

# **A Treatise on Regulatory Compliance**

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## **Abstract**

This treatise provides some insights into certain assumptions related to regulatory compliance and the implications for regulatory researchers and policy-makers for the future development of rules/regulations (rules)(1). Once regulatory compliance decision making moves from requiring full compliance with all rules and moves to a substantial regulatory compliance decision making approach, the measurement and monitoring systems employed to assess programs/facilities (facilities)(2) change dramatically. This short treatise provides some thoughts related to these changes.

**Keywords:** Regulatory Compliance, Risk Assessment, Key Indicators, Licensing, Monitoring, Measurement.

## **1. Introduction**

Regulatory compliance is a sub-discipline within regulatory science which focuses on measurement, monitoring systems, risk assessment, and decision making based upon regulatory compliance scoring. Regulatory compliance is dominated by

nominal scale measurement, either a facility is in or out of compliance with specific rules. There is no middle ground with regulatory compliance as there is with more quality measurements which are generally measured on an ordinal scale. Another factor with regulatory compliance data is that it generally follows a very skewed frequency distribution which limits analyses to non-parametric statistics. Because of the skewed data distribution, dichotomization of data is warranted given the lack of variance in the regulatory compliance frequency distribution - the majority of facilities are either in full or substantial regulatory compliance (some jurisdictions can run as high as 60-70% ).

An assumption within regulatory compliance is that full regulatory compliance, that is, 100% compliance with all rules, is the best possible scenario for the services being delivered and assessed. It is also assumed that all rules have an equal weight in their relative impact on the desired service delivery model. This short treatise will provide the past 40 years of research delving into regulatory compliance measurement and will provide some guidance to regulatory researchers and policy-makers as they move forward with both research and policy development related to rules.

The results reported are drawn from the human services delivery systems in the United States and Canada, such as early care and education, as well as child and adult residential services. The results are from state and provincial level licensing systems involving 10000's of facilities serving 100000's of clients. All the data are part of an international regulatory compliance data

base maintained at the Research Institute for Key Indicators and the Pennsylvania State University. Please see the following website for the data base (<https://data.mendeley.com/datasets/kzk6xssx4d/1>).

## 2. Methods

Alternate methodologies, logic models, and algorithms were developed directly from this Theory of Regulatory Compliance once it was determined that substantial regulatory compliance produced better results than full regulatory compliance. These methodologies created a differential monitoring or targeted monitoring approach based upon risk assessment which measures client morbidity and/or mortality when individual rule non-compliance is assessed, and the determination of key statistical predictors for overall regulatory compliance(3).

Briefly these methodologies provide cost effective and efficient means for the ongoing monitoring of human service delivery systems by selecting and reviewing only those rules that either have a positive impact on clients, statistically predict overall regulatory compliance, or protect the health and safety of clients(4). Based upon regulatory compliance history data, decisions could be made as to the frequency and depth of the reviews or inspections. Abbreviated reviews, such as key indicator or risk assessments, would only be done with those facilities with a history of high regulatory compliance. Those facilities with a history of high regulatory non-compliance would continue to receive

full regulatory compliance reviews as they did in the past.

## 3. Results

Prior to 1979, it was always assumed that there was a linear relationship between regulatory compliance measures and program quality measures of human service facilities. In a study during that year which compared results from early care and education programs, in particular, child care centers, this assumption did hold up when one went from low regulatory compliance to substantial regulatory compliance. However, the results from substantial regulatory compliance to full (100%) regulatory compliance did not show the same linear relationship. Rather, it showed that those programs that were in substantial rather than full compliance were actually scoring higher on the program quality measures.

Since 1979, this result has been replicated in many other early care and education delivery systems both nationally in the United States (Head Start)(5) and in several states (Georgia, Indiana, Pennsylvania)(6). In all these studies, one finds a non-linear relationship between regulatory compliance and the overall quality of the facilities being assessed rather than a linear relationship.

## 4. Discussion

Based upon the results above, there are several assumptions within regulatory compliance that need to be reconsidered.

