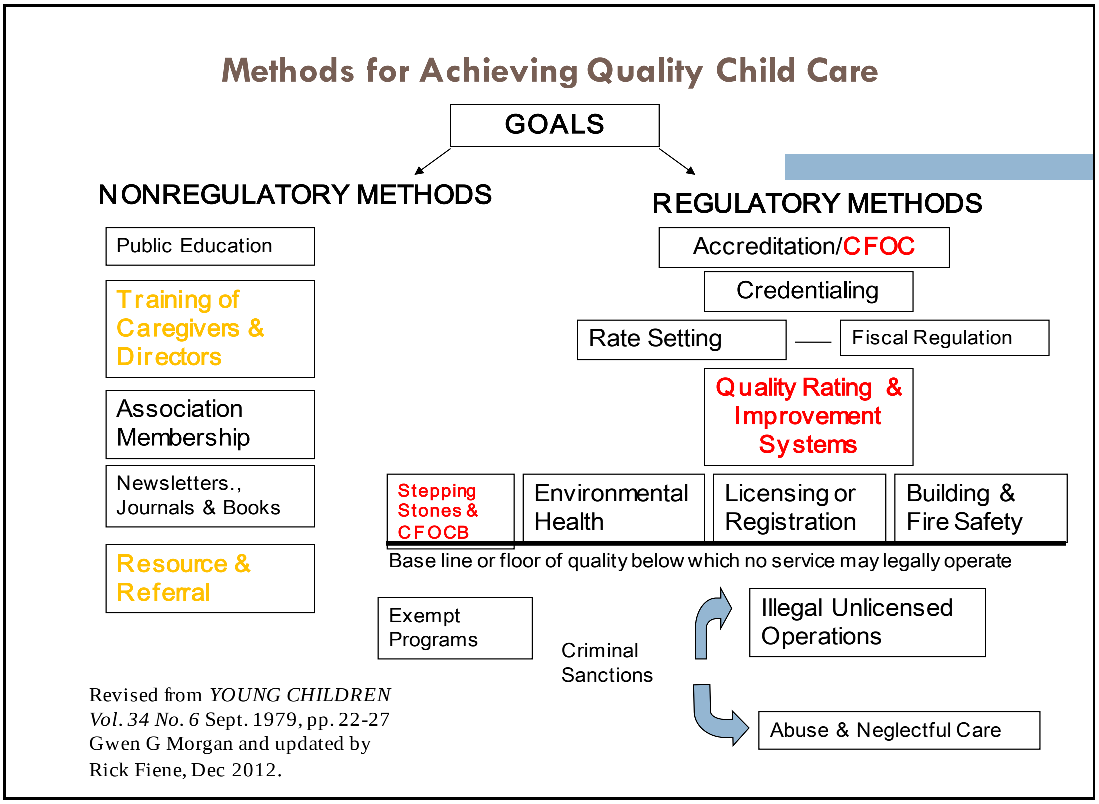
Legend:

CI = Comprehensive Review Instrument; KIM = Key Indicator Rules; RAM = Risk Assessment Rules; CFOCB = Caring for Our Children Basics; RAMRW = Risk Assessment Relative Weighted Rules; SS = Stepping Stones to Caring for Our Children; HSPS = Head Start Performance Standards; QRIS = Quality Rating and Improvement Systems; CFOC = Caring for Our Children; PQI = Program Quality Indicators; CLASS = Classroom Assessment Scoring System; ERS = Environmental Rating Scales; RC = Regulatory Compliance/Licensing; PQ = Program Quality.

The above figure provides the linear relationship between regulatory compliance and program quality with all the licensing related methods and all the program quality tools and standards that are active in the CCEE:Child Care and Early Education field. This proposed spectrum builds off Gwen Morgan's work (see the attached slide taken from presentations and webinars done in the past on Dr Morgan's research work) which was first proposed in the 1970s regarding the relationship of various quality systems. Figure 1 attempts to expand and more clearly show the linear relationship of these systems and how they relate to each other. The interesting finding with these various systems is when data distributions are compared from one approach to another in that many of the data distributions are not linear but have more of a non-linear distribution.

For example, licensing/regulatory compliance systems are more skewed than data distributions that deal with more quality, such as CLASS or ERS (see Fiene's Data Distribution Research Abstract on this relationship).

The reason for proposing this new Spectrum Idea is that many times in the CCEE research literature, the continuity or continuum of these various systems is lost and the potential building block enhancements are not taken advantage of when this occurs. If we truly want to build a high quality CCEE system we need to incorporate all these above resources in doing so. They have been demonstrated over the years to be effective and efficient methods for improving quality, we just need to look at them all together.



Methods for Achieving Quality Child Care by Gwen Morgan really depicts the key regulatory and non-regulatory methods for improving child care quality. I have used this conceptual framework in my design of the Early Childhood Program Quality Indicator Model (ECPQIM) over its four generational development starting back in 1985 with IPM/ICS and most recently with DMLMA (2012). The reader should pay particular attention to the new items added to the model since they add more structure and depth to it. Not all of these are even possible but should be given consideration based upon the resources in a particular state.

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