nara National Association for Regulatory Administration

REGULATORY SCIENCE AND THE HUMAN CARE OVERSIGHT INDUSTRY

Using Scientific Methods to inform practice and policy

Abstract

Regulatory science within the human care industry is the study of strategies and tools used to assess safety, quality and effectiveness of programs serving and caring for vulnerable populations. This paper discusses why this emerging field can use regulatory science principles to develop tools, evaluate products and inform policy

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About the Authors

Perhaps one of the largest impacts to the field of regulatory science, specifically in the field of human care licensing, has come from Dr. Richard Fiene. Dr. Fiene, a research psychologist. He has over 50 years of experience doing extensive research and publishing on the key components of improving child care regulatory oversight through the differential monitoring systems inclusive of predictive regulatory compliance indicators (key indicators), risk assessments, and quality rating & improvement systems.

> *"What I have found in my most recent readings is that regulatory science is being applied in many different content silos from the FDA, to economics, to banking, and of course within the human services, particularly adult and child residential services. What appears to be lacking is a unifying theory that goes across these disparate content areas. The field of regulatory science is a very young field. Although regulations have been kicking around for well over 100 years, the science behind regulations is probably a quarter of this time. So, there is not a great deal of empirical evidence to draw upon which is discouraging but it is very encouraging and exciting at the same time because so much needs to be accomplished in establishing regulatory science theory." (Fiene, 2023)*

Dr. Sonya Stevens has over 10 years of experience working in the regulatory field doing analysis, methodology and research development as well as project management. Dr. Stevens is currently NARA's project manager partnering with agencies as they strive to improve their regulatory systems. Our hope is that this paper, along with a NARA's new "Regulatory Science" course, will encourage all licensing agencies within human care to use holistic and data-driven opportunities using scientific methods when considering oversight improvements.

Introductory Summary and Commentary

The early learning industry has been the primary focus of human care regulatory advancements over the past 50 years. While the lessons learned in early learning are adaptable to other human care fields, the same methodology can be transferred to other fields such as adult care and child welfare services. However, there is the need to conduct scientific tests and products into all human care regulatory fields. Protecting customer safety is one of the core responsibilities of regulatory science. Human services combine various fields, including law, public policy, data analysis, and risk assessment to inform and guide regulatory decision making. The goal is to ensure regulatory compliance with licensing requirements crucial for maintaining quality standards and safeguarding the well-being of individuals receiving care.

Advancing regulatory science within human care services is ever more possible with the emergence of new technologies. Technology allows for more efficient data collection and analysis through data management and analysis software, automation and even real-time monitoring. These technological tools are increasing the ability for informed decision-making, particularly through tools like big data analytics, leading to streamline processes and enhanced regulatory compliance through accountability,

efficiency, and transparency (ACF.gov, 2012). However, technology alone cannot fully address the risks and responsibilities of licensing agencies without sound research and methodologies to ensure the validity, reliability, and credibility of oversight structured approaches to oversight policy and systems.

What is Regulatory Science?

The emergence of Regulatory Science

Regulatory Science is a relatively new and emerging discipline that specifically responds to the need to include scientific methodology into policy decision-making within the regulatory fields. The work has historically focused on fields such as medical, engineering and environmental sciences. In fact, the term "regulatory science" first occurred in 1970 shortly after the formation of the Environmental Protection Agency (EPA) through an internal memorandum describing how science was used to develop regulations by that agency. The term, while defined in multiple ways, was not quickly accepted as it was not viewed as significantly different from other areas of scientific research. Over time, the term became more widely used in response to the need for more valid and reliable means to meet social needs. Specifically, regulatory science has evolved because policy makers and regulators struggle to apply science reliably; most commonly to limit using judgement when making policy decisions resulting in overly protective approaches to licensing oversight (Moghissi, Auffret, Calderone & Steen, 2018).

The field of regulatory science has emerged as a critical and multidisciplinary domain dedicated to understanding and enhancing the effectiveness and efficiency of regulatory systems. This field applies scientific methodologies to the study of regulations, the behavior of regulated entities, and the ultimate impact of these rules on desired outcomes. The limitations inherent in traditional regulatory approaches, which were often based on expert opinions and anecdotal evidence rather than rigorous empirical testing has highlighted the necessity for developing innovative theories and methodologies firmly rooted in research and data.

Regulatory Science as it relates to Human Care Oversight

Regulatory science in the human care industry is a field that uses scientific methods to evaluate or develop tools, methods, standards, and systems that support a better understanding of safety, quality, and effectiveness of licensing systems. It plays a crucial role in the human care licensing system development and assessment by ensuring safety, efficacy, and quality of services, products, and practices that ultimately lead to the protection and well-being of individuals receiving care.

Understanding all Aspects of Regulatory Science

Regulatory science consists of more than simply using data and analytics to guide decisions regarding licensing systems and practices. While scientific methodology is applied, scientists in this field also need to be knowledgeable and proficient in the areas of:

- **Ethics:** Remaining impartial and open to all findings, especially when they conflict with desired outcomes:

> *"In communicating scientific information, the scientific community or an individual scientist may not exaggerate or minimize beneficial or adverse effects of an agent, a situation, a condition, or any other relevant issue."*

- **Communication:** The ability to translate scientific processes and findings to increase social validity (the acceptability of the outcomes, as perceived by the individuals involved in use and usability within the regulatory environment).
- **Transparency:** Providing accurate and timely information regarding methods, limitations, dependencies and outcomes to the affected community.

  > *"Those who make a scientific claim including a claim addressing a regulatory science issue must provide their assumptions, judgments, and similar parts to the affected community in a language that is understandable to a knowledgeable nonspecialist."*
- **Stakeholder Engagement**: Effectively including decision makers, directly impacted groups, facilitators, and indirectly impacted groups

Emerging Topics

Theory of Regulatory Compliance: At the core of Richard Fiene's contributions to regulatory science lies the Diminishing Returns Theory of Regulatory Compliance (TRC+)(Fiene, 2023). This theory posits that the relationship between regulatory compliance and program quality or client outcomes is not linear but rather follows a curvilinear pattern. This implies that while initial efforts to improve compliance can lead to significant gains in quality and safety, the impact of subsequent increases in compliance diminishes progressively. Eventually, a point is reached where further regulatory efforts yield only marginal, and sometimes even negative, returns in terms of tangible improvements. Research suggests that there exists a "sweet spot" of substantial compliance, often estimated to be around 80-90%, where an optimal balance is achieved between the resources invested in regulation and the positive outcomes observed

The Relationship Between Regulatory Compliance Theory and Differential Monitoring: Differential monitoring represents a significant paradigm shift in regulatory oversight, moving away from uniform approaches towards a more targeted and adaptive strategy. At its core, differential monitoring is defined as a tailored approach to regulatory oversight that adjusts the intensity and frequency of monitoring activities based on a regulated entity's compliance history and identified risk profile (Fiene, 2023). The fundamental purpose of this approach is to optimize the utilization of often limited regulatory resources by concentrating more attention and scrutiny on programs or facilities that have a history of non-compliance or that have been identified as carrying a higher level of risk.

The Critical Role of Risk Assessment in Regulatory Compliance: Risk assessment plays a pivotal role in modern regulatory compliance, providing a systematic framework for identifying and evaluating potential threats to desired outcomes. In the context of regulatory compliance, risk assessment involves the process of systematically identifying potential hazards or specific areas of non-compliance that could lead to negative consequences, such as harm to individuals, environmental damage, or financial instability. Richard Fiene's Theory of Regulatory Compliance strongly emphasizes the importance of

integrating a risk-based approach into regulatory practices. This aligns with the fundamental principle of TRC+ that not all regulatory rules are equally significant in their impact on achieving desired outcomes.

Key Indicators: Identifying Predictors of Regulatory Compliance: Key indicators represent a valuable tool in the measurement and monitoring of regulatory compliance. They are defined as a carefully selected subset of regulatory rules or standards that have been statistically demonstrated to predict overall compliance with the entire body of regulations. By focusing on the monitoring of these key indicators, regulatory agencies can gain a reliable understanding of a program's or facility's overall compliance status without the need to conduct a full and comprehensive inspection of every single rule (Fiene, 2023). The strategic use of key indicators can lead to significant reductions in the time, resources, and costs associated with routine regulatory monitoring, particularly for programs that have a consistent history of high compliance.

Measuring Compliance: The Development and Application of Regulatory Compliance Scales: Regulatory Compliance Scale (RCS) has been developed as an ordinal scale metric designed to provide a more nuanced assessment of regulatory compliance, moving beyond the simple binary classification of in or out of compliance (Fiene, 2023). The RCS allows for the measurement of varying degrees of compliance, potentially capturing instances of partial compliance or differentiating between levels of non-compliance based on their severity or scope. By offering a more continuous measure of compliance, the RCS facilitates the use of more advanced statistical analyses and can contribute to a richer understanding of the intricate relationships between compliance levels and other important variables, such as program quality and client outcomes.

Enhancing Quality in Early Childhood Programs: The Integrated Approach the Early Childhood Program Quality Improvement and Indicator Model (ECPQIM) represents a significant step towards a more holistic and integrated approach to enhancing the quality of early childhood education programs. ECPQIM is a framework designed to effectively integrate regulatory compliance efforts with broader initiatives aimed at improving program quality. This model is characterized as a fourth-generation model (ECPQIM4), indicating its evolution and incorporation of various monitoring systems currently in use within the early care and education sector. The overarching aim of the ECPQIM is to establish a robust and comprehensive system for both assessing and ultimately improving the overall quality of early care and education programs by considering not only their adherence to regulatory requirements but also a range of other critical indicators of quality (Fiene, 2023).

The Importance of Regulatory Science in the Human Care Field

Due to the rapid advancement of technology, licensing agencies generate substantial amounts of data that can be analyzed to make informed decisions. These data can be used to advance regulatory science frameworks through analyze trends, patterns, and performance metrics to identify areas of concern or improvement. Data-driven insights enable regulators to make evidence-based decisions, allocate resources effectively, and prioritize enforcement actions where they are most needed.

The practice of employing regulatory science provides a formal framework of knowledge transfer and debate through identifying, interconnecting and characterizing methods of discovery using various data points and analysis. When regulatory science is not embedded into human service administrations, oversight systems are subject to significant risks and consequences. Most notably these risks include effectiveness, accountability and trust.

Effectiveness: Effectiveness in regulatory science focuses on the scientific underpinnings of regulations inclusive of the administrative and legal outcomes. This includes identifying the right rules and oversight practices that ensure the safety, performance and quality of the regulatory products. Additionally, scientific processes can help to streamline the evaluation and approval process, making it more efficient and effective.

Accountability: Licensing plays a vital role in ensuring accountability within human service systems. Accountability in regulatory science ensures that regulatory bodies and licensed professionals are responsible for upholding standards and protecting public safety, often through mechanisms like transparent processes, consequences for non-compliance, and public reporting (Mann & Rasmussen, 2023).

Trust: Trust in regulatory science and licensing is crucial for public health and safety, and it's built through transparency, accountability, and evidence-based decision-making, ensuring the safety, efficacy, and quality of regulated products. It's crucial to the field of regulatory science to manage "the reliability of scientific claims. How can a regulator; a judge; a member of a legislative body; a reporter; or anyone else judge the validity of a claim". Without the science, personal opinions and ideas lack the evidence to invoke public trust (Hilton, Bhuller, Doe, Wolf & Currie, 2023)..

Applying Regulatory Science to Your Agency

Research within regulatory science is an inclusive process whereby "moments of opportunity" are critical because key players can learn from one another – it is a process that contributes to the greater knowledge through debate around findings rather than simply solving problems. The main challenge for applying research to policy is knowing those moments of opportunity and then acting effectively to take advantage of them. These moments include the stages of idea generation, design, data gathering, analysis, and application.

Licensing agencies generate substantial amounts of data that can be analyzed to make informed decisions. Regulators can use regulatory science frameworks to analyze trends, patterns, and performance metrics to identify areas of strength, concern or improvement. Data-driven insights enable regulators to make evidence-based decisions regarding rules and policy, products and systems, allocate resources effectively, and prioritize enforcement actions where they are most needed.

Conclusions

Regulatory science specific to human care administration is relatively new. Innovative methods and strategies emerge yearly. Furthermore, the rise of regulatory science signifies a fundamental shift from a primarily prescriptive, top-down style of regulation to a more evidence-based and adaptive framework. This evolution acknowledges that truly effective regulation necessitates a scientific understanding of human behavior, the dynamics of organizations, and the actual impact of rules on achieving desired societal outcomes.

There is a general sense of urgency to reinforce regulatory science as a crucial science to delivering data-based decision-making in human care licensing. Unfortunately, many agencies do not have the skills or resources needed to advance the science; not just the financial resources but also supportive scientific ecosystems to continue the advancements in this important work. To adequately advance this emerging field, our communities need to:

1. Address the shortage of experienced regulatory scientists,
2. advocacy to institutions of higher learning to create an academic culture that understands the need to develop regulatory scientists,
3. increase collaborations between the regulatory and the scientific communities,
4. create safe spaces that support collaboration and participation within regulatory research and projects, and
5. begin to create a shared understanding of the need to advance human care licensing through more developed approaches that are inclusive of client perspectives. (Institute of Medicine, 2012)

NARA is committed to advancing the field of regulatory science by building existing scientific evidence and strategies while working with agencies to develop data-driven and evidence-based licensing and assessment tools. Regulatory science is not just about following regulations; it's about understanding the science behind those regulations and using that knowledge to make informed decisions.

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Course Goal

The goal of this course is to introduce and familiarize human care regulators with the concepts, basic principles and components of regulatory science as a field of study in human care licensing industries.

This course will take approximately two hours to complete all three modules. Each module explores important topics in understanding the concepts of regulatory science with human care licensing. There will be resources and articles embedded which you can either download or bookmark for your reference.

Course Modules:

- Module 1: Introduction to Regulatory Science in Human Care Licensing
- Module 2: Roles and Responsibilities of Regulatory Scientists
- Module 3: Subject Areas for Regulatory Research and Practice

Module 1: Introduction to Regulatory Science

Learning Objectives:

- Explain the meaning, history, and foundation of regulatory science.
- Explain the importance of regulatory science to human care licensing.

What is Regulatory Science?

Regulatory Science is a relatively new and emerging discipline that specifically responds to the need to include scientific methodology into policy decision-making within the regulatory fields. The work has historically focused on fields such as medical, engineering and environmental sciences.

Science is the systematic study of the structure and behavior of the physical and natural world through observation, experimentation, and the testing of theories against the evidence obtained. [Oxford Languages Dictionary]

Expandable Boxes

The term “regulatory science” first occurred in 1970 shortly after the formation of the Environmental Protection Agency (EPA) through an internal memorandum describing how science was used to develop regulations by that agency. The term, while defined in multiple ways, was not quickly accepted as it was not viewed as significantly different from other areas of scientific research.
Over time, the term became more widely used in response to the need for more valid and reliable means to meet social needs. Specifically, regulatory science has evolved because policy makers and regulators struggle to apply science reliably; most commonly, to limit using judgement when making policy decisions resulting in overly protective approaches to licensing oversight (Moghissi, Auffret, Calderone & Steen, 2018).
Society and one’s own personal actions are greatly influenced by scientific findings. Science is behind everyday activities like the supplements we take for our health, how a building is designed, or even the rules and laws that we follow daily. Everyday science impacts behaviors and activities, even though we are not aware of the history behind it..
Science as a study is not a new concept. There have been discoveries since the beginning of time. Everyone and everything in some way has been impacted through scientific research.

Activity: How Are You Affected by Science?

Activity Type: Reflecting to Make Connections

Science is broadly defined as the systematic study of the structure and behavior of the physical and natural world through observation, experimentation, and the testing of theories against the evidence obtained. Science is intended to provide information centered on cause and effect.

Take a moment to think about your day and the many influences scientific studies have on your daily activities. What revelations that came from scientific studies impacted how you interacted with others or managed your personal behaviors? Expand the box to review examples of how science has impacted all of us.

Expandable Box or Container

Example
• Science has led to advancements in medicine and surgical technologies which have improved health and life expectancy. • Science led us to the invention of technologies like cell phones that have dramatically changed how we communicate. • Scientific understanding of weather patterns has helped many people prepare for extreme weather events. • Science is essential for building homes, roads, and other infrastructures to ensure our safety. • Scientific principles are used in cooking, like understanding how heat changes food and methods that are critical to ensure healthy practices.

How does Regulatory Science Connect with Human Care Licensing?

Licensing in the human care regulatory industry establishes standards to which providers must legally operate. Regulatory science informs the development and implementation systems of those standards, ensuring providers and caregivers meet those standards and protects the public from harm while promoting quality care.

Regulatory science in the human care industry is a field that uses scientific methods to inform, evaluate or develop tools, methods, standards, and systems that support a better understanding of safety, quality, and effectiveness of licensing systems. It plays a crucial role in the human care licensing system development and assessment by ensuring safety, efficacy, and quality of services, products, and practices that ultimately lead to the protection and well-being of individuals receiving care.

Regulatory affairs focus on the practical aspects of creating and applying regulatory requirements to ensure compliance while regulatory science is more concerned with the scientific basis for those regulations and the development of methodologies and standards used in regulatory decision-making.

Overall, there are two pillars to regulatory science; preventing harm (do no harm) and increasing benefit (do good). It is a dynamic tension where they are generally in balance but can get out of balance at times and one offsets the other. If you look at any regulatory setting, these are the two underlying concepts that the rules/regulations/standards are attempting to enhance: reduce risk + increase benefits. It doesn't matter if it is a child care center, foster home, new drug or product or device, etc. We want to build protection and hopefully help to enhance whatever we are attempting. These two pillars can best be defined in three areas of licensing work; standards development, safety and efficacy, and monitoring and enforcement.

The Emergence of Regulatory Science in Human Care Licensing

Perhaps the most relevant and notable scientific contributions to human care licensing has come largely from Dr. Richard Fiene. Dr. Fiene's research into child care quality and licensing oversight has spanned over 50 years. He Initially focused on developmental psychology and child care but transitioned to macro-system research, particularly in public policy, licensing, and regulatory compliance. His career began at the University of North Carolina at Greensboro, directing a national child care demonstration center. He then moved to Pennsylvania to develop a monitoring system for child care programs, which led to his involvement in creating the Child Development Program Evaluation (CDPE).

Fiene's work expanded into developing methodologies for monitoring child care standards, including key indicators, risk assessment, and differential monitoring. He collaborated with federal and state agencies to pilot and validate these approaches.

While Fiene's journey highlights the impact of regulatory science on child care quality and policy, it also serves a blueprint advocating for research scientists to explore the potential to improve outcomes for all adults, children and families in human care settings. "The research work has resulted in major improvements in child care by having more effective and efficient monitoring and licensing systems, voluntary standards for all early care and education, better decision making related to child care policy, and a better balance between regulatory compliance and program quality in the early care and education field."

To read the Dr. Fiene's entire professional journey click Dr. Richard Fiene

Applying Regulatory Science to Standard Development:

Unfortunately, laws and regulations protecting individuals in human care are rarely proactive but are usually created *following* a devastating event or even one that resulted in little harm but is perceived to potentially cause larger harm or damage. When regulatory science is used effectively to develop rules and licensing requirements, there is a focus placed on the scientific evidence needed to evaluate rules or regulations for the performance and safety rather than creating undue burden on provider or caregiver. Here are some examples of events that can lead to regulatory changes:

Expandable boxes or containers

Examples:
Inadequate staffing: Instances of understaffed facilities leading to neglect or harm have prompted regulations mandating minimum staffing ratios or training requirements.
Neglect and abuse: High-profile cases of abuse or neglect in facilities can trigger stricter licensing standards to prevent future incidents.
Inadequate facility conditions: Events like fires or structural failures can lead to regulations requiring improved safety measures, building codes, or sanitation standards.
Outbreaks of illness: Pandemics or outbreaks of infectious diseases can lead to temporary or permanent changes in licensing regulations, such as requirements for infection control protocols or visitor restrictions.
Changes in resident populations: Shifts in the types of residents served, like increased numbers of individuals with complex medical needs, can necessitate changes in staffing requirements, training, or facility design.
Legal challenges: Court cases or legal challenges to existing regulations can lead to revisions or clarifications to ensure compliance and protect residents' rights.
Public outcry: Public awareness campaigns or media coverage of problems in facilities can pressure policymakers to enact stricter regulations or increase funding for oversight and enforcement.
Limited resources: Agencies faced with being asked to do more without an increase in staff. As noted, in part, this inspired the regulatory compliance theory with diminishing returns that demonstrated how licensing decisions can be made to issue full licenses based on substantial regulatory compliance.

Applying Regulatory Science to Safety and Efficacy:

How many times have you experienced administrative decisions that didn't seem well thought out and were put into place to address one hot issue, but you could see other adverse impacts that were possible because of that decision? Regulatory science ensures there are avenues to test or pilot regulatory rules and systems with scientifically sound methodology providing the necessary data to assess a rule or practice change with a holistic impact to client safety and efficacy. Click to read a portion of one study that explored and outlined unintended impacts of child care regulations:

Expandable boxes or containers

Example Study: Full Article
The empirical results show that tougher regulations appear to be associated with higher quality and price…First, there is a significant amount of input substitution in response to regulations: a tougher regulation on one input affects the use of other inputs as well as the regulated input. For example, regulations that require higher staff qualifications cause centers to employ fewer staff members per child. Second, tougher regulations induce greater violation, indicating that enforcement is far from perfect. Third, other research suggests that many of the regulated inputs are in fact not very productive in improving quality. The only input that has been found to have robust positive effects on quality is recent staff training in early childhood development (Blau, 1997, Blau, 2000).
The most striking empirical finding is that tougher regulations result in lower wages for workers in day care centers. This is a robust finding and suggests that tougher regulations increase costs. Given that prices fail to rise in response to tougher regulations, the cost increase is absorbed by workers in the form of lower earnings. This finding suggests that the incidence of child care regulations is mainly on workers in the regulated day care center sector, an unintended consequence of child care regulations.

Applying Regulatory Science to Monitoring and Enforcement:

Regulatory Science can also support the development of monitoring tools such as monitoring checklists, risk assessments, licensing services, predictive analytics, measurements and information technology systems, as well as enforcement processes designed to assess compliance. Some key areas where this work focuses on are ensuring the intended users can reliably use the tools, the system is accomplishing what was intended through validation studies, and identifying potential risks associated with the design to ensure correction before harm is done.

Applying scientific methods to testing monitoring and enforcement systems ensure they are not only valid, but also reliable and usable. Click on the picture to read an excerpt from a study completed regarding the foster care home study process. The full article is available as well.

Expandable box

Article Excerpt: Click to see the Full Article
The variation in regulations combined with the vast differences in home study assessors' background and training often leads to assessment results that vary greatly (Depanfilis and Girvin, 2005, Rossi et al., 1999). Rossi et al. (1999) conducted a study using regression analysis and found that while assessors utilized the same characteristics when making decisions, the decisions themselves varied greatly. More recently, some agencies have begun to employ various risk assessment tools throughout child welfare to improve decision making of child removal and placement into out of home care (Cuccaro-Alamin et al., 2017). However, Cuccaro-Alamin et al. (2017), highlight the fact that while standardized tools are often more effective than simple clinical judgement, there are also multiple operational and statistical limitations to using those tools including the tool's validity and reliability, the usability and cost, limited accuracy, and inconsistent use amongst others. (Stevens, Fiene, Blevens & Salzer, 2020)

Activity: History of Regulatory Science

Activity Type: Select All That Apply

The evolution of regulatory science in human care licensing is only just emerging. Understanding the context and purpose is important because it provides the justification for the advancement licensing oversight:

Historical context and purpose of regulatory science include: (select all the answers that apply).

- Regulatory science ignores the impact rules have on policy and licensing systems.
- Regulatory Science focuses on two pillars including “do no harm” and “do good”. **(CORRECT)**
- Scientific discoveries currently dictate all policies and procedures followed by regulated human care facilities.
- The term “regulatory science” first occurred in 1970 shortly after the formation of the Environmental Protection Agency (EPA)**. (CORRECT)**
- Regulatory science has evolved primarily because policy makers and regulators struggle with limiting judgement when making policy decisions resulting in overly protective approaches to licensing oversight**. (CORRECT)**

Answer Response boxes

1. You are correct!
2. You selected an incorrect response. Regulatory science was first coined as a field of potential study in 1970 in a memo put out by the EPA. It focuses mainly on the impact rules and regulatory systems have on the licensing field and the safety and well-being of those being provided care through two primary pillars of “do no harm” and “do good”. This allows policy makers to make policy decisions based on science rather than personal judgement to their approach in licensing oversight. Because there isn’t much research in the human care regulatory field, policies and procedures are limited in the foundation of scientific evidence.

3.

Activity: Functions of Regulatory Science

Activity Type: Multiple Choice and True/False

It's important to understand the forces that drive regulatory advancement and role regulatory research can play in its evolution. Select the correct response to the following questions.

1. Regulatory science can be effective to support rule development because:
    a. New laws and regulations protecting individuals in human care are rarely proactive.
    b. Rules are often created based on an event rather than evidence.
    c. Perceptions of potential harm or damage can influence rules without justifiable evidence.
    d. All of the above. (CORRECT)

Answer Response boxes

1. You are correct!
2. You did not select the correct response. The correct response is "All of the Above". Rules or regulations are very often created or modified based on an event or perception of how an event may impact health or safety. It is often proactive rather than based on scientific evidence.

2. Regulatory science in the human care industry is a field that:
    a. Tell policy makers what to do.
    b. Use scientific methods to assist in better understanding the safety, quality, and effectiveness of licensing systems. (CORRECT)
    c. Justify policy positions of state or provincial governments.
    d. Guarantees better outcomes for staff.

Answer Response boxes

1. You are correct!
2. You did not select the correct response. The correct response is "Uses scientific methods to assist in better understanding the safety, quality, and effectiveness of licensing systems". While regulatory science can inform policy makers and assist with the examination of policy positions, it is not appropriate to use science to guarantee outcomes or ignore results due to desired outcomes.

3. Regulatory science supports regulatory systems with scientifically sound methods that provide necessary data to assess:
    a. Client safety.
    b. Oversight efficiency.

c. Regulatory efficacy.
d. All of the above. (CORRECT)

Answer Response boxes

1. You are correct!
2. You did not select the correct response. The correct response is "All of the Above". Using scientifically sound methods, regulatory science can support regulatory systems with a focus on client safety, oversight efficiency and efficacy.

4. Regulatory agencies focus on the practical aspects of creating and applying regulatory requirements to ensure compliance while regulatory science is more concerned with the scientific basis for those regulations and the development of methodologies and standards used in regulatory decision-making.
   a. True (CORRECT)
   b. False

Answer Response boxes

1. You are correct!
2. You did not select the correct response. The correct response is "True". Regulatory agencies' role is to focus on the practical aspects of creating and applying regulatory requirements while regulatory science is more concerned with the scientific basis for those regulations and how they are used in regulatory decision-making.

5. One of the key areas where this work focuses on is:
   a. Influencing policy to ensure greater financial benefits to consumers.
   b. Identifying potential risks associated with the design to ensure correction before harm is done. (CORRECT)
   c. Control all procedures and practices of the licensing agency.
   d. All of the above.

Answer Response boxes

3. You are correct!
4. You did not select the correct response. The correct response is "**Identifying potential risks associated with the design to ensure correction before harm is done**". While there are many other key areas of regulatory science it should not be the role of regulatory science to advance financial outcomes for the consumers or try to control how an agency does its work.

Module 2: Roles and Responsibilities of Regulatory Scientists

Learning Objectives:

- Understand the ethical role that regulatory scientists play in licensing systems.
- Understand the importance of all aspects of research.
- Learn about the common scientific methods currently used in the licensing field.

Understanding the Role of the Regulatory Scientist

Regulatory science consists of more than simply using data and analytics to guide decisions regarding licensing systems and practices. While scientific methodology is applied, scientists in this field also need to be knowledgeable and proficient in their ethical obligations to the study, vulnerable populations, agencies and clients to which licensed programs serve. It's also critical to understand how research is conducted and the various tools available.

Responsibilities and Standards of Regulatory Scientists

Reflecting to Make Connections

Regulatory scientists play a crucial role in ensuring the safety, efficacy, and quality of regulated products by understanding the regulatory process, conducting studies, communicating findings to regulatory agencies, and developing new methods for product evaluation.

Take a moment to think about your work in licensing or policy development. It is common for regulatory science to be employed without the distinct knowledge of those taking part. Have there been times when you were asked to conduct, participate, or provide feedback in a new process?

Expandable Box or Container

Examples

- Completing surveys detailing how much time is being spent on work tasks.
- Testing new technologies like laptops for monitoring activities.
- Participating in a working group to explore solutions to a problem.
- Listening sessions to provide feedback on a new practice or rule.
- Volunteering to be a pilot tester.

Understanding and Maintaining Research Standards

Regulatory science aims to provide systematic steps that are transparent to everyone when conducting research. Understanding the steps of conducting research as well as ethical practices are critical when considering regulatory research in any agency.

Internal Review Boards

The first step is to understand when you should submit your study plan to an Institutional Review Board (IRB) for review prior to any data collection. You should include an IRB review when your study plan meets the definition of **research** (regardless of funding or location), involves **human subjects** and is intended to be **generalizable**.

Click the arrow for definitions.
Expandable Boxes or Containers

Federal Definition of Research: "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." - 45 CFR 46.102(l)
Generalizable knowledge: The purpose or intent is to develop or test scientific theories or hypotheses, or to draw conclusions that are intended to be applied or shared beyond the populations or situations being studied.
Human Subjects: "A human subject is "a living individual about whom an investigator (whether professional or student) conducting research: ● Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or ● Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." - 45 CFR 46

IRBs are embedded in institutions of higher education, state governments and the federal government. Check with your agency to understand which IRB should be consulted based on your research, data you intend to gather and the funding source.

Ethical Standards: Respect for Persons & Autonomy

Ethical research ensures responsible and accountable conduct of the research itself, protects participants, maintains integrity, and fosters public trust in scientific findings. This begins with voluntary participation. In general, when conducting regulatory research, individuals should never be coerced or pressured into taking part in the research. There are three primary ways researchers use to ensure the research maintains respect for all people and their autonomy.

Expandable Boxes or Containers

Informed Consent: This step typically includes a written description of the research study. It may also include a conversation. Before including any individual in research, they must provide consent. Participants must be fully informed about the purpose of the research, the procedures that will be followed, potential risks and benefits, and their right to withdraw at any time.
Confidentiality: When any data is collected from participants, or even using licensing data like inspection reports, individual data should be kept confidential and protected from unauthorized access. The best way to do this is to, whenever possible, gather data without any personal identifiers.
Anonymity: When the researcher has personal information about a participant or subject, it should be kept secure to protect privacy. This is often done through changing names (and other identifiers) to a research number and securing the personal information.

Ethical Standards: Beneficence & nonmaleficence

Directly related to “do no harm” and “do good” that we introduced earlier, In research, beneficence (promoting well-being) and nonmaleficence (avoiding harm) are ethical principles that not only ensures participant risks are minimized while benefits are maximized, it also fosters trust in research and its findings.

Expandable Boxes or Containers

Beneficence: Regulatory Scientists have an obligation to act in ways that benefit others and promote their well-being. This is accomplished through designing and conducting studies that; 1) safeguard the rights, safety and well-being (physical, psychological and fiscal) of participants and research subjects, 2) ensure the research itself does not impact that well-being, and 3) provide useful and valuable knowledge and outcomes that improve outcomes for individuals in care.
Nonmaleficence: Regulatory scientists have a duty to avoid causing harm to research participants. This is accomplished through carefully assessing and mitigating real or potential risks associated with the research (physically, psychologically, fiscally). Researchers must avoid harm at all costs by not exposing them to unnecessary or avoidable risks and addressing any real or perceived harm promptly. Overall, the well-being of individuals or groups is much more important than any research goals.

Ethical Standards: Justice & Fairness

Ethical regulatory scientists should adhere to the ethical principle of “respect for persons” by ensuring participants are treated with dignity and their rights are projected. By doing this, the researcher not only acts ethically and in good faith but is promoting the integrity and validity of research findings because findings are less likely to be challenged.

Expandable Boxes or Containers

Avoiding Exploitation: Ethical research prevents the exploitation of vulnerable populations, those that have limited access to resources, or are otherwise marginalized ensuring that anyone or any group does not disproportionately take on more risk while others gain higher rewards.
Fair Recruitment and Subject Selection: Participants or licensing data samples should be selected fairly, founded in relevance to research questions, and not based on discriminatory criteria like easy access or aligned values. Ethical researchers should promote inclusivity because great outcomes are achieved when there is diversity in voice and perspective.
Avoiding Bias: Researchers must strive to avoid bias in their research design and execution, ensuring that all research findings are not skewed by unfair selection or treatment.
Ensuring the Relevance of Research Questions: The research questions being asked should be relevant to the individuals or communities participating in the study. This ensures that their contribution is meaningful and beneficial.

Ethical Standards: Research Integrity

When research is conducted ethically, it builds trust in the scientific community and the research process. Research practices with superior integrity can lead to long-term benefits for individuals and communities, as research findings are used to inform policies and practices that promote health, safety and efficacy. This includes the following:

Expandable Boxes or Containers

Avoiding Fabrication and Falsification: It can be tempting to exaggerate or minimize the benefits or adverse effects of research finding into a particular narrative or political agenda. However, it is highly unethical to fabricate, falsify, or misrepresent data. As a regulatory scientist you must Remain impartial and open to all findings, especially when they conflict with desired outcomes:
Transparency: Regulatory scientists should be transparent about their methods, data and any real or potential conflicts of interest. Providing accurate and timely information regarding methods, limitations, dependencies and outcomes to the affected community, in a language and manner that is understandable to the intended reader is critical.
Objectivity: Unfortunately, it isn't uncommon to find research with undertones of explicit or implicit bias. This can cause results to be questioned and perhaps not even valued. Regulatory scientists should always stive to avoid bias in their design, data analysis and interpretation, and reporting.
Honesty and Accuracy: Regulatory Science activities should always be completed with an open mind and willingness to accept the results, even when the results are not what was desired. Researchers must report data, methods, and results honestly and accurately.

Activity: Identifying the Ethical Need

Activity Type: Scenario and answer match

Read the scenario and select the appropriate ethical standard being applied to each scenario.

As the researcher in your agency, a senior administrator comes to you to ask if you can find out why monitoring visits may not reach completion by the end of the year. You remind yourself of your ethical responsibilities as a scientist and ensure all ethical considerations are in place.

Scenario	Ethical Standard
You have some pretty good guessing as to why monitoring visits are not getting done – after all, you've heard all the rumors. But you resist the urge to jump to conclusions and decide instead to keep an open mind and commit to being honest, transparent and objective.	Research Integrity
As you consider the work, you begin to consider who will provide quick and easy access to the information you might need so you can get the job done faster. Again, you catch yourself and remember there are better outcomes when there is diversity in voice and perspective.	Justice & Fairness
You know that staff have full caseloads and have recently complained about how much they are required to do. You begin to wonder how your work will need to consider the added time and stress that will be placed on them.	Beneficence & nonmaleficence
Knowing that you will see information about individuals, both staff and providers, you begin to consider how you will ensure your research will ensure results won't highlight anyone or identify any specific groups.	Respect for Persons & Autonomy

Answer Response boxes

e. You are correct!
f. You did not select the correct response. Please try again.

Communicating Research Needs, Methods, and Findings

The ability to translate scientific processes and findings so that agencies, field staff and licensed providers or caregivers understand the purpose, the process and the outcomes increases acceptance of the outcomes. To effectively advance knowledge, inform policy, foster public understanding, and lead to better decision-making and regulatory progress, a regulatory scientist must be effective at communicating research needs, methods, and findings. There are some key strategies you can use.

Expandable Boxes or Containers

Understand Your Audience: First ask who needs to know about your research and why. Are they fellow researchers, the public, policymakers or a specific group? Once you know this you can adjust the language, level of detail and the format to suit their interest and knowledge, including what is most important to them.
Use Clear and Concise Language: Research scientists tend to get lost in research jargon and explain every detail. This makes sense because researchers must be prepared to explain the methods and analysis to other researchers. However, depending on the audience, you should use plain language and avoid technical terms ensuring the information is easy to follow.
Leverage Visuals: Charts, graphs, infographics and images illustrate complex data and concepts summarize key findings in a visually appealing and easy-to-understand format. When needed, videos can be a great way to engage a wider audience in a dynamic way.
Choose the Right Communication Channels: Depending on the intended audience you can consider academic journals, conferences and seminars, websites and blogs, policy briefs and reports, newsletters, and press releases.

Remember your ethical obligations! In addition to ensuring your work is accessible and easy to understand, you must also ensure it is fair and accurate so don't hesitate to solicit feedback and remain transparent. Finally, don't forget about the follow-up: Stay engaged and respond to questions and feedback.

Activity: Identifying the Communication Strategy

Activity Type: Multiple Choice

Read each example below and select the most appropriate answer identifying the communication strategy used.

1. When writing your final report, you prioritize direct and simple terms that are well known and understood by the agency:
    a. Understanding the audience.
    b. **Using clear and concise language. (CORRECT)**
    c. Leveridge visuals.
    d. All of the above.

Answer Response boxes

3. You are correct!
4. You did not select the correct response. The correct response is "Using clear and concise language".

2. Because the report is long and detailed, you create an executive summary for your agency leadership and an abbreviated presentation for the staff:
    a. **Understanding the audience. (CORRECT)**
    b. Using clear and concise language.
    c. Leveridge visuals.
    d. All of the above.

Answer Response boxes

3. You are correct!
4. You did not select the correct response. The correct response is "Understanding the audience".

3. As you launch your research you plan to have an informational session for those most impacted by the work. You create a slide deck filled with engaging and informative graphs and images that you know will help with understanding. You create simple and direct talking points focusing on one main idea at a time.
    a. Understanding the audience.
    b. Using clear and concise language.
    c. Leveridge visuals.
    d. All of the above. (CORRECT)

Answer Response boxes

g. You are correct!
h. You did not select the correct response. The correct response is "All of the above".

4. To help explain some of the more complex findings from your research, you include a few graphs and charts ensuring they are clean with aesthetically easy to read color palette and typography.
    a. Understanding the Audience.
    b. Using clear and concise language.
    c. **Leveridge visuals. (CORRECT)**
    d. All of the above.

Answer Response boxes

3. You are correct!
4. You did not select the correct response. The correct response is "Leveridge visuals".

Design Steps Required for Regulatory Research Development

Using established steps when conducting regulatory research is crucial because they provide a structured approach to gather, analyze, and interpret information, and ensure the reliability and validity of research findings by providing the avenue to replicate results. Regulatory research, like most other research, most commonly follows six steps. Some theories and methods require additional steps, but we won't get into that in this course. They include identifying research questions, conducting a literature review, method design, data collection, analysis and interpretation, and reporting. Let's take a closure look at each of these steps.

Step 1: Identify Research Question(s)

Have you heard the adage, “all roads lead to Rome?” In research the saying would be something like “all right questions lead to the right answers.” To get to the answer you must know the questions to ask that are directly connected to a problem needing to be solved. Good research understands this.

Well-defined research questions are crucial as they provide a clear focus and direction for the entire research process. Research questions guide problem identification, study design, data collection, and interpretation of findings, ensuring the research remains targeted and meaningful. You might think that developing research questions is the easy part of a regulatory scientist’s job; however, what seems like a simple task often falls into common mistakes that lead to failed research. Check each (box, circle, symbol) to learn more.

Expandable Boxes or Containers

Mistake: A question that is too general or lacks focus can lead to chaotic and unfocused research and makes it difficult to draw meaningful conclusions.	**Solution:** It’s important to ensure your question(s) pinpoints specific aspects or variables and focus on a particular issue or problem.
Mistake: Using words or phrases that steer respondents towards a particular response invites ethical questions to the entire study.	**Solution:** Present options or topics in a balanced and impartial manner.
Mistake: And asking two or more things in one question can confuse the purpose and direction of how data is collected and lead to inaccurate responses or conclusions.	**Solution:** Keep each question focused on one topic at a time.
Mistake: Questions that are overly complex or ambitious and/or require resources or time you don't have.	**Solution:** Ensure research questions are practical given your available date, resources, and time constraints.
Mistake: Using vague or ambiguous language can lead to misunderstandings about the intent of your research.	**Solution:** Include precision and detail in your wording to enhance clarity.

Step 2: Conduct a Literature Review

Scouring the web looking for all the related research sounds time consuming – and it is. It's also important to ensure your research has a strong foundation of existing knowledge to build your research questions and methodology. The purpose of this is to ensure your research hasn't already been done, identify any gaps in knowledge, and justify the work thereby providing the relevance and credibility of the study. Just like developing research questions there are some common mistakes researchers should avoid.

Expandable Boxes or Containers

Mistake: Using unverified and unreputable materials can undermine the credibility of the literature review.	**Solution:** Whenever possible, use scholarly material from reputable sources. Ensure it includes foundational studies that have shaped the current understanding of your topic.
Mistake: Summarizing without fully analyzing and connecting the literature to one another implying your study may not fit into the big picture.	**Solution:** Thoroughly connect each piece of literature together to create an interconnected picture. It should demonstrate the connections that lead to the broader understanding of the topic.
Mistake: Adding findings and information that don't relate to your research question confusing readers.	**Solution:** Remember the importance of precision of the research question(s)? Literature included in your review should always support your study and maintain focus directly related to your question.
Mistake: Neglecting to carefully organize the structure of the review, hindering the reader's ability to understand and engage with the content.	**Solution:** Use clear headings, subheadings and transitions that assist the reader to move through the review.
Mistake: Inadequately citing, improper referencing or worse – unintentional or intentional plagiarism directly impacts the credibility of the review and the entire study.	**Solution:** Always, always, always cite your sources properly. This avoids presenting or appearing to present some else's work as your own.

Step 3: Research Design

A strong research design is crucial for conducting valid and reliable research, ensuring that studies are conducted systematically, methods align with the research questions, and conclusions are trustworthy. It acts as a roadmap, guiding data collection, analysis, and interpretation to achieve accurate and meaningful results. Once you have designed your research questions thoroughly, completed a comprehensive literature review, it is time to do a research design.

Choosing the right method, selecting appropriate samples or populations, defining a data collection and analysis plans are all components of a strong design. While we go into more detail around design options and examples in the next section, here are two common mistakes to avoid and possible solutions.

Expandable Boxes or Containers

Mistake: Selecting a research design that doesn't align with your research questions or is not possible with the data you are able to obtain.	**Solution:** This is another road that leads to the research question. Here is another opportunity to carefully consider if the questions are indeed suitable for the type of data you need to collect and ensure you have the right resources before landing your design.
Mistake: Using inappropriate or biased sampling techniques leading to unrepresented sample and invalid results.	**Solution:** The methods you chose should include sampling methods and size that represent the population. Consider random sampling techniques to avoid unintended bias.

Step 4: Collect Data

Data collection is at the heart of all regulatory research because it provides the evidence needed to answer your research questions by identifying trends and generating the insights that inform findings. Data collection is the process of generating and storing information that will ultimately be used in the next steps of research. Accurate data collection is also important to ensure the reliability of findings and allows other researchers to replicate and validate your findings. There are five common mistakes made during this phase of research.

Expandable Boxes or Containers

Mistake: Failing to identify and address errors, inconsistencies, and missing values in the data.	**Solution:** Employ robust data cleaning practices and procedures, including data validation and error correction.
Mistake: Neglecting to collect all necessary data or collecting data from an incomplete sample.	**Solution:** Consider developing a comprehensive data collection plan to ensure that all necessary data is collected from the appropriate sample. While this is an added step it is especially valuable when there are multiple data collection points or collectors.
Mistake: Not verifying the accuracy and reliability of the collected data.	**Solution:** Implement data validation techniques, such as checking for outliers and inconsistencies.
Mistake: Failing to comply with data privacy laws and regulations.	**Solution:** Ensure that data collection and storage practices comply with your agencies' policies and with relevant laws and regulations.
Mistake: Being more concerned about the amount of data collected rather than the quality and relevance of the data.	**Solution:** It isn't about how much data you have; it's about the right amount. Focus on collecting high-quality, relevant data that is sufficient to answer the research question – nothing more.

Step 5: Analyze Data

This is where the magic happens! Using appropriate statistical or qualitative analysis techniques will allow you to find meaningful insight and interpret findings – or put another way, take you on the road to those research questions. And as always, ensure you are aware of the three top common mistakes made along the way and avoid them.

Expandable Boxes or Containers

Mistake: Choosing the wrong or inappropriate statistical methods or misinterpreting statistical results.	**Solution:** Refer to your literature review or other reputable sources to ensure the analytical tools you are using match your methods. You can also consult with a statistician to ensure you interpret results appropriately and carefully.
Mistake: Confusing or not fully understanding correlation (a relationship between two variables) versus causation (one variable directly influencing another). Incorrect interpretations can lead to flawed recommendations.	**Solution:** Be cautious when drawing causal conclusions; what may appear to be direct relations may be influenced by other variables. Consider other potential explanations for all observed relationships. Be on the lookout for confounding variables. This is another place to have an expert or peer review.
Mistake: Analyzing data for the purpose of fitting into a desired result or fit into the training data. This is called “Overfitting” and leads to poor performance on new, unseen data.	**Solution:** In addition to the right model selection, ensure to also use validation and simply avoid overfitting.

Step 6: Present Your Findings

When research concludes and you have your questions answered, it's important to remember that it isn't the end of the road. It's important to also share the information. In the section of this training titled "Communicating Research Needs, Methods, and Findings" we covered the importance of being clear and concise, ensuring there is enough (but not too much) information presented and an easy-to-follow format. Remember to tailor your information to the specific audience and use graphics appropriately. Finally, ensuring you adhere to all ethical obligations including avoiding plagiarism.

Activity: Which design step is it?

Using the same scenario as before, complete the activity. As a reminder this is the scene: As the researcher in your agency, a senior administrator comes to you to ask if you can find out why monitoring visits may not reach completion by the end of the year. You begin the process of building your plan.

Activity Type: Scenario and answer match

Match the step of research to the scenario

Scenario	Step
Knowing this could result in exploring too many variables to effectively find useful results, you ask the administrator leading and increasingly more specific questions to really get at the heart of the problem and narrow the scope to something meaningful and manageable.	Step One: Identifying research questions
As you begin a research project and consider the methodology that will best answer the underlining issues, you begin to wonder if there are other studies out there that could assist your development and assist to strengthen potential findings or recommendations. You start to scour the internet for any information…	Step Two: Conducting a literature review
You're pretty sure you know the direction your research needs to go and have tentatively considered how to do it. But you ask the head of the research department to review your plan to make sure the methodology is sound and appropriate.	Step Three: Selecting the appropriate methods
You hold two work groups, one listening session, and send out a survey (including consent information - of course) to all the licensors to truly understand the various components and barriers of the performance around monitoring visits. At the same time, the IT department provides a report on completion rates.	Step Four: Data Collection
Finally, you have all the information possible, and it seems like there won't be any new information even if you kept digging. You begin to move data into themes and start to draw some conclusions.	Step Five: Data Analysis and findings
As you begin to prepare separate presentations for your divisional leadership and the staff who participated in the data collection, your senior administrator lets you know that the governor has asked for an executive summary. You understand that this could lead to press inquiries, so you decide to be prepared and begin to create multiple avenues to clearly highlight your findings.	Step Six: Reporting

Answer Response boxes

5. You are correct!
6. You did not select the correct response. Please try again.

Types of Theoretical Frameworks Commonly Used in Licensing Research

A theoretical framework is a formal theory that guides the process of identifying and researching a problem. It ensures researchers have existing knowledge that provides the basis to make a hypothesis and choose appropriate methods, setting you up for success.

Regulatory Science commonly uses research frameworks that view individuals, families, and communities as interconnected systems, emphasizing that each part influences and is influenced by the whole, helping regulatory agencies understand complex dynamics and develop effective interventions.

There are many scientific frameworks that have proven to be useful in regulatory science. This section will introduce four of the commonly used frameworks as well as highlight some of the data analysis tools. While we won't go into detail, each section has a link to either useful websites or articles so you can learn more.

Method 1: Grounded Theory

Grounded theory was founded by Glaser and Strauss in in 1967 with their first publication *The Discovery of Grounded Theory: Strategies for Qualitative Research*. This theory uses well-known methodology including qualitative and quantitative data generation techniques. The purpose is to discover or contrast theory from data using systematic data collection and comparative analysis methods. This theory is perhaps the most used theory in regulatory science because it is inherently flexible. Various methods can be employed to interconnect information and inform various elements in regulatory research. The process is both iterative and dynamic meaning not one directional. (Chun, Birks & Francis, 2019).

