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

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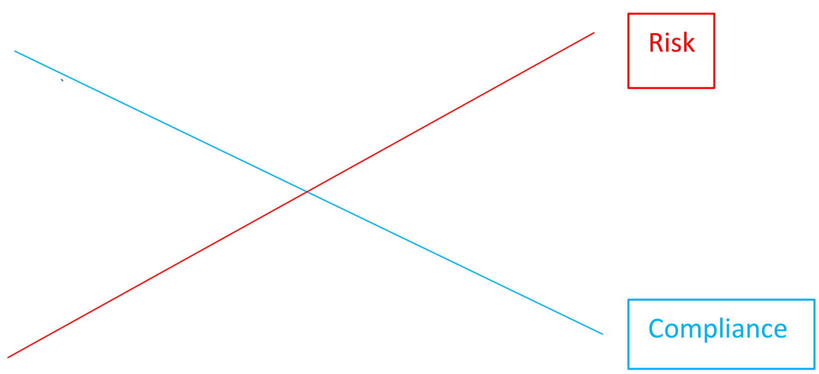
This research abstract will highlight how the reduction of risk and the increase in compliance are the twin pillars of regulatory compliance. As one can see from figure 1 below these two pillars of risk and compliance are not independent of each other but rather inter-dependent. As one increases, the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

Figure 1: Relationship Between Risk Reduction and Compliance

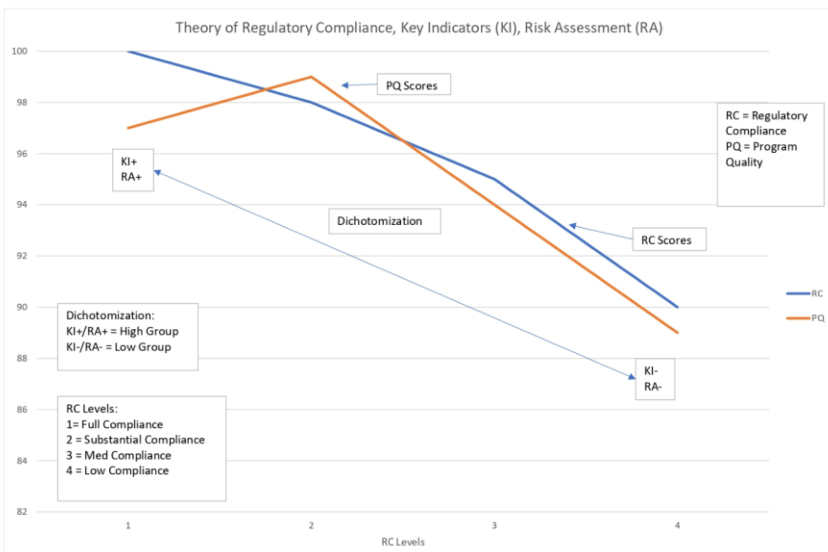


The above Figure 1 depicts the proposed relationship between the pillars of regulatory compliance: risk reduction and increased compliance. It depicts a relationship similar to more well-known relationships such as the economic supply and demand relationship or the management effectiveness and efficiency 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 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.

<u>Figure 2: Theory of Regulatory Compliance</u>



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

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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.

<u>Table 3: Key Indicator Compliance based upon History and Individual Reviews</u>

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.

Regulatory Compliance Scale Trials and Tribulations (Enhanced Version)

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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 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

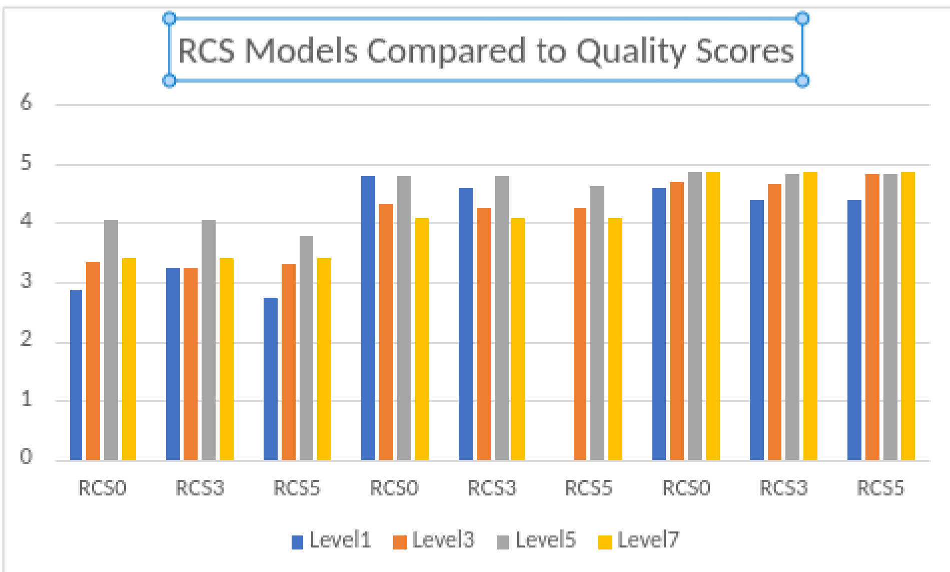
Jurisdictions	**Model**	**Level 1**	**Level 3**	**Level 5**	**Level 7**
Jurisdiction1	**RCS0**	**2.85**	**3.34**	**4.05**	**3.40**
	RCS3	3.24	3.23	4.05	3.40
	RCS5	2.73	3.32	3.77	3.40
Jurisdiction2	RCS0	4.81	4.31	4.80	4.10
	RCS3	**4.59**	**4.25**	**4.80**	**4.10**
	RCS5	---	4.26	4.64	4.10
Jurisdiction3	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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TRC+: Regulatory Compliance Theory of Diminishing Returns

