INTRODUCTION

TO

REGULATORY ENGINEERING

A. Alan Moghissi

Arnold Feldman

INTRODUCTION

Regulatory engineering as applied to the regulatory process has been practiced for several decades, but only recently has it been recognized as a new engineering discipline. However, there appears to be some confusion on the nature of regulatory engineering and the most prevalent vision is that it deals with how one complies with regulations notably occupational safety and environmental. In fact, regulatory engineering is a part of technical area which includes all scientific disciplines ranging from natural sciences, social sciences, medicine, to engineering. Regulatory science, including regulatory engineering, is traceable to certain actions at the U.S. Environmental Protection Agency which lead to the formation of the Institute for Regulatory Science (RSI) in 1985. Many engineering disciplines include activities dealing with regulatory engineering. Consequently, there are regulatory mechanical engineering, regulatory chemical engineering, regulatory civil engineering, etc. Probably the engineering profession that first recognized regulatory engineering as a new engineering field was the American Society of Mechanical Engineers, also known as ASME International.

The classical evolution of technology based on engineering research follows a four-step process. As shown In Figure 1, the process starts with research, typically leading to a publication. The third step consisting of pilot plant attempts to scale up the process. There is a major difference between many parameters in laboratory/development scale and production-scale activities. For example, heat transfer in the laboratory-scale studies are reasonably fast. In contrast, heat transfer in production from one point to the entire production is of concern. In the past and to some extent today, pilot plants, consisted of a reasonably large-scale facility but not producing a product for sale.

The advancement of mathematical modeling has significantly reduced the need for a physical pilot plant. Regulatory engineer needs to know the level of maturity and the level of reliability of the engineering specifically for permit application, preparation, and other governmental requirements.

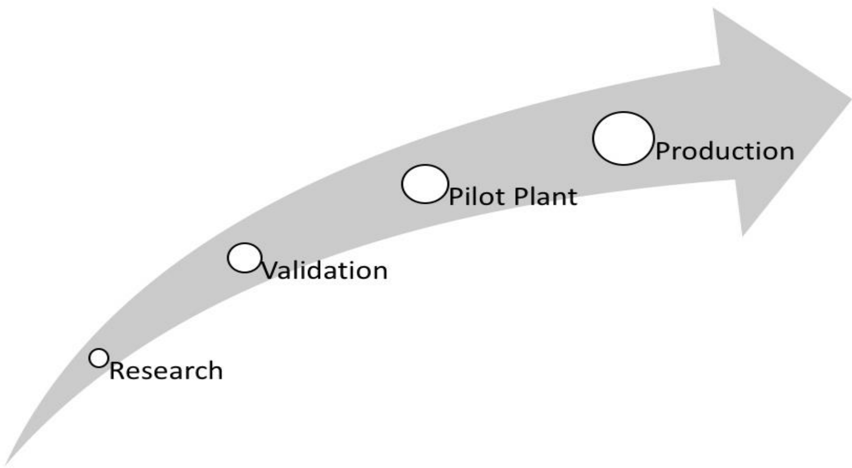

Figure 1. Evolution of Technology

There is a widespread confusion on the definition of regulatory science including regulatory engineering. Based on the definition of regulatory science, regulatory engineering can be generally defined as:

> *Regulatory engineering consists of applied version of various engineering disciplines to the regulatory judicial, and legislative processes.*

The community of regulatory engineering consists of the following:

1. Engineers working at regulatory agencies at Federal, State, Tribal, and Local agencies. These include, but are not limited to, Environmental Protection Agency, Fish and Wildlife Service, Food and Drug Administration, Nuclear Regulatory Commission, the Departments of Labor, and the Department of Interior. This group develops regulations and applies them to licensing, permitting and enforcement of the Regulated Community.

2. Engineers supporting the regulated community. To be more specific, certain regulatory engineers perform analysis and evaluation of construction, operational or industrial projects and processes to ensure regulatory compliance with engineering or architectural standards, practices, principles and methods. Regulatory engineers may serve as a project coordinator and provide guidance and direction to engineering or architectural consultants and assigned specialists, technicians and inspectors.

3. The Engineering Community with a vested interest in regulatory engineering including members of the engineering profession (i.e., members of professional societies such as ASME), academia, legislators, non-governmental organizations and the public.