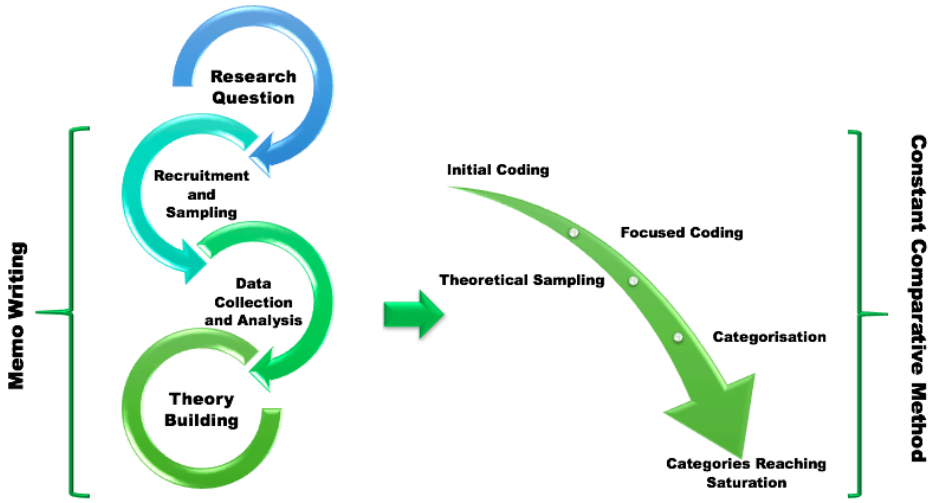


Image from Uibariu, A., (2018). "Training the Watchdogs to Bark: A theoretical Framework to Assist Public Sector Practitioners in Identifying, Reporting and Taking Action against State Crimes Against Democracy.

If you would like to learn more click on (image, shape, word): Article

Method 2: Context, Input, Process and Product (CIPP)

The CIPP model was created by Daniel Stufflebeam in the 1960s. Without knowing it, many organizations use the foundation of this model to inform decisions through systematically collecting program information to identify strengths and limitations of their policy and processes. Within research, these steps are carefully designed to ensure Information gained is then used to improve program quality or effectiveness and plan for future improvements. It uses four stages of evaluation systematically to focus on continuous evaluation including the context (goals or mission), the input (plans and resources), the process (components or practice), and the product (outcomes).

The Yale Poorvu Center for Teaching and Learning provides a summary and resources using the CIPP program assessment. You can click on this link to learn more.

Method 3: Waterfall

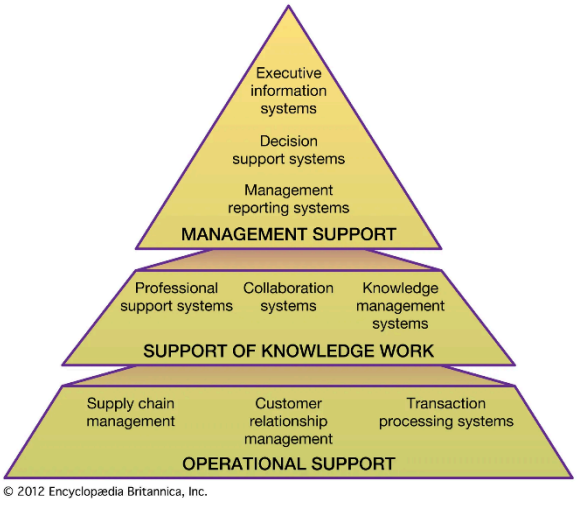
Dr. Winston Royce introduced the foundational structure of the waterfall method in 1970 to manage the emerging development of large software. While this method is geared toward project management, it most commonly used when developing new IT systems and provides a foundation that is useful when designing other system approaches such as monitoring systems, assessing rules and regulations as well as other program improvements. It is a sequential, linear approach using five specific steps: requirement development, design, implementation, testing and deployment. Each step must be completed before the next step can begin and is an excellent guide when designing research methods.

The Management.org Library provides a complete guide that can be referenced when choosing your research methods. Click here to be directed to the website.

Method 4: Information Systems Theory

The work of a regulatory scientist is directly impacted by the software and hardware an agency uses to collect, analyze and inform their policy and practice decisions. Information Systems Theory uses models to understand how the interconnected parts of a system are designed, used and impact organizations and society. (Chatterjee, 2012).

While the work of a regulatory scientist rarely relies solely on information systems theory, the impact of information systems can make a huge difference on the methods of discovery. The good news is that information systems theory follows the same research steps as any other theory listed here and can be integrated dependably.



If you would like to learn more click on (image, shape, word) to learn more: Article

Types of Analysis Tool Commonly Used in Licensing Research

Next, we will take a look at a few common analysis tools used in regulatory research. Keep in mind, each of the four frameworks highlighted in this course typically use mixed methods, meaning a combination of quantitative and qualitative data collection and analysis tools. However, for the purpose of this course we will look at them separately.

Note: You will hear the terms ordinal data and nominal data throughout the remainder of the training. Ordinal data is qualitative data that is categorized in a specific ranked order or hierarchy. Nominal data is qualitative data that is categorized based only on descriptive characteristics. This kind of data has no ranked order or hierarchy.

Qualitative Analysis Tools

Qualitative data is descriptive, meaning it tells a story. The purpose of collecting qualitative data is to understand concepts, characteristics and experiences of individuals or groups. These are collected through interviews, observations, focus groups or listening sessions, and open-ended surveys.

There are five common qualitative analysis tools commonly used in human care regulatory science. Click on each (shape, image, symbol).

Expandable boxes or containers

Thematic Analysis: The process of identifying, analyzing, and reporting patterns (themes) within data. This involves careful reading and interpreting the material to gain meaning and understanding.
Content Analysis: This is used to determine the presence of certain words, themes, or concepts within some given qualitative data. Regulatory scientists use manual coding or coding software to analyze qualitative data to examine trends and patterns.
Narrative Analysis: Unlike thematic analysis that looks for themes, or content analysis that groups data to find the larger content, narrative analysis focuses on interpreting human experiences and motivations. This is done by looking closely at the stories (the narratives) in a particular context.
Discourse Analysis: This is used to examine how language is used in social contexts to understand power dynamics, communication styles, and meaning-making processes. Unlike more systematic methods (i.e. thematic or content analysis), researchers make interpretations based on both the details of the material itself and contextual knowledge.
Interpretive Phenomenological Analysis (IPA): This tool focuses on understanding how individuals make sense of their lived experiences and is very commonly used in programmatic evaluations in social work because it attempts to provide a rich, detailed account of participants' perspectives. This tool is unique because it is an inductive approach, meaning that researchers generate themes and interpretations from the data rather than testing pre-existing theories.

Quantitative Analysis Tools

Quantitative research uses numerical data, including measurable variables and quantifiable observations, and standardized procedures to systematically analyze information to objectively identify patterns, test or validate hypotheses , and draw conclusions. Data collection can include survey responses with numerical scales, licensing regulatory compliance data, demographic data, and more. The key to quantitative analysis in regulatory science is the ability to collect or translate data numerically in descriptive (to describe characteristics of a population or phenomenon), correlational (the relationship between two variables) or causal-correlational/quasi-experimental (cause and effect) research.

There are four common qualitative analysis tools commonly used in human care regulatory science. Click on each (shape, image, symbol).

Expandable boxes or containers

PHI COEFFICIENT: Typically used in descriptive research and with nominal data, the phi coefficient is a statistical measure used to assess the strength of association between two binary (dichotomous) variables, ranging from -1 to +1, with 0 indicating no association.
CHI SQUARE: Typically used in descriptive or causal-comparative research, A Pearson's chi-square test is a statistical test used with categorical (or ordinal) data to examine the relationship between two variables to test whether your data are significantly different from what you expected and assess if the proposed model matches the observed data.
Correlation Analysis: As the name suggests, this is typically used in correlational research. It calculates and measures the strength in the linear relationships or the change in one variable due to the change in the other. As an example, this is commonly used when program quality tools are compared to licensing data.
ANOVA: ANOVA, which stands for Analysis of Variance, is typically used in either correlational or causal-correlational/experimental research. It is a statistical test used to analyze the difference between the means of three or more variables to see if there is a significant difference between them. A one-way ANOVA uses one independent variable, while a two-way ANOVA uses two independent variables. As an example, this is used when comparisons are made across multiple states or provinces looking at differences.

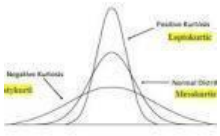
Characteristics of Regulatory Research Methods

At its core, regulatory science uses empirical data to make informed decisions using scientific methods when assessing rules and regulations and licensing systems. This involves measurement issues, such as the limitations of nominal data, skewed data distribution, ceiling effects, lack of variance, and so on. Click on each (shape, image) to learn more:

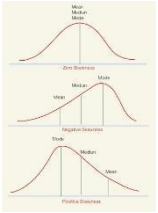
Expandable box or container

Example: All regulatory scientists, when they are working with a licensing a regulatory compliance data set, should graph the data distribution to test for how skewed the data are, look for **kurtosis** and **skewness** in the data. These statistical concepts will help in determining the best way of analyzing the data. It will tell you about the variance in the data distribution. The graphing will easily depict if a **ceiling effect** is present or not.

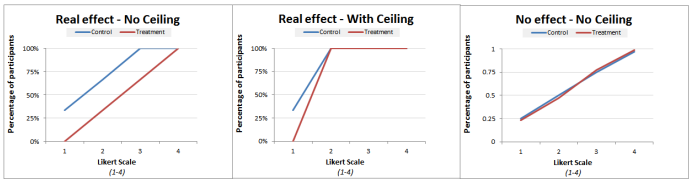
Kurtosis describes the "tailedness" or "peakedness" of a data distribution to determine the presence and frequency of outliers in a dataset.



When data is skewed, it means the data distribution is not symmetrical, creating an uneven curve on a graph making it difficult to accurately represent the data's primary tendency and impact statistical analysis.



A ceiling effect refers to a situation where an independent variable no longer has an effect on a dependent variable or the level in which the variance is no longer measurable. This limits the ability to detect differences or changes, indicating the measurement instrument is not sensitive enough to capture variations above a certain level.



Using these findings, you can adequately assess licensing systems such as monitoring checklists and think through the most effective and efficient approaches to ensure reliability and validity in the collection of data and assessment.

Expandable box or container

Example: Once you have determined the parameters of the data distribution, it will determine the types of analyses that can be performed on the data. For example, licensing and regulatory compliance data are generally nominal (Yes/No) format in measurement. This will limit the types of statistical tests that can be performed on the data. But by looking at the graph of the data distribution there may be useful data transformations that can be done such as grouping the nominal-based data into buckets that fall into an ordinal format based upon the theory of regulatory compliance: 7 = Full Compliance; 5= Substantial Compliance; 3 = Mediocre Compliance; 1 = Low Compliance. This type of structuring which creates a Regulatory Compliance Scale is more effective and efficient in understanding your regulatory compliance data and assessment.

Finally, the circle of science is connected by using a big picture lens to see how rules and regulations tie to program quality via professional development.

Expandable box or container

Example: Once you have your data analyzed, you should be able to ascertain the levels of compliance in each rule/regulation. The next step is to determine where programs are having difficulty complying with certain rules/regulations and create a correction plan. For example, training and technical assistance could be provided based upon these results.

Additionally, keep in mind that quality rating systems are typically done with the same system described here. So, if a quality system is used in the jurisdiction, data could be compared from the quality assessment to the licensing system to determine how the rules/regulations match up with program quality data.

Activity: Which Analytical Tool Is It?

Activity Type: Matching

Regulatory science research should use proven and reliable analytical tools – Match the tools' purpose with the correct tool.

Purpose	Tool
Assesses the strength of association between two binary (dichotomous) variables, ranging from -1 to +1, with 0 indicating no association.	PHI Coefficient
Identifying, analyzing, and reporting patterns (themes) within data.	Thematic Analysis
Examines the relationship between two variables to test whether your data are significantly different from what you expected	CHI Square
Determines the presence of certain words, themes, or concepts within qualitative data.	Content Analysis
Calculates and measures the strength in the linear relationships or the change in one variable due to the change in the other.	Correlation Analysis
Examines how language is used in social contexts to understand power dynamics, communication styles, and meaning-making processes.	Discourse Analysis
Focuses on interpreting human experiences and motivations.	Narrative Analysis
Analyzes the difference between the means of three or more variables to see if there is a significant difference between them.	ANOVA

Answer Response boxes

7. You are correct!
8. You did not select the correct response. The correct response is: ● *PHI Coefficient:* Assesses the strength of association between two binary (dichotomous) variables, ranging from -1 to +1, with 0 indicating no association. ● *Thematic Analysis:* Identifying, analyzing, and reporting patterns (themes) within data. ● *CHI Square:* Examines the relationship between two variables to test whether your data are significantly different from what you expected

- *Content Analysis*: Determines the presence of certain words, themes, or concepts within qualitative data.
- *Correlation Analysis:* Calculates and measures the strength in the linear relationships or the change in one variable due to the change in the other.
- *Discourse Analysis:* Examines how language is used in social contexts to understand power dynamics, communication styles, and meaning-making processes.
- *Narrative Analysis:* Focuses on interpreting human experiences and motivations.
- *ANOVA*: Analyzes the difference between the means of three or more variables to see if there is a significant difference between them.

Summary: Purpose of Methodological Design

In summary, the importance and primary purpose of methodological design in regulatory research is to provide a structured and systematic plan to keep a project on the right road. It ensures you understand and focus on the intended problem you are trying to solve through carefully constructed research questions, grounded and appropriate theories, methods, and the right analytical tools are used to provide valid and reliable results. When used holistically and appropriately, methodological design helps regulatory scientists achieve their objectives and contribute meaningfully to the licensing field.

Module 3: A Look into Current Regulatory Science Research in Human Care Licensing

Learning Objectives:

- Identify the overarching theoretical approaches to regulatory science in licensing.
- Summarize practices currently being modeled based on regulatory science discoveries.
- Explore areas where regulatory scientific advancements are needed.

Overview Licensing Theories

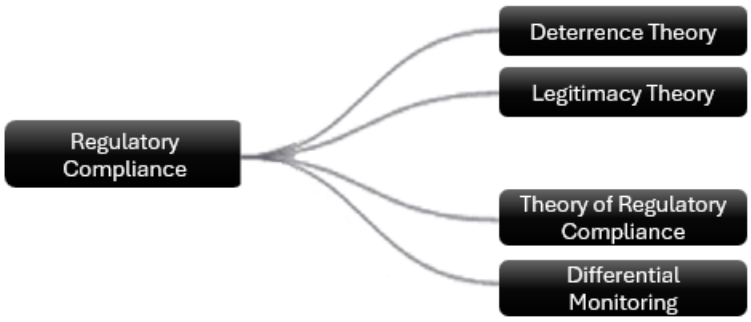
Licensing theories explore the reasons behind and consequences of government regulations, particularly occupational licensing which require individuals in fields like adult residential care, child care, and child welfare settings to obtain a license to practice. These theories examine how licensing affects agencies, regulatory staff, providers/caregivers, consumers, and the overall economy. Regulatory research can explore a wide range of varied perspectives ranging from consumer motivation, protection and prevention to market efficiency.

Theories of Regulatory Compliance

There are several theories of regulatory compliance that have been highlighted in the overall regulatory science research literature (Ayers, I. & Braithwaite, J., 1992), (Sutinen, J.G. and Kuperan, K., 1999), (Fiene, 1985), but for the purposes of this course, we will focus on four main theories of regulatory compliance used specifically in human care licensing research.

The first two, **deterrence theory** and **legitimacy Theory**, focus on the motivation for providers and caregivers to follow licensing rules and regulations. Regulatory studies can help to highlight the most effective strategies to find a balance between deterrence and legitimacy that works for a specific community.

The **Theory of Regulatory Science** and **Differential Monitoring**, developed by Richard Fiene, proposes that regulatory compliance is not always about achieving 100% adherence to all rules, but rather about finding a balance between "do no harm" rules and "best practice" standards. This theory suggests that a differential monitoring approach, focusing on key indicators, risk assessment, and quality indicators can be more efficient and effective in achieving desired outcomes. Since this theory was specifically developed within the context of human service delivery systems and NARA has several examples of its effectiveness across jurisdictions in the US and Canada, it will be the focal point of this course.



Deterrence Theory

Deterrence theory focuses on preventing non-compliance through the fear of punishment, while legitimacy theory emphasizes the importance of trust with the oversight agency and acceptance of the law and its enforcement. Deterrence theory suggests that individuals are less likely to engage in poor behavior if they fear the consequences of being caught and punished. In the context of licensing, this theory suggests that the threat of sanctions, such as fines or license revocation, can deter individuals from engaging in illegal or unethical practices. Unfortunately, this may not influence individuals who are not rational or believe the risks of being caught are worth the action.

Legitimacy Theory

Legitimacy theory argues that compliance with the law is more likely when individuals perceive the regulations and their regulators as just and fair. It also suggests that licensing agencies need to maintain public trust and acceptance to be seen as legitimate and contribute to public trust in a profession.

Click the (shape, picture, arrow)

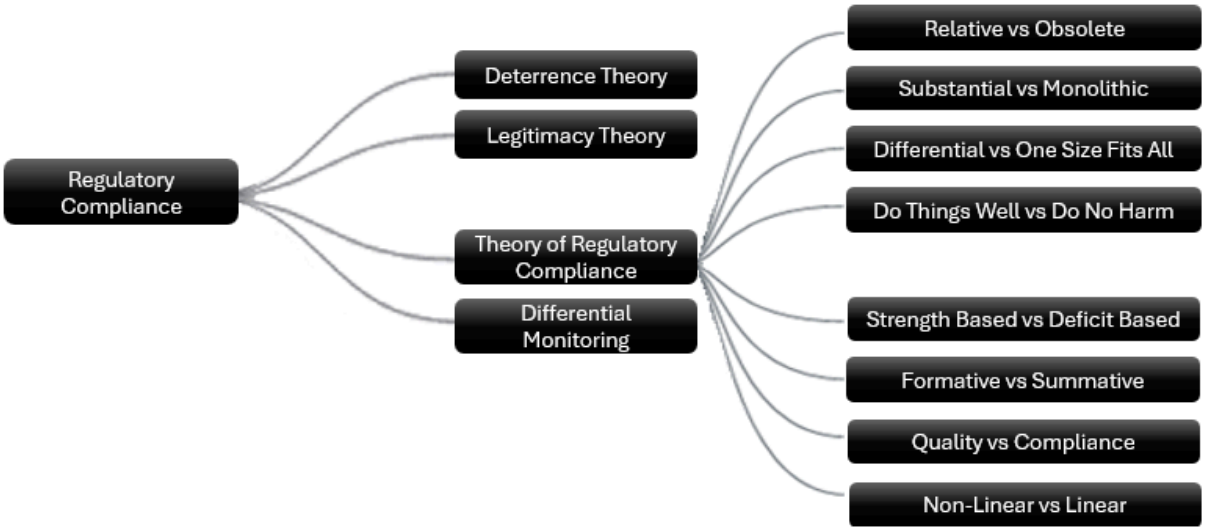
Expandable box or container

While deterrence theory and legitimacy theory can be seen as complementary rather than contradictory. There has been a considerable shift in the profession to increase public trust and motivation toward intrinsic compliance. This has been done through increased transparency, responsiveness to public complaints and concerns. And ensuring licensing requirements and enforcement practices reflect societal values and expectations.

Theory of Regulatory Compliance - Program Monitoring Paradigm Key Elements

The theory of regulatory compliance as outlined by Richard Fiene, suggests there is a need within the regulatory science community to think through the best methods for measuring regulatory compliance. Paradigms such as the differences between individual or aggregate rules, differences in compliance levels needed to ensure health and safety for those in care, the varying importance of each rule, the exchange between compliance and quality, and so on.

Overall, there are eight (8) key elements/dichotomies Fiene provides for us to consider in thinking about the implications of the theory of regulatory compliance.



If you would like to read the full ***Journal of Regulatory Science*** publication (Fiene, 2022) you can click here: [Regulatory Compliance Monitoring Paradigms and the Relationship of Regulatory Compliance/Licensing with Program Quality: A Policy Commentary]

Relative vs. Absolute Compliance

If you accept the theory of regulatory compliance, then it leads to a potentially new paradigm. The relative vs. absolute paradigm refers to two different ways of thinking or approaches to understanding and measuring compliance with regulations.

Click on each paradigm to learn more:

Expandable boxes or containers

The absolute paradigm views all standards as equally important and aims for full compliance with all regulations. This is historically how licensing agencies operated - through comprehensive monitoring systems where all rules are inspected, and all areas of non-compliance are treated equal. This paradigm was dominant from when rules and regulations were first introduced in the late 1880's and continued as the dominant paradigm until the 1970's.
The relative paradigm acknowledges that all rules and standards are not created equal and may have a differential impact on outcomes. This suggests that focusing on key indicators and substantial (as opposed to comprehensive) compliance can be more effective than striving for 100% compliance with all rules. This has led to additional practices including differential monitoring systems that have been adopted in many agencies over the past two decades. We will discuss this in more detail later in the course. The relative/differential paradigm was first introduced in the 1980's when Fiene proposed the theory of regulatory compliance (Fiene, 1985a) and its associated methodologies (Fiene, 1985b).

Substantial vs Monolithic Monitoring

A "substantial compliance" approach allows for some deviation from strict adherence to all rules, while still achieving the intended goals of the regulation (“spirit” of the law). For example, educational requirements may ask for a specific credential, but experience may be considered equivalent to achieve the same compliance determination.

A "monolithic compliance" approach requires full and strict adherence to all rules (“letter” of the law), with no exceptions. For example, a program may be required to have a policy for a service they don’t provide because it is in the rules, and they may one day choose to begin that service.

These same concepts are also true when considering how compliance monitoring is viewed. Click on each paradigm to learn more:

Expandable boxes or containers

In a **substantial regulatory monitoring** system, programs are monitored based on their past compliance history. 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. This can lead to higher efficiency because it allows for some flexibility.
Monolithic regulatory monitoring systems are considered a one-size-fits-all approach where everyone gets the same type of review or inspection. This is typically found in an absolute paradigm where all rules are inspected at every visit with little to no room for deviation, even when it seems inefficient or even unnecessary. While this paradigm is strict it also ensures levels of consistency are achievable.

Differential Monitoring vs One Size Fits All

Differential monitoring focuses on tailoring monitoring efforts based on individual characteristics, like past compliance history, risk assessments and key indicators to guide the frequency and scope of monitoring visits. A "one size fits all" monitoring approach applies the same approach to everyone, regardless of individual differences.

Click on each paradigm to learn more:

Expandable boxes or containers

There are many benefits to **differential monitoring**. Most notably, streamlining resources by focusing on the facilities with higher risk of non-compliance to provide more support to those that need it rather than those that don't. For example, a provider with high compliance may receive one abbreviated monitoring visit a year providing the time for the inspector to increase support to another provider that requires more inclusive technical assistance.
A one size fits all monitoring system has been a regulatory agency go-to for many decades. It provides a consistent and easy pathway to procedure creation resulting in consistent onboarding, training and assessment of regulators. However, it is often less efficient because it puts unnecessary burden on high performing providers leaving less time for the regulator to provide needed support to programs that need it.

We will discuss differential monitoring in greater detail later in this module.

Do Things Well vs Do No Harm

“Doing things well” focuses on quality of services while “doing no harm” focuses on protecting the health and safety of the consumer and those that are licensed. Both are important in any regulatory compliance monitoring system. In fact, the key mission of most licensing agencies is to ensure health and safety of clients and avoid harming services or clients. But a balance between the two paradigms produces better outcomes.

Click on each paradigm to learn more:

Expandable boxes or containers

“Doing things well” focuses their system design on the 95% of the programs that are "doing things well" and adjusting for the services needed to fit the needs of the other 5%. This is found throughout the differential and relative paradigms.
"Doing no harm" places an emphasis on creating a system that focuses on the "least common denominator", or the 5% of the non-optimal programs and imposes those systems to everyone ensuring they are "doing no harm". This is found in relation to the absolute and full paradigms.

Strength Based vs Deficit Based

A strength-based monitoring system considers the results of a monitoring visit or inspection as a glass “half full”. It builds on existing strengths to achieve licensing requirements or higher quality and promotes long term success. Conversely, a deficit-based system will view the results of a monitoring visit or inspection as “half empty”. It highlights shortcomings, weaknesses, of the program.

Click on each paradigm to learn more:

Expandable boxes or containers

A strength-based approach is nonpunitive and is not interested in catching programs not doing well. For example, a strength-based approach might highlight a provider’s strong problem-solving skills rather than the minor infractions they were trying to solve or their strong leadership qualities around staff mistakes resulting in a non-compliance. This approach often improves engagement, increases motivation and assists in maintaining sustainable results.
While **a deficit-based** approach highlights the program's shortcomings, the intent is to address deficits and minimize weaknesses to meet licensing requirements quickly through the threat of financial or other sanctions. For example, a deficit-based approach might focus on where the provider is lacking in knowledge rather than on knowledge gains. Unfortunately, this approach can demotivate providers and hinder long-term growth.

Formative vs. Summative Monitoring

Formative compliance monitoring systems emphasize constant quality improvement and getting better. The formative paradigm is most often found with a differential and relative systems emphasis; they are constantly assessing areas that require additional support for needed compliance. Summative monitoring, found in absolute and full regulatory compliance monitoring systems, place the emphasis on being the gatekeeper 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 rather than supporting growth and further improvement.

Click on each paradigm to learn more:

Expandable boxes or containers

Formative compliance monitoring systems help licensing authorities assess the continuous improvement process of their provider community. This is a crucial role once a provider has obtained their license because it allows the regulatory agency to identify areas where providers might need additional support or resources.
The purpose of a **summative compliance monitoring** visit is to evaluate a provider's program when determining the overall mastery of compliance to all the licensing rules. This is a crucial role in licensing to determine whether an applicant has met all licensing requirements to operate. However, it doesn't monitor improvement or identify areas that may need additional support or resources.
Like other areas, regulatory science can assist licensing agencies striving to find a balance between supporting the growth and continuous improvement (formative) of licensed programs and their duty to ensure programs that could harm individuals are not allowed to operate (Summative).

Program Quality vs. Program Compliance

Program compliance focuses on adhering to regulations and legal requirements to operate legally, while **program quality** emphasizes the overall effectiveness and well-being of participants, often exceeding minimum compliance standards. Remember, licensing serves as a baseline for safety and legal operation, while quality initiatives aim to improve the experience and outcomes for those served by the program. However, effective licensing systems understand there is a paradigm and strive to find that balance.

Click on each paradigm to learn more:

Expandable boxes or containers

Within an absolute/full regulatory compliance monitoring system the focus is on **program compliance** with the emphasis on full, 100% compliance. Licensing is basically a closed system and has an upper limit with full compliance (100%) with all rules. 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 (Fiene, 2019) which will be discussed later in the module.
Program quality is found most often in quality improvement and quality systems. However, it has also emerged more recently in differential/relative regulatory compliance monitoring systems because attaining a perfect monitoring score is increasingly more difficult to attain while an open system tends to be more flexible and far reaching. In other words, it is far more difficult to distinguish between the best programs and the mediocre programs within licensing but more successful in quality rating systems.

Non-Linear vs. Linear

Within regulatory compliance monitoring systems there is the assumption that the data are linear in nature. This means that as compliance with rules increases positive outcomes for clients increases as well. However, empirical data does not support this conclusion. Rather, the data suggests that the relationship is more non-linear creating 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. This led to the development of the Theory of Diminishing Returns which we will review in more depth shortly.

Paradigm Summary

As the regulatory science and administrative fields continue to think about appropriate measurement system design and implementation, it's important to find the right balance between each of the paradigms and the systems' key elements to fit the needs of regulatory goals.

Click here to read more about how these paradigm considerations contributed to the field of regulatory science

Expandable box or container

Through regulatory scientific methods, Dr, Fiene found that there appears to be a "sweet spot" or balancing of key rules that predict client outcomes more effectively than 100% or full compliance with all rules. Ultimately, this is the essence of the Theory of Regulatory Compliance (Fiene, 2019) and subsequently the Theory of Diminishing Returns (Fiene, 2022) – substantial compliance with all standards or full compliance with a select group of standards that predict overall substantial compliance and/or positive client outcomes.

Activity: Which Paradigm Is It?

Activity Type: Multiple Choice

Finding the right balance between paradigms can be challenging. Read each scenario and choose the paradigm being considered.

1. A _____ approach is nonpunitive and is not interested in catching programs not doing well while a _____ approach highlights the programs' shortcomings.
    - **a. Strength-Based vs. Deficit Based. (CORRECT)**
    - b. Program Quality vs. Program Compliance
    - c. Relative vs. Absolute Compliance
    - d. Substantial vs. Monolithic Monitoring

Answer Response boxes

You are correct!
You did not select the correct response. **A strength-based** approach is nonpunitive and is not interested in catching programs not doing well. While **a deficit-based** approach highlights the programs' shortcomings.

2. _____ aims to improve the experience and outcomes for those served by the program while _____ focuses on ensuring foundational health and safety requirements are met.
    - a. Differential Monitoring vs. One Size Fits All
    - b. Formative vs. Summative Monitoring
    - **c. Do Things Well vs. Do No Harm. (CORRECT)**
    - d. Non-Linear vs. Linear

Answer Response boxes

You are correct!
You did not select the correct response. **"Do things well"** aims to improve the experience and outcomes for those served by the program while **"Do no harm"** focuses on ensuring foundational health and safety requirements are met.

3. The _____ theory acknowledges that all rules and standards are not created equal and may have a differential impact on outcomes while _____ views all standards as equally important and aims for full compliance with all regulations.
    - a. Strength-Based vs. Deficit Based
    - b. Non-Linear vs. Linear
    - c. **Relative vs. Absolute Compliance (CORRECT)**
    - d. All of the above.

Answer Response boxes

You are correct!
You did not select the correct response. The **relative paradigm** acknowledges that all rules and standards are not created equal and may have a differential impact on outcomes while **absolute compliance** views all standards as equally important and aims for full compliance with all regulations.

4. _____ monitoring systems assess the continuous improvement process of their provider community while _____ monitoring visit evaluate mastery of compliance to all the licensing rules.
    - **a. Formative vs. Summative Monitoring (CORRECT)**
    - b. Relative vs. Absolute Compliance
    - c. Strength-Based vs. Deficit Based.
    - d. Do Things Well vs. Do No Harm.

Answer Response boxes

You are correct!
You did not select the correct response. **Formative monitoring** systems assess the continuous improvement process of their provider community while **summative monitoring** visit evaluate mastery of compliance to all the licensing rules.

5. _____ focuses on tailoring monitoring efforts based on individual characteristics to guide the frequency and scope of monitoring visits while a _____ monitoring approach applies the same approach to everyone.
    - a. .
    - **b. .**
    - c. .
    - d. Differential Monitoring vs. One Size Fits All **(CORRECT)**
    - e.

Answer Response boxes

You are correct!
You did not select the correct response. **Differential monitoring** focuses on tailoring monitoring efforts based on individual characteristics to guide the frequency and scope of monitoring visits while a **one size fits all** monitoring approach applies the same approach to everyone.

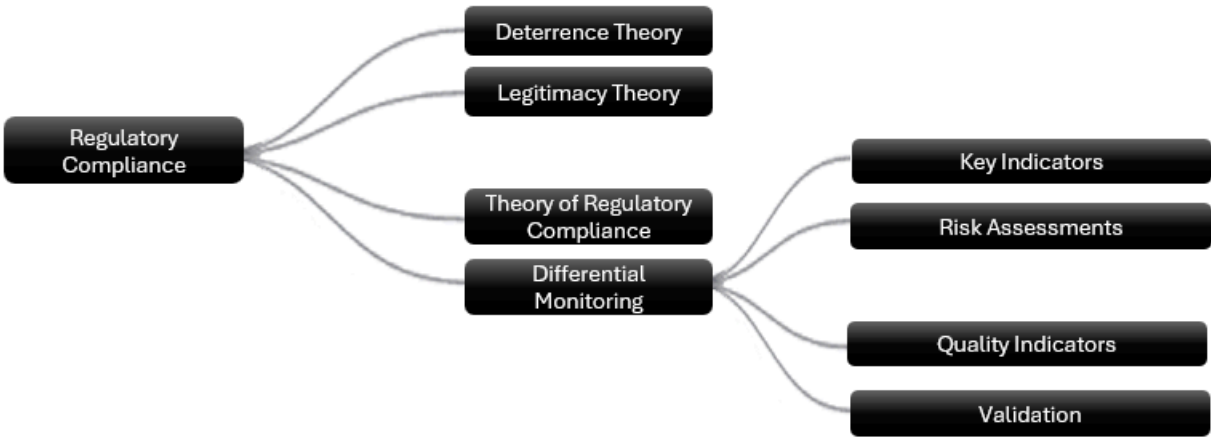
Differential Monitoring Approach

Differential monitoring (DM) represents a momentous change in thinking in regulatory oversight. DM moves away from regular approaches where inspections require a full review of licensing reviews at every monitoring visit towards a more focused and adaptive strategy. It recognizes that not every provider, program or caregiver benefits from the same level of oversight or levels of support and offers a more nuanced and flexible approach to regulatory assessments.

Click the (shape, arrow, picture) to learn more about key indicators within the differential monitoring approach:

Expandable boxes or containers

Differential monitoring adjusts the amount and frequency of monitoring activities based on a regulated entity's compliance history and identified risk profile. The purpose of this approach is to optimize the use of limited resources by concentrating more attention on programs or facilities that have a history of non-compliance or that have been identified as carrying a higher level of risk.
There are four components of an effective and valid differential monitoring system, and each component is firmly grounded using scientific methodologies. They include key indicators, risk assessment, quality indicators and ongoing validation. Let’s explore each of these components in more detail.



Key Indicators

Key indicators are defined as a carefully selected subset of regulatory rules or standards that have statistically demonstrated to predict overall compliance with the entire body of regulations. According to Fiene and Nixon (1981), by focusing on key indicators, regulatory agencies can gain a reliable understanding of overall compliance status without conducting a full or comprehensive inspection of every single rule. The use of key indicators can lead to significant reductions in the time, resources, and costs associated with routine regulatory monitoring, particularly for programs that have a history of high compliance.

Click the (shape, arrow, picture) to learn more about key indicators within the differential monitoring approach:

Expandable boxes or containers

A key indicator monitoring approach employs using only those rules, standards, or regulations that statistically predict overall compliance with all the rules, standards, or regulations. In other words, if a program is 100% in compliance with the Key Indicators the program will also be in substantial to full compliance with all rules, standards, or regulations. The reverse is also true in that if a program is not 100% in compliance with the Key Indicators the program will also have other areas of non-compliance with all the rules, standards, or regulations.
This process of finding key indicators involves analyzing compliance data to determine which rules, when adhered to, are most likely to ensure compliance with all other rules. In some cases, indicators are also chosen by consensus based on their critical importance to protecting child health and safety which deals with the risk assessment methodology to be discussed shortly.
While key indicators are just one part of the differential monitoring approach, there are specific research steps that are needed that can be found described throughout the scientific literature. Please visit the NARA website on the differential monitoring and key indicator approach and methodology (https://www.naralicensing.org/key-indicators).
Main considerations include: 1. Utilizing a full year of compliance data. If a full year of compliance data is not available, a representative stratified random sample would be needed. 2. Identify those providers that are low or high compliance (approximately the top 20% and bottom 20%) 3. For each one identified in those two categories, using a frequency count of how many high compliance providers were out of compliance with the same items and how many low-group providers were out of compliance with the item. For statistical purposes, a 2x2 matrix is constructed which depicts this relationship. For those interested in learning the specific statistical methodology, the **NARA Program Monitoring Systems** course deals with this specifically. Also, NARA's ***Licensing Curriculum Chapter 11 on Measurement Tools and Systems*** deals with the specifics of the methodology.

The objective of the sorting and selection procedure is to identify those items from the comprehensive instrument that are useful for distinguishing between high- and low-group providers. These items are then designated as predictor items.

Click here to learn more: An Instrument-Based Program Monitoring System: A New Tool for Day Care Monitoring. Volume 1: Guide for Policymakers.

Risk Assessment

Risk assessment plays a vital role in modern regulatory compliance and is a key component within the differential monitoring approach. In the context of regulatory compliance, risk assessment involves the process of scientifically identifying potential hazards or specific areas of non-compliance that could lead to negative consequences, such as harm to individuals, environmental damage, or financial damage. Dr. Fiene's Theory of Regulatory Compliance emphasizes the importance of integrating a risk-based approach into all regulatory practices. The foundational premise is that not all regulatory rules are equally significant in their impact on achieving desired outcomes or potential consequences if not kept in compliance. (Fiene, 2025). For the learner who is interested in learning more about key indicators and risk assessment, in addition to Dr Fiene's publications, NARA's other course on **Program Monitoring Systems** will address these two methodologies in greater detail.

Click the (shape, arrow, picture) to learn more about risk assessment within the differential monitoring approach:

Expandable boxes or containers

By "weighting" regulations or rules a scoring system provides a means to identify those areas that place clients at greatest risk for mortality or morbidity.
Weighting regulations is done through surveys. Surveys are sent to a representative sample of the populations where each participant assigns a Likert scale score to each rule. Analysis includes mean and mode considerations until a weight is assigned. This process typically involves several key steps, including identifying relevant variables, calculating initial weights, and refining weights based on population characteristics.
Weighting is required when a differential monitoring approach employs a substantial regulatory compliance scale based upon the theory of regulatory compliance; but it is not required, although recommended, when a full 100% regulatory compliance scale is used. (Fiene, 2024)
Another step in the evolution of the risk assessment is the qualitative risk assessment. This assessment takes the original theory and expands it into an approach that identifies and evaluates potential risk based on descriptive analysis rather than numerical probabilities. This methodology typically involves assessing two key dimensions of risk: the likelihood of the risk event occurring and the severity of its potential impact. These dimensions are then rated using non-numerical scales (e.g. "high," "medium," and "low,") or by a risk matrix where likelihood and impact categories intersect to providing an overall risk rating (Fiene, 2025)

You can dive deeper into these components of the differential monitoring approach by clicking on this link: The Theory of Regulatory Compliance and its Relationship to Differential Monitoring, Key Indicators, and Risk Assessment Methodologies

Quality Indicators

When we think about regulatory compliance measurement, we are discussing licensing systems. When we think about quality, we are discussing Quality Rating and Improvement Systems (QRIS), accreditation and other professional Regulatory Compliance & Monitoring Systems. This work is newly emerging and is heavily concentrated in the early learning fields – suggesting a need for further research into other regulatory areas within human care.

The Early Childhood Program Quality Improvement and Indicators Model (ECPQIM) may provide us with a comprehensive, overarching approach and model to tying quality indicators together with licensing indicators, risk assessment, and differential monitoring along with QRIS, accreditation, and professional development systems.

Click the (shape, arrow, picture) to learn more about this model as it relates to early childhood programming and the differential monitoring approach:

Expandable boxes or containers

Quality indicator methodologies use the same statistical methods as the key indicator research, and apply them to accreditation, QRIS, and professional development quality initiatives. Through this research, key predictor performance indicators have been identified that predicted overall performance of a program. These key predictor rules and performance indicators were then used to develop a new type of scale/tool that measures both licensing and quality levels.
This new scale or tool is called “The Early Childhood Education Quality Indicators Scale” (ECEQIS) and was pilot tested for reliability and validity in the Province of Saskatchewan’s Ministry of Education by the National Association for Regulatory Administration (NARA) with resounding results (NARA, 2023b) You can read the entire report here.
The aim of the ECPQIM is to create a comprehensive system for both assessing and improving the overall quality of early care and education programs through a program's adherence to regulatory requirements and critical indicators of quality like professional development, training, and technical assistance (Fiene, 2024).
The ECPQIM represents a significant step towards a more integrated approach between licensing regulatory compliance systems and quality systems with broader initiatives aimed at improving program quality (Fiene, 2013)

Validation

How do we know new regulatory components are valid, reliable, and relevant? Continuous and ongoing validation studies are a crucial step in any research – a step that is often overlooked. Validation studies determine if the differential monitoring systems designed are working as intended and continue to meet the overall mission and goals of protection through prevention. This matters because continuous and better validation provides:

- Necessary evidence that licensing agencies and licensing are meeting regulatory standards.
- Assurances that licensing systems and monitoring tools are effective for their intended use.
- The foundation needed to establish scientific credibility for new methods or processes.
- A key component of quality assurance programs, ensuring that licensing and monitoring systems meet predefined standards and regulatory requirements.

Activity: Which Theory Is It?

Activity Type: Matching or drag and drop

Licensing theories examine how licensing affects agencies, regulatory staff, providers/caregivers, consumers, and the overall economy. Match the research scenario to the primary theory being considered.

Activity	Step	Expandable Response Box
A continuous quality report highlighted an alarming trend of increased adult abuse in one city. The licensing office responds by sending additional teams of regulators to that city to conduct focused and throughout inspections resulting in multiple civil penalties issued and even two licenses being revoked.	Deterrence Theory	This is an example of **Deterrence Theory**: The intent of the fines or closures is to dissuade these behaviors in the future by demonstrating that there are consequences for non-compliances.
With the recent budget cuts and an increase in adult care facilities, the department has begun to develop a plan to recreate their system that will allow for some flexibility in meeting less critical requirements while ensuring the health and safety of the clients are maintained. They dive into a study to consider the differences between individual or aggregate rules, differences in compliance levels needed to ensure health and safety for those in care, and the varying importance of each rule.	Theory of Regulatory Compliance	This is an example of the **Theory of Regulatory Compliance**: This agency is considering many of the paradigms such as the differences between individual or aggregate rules, differences in compliance levels needed to ensure health and safety for those in care, the varying the exchange between compliance and quality, and so on
A licensor just left a child care center that demonstrated perfect compliance – in fact, they only had one non-compliance last year! The licensor can't help but be frustrated that the visit took almost as long as the one they did yesterday that had over 30 non-compliances, even after visiting that site twice last month due to complaint inspections. Based on licensor feedback like this, the agency begins to explore ways to recognize the excellent programs with abbreviated inspection and free up licensors' time to provide higher levels of support to programs that really need it.	Differential Monitoring	This is an example of **Differential Monitoring**: The licensing agency uses different levels of scrutiny for different childcare facilities, based on their past compliance history.
The state's foster care system is accused of failing to uphold its duty to provide safe and stable placements for children, impacting the child's legal right to permanency. The agency	Legitimacy Theory	This is an example of Legitimacy Theory: Licensing agencies need to maintain public trust and acceptance to be seen

begins to dive into their historical data to assess the licensing and placement trends in their foster homes. They find that licensing and placement trends have been largely unchanged over the past several years. They begin a qualitative study to explore the cause of the perception shift.		as legitimate and contribute to public trust in a profession.

Research Consideration within Regulatory Science

While there are many considerations a regulatory scientist must keep in mind when conducting studies in the regulatory licensing system, there are three that are particularly important.

Click the (shape, arrow, picture) to learn more about key indicators within the differential monitoring approach:

Expandable boxes or containers

The Regulatory Compliance Scale (RCS) is a tool that combines the number of violations to categorize the performance of a provider on an ordinal scale rather than a frequency count.
The “ceiling effect” also known as the “theory of regulatory compliance diminishing returns” suggests that as regulatory compliance increases from substantial compliance to full compliance, program quality shows either no or decreased improvement over.
The premise of the Uncertainty Certainty Matrix (UCM) is that individual decision-making matches reality. The UCM is useful in licensing decision making when validating licensing decisions to determine individual inspector bias in regulatory compliance.

Let’s look at these a bit more:

Regulatory Compliance Scale

Recently (2022), Fiene introduced the concept of regulatory compliance scales. The scale was developed based on years of research into regulatory compliance data distributions and has shown that utilizing a scale rather than just counting the number of violations is a better metric in measuring a programs' regulatory compliance.

RCS	Definitions/Levels	Rule Violations
7	Full 100% Compliance	0 Violations
5	Substantial Compliance	1-3 Violations
3	Mediocre Compliance	4-9 Violations
1	Low/Non-Optimal Compliance	10+ Violations

Fiene, R. (2023). Theory of Regulatory Compliance, Regulatory Compliance Scale, and Differential Monitoring. doi 10.13140/RG.2.2.27748.39042

Fiene, R. (2025). Development of a Regulatory Compliance Scale. Research Institute for Key Indicators Data Lab, The Pennsylvania State University.

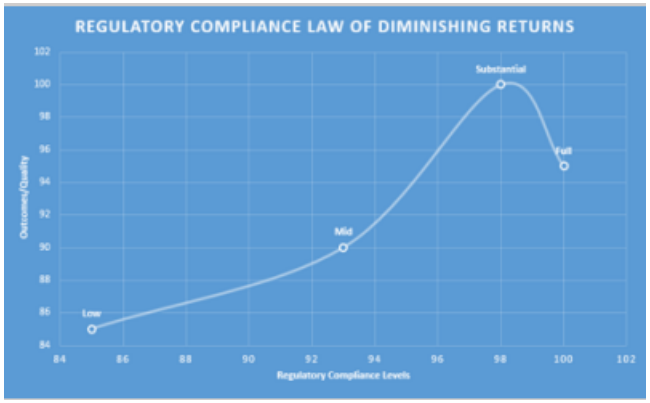
When using the regulatory compliance scale, a researcher puts violations into buckets as seen in the above table. When the data are moved from frequency counts of violation data into these buckets/categories, programs are better able to identify better (or worse) performing programs.

Regulatory compliance scales are in need of additional validation studies to determine their full efficacy in helping to rank order facilities according to regulatory compliance and to determine the thresholds for each of the buckets/categories on the scale. The initial results (Fiene, 2025) are very promising but these need to be validated with additional studies.

Theory of Diminishing Returns (aka Ceiling Effect)

The law of diminishing returns, also known as the law of diminishing marginal productivity, was originally developed to explain economic trends within product industries. The principle states that as one input (like labor) is increased while other inputs (like capital) are held constant the increase in output (the product) will eventually decrease. This means while adding more and more of a single input will initially increase output, the output will eventually decrease even if more input (like labor or capital) is added.

The Regulatory Compliance Theory of Diminishing Returns is similar in that while increasing compliance with regulations can initially improve program quality, further increases in compliance slows or even decreases quality improvement. This means that at some point, the added benefits of more compliance become insignificant, and may even lead to negative consequences. From a public policy and licensing decision making point of view, beyond a certain point, investing more resources to achieve perfect compliance won't significantly improve outcomes.



Click the (shape, arrow, picture) to:

Expandable box or container

The theory is based on research in various areas, including early childhood education, adult care, and environmental protection. Research suggests that there exists a "sweet spot" of substantial compliance, estimated to be around 98-99%, where an optimal balance is achieved between the resources invested and the positive outcomes observed. (Fiene, 2022)

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

Uncertainty-Certainty Matrix

An "Uncertainty Matrix" is a strategic planning tool consisting of a 2X2 grid to categorize potential events based on hypothesized impacts, especially those with a high level of uncertainty (or unknown outcomes). In regulatory science, the Uncertainty-Certainty Matrix (UCM) can help assess the validity and reliability of regulatory decisions and identify risks and associated opportunities and be a valuable tool to identify potential bias in assessments.

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 (--)

Click the (shape, arrow, picture) to:

Expandable box or container

The goal of regulatory decision-making is to maximize the instances of agreement (certainty) and to minimize the occurrences of disagreement (uncertainty) between the regulatory decision and the true state of compliance. In other words, to minimize errors in compliance or non-compliance citations. Disagreements that result in false negatives (marked as compliance when out of compliance) are of particular concern in regulatory contexts due to the potential for increased risk to the individuals being regulated.
The UCM allows for the calculation of a coefficient that quantifies the level of agreement or disagreement, effectively indicating the degree of certainty or uncertainty associated with regulatory decisions.
A coefficient value closer to +1 signifies a high level of agreement (certainty), a value closer to -1 indicates significant disagreement (uncertainty), and a value near 0 suggests a level of randomness in the decision-making process. A horizontal or vertical pattern in the data, with little or no diagonal indication, can suggest the presence of a bias.

