The Principles of Regulatory Compliance Measurement

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The principles of regulatory compliance measurement will be described in this short technical research note covering comprehensive licensing inspections, abbreviated licensing inspections through weighted risk assessment, and how the resultant scoring protocols can be used to make licensing decisions.

Usually when one thinks about regulatory compliance the number of violations are generally the prominent number that most people associate with measuring this concept. So zero (0) violations on a comprehensive licensing inspection is a very good result or number. But what is a not so good number when thinking about regulatory compliance. Based upon the past 40 years of licensing research in which I have established and maintained an international data base related to regulatory compliance, there are trends in data which will help to inform us about what potential thresholds could be in thinking about the number of violations. There is a brief footnote to add to this discussion and that is the impact of the Theory of Regulatory Compliance (Fiene, 1985, 2016, 2019) in which substantial (1-2 violations of low risk rules) and not full compliance (0 violations) is more characteristic of high quality programs.

After taking the Theory of Regulatory Compliance into account, the following ranges based upon the international data base provides us with the following: a provisional level of regulatory non-compliance is between 3 - 7 violations while a low level of regulatory non-compliance is 8+ violations. This results are based upon annual comprehensive licensing inspections in which all rules are measured for compliance.   The scoring and license decision making is rather straightforward where if a program has 0 - 2 violations than they would receive a full license; 3 - 7 violations would result in a provisional license with a good deal of technical assistance; and 8+ violations would result in negative sanctions being applied. This scoring protocol takes prevalence data into account but not the relative weight or risk assessment of regulatory non-compliance. That is where differential monitoring can play a role in constructing a licensing risk assessment matrix which is used by a number of jurisdictions in the US and Canada.

Weighted Risk Assessment Matrices have been used to make determinations about individual rules and how often to monitor a program but have not been used in conjunction with License Decision Making as outlined in the above paragraphs. Depicted below is a standard 3 x 3 Risk Assessment Matrix format that is used by the majority of jurisdictions in the US and Canada. In

the more general research literature on risk assessment, the cells may vary from this 3 x 3 format and might use a 4 x 4 or 5 x 5 format, but the result is the same.

Standard Risk Assessment Matrix: 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 with a high likelihood that it will occur, while (I) indicates a very low or no risk rule 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.

Let's merge the risk assessment designation with the regulatory non-compliance probability data from the earlier paragraphs in the following manner: A = (High Risk Rule) + (8+ Violations); B = (High Risk Rule) + (3-7 Violations); C = (High Risk Rule) + (1-2 Violations); D = (Medium Risk Rule) + (8+ Violations); E = (Medium Risk Rule) + (3-7 Violations); F = (Medium Risk Rule) + (1-2 Violations); G = (Low Risk Rule) + (8+ Violations); H = (Low Risk Rule) + (3-7 Violations); I = (Low Risk Rule) + (1-2 Violations).

The last step is now to take the results of the above 3 x 3 Risk Assessment Matrix and combine this with license decision making as was outlined in the above paragraphs for comprehensive inspections. Risk scores are the predominant factor but the probability or prevalence scores do factor into the overall equation in the following manner especially at the high probability levels: A, B, C, D = Negative sanctions; E, F, G = Provisional license; H, I = Full license.

Risk Assessment, Regulatory Non-Compliance and License Decision Making Matrix

A = Negative sanction	B = Negative sanction	C = Negative sanction
D = Negative sanction	E = Provisional license	F = Provisional license
G = Provisional license	H = Full license	I = Full license

By utilizing this matrix a jurisdiction can now account for both risk assessment and regulatory non-compliance data at the same time in order to make a more informed licensing decision. A validation study is being conducted in the state of Washington to determine the effectiveness of these above two matrices (Stevens & Fiene, 2019).

References:

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