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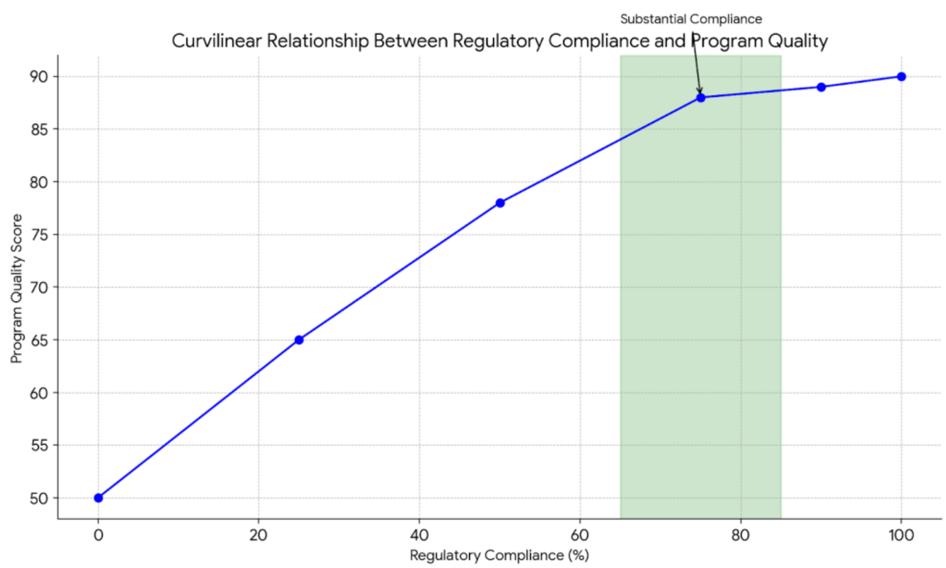
This research abstract will update the relationship between regulatory compliance and program quality (depicted in the below graph) using three equations listed below which deal with a simple linear model at the low compliance range, a threshold model at the midpoint compliance range, and a diminishing 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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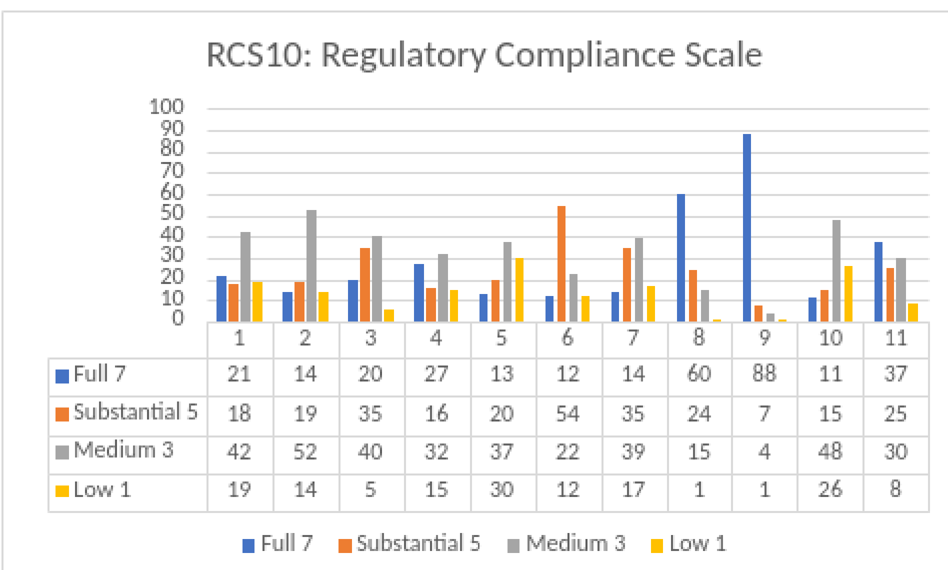
Regulatory Compliance Scale: Results from 11 Studies in 10 States and Canadian Provinces

February 2024

This research abstract will provide 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 and below graphic



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

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January 2024

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

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

It became clear after these findings in the 1970's-80's and then in the 2010's when replication studies were completed that substantial regulatory compliance could not be ignored based upon this new theory of regulatory compliance in which substantial compliance acted as a "sweet spot" of best outcomes or results when comparing regulatory compliance and program quality scores. The nominal metric needed to be revised and more of an ordinal metric was to be its replacement. Because now it wasn’t just being in or out of compliance, but it mattered which rules were in or out of compliance and how they were distributed. This revised application involved aggregate rules and does not apply to individual rule scoring. The studies completed between 1970 and 2010 involved aggregate rules and not individual rules. To determine if the nominal to ordinal metric needs to be revised still needs empirical data to back this change.

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

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

Without the Theory of Regulatory Compliance, differential and integrative monitoring would not be needed because regulatory compliance would have had a linear relationship with program quality and full compliance would have been the ultimate goal. There would have been no need for targeted rule enforcement or reviews because all rules would have had an equal weight when it came to protecting clients and any individual rule would have predicted overall compliance. But it "just ain't so" as it is said. The need to make adjustments is brought about by the theory and it has not been the same ever since.

Regulatory Compliance Scales and Program Monitoring Systems

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.

Conclusion:

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

These concepts offer a shift from traditional "one-size-fits-all" compliance models to more flexible and nuanced approaches that consider risk, program quality, and degrees of compliance. This can lead to more efficient and effective regulatory systems that support program improvement while protecting public safety.

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

RIKI – Research Institute for Key Indicators Data Laboratory Penn State University Edna Bennett Pierce Prevention Research Center and NARA

in strategic partnership with NARA – National Association for Regulatory Administration and affiliated with the Penn State University Edna Bennett Pierce Prevention Research Center

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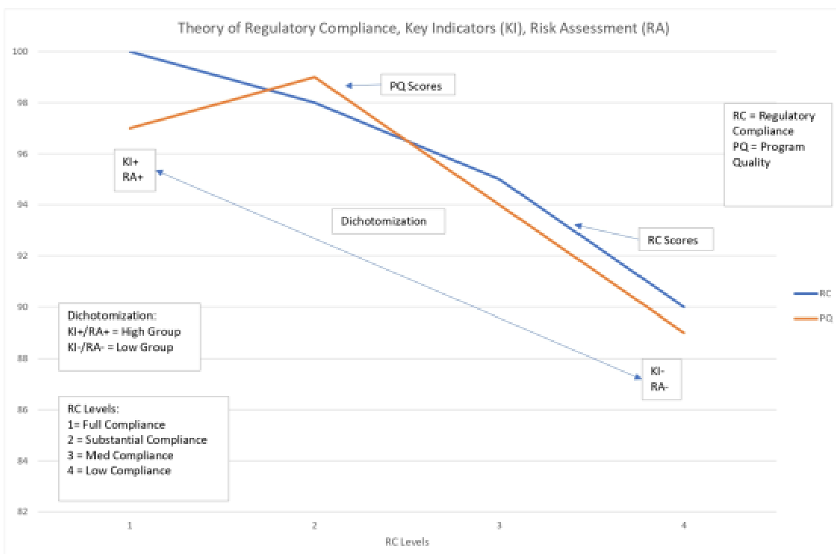
Theory of Regulatory Compliance, Key Indicators, Risk Assessment and Dichotomization Graphic

Posted on December 24, 2023 by Dr Fiene

Here is a graphic that captures the relationship of the Theory of Regulatory Compliance, Key Indicators, Risk Assessment, and the dichotomization of licensing data (all these topics have been discussed at great length in the RIKINotes Blog over the past year):



A picture is worth a 1000 words, but in the above case, I am sure a couple of words of explanation would be helpful for those who are left hemisphere dominated rather than right hemisphere dominated as I am. Here are the essential elements of the above graphic.

RA = Risk Assessment rules insures that all the high risk rules are in compliance. This is non-negotiable, all of them are in place for any type of inspection review: full, comprehensive and/or abbreviated. KI = Key Indicators are a bit more flexible because it is based upon probabilities and the predictor rules are generally not as heavily weighted as is the case with risk assessment rules.

