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

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September 2024

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

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

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

Pennsylvania. But as is clearly evident the science behind licensing and regulatory compliance lagged by many decades. Licensing grew at a slow pace in the human services during the twentieth century and it was not until the late 1960's to early 1970's that human services began to really expand and grow in terms of the number of programs. Other industries grew in a corresponding way with most of the growth in later portions of the previous century. The pharmaceutical industry is a perfect example of this. In fact, regulatory science has really grown out of this need to regulate the pharmacological industry. The Food and Drug Administration (FDA) is the leading federal agency in pursuing the expansion and dissemination of regulatory science with the establishment of national centers across the USA.

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

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

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

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

of programs that were in substantial vs full regulatory compliance. It was in some cases in subsequent studies (2010's) which replicated these initial studies in the 1970's where the relationship followed more of a diminishing returns type of curve. Not always but definitely a ceiling effect was always observed in the data.

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

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

predictor rules, risk assessment rules, nominal data, and dichotomization of data. All these additional concepts will be dealt with in the following sections of this article.

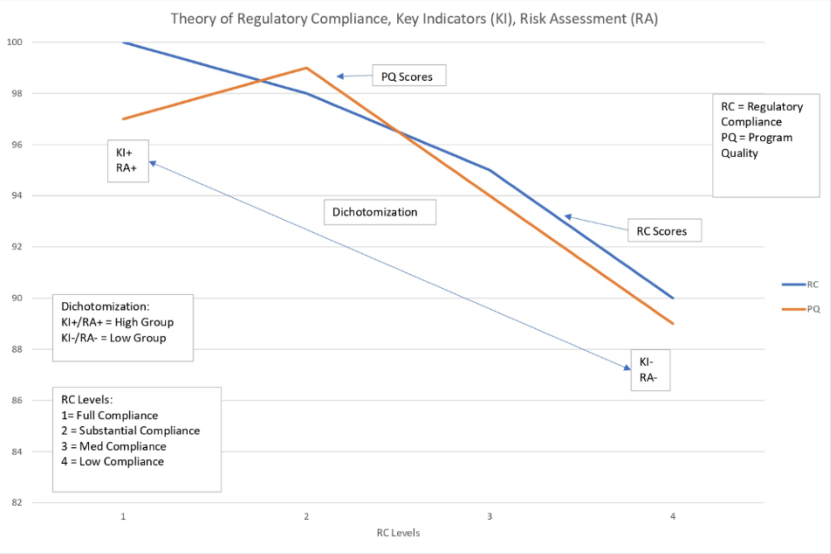


Figure 1: Theory of Regulatory Compliance

Let's turn our attention to some of the spin off methodologies and approaches from the theory of regulatory compliance. The first one to consider is differential monitoring because it is the most significant in altering the licensing landscape in how programs are monitored, reviewed, and inspected. Differential monitoring is about focused reviews rather than a one size fits all approach which again was predominant in the standard uniform program monitoring paradigm. Because the theory of regulatory compliance introduced the importance of substantial regulatory compliance into the new and revised paradigm when it comes to program monitoring, it ushered in more targeted inspections or reviews which focused on key predictor

rules or rules that placed clients at particular risk, more so than other rules and regulations. There was also part of this new paradigm the notion of reviewing programs less often but that was removed from the differential monitoring approach because all the research into program monitoring indicated that just reviewing the program more frequently brought about more positive change in regulatory compliance and quality.

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

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

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

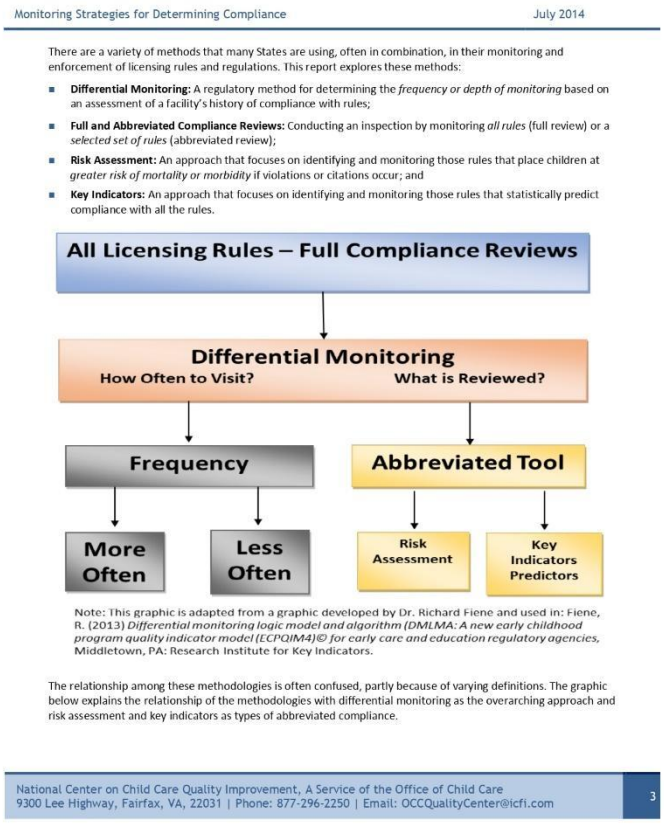


Figure 2: Regulatory Compliance's Differential Monitoring Approaches

This is the highly recommended way to utilize differential monitoring, but many jurisdictions/states/provinces use either the risk assessment or the key indicator

methodologies, few are utilizing both. Hopefully this will change as the regulatory science field matures over the upcoming decades.