To read a detailed account and see how to calculate the coefficient you can download:
Uncertainty-Certainty Matrix for Validation and Reliability Studies

UCM Coefficient Range	Interpretation	Recommended Action
+.25 to +1.00	Acceptable agreement (certainty)	No immediate action required; the regulatory compliance status determined is likely accurate and verified through a high degree of agreement between the decision and the actual state.
+.24 to -.24	Random agreement/disagreement (uncertainty)	Requires focused reliability training for assessors to enhance consistency in their judgments and reduce the level of randomness in their decision-making processes.
-.25 to -1.00	Severe disagreement (uncertainty)	Demands an immediate and thorough review of existing reliability training protocols and potentially a comprehensive re-evaluation of the targeted rules and regulations to ensure clarity, consistency in interpretation, and uniformity in application across assessors.

The Uncertainty-Certainty Matrix (UCM) serves as a valuable framework within regulatory science for analyzing the degree of agreement between a regulatory decision regarding compliance and the actual state of compliance. Rooted in the principles of a Confusion Matrix commonly used in decision-making research, the UCM is specifically adapted for the context of regulatory compliance and licensing measurement. Its application is particularly relevant when dealing with binary or nominal regulatory compliance data, where each rule or regulation is assessed as either being in compliance or out of compliance. The primary utility of the UCM lies in its ability to help assess the reliability and validity of regulatory decisions, including those made through differential monitoring approaches such as reviews based on key indicators.

Activity: True/False

Activity Type: True/False

The rule formulation steps ensure that rules are based on current, valid, and thorough research. Review each question and select the best answer.

1. Increasing compliance with regulations will always improve program quality.
    a. True
    b. False (CORRECT)

Answer Response boxes

You are correct!
You did not select the correct response. The correct answer is False: Increasing compliance with regulations can initially improve program quality but further increases in compliance slows or even decreases quality improvement.

2. A tendency for a particular inspector to consistently rate facilities either in compliance or out of compliance, regardless of the actual situation, can be revealed through patterns in the Uncertainty-Certainty Matrix results.
    a. **True (CORRECT)**
    b. False

Answer Response boxes

You are correct!
You did not select the correct response. The correct answer is True: The Uncertainty-Certainty Matrix results can identify the presence of bias in some cases.

3. Utilizing a scale rather than just counting the number of violations is a better metric in measuring a programs' regulatory compliance.
    a. **True (CORRECT)**
    b. False

Answer Response boxes

You are correct!
You did not select the correct response. The correct answer is True: When the data are moved from frequency counts into buckets or categories, programs are better able to identify better (or worse) performing programs.

4. Research suggests that there exists a "sweet spot" of substantial compliance, estimated to be around 88-89%, where an optimal balance is achieved between the resources invested and the positive outcomes observed.?
    a. True
    b. False (CORRECT)

Answer Response boxes

You are correct!
You did not select the correct response. The correct answer is False: The “sweet spot” of substantial compliance is estimated to be around 98-99%.

5. A coefficient value closer to +1 signifies a high level of agreement (certainty) while a value closer to -1 indicates significant disagreement (uncertainty).
    a. **True (CORRECT)**
    b. False

Answer Response boxes

You are correct!
You did not select the correct response. The correct answer is True: A coefficient value closer to +1 signifies a high level of agreement (certainty) while a value closer to -1 indicates significant disagreement (uncertainty).

Activity: Gaps in Research:

Activity Type: Reflecting to Make Connections

We began this course with the history of regulatory science and learned that it is truly in infancy. Thanks to Dr. Fiene and other research scientists like him, we have the beginnings of a research roadmap. But there is still work to be done – there will always be work in research! The aim of this course has been to highlight the importance of scientific research in licensing and outline some of the foundational theories and methods.

Take a moment to write down ways you can/will contribute to the field of regulatory science in human care licensing. What problems or further advancements would you like to see? What gaps in the current knowledge or empirical evidence still exist?

Click on each (image, number) to read suggestions and ideas from the research field:

Expandable boxes or containers

1. The relationship between Regulatory Compliance & Monitoring Systems in the context of client outcomes. Are clients healthier and safer in highly compliant programs and are there fewer injuries in programs with high compliance?
2. Regulatory Science research has been mainly concentrated in the field of child care and early learning. However, human care licensing maintains the same, or similar foundational beliefs and monitoring systems. More empirical studies are needed to evaluate the impacts of different differential monitoring strategies on compliance outcomes across a wider range of industries and regulatory domains.
3. There still needs to be additional research that continues to validate the rules/standards and monitoring measures demonstrating regulatory compliance theories as accurate and relevant across licensing.
4. Due to limited research in licensing itself, measurement and statistical methods need further development and refinement. For example, this idea of moving from nominal measurements to an original measurement scale is still a theory and could be a critical change in theory.
5. Further investigation regarding the optimal levels of substantial compliance that are appropriate for different types of regulations and across various regulated sectors would provide valuable guidance for policymakers.
6. Longitudinal studies could be used to examine the long-term impact of differential monitoring systems on sustained compliance rates and overall outcomes.

Conclusion

We hope that through this course we have provided you with a foundation in thinking about how regulatory science can be applied to human services licensing and regulatory administration. Human services licensing and regulatory administration have been part of the landscape when it comes to establishing rules and regulations for programs, it is the application of regulatory science that is relatively new.

As you can see from the previous activity in looking at gaps in the regulatory science research done to date, there is still a great deal of work to be done and questions to be answered. Hopefully, this course has given you some insights into how to deal with answering some of these key questions in the licensing and regulatory administration field through the use of regulatory science.

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Full versus Substantial Regulatory Compliance

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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.

The Theory of Regulatory Compliance* and Its Implications for Regulatory Science

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January 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, and dichotomization of skewed licensing data distributions.

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 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. 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 the 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 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.

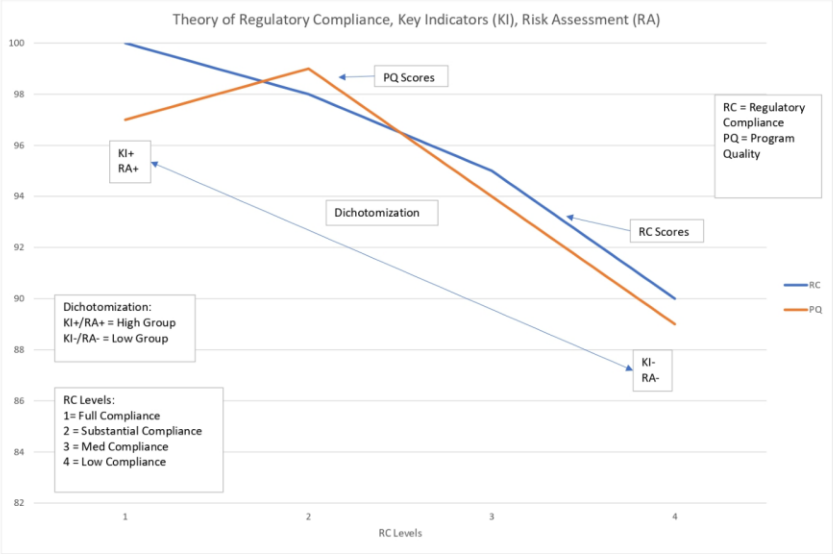


Figure 1: Theory of Regulatory Compliance

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 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.

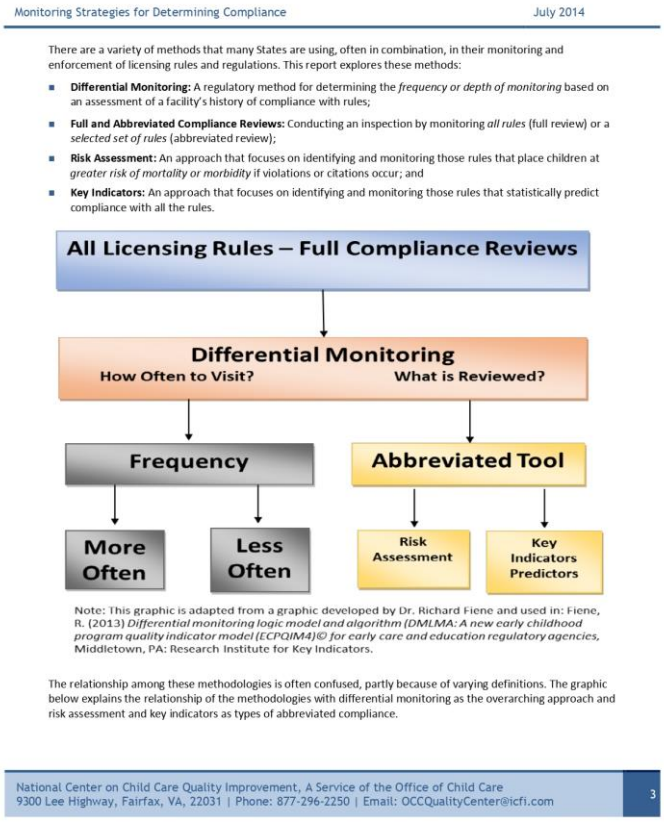


Figure 2: Differential Monitoring Approaches

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. 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:

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

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

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

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

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 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

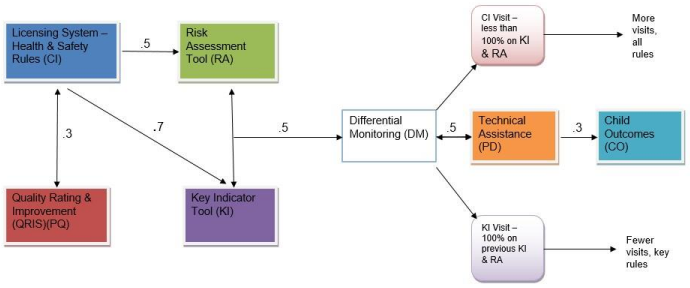
Scoring Level	**Individual Rule**		**Aggregate Rules**	**Individual Rule**
Scale	**Instrument based**	***Scale***	**Differential**	**Integrated**
7	Full Compliance	7	Full Compliance	Exceeds Compliance
-	---	5	Substantial	Full Compliance
-	---	3	Mediocre	Substantial
1	Out of Compliance	1	Low	Mediocre/Low

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, 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 Improvement and Indicator Model has been proposed to build off the results of the theory of regulatory compliance and to build a robust program monitoring system that both differentiates and integrates. See the following Figure 3 which provides a logic model for how the model would play out.



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

1

Figure 3: Early Childhood Program Quality 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) 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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Note:

In the regulatory science research literature and in this article both the theory of regulatory compliance as well as the regulatory compliance theory of diminishing returns are used interchangeably.

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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

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

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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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Fiene (2022). Regulatory Compliance Scale, ***RIKINotes Blog***, January 2022.

Fiene (2023a). ***Licensing Measurement & Monitoring Systems***, Research Institute for Key Indicators, Elizabethtown, Pennsylvania.

Fiene (2023b). Ceiling Effect/Diminishing Returns, Regulatory Compliance Scale, and Quality Indicators Scale, ***Mendeley Data,*** doi: 10.17632/gc423hprcs.1

NARA (2023). ***Saskatchewan Differential Monitoring/Quality Indicators Scale Validation Study***, National Association for Regulatory Administration, Fredericksburg, Virginia.

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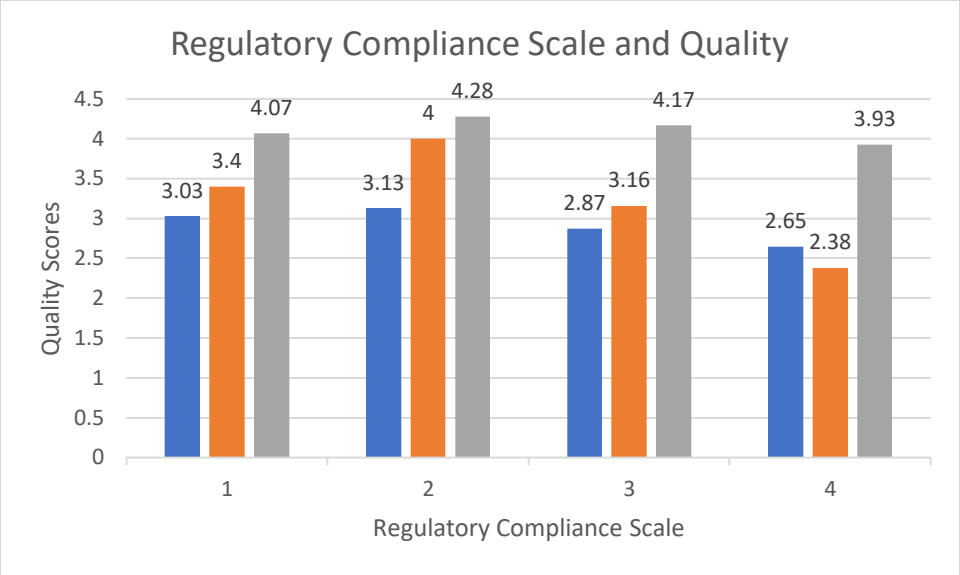
This technical research note/abstract provides a data matrix (below table) depicting the relationship between regulatory compliance and program quality. The data clearly demonstrate the regulatory compliance theory of diminishing returns which depicts the ceiling or plateau effect in this relationship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

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June 2023

Introduction

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

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

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

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

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

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

Ensuring Legal and Ethical Practices

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

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

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

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

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

Protection of Consumers and Public Interest

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

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

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

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

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

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

Financial Stability and Risk Management

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

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

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

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

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

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

Preserving Competitive Market Environment

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

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

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

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

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

Establishing Trust and Credibility

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

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

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

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

Penalties and Consequences of Non-Compliance

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

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

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

Compliance Programs and Frameworks

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

Here are some common compliance programs and frameworks:

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

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

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

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

Role of Technology in Regulatory Compliance and monitoring and reporting tools

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

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

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

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

Conclusion Recap of the importance of the theory of regulatory compliance

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Figure 1: Kappa Coefficient

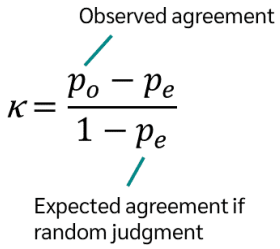

Figure 2: Uncertainty-Certainty Coefficient

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

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

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

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

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

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

Another example which involves either Random Clinical Trials (RCT) or the use of abbreviated inspections (AI) and the results from these two interventions. The decision making in both RCT and AI is

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

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

Uncertainty-Certainty Matrix for Validation and Reliability Studies

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

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

Table 4

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

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

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

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

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

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

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

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

Table 5

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

Table 6

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

Table 7

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

Table 8

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

Table 9

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

Table 10

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

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

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

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

Uncertainty-Certainty Matrix for Differential Monitoring Studies

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

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

Table 11

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

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

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

Tables 12-18 below will demonstrate the following relationships:

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

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

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

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

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

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

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

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

Table 12

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

Table 13

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

Table 14

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

Table 15

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

Table 16

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

Table 17

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

Table 18

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

Tables 12 – 18 demonstrate the different results based on the relationship between individual regulatory compliance and if a program is either a high performer or a low performer. These tables are provided as guidance for understanding the essence of differential monitoring and regulatory compliance which has various nuances when it comes to data distributions. This research abstract hopefully can be used as a guide in determining from a data utilization point of view how to make important regulatory compliance policy decisions, such as: which rules

are excellent key indicator rules, which are performing as high risk rules, importance of full compliance, what to do when substantial compliance needs to be employed, are there difficult rules to comply with, how well are our programs performing, and do we have less than optimal rules that are in need of revision.

Research Note:

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

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

$$FC = ((A)(D)) - ((B)(C)) / \sqrt{(WXYZ)}$$

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

$$FC^* = ((A)(D)) - ((B^3)(C)) / \sqrt{(WXYZ)}$$

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

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

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

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

Development of a Regulatory Compliance Scale

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April 2025

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

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

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

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

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

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

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

Introduction to the Regulatory Compliance Scale

The theory of regulatory compliance has been proven in multiple studies over the past four decades and has been utilized extensively in the creation of differential monitoring and its spin off methodologies of risk assessment and key indicators (Fiene, 2025). In fact, differential monitoring would not have been possible without the theory of regulatory compliance because

the paradigm which it replaced, one of one-size-fits-all monitoring or uniform monitoring would have predominated. However, with the theory of regulatory compliance which introduced the importance of substantial regulatory compliance and the search for the right rules/regulations that made a difference in client's lives, rather than emphasizing more or less regulations or rules.

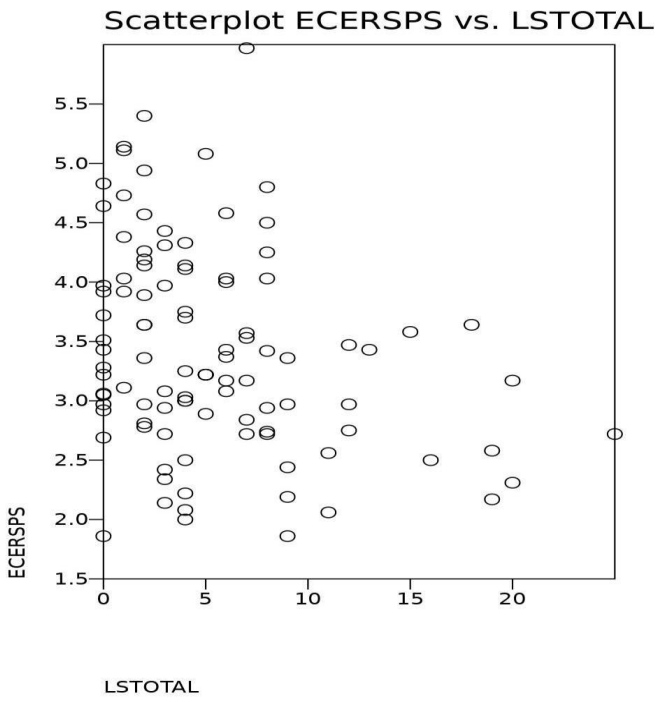
The theory of regulatory compliance has another application when it comes to regulatory compliance measurement in helping to move the licensing field from a nominal based measurement strategy to one of ordinal based measurement. The new measurement strategy is the Regulatory Compliance Scale (RCS) and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

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

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

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

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

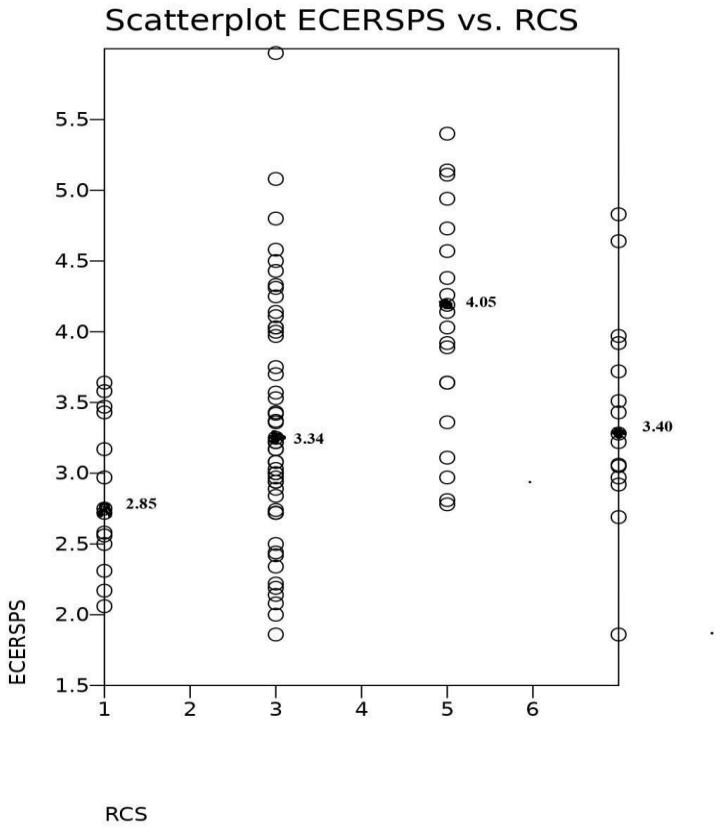


The following figure below depicts what occurs when the individual violation data are grouped according to the theory of regulatory compliance in which a substantial compliance category is introduced, and the data are moved from a nominally based metric to an ordinally based metric of full, substantial,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

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

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

completed before it would be recommended as a new Scale to be used for making licensing decisions.



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

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

Regulatory Compliance Scale Studies

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

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

Methodology

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

RCS Models used for analyses

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

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

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

Results

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

RCS Model Results compared to Quality Scales

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

*Statistically significant .05 level;

**Statistically significant .01 level.

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

RCS Fibonacci Models

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

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

ANOVAs Comparing the RCS Models with Program Quality

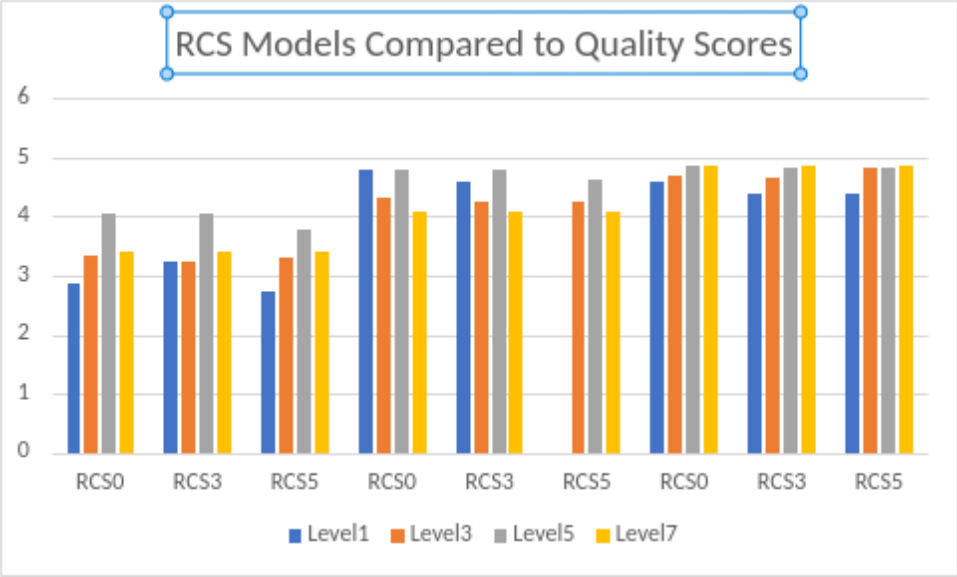
Jurisdictions	**Model**	**Level 1**	**Level 3**	**Level 5**	**Level 7**
Jurisdiction1	**RCS0**	**2.85**	**3.34**	**4.05**	**3.40**
	RCS3	3.24	3.23	4.05	3.40
	RCS5	2.73	3.32	3.77	3.40
Jurisdiction2	RCS0	4.81	4.31	4.80	4.10
	RCS3	**4.59**	**4.25**	**4.80**	**4.10**
	RCS5	---	4.26	4.64	4.10
Jurisdiction3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

Discussion

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

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

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



Additional Analyses Comparing the 11 Studies

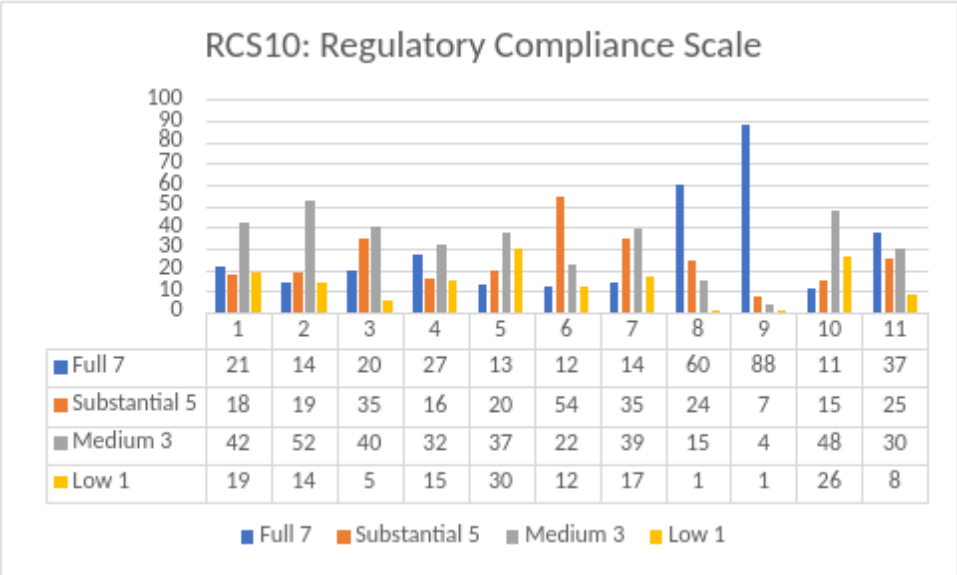
This section provides the results from 11 studies from 10 states and Canadian Provinces in which the proposed new Regulatory Compliance Scale (RCS) was utilized as a byproduct of a differential monitoring implementation or validation study. These studies were undertaken over a decade long period (2013-2023).

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

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

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

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



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

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

Regulatory Compliance Scale Extensions

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

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

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

Regulatory Compliance x Program Quality Grid Model

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

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

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

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

Regulatory Compliance Scoring System and Scale (RC3S)

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

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

Regulatory Compliance Scaling for Decision Making

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

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

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

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

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

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

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

Conclusion

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

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

It became clear after these findings in the 1970's-80's and then in the 2010's when replication studies were completed that substantial regulatory compliance could not be ignored based upon this new theory of regulatory compliance in which substantial compliance acted as a "sweet spot" of best outcomes or results when comparing regulatory compliance and program quality scores. The nominal metric needed to be revised and more of an ordinal metric was to be its

replacement. Because now it wasn't just being in or out of compliance, but it mattered which rules were in or out of compliance and how they were distributed. This revised application involved aggregate rules and does not apply to individual rule scoring. The studies completed between 1970 and 2010 involved aggregate rules and not individual rules. To determine if the nominal to ordinal metric needs to be revised still needs empirical data to back this change.

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

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

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

Regulatory Compliance Scales and Program Monitoring Systems

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

The above table attempts to summarize in tabular form the previous paragraphs in describing the relationship between program monitoring and licensing measurement scaling via a proposed regulatory compliance scale. As one can see this moves the paradigm from a nominal to an ordinal measurement rubric and depicts the differences in the measurement focus either at the

individual rule or aggregate rules scoring levels. It also considers the significance of substantial compliance given the theory of regulatory compliance in which substantial compliance focus is a "*sweet spot*" phenomenon as identified in the regulatory science research literature. It is hoped that the regulatory science field takes these paradigm shifts into consideration in moving forward with building licensing decision making systems and how licenses are issued to facilities.

As a final footnote, keep in mind that the Theory of Regulatory Compliance applies to the relationship between regulatory compliance and program quality and does not apply to regulatory compliance in and of itself related to health and safety. When dealing with regulatory compliance, full compliance is the ultimate goal with individual rules and in determining which rules are predictive rules. It is the preferred methodology in order to eliminate false negatives and decreasing false positives in making licensing decisions related to regulatory compliance.

These above concepts all relate to the field of regulatory compliance and how to make informed decisions about licensing, particularly in the context of program monitoring. Here's how they connect:

Regulatory Compliance Scales:

These scales move away from a binary "compliant" or "non-compliant" approach to regulations. Instead, they acknowledge degrees of compliance, recognizing that minor deviations may not be as detrimental as major ones.

They provide a framework for evaluating the severity and frequency of non-compliance, allowing for more nuanced licensing decisions.

Instrument Based Program Monitoring (IBPM):

This is the traditional method of monitoring compliance, relying on standardized instruments and checklists to assess adherence to specific rules.

It's a comprehensive approach, but can be time-consuming and inflexible, potentially leading to over-regulation or missing important aspects of program quality.

Differential Monitoring (DM):

This approach takes into account the risk associated with different regulations, focusing monitoring efforts on areas with the highest potential for harm or non-compliance.

It allows for a more efficient use of resources and can be tailored to the specific needs of each program.

DM often utilizes Regulatory Compliance Scales to determine the severity of non-compliance and guide the level of monitoring needed.

Integrative Monitoring Systems (IMS):

These systems go beyond simply checking compliance and aim to assess the overall quality of a program.

They integrate data from various sources, including IBPM, DM, and other program-specific metrics, to provide a holistic picture of performance.

IMS can inform licensing decisions by considering not only compliance but also program effectiveness in achieving its goals.

Here's a simplified analogy to illustrate the relationships:

Think of regulations as traffic rules.

IBPM is like a police officer checking every car for every violation, regardless of severity.

DM is like a police officer focusing on patrolling areas with high accident rates or known reckless drivers.

Regulatory Compliance Scales are like different levels of fines based on the severity of the traffic violation.

IMS is like a traffic management system that collects data on accidents, traffic flow, and road conditions to optimize traffic flow and safety.

Relationships:

RCS forms the foundation for DM and IMS by providing a way to assess degrees of compliance.

IBPM provides data for RCS and can be incorporated (with adaptations) into DM and IMS.

DM builds on RCS and IBPM by differentiating the intensity of monitoring based on risk and compliance.

IMS is the most comprehensive approach, integrating RCS, IBPM, DM, and additional data sources for a deeper understanding of program performance.

Regulatory Compliance Scales can be used within any of the monitoring approaches to provide a more nuanced assessment of compliance.

IBPM can be a starting point for differential monitoring, providing data on rule compliance to inform risk assessments.

Differential monitoring can be integrated into an integrative monitoring system, along with other data sources, to provide a comprehensive picture of program performance.

Here are some additional points to consider:

The choice of the most appropriate approach will depend on the specific context, such as the type of program being regulated and the available resources.

Implementation of these alternative paradigms requires careful planning and training of regulators and program providers.

Ongoing research and evaluation are needed to refine these approaches and ensure their effectiveness.

These alternative paradigms offer a more flexible and effective approach to licensing decisionmaking compared to the traditional IBPM approach. They allow for a better

understanding of program strengths and weaknesses, optimize resource allocation, and ultimately lead to better regulatory outcomes.

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

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

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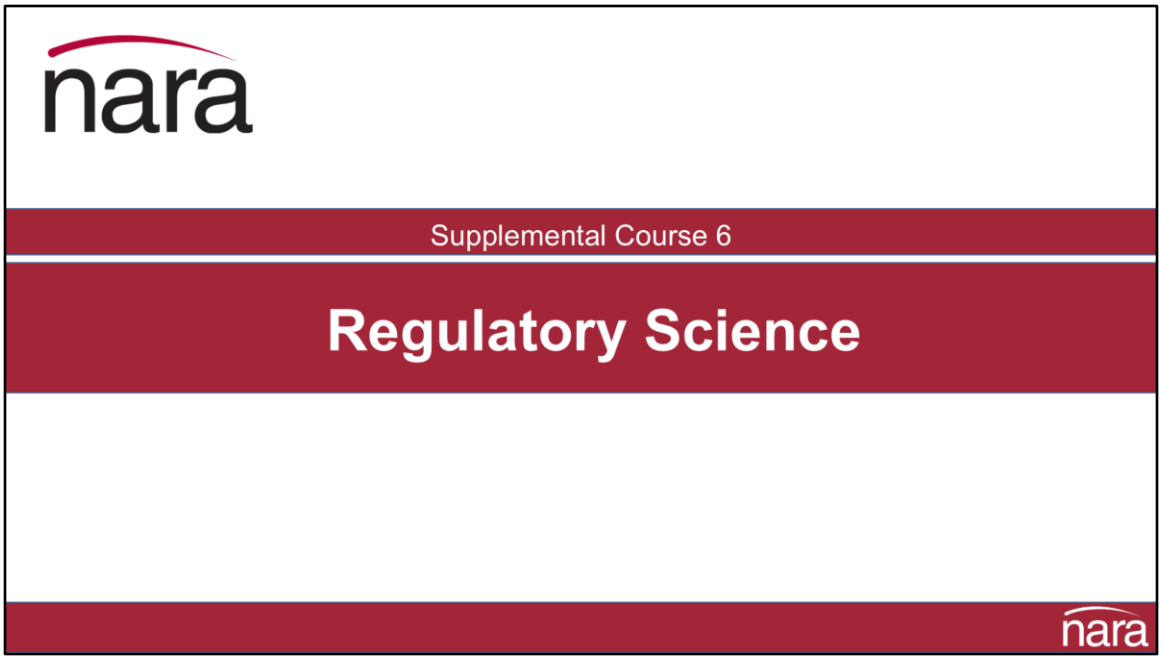
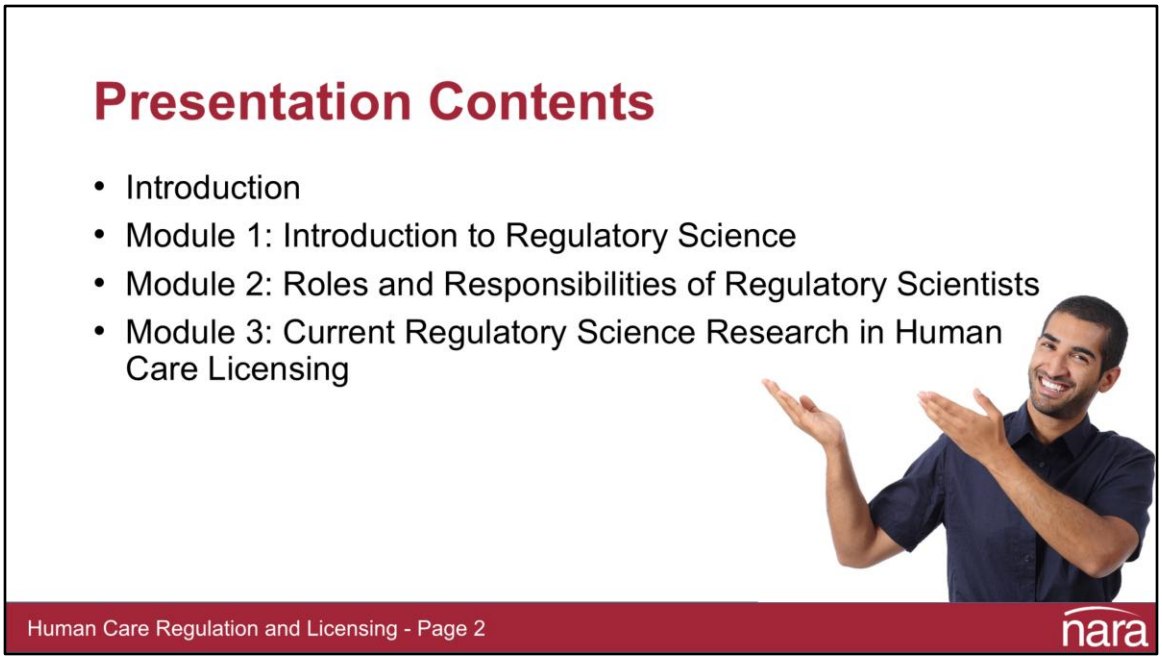


Notes to Instructor:

Welcome all participants and review the course goal.

Course Goal:
The goal of this course is to provide an introduction to the purpose and historical significance of human care regulation and how it has evolved over the years. Additionally, the course includes an overview of the phases of licensure.



Notes to Instructor:

Review the presentation layout with course participants.

Introduction

The goal of this course is to introduce and familiarize human care regulators with the concepts, basic principles and components of regulatory science as a field of study in human care licensing industries.

This course will take approximately two hours to complete all three modules. Each module explores important topics in understanding the concepts of regulatory science with human care licensing. There will be resources and articles throughout for your reference.
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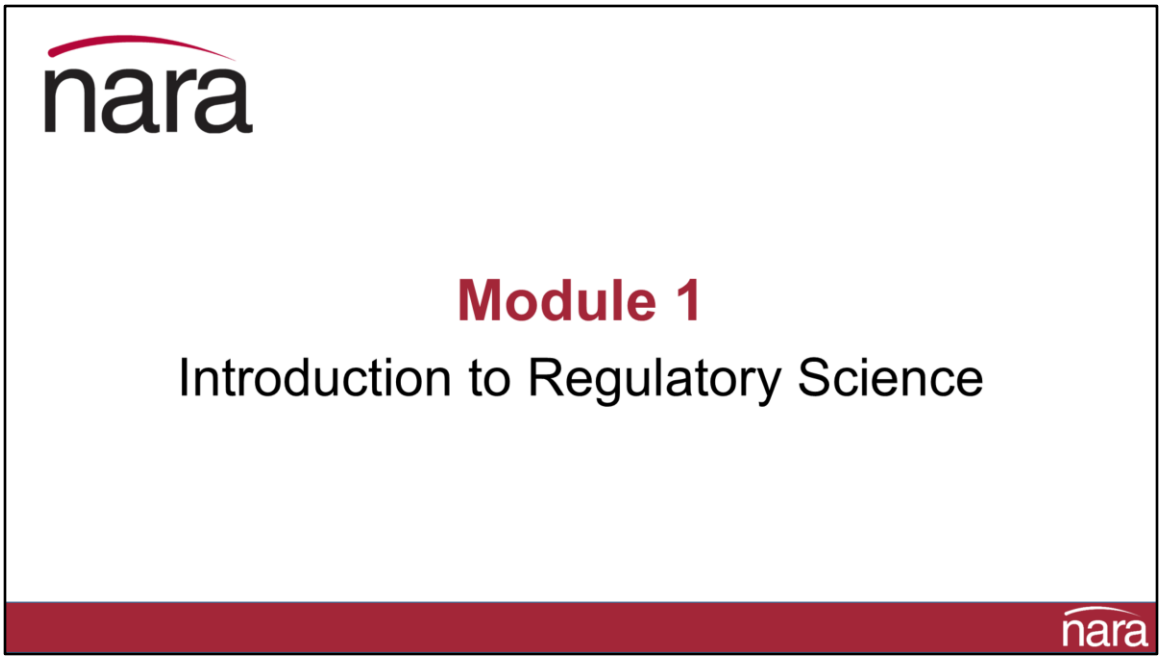
Course Modules:
- Module 1: Introduction to Regulatory Science in Human Care Licensing
- Module 2: Roles and Responsibilities of Regulatory Scientists

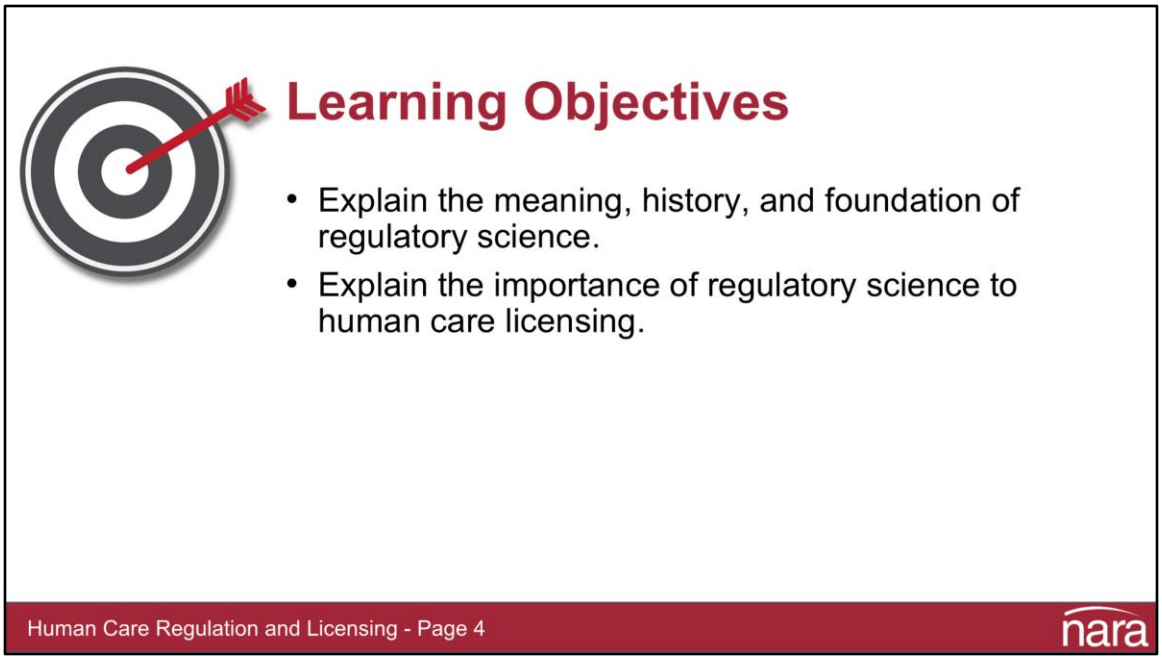
- Module 3: Current Regulatory Science Research in Human Care Licensing



Notes to Instructor:

Introduce module

Module 1: What Is Human Care Regulation?



Notes to Instructor:

Review learning objectives with course participants.

Learning Objectives:

- Explain the purpose and importance of human care regulation.
- Define regulatory administration.

What Is Regulatory Science?

Science is the systematic study of the structure and behavior of the physical and natural world through observation, experimentation, and the testing of theories against the evidence obtained.
[Oxford Languages Dictionary]

Regulatory Science is a relatively new and emerging discipline that specifically responds to the need to include scientific methodology into policy decision-making within the regulatory fields. The work has historically focused on fields such as medical, engineering and environmental sciences.

Historical Foundation

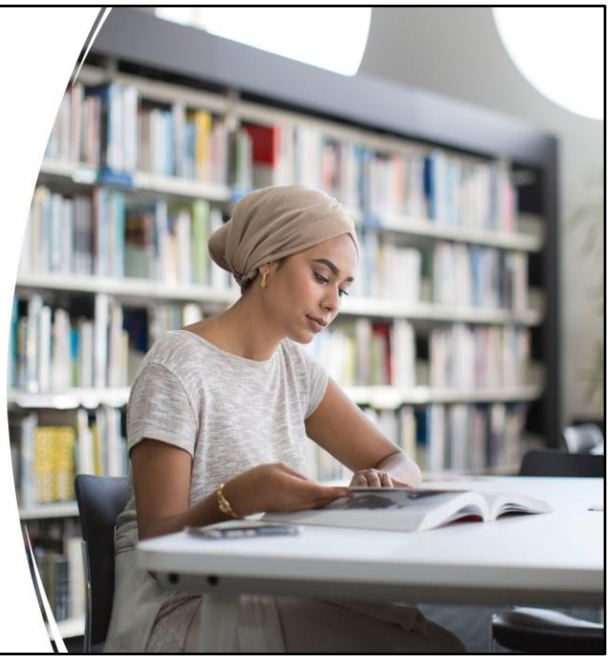
The term "regulatory science" first occurred in 1970 shortly after the formation of the Environmental Protection Agency (EPA).

The term "regulatory science" first occurred in 1970 shortly after the formation of the Environmental Protection Agency (EPA) through an internal memorandum describing how science was used to develop regulations by that agency. The term, while defined in multiple ways, was not quickly accepted as it was not viewed as significantly different from other areas of scientific research.

Over time, the term became more widely used in response to the need for more valid and reliable means to meet social needs. Specifically, regulatory science has evolved because policy makers and regulators struggle to apply science reliably; most commonly, to limit using judgement when making policy decisions resulting in overly protective approaches to licensing oversight (Moghissi, Auffret, Calderone & Steen, 2018).

Importance of Regulatory Science

There have been discoveries since the beginning of time. Everyone and everything in some way has been impacted through scientific research.



Society and one's own personal actions are greatly influenced by scientific findings. Science is behind everyday activities like the supplements we take for our health, how a building is designed, or even the rules and laws that we follow daily. Everyday science impacts behaviors and activities, even though we are not aware of the history behind it.

Science as a study is not a new concept. There have been discoveries since the beginning of time. Everyone and everything in some way has been impacted through scientific research.

Society and one's own personal actions are greatly influenced by scientific findings. Science is behind everyday activities like the supplements we take for our health, how a building is designed, or even the rules and laws that we follow daily. Everyday science impacts behaviors and activities, even though we are not aware of the history behind it.

Science as a study is not a new concept. There have been discoveries since the beginning of time. Everyone and everything in some way has been impacted through scientific research.

Activity: How are you Affected by Science?

What revelations that came from scientific studies impacted how you interacted with others or managed your personal behaviors?

Notes to Instructor:

Supplies needed: Chart paper, markers

Group discussion:
Science is broadly defined as the systematic study of the structure and behavior of the physical and natural world through observation, experimentation, and the testing of theories against the evidence obtained. Science is intended to provide information centered on cause and effect.

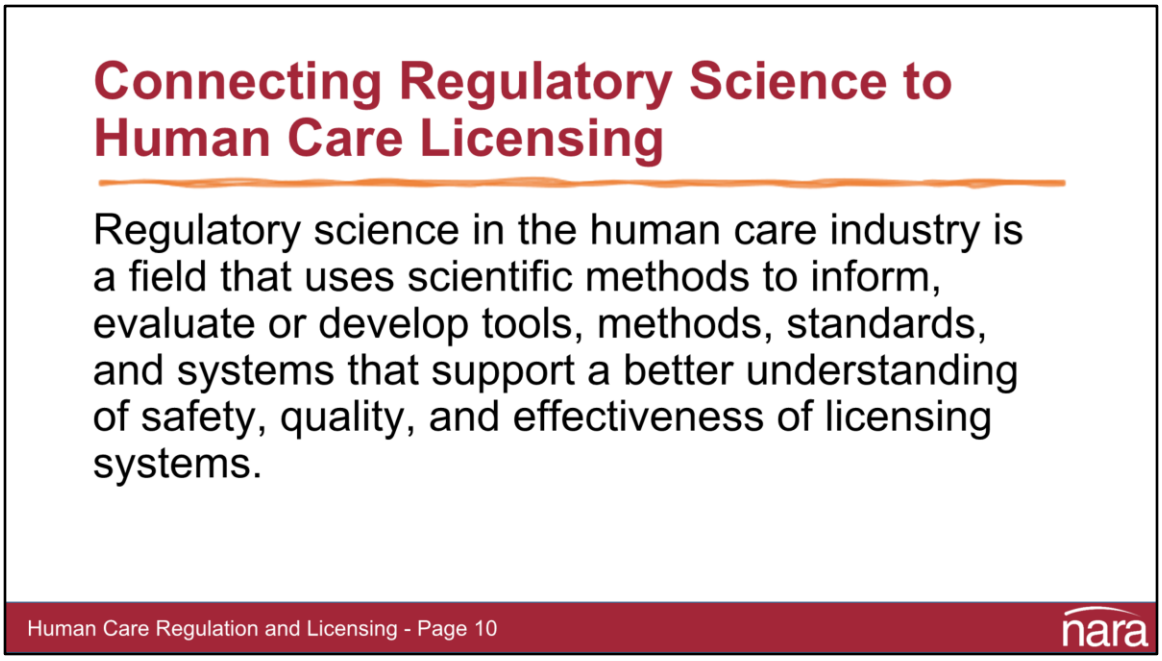
Take a moment to think about your day and the many influences scientific studies have on your daily activities. What revelations that came from scientific studies impacted how you interacted with others or managed your personal behaviors?

Examples
Scientific impacts that impacts everyone's lives:

- Science has led to advancements in medicine and surgical technologies which have improved health and life expectancy.
- Science led us to the invention of technologies like cell phones that

have dramatically changed how we communicate.

- Scientific understanding of weather patterns has helped many people prepare for extreme weather events.
- Science is essential for building homes, roads, and other infrastructures to ensure our safety.
- Scientific principles are used in cooking, like understanding how heat changes food and methods that are critical to ensure healthy practices.



Licensing in the human care regulatory industry establishes standards to which providers must legally operate. Regulatory science informs the development and implementation systems of those standards, ensuring providers and caregivers meet those standards and protects the public from harm while promoting quality care.

Regulatory science in the human care industry is a field that uses scientific methods to inform, evaluate or develop tools, methods, standards, and systems that support a better understanding of safety, quality, and effectiveness of licensing systems. It plays a crucial role in the human care licensing system development and assessment by ensuring safety, efficacy, and quality of services, products, and practices that ultimately lead to the protection and well-being of individuals receiving care.

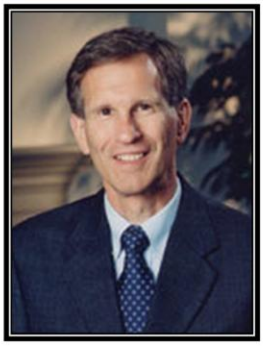
Regulatory affairs focus on the practical aspects of creating and applying regulatory requirements to ensure compliance while regulatory science is more concerned with the scientific basis for those regulations and the development of methodologies and standards used in regulatory decision-making.