As described later in this document, regulations are often developed based on insufficient technical information. The technical staff of regulatory agencies try to use existing technical information by making assumptions and similar processes. Many publications that attempt to respond to regulatory needs include assertions or “claims”. The results of these publications are not necessarily reproducible unless their assumption, assertion or claims are included in the reproduction process reevaluation.

METRICS FOR EVALUATION
REGULATORY ENGINEERING CLAIMS

The Metrics for the Evaluation of Regulatory Engineering Claims (MEREC) were developed based on Best Available Regulatory Science and Metrics for Evaluation of Regulatory Scientific Claims to address the unique nature of regulatory engineering and provide avenues for addressing its needs. As shown in Figure 2, the MEREC is based on five general Principles of Best Available Regulatory Engineering that follow and three Pillars of Engineering Claims below. The Principles of Best Available Regulatory Engineering are:

1. **Open-Mindedness Principle:** Every claim on the development of a new technology/product or identification of a potential human health/environmental problem requires the willingness to carefully evaluate the claim. Although this principle is a key to all technological advancements the past theocracies, governmental agencies, and many others have rejected an idea because of the lack of appreciation for innovative processes.

2. **Skepticism Principle:** It is incumbent upon those who make a technical claim to provide sufficient scientific and technical evidence supporting their claim. There is no contradiction between this principle and the *Open-Mindedness Principle* as the technical community has developed well-established processes to provide opportunity to those who make a claim to provide the necessary evidence. Note that the EPA plays a key role in reaching the balance.

1. **Engineering Rules Principle:** One of the most important subjects in MEREC is compliance with Engineering Rules Principle. All scientific and engineering disciplines use certain accepted methods, processes, and techniques in pursuit of their technical activities.

2. **Ethical Rules Principle:** This principle covers several elements including:

   - Truthfulness,
   - Communicability,
   - Transparency, and
   - Engineering ethics.

   This Principle requires that those who make an engineering claim must describe their assumptions, judgments, and default data in a language that is understandable to the affected communities. In addition, they must also describe if their engineering claim includes areas outside the purview of science and engineering. Violation of this principle is one the primary reasons for disagreements of technical foundation of policy decisions and numerous other areas of public interest.

   A key element of Ethical Rules Principle is the application of Jeffersonian Principle initially promoted by William Ruckelshaus; the first administrator of the Environmental Protection Agency (EPA) who returned to the EPA during the Reagan administration. Jeffersonian Principle may be used to categorize the recipient of technical information as follows

The Jeffersonian Principle categorizes the recipient of technical information into three groups. The first group consists of specialists in relevant engineering. The second group consists of knowledgeable non-specialists and third group is the general public, sometimes referred to as six graders.

The Jeffersonian Principle provides a process to implement the Ethical Rules Principle of Regulatory Engineering by requiring that regulatory engineering information must be translated into a language that is understandable to knowledgeable non-specialists especially fellow engineers. The overwhelming majority of business management individuals, engineers, scientists, elected individuals, and appointed officials fall into this category.

3. **Reproducibility Principle:** The ultimate proof of the validity of a claim dealing with technical information is to be reproducible by those who have the necessary competency, skills and needed equipment and facilities to reproduce the claim.