The bottom line is that regulatory compliance is important in ensuring that clients are safe and healthy. However, the relationship with quality is a bit more complex based upon the Theory of Regulatory Compliance. There is not the same relationship to program quality as there is to health & safety. Substantial compliance appears to be more effective in determining overall program quality rather than full regulatory compliance with all rules. That is depicted in the curvilinear relationship between Regulatory Compliance (RC) and Program Quality (PQ) as one moves along the RC Levels (1 – 4 = Full – Low Compliance).

And finally, data dichotomization helps to eliminate false negatives and decrease the impact of false positives when taken to the extremes (moving from a 25/50/25 model to 5/90/5 model in distinguishing between high and low regulatory compliance (KI+/RA+ & KI-/RA-)). The rules will not change usually but their phi coefficients will increase significantly. Data dichotomization is not generally recommended but with the extreme skewness in licensing data it is warranted and fits with the measurement of licensing data at the nominal level as well as the theoretical structure of the data distribution based upon full and substantial levels of regulatory compliance being the predominant number of programs. There generally are far fewer programs at a medium or low level of regulatory compliance.

The above graphic helps to summarize several concepts related to differential monitoring and the theory of regulatory compliance. It is suggested that previous RIKINotes posts and the RIKI Selected Publications webpage be consulted for a more detailed rendition of what is presented in this post. The technical research notes on the RIKI Selected Publications provide a more in-depth analysis of the above concepts.

About Dr Fiene

Dr. Rick Fiene has spent his professional career in improving the quality of child care in various states, nationally, and internationally. He has done extensive research and publishing on the key components in improving child care quality through an early childhood program quality indicator model of training, technical assistance, quality rating & improvement systems, professional development, mentoring, licensing, risk assessment, differential program monitoring, and accreditation. Dr. Fiene is a retired professor of human development & psychology (Penn State University) where he was department head and director of the Capital Area Early Childhood Research and Training Institute.

View all posts by Dr Fiene →

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RIKI – Research Institute for Key Indicators Data Laboratory Penn State University Edna Bennett Pierce Prevention Research Center and NARA

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.

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 Uncertainty-Certainty Matrix for Licensing Decision Making: Policy and Program Implications

Richard Fiene PhD

Research Institute for Key Indicators Data Lab/Penn State University

December 2023

This abstract will take the Confusion Matrix which is a well-known metric in the decision-making 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. 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:

<u>Table 1: Uncertainty-Certainty Matrix (UCM) Logic Model</u>

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.

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

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.

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UCM Matrix: Uncertain-Certainty Matrix

Certain **A**	*UnCertain* **B**	*UnCertain* **C**	*Certain* **D**	*Random* **A+B**	*Random* **A+C**	*Random* **B+D**	*Random* **C+D**	*Certain* **A*D**	*UnCertain* **B*C**	*Random* **SUM**	*Random* **SQRT**	*+/-* **SUB**	*+/0/-* **PHI**	*Matrix* ***Result***
50	0	0	50	50	50	50	50	2500	0	6250000	2500	**2500**	1	***Certain***
25	25	25	25	50	50	50	50	625	625	6250000	2500	**0**	0	***Random***
0	50	50	0	50	50	50	50	0	2500	6250000	2500	**-2500**	-1	***Uncertain***

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

The Model

UCM Matrix Logic		**Decision Regarding**	**Regulatory Compliance**
		(+) In Compliance	(-) Not In Compliance
Actual State of	(+) In Compliance	50	0
Compliance	(-) Not In Compliance	0	50

Certain Matrix

UCM Matrix Logic		**Decision Regarding**	**Regulatory Compliance**
		(+) In Compliance	(-) Not In Compliance
Actual State of	(+) In Compliance	25	25
Compliance	(-) Not In Compliance	25	25

Random Matrix

UCM Matrix Logic		**Decision Regarding**	**Regulatory Compliance**
		(+) In Compliance	(-) Not In Compliance
Actual State of	(+) In Compliance	0	50
Compliance	(-) Not In Compliance	50	0

Uncertain Matrix

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	

Full versus Substantial Regulatory Compliance

Richard Fiene PhD

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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.

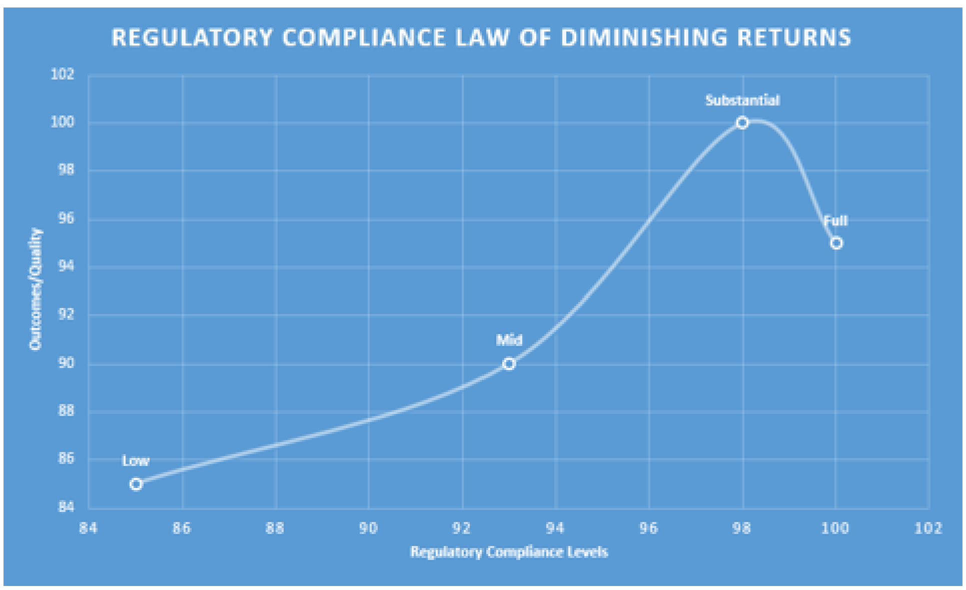
This brief abstract is presented in the interest of attempting to get additional empirical evidence in the research literature related to regulatory compliance outcomes. So far in this study, it is demonstrating that overall regulatory compliance is not significantly related to preventing child injuries, 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.