Overall, there are two pillars to regulatory science; preventing harm (do no harm) and increasing benefit (do good). It is a dynamic tension where they are generally in

balance but can get out of balance at times and one offsets the other. If you look at any regulatory setting, these are the two underlying concepts that the rules/regulations/standards are attempting to enhance: reduce risk + increase benefits. It doesn't matter if it is a child care center, foster home, new drug or product or device, etc. We want to build protection and hopefully help to enhance whatever we are attempting. These two pillars can best be defined in three areas of licensing work; standards development, safety and efficacy, and monitoring and enforcement.

The Emergence of Regulatory Science in Human Care Licensing

Dr. Richard Fiene's life's work serves a blueprint advocating for research scientists to explore the potential to improve outcomes for all adults, children and families in human care settings.



Perhaps the most relevant and notable scientific contributions to human care licensing has come largely from Dr. Richard Fiene. Dr. Fiene's research into child care quality and licensing oversight has spanned over 50 years. He Initially focused on developmental psychology and child care but transitioned to macro-system research, particularly in public policy, licensing, and regulatory compliance. His career began at the University of North Carolina at Greensboro, directing a national child care demonstration center. He then moved to Pennsylvania to develop a monitoring system for child care programs, which led to his involvement in creating the Child Development Program Evaluation (CDPE).

Fiene's work expanded into developing methodologies for monitoring child care standards, including key indicators, risk assessment, and differential monitoring. He collaborated with federal and state agencies to pilot and validate these approaches.

While Fiene's journey highlights the impact of regulatory science on child care quality and policy, it also serves a blueprint advocating for research scientists to explore the potential to improve outcomes for all adults, children and families in human care settings. "The research work has resulted in major improvements in child care by having more effective and efficient monitoring and licensing systems, voluntary

standards for all early care and education, better decision making related to child care policy, and a better balance between regulatory compliance and program quality in the early care and education field."

Unfortunately, laws and regulations protecting individuals in human care are rarely proactive but are usually created *following* a devastating event or even one that resulted in little harm but is perceived to potentially cause larger harm or damage. When regulatory science is used effectively to develop rules and licensing requirements, there is a focus placed on the scientific evidence needed to evaluate rules or regulations for the performance and safety rather than creating undue burden on provider or caregiver. Some examples of events that can lead to regulatory changes include:

Examples:

- Inadequate staffing: Instances of understaffed facilities leading to neglect or harm have prompted regulations mandating minimum staffing ratios or training requirements.
- Neglect and abuse: High-profile cases of abuse or neglect in facilities can trigger stricter licensing standards to prevent future incidents.
- Inadequate facility conditions: Events like fires or structural failures can lead to regulations requiring improved safety measures, building codes, or sanitation standards.
- Outbreaks of illness: Pandemics or outbreaks of infectious diseases can lead to

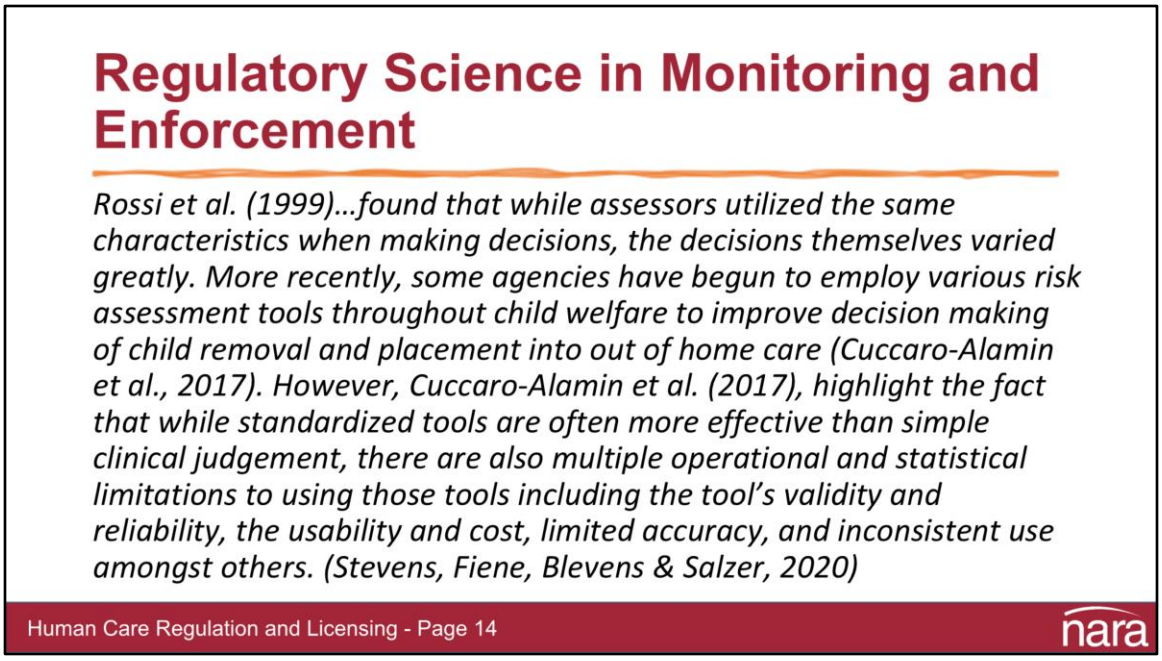
temporary or permanent changes in licensing regulations, such as requirements for infection control protocols or visitor restrictions.

- Changes in resident populations: Shifts in the types of residents served, like increased numbers of individuals with complex medical needs, can necessitate changes in staffing requirements, training, or facility design.
- Legal challenges: Court cases or legal challenges to existing regulations can lead to revisions or clarifications to ensure compliance and protect residents' rights.
- Public outcry: Public awareness campaigns or media coverage of problems in facilities can pressure policymakers to enact stricter regulations or increase funding for oversight and enforcement.
- Limited resources: Agencies faced with being asked to do more without an increase in staff. As noted, in part, this inspired the regulatory compliance theory with diminishing returns that demonstrated how licensing decisions can be made to issue full licenses based on substantial regulatory compliance.

Regulatory Science in Safety and Efficacy

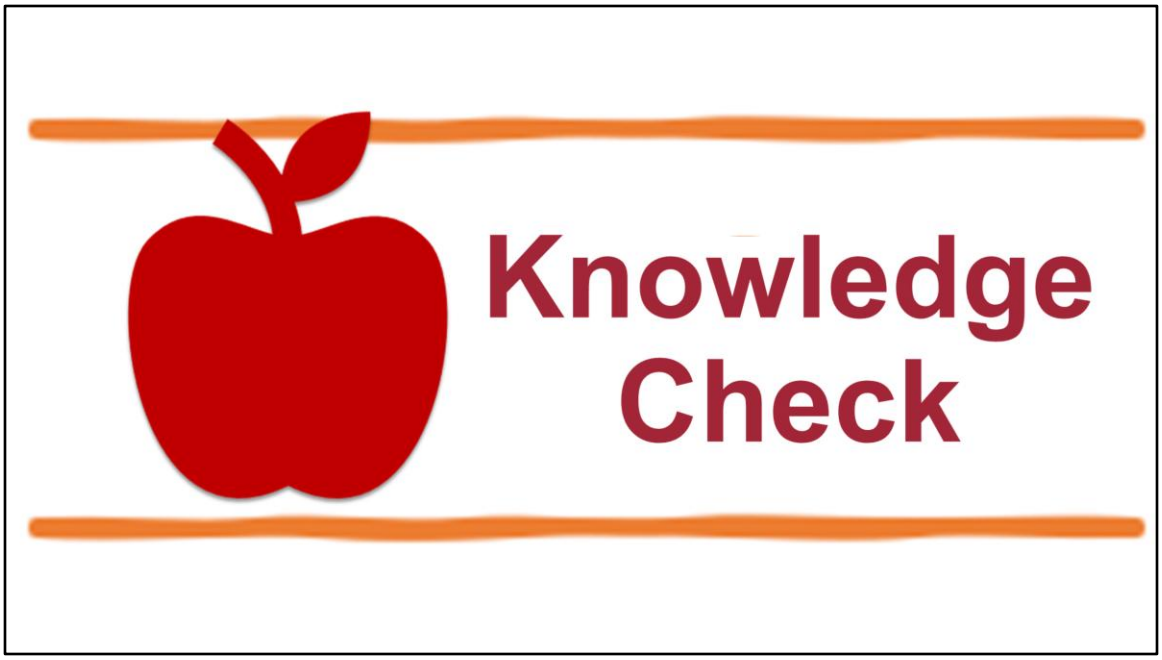
"The empirical results show that tougher regulations appear to be associated with higher quality and price…First, there is a significant amount of input substitution in response to regulations: a tougher regulation on one input affects the use of other inputs as well as the regulated input. For example, regulations that require higher staff qualifications cause centers to employ fewer staff members per child. Second, tougher regulations induce greater violation, indicating that enforcement is far from perfect. Third, other research suggests that many of the regulated inputs are in fact not very productive in improving quality. The only input that has been found to have robust positive effects on quality is recent staff training in early childhood development."

How many times have you experienced administrative decisions that didn't seem well thought out and were put into place to address one hot issue, but you could see other adverse impacts that were possible because of that decision? Regulatory science ensures there are avenues to test or pilot regulatory rules and systems with scientifically sound methodology providing the necessary data to assess a rule or practice change with a holistic impact to client safety and efficacy. Take a moment and read this excerpt from an article that explored and outlined unintended impacts of child care regulations: How do you see the impact of these studies impacting your work?



Regulatory Science can also support the development of monitoring tools such as monitoring checklists, risk assessments, licensing services, predictive analytics, measurements and information technology systems, as well as enforcement processes designed to assess compliance. Some key areas where this work focuses on are ensuring the intended users can reliably use the tools, the system is accomplishing what was intended through validation studies, and identifying potential risks associated with the design to ensure correction before harm is done.

Applying scientific methods to testing monitoring and enforcement systems ensure they are not only valid, but also reliable and usable. Now read an excerpt from a study completed regarding the foster care home study process. How do you see the impact of this study impacting your work?



Note to instructor:

Large group activity: Explain to the group that it is time to check their knowledge. Questions on the next slides are aligned with the module's learning objectives. Read the question and all answer options that appear on the slide. Once everyone has heard the question and thought of an answer, ask for a volunteer to give their answer. Discuss as a group and/or go back to the relevant slides to review the content if needed.

Go to next slide for the first question.

Knowledge Check

Learning Objective: Explain the meaning, history, and foundation of regulatory science.

Question #1

Regulatory science ignores the impact rules have on policy and licensing systems.

a. True

b. False

nara

Note to instructor:

Question:
Regulatory science ignores the impact rules have on policy and licensing systems.

a. True
b. False (CORRECT)

Review the following slide if needed:

- Historical Foundation
- Connecting Regulatory Science to Human Care Licensing

Knowledge Check

Learning Objective: Explain the meaning, history, and foundation of regulatory science.

Question #2

Regulatory Science focuses on two pillars including “do no harm” and “do good”.

a. True

b. False

nara

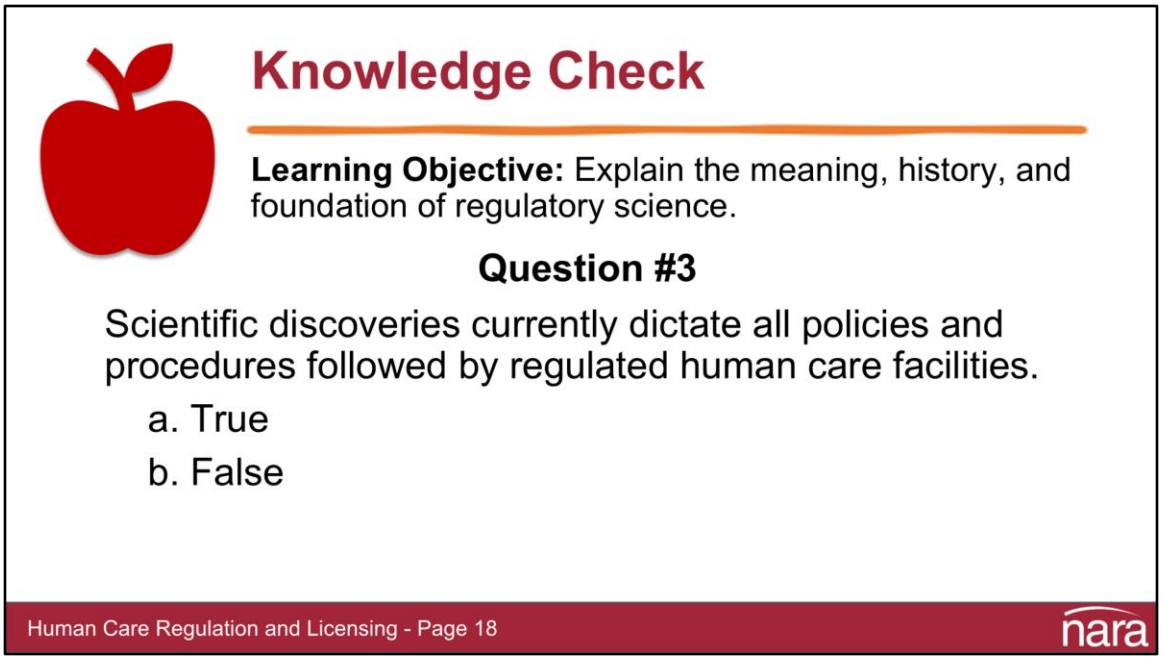
Note to instructor:

Question:
Regulatory Science focuses on two pillars including “do no harm” and “do good”.

a. True (Correct)
b. False

Review the following slide if needed:

- Connecting Regulatory Science to Human Care Licensing



Note to instructor:

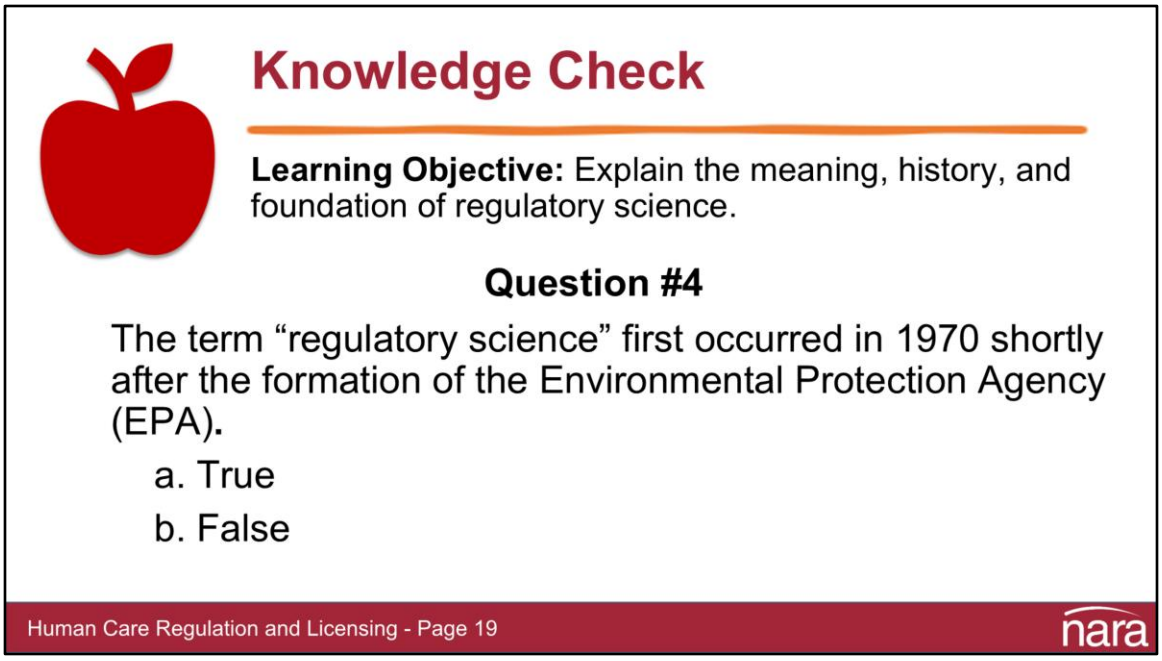
Question:

Scientific discoveries currently dictate all policies and procedures followed by regulated human care facilities.

a. True
b. False (CORRECT)

Review the following slide if needed:

- Applying Regulatory Science to Standard Development.



Note to instructor:

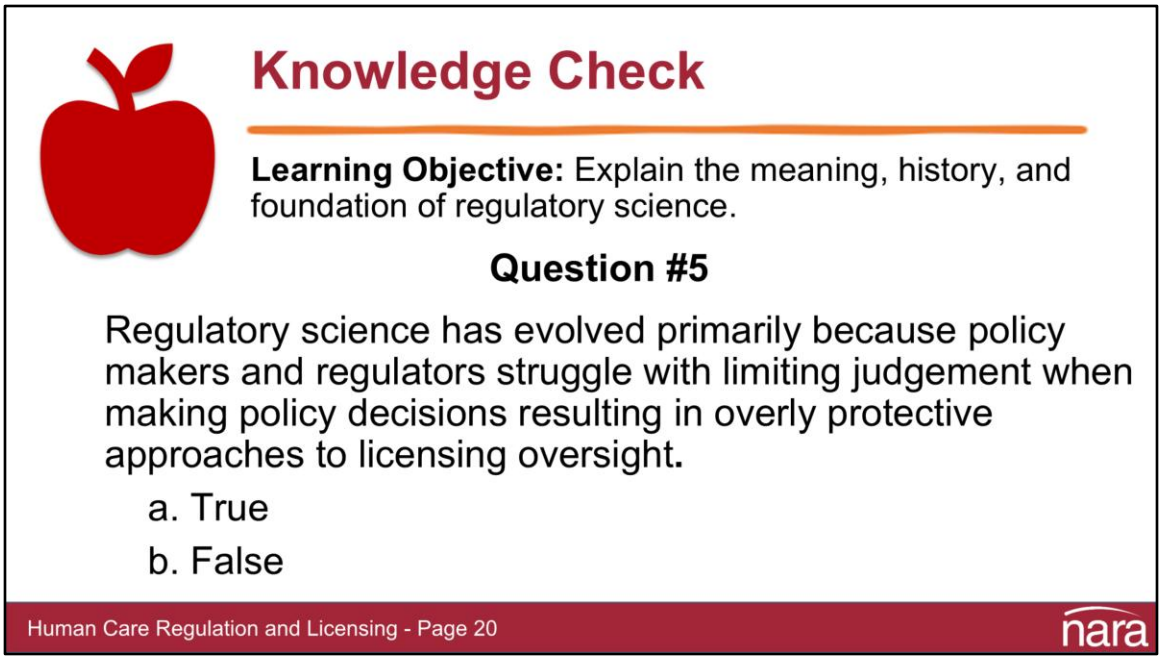
Question:

The term “regulatory science” first occurred in 1970 shortly after the formation of the Environmental Protection Agency (EPA).

a. True (Correct)
b. False

Review the following slide if needed:

- Historical Foundation



Note to instructor:

Question:

Regulatory science has evolved primarily because policy makers and regulators struggle with limiting judgement when making policy decisions resulting in overly protective approaches to licensing oversight**.**

a. True (Correct)
b. False

Review the following slide if needed:

- What Is Regulatory Science?
- Applying Regulatory Science to Standard Development

Knowledge Check

- **Learning Objective:** Explain the importance of regulatory science to human care licensing.

Question #6

Regulatory science can be effective to support rule development because:

a. New laws and regulations protecting individuals in human care are rarely proactive.

b. Rules are often created based on an event rather than evidence.

c. Perceptions of potential harm or damage can influence rules without justifiable evidence.

d. All of the above.

Note to instructor:

It's important to understand the forces that drive regulatory advancement and role regulatory research can play in its evolution. Select the correct response to the following questions.

Question:

Regulatory science can be effective to support rule development because:

a. New laws and regulations protecting individuals in human care are rarely proactive.
b. Rules are often created based on an event rather than evidence.
c. Perceptions of potential harm or damage can influence rules without justifiable evidence.
d. All of the above. (CORRECT)

Review the following slide if needed:

- Applying Regulatory Science to Standard Development

Knowledge Check

- **Learning Objective:** Explain the importance of regulatory science to human care licensing.

Question #7

Regulatory science in the human care industry is a field that:

a. Tell policy makers what to do.

b. Use scientific methods to assist in better understanding the safety, quality, and effectiveness of licensing systems.

c. Justify policy positions of state or provincial governments.

d. Guarantees better outcomes for staff.

Note to instructor:

Question:

1. Regulatory science in the human care industry is a field that:
   a. Tell policy makers what to do.
   b. Use scientific methods to assist in better understanding the safety, quality, and effectiveness of licensing systems. **(CORRECT)**
   c. Justify policy positions of state or provincial governments.
   d. Guarantees better outcomes for staff.

Review the following slide if needed:

- Regulatory Science in Safety and Efficacy

Knowledge Check

Learning Objective: Explain the importance of regulatory science to human care licensing. .

Question #8

One of the key areas where this work focuses on is: :

a. Influencing policy to ensure greater financial benefits to consumers.
b. Identifying potential risks associated with the design to ensure correction before harm is done.
c. Control all procedures and practices of the licensing agency.
d. All of the above

Note to instructor:

Question:

1. One of the key areas where this work focuses on is:
   a. Influencing policy to ensure greater financial benefits to consumers.
   b. Identifying potential risks associated with the design to ensure correction before harm is done. (CORRECT)
   c. Control all procedures and practices of the licensing agency.
   d. All of the above.

   Review the following slide if needed:
   - Applying Regulatory Science to Standard Development
   - Regulatory Science in Safety and Efficacy

Knowledge Check

Learning Objective: Explain the importance of regulatory science to human care licensing. .

Question #9

Regulatory agencies focus on the practical aspects of creating and applying regulatory requirements to ensure compliance while regulatory science is more concerned with the scientific basis for those regulations and the development of methodologies and standards used in regulatory decision-making.

a. True

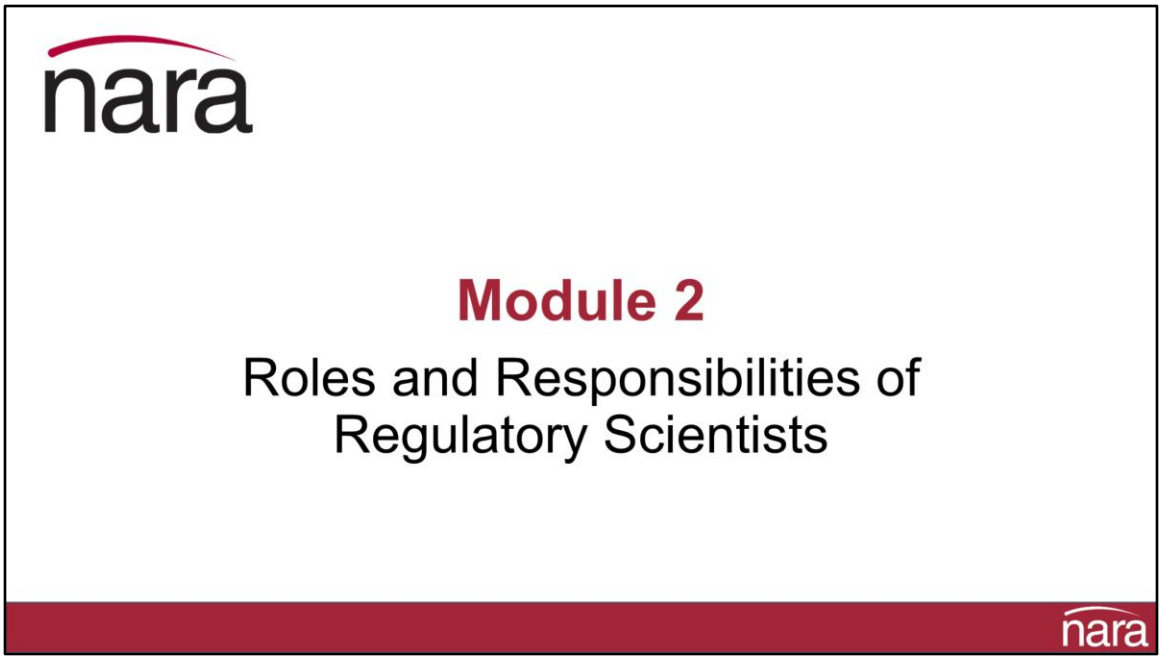
b. False

Note to instructor:

Question:

1. Regulatory agencies focus on the practical aspects of creating and applying regulatory requirements to ensure compliance while regulatory science is more concerned with the scientific basis for those regulations and the development of methodologies and standards used in regulatory decision-making.
   a. **True (CORRECT)**
   b. False

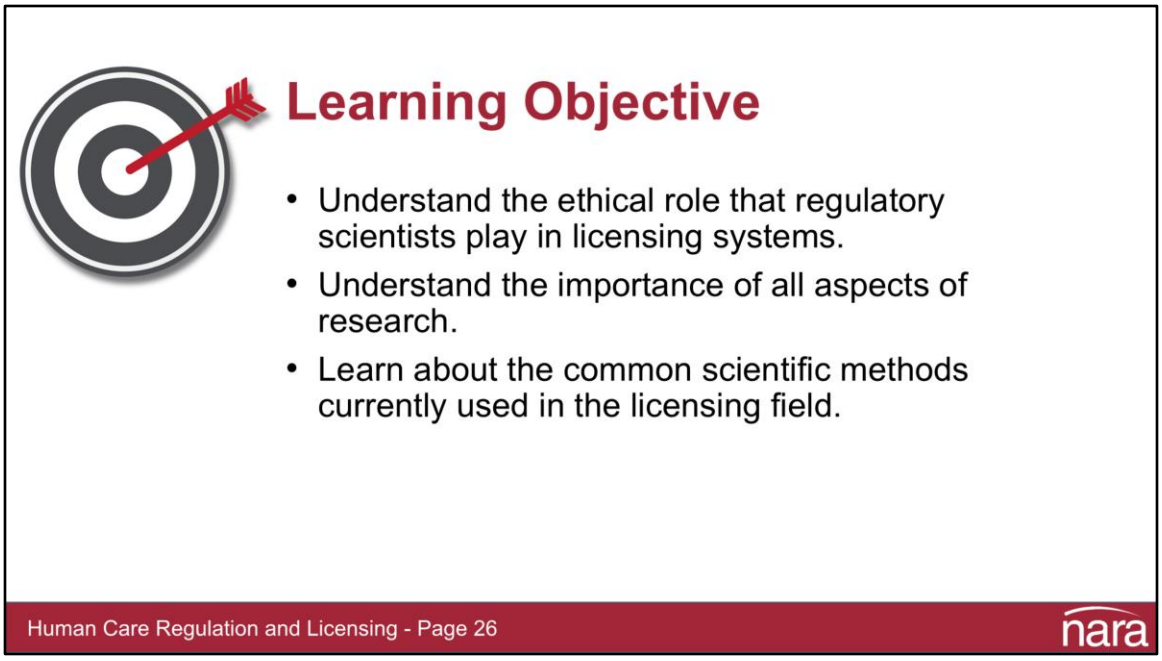
   Review the following slide if needed:
   - Connecting Regulatory Science to Human Care Licensing



Notes to Instructor:

Introduce module

Module 2: Roles and Responsibilities of Regulatory Scientists

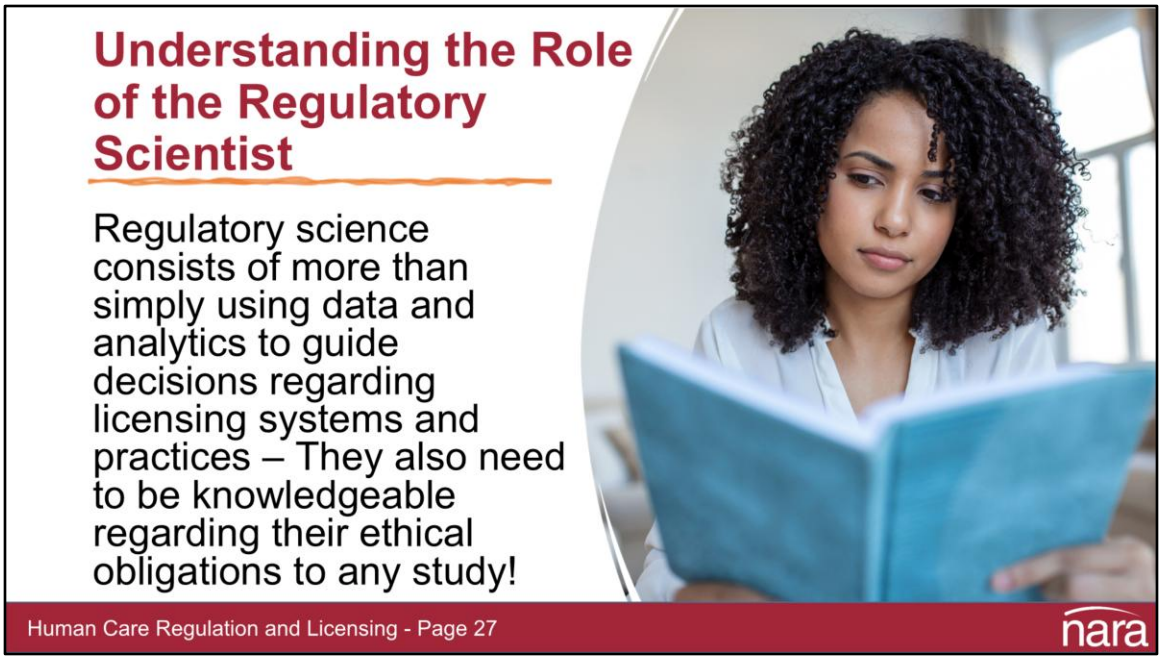


Notes to Instructor:

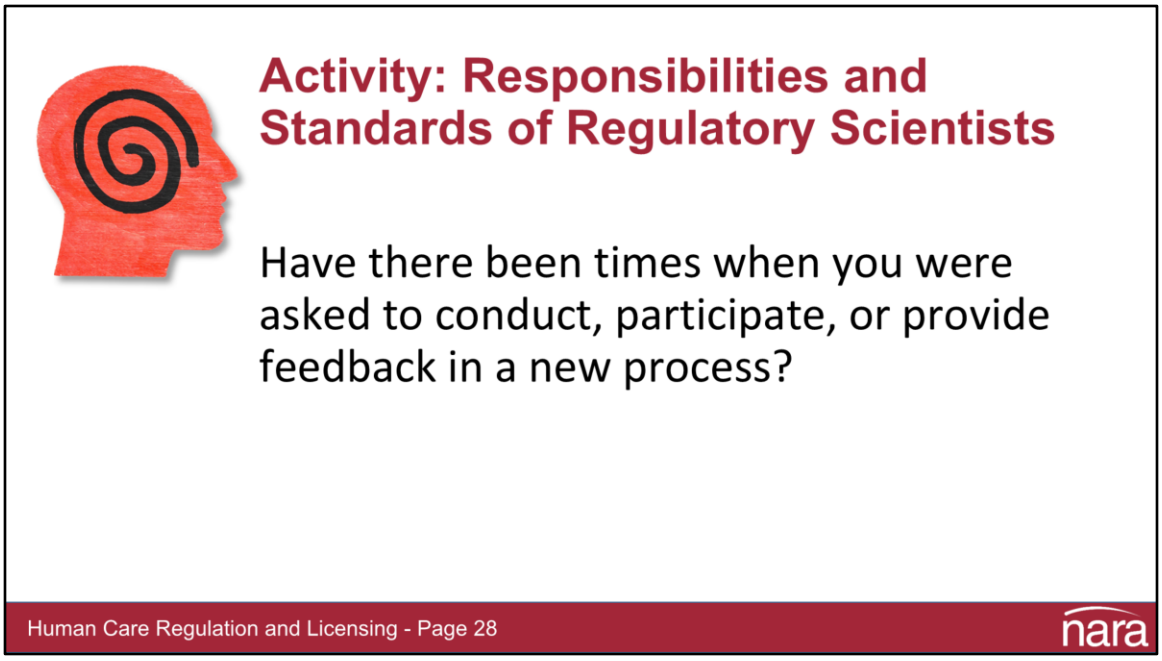
Review learning objective with course participants.

Learning Objective:

- Understand the ethical role that regulatory scientists play in licensing systems.
- Understand the importance of all aspects of research.
- Learn about the common scientific methods currently used in the licensing field.



Regulatory science consists of more than simply using data and analytics to guide decisions regarding licensing systems and practices. While scientific methodology is applied, scientists in this field also need to be knowledgeable and proficient in their ethical obligations to the study, vulnerable populations, agencies and clients to which licensed programs serve. It's also critical to understand how research is conducted and the various tools available.



Notes to Instructor:

Supplies needed: Chart paper, markers

Group discussion:
Regulatory scientists play a crucial role in ensuring the safety, efficacy, and quality of regulated products by understanding the regulatory process, conducting studies, communicating findings to regulatory agencies, and developing new methods for product evaluation.

Take a moment to think about your work in licensing or policy development. It is common for regulatory science to be employed without the distinct knowledge of those taking part. Have there been times when you were asked to conduct, participate, or provide feedback in a new process? How did you participate and what were your impressions of the process?

Examples

- Completing surveys detailing how much time is being spent on work

tasks.

- Testing new technologies like laptops for monitoring activities.
- Participating in a working group to explore solutions to a problem.
- Listening sessions to provide feedback on a new practice or rule.
- Volunteering to be a pilot tester.

Understanding and Maintaining Research Standards

- Regulatory science aims to provide systematic steps that are transparent to everyone when conducting research.
- Understanding the steps of conducting research as well as ethical practices are critical when considering regulatory research in any agency.

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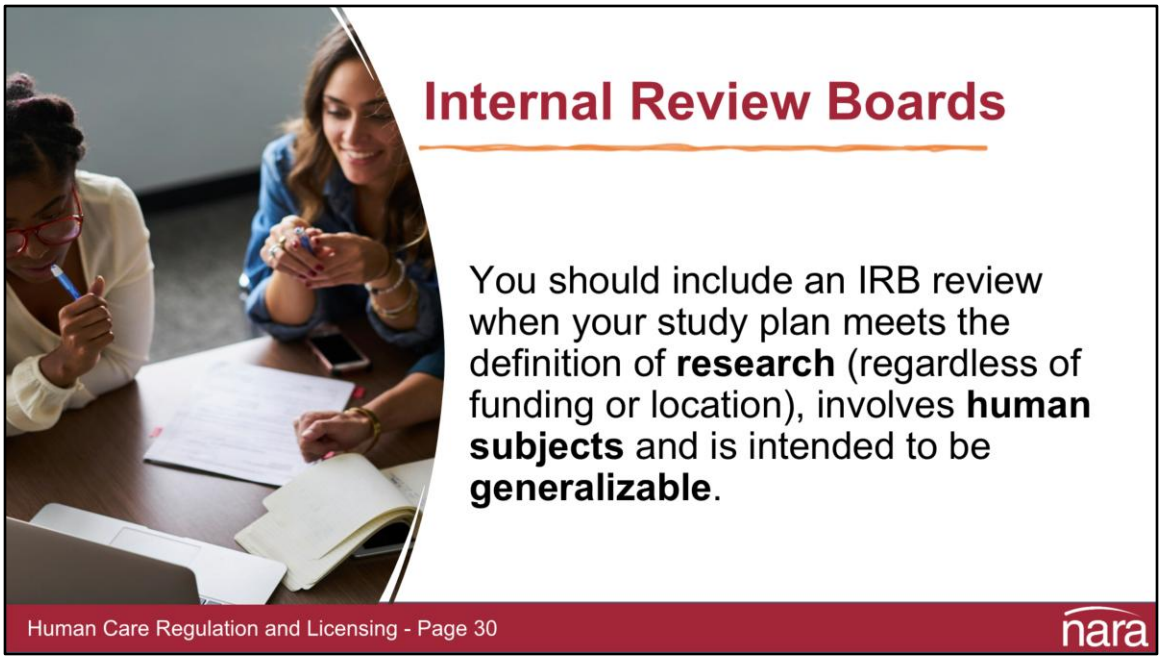
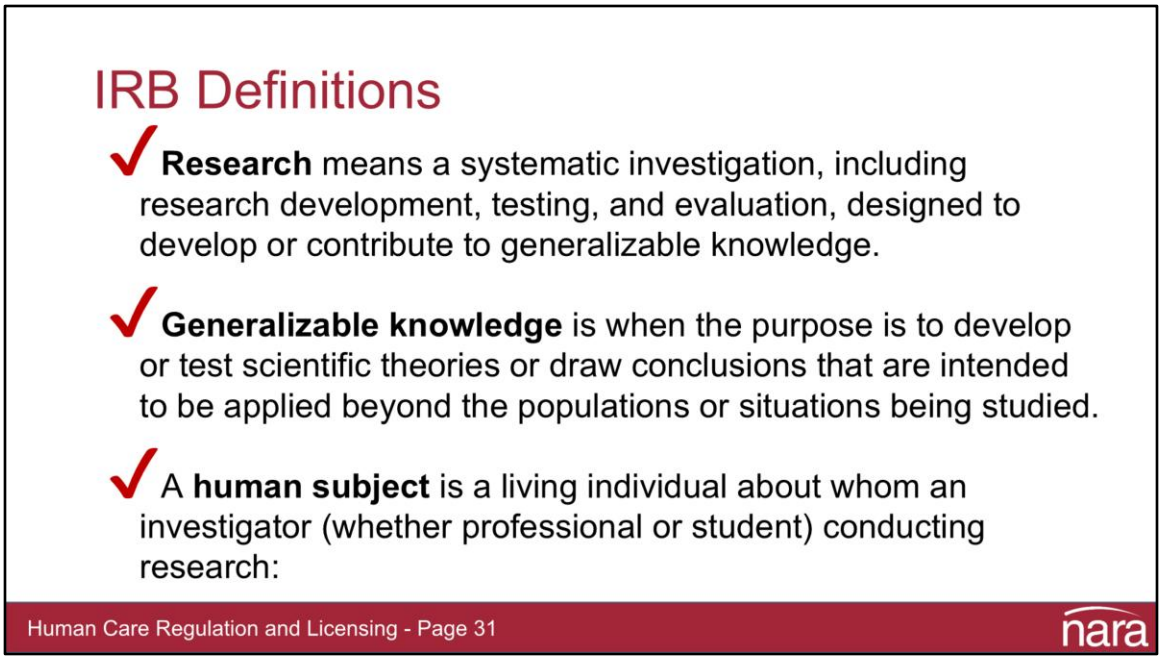
Regulatory science aims to provide systematic steps that are transparent to everyone when conducting research. Understanding the steps of conducting research as well as ethical practices are critical when considering regulatory research in any agency.



The first step is to understand when you should submit your study plan to an Institutional Review Board (IRB) for review prior to any data collection. You should include an IRB review when your study plan meets the definition of **research** (regardless of funding or location), involves **human subjects** and is intended to be **generalizable**.

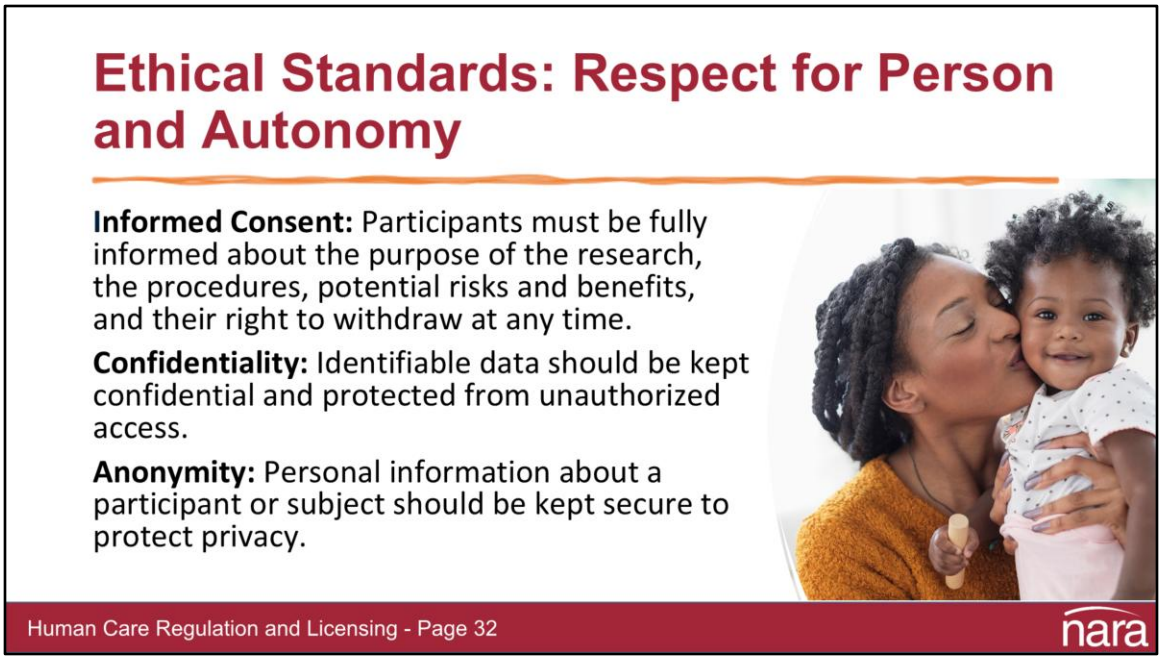
IRBs are embedded in institutions of higher education, state governments and the federal government. Check with your agency to understand which IRB should be consulted based on your research, data you intend to gather and the funding source. Now let's look deeper into those definitions in bold.



Federal Definition of Research: “Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” - 45 CFR 46.102(l)

Generalizable knowledge: The purpose or intent is to develop or test scientific theories or hypotheses, or to draw conclusions that are intended to be applied or shared beyond the populations or situations being studied.

Human Subjects: “A human subject is "a living individual about whom an investigator (whether professional or student) conducting research:
Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." - 45 CFR 46



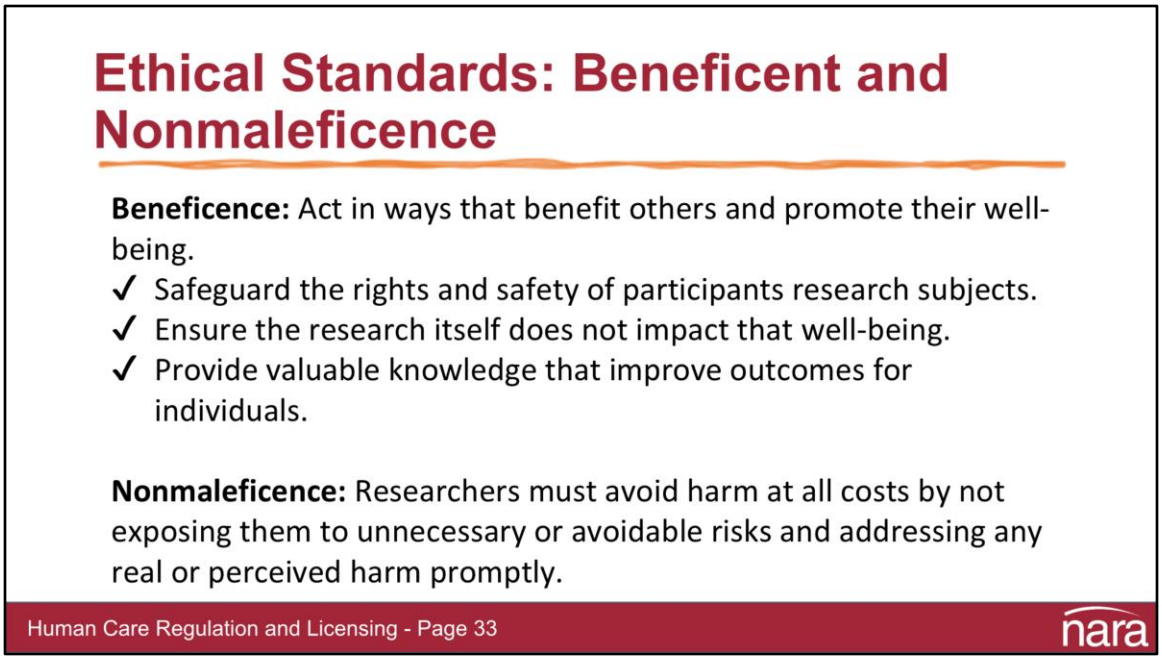
Ethical research ensures responsible and accountable conduct of the research itself, protects participants, maintains integrity, and fosters public trust in scientific findings. This begins with voluntary participation. In general, when conducting regulatory research, individuals should never be coerced or pressured into taking part in the research. There are three primary ways researchers use to ensure the research maintains respect for all people and their autonomy.

Informed Consent: This step typically includes a written description of the research study. It may also include a conversation. Before including any individual in research, they must provide consent. Participants must be fully informed about the purpose of the research, the procedures that will be followed, potential risks and benefits, and their right to withdraw at any time.

Confidentiality: When any data is collected from participants, or even using licensing data like inspection reports, individual data should be kept confidential and protected from unauthorized access. The best way to do this is to, whenever possible, gather data without any personal identifiers.

Anonymity: When the researcher has personal information about a participant or subject, it should be kept secure to protect privacy. This is often done through changing names (and other identifiers) to a research number and securing the

personal information.



Directly related to "do no harm" and "do good" that we introduced earlier, In research, beneficence (promoting well-being) and nonmaleficence (avoiding harm) are ethical principles that not only ensures participant risks are minimized while benefits are maximized, but it also fosters trust in research and its findings.

Beneficence: Regulatory Scientists have an obligation to act in ways that benefit others and promote their well-being. This is accomplished through designing and conducting studies that; 1) safeguard the rights, safety and well-being (physical, psychological and fiscal) of participants and research subjects, 2) ensure the research itself does not impact that well-being, and 3) provide useful and valuable knowledge and outcomes that improve outcomes for individuals in care.

Nonmaleficence: Regulatory scientists have a duty to avoid causing harm to research participants. This is accomplished through carefully assessing and mitigating real or potential risks associated with the research (physically, psychologically, fiscally). Researchers must avoid harm at all costs by not exposing them to unnecessary or avoidable risks and addressing any real or perceived harm promptly. Overall, the well-being of individuals or groups is much more important than any research goals.

Ethical regulatory scientists should adhere to the ethical principle of "respect for persons" by ensuring participants are treated with dignity and their rights are projected. By doing this, the researcher not only acts ethically and in good faith but is promoting the integrity and validity of research findings because findings are less likely to be challenged.

- **Avoiding Exploitation:** Ethical research prevents the exploitation of vulnerable populations, those that have limited access to resources, or are otherwise marginalized ensuring that anyone or any group does not disproportionately take on more risk while others gain higher rewards.
- **Fair Recruitment and Subject Selection:** Participants or licensing data samples should be selected fairly, founded in relevance to research questions, and not based on discriminatory criteria like easy access or aligned values. Ethical researchers should promote inclusivity because great outcomes are achieved when there is diversity in voice and perspective.
- **Avoiding Bias:** Researchers must strive to avoid bias in their research design and execution, ensuring that all research findings are not skewed by unfair selection or treatment.
- **Ensuring the Relevance of Research Questions:** The research questions being asked should be relevant to the individuals or communities participating in the study. This ensures that their contribution is meaningful and beneficial.