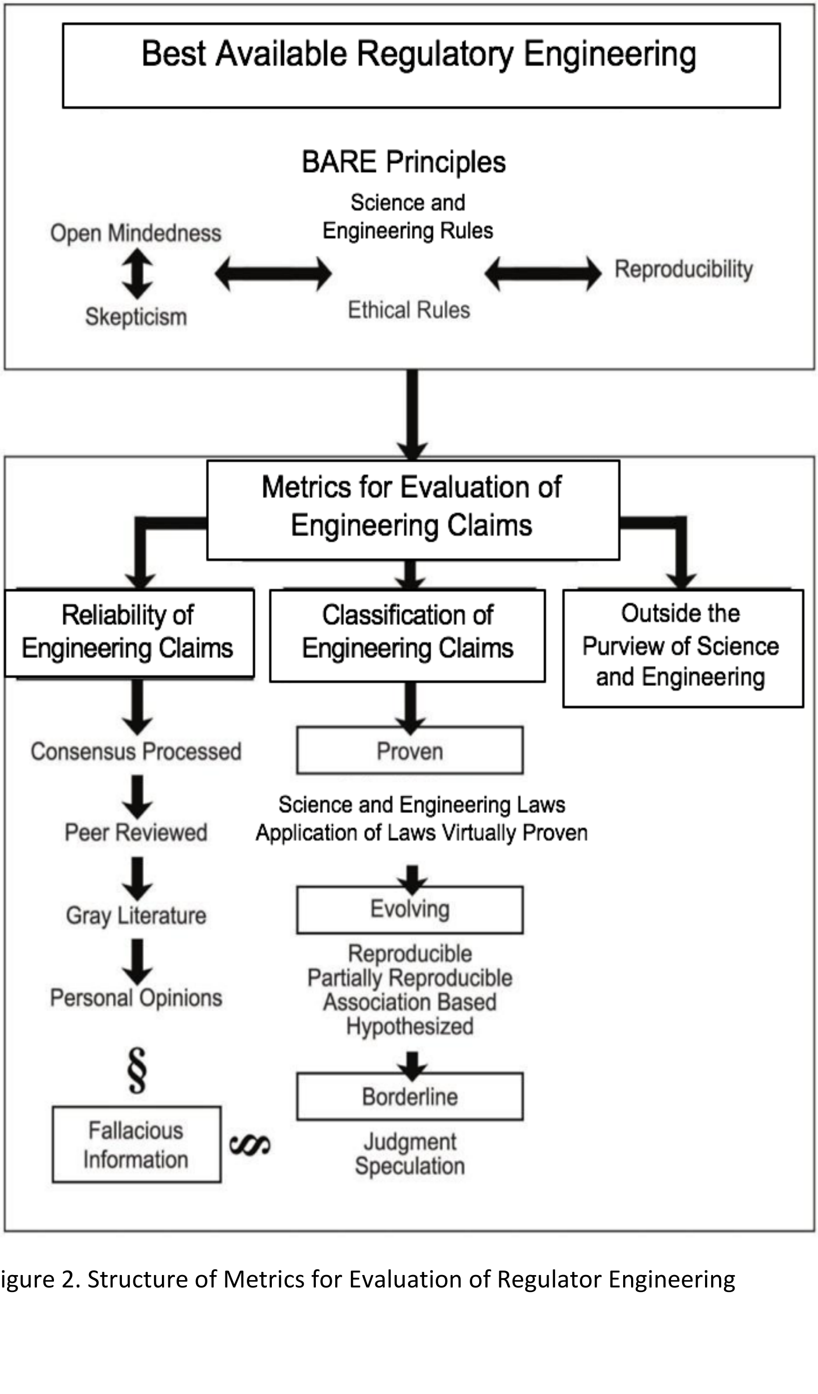

Figure 2. Structure of Metrics for Evaluation of Regulator Engineering

PILLARS OF ENGINEERING CLAIMS

Pillar I: Classification of Engineering Claims

One of the primary reasons for the uniqueness of regulatory engineering is the need to consider the level of maturity of a regulatory engineering claim. Surely one would have more confidence in a claim that is based on a scientific law and engineering principles as compared to a judgment of an engineer or a scientist.

1. **Proven Science and Engineering Claim:** The cornerstone of this claim is compliance with *Reproducibility Principle* implying that any investigator who has the necessary education, skills and the proper equipment can reproduce it. Therefore, this technical information does not require assumptions or any other conditions for its validity. This claim includes those segments of applied sciences and engineering that are entirely based on scientific laws and engineering principles that exclude assumptions.

2. **Evolving Engineering Claims:** The overwhelming technical advances in virtually all disciplines are evolving engineering claims. As the following description shows one can identify many groups within this pillar, however, it is likely most of these would be a subpart of the following claim or pillar.

   - **Reproducible Engineering Claims:** Reliable information dealing with a subject that is not completely understood constitutes the core of this claim. The engineering claim in this class must comply with *Reproducibility Principle*. Advancements in various engineering; and related disciplines are based on the desire of investigators to improve knowledge.

- **Partially Reproducible Engineering Claims:** This claim consists of an extension of the applicability of a technology or an engineering activity beyond its original design.