One, public policies that require full (100%) compliance with all rules may

not be in the best interests of the clients being served. Potentially, emphasis on substantial regulatory compliance may be a more effective and efficient public policy related to client outcomes related to health, safety and quality of life. Keep in mind that substantial compliance is still very high regulatory compliance (99-97% compliance with all rules). As stated above, regulatory compliance data are extremely skewed data and are not normally distributed data. There is very little variance in the data and the majority of programs are in either full or substantial regulatory compliance.

Two, if a jurisdiction focuses on a substantial regulatory compliance public policy it opens up many system enhancements, such as differential or targeted monitoring, risk assessment analysis and statistical key indicator rules which have been demonstrated to be cost effective and efficient approaches to reviewing program performance. In a full regulatory compliance public policy focus, none of these system enhancements can be employed with the possible exception of the key indicator approach as delineated in number four below.

Three, if a jurisdiction takes the position that all rules are not equal than a risk assessment or weighting approach becomes an alternative approach based upon the assumption that certain rules place clients at greater risk of morbidity or mortality.

Four, even if a jurisdiction does not have a licensing law which allows issuing licenses on the basis of substantial compliance there is the possibility key indicators could still be used for abbreviated reviews or inspections, if their legal counsel is willing to support

the use of this approach, since key indicators statistically predict full regulatory compliance. In other words, all rules are statistically predicted to be in regulatory compliance based upon the results of the key indicators. So technically all rules have been reviewed albeit short of a full review or inspection.

Five, based upon previous research, utilizing a risk assessment approach along with a key indicator approach is the most cost effective and efficient differential monitoring system model. The reason is that both predictive rules and the most critical rules are always assessed when a site visit review or inspection is done. Many more jurisdictions use a risk assessment approach at this point, but there is a loss of predictive regulatory compliance by just using this approach.

Six, based upon previous regulatory compliance history, only those facilities in high regulatory compliance would be eligible for abbreviated key indicator and risk assessment reviews. Those facilities with a history of high regulatory non-compliance would continue to receive full regulatory compliance reviews. This gets at the essence of the differential monitoring approach which is cost neutral. Resources are re-allocated from the abbreviated reviews to more in-depth full regulatory compliance reviews.

Seven, based upon the use of the key indicator and risk assessment methodologies within a differential monitoring approach, it is possible to identify over multiple jurisdictions if their are generic rules that meet the criteria of risk abatement and prediction. Such an application has occurred in the United States with the creation of early care and education standards entitled *Caring*

for *Our Children Basics* published by the Administration for Children and Families, US Department of Health and Human Services (2015).

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## 5. Conclusion

Regulatory compliance is relatively new in applying empirical evidence and basic scientific principles to its decision making. In the past, it had been dominated by case studies and long narrative reports which did not lend itself to quantitative analyses. There is a need to more clearly apply empirical evidence and the scientific method to rule development. Certain assumptions, such as full regulatory compliance as a sound public policy is lacking in empirical evidence. This treatise on a theory of regulatory compliance is provided for its heuristic value for both regulatory researchers and policymakers in rethinking some basic regulatory compliance assumptions.

It is not about more or less rules but finding the "right rules" that protect clients, predict overall regulatory compliance, and produce positive client outcomes.

## 6. Declaration of Conflicting Interest

The author declares no conflicts of interest.

## 7. Author Contact Information:

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## 8. References

- (1) I will use rules whenever I am referring to rules and/or regulations.
- (2) I will use facilities whenever I am referring to programs and/or facilities.
- (3) *Differential Monitoring, Risk Assessment and Key Indicator Methodologies*, Research Institute for Key Indicators, retrieved from <http://RIKInstitute.com/national>.
- (4) *ibid.*
- (5) *Head Start Key Indicators Report*, Research Institute for Key Indicators, retrieved from <http://RIKInstitute.com/riki> reports.
- (6) *State Key Indicators Reports*, Research Institute for Key Indicators, retrieved from <http://RIKInstitute.com/riki> reports.