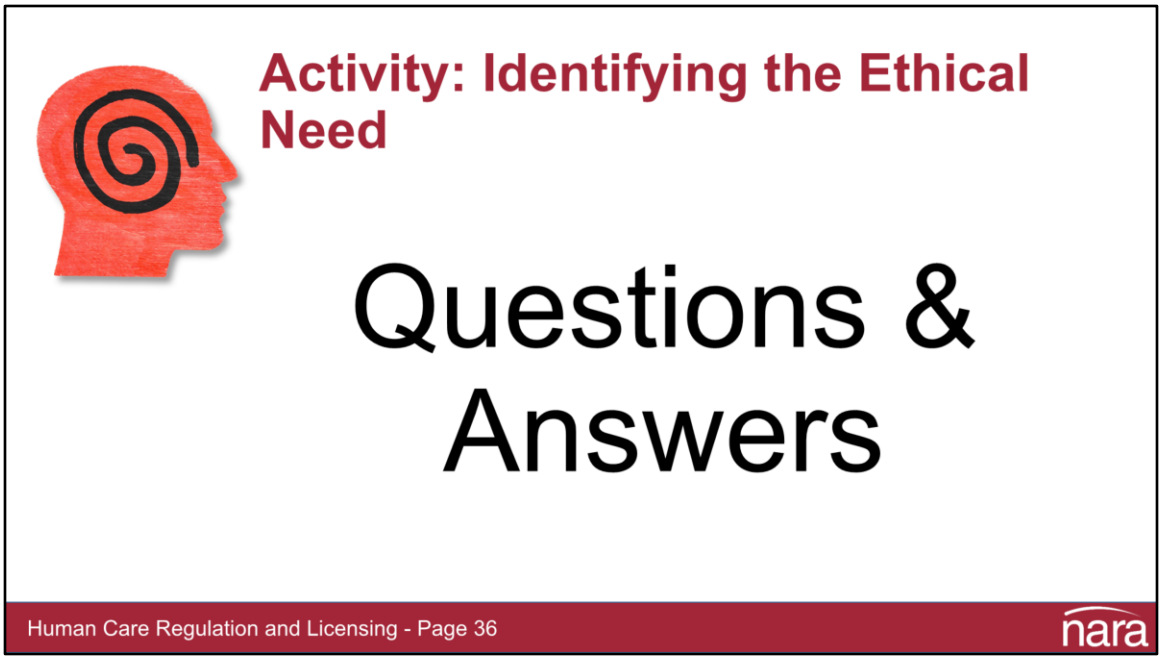
When research is conducted ethically, it builds trust in the scientific community and the research process. Research practices with superior integrity can lead to long-term benefits for individuals and communities, as research findings are used to inform policies and practices that promote health, safety and efficacy. This includes the following:

Avoiding Fabrication and Falsification: It can be tempting to exaggerate or minimize the benefits or adverse effects of research finding into a particular narrative or political agenda. However, it is highly unethical to fabricate, falsify, or misrepresent data. As a regulatory scientist you must Remain impartial and open to all findings, especially when they conflict with desired outcomes:

Transparency: Regulatory scientists should be transparent about their methods, data and any real or potential conflicts of interest. Providing accurate and timely information regarding methods, limitations, dependencies and outcomes to the affected community, in a language and manner that is understandable to the intended reader is critical.

Objectivity: Unfortunately, it isn't uncommon to find research with undertones of explicit or implicit bias. This can cause results to be questioned and perhaps not even valued. Regulatory scientists should always stive to avoid bias in their design, data analysis and interpretation, and reporting.

Honesty and Accuracy: Regulatory Science activities should always be completed with an open mind and willingness to accept the results, even when the results are not what was desired. Researchers must report data, methods, and results honestly and accurately.



Note to Instructor:

Supplies needed: Index cards and marker

Before class: Fold each index card in half. Write each ethical consideration with answer options on the outside flap of the index card so that it is visible to the participant. Write the ethical consideration answer on the inside flap so that it is not visible to the participant. You may want to place a small piece of tape on the flap to keep it closed.

During class: Divide the participants into 4 small groups or partners. Give each group a question. Encourage them to read the ethical consideration written on the outside, discuss, and choose the ethical consideration they think is correct. Then allow the groups to open the flap to see if they are correct and allow time for the group to discuss. Once all groups have completed the activity, conduct a debrief of each groups findings.

Read the general scenario to the group: **As the researcher in your agency, a senior administrator comes to you to ask if you can find out why monitoring visits may not reach completion by the end of the year. You remind yourself of your ethical responsibilities as a scientist and ensure all ethical considerations are in place.**

Match the consideration with the ethical need being addressed.

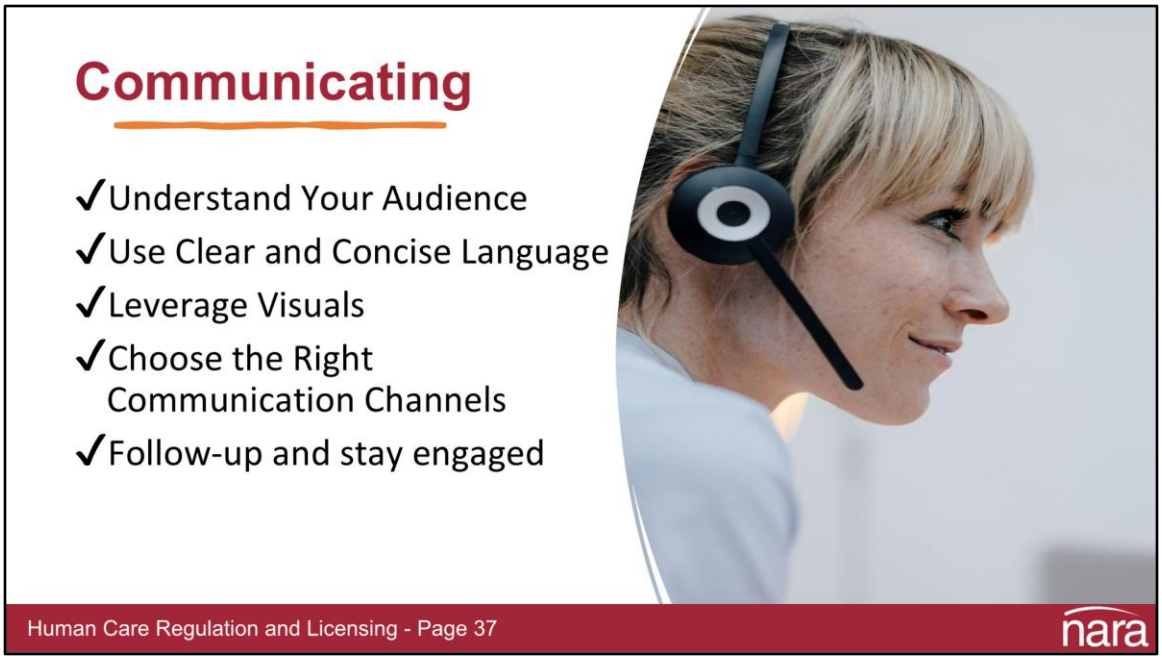
1. Outside
You have some pretty good guessing as to why monitoring visits are not getting done – after all, you've heard all the rumors. But you resist the urge to jump to conclusions and decide instead to keep an open mind and commit to being honest, transparent and objective.
Research Integrity
Justice & Fairness
Beneficence & nonmaleficence
Respect for person & Autonomy
Inside
Research Integrity

2. Outside
As you consider the work, you begin to consider who will provide quick and easy access to the information you might need so you can get the job done faster. Again, you catch yourself and remember there are better outcomes when there is diversity in voice and perspective.
Research Integrity
Justice & Fairness
Beneficence & nonmaleficence
Respect for person & Autonomy
Inside
Justice & Fairness

3. Outside
You know that staff have full caseloads and have recently complained about how much they are required to do. You begin to wonder how your work will need to consider the added time and stress that will be placed on them.
Research Integrity
Justice & Fairness
Beneficence & nonmaleficence
Respect for person & Autonomy
Inside
Beneficence & nonmaleficence

4. Outside
Knowing that you will see information about individuals, both staff and providers, you begin to consider how you will ensure your research will ensure results won't highlight anyone or identify any specific groups.

Research Integrity
Justice & Fairness
Beneficence & nonmaleficence
Respect for person & Autonomy
Inside
Respect for Persons & Autonomy



The ability to translate scientific processes and findings so that agencies, field staff and licensed providers or caregivers understand the purpose, the process and the outcomes increases acceptance of the outcomes. To effectively advance knowledge, inform policy, foster public understanding, and lead to better decision-making and regulatory progress, a regulatory scientist must be effective at communicating research needs, methods, and findings. There are some key strategies you can use.

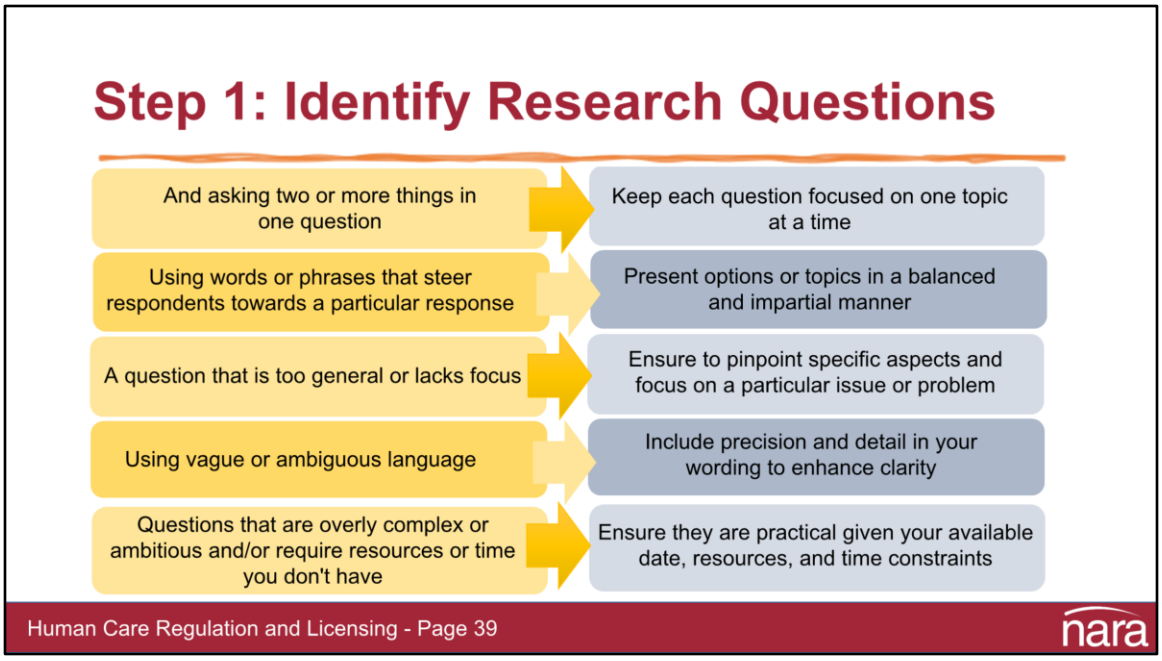
- **Understand Your Audience:** First ask who needs to know about your research and why. Are they fellow researchers, the public, policymakers or a specific group? Once you know this you can adjust the language, level of detail and the format to suit their interest and knowledge, including what is most important to them.
- **Use Clear and Concise Language:** Research scientists tend to get lost in research jargon and explain every detail. This makes sense because researchers must be prepared to explain the methods and analysis to other researchers. However, depending on the audience, you should use plain language and avoid technical terms ensuring the information is easy to follow.
- **Leverage Visuals:** Charts, graphs, infographics and images illustrate complex data and concepts summarize key findings in a visually appealing and easy-to-

understand format. When needed, videos can be a great way to engage a wider audience in a dynamic way.

- **Choose the Right Communication Channels:** Depending on the intended audience you can consider academic journals, conferences and seminars, websites and blogs, policy briefs and reports, newsletters, and press releases.

Remember your ethical obligations! In addition to ensuring your work is accessible and easy to understand, you must also ensure it is fair and accurate so don't hesitate to solicit feedback and remain transparent. Finally, don't forget about the **follow-up: Stay engaged** and respond to questions and feedback.

Using established steps when conducting regulatory research is crucial because they provide a structured approach to gather, analyze, and interpret information, and ensure the reliability and validity of research findings by providing the avenue to replicate results. Regulatory research, like most other research, most commonly follows six steps. Some theories and methods require additional steps, but we won't get into that in this course. They include identifying research questions, conducting a literature review, method design, data collection, analysis and interpretation, and reporting. Let's take a closure look at each of these steps.



Have you heard the adage, “all roads lead to Rome?” In research the saying would be something like “all right questions lead to the right answers.” To get to the answer you must know the questions to ask that are directly connected to a problem needing to be solved. Good research understands this.

Well-defined research questions are crucial as they provide a clear focus and direction for the entire research process. Research questions guide problem identification, study design, data collection, and interpretation of findings, ensuring the research remains targeted and meaningful. You might think that developing research questions Is the easy part of a regulatory scientist’s job; however, what seems like a simple task often falls into common mistakes that lead to failed research.

Mistake: A question that is too general or lacks focus can lead to chaotic and unfocused research and makes it difficult to draw meaningful conclusions.

Solution: It’s important to ensure your question(s) pinpoints specific aspects or variables and focus on a particular issue or problem.

Mistake: Using words or phrases that steer respondents towards a particular response invites ethical questions to the entire study.

Solution: Present options or topics in a balanced and impartial manner.

Mistake: And asking two or more things in one question can confuse the purpose and direction of how data is collected and lead to inaccurate responses or conclusions.

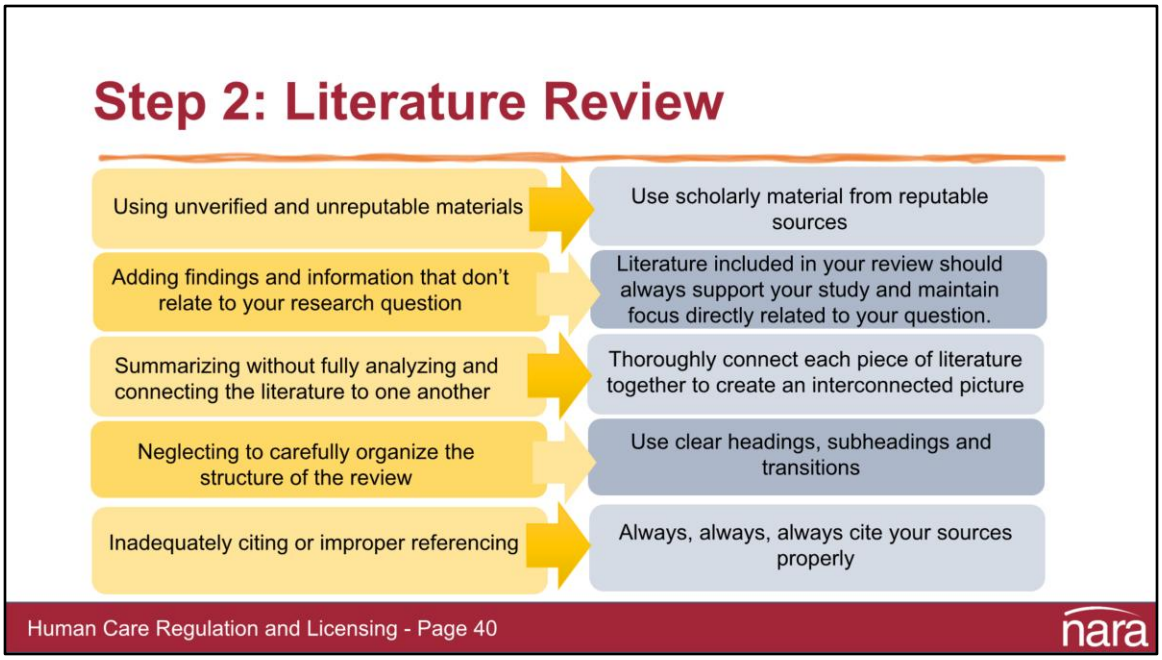
Solution: Keep each question focused on one topic at a time.

Mistake: Questions that are overly complex or ambitious and/or require resources or time you don't have.

Solution: Ensure research questions are practical given your available date, resources, and time constraints.

Mistake: Using vague or ambiguous language can lead to misunderstandings about the intent of your research.

Solution: Include precision and detail in your wording to enhance clarity.



Scouring the web looking for all the related research sounds time consuming – and it is. It's also important to ensure your research has a strong foundation of existing knowledge to build your research questions and methodology. The purpose of this is to ensure your research hasn't already been done, identify any gaps in knowledge, and justify the work thereby providing the relevance and credibility of the study. Just like developing research questions there are some common mistakes researchers should avoid.

Mistake: Using unverified and unreputable materials can undermine the credibility of the literature review.
Solution: Whenever possible, use scholarly material from reputable sources. Ensure it includes foundational studies that have shaped the current understanding of your topic.

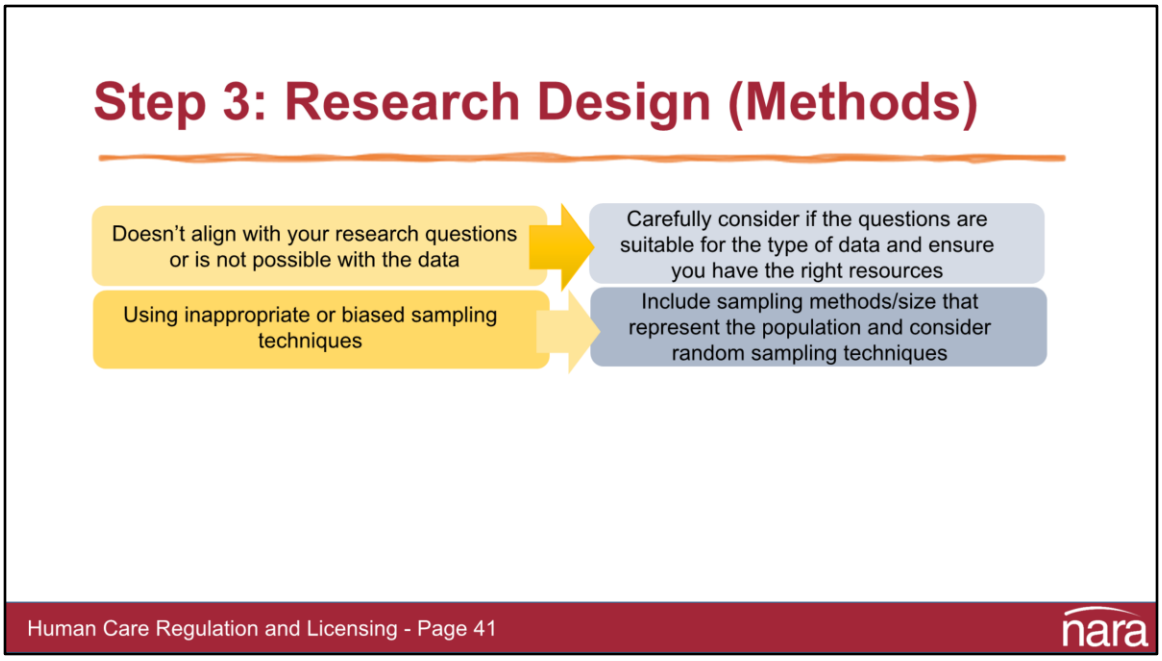
Mistake: Summarizing without fully analyzing and connecting the literature to one another implying your study may not fit into the big picture.
Solution: Thoroughly connect each piece of literature together to create an interconnected picture. It should demonstrate the connections that lead to the

broader understanding of the topic.

Mistake: Adding findings and information that don't relate to your research question confusing readers.
Solution: Remember the importance of precision of the research question(s)? Literature included in your review should always support your study and maintain focus directly related to your question.

Mistake: Neglecting to carefully organize the structure of the review, hindering the reader's ability to understand and engage with the content.
Solution: Use clear headings, subheadings and transitions that assist the reader to move through the review.

Mistake: Inadequately citing, improper referencing or worse – unintentional or intentional plagiarism directly impacts the credibility of the review and the entire study.
Solution: Always, always, always cite your sources properly. This avoids presenting or appearing to present some else's work as your own.

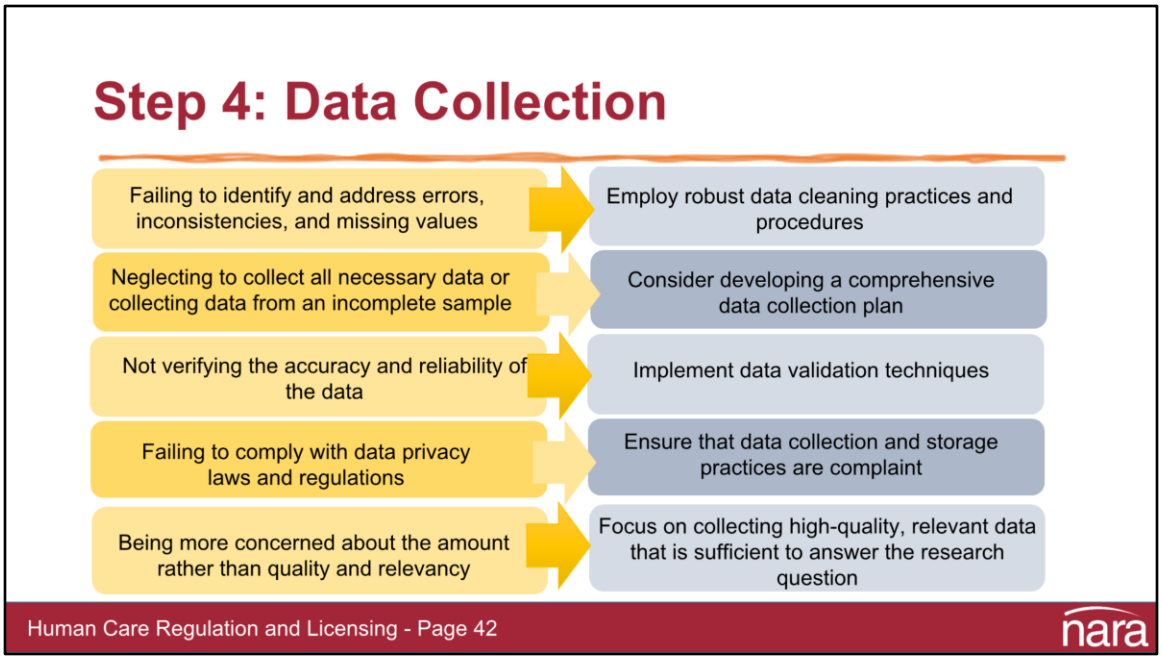


A strong research design is crucial for conducting valid and reliable research, ensuring that studies are conducted systematically, methods align with the research questions, and conclusions are trustworthy. It acts as a roadmap, guiding data collection, analysis, and interpretation to achieve accurate and meaningful results. Once you have designed your research questions thoroughly, completed a comprehensive literature review, it is time to do a research design.

Choosing the right method, selecting appropriate samples or populations, defining a data collection and analysis plans are all components of a strong design. While we go into more detail around design options and examples in the next section, here are two common mistakes to avoid and possible solutions.

Mistake: Selecting a research design that doesn't align with your research questions or is not possible with the data you are able to obtain.
Solution: This is another road that leads to the research question. Here is another opportunity to carefully consider if the questions are indeed suitable for the type of data you need to collect and ensure you have the right resources before landing your design.

Mistake: Using inappropriate or biased sampling techniques leading to unrepresented sample and invalid results.
Solution: The methods you chose should include sampling methods and size that represent the population. Consider random sampling techniques to avoid unintended bias.



Data collection is at the heart of all regulatory research because it provides the evidence needed to answer your research questions by identifying trends and generating the insights that inform findings. Data collection is the process of generating and storing information that will ultimately be used in the next steps of research. Accurate data collection is also important to ensure the reliability of findings and allows other researchers to replicate and validate your findings. There are five common mistakes made during this phase of research.

Mistake: Failing to identify and address errors, inconsistencies, and missing values in the data.
Solution: Employ robust data cleaning practices and procedures, including data validation and error correction.

Mistake: Neglecting to collect all necessary data or collecting data from an incomplete sample.

Solution: Consider developing a comprehensive data collection plan to ensure that all necessary data is collected from the appropriate sample. While this is an added

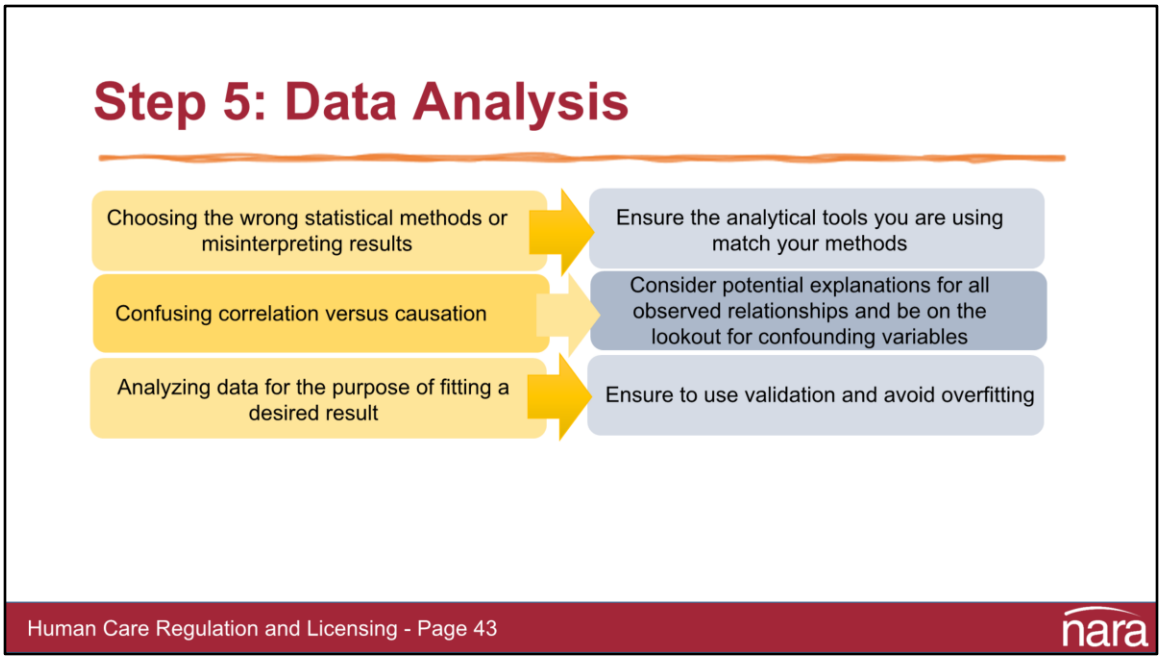
step it is especially valuable when there are multiple data collection points or collectors.

Mistake: Not verifying the accuracy and reliability of the collected data.
Solution: Implement data validation techniques, such as checking for outliers and inconsistencies.

Mistake: Failing to comply with data privacy laws and regulations.
Solution: Ensure that data collection and storage practices comply with your agencies' policies and with relevant laws and regulations.

Mistake: Being more concerned about the amount of data collected rather than the quality and relevance of the data.

Solution: It isn't about how much data you have; it's about the right amount. Focus on collecting high-quality, relevant data that is sufficient to answer the research question – nothing more.



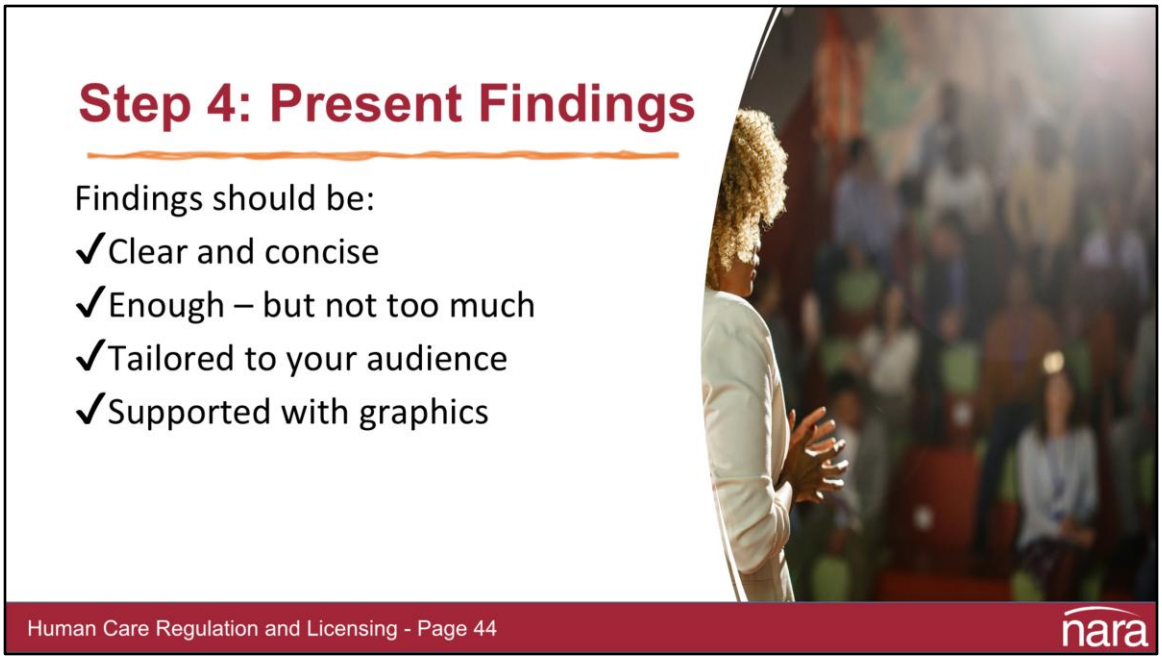
This is where the magic happens! Using appropriate statistical or qualitative analysis techniques will allow you to find meaningful insight and interpret findings – or put another way, take you on the road to those research questions. And as always, ensure you are aware of the three top common mistakes made along the way and avoid them.

Mistake: Choosing the wrong or inappropriate statistical methods or misinterpreting statistical results.
Solution: Refer to your literature review or other reputable sources to ensure the analytical tools you are using match your methods. You can also consult with a statistician to ensure you interpret results appropriately and carefully.

Mistake: Confusing or not fully understanding correlation (a relationship between two variables) versus causation (one variable directly influencing another). Incorrect interpretations can lead to flawed recommendations.
Solution: Be cautious when drawing causal conclusions; what may appear to be direct relations may be influenced by other variables. Consider other potential explanations for all observed relationships. Be on the lookout for confounding

variables. This is another place to have an expert or peer review.

Mistake: Analyzing data for the purpose of fitting into a desired result or fit into the training data. This is called “Overfitting” and leads to poor performance on new, unseen data.
Solution: In addition to the right model selection, ensure to also use validation and simply avoid overfitting.



When research concludes and you have your questions answered, it's important to remember that it isn't the end of the road. It's important to also share the information. In the section of this training titled "Communicating Research Needs, Methods, and Findings" we covered the importance of being clear and concise, ensuring there is enough (but not too much) information presented and an easy-to-follow format. Remember to tailor your information to the specific audience and use graphics appropriately. Finally, ensuring you adhere to all ethical obligations including avoiding plagiarism.

Activity: Which Design Step is it?

Find your match!

nara

Note to Instructor:

Supplies needed: Index cards and marker

Before class: Write each Consideration (below) on an index card. Write the Step (below) on a separate card. Shuffle so that the cards are well mixed.

During class, give each person one card (note: If the group is large, make multiples of each card or if the group is smaller, each person can have nonmatching type and definition cards to make multiple matches). Allow time for participants to move around and find their match. Once they make a match, they can discuss what they scenario and what other considerations they may think about for that step. Once everyone finds their match and has had time to discuss, conduct a group discussion based on small group discussions and discoveries.

Remind the class about the scenario: **As the researcher in your agency, a senior administrator comes to you to ask if you can find out why monitoring visits may not reach completion by the end of the year. You begin the process of building**

your plan.

Knowing this could result in exploring too many variables to effectively find useful results, you ask the administrator leading and increasingly more specific questions to really get at the heart of the problem and narrow the scope to something meaningful and manageable.

Identifying research questions

As you begin a research project and consider the methodology that will best answer the underlining issues, you begin to wonder if there are other studies out there that could assist your development and assist to strengthen potential findings or recommendations. You start to scour the internet for any information…

Conducting a literature review

You're pretty sure you know the direction your research needs to go and have tentatively considered how to do it. But you ask the head of the research department to review your plan to make sure the methodology is sound and appropriate.

Selecting the appropriate methods

You hold two work groups, one listening session, and send out a survey (including consent information - of course) to all the licensors to truly understand the various components and barriers of the performance around monitoring visits. At the same time, the IT department provides a report on completion rates.

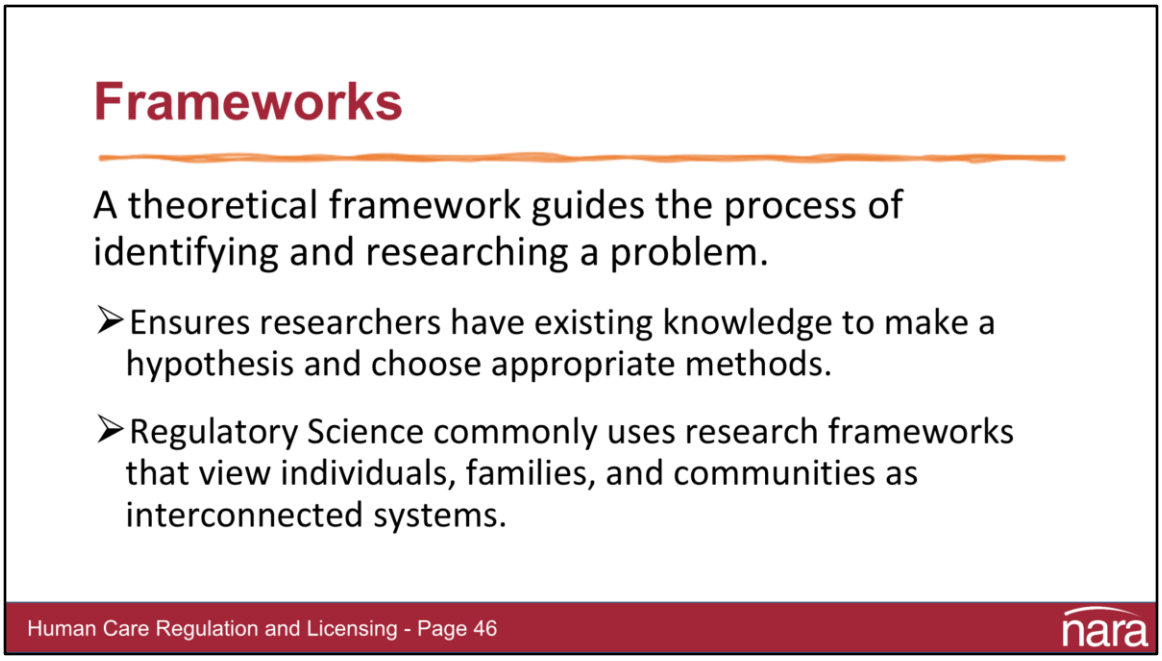
Data Collection

Finally, you have all the information possible, and it seems like there won't be any new information even if you kept digging. You begin to move data into themes and start to draw some conclusions.

Data Analysis and findings

As you begin to prepare separate presentations for your divisional leadership and the staff who participated in the data collection, your senior administrator lets you know that the governor has asked for an executive summary. You understand that this could lead to press inquiries, so you decide to be prepared and begin to create multiple avenues to clearly highlight your findings.

Reporting



A theoretical framework is a formal theory that guides the process of identifying and researching a problem. It ensures researchers have existing knowledge that provides the basis to make a hypothesis and choose appropriate methods, setting you up for success.

Regulatory Science commonly uses research frameworks that view individuals, families, and communities as interconnected systems, emphasizing that each part influences and is influenced by the whole, helping regulatory agencies understand complex dynamics and develop effective interventions.

There are many scientific frameworks that have proven to be useful in regulatory science. This section will introduce four of the commonly used frameworks as well as highlight some of the data analysis tools. While we won't go into detail, each section has a link to either useful websites or articles so you can learn more.

1. Grounded Theory

- Various methods can be employed to interconnect information.
- The process is both iterative and dynamic meaning not one directional.

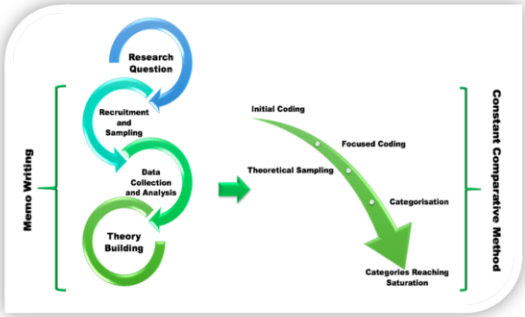


Image from Uibariu, A., (2018). Training the Watchdogs to Bark: A theoretical framework to assist public sector practitioners in identifying, reporting and taking action against state crimes against democracy

Scan the QR code for more information on grounded theory

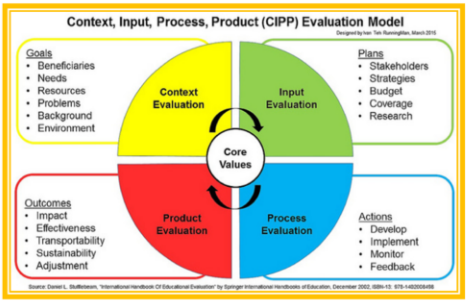
Grounded theory was founded by Glaser and Strauss in in 1967 with their first publication “The Discovery of Grounded Theory: Strategies for Qualitative Research”. This theory uses well-known methodology including qualitative and quantitative data generation techniques. The purpose is to discover or contrast theory from data using systematic data collection and comparative analysis methods. This theory is perhaps the most used theory in regulatory science because it is inherently flexible. Various methods can be employed to interconnect information and inform various elements in regulatory research. The process is both iterative and dynamic meaning not one directional. (Chun, Birks & Francis, 2019)..

2. Context, Input, Process and Product

CIPP informs decisions through systematically collecting program information to identify strengths and limitations of policy and processes. It uses four stages of evaluation systematically to focus on continuous evaluation:

1. Context: Goals/Mission
2. Input: Plans/Resources
3. Process: Components/Practice
4. Product: Outcomes

Scan the QR code for more information on CIPP



The CIPP model was created by Daniel Stufflebeam in the 1960s. Without knowing it, many organizations use the foundation of this model to inform decisions through systematically collecting program information to identify strengths and limitations of their policy and processes. Within research, these steps are carefully designed to ensure Information gained is then used to improve program quality or effectiveness and plan for future improvements. It uses four stages of evaluation systematically to focus on continuous evaluation including the context (goals or mission), the input (plans and resources), the process (components or practice), and the product (outcomes).

The Yale Poorvu Center for Teaching and Learning provides a summary and resources using the CIPP program assessment. You can click on this link to learn more.

3. Waterfall

Waterfall is a 5 step linear approach used when designing systems such as monitoring systems:

1. Requirement development
2. Design
3. Implementation
4. Testing
5. Deployment

Scan the QR code for more information on Waterfall

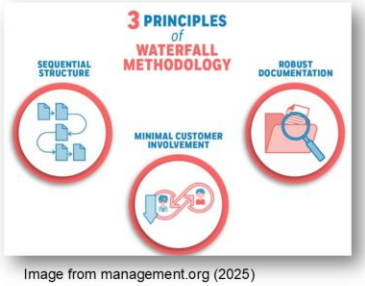
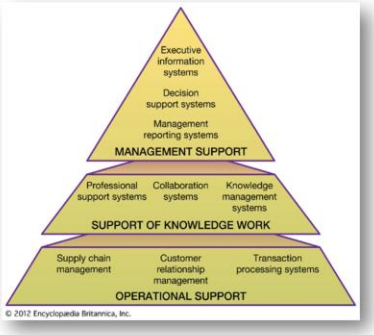


Image from management.org (2025)

Dr. Winston Royce introduced the foundational structure of the waterfall method in 1970 to manage the emerging development of large software. While this method is geared toward project management, it most commonly used when developing new IT systems and provides a foundation that is useful when designing other system approaches such as monitoring systems, assessing rules and regulations as well as other program improvements. It is a sequential, linear approach using five specific steps: requirement development, design, implementation, testing and deployment. Each step must be completed before the next step can begin and is an excellent guide when designing research methods. This method requires a step be fully completed before moving to the next step, relies minimally on user input and has a very robust documentation requirement.

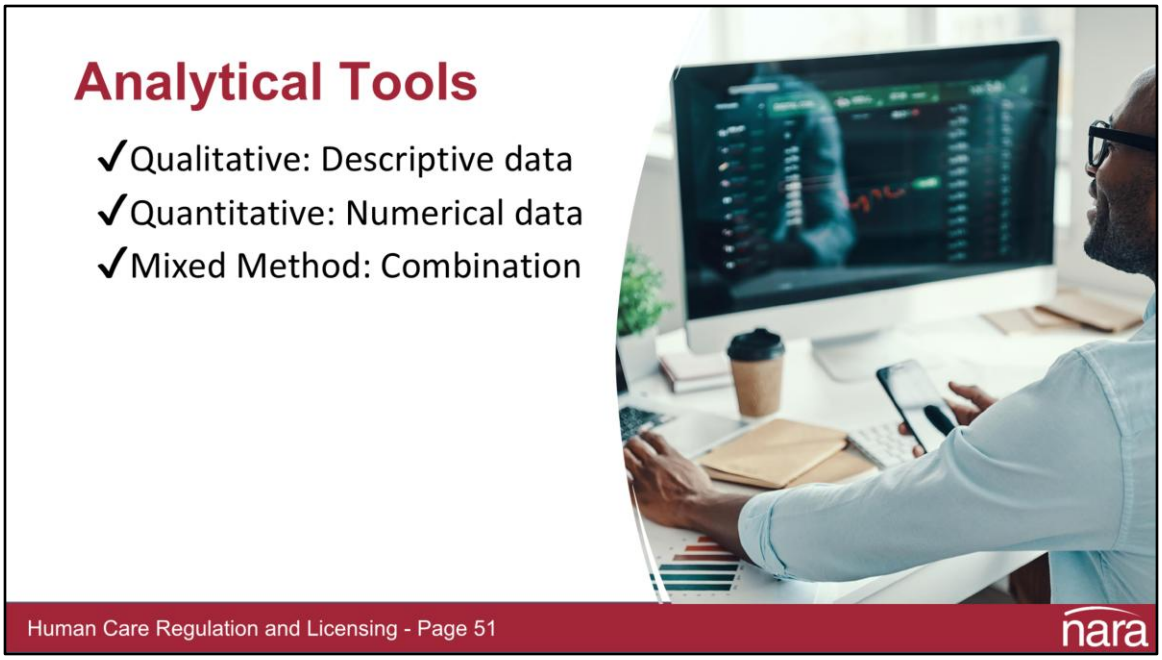
4. Information Systems Theory

- Information Systems Theory uses models to understand how the interconnected parts of a system are designed, used and impact organizations and society. (Chatterjee, 2012).
- Information systems theory follows the same research steps as any other theory listed here and can be integrated dependably.



The work of a regulatory scientist is directly impacted by the software and hardware an agency uses to collect, analyze and inform their policy and practice decisions. Information Systems Theory uses models to understand how the interconnected parts of a system are designed, used and impact organizations and society. (Chatterjee, 2012).

While the work of a regulatory scientist rarely relies solely on information systems theory, the impact of information systems can make a huge difference on the methods of discovery. The good news is that information systems theory follows the same research steps as any other theory listed here and can be integrated dependably.



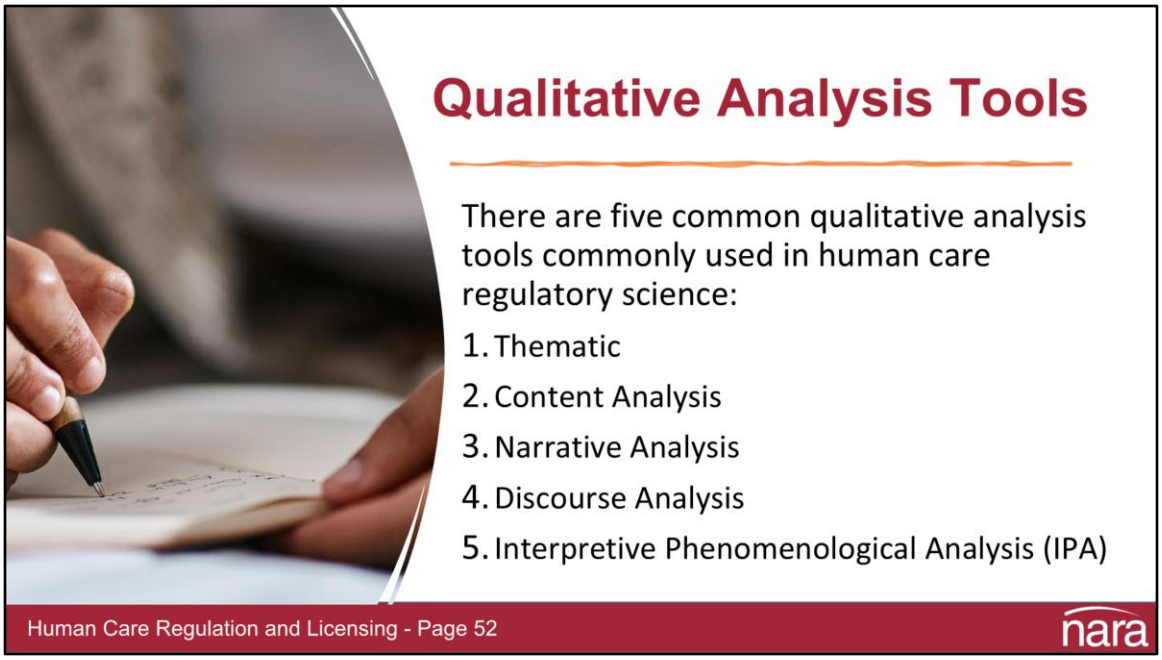
Next, we will take a look at a few common analysis tools used in regulatory research. Keep in mind, each of the four frameworks highlighted in this course typically use mixed methods, meaning a combination of quantitative and qualitative data collection and analysis tools. However, for the purpose of this course we will look at them separately.

Qualitative data is descriptive, meaning it tells a story. The purpose of collecting qualitative data is to understand concepts, characteristics and experiences of individuals or groups. These are collected through interviews, observations, focus groups or listening sessions, and open-ended surveys.

Quantitative research uses numerical data, including measurable variables and quantifiable observations, and standardized procedures to systematically analyze information to objectively identify patterns, test or validate hypotheses , and draw conclusions. Data collection can include survey responses with numerical scales, licensing regulatory compliance data, demographic data, and more. The key to quantitative analysis in regulatory science is the ability to collect or translate data numerically in descriptive (to describe characteristics of a population or

phenomenon), correlational (the relationship between two variables) or causal-correlational/quasi-experimental (cause and effect) research.

Note: You will hear the terms ordinal data and nominal data throughout the remainder of the training. Ordinal data is qualitative data that is categorized in a specific ranked order or hierarchy. Nominal data is qualitative data that is categorized based only on descriptive characteristics. This kind of data has no ranked order or hierarchy.



There are five common qualitative analysis tools commonly used in human care regulatory science.

Thematic Analysis: The process of identifying, analyzing, and reporting patterns (themes) within data. This involves careful reading and interpreting the material to gain meaning and understanding.

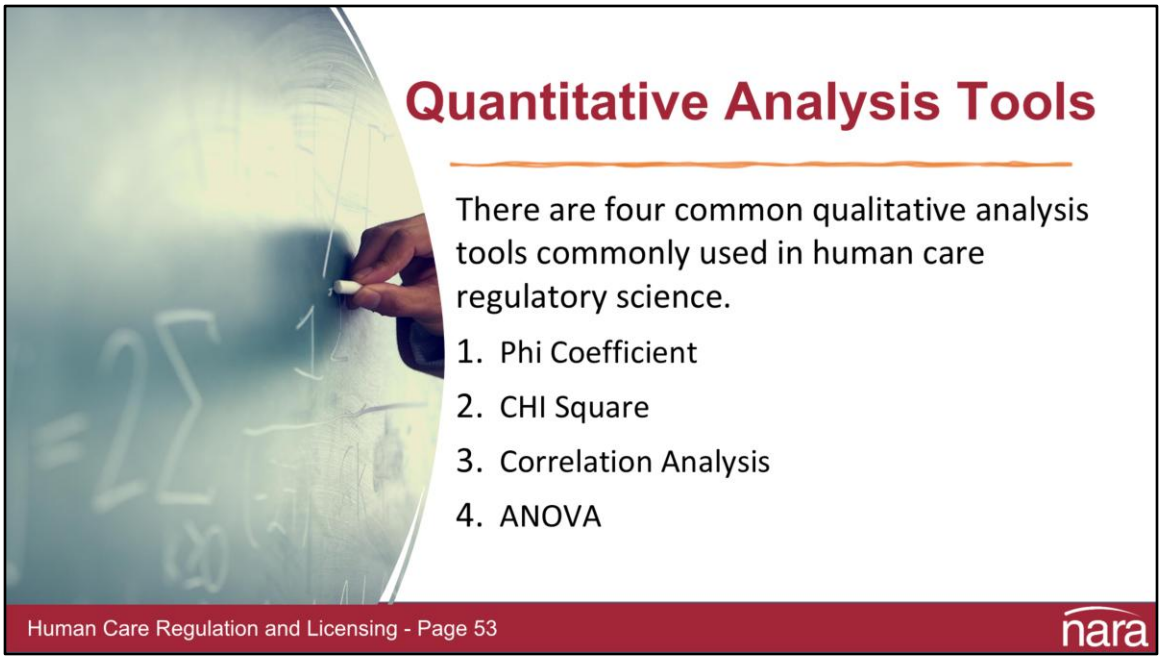
Content Analysis: This is used to determine the presence of certain words, themes, or concepts within some given qualitative data. Regulatory scientists use manual coding or coding software to analyze qualitative data to examine trends and patterns.