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

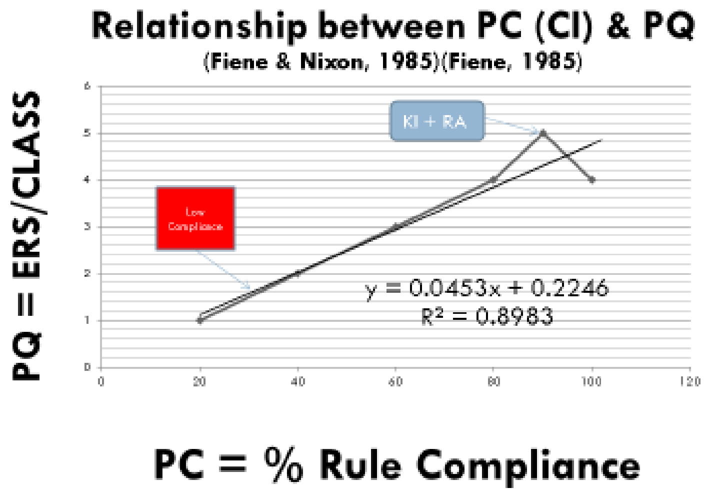
Richard Fiene PhD

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.



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

Key Indicator Formula Matrix

5

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

6

- **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.

Key Indicator Statistical Methodology

7

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

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)

8

- 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

Legend:

9

- 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
- $\Sigma R1$ = 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)

10

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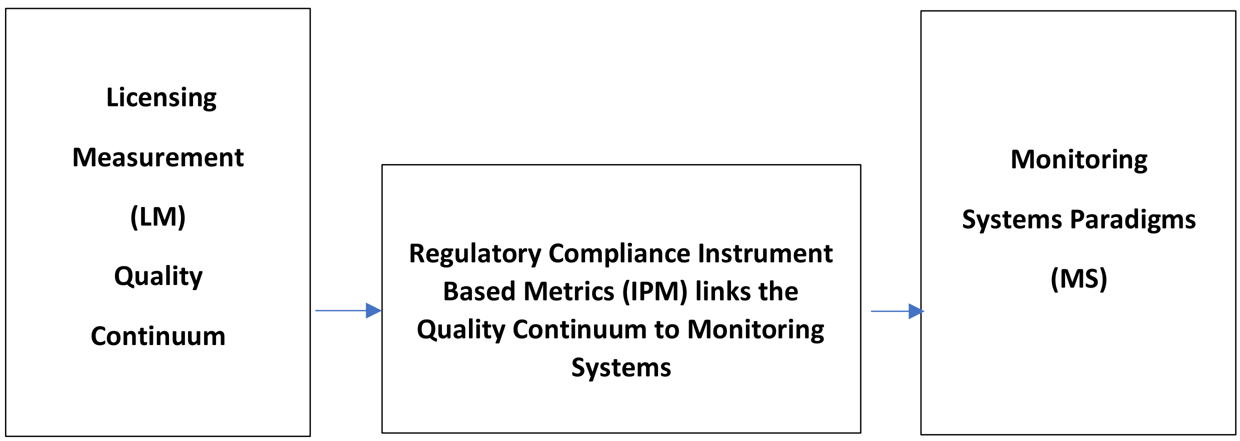
Relationship Amongst Regulatory Compliance Metrics, Monitoring Paradigms, and Licensing Measurement Quality Continuum Graphic and Matrix

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.

<u>Matrix: Comparing Regulatory Compliance, Quality, and Monitoring Systems Paradigms</u>

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

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

Richard Fiene PhD

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May 2023

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

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Research Institute for Key Indicators/Penn State

March 2023

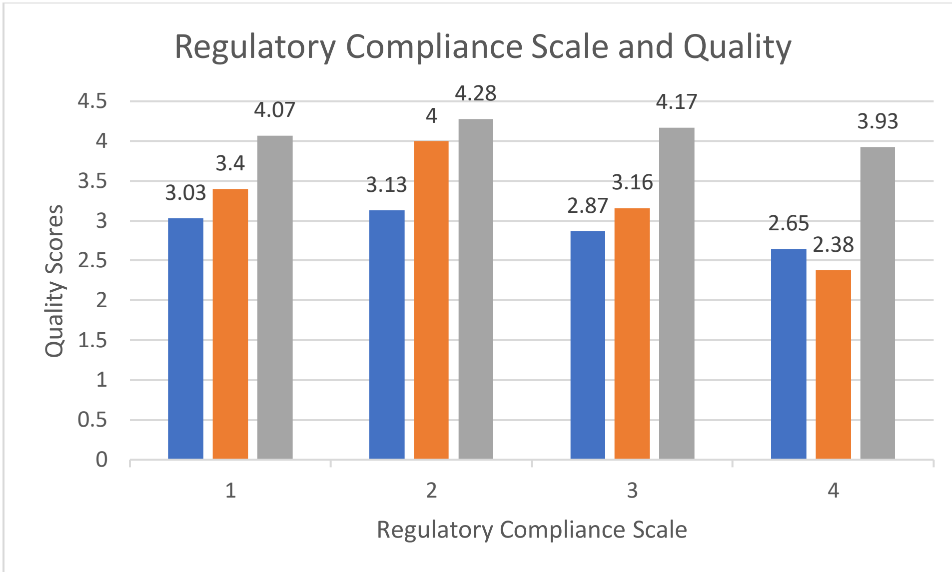
This technical research note/abstract provides a data matrix (below table) depicting the relationship between regulatory compliance and program quality. The data clearly demonstrate the regulatory compliance theory of diminishing returns which depicts the ceiling or plateau effect in this relationship 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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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.