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

The reason for selecting this matrix is the nature of licensing data, it is binary or nominal in measurement. Either a rule/regulation is in-compliance or out of compliance. Presently most jurisdictions deal with regulatory compliance measurement in this nominal level or binary level. There is to be no gray area, this is a clear distinction in making a licensing decision about regulatory compliance. The UCM also takes the concept of Inter-Rater Reliability (IRR) a step further in introducing an uncertainty dimension that is very important in licensing decision

making which is not as critical when calculating IRR. It is moving from an individual metric to a group metric involving regulatory compliance with rules.

The key pieces to the UCM are the following: the decision (D) regarding regulatory compliance and actual state (S) of regulatory compliance. Plus (+) = In-compliance or Minus (-) = Out of compliance. So, let's build the matrix in the following table (Table 1):

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

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

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

Disagreements raise concerns in general, but the disagreements are of two types: false positives and false negatives. A false positive is when a decision is made that a rule/regulation is out of compliance when it is in compliance. Not a good thing but its twin disagreement is worse where with false negatives it is decided that a rule/regulation is in compliance when it is

out of compliance. False negatives need to be avoided because they place clients at extreme risk, more so than a false positive. False positives should also be avoided but it is more important to deal with the false negatives first before addressing the false positives.

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

Regulatory Compliance has 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/non-linear relationship between regulatory compliance and program quality was discovered. This upset the prevailing paradigm and suggested we needed a new approach to addressing the relationship between regulatory compliance and program quality as mentioned earlier in this article.

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

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

apparent that in dealing with the infusion of quality into rule formulation, a return to the individual rule approach makes the most sense.

The next iteration of the Regulatory Compliance Scale will contain the following categories: Exceeding Full compliance, Full compliance, Substantial compliance, and Mediocre compliance to adjust for the infusion of the quality element. This differs slightly from the original aggregate rule Regulatory Compliance Scale where the categories were Full compliance, Substantial compliance, Mediocre compliance, and Low compliance where only licensing health and safety elements were considered (see the Table 2 below which depicts the regulatory compliance scales and program monitoring systems side by side).

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

Table 2: Regulatory Compliance Scales and Program Monitoring Systems

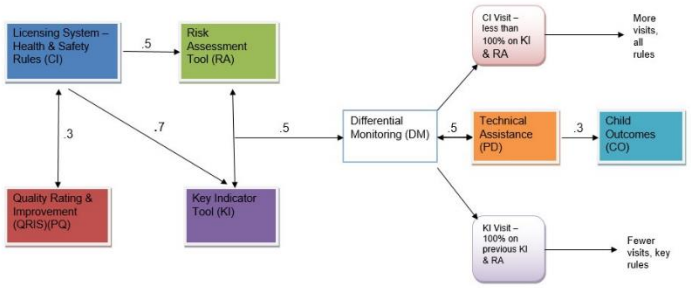
Scoring Level	**Individual Rule**		**Aggregate Rules**	**Individual Rule**
Scale	**Instrument based**	***Scale***	**Differential**	**Integrated**
7	Full Compliance	7	Full Compliance	Exceeds Compliance
-	---	5	Substantial	Full Compliance
-	---	3	Mediocre	Substantial
1	Out of Compliance	1	Low	Mediocre/Low

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

As a final footnote, keep in mind that the theory of regulatory compliance applies to the relationship between regulatory compliance and program quality and does not apply to regulatory compliance in and of itself related to health and safety. When dealing with regulatory compliance, full compliance is the ultimate goal with individual rules and in determining which rules are predictive rules. It is the preferred methodology in order to eliminate false negatives and decreasing false positives in making licensing decisions related to regulatory compliance. So, this creates an interesting caveat in that the theory of regulatory compliance predicts a non-linear relationship between regulatory compliance and quality but a linear relationship when dealing with regulatory compliance and the safety of clients.

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

1) The theory of regulatory compliance has ushered in a new paradigm demonstrating the importance of substantial compliance and putting it on equal footing with full 100% regulatory compliance.
2) Regulatory compliance will not get us to quality on its own, rules and regulations need an infusion of quality so there is the need to balance regulatory compliance and quality standards in any future promulgation of rules and regulations.
3) How does all this fit together? An Early Childhood Program Quality/Regulatory Compliance Improvement and Indicator Model has been proposed to build off the results of the theory of regulatory compliance and to build a robust program monitoring system that both differentiates and integrates. See the following Figure 3 which provides a logic model for how the model would play out.



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

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Figure 3: Regulatory Compliance Improvement and Indicator Model

4) All the studies and research presented in this article are from the human services area. It will be interesting to see if other industries in the medical, scientific, and economic arenas demonstrate the same type of relationship between regulatory compliance in their respective industries and sets of rules and regulations and the ultimate quality of the products they produce.
5) The ceiling effect, diminishing returns, plateauing all depict a curvilinear relationship rather than a linear relationship. As additional studies are completed, this relationship needs to be fine-tuned. Hopefully moving from a nominal measurement strategy to one that is more ordinally based via the Regulatory Compliance Scale will help to fine-tune that relationship.
6) The idiosyncratic nature of licensing data distributions needs to be dealt with statistically because of severe skewness in the data which limits the analytical frames that can be used. Various weighting schemes are being attempted in order to build in more variance in the data and the infusion of more quality standards into rule formulation should help.
7) *The theory of regulatory compliance has led us on a quest to find the "right rules" via regulatory science. It is all about following the empirical data wherever it leads rather than a more political approach which involves over-regulation or deregulation. The methods presented in this paper will hopefully guide regulatory scientists on this future quest. It is about data utilization and using the risk assessment and key indicator*

methodologies in order to identify these "right rules" that keep clients safe and promote overall quality of setting.

8) Hopefully, this article has given the reader the necessary background to understand this new paradigm for licensing measurement and monitoring systems with all its intricacies and foibles.

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