Narrative Analysis: Unlike thematic analysis that looks for themes, or content analysis that groups data to find the larger content, narrative analysis focuses on interpreting human experiences and motivations. This is done by looking closely at

the stories (the narratives) in a particular context.

Discourse Analysis: This is used to examine how language is used in social contexts to understand power dynamics, communication styles, and meaning-making processes. Unlike more systematic methods (i.e. thematic or content analysis), researchers make interpretations based on both the details of the material itself and contextual knowledge.

Interpretive Phenomenological Analysis (IPA): This tool focuses on understanding how individuals make sense of their lived experiences and is very commonly used in programmatic evaluations in social work because it attempts to provide a rich, detailed account of participants' perspectives. This tool is unique because it is an inductive approach, meaning that researchers generate themes and interpretations from the data rather than testing pre-existing theories.



There are four common qualitative analysis tools commonly used in human care regulatory science.

PHI COEFFICIENT: Typically used in descriptive research and with nominal data, the phi coefficient is a statistical measure used to assess the strength of association between two binary (dichotomous) variables, ranging from -1 to +1, with 0 indicating no association.

CHI SQUARE: Typically used in descriptive or causal-comparative research, A Pearson's chi-square test is a statistical test used with categorical (or ordinal) data to examine the relationship between two variables to test whether your data are significantly different from what you expected and assess if the proposed model matches the observed data.

Correlation Analysis: As the name suggests, this is typically used in correlational research. It calculates and measures the strength in the linear relationships or the change in one variable due to the change in the other. As an example, this is commonly used when program quality tools are compared to licensing data.

ANOVA: ANOVA, which stands for Analysis of Variance, is typically used in either correlational or causal-correlational/experimental research. It is a statistical test used to analyze the difference between the means of three or more variables to see if there is a significant difference between them. A one-way ANOVA uses one independent variable, while a two-way ANOVA uses two independent variables. As an example, this is used when comparisons are made across multiple states or provinces looking at differences.

Characteristics of Regulatory Research Methods

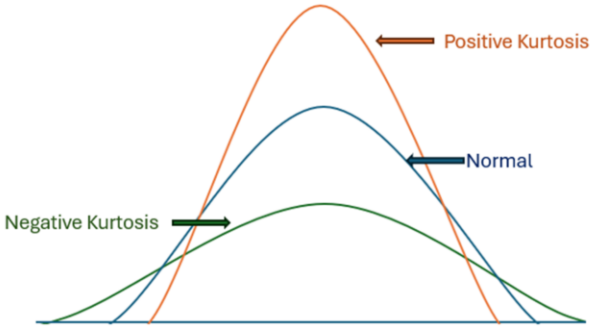
All regulatory scientists should graph the data distribution to look for **kurtosis** and **skewness** in the data and depict if a **ceiling effect** is present or not.

At its core, regulatory science uses empirical data to make informed decisions using scientific methods when assessing rules and regulations and licensing systems. This involves measurement issues, such as the limitations of nominal data, skewed data distribution, ceiling effects, lack of variance, and so on.

All regulatory scientists, when they are working with a licensing a regulatory compliance data set, should graph the data distribution to test for how skewed the data are, look for **kurtosis** and **skewness** in the data. These statistical concepts will help in determining the best way of analyzing the data. It will tell you about the variance in the data distribution. The graphing will easily depict if a **ceiling effect** is present or not.

Kurtosis

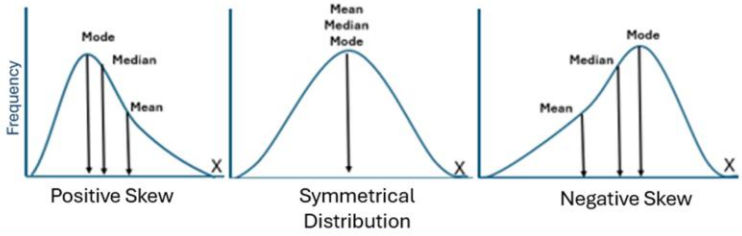
Kurtosis describes the "tailedness" or "peakedness" to determine the presence and frequency of outliers in a dataset.



Kurtosis describes the "tailedness" or "peakedness" of a data distribution to determine the presence and frequency of outliers in a dataset.

Skewness

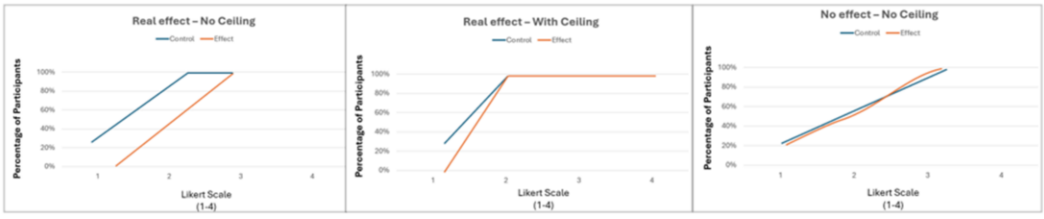
When data is skewed, it means the data distribution is not symmetrical, creating an uneven curve on a graph making it difficult to accurately represent the data's primary tendency and impact statistical analysis.



When data is skewed, it means the data distribution is not symmetrical, creating an uneven curve on a graph making it difficult to accurately represent the data's primary tendency and impact statistical analysis.

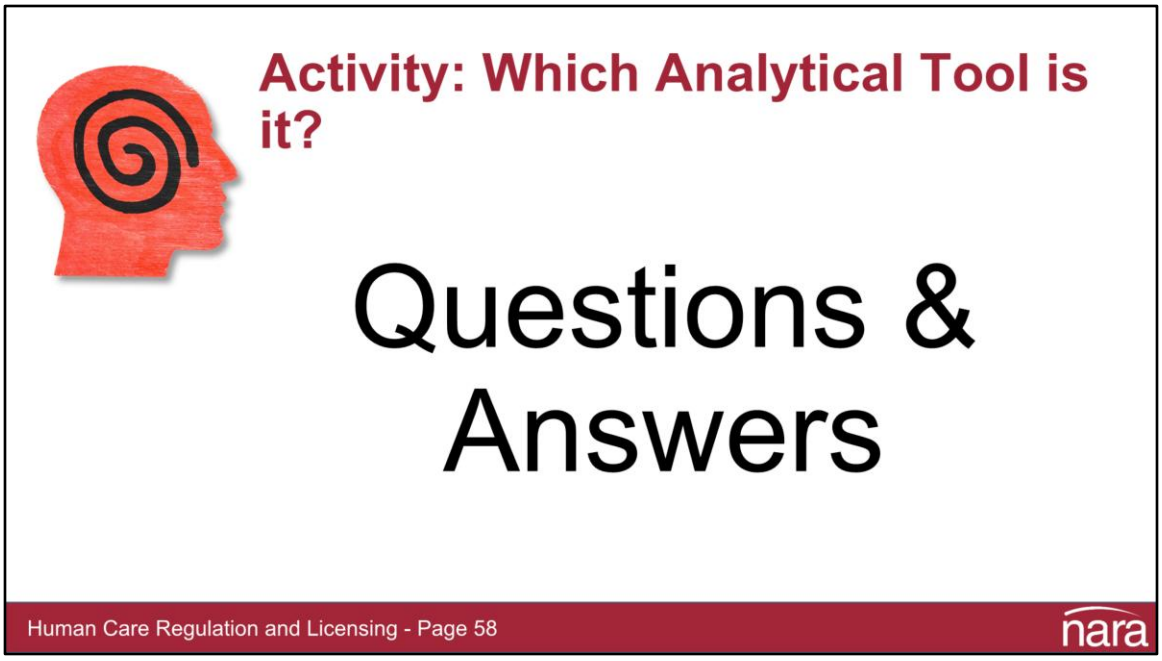
Characteristics of Regulatory Research Methods

A ceiling effect refers to a situation where an independent variable no longer influences a dependent variable or the level in which the variance is no longer measurable.



nara

A ceiling effect refers to a situation where an independent variable no longer has an effect on a dependent variable or the level in which the variance is no longer measurable. This limits the ability to detect differences or changes, indica ting the measurement instrument is not sensitive enough to capture variations above a certain level.



Note to Instructor:

Supplies needed: Index cards and marker

Before class: Use one index card for each group (as many are needed) listing all the possible tools: This will serve as the answer options.

PHI Coefficient
Thematic Analysis
CHI Square
Content Analysis
Correlation Analysis
Discourse Analysis
Narrative Analysis
ANOVA

Next: Fold additional index card in half (enough for each group to have one of each- 8 total for each group). Write each definition on the outside flap of the index card so that it is visible to the group. Write the analytical tool answer on the inside flap so that it is not visible to the participant. You may want to place a small piece of tape on the flap to keep it closed.

During class: Divide the participants into 4 small groups or partners. Give each group a question. Encourage them to read the definition written on the outside, discuss, and choose the tool they think is correct. Then allow the groups to open the flap to see if they are correct and allow time for the group to discuss. Once all groups have completed the activity, conduct a debrief of each groups findings.

1. Outside
Assesses the strength of association between two binary (dichotomous) variables, ranging from -1 to +1, with 0 indicating no association.
Inside
PHI Coefficient

2. Outside
Identifying, analyzing, and reporting patterns (themes) within data.
Inside
Thematic Analysis

3. Outside
Examines the relationship between two variables to test whether your data are significantly different from what you expected
Inside
CHI Square

4. Outside
Determines the presence of certain words, themes, or concepts within qualitative data.
Inside
Content Analysis

5. Outside
Calculates and measures the strength in the linear relationships or the change in one variable due to the change in the other.
Inside
Correlation Analysis

6. Outside
Focuses on interpreting human experiences and motivations.
Inside
Narrative Analysis

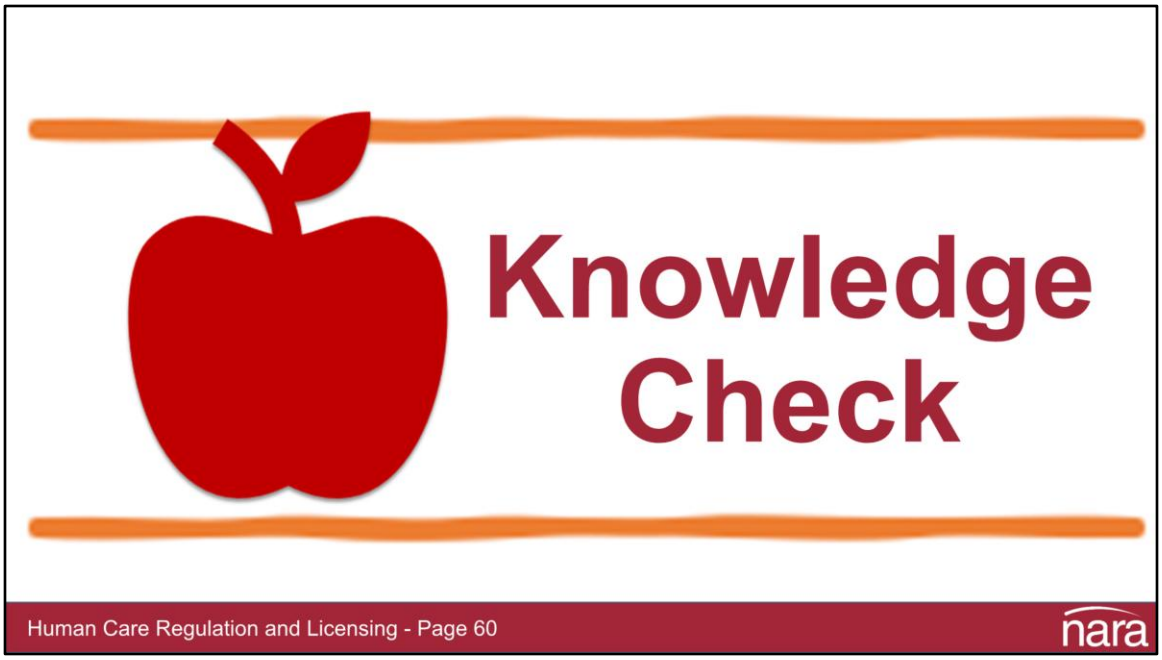
7. Outside
Examines how language is used in social contexts to understand power dynamics, communication styles, and meaning-making processes.
Inside
Discourse Analysis

8. Outside
Analyzes the difference between the means of three or more variables to see if there is a significant difference between them.
Inside
ANOVA

Purpose of Methodological Design

Careful Method design ensures you can focus on the intended problem through carefully constructed research questions, grounded and appropriate theories, methods, and the right analytical tools

In summary, the importance and primary purpose of methodological design in regulatory research is to provide a structured and systematic plan to keep a project on the right road. It ensures you understand and focus on the intended problem you are trying to solve through carefully constructed research questions, grounded and appropriate theories, methods, and the right analytical tools are used to provide valid and reliable results. When used holistically and appropriately, methodological design helps regulatory scientists achieve their objectives and contribute meaningfully to the licensing field.

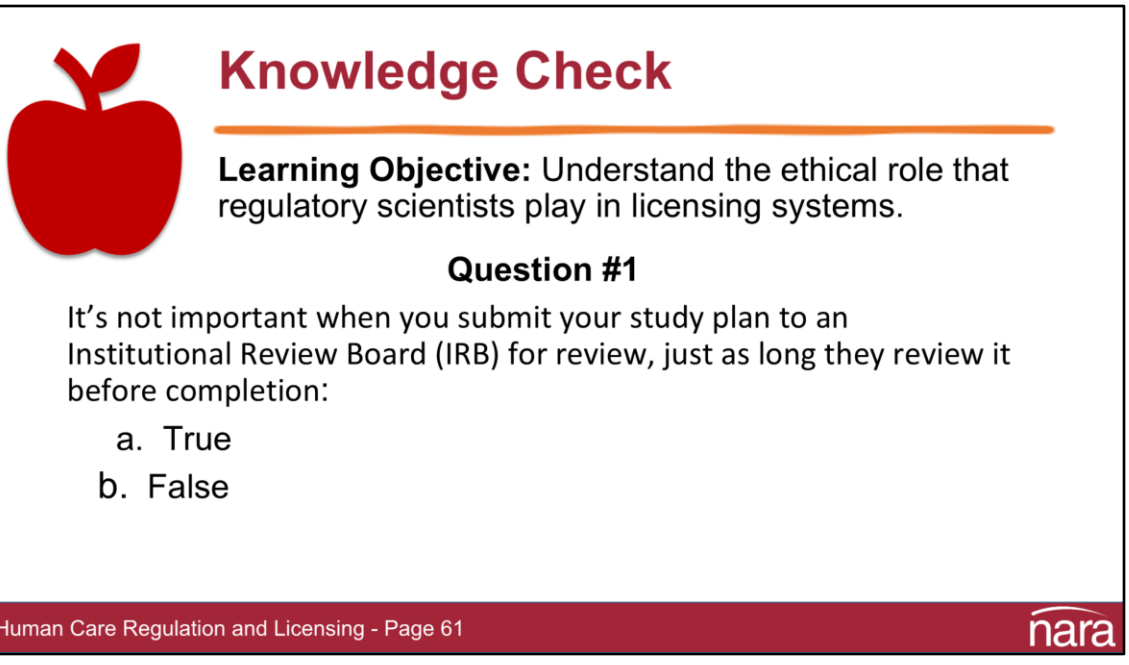


Note to instructor:

Large group activity: Explain to the group that it is time to check their knowledge. Questions on the next slides are aligned with the module's learning objectives. Read the question and all answer options that appear on the slide. Once everyone has heard the question and thought of an answer, ask for a volunteer to give their answer. Discuss as a group and/or go back to the relevant slides to review the content if needed.

Go to next slide for the first question.

Understand the ethical role that regulatory scientists play in licensing systems.
Understand the importance of all aspects of research.
Learn about the common scientific methods currently used in the licensing field.



Note to instructor:

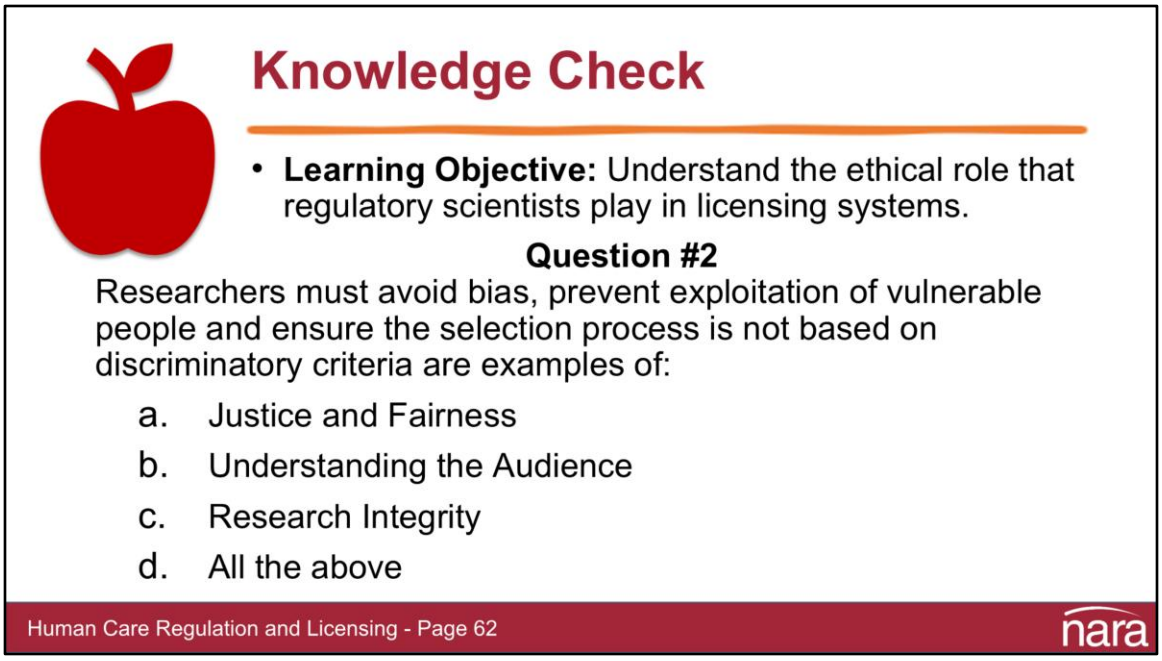
Question:

It's not important when you submit your study plan to an Institutional Review Board (IRB) for review, just as long they review it before completion:

a. True
b. **False (Correct)**

Review the following slide if needed:

- Internal Review Boards



Note to instructor:

Question:

Researchers must avoid bias, prevent exploitation of vulnerable people and ensure the selection process is not based on discriminatory criteria are all examples of:

a. Justice and Fairness (CORRECT)
b. Understanding the Audience
c. Research Integrity
d. All of the above

Review the following slide if needed:

- Ethical Standards: Justice and Fairness

Knowledge Check

- **Learning Objective:** Understand the ethical role that regulatory scientists play in licensing systems.

Question #3

Individual data should be kept confidential and protected from unauthorized access:

a. True

b. False

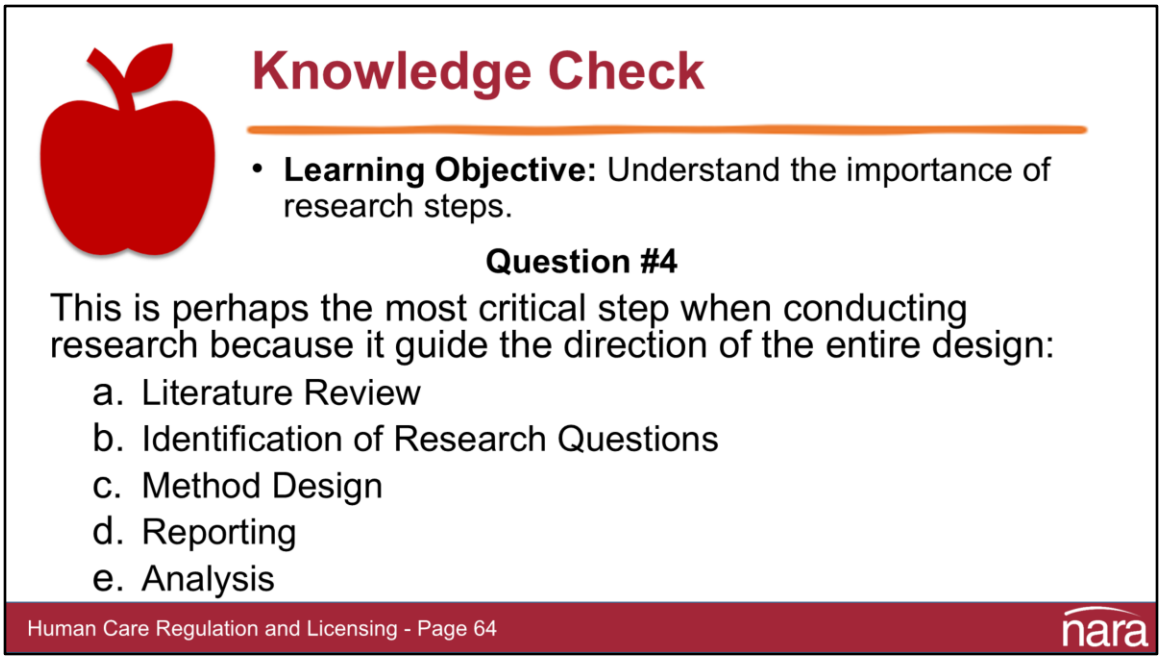
Note to instructor:
Question:

Individual data should be kept confidential and protected from unauthorized access:
a. **True (Correct)**
b. False

Review the following slides if needed:
- Ethical Standards: Respect for persons and autonomy

Instructor Note: Ask a follow up question if time and interest allows:

Bonus Question: What's the best way to ensure this happens?
Possible Answers:
- Don't collect identifiable information to begin with!
- Code identifiable information with a research number and remove all names, addresses, etc.



Note to instructor:

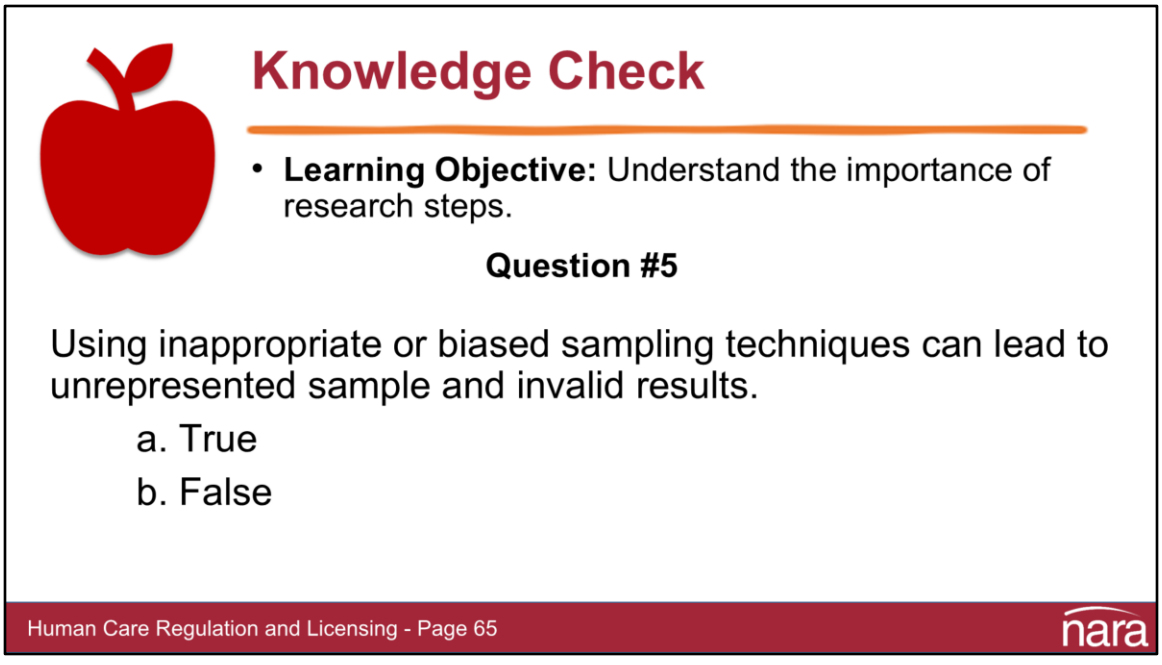
Question:

This is perhaps the most critical step when conducting research because it guide the direction of the entire design:

a. Literature Review
b. Identification of Research Questions (CORRECT)
c. Method Design
d. Reporting
e. Analysis

Review the following slides if needed:

- Step 1: Identify Research Question



Note to instructor:

Question:

Using inappropriate or biased sampling techniques can lead to unrepresented sample and invalid results.

a. **True (Correct)**
b. False

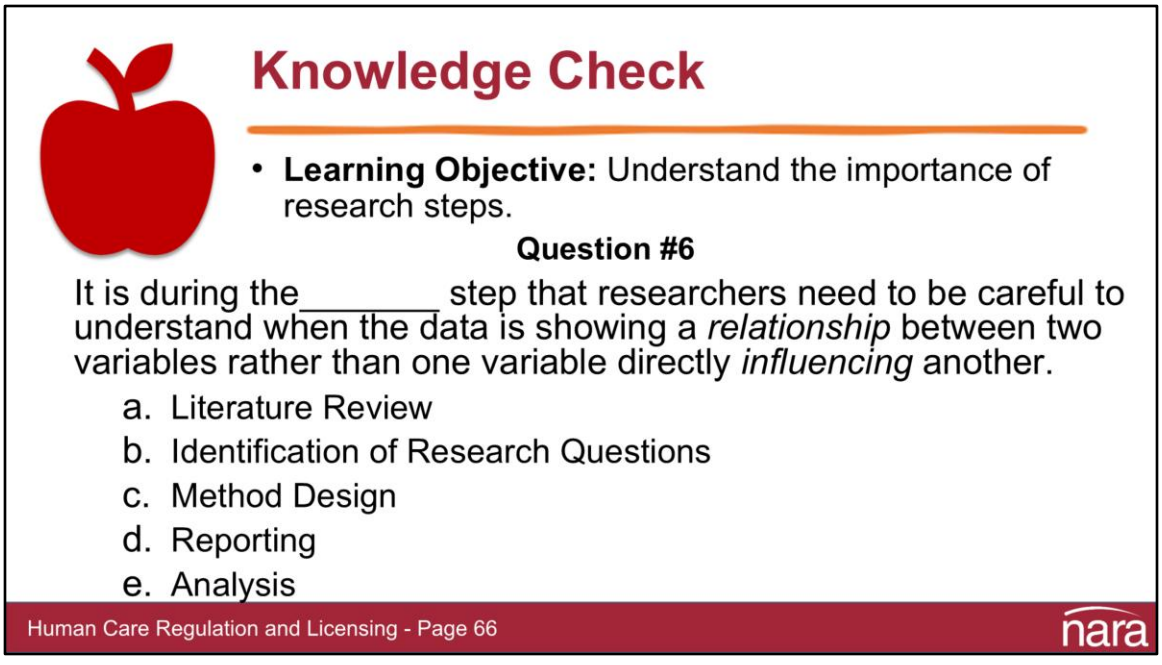
Review the following slides if needed:

- Step 3: Research Design (Methods)

Bonus Question: What strategies can you use to ensure you are not using biased or inappropriate samples?

Possible Answers:

- Align them to the research questions
- Have a peer reviewer look over the design
- Ensure the sample size is appropriate for reliable results.



Note to instructor:

Question:

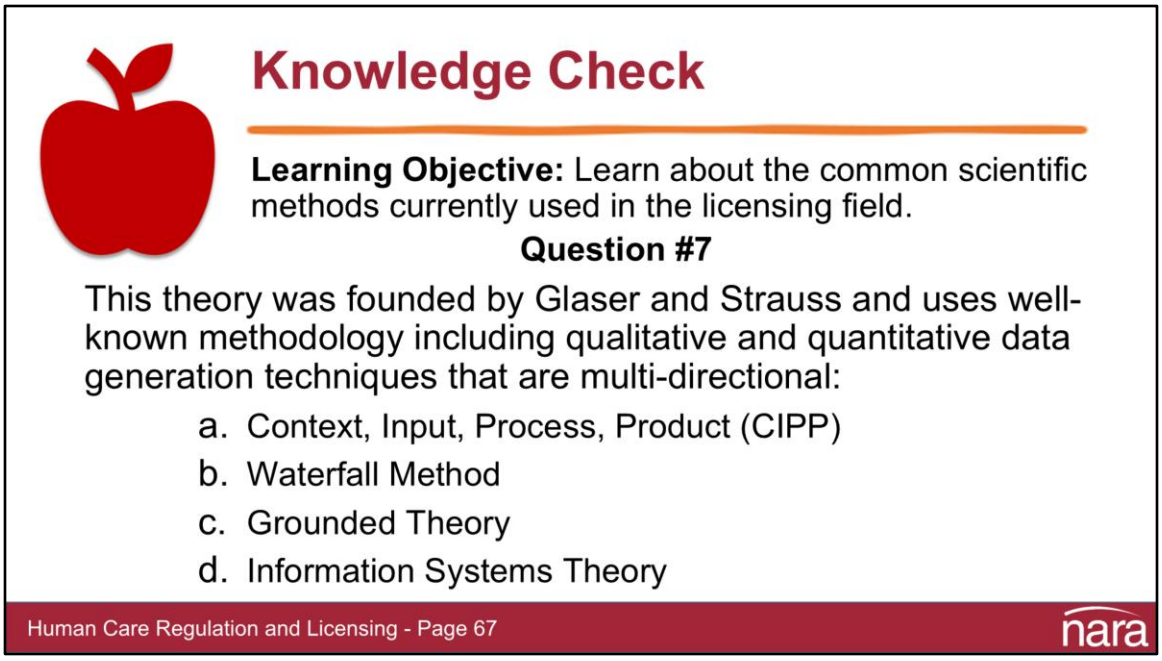
It is during the_____that researchers need to be careful to understand when the data is showing a relationship between two variables rather than one variable directly influencing another.

a. Literature Review
b. Identification of Research Questions
c. Method Design
d. Reporting
e. Analysis (CORRECT)

Review the following slides if needed:

- Step 5: Analysis

[Correlation versus causation]



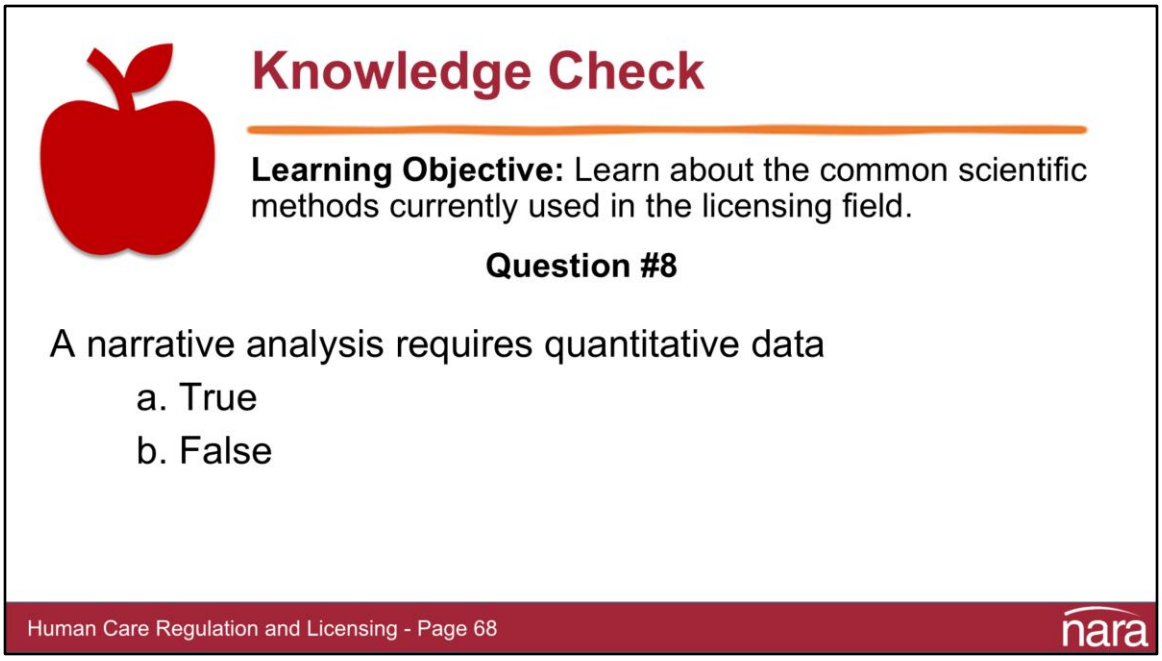
Note to instructor:

Question:
This theory was founded by Glaser and Strauss and uses well-known methodology including qualitative and quantitative data generation techniques that are multi-directional:

a. Context, Input, Process, Product (CIPP)
b. Waterfall Method
c. Grounded Theory (CORRECT)
d. Information Systems Theory

Review the following slides if needed:

- 1. Ground Theory



Note to instructor:

Question:

A narrative analysis requires quantitative data

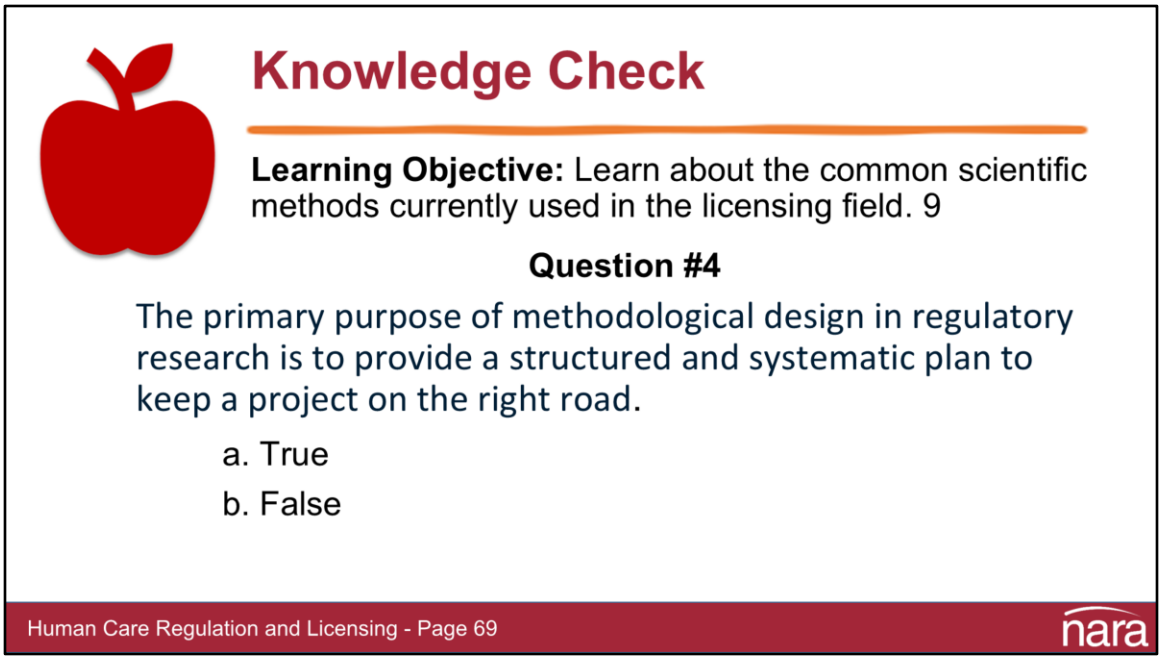
a. True
b. False (CORRECT)

Review the following slides if needed:

- Qualitative Analysis Tools
- Quantitative Analysis Tools

Bonus Question: Can you name any of the four qualitative analysis tools commonly used in human care regulatory science that we talked about today.

1. Phi Coefficient
2. CHI Square
3. Correlation Analysis
4. ANOVA



Note to instructor:

Question:

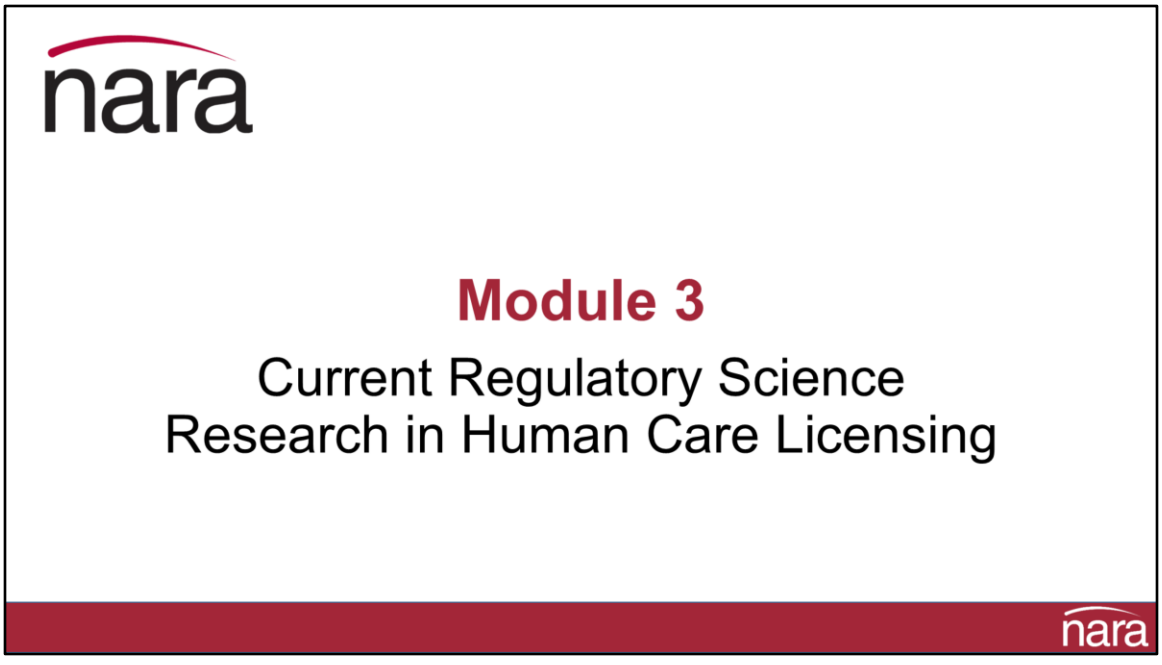
The primary purpose of methodological design in regulatory research is to provide a structured and systematic plan to keep a project on the right road.

a. True (CORRECT)

b. False

Review the following slides if needed:

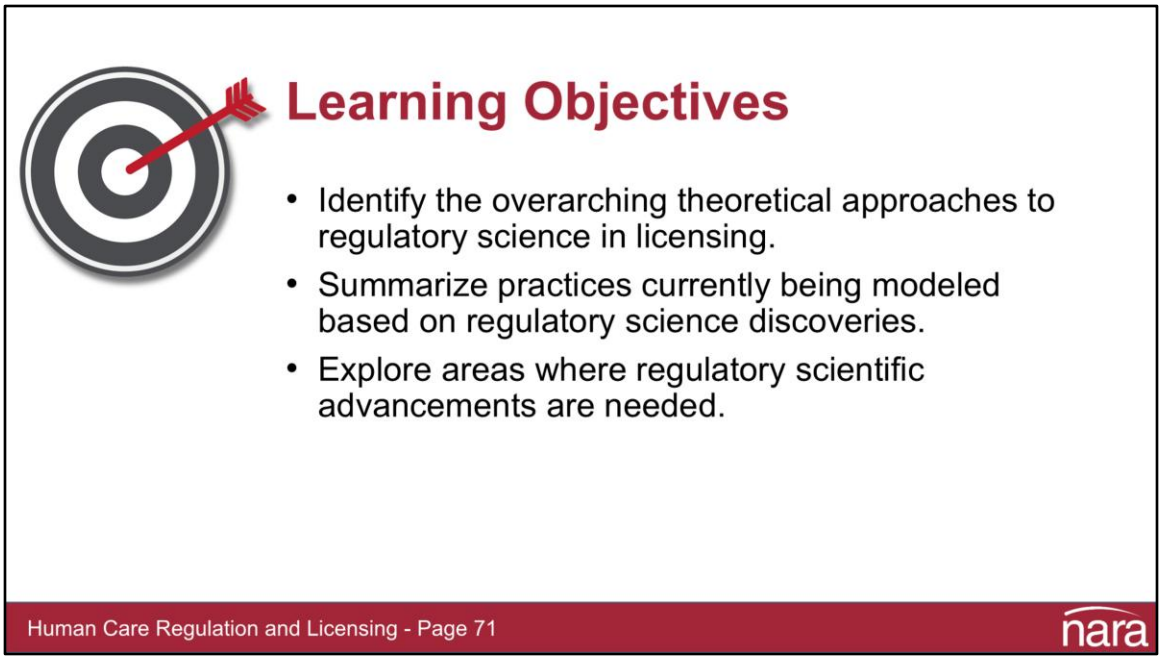
- **Purpose of Methodological Design**



Notes to Instructor:

Introduce module

Module 3: Concepts of Licensing

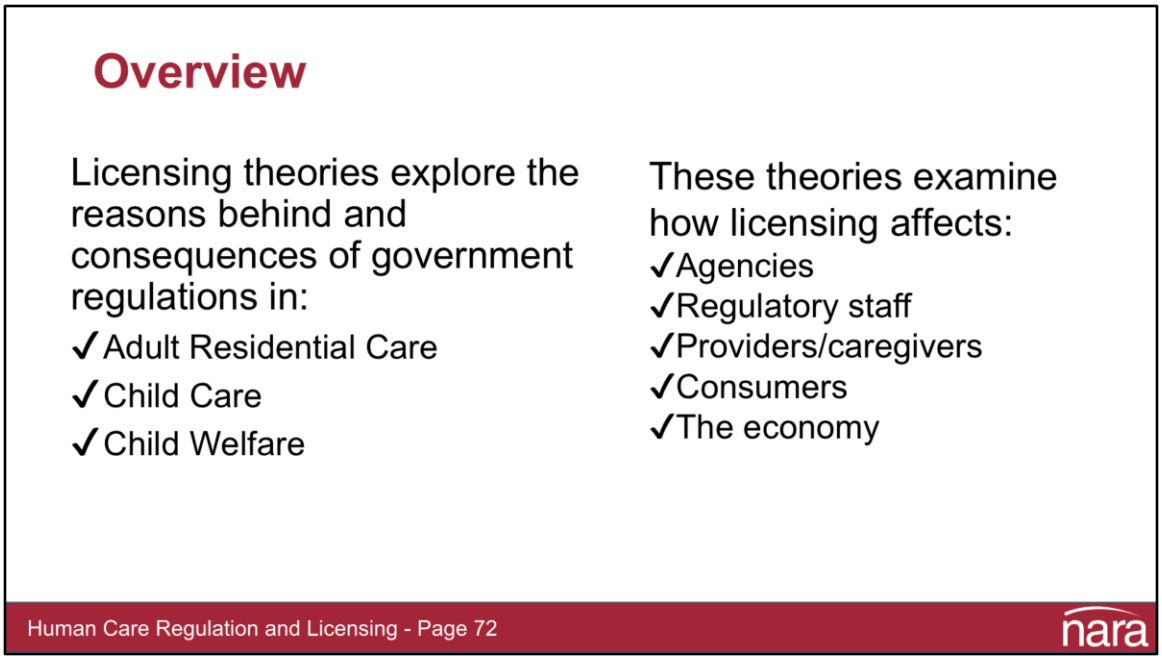


Notes to Instructor:

Review learning objectives with course participants.

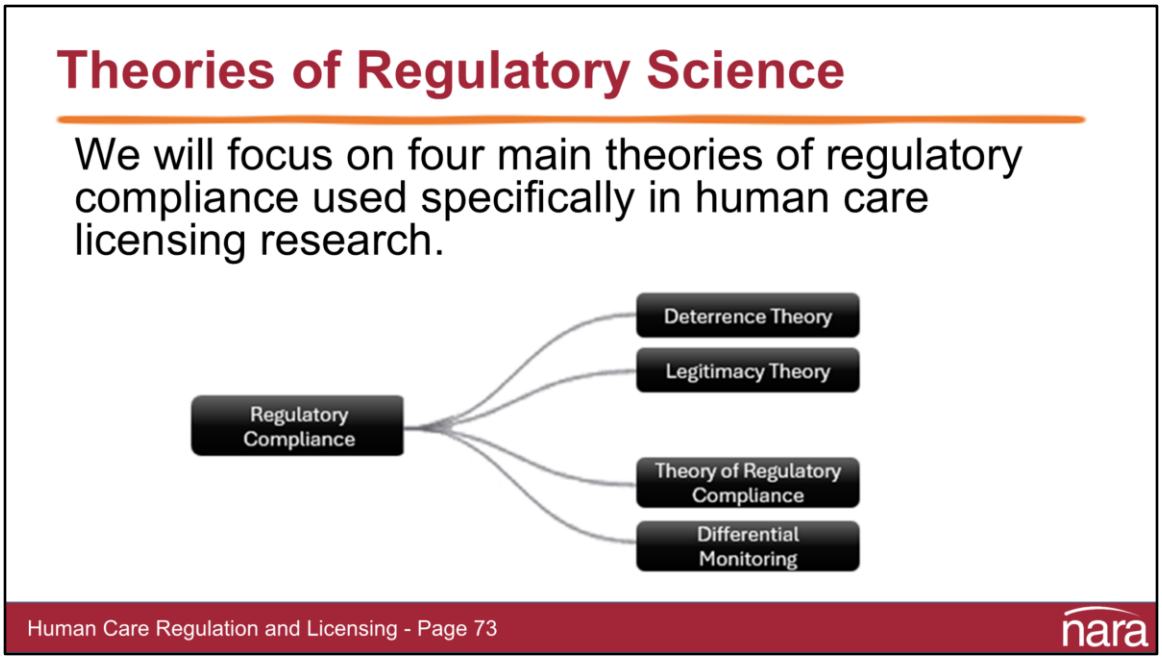
Learning Objectives:

- Identify the overarching theoretical approaches to regulatory science in licensing.
- Summarize practices currently being modeled based on regulatory science discoveries.
- Explore areas where regulatory scientific advancements are needed.



In Module 1 and 2, we learned the role of regulatory science and regulatory scientists in the field of human care licensing. Now lets look into specific revelations and practices that have been developed using scientific methos.

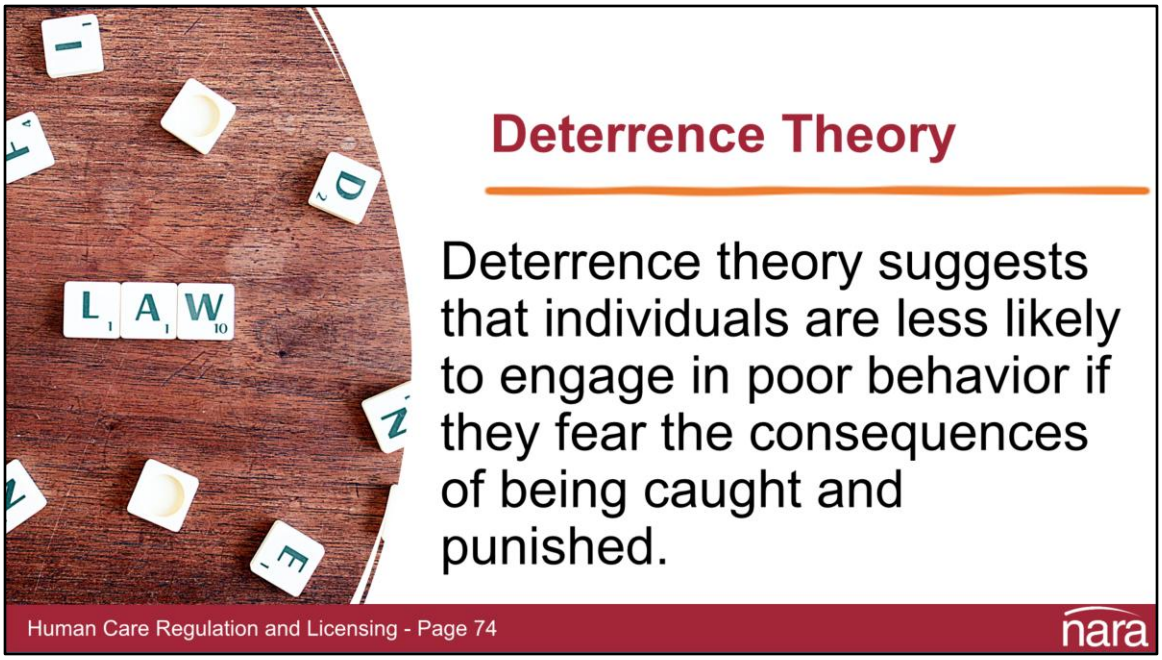
Licensing theories explore the reasons behind and consequences of government regulations, particularly occupational licensing which require individuals in fields like adult residential care, child care, and child welfare settings to obtain a license to practice. These theories examine how licensing affects agencies, regulatory staff, providers/caregivers, consumers, and the overall economy. Regulatory research can explore a wide range of varied perspectives ranging from consumer motivation, protection and prevention to market efficiency.