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>

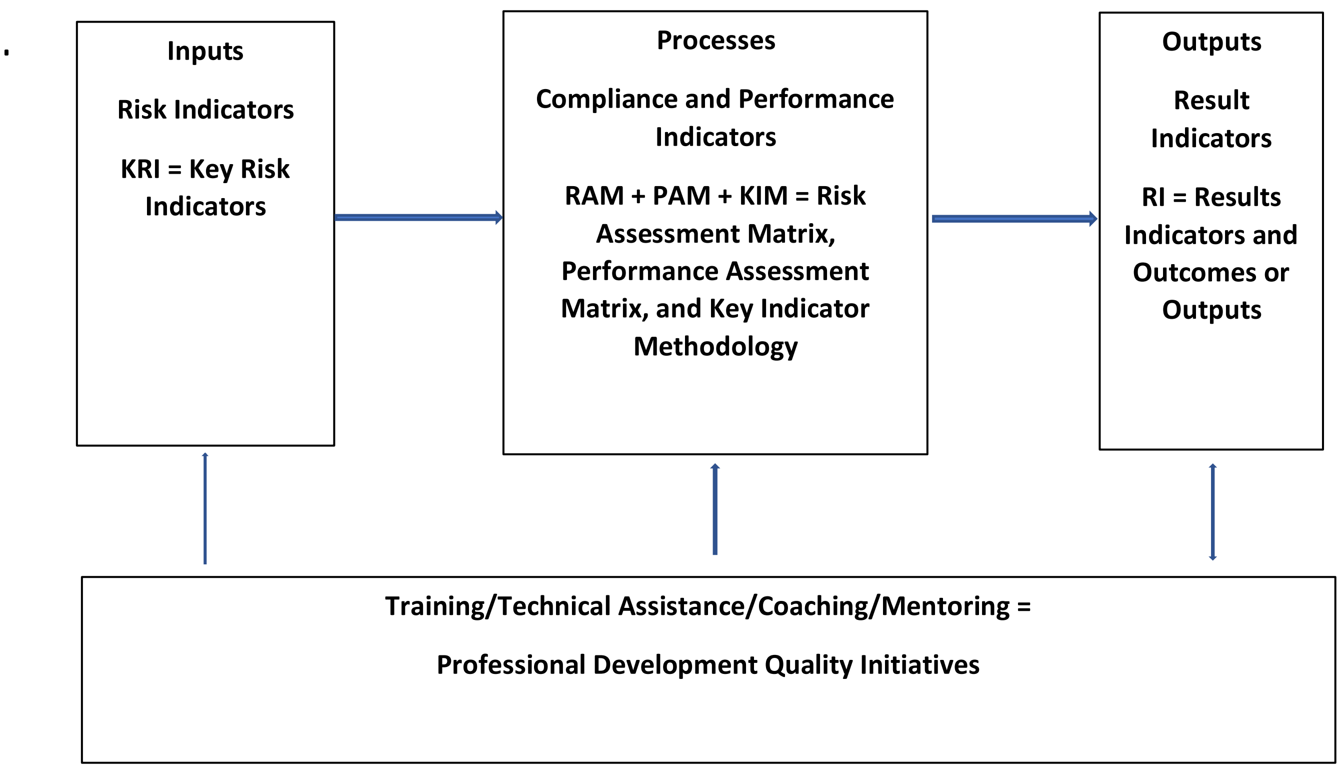
Fiene, R. (2019). A treatise on Regulatory Compliance. *Journal of Regulatory Science*, Volume 7, 2019. https://doi.org/10.21423/jrs-v07fiene

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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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.

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. The 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. 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.

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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.

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.

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.

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.

Regulatory Compliance & Program Quality Grid Model: Technical Research Note

Richard Fiene, Ph.D.

December 2020

Depicted below if 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"** represent 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 italized "***X***" is an outlier that has also been identified in the research literature in which sometimes (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 mitigate 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%**	**5QualityAddons**
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.

Theory of Regulatory Compliance Models

Richard Fiene, Ph.D.

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.

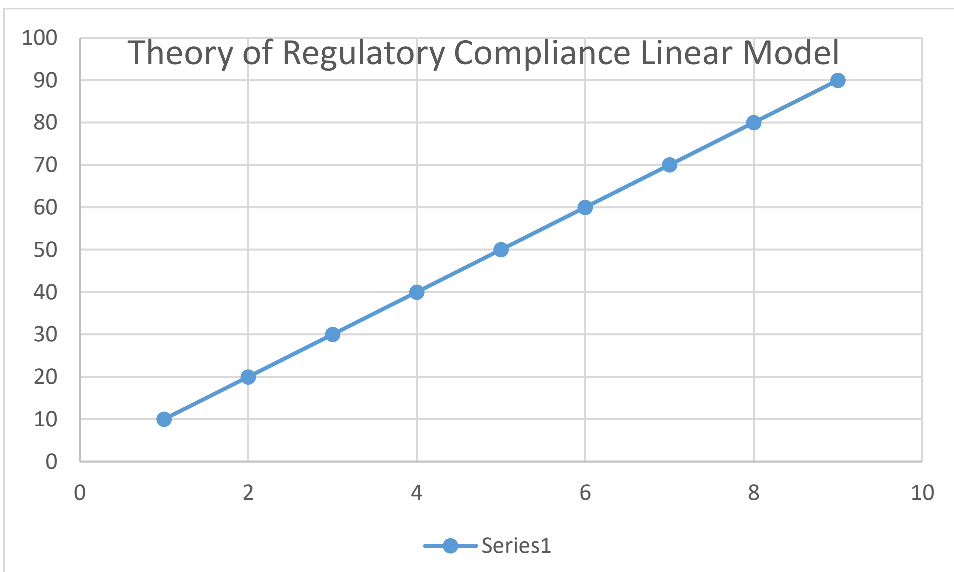


Figure 1

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).

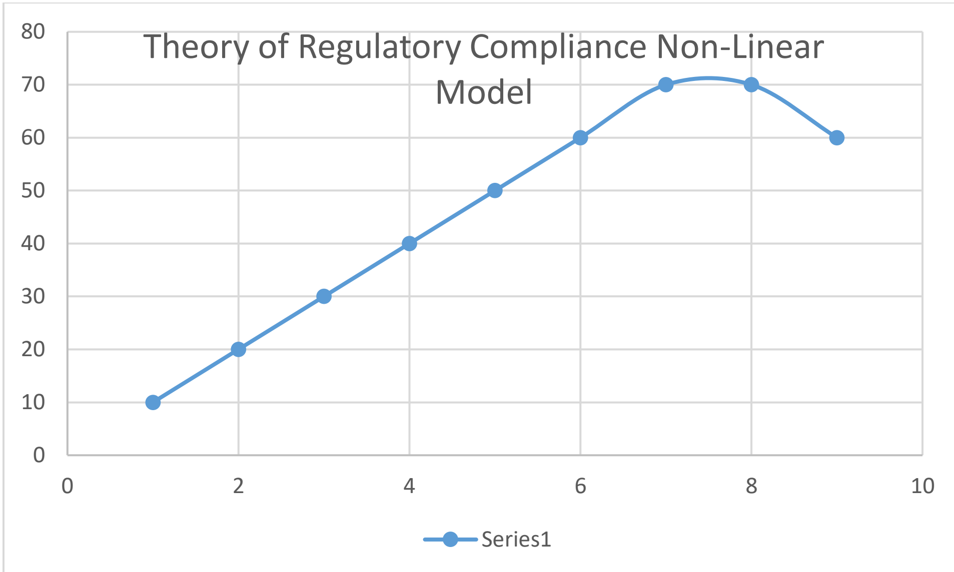


Figure 2

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 Model rather than a Non-Linear Model. The Stepped Model appears to explain more fully how certain less important rules can be significant predictors of overall compliance and quality.