- **Association Based Engineering Claims:** This claim is based on the notion that comparing two engineering techniques, one functioning and other one not functioning, can lead to the assessment of the cause of failure.

- **Hypothesized Engineering Claims:** As the title implies this claim attempts to convert an observation or thought to a potential technology or an engineering activity.

3. **Borderline Engineering Claims:** In many cases the society is facing a decision to take or not take an action without having any engineering information. The two classes in this category are:

- **Technical Judgment:** If a decision must be made without having the needed information, the necessary data, or other technical requirements and skills a process known as expert judgment is used. It consists of asking several presumably knowledgeable individuals to give answers to specific questions and statistically assess the results. Note that information in this class is often an educated guess.

- **Speculation:** This claim consists of information that cannot meet standards described in any of the above classes. It is often based on the intuition of an individual who wants to stimulate a discussion or initiate a research project.

4. **Fallacious Information:** Also known as a fallacious engineering claim, this class is the engineering version of “pseudoscience”, “junk science”, or “politically-processed science”. There are those who justify the dissemination of Fallacious information on basis that it is necessary to exaggerate a problem in order to move the population to accomplish a noble goal. What is being overlooked is the long-term damage that misinformation causes.

Pillar II: Assessment of the Reliability of Engineering Claim

One of the key issues in managing regulatory engineering is the reliability of technical information. A regulator, a judge, a legislator, or those who are being regulated must be convinced that the technical foundation of the regulatory decision is sound. The reliability of regulatory engineering, can be categorized as follows:

1. **Personal Opinions:** Expression of views by individuals regardless of their training, education, experience, social agenda, or their technical validity is the foundation of a free society.

2. **Gray Literature:** Written information prepared by government agencies, advocacy groups, and individuals that have not been or cannot be “peer reviewed” falls in this category and often is the written version of personal opinions.

3. **Peer-Reviewed Engineering Claim:** The value of "peer review" and similar processes in assessing the validity of technical assertions has been known and accepted for at least two centuries. Peer review is used routinely by editors of technical journals to accept, reject, or ask for revision of a submitted manuscript. It is also the standard process used by funding agencies to evaluate a submitted request for funding. It is also the process used by commercial/industrial entities to accept research and development for further commercialization. Independent peer review is also truly the only option to evaluate regulatory engineering claims.

4. **Consensus-Processed Engineering Claim:** This category consists of information resulting from a process used to resolve disputes, particularly those in contested areas of regulatory engineering. This process is particularly useful for information that includes assumptions, judgments, inclusion of default data and other areas.

Pillar III. Areas Outside the Purview of Science and Engineering

One of the most complex and often misused or abused area of regulatory engineering is the intrusion of societal goals, ideology, and numerous nontechnical subjects in regulatory engineering decisions. The intrusion of religion, ideology, or any other societal objective in the regulatory engineering process inherently jeopardizes the objectivity and consequently the acceptability of technical information.

The role of the engineer is to provide engineering options that underlies a potential regulatory decision. Although the religious, cultural, and tradition of various countries such as US, India, Germany, Brazil, Israel, and Saudi Arabia are different, the engineering foundation of a regulatory decision, with few exceptions, should be similar in these countries.

THREE PHASES OF REGULATORY ENGINEERING

The application of regulatory engineering is Similar to regulatory science, and is based on three phases:

1. During the first *Initial Phase* regulations are promulgated although the needed scientific and engineering information is less than adequate. The decisions in the phase are based on following:

    - There are legal mandates with a deadline.
    - A device or equipment is needed to save human life or protect the environment, and there is no alternative for that item.
    - The approval would enhance the quality of life or environment.

2. During the second *Exploratory phase* an attempt is made to enhance the relevant knowledge. In addition, the engineering consequences of the first phase are evaluated. In many cases, research and development are initiated with the objective not only to evaluate the initial decision but to evaluate potential alternatives.

3. Finally, during the *Standard Operating Phase*, the results of the second phase are used to reach a decision that improves the reproducibility of the objective of the approved item. There is ample evidence that in many cases that *Standard Operating Phase* decisions may have to be reevaluated based on evolution of technology, replacement of a segment of a device/equipment or other reasons. However, in effect the process consists of repeating the second phase.

APPLICATION OF REGULATORY