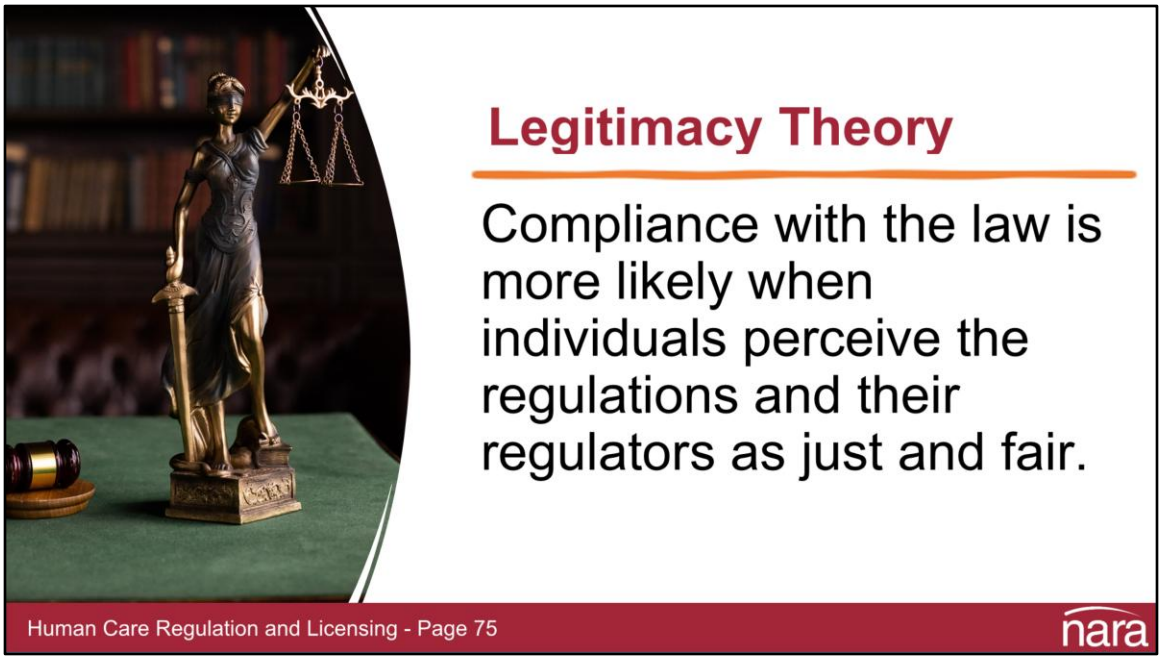
There are several theories of regulatory compliance that have been highlighted in the overall regulatory science research literature (Ayers, I. & Braithwaite, J., 1992), (Sutinen, J.G. and Kuperan, K., 1999), (Fiene, 1985), but for the purposes of this course, we will focus on four main theories of regulatory compliance used specifically in human care licensing research.

The first two, **deterrence theory** and **legitimacy Theory**, focus on the motivation for providers and caregivers to follow licensing rules and regulations. Regulatory studies can help to highlight the most effective strategies to find a balance between deterrence and legitimacy that works for a specific community.

The **Theory of Regulatory Science** and **Differential Monitoring**, developed by Richard Fiene, proposes that regulatory compliance is not always about achieving 100% adherence to all rules, but rather about finding a balance between "do no harm" rules and "best practice" standards. This theory suggests that a differential monitoring approach, focusing on key indicators, risk assessment, and quality indicators can be more efficient and effective in achieving desired outcomes. Since this theory was specifically developed within the context of human service delivery systems and NARA has several examples of its effectiveness across jurisdictions in the US and Canada, it will be the focal point of this course.



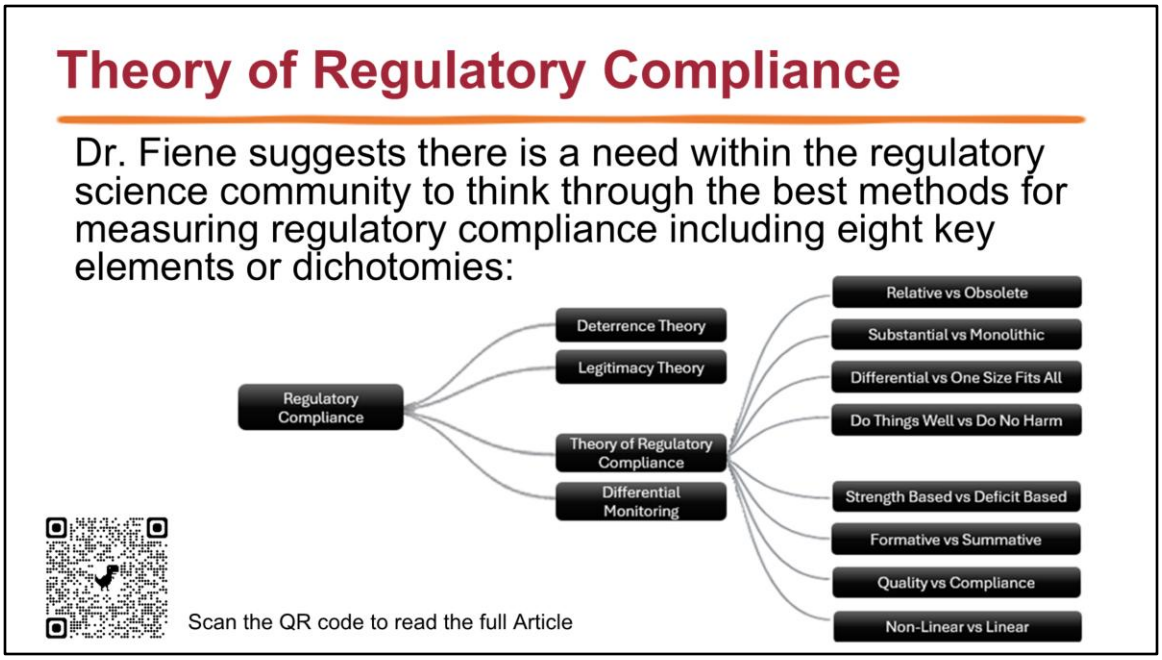
Deterrence theory focuses on preventing non-compliance through the fear of punishment, while legitimacy theory emphasizes the importance of trust with the oversight agency and acceptance of the law and its enforcement. Deterrence theory suggests that individuals are less likely to engage in poor behavior if they fear the consequences of being caught and punished. In the context of licensing, this theory suggests that the threat of sanctions, such as fines or license revocation, can deter individuals from engaging in illegal or unethical practices. Unfortunately, this may not influence individuals who are not rational or believe the risks of being caught are worth the action.



Concept 5: Licensing derives its authority solely from statutory law.

Legitimacy theory argues that compliance with the law is more likely when individuals perceive the regulations and their regulators as just and fair. It also suggests that licensing agencies need to maintain public trust and acceptance to be seen as legitimate and contribute to public trust in a profession.

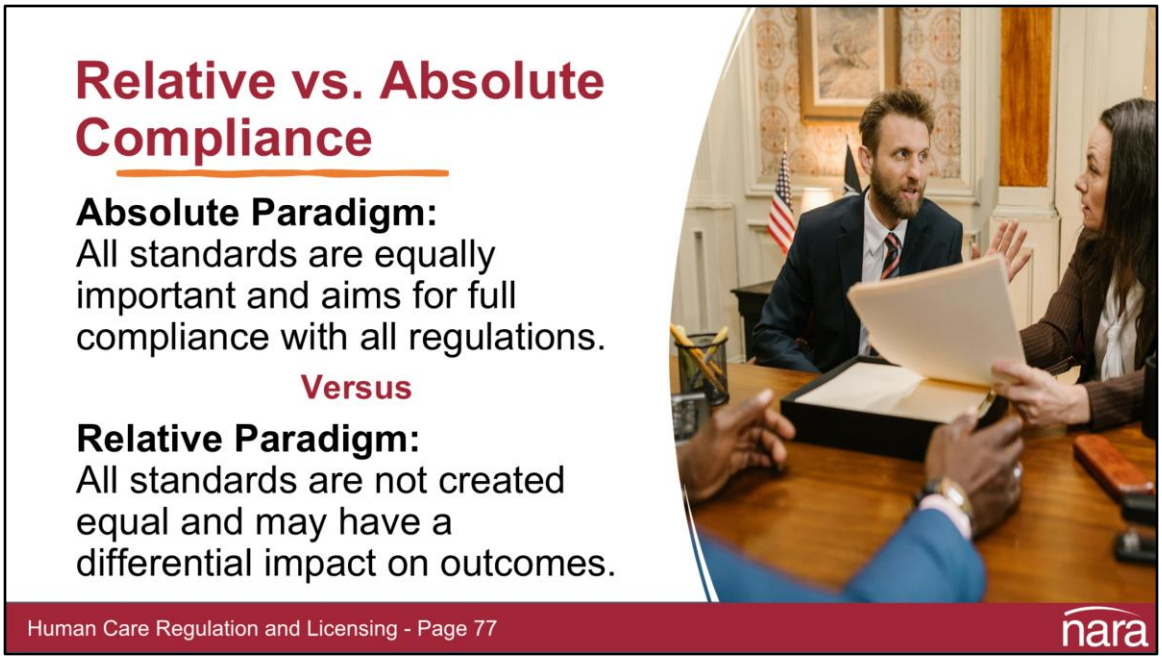
While deterrence theory and legitimacy theory can be seen as complementary rather than contradictory. There has been a considerable shift in the profession to increase public trust and motivation toward intrinsic compliance. This has been done through increased transparency, responsiveness to public complaints and concerns. And ensuring licensing requirements and enforcement practices reflect societal values and expectations.



The theory of regulatory compliance as outlined by Richard Fiene, suggests there is a need within the regulatory science community to think through the best methods for measuring regulatory compliance. Paradigms such as the differences between individual or aggregate rules, differences in compliance levels needed to ensure health and safety for those in care, the varying importance of each rule, the exchange between compliance and quality, and so on.

Overall, there are eight (8) key elements/dichotomies Fiene provides for us to consider in thinking about the implications of the theory of regulatory compliance.

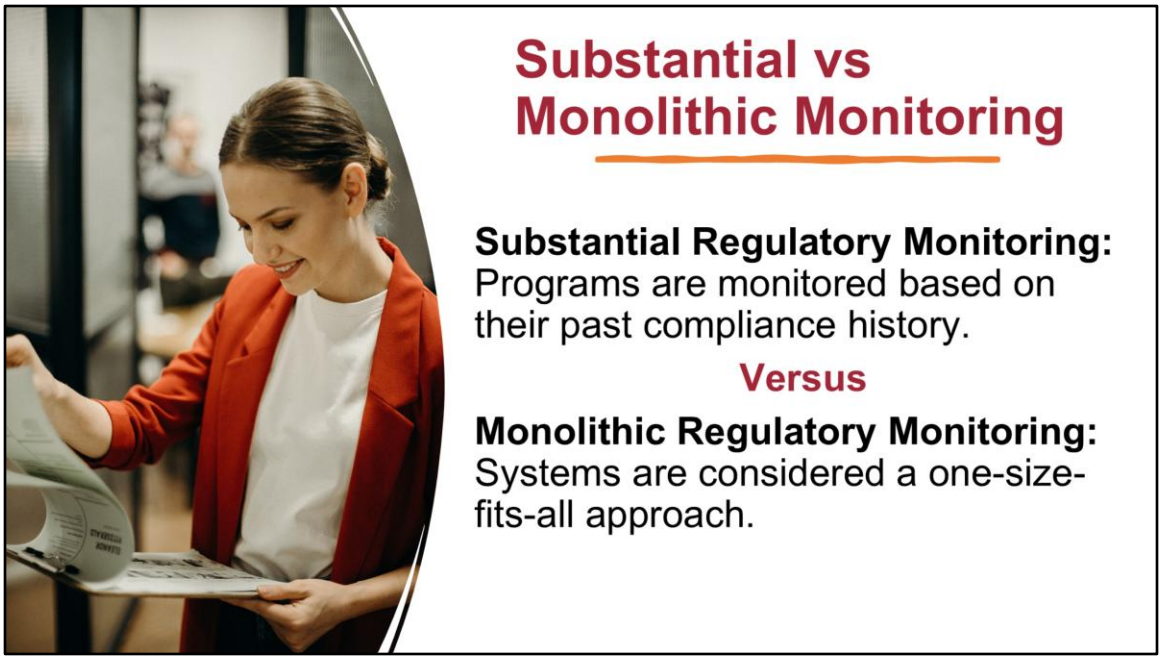
If you would like to read the full ***Journal of Regulatory Science*** publication (Fiene, 2022) you can scan the QR code on the slide to save the article. Next, we are going to go through each of the eight paradigms listed here.



If you accept the theory of regulatory compliance, then it leads to a potentially new paradigm. The relative vs. absolute paradigm refers to two different ways of thinking or approaches to understanding and measuring compliance with regulations.

The absolute paradigm views all standards as equally important and aims for full compliance with all regulations. This is historically how licensing agencies operated - through comprehensive monitoring systems where all rules are inspected, and all areas of non-compliance are treated equal. This paradigm was dominant from when rules and regulations were first introduced in the late 1880's and continued as the dominant paradigm until the 1970's.

The relative paradigm acknowledges that all rules and standards are not created equal and may have a differential impact on outcomes. This suggests that focusing on key indicators and substantial (as opposed to comprehensive) compliance can be more effective than striving for 100% compliance with all rules. This has led to additional practices including differential monitoring systems that have been adopted in many agencies over the past two decades. We will discuss this in more detail later in the course. The relative/differential paradigm was first introduced in the 1980's when Fiene proposed the theory of regulatory compliance (Fiene, 1985a) and its associated methodologies (Fiene, 1985b).



A "substantial compliance" approach allows for some deviation from strict adherence to all rules, while still achieving the intended goals of the regulation (“spirit” of the law). For example, educational requirements may ask for a specific credential, but experience may be considered equivalent to achieve the same compliance determination.

A "monolithic compliance" approach requires full and strict adherence to all rules (“letter” of the law), with no exceptions. For example, a program may be required to have a policy for a service they don’t provide because it is in the rules, and they may one day choose to begin that service.

These same concepts are also true when considering how compliance monitoring is viewed:

In a **substantial regulatory monitoring** system, programs are monitored based on their past compliance history. 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. This can lead to higher efficiency because it allows for some flexibility.

Monolithic regulatory monitoring systems are considered a one-size-fits-all

approach where everyone gets the same type of review or inspection. This is typically found in an absolute paradigm where all rules are inspected at every visit with little to no room for deviation, even when it seems inefficient or even unnecessary. While this paradigm is strict it also ensures levels of consistency are achievable.

Concept 6: Licensing derives its authority solely from statutory law.

Differential monitoring focuses on tailoring monitoring efforts based on individual characteristics, like past compliance history, risk assessments and key indicators to guide the frequency and scope of monitoring visits. A "one size fits all" monitoring approach applies the same approach to everyone, regardless of individual differences.

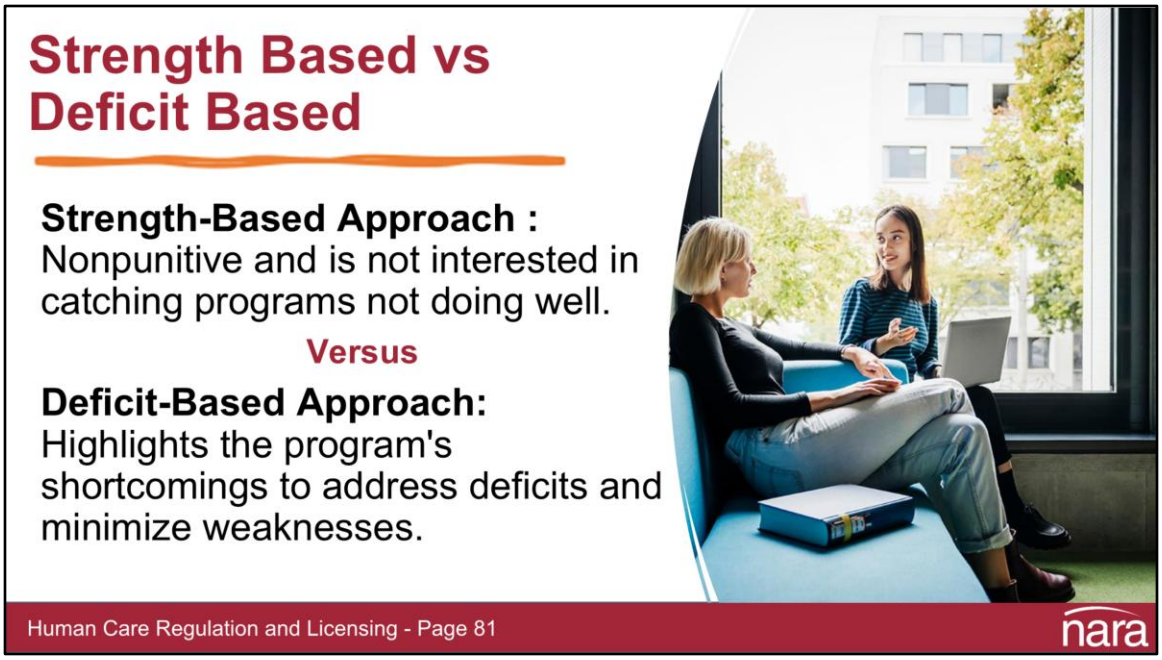
There are many benefits to differential monitoring. Most notably, streamlining resources by focusing on the facilities with higher risk of non-compliance to provide more support to those that need it rather than those that don't. For example, a provider with high compliance may receive one abbreviated monitoring visit a year providing the time for the inspector to increase support to another provider that requires more inclusive technical assistance.

A one size fits all monitoring system has been a regulatory agency go-to for many decades. It provides a consistent and easy pathway to procedure creation resulting in consistent onboarding, training and assessment of regulators. However, it is often less efficient because it puts unnecessary burden on high performing providers leaving less time for the regulator to provide needed support to programs that need it.

"Doing things well" focuses on quality of services while "doing no harm" focuses on protecting the health and safety of the consumer and those that are licensed. Both are important in any regulatory compliance monitoring system. In fact, the key mission of most licensing agencies is to ensure health and safety of clients and avoid harming services or clients. But a balance between the two paradigms produces better outcomes.

"Doing things well" focuses their system design on the 95% of the programs that are "doing things well" and adjusting for the services needed to fit the needs of the other 5%. This is found throughout the differential and relative paradigms.

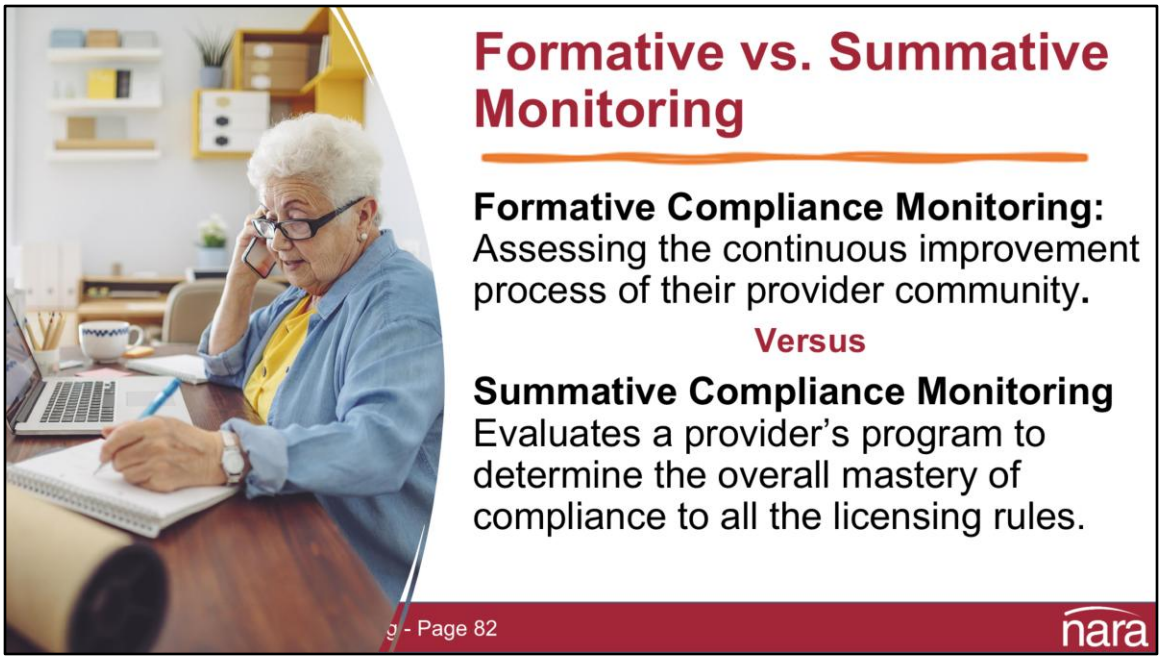
"Doing no harm" places an emphasis on creating a system that focuses on the "least common denominator", or the 5% of the non-optimal programs and imposes those systems to everyone ensuring they are "doing no harm". This is found in relation to the absolute and full paradigms.



A strength-based monitoring system considers the results of a monitoring visit or inspection as a glass “half full”. It builds on existing strengths to achieve licensing requirements or higher quality and promotes long term success. Conversely, a deficit-based system will view the results of a monitoring visit or inspection as “half empty”. It highlights shortcomings, weaknesses, of the program.

A strength-based approach is nonpunitive and is not interested in catching programs not doing well. For example, a strength-based approach might highlight a provider’s strong problem-solving skills rather than the minor infractions they were trying to solve or their strong leadership qualities around staff mistakes resulting in a non-compliance. This approach often improves engagement, increases motivation and assists in maintaining sustainable results.

While a deficit-based approach highlights the program's shortcomings, the intent is to address deficits and minimize weaknesses to meet licensing requirements quickly through the threat of financial or other sanctions. For example, a deficit-based approach might focus on where the provider is lacking in knowledge rather than on knowledge gains. Unfortunately, this approach can demotivate providers and hinder long-term growth.



Formative compliance monitoring systems emphasize constant quality improvement and getting better. The formative paradigm is most often found with a differential and relative systems emphasis; they are constantly assessing areas that require additional support for needed compliance. Summative monitoring, found in absolute and full regulatory compliance monitoring systems, place the emphasis on being the gatekeeper 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 rather than supporting growth and further improvement.

Formative compliance monitoring systems help licensing authorities assess the continuous improvement process of their provider community. This is a crucial role once a provider has obtained their license because it allows the regulatory agency to identify areas where providers might need additional support or resources.

The purpose of a **summative compliance monitoring** visit is to evaluate a provider's program when determining the overall mastery of compliance to all the licensing rules. This is a crucial role in licensing to determine whether an applicant has met all licensing requirements to operate. However, it doesn't monitor improvement or identify areas that may need additional support or resources.

Like other areas, regulatory science can assist licensing agencies striving to find a

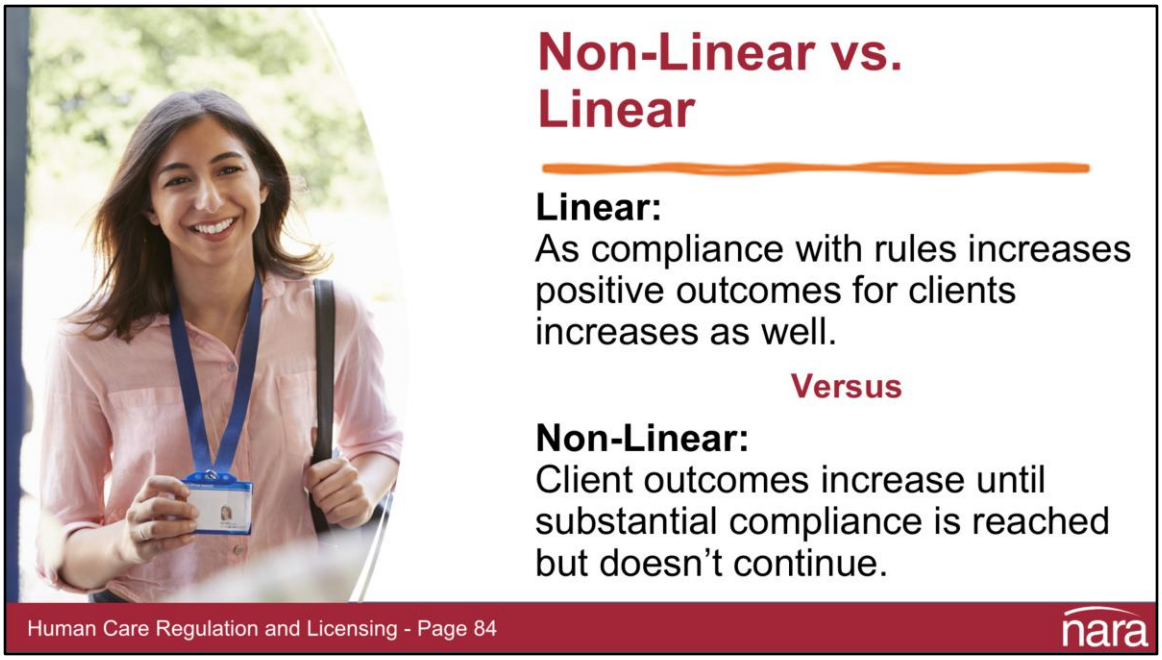
balance between supporting the growth and continuous improvement (formative) of licensed programs and their duty to ensure programs that could harm individuals are not allowed to operate (Summative).

Program compliance focuses on adhering to regulations and legal requirements to operate legally, while **program quality** emphasizes the overall effectiveness and well-being of participants, often exceeding minimum compliance standards. Remember, licensing serves as a baseline for safety and legal operation, while quality initiatives aim to improve the experience and outcomes for those served by the program. However, effective licensing systems understand there is a paradigm and strive to find that balance.

Within an absolute/full regulatory compliance monitoring system the focus is on **program compliance** with the emphasis on full, 100% compliance. Licensing is basically a closed system and has an upper limit with full compliance (100%) with all rules. 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 (Fiene, 2019) which will be discussed later in the module.

Program quality is found most often in quality improvement and quality systems. However, it has also emerged more recently in differential/relative regulatory compliance monitoring systems because attaining a perfect monitoring score is increasingly more difficult to attain while an open system tends to be more flexible and far reaching. In other words, it is far more difficult to distinguish between the

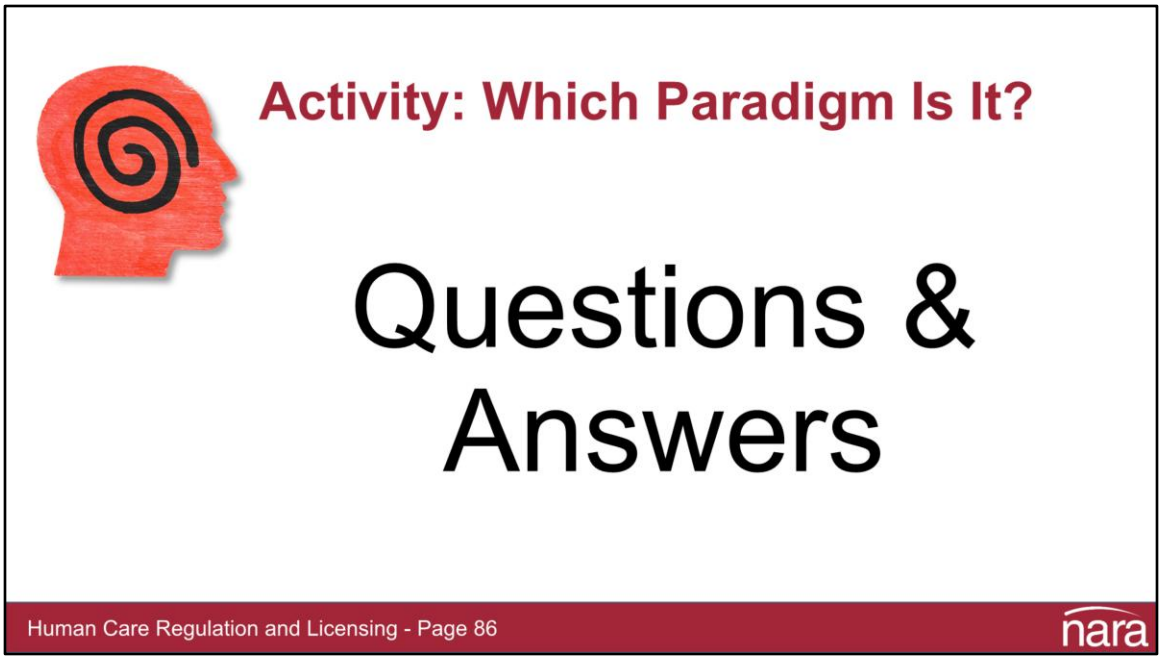
best programs and the mediocre programs within licensing but more successful in quality rating systems.



Within regulatory compliance monitoring systems there is the assumption that the data are linear in nature. This means that as compliance with rules increases positive outcomes for clients increases as well. However, empirical data does not support this conclusion. Rather, the data suggests that the relationship is more non-linear creating 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. This led to the development of the Theory of Diminishing Returns which we will review in more depth shortly.

As the regulatory science and administrative fields continue to think about appropriate measurement system design and implementation, it's important to find the right balance between each of the paradigms and the systems' key elements to fit the needs of regulatory goals.

Through regulatory scientific methods, Dr, Fiene found that there appears to be a "sweet spot" or balancing of key rules that predict client outcomes more effectively than 100% or full compliance with all rules. Ultimately, this is the essence of the Theory of Regulatory Compliance (Fiene, 2019) and subsequently the Theory of Diminishing Returns (Fiene, 2022) – substantial compliance with all standards or full compliance with a select group of standards that predict overall substantial compliance and/or positive client outcomes.



Note to Instructor:

Supplies needed: Index cards and marker

Before class: Fold each index card in half. Write each question with answer options on the outside flap of the index card so that it is visible to the participant. Write the answer on the inside flap so that it is not visible to the participant. You may want to place a small piece of tape on the flap to keep it closed.

During class: Divide the participants into small groups or partners. Give each group a question. Encourage them to read the question and answer options, discuss, and choose the answer they think is correct. Then allow the groups to open the flap to see if they are correct and allow time for the group to discuss. Once all groups have completed the activity, conduct a debrief of each groups findings.

Introduction: This module explained the eight paradigms of regulatory compliance theory. Read the question, discuss, and select an answer. Once your group thinks they have the correct answer, open the flap to reveal the correct answer. Spend time discussing why you got the answer right or wrong.

1. A _____ approach is nonpunitive and is not interested in catching programs not doing well while a _____ approach highlights the programs' shortcomings.
   a. Strength-Based vs. Deficit Based.
   b. Program Quality vs. Program Compliance
   c. Relative vs. Absolute Compliance
   d. Substantial vs. Monolithic Monitoring

   Strength-Based vs. Deficit Based. (CORRECT)

2. _____ aims to improve the experience and outcomes for those served by the program while _____ focuses on ensuring foundational health and safety requirements are met.
   a. Differential Monitoring vs. One Size Fits All
   b. Formative vs. Summative Monitoring
   c. Do Things Well vs. Do No Harm
   d. Non-Linear vs. Linear

   Do Things Well vs. Do No Harm. (CORRECT)

3. The _____ theory acknowledges that all rules and standards are not created equal and may have a differential impact on outcomes while _____ views all standards as equally important and aims for full compliance with all regulations.
   a. Strength-Based vs. Deficit Based
   b. Non-Linear vs. Linear
   c. Relative vs. Absolute Compliance
   d. All of the above.

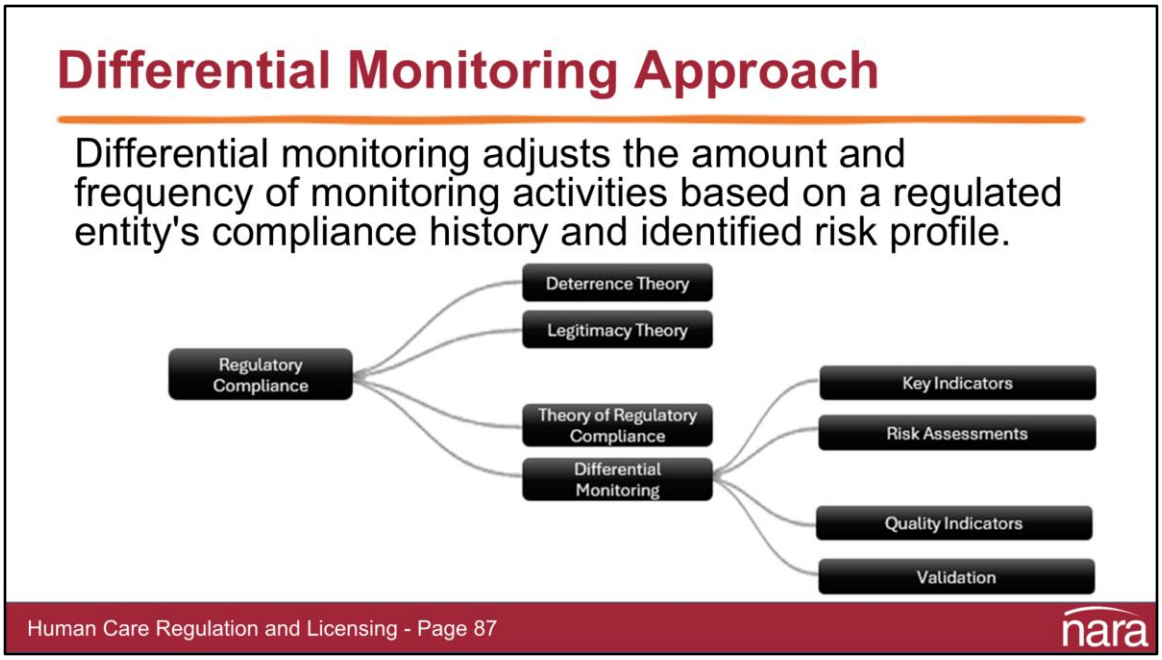
   Relative vs. Absolute Compliance (CORRECT)

4. _____ monitoring systems assess the continuous improvement process of their provider community while _____ monitoring visit evaluate mastery of compliance to all the licensing rules.
   a. Formative vs. Summative Monitoring
   b. Relative vs. Absolute Compliance
   c. Strength-Based vs. Deficit Based.
   d. Do Things Well vs. Do No Harm.

   Formative vs. Summative Monitoring (CORRECT)

5. _____ focuses on tailoring monitoring efforts based on individual characteristics to guide the frequency and scope of monitoring visits while a _____ monitoring approach applies the same approach to everyone.
   a. Do Things Well vs. Do No Harm.
   b. Formative vs. Summative Monitoring
   c. Differential Monitoring vs. One Size Fits All
   d. Strength-Based vs. Deficit Based.

   Differential Monitoring vs. One Size Fits All (CORRECT)



Differential monitoring (DM) represents a momentous change in thinking in regulatory oversight. DM moves away from regular approaches where inspections require a full review of licensing reviews at every monitoring visit towards a more focused and adaptive strategy. It recognizes that not every provider, program or caregiver benefits from the same level of oversight or levels of support and offers a more nuanced and flexible approach to regulatory assessments.

Differential monitoring adjusts the amount and frequency of monitoring activities based on a regulated entity's compliance history and identified risk profile. The purpose of this approach is to optimize the use of limited resources by concentrating more attention on programs or facilities that have a history of non-compliance or that have been identified as carrying a higher level of risk.

There are four components of an effective and valid differential monitoring system, and each component is firmly grounded using scientific methodologies. They include key indicators, risk assessment, quality indicators and ongoing validation. Let's explore each of these components in more detail.

Key Indicators

A carefully selected subset of regulatory rules or standards that have statistically demonstrated to predict overall compliance with the entire body of regulations.

Main Considerations
Full Year of compliance data
Identify those providers that are low or high compliance
count how many high compliance providers were out of compliance with the same items and how many low-group providers were out of compliance with the item.

Key indicators are defined as a carefully selected subset of regulatory rules or standards that have statistically demonstrated to predict overall compliance with the entire body of regulations. According to Fiene and Nixon (1981), by focusing on key indicators, regulatory agencies can gain a reliable understanding of overall compliance status without conducting a full or comprehensive inspection of every single rule. The use of key indicators can lead to significant reductions in the time, resources, and costs associated with routine regulatory monitoring, particularly for programs that have a history of high compliance.

A key indicator monitoring approach employs using only those rules, standards, or regulations that statistically predict overall compliance with all the rules, standards, or regulations. In other words, if a program is 100% in compliance with the Key Indicators the program will also be in substantial to full compliance with all rules, standards, or regulations. The reverse is also true in that if a program is not 100% in compliance with the Key Indicators the program will also have other areas of non-compliance with all the rules, standards, or regulations.

This process of finding key indicators involves analyzing compliance data to determine which rules, when adhered to, are most likely to ensure compliance with all other rules. In some cases, indicators are also chosen by consensus based on their critical importance to protecting child health and safety which deals with the risk

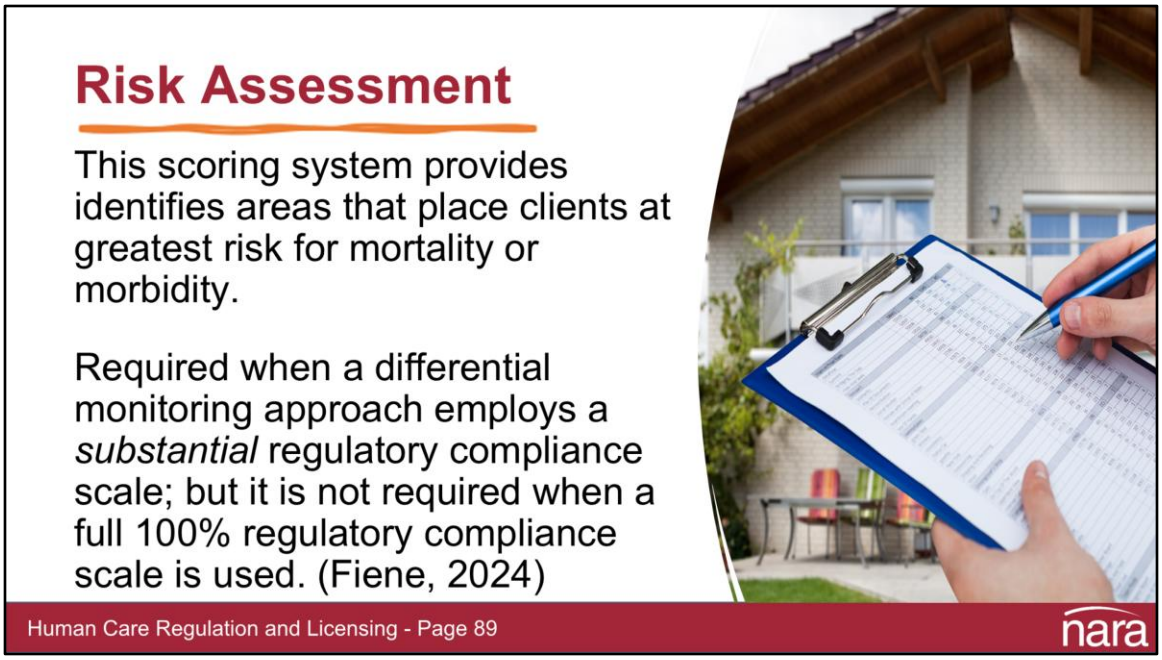
assessment methodology to be discussed shortly.

While key indicators are just one part of the differential monitoring approach, there are specific research steps that are needed that can be found described throughout the scientific literature. Please visit the NARA website on the differential monitoring and key indicator approach and methodology (https://www.naralicensing.org/key-indicators).

Main considerations include:

1. Utilizing a full year of compliance data. If a full year of compliance data is not available, a representative stratified random sample would be needed.
2. Identify those providers that are low or high compliance (approximately the top 20% and bottom 20%)
3. For each one identified in those two categories, using a frequency count of how many high compliance providers were out of compliance with the same items and how many low-group providers were out of compliance with the item. For statistical purposes, a 2x2 matrix is constructed which depicts this relationship. For those interested in learning the specific statistical methodology, the **NARA Program Monitoring Systems** course deals with this specifically. Also, NARA's ***Licensing Curriculum Chapter 11 on Measurement Tools and Systems*** deals with the specifics of the methodology.

Can this be included in the layer?

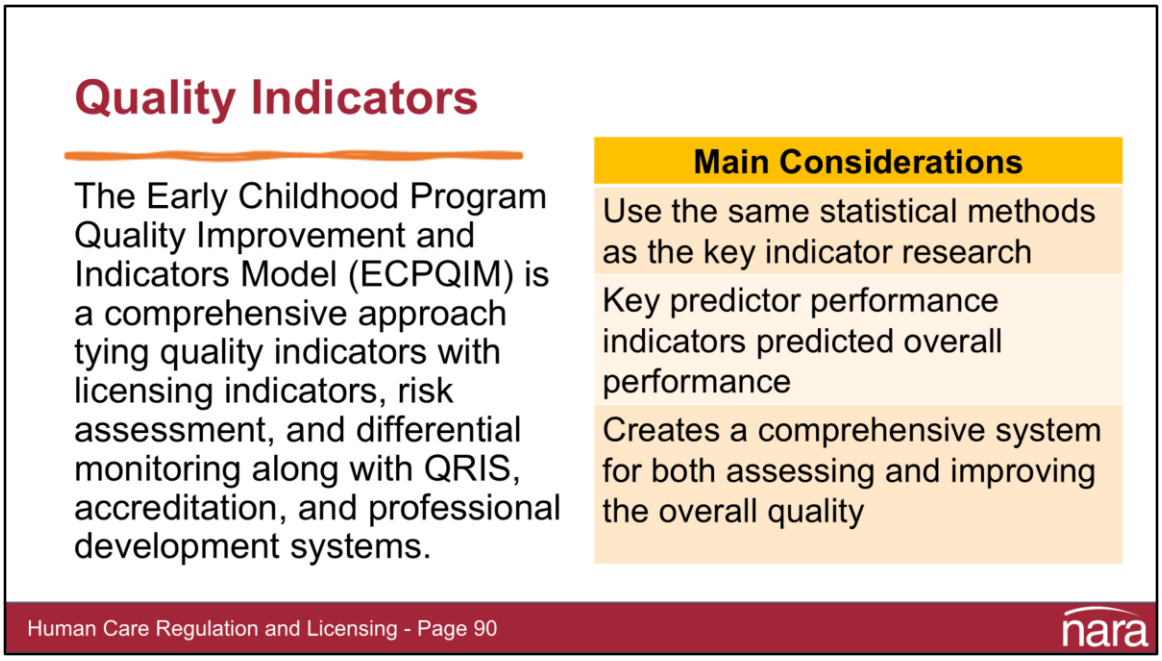


Risk assessment plays a vital role in modern regulatory compliance and is a key component within the differential monitoring approach. In the context of regulatory compliance, risk assessment involves the process of scientifically identifying potential hazards or specific areas of non-compliance that could lead to negative consequences, such as harm to individuals, environmental damage, or financial damage. Dr. Fiene's Theory of Regulatory Compliance emphasizes the importance of integrating a risk-based approach into all regulatory practices. The foundational premise is that not all regulatory rules are equally significant in their impact on achieving desired outcomes or potential consequences if not kept in compliance. (Fiene, 2025). For the learner who is interested in learning more about key indicators and risk assessment, in addition to Dr Fiene's publications, NARA's other course on **Program Monitoring Systems** will address these two methodologies in greater detail.

By "weighting" regulations or rules a scoring system provides a means to identify those areas that place clients at greatest risk for mortality or morbidity.
Weighting regulations is done through surveys. Surveys are sent to a representative sample of the populations where each participant assigns a Likert scale score to each rule. Analysis includes mean and mode considerations until a weight is assigned. This process typically involves several key steps, including identifying relevant variables, calculating initial weights, and refining weights based on population characteristics.

Weighting is required when a differential monitoring approach employs a substantial regulatory compliance scale based upon the theory of regulatory compliance; but it is not required, although recommended, when a full 100% regulatory compliance scale is used. (Fiene, 2024)

Another step in the evolution of the risk assessment is the qualitative risk assessment. This assessment takes the original theory and expands it into an approach that identifies and evaluates potential risk based on descriptive analysis rather than numerical probabilities. This methodology typically involves assessing two key dimensions of risk: the likelihood of the risk event occurring and the severity of its potential impact. These dimensions are then rated using non-numerical scales (e.g. "high," "medium," and "low,") or by a risk matrix where likelihood and impact categories intersect to providing an overall risk rating (Fiene, 2025)



When we think about regulatory compliance measurement, we are discussing licensing systems. When we think about quality, we are discussing Quality Rating and Improvement Systems (QRIS), accreditation and other professional Regulatory Compliance & Monitoring Systems. This work is newly emerging and is heavily concentrated in the early learning fields – suggesting a need for further research into other regulatory areas within human care.

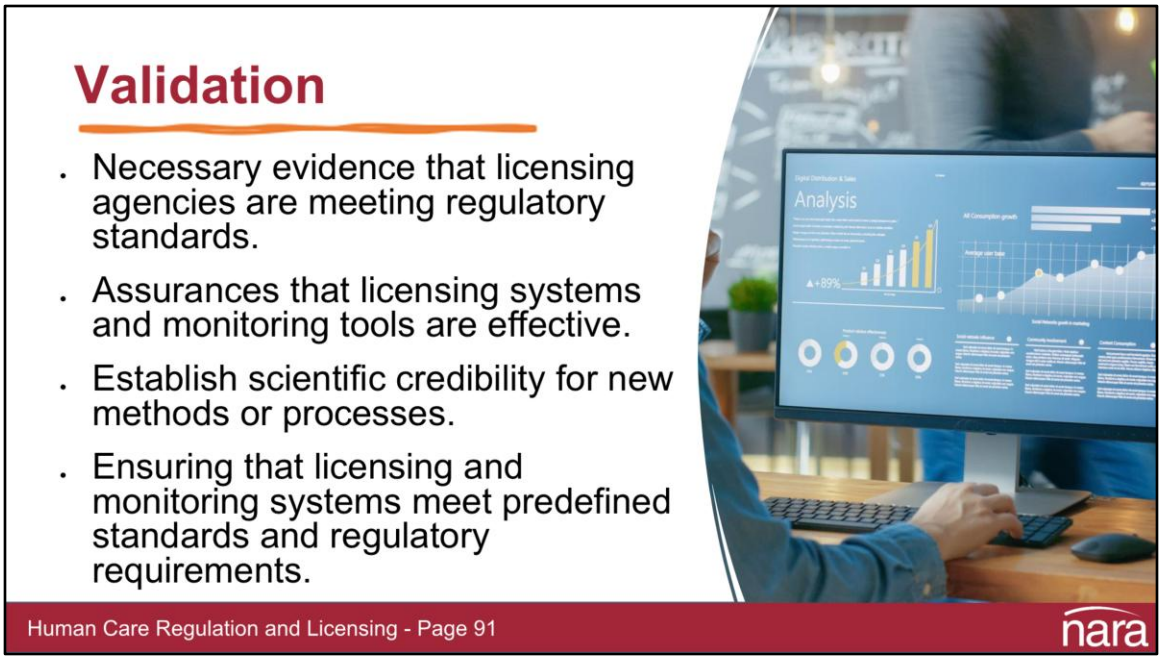
The Early Childhood Program Quality Improvement and Indicators Model (ECPQIM) may provide us with a comprehensive, overarching approach and model to tying quality indicators together with licensing indicators, risk assessment, and differential monitoring along with QRIS, accreditation, and professional development systems.