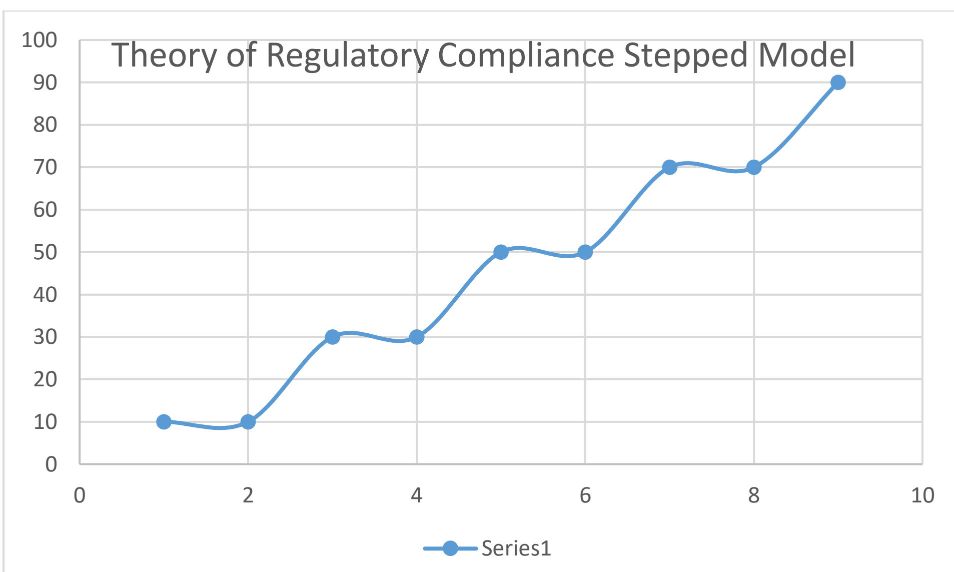


Figure 3

This last model 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 to the next rather than focusing on the plateau. So rather than having just one plateau, this model suggests that there are several plateaus.

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

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.

Regulatory Compliance Law of Diminishing Returns

Richard Fiene, Ph.D.

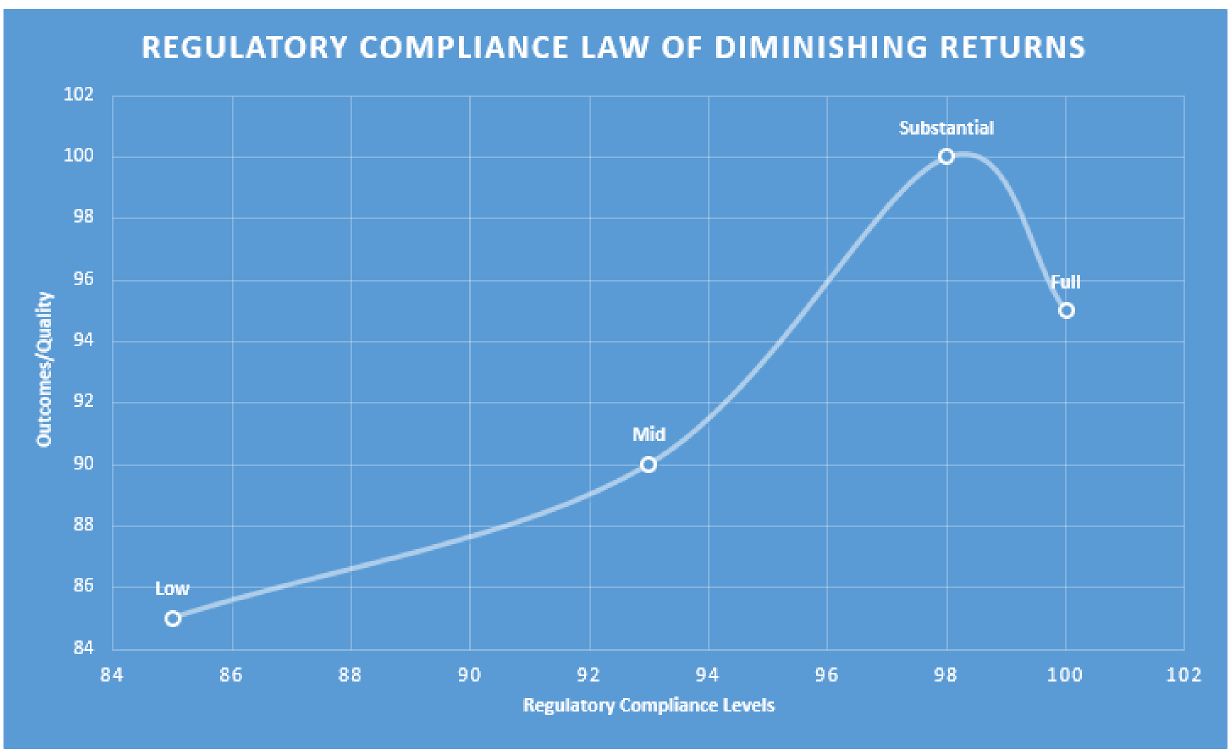
Research Institute for Key Indicators and Penn State University

January 2020

This brief technical research note will provide an update regarding the relationship between regulatory compliance and program quality/outcomes. Based upon the most recent research from studies with the national Head Start program, early care and education programs in Georgia and Washington, it is possible now to begin to address the limitations of full regulatory compliance and its lack of support for program quality/outcomes. The following figure (Figure 1) provides a graphic display of the relationship between these variables from the above-mentioned studies.

For sake of presentation, the data have been smooth-out so that it presents a clearer picture of the relationship. The important aspect of this relationship is not moving from low compliance to mid and substantial compliance. The relationship holds up as it should in demonstrating a consistent linear distribution. The most important aspect is in moving from substantial to full regulatory compliance in which the linear relationship breaks down and there is at least a plateau effect and in many cases a statistically significant drop off in quality outcomes (see Chart 1).

Figure 1: Relationship Between Regulatory Compliance and Program Quality/Outcomes



Based upon the empirical evidence from the above-mentioned studies (see Chart 1), it provides support in demonstrating the need to re-think how we approach regulatory compliance. It would appear to be more cost effective and efficient to determine which rules/regulations have the greatest impact on quality outcomes rather than looking at all rules/regulations as being equal in importance. So does regulatory compliance follow the economic rules of the law of diminishing returns in providing a healthy and safe setting for our clients. And do these findings in human services generalize to other services in the private economic sectors?

The following chart (Chart 1) provides data distributions from states and a national organization showing the relationship between specific program quality tools (ERS and CLASS) and regulatory compliance (RC) data. The last row gives the result as either the data dropping off or plateauing.

Chart 1: Data Distributions for ERS and CLASS from Selected States

RC	**ERS1**	**ERS2**	**CLASS1**	**CLASS2**	**CLASS3**	**CLASS4**	**CLASS5**
Full	3.84	3.40	5.91	2.55	3.03	5.99	5.59
Subst	4.26	3.77	6.22	2.77	3.15	5.93	5.50
Medium	4.18	3.26	-----	-----	2.87	5.85	5.37
Low1	3.92	2.51	6.14	2.55	2.65	5.71	5.32
Low2	-----	-----	-----	-----	2.56	5.52	4.93
Result	Drop Off	Drop Off	Drop Off	Drop Off	Drop Off	Plateau	Plateau
P values	.03	.001	n.s.	n.s.	.001	.001	.003

It is evident from the above data displays in Chart 1 that there is a plateau effect (n = 2) or in 5 cases the average quality scores showed a statistically significant decrease.