Quality indicator methodologies use the same statistical methods as the key indicator research, and apply them to accreditation, QRIS, and professional development quality initiatives. Through this research, key predictor performance indicators have been identified that predicted overall performance of a program. These key predictor rules and performance indicators were then used to develop a new type of scale/tool that measures both licensing and quality levels.

This new scale or tool is called “The Early Childhood Education Quality Indicators Scale” (ECEQIS) and was pilot tested for reliability and validity in the Province of

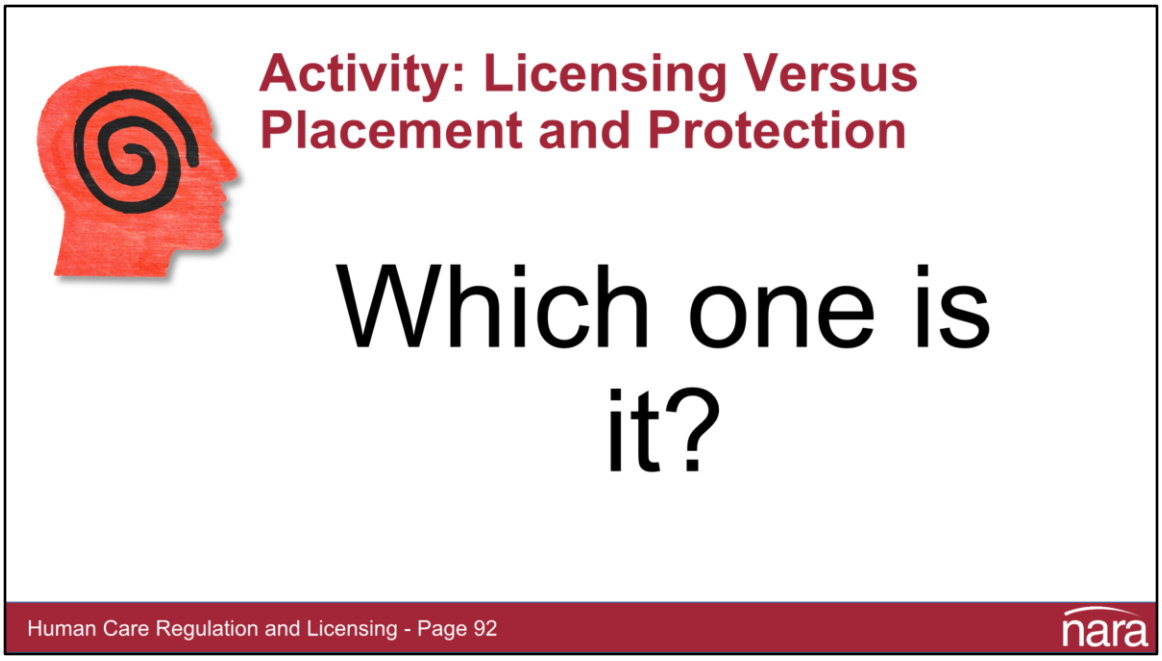
Saskatchewan's Ministry of Education by the National Association for Regulatory Administration (NARA) with resounding results (NARA, 2023b) You can read the entire report here.

The aim of the ECPQIM is to create a comprehensive system for both assessing and improving the overall quality of early care and education programs through a program's adherence to regulatory requirements and critical indicators of quality like professional development, training, and technical assistance (Fiene, 2024).
The ECPQIM represents a significant step towards a more integrated approach between licensing regulatory compliance systems and quality systems with broader initiatives aimed at improving program quality (Fiene, 2013)



How do we know new regulatory components are valid, reliable, and relevant? Continuous and ongoing validation studies are a crucial step in any research, and a step that is often overlooked. Validation studies determine if the differential monitoring systems designed are working as intended and continue to meet the overall mission and goals of protection through prevention. This matters because continuous and better validation provides:

- Necessary evidence that licensing agencies and licensing are meeting regulatory standards.
- Assurances that licensing systems and monitoring tools are effective for their intended use.
- The foundation needed to establish scientific credibility for new methods or processes.
- A key component of quality assurance programs, ensuring that licensing and monitoring systems meet predefined standards and regulatory requirements.



Note to Instructor:

Supplies needed: Chart paper, strips of paper with scenarios, tape

Before activity: Hang a pieces of chart paper on the wall with four columns. Write Column headings **"DETERRENCE THEORY", "LEGITIMACY THEORY", "THEORY OF REGULATORY COMPLIANCE"** and **"DIFFERENTIAL MONITORING".** Using a printer or writing by hand, create strips of paper with all scenarios (below).

During class: Divide the participants into 4 groups or partners. Give each group one descriptions. Encourage them to read the description, discuss, and choose which chart paper it belongs (licensing or placement and protective services). Then allow the groups to tape their strip of paper to the chart paper. Once all groups have completed the activity, conduct a debrief by reviewing each scenario and offer gentle corrections for strips in the wrong place.

Introduction: This module reviewed four of the different regulatory theories commonly used in licensing systems. Read the scenario, discuss, and tape the description to the correct chart paper.

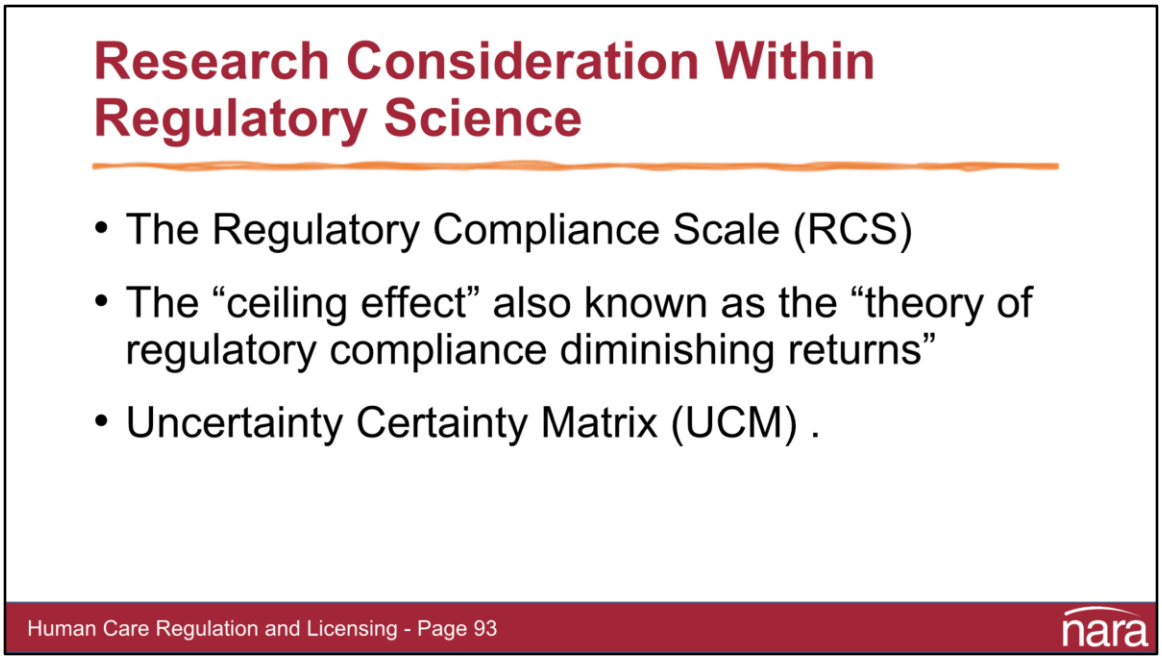
- **A continuous quality report highlighted an alarming trend of increased adult**

abuse in one city. The licensing office responds by sending additional teams of regulators to that city to conduct focused and throughout inspections resulting in multiple civil penalties issued and even two licenses being revoked.

- **With the recent budget cuts and an increase in adult care facilities, the department has begun to develop a plan to recreate their system that will allow for some flexibility in meeting less critical requirements while ensuring the health and safety of the clients are maintained. They dive into a study to consider the differences between individual or aggregate rules, differences in compliance levels needed to ensure health and safety for those in care, and the varying importance of each rule.**

- **A licensor just left a child care center that demonstrated perfect compliance – in fact, they only had one non-compliance last year! The licensor can't help but be frustrated that the visit took almost as long as the one they did yesterday that had over 30 non-compliances, even after visiting that site twice last month due to complaint inspections. Based on licensor feedback like this, the agency begins to explore ways to recognize the excellent programs with abbreviated inspection and free up licensors' time to provide higher levels of support to programs that really need it.**

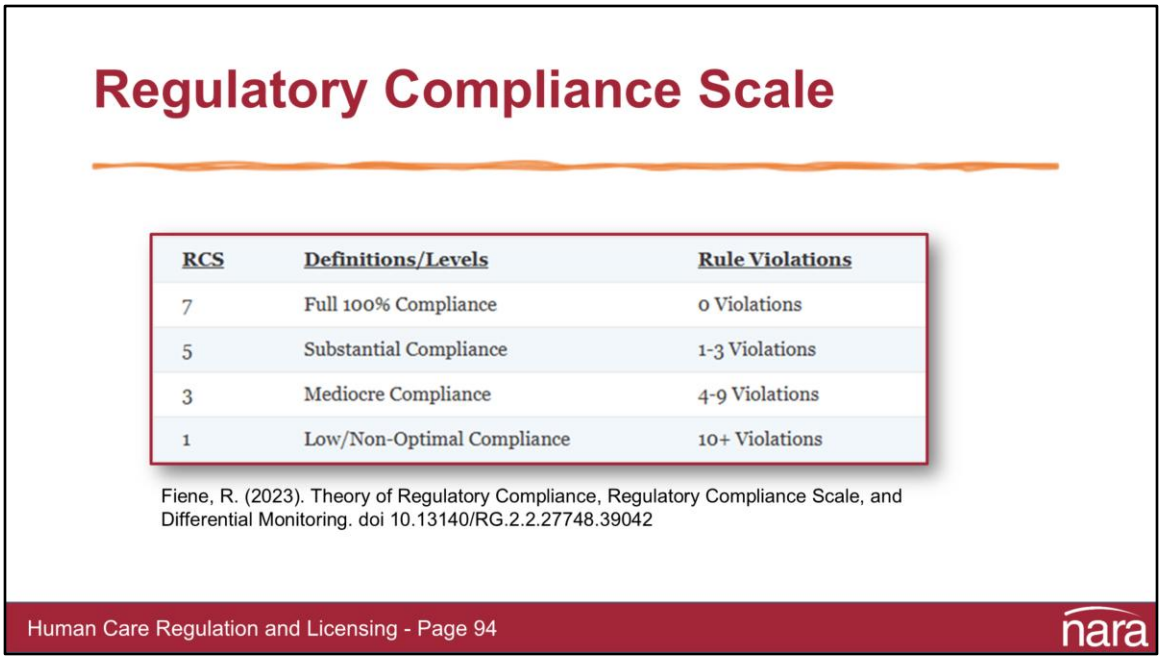
- **The state's foster care system is accused of failing to uphold its duty to provide safe and stable placements for children, impacting the child's legal right to permanency. The agency begins to dive into their historical data to assess the licensing and placement trends in their foster homes. They find that licensing and placement trends have been largely unchanged over the past several years. They begin a qualitative study to explore the cause of the perception shift.**



While there are many considerations a regulatory scientist must keep in mind when conducting studies in the regulatory licensing system, there are three that are particularly important.

- is a tool that combines the number of violations to categorize the performance of a provider on an ordinal scale rather than a frequency count.
- The "ceiling effect" also known as the "theory of regulatory compliance diminishing returns" suggests that as regulatory compliance increases from substantial compliance to full compliance, program quality shows either no or decreased improvement over.
- The premise of the Uncertainty Certainty Matrix (UCM) is that individual decision-making matches reality. The UCM is useful in licensing decision making when validating licensing decisions to determine individual inspector bias in regulatory compliance.

Let's look at these a bit more:

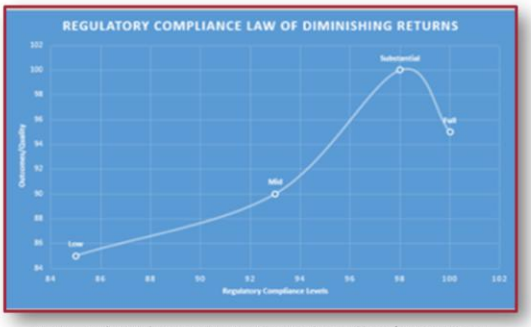


Recently (2022), Fiene introduced the concept of regulatory compliance scales. The scale was developed based on years of research into regulatory compliance data distributions and has shown that utilizing a scale rather than just counting the number of violations is a better metric in measuring a program's regulatory compliance.

When using the regulatory compliance scale, a researcher puts violations into buckets as seen in the above table. When the data are moved from frequency counts of violation data into these buckets/categories, programs are better able to identify better (or worse) performing programs.

Regulatory compliance scales need additional validation studies to determine their full efficacy in helping to rank order facilities according to regulatory compliance and to determine the thresholds for each of the buckets/categories on the scale. The initial results (Fiene, 2025) are very promising but these need to be validated with additional studies.

Theory of Diminishing Returns (Ceiling Effect)



Fiene, R. (2023). Introducing the Ceiling Effect/Diminishing Returns, Regulatory Compliance Scale, and the Quality Indicators Scale to Regulatory Science.

Eventually the added benefits of more compliance become insignificant and may even lead to negative consequences. Therefore, investing more resources to achieve perfect compliance won't significantly improve outcomes.

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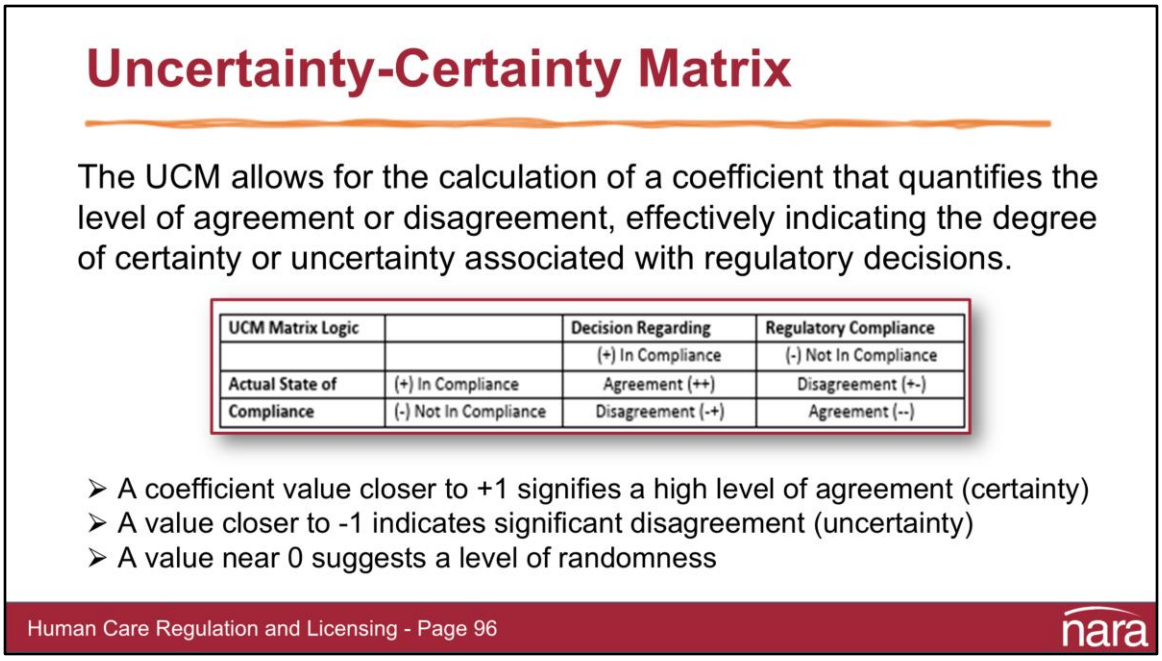
Theory of Diminishing Returns (aka Ceiling Effect)

The law of diminishing returns, also known as the law of diminishing marginal productivity, was originally developed to explain economic trends within product industries. The principle states that as one input (like labor) is increased while other inputs (like capital) are held constant the increase in output (the product) will eventually decrease. This means while adding more and more of a single input will initially increase output, the output will eventually decrease even if more input (like labor or capital) is added.

The Regulatory Compliance Theory of Diminishing Returns is similar in that while increasing compliance with regulations can initially improve program quality, further increases in compliance slows, or even decreases quality improvement. This means that at some point, the added benefits of more compliance become insignificant, and may even lead to negative consequences. From a public policy and licensing decision making point of view, 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. Research suggests that there exists a "sweet spot" of substantial compliance, estimated to be around 98-99%, where an optimal balance is achieved between the resources invested and the positive

outcomes observed. (Fiene, 2022).



Uncertainty-Certainty Matrix

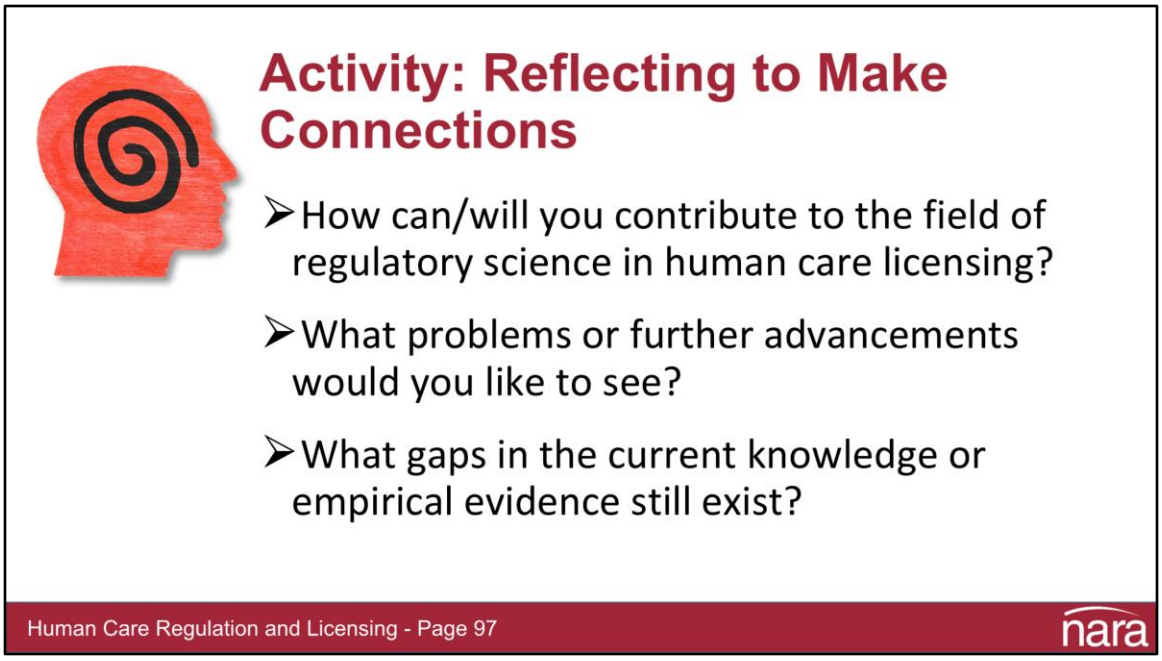
An "Uncertainty Matrix" is a strategic planning tool consisting of a 2X2 grid to categorize potential events based on hypothesized impacts, especially those with a high level of uncertainty (or unknown outcomes). In regulatory science, the Uncertainty-Certainty Matrix (UCM) can help assess the validity and reliability of regulatory decisions and identify risks and associated opportunities and be a valuable tool to identify potential bias in assessments.

The goal of regulatory decision-making is to maximize the instances of agreement (certainty) and to minimize the occurrences of disagreement (uncertainty) between the regulatory decision and the true state of compliance. In other words, to minimize errors in compliance or non-compliance citations. Disagreements that result in false negatives (marked as compliance when out of compliance) are of particular concern in regulatory contexts due to the potential for increased risk to the individuals being regulated.

The UCM allows for the calculation of a coefficient that quantifies the level of agreement or disagreement, effectively indicating the degree of certainty or uncertainty associated with regulatory decisions.

A coefficient value closer to +1 signifies a high level of agreement (certainty), a value

closer to -1 indicates significant disagreement (uncertainty), and a value near 0 suggests a level of randomness in the decision-making process. A horizontal or vertical pattern in the data, with little or no diagonal indication, can suggest the presence of a bias.



Notes to Instructor:

Group discussion:
We began this course with the history of regulatory science and learned that it is truly in infancy. Thanks to Dr. Fiene and other research scientists like him, we have the beginnings of a research roadmap. But there is still work to be done – there will always be work in research! The aim of this course has been to highlight the importance of scientific research in licensing and outline some of the foundational theories and methods.

Take a moment to write down ways you can/will contribute to the field of regulatory science in human care licensing. What problems or further advancements would you like to see? What gaps in the current knowledge or empirical evidence still exist?

Examples
1. The relationship between Regulatory Compliance & Monitoring Systems in the context of client outcomes. Are clients healthier and safer in highly compliant programs and are there fewer injuries in programs with high compliance?
2. Regulatory Science research has been mainly concentrated in the field of child

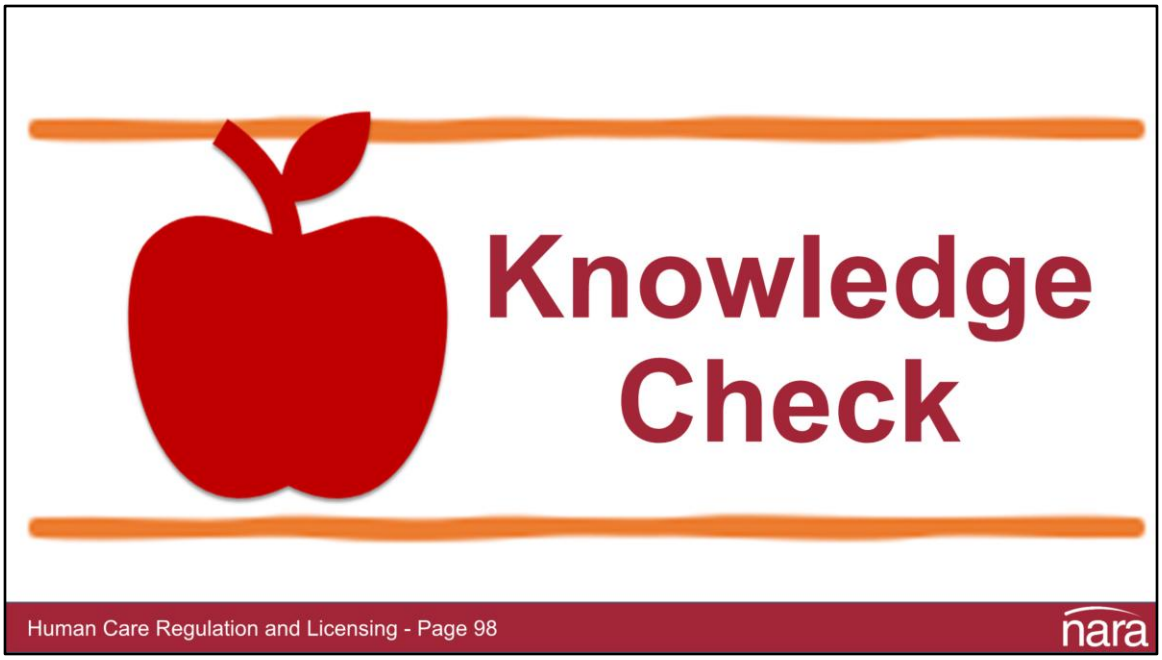
care and early learning. However, human care licensing maintains the same, or similar foundational beliefs and monitoring systems. More empirical studies are needed to evaluate the impacts of different differential monitoring strategies on compliance outcomes across a wider range of industries and regulatory domains.

3. There still needs to be additional research that continues to validate the rules/standards and monitoring measures demonstrating regulatory compliance theories as accurate and relevant across licensing.
4. Due to limited research in licensing itself, measurement and statistical methods need further development and refinement. For example, this idea of moving from nominal measurements to an original measurement scale is still a theory and could be a critical change in theory.
5. Further investigation regarding the optimal levels of substantial compliance that are appropriate for different types of regulations and across various regulated sectors would provide valuable guidance for policymakers.
6. Longitudinal studies could be used to examine the long-term impact of differential monitoring systems on sustained compliance rates and overall outcomes.

Conclude the course with:

Through this course we hope you have a firm foundation in thinking about how regulatory science can be applied to human services licensing and regulatory administration. Human services licensing and regulatory administration have long been part of the landscape when it comes to establishing rules and regulations for programs, it is the application of regulatory science that is relatively new.

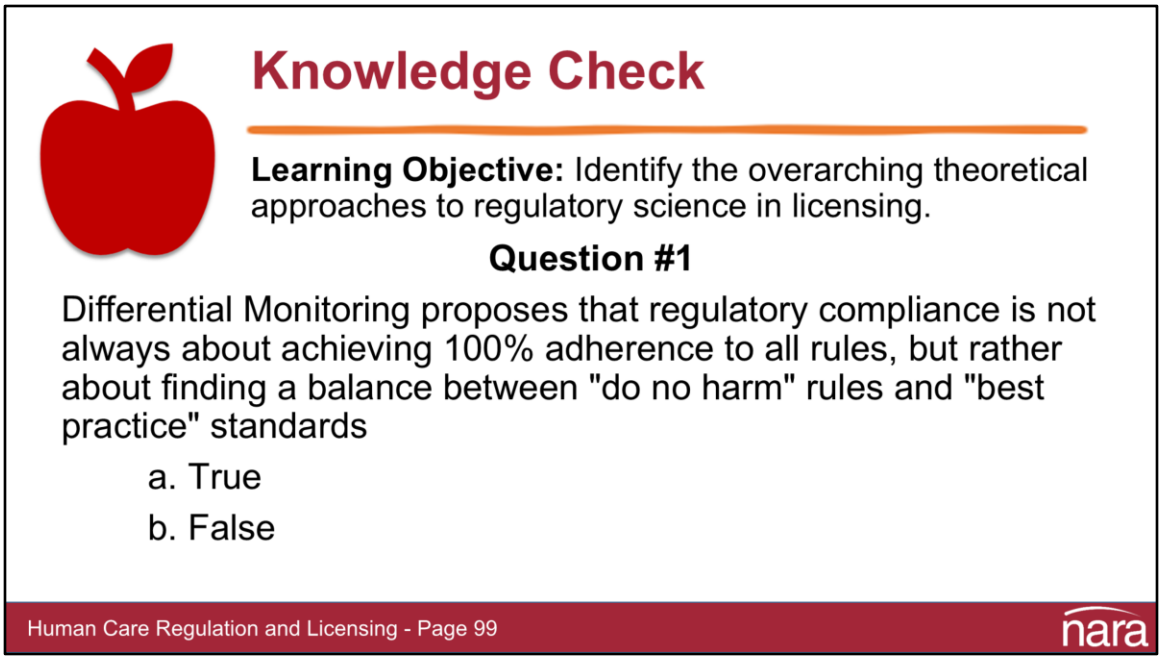
While considering the regulatory science research thus far and thinking about the gaps that remain, we hope you can see there is still a great deal of work to be done and questions to be answered. Hopefully, this course has given you some insights into how to deal with answering some of these key questions in the licensing and regulatory administration field using regulatory science.



Note to instructor:

Large group activity: Explain to the group that it is time to check their knowledge. Questions on the next slides are aligned with the module's learning objectives. Read the question and all answer options that appear on the slide. Once everyone has heard the question and thought of an answer, ask for a volunteer to give their answer. Discuss as a group and/or go back to the relevant slides to review the content if needed.

Go to next slide for the first question.



Note to instructor:

Question:

Differential Monitoring proposes that regulatory compliance is not always about achieving 100% adherence to all rules, but rather about finding a balance between "do no harm" rules and "best practice" standards.

a. True (CORRECT)

b. False

Review the following slides if needed:

- Differential Monitoring versus One-Size-Fits-All
- Do Things Well versus Do No Harm
- Theory of Diminishing Returns

Instructor Note: Ask a follow up question if time and interest allows:

Knowledge Check

Learning Objective: Identify the overarching theoretical approaches to regulatory science in licensing.

Question #2

_____ theory focuses on preventing non-compliance through the fear of punishment, while _____ theory emphasizes the importance of trust with the oversight agency and acceptance of the law and its enforcement.

a. Deterrence & Regulatory Compliance
b. Relative & Differential
c. Deterrence & Legitimacy

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Note to instructor:

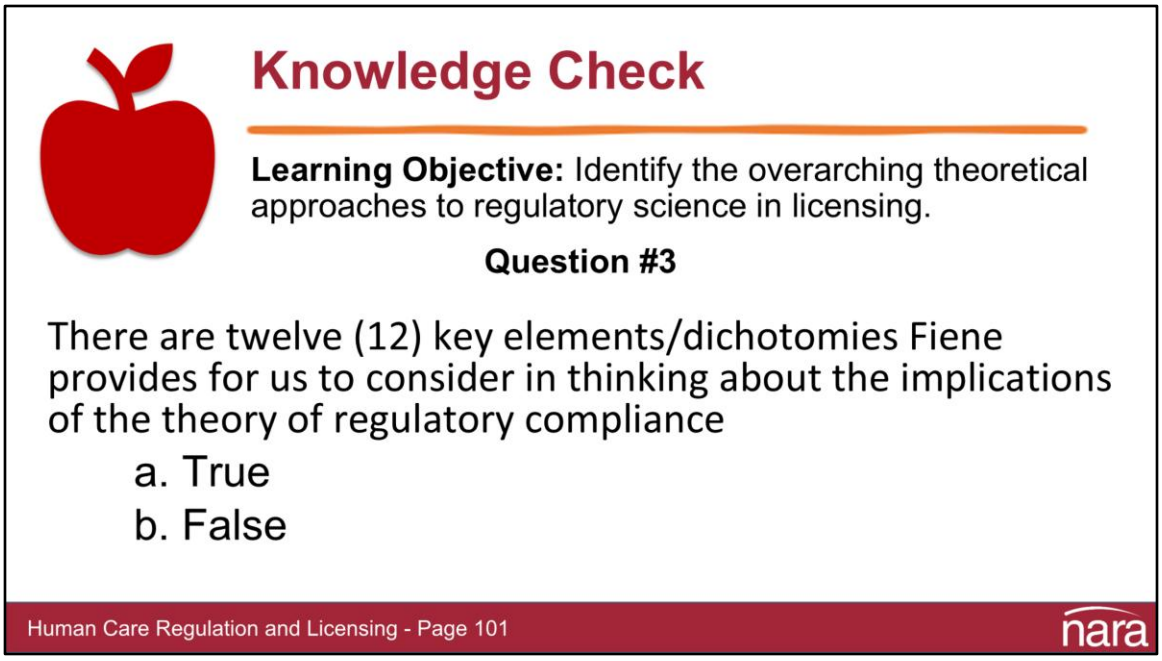
Question:

_____ theory focuses on preventing non-compliance through the fear of punishment, while _____ theory emphasizes the importance of trust with the oversight agency and acceptance of the law and its enforcement.

a. Deterrence & Regulatory Compliance
b. Relative & Differential
c. **Deterrence & Legitimacy (CORRECT)**

Review the following slide if needed:

- Deterrence Theory
- Legitimacy Theory



Note to instructor:

Question:

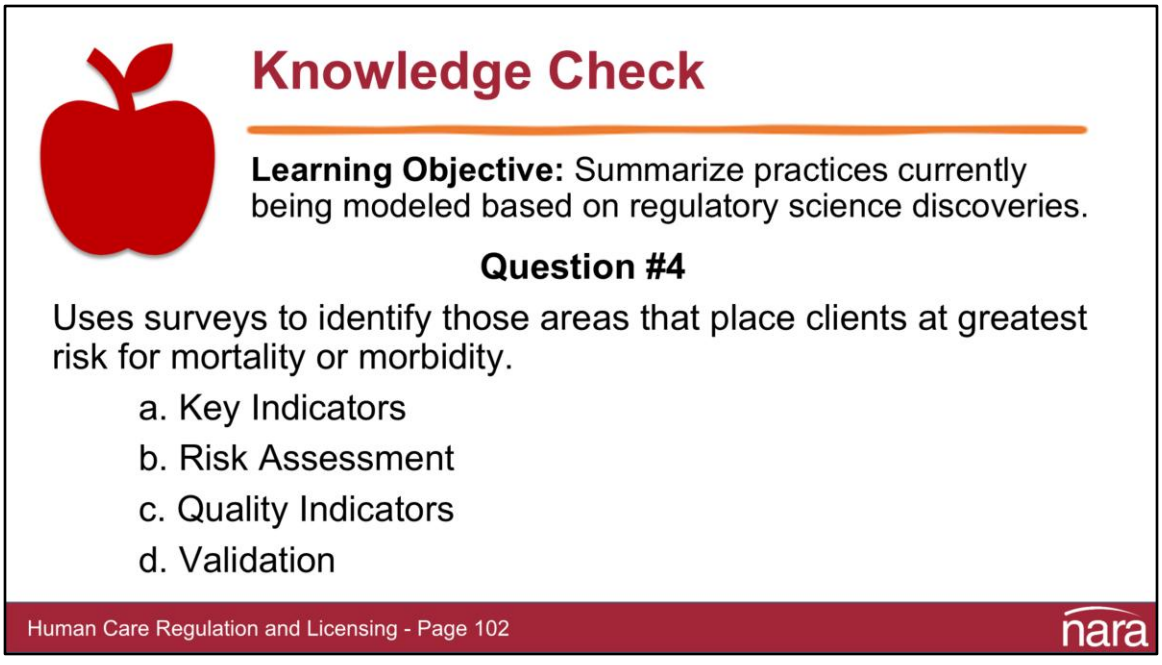
There are twelve (12) key elements/dichotomies Fiene provides for us to consider in thinking about the implications of the theory of regulatory compliance

a. True
b. **False (CORRECT)**

Review the following slide if needed:

- Theory of Regulatory Compliance

Bonus Question: Can you name each of the 8 paradigms?
Answer:
Relative vs. Obsolete
Substantive vs. Monolithic
Differential vs. One-Size Fits All
Do things well vs Do No Harm
Strength Based vs. Deficit Based
Formative vs. Summative
Quality vs. Compliance
Non-Linear vs. Linear



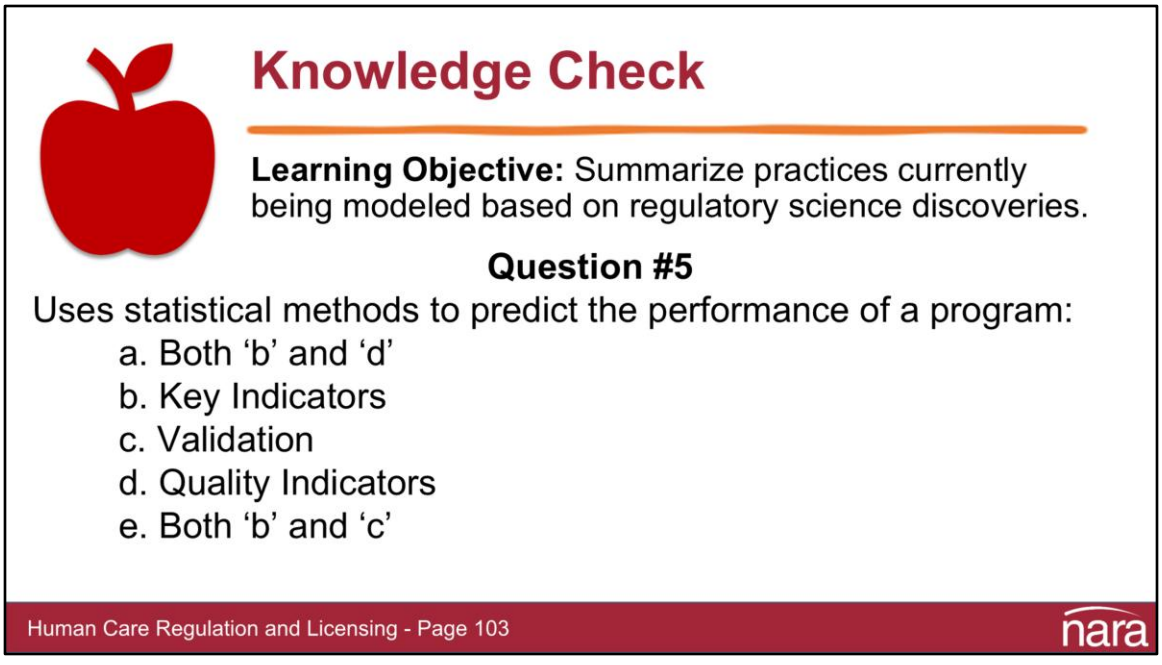
Note to instructor:

Question:

Uses surveys to identify those areas that place clients at greatest risk for mortality or morbidity.
a. Key Indicators
b. **Risk Assessment (CORRECT)**
c. Quality Indicators
d. Validation

Review the following slide if needed:

- Risk Assessment



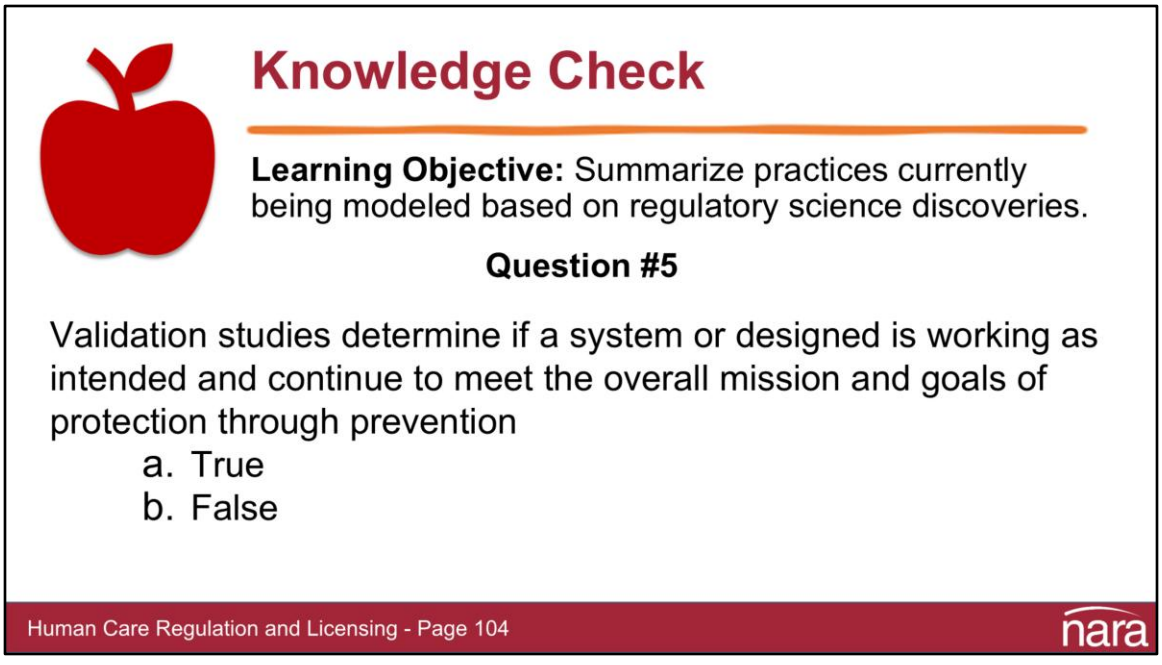
Note to instructor:

Question:

Uses statistical methods to predict the performance of a program:
a. **Both 'b' and 'd' (CORRECT)**
b. Key Indicators
c. Validation
d. Quality Indicators
e. Both 'b' and 'c'

Review the following slide if needed:

- Key Indicators
- Quality Indicators



Note to instructor:

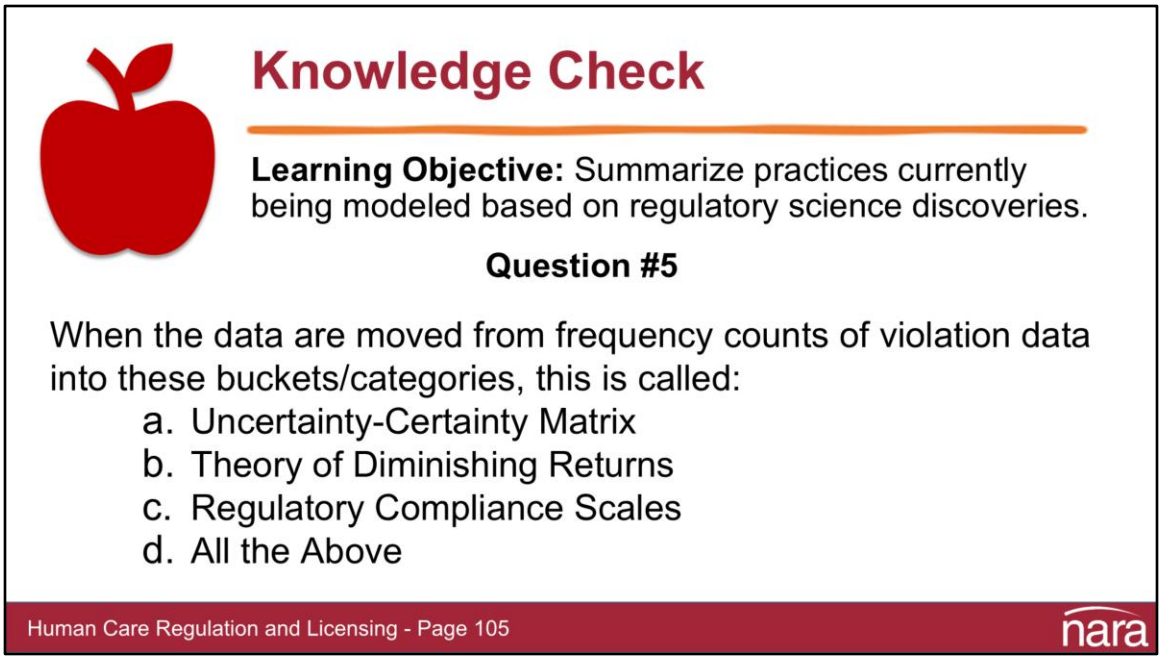
Question:

Validation studies determine if a system or designed is working as intended and continue to meet the overall mission and goals of protection through prevention

a. **True (CORRECT)**
b. False

Review the following slide if needed:
- Validation

Instructor Note: Ask a follow up question if time and interest allows:



Note to instructor:

Question:

When the data are moved from frequency counts of violation data into these buckets/categories, this is called:

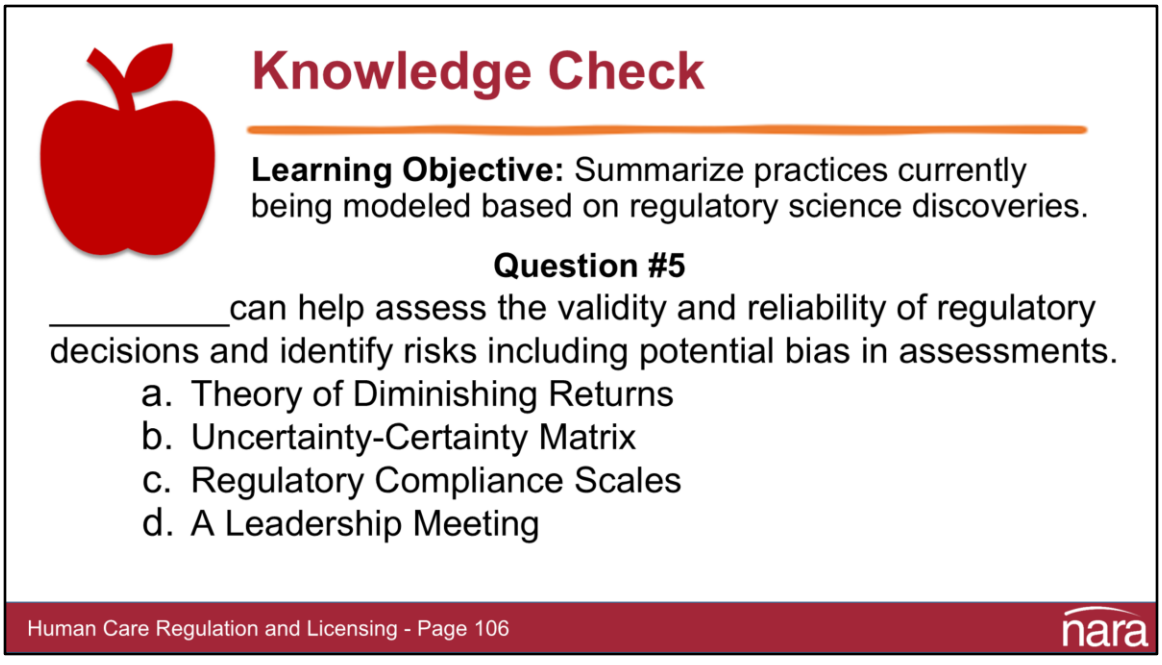
a. Uncertainty-Certainty Matrix
b. Theory of Diminishing Returns
c. Regulatory Compliance Scales (CORRECT)
d. All the Above

Review the following slide if needed:

- Regulatory Compliance Scales

Instructor Note: Ask a follow up question if time and interest allows:

Bonus Question: Can you explain how this benefits licensing programs?
Answer: Research into regulatory compliance data distributions and has shown that utilizing a scale rather than just counting the number of violations is a better metric in measuring a program's regulatory compliance



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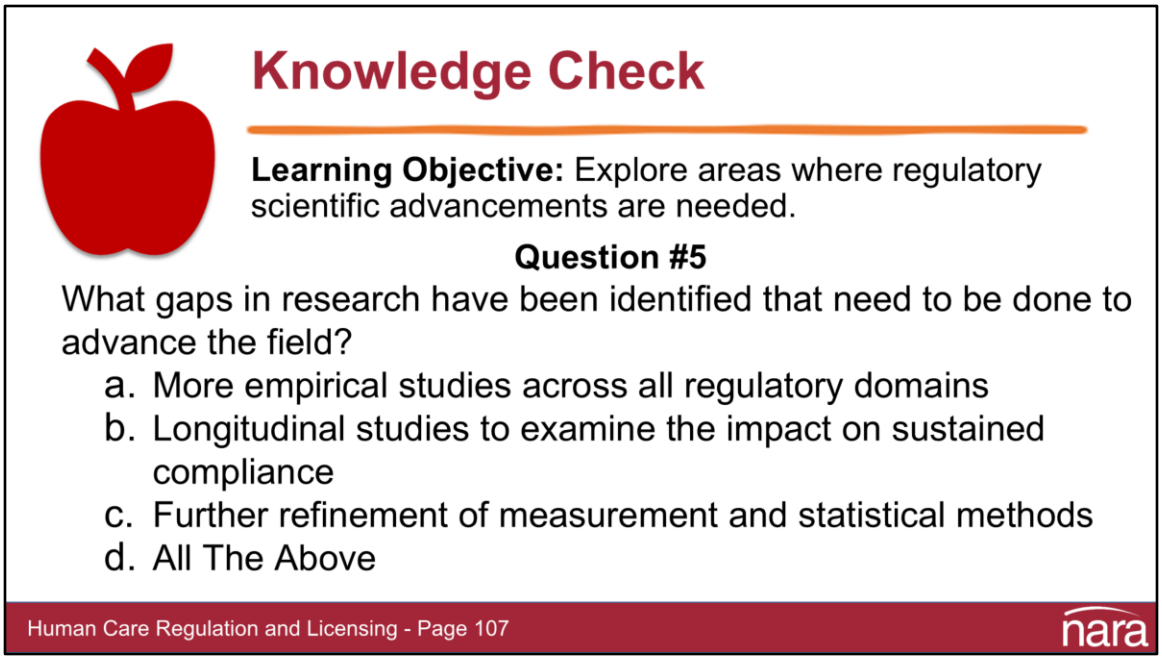

Note to instructor:

Question:

What gaps in research have been identified that need to be done to advance the field?

a. More empirical studies across all regulatory domains
b. Longitudinal studies to examine the impact on sustained compliance
c. Further refinement of measurement and statistical methods
d. All The Above (CORRECT)

Review the following slide if needed:

- Reflecting to Make Connections

Instructor Note: Ask a follow up question if time and interest allows:

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