Regulatory Compliance Scoring System and Scale

Richard Fiene, Ph.D.

Research Institute for Key Indicators and Penn State

National Association for Regulatory Administration

December 2019

By 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 indicate increasing risk of non-compliance and a lower level of overall regulatory compliance which is not a good think 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 up 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.

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.

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:

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

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.

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.

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.

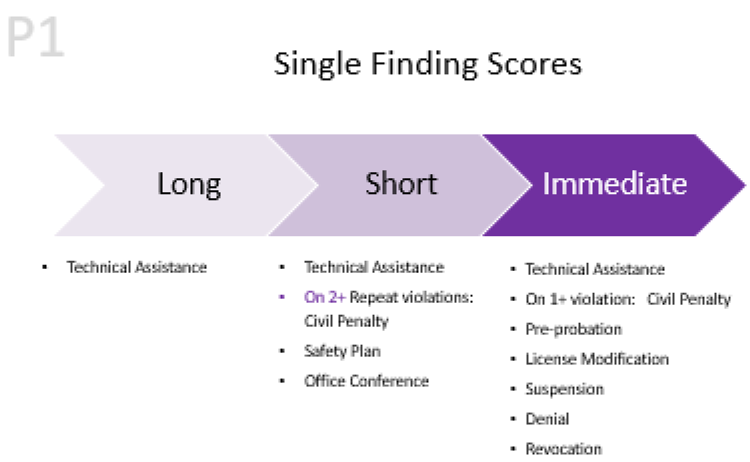
Washington State's HB 1661 (2017) redefined the department's facility licensing compliance agreement (FLCA) process. One feature of this new process is to allow licensed providers to appeal violations noted on the FLCA that do not involve "health and safety standards.[1]" To determine what licensing 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:

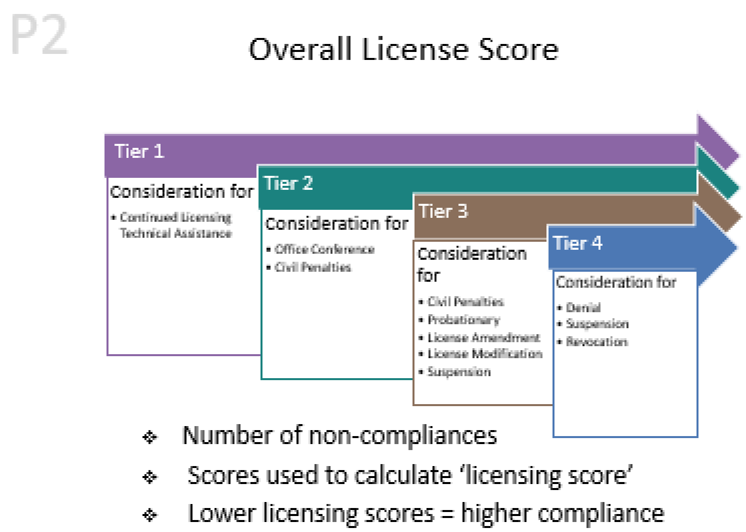
Step 2:

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
	Immediate	**9**	**8**	**7**
Risk/Severity	**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.

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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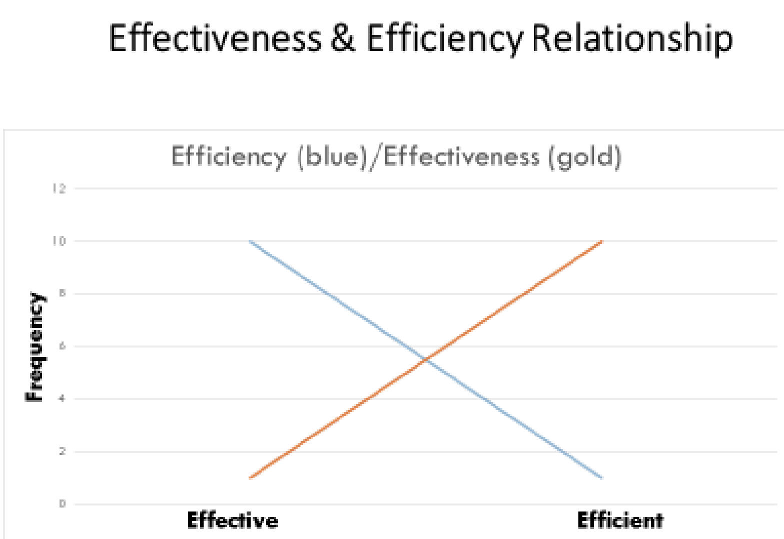
Effectiveness and Efficiency Relationship Leading to Cost Benefit

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 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.

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

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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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.

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

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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.

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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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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.

Regulatory Compliance Key Indicator Metric and Matrix Update/Revision Technical Research Note

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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), false negatives could be either eliminated or reduced to the point of no concern.

However, in the event that substantial compliance rather than full compliance is used as the thresh old 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 in order to take into account 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) it will basically eliminate the use of any results in which a false negative occurs when substantial compliance is determined. The table below displays the variables of the Regulatory Compliance Key Indicator Matrix (RCKIM).

RCKIM	High RC Group	RC Low Group	Totals
KI In Compliance	A	B^3	Y
KI Violations	C	D	Z
Totals	W	X	

Regulatory Compliance Key Indicator Matrix (RCKIM)

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 those 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. Below are some data displays to support this revision/update:

RCKIM: Regulatory Compliance Key Indicator Metric (Fiene, 2023)

A	B	C	D	E	F	G	H	I	J	K	L	M	N
20	24	30	26	44	56	50	50	520	720	6160000	2481.934729	-200	-0.080582
20	0	30	26	20	56	50	26	520	0	1456000	1206.64825	520	0.430946
20	1000	30	26	1020	56	50	1026	520	30000	2.93E+09	54131.83906	-29480	-0.544596
20	1	30	26	21	56	50	27	520	30	1587600	1260	490	0.388889
20	24	1000	26	44	1026	1020	50	520	24000	2.3E+09	47982.7469	-23480	-0.489343
20	0	0	26	20	26	20	26	520	0	270400	520	520	1
0	24	30	0	24	30	30	24	0	720	518400	720	-720	-1
25	25	25	25	50	50	50	50	625	625	6250000	2500	0	0
20	5	30	26	25	56	50	31	520	150	2170000	1473.091986	370	0.251172
20	5	10	26	25	36	30	31	520	50	837000	914.8770409	470	0.51373
20	24	30	6	44	36	50	30	120	720	2376000	1541.427909	-600	-0.389249
10	24	30	6	34	36	40	30	60	720	1468800	1211.940593	-660	-0.544581

Variables Reference

Excel = RCKIM Variables

a=a OK
b=b False Negative (-)
c=c False Positive (+)
d=d OK
e=a+b
f=c+d
g=a+c
h=b+d
i=a*d
j=b*c
k=w*x*y*z
l=sqrt wxyz
m=(a*d)-(b*c)
n=fc +=OK
0=Random
-=NULL

Regulatory Compliance Key Indicator Equations/Algorithms and 2 x 2 Matrix:

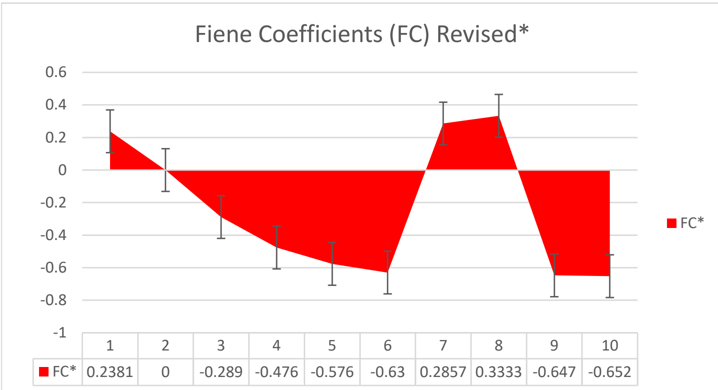
*fc = ((a*d) - (b*c)) / sqrt wxyz* — Full Regulatory Compliance
fc = ((a*d) - ((b^3*c)) / sqrt wxyz* — Substantial Regulatory Compliance

A	*B^3*	*W*
C	*D*	*X*
Y	*Z*	*RCKIMatrix*

(Fiene (2023). Regulatory Compliance Key Indicator Metric & Matrix. Research Institute for Key Indicators, Etown, PA.)

A	B	C	D	E	F	G	H	I	J	K	L	M	N=FC	B^3
20	1	50	20	21	70	70	21	400	50	2160900	1470	350	0.238095	1
20	2	50	20	22	70	70	22	400	100	2371600	1540	300	0.194805	8
20	3	50	20	23	70	70	23	400	150	2592100	1610	250	0.15528	27
20	4	50	20	24	70	70	24	400	200	2822400	1680	200	0.119048	64
20	5	50	20	25	70	70	25	400	250	3062500	1750	150	0.085714	125
20	6	50	20	26	70	70	26	400	300	3312400	1820	100	0.054945	216
20	0	50	20	20	70	70	20	400	0	1960000	1400	400	0.285714	0
20	0	40	20	20	60	60	20	400	0	1440000	1200	400	0.333333	0
20	10	40	20	30	60	60	30	400	400	3240000	1800	0	0	1000
20	11	40	20	31	60	60	31	400	440	3459600	1860	-40	-0.021505	1331

A	B^3	C	D	A+B	C+D	A+C	B+D	A*D	B*C	WXYZ	sqrtWXYZ	(A*D)-(B*C)	FC*
20	1	50	20	21	70	70	21	400	50	2160900	1470	350	0.238095
20	8	50	20	28	70	70	28	400	400	3841600	1960	0	0
20	27	50	20	47	70	70	47	400	1350	10824100	3290	-950	-0.288754
20	64	50	20	84	70	70	84	400	3200	34574400	5880	-2800	-0.47619
20	125	50	20	145	70	70	145	400	6250	1.03E+08	10150	-5850	-0.576355
20	216	50	20	236	70	70	236	400	10800	2.73E+08	16520	-10400	-0.62954
20	0	50	20	20	70	70	20	400	0	1960000	1400	400	0.285714
20	0	40	20	20	60	60	20	400	0	1440000	1200	400	0.333333
20	1000	40	20	1020	60	60	1020	400	40000	3.75E+09	61200	-39600	-0.647059
20	1331	40	20	1351	60	60	1351	400	53240	6.57E+09	81060	-52840	-0.651863



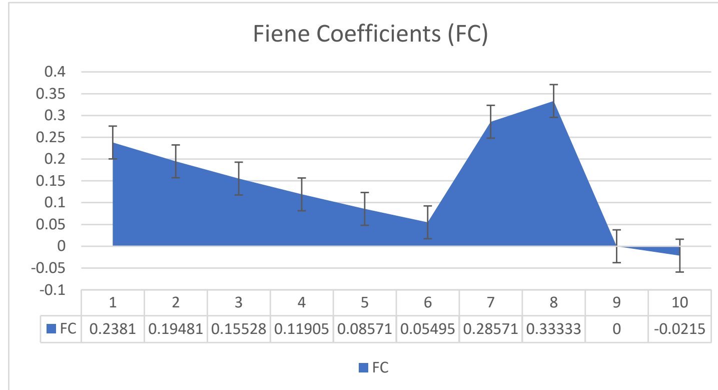
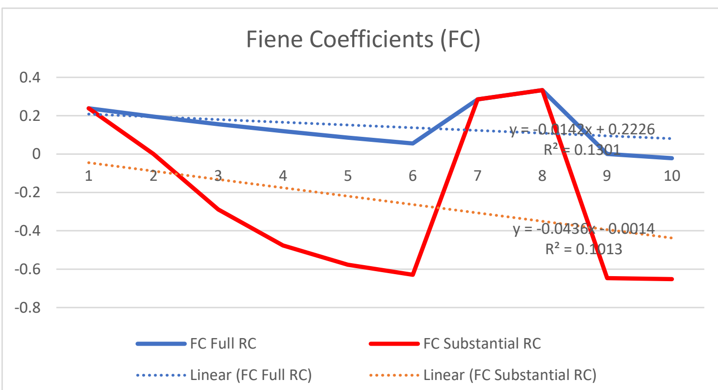


Chart 1: Revised/Updated Fiene Coefficients

Chart 2: Standard Fiene Coefficients

It is clear from the above two charts that the revised/updated Fiene Coefficients take the risk factor more into account than the standard Fiene Coefficient.
Using Chart 1 will be a more effective and efficient methodology to determing the regulatory compliance key indicators, especially when substantial compliance is utilized in determining the high regulatory compliant group. Chart 1 utilizies a weighting factor while that is not the case in Chart 2.
When full compliance is utilized in determining the high regulatory compliance group than Chart 2: Standard Fiene Coefficients is sufficient.



0.238095	0.238095	1
0.194805	0	2
0.15528	-0.288754	3
0.119048	-0.47619	4
0.085714	-0.576355	5
0.054945	-0.62954	6
0.285714	0.285714	7
0.333333	0.333333	8
0	-0.647059	9
-0.021505	-0.651863	10
FC Full	FC Subst	Pairings

Chart 3: Fiene Coefficients side by side for full regulatory compliance and substantial regulatory compliance.

FC for substantial regulatory compliance clearly demonstrates the effectiveness and efficiency of the revised and updated Regulatory Compliance Key Indicator Metric.
It eliminates any potential key indicator that has significant false negatives present within the Regulatory Compliance Key Indicator Matrix.
It should be noted the perfect match on the 7th and 8th pairing when there are not any false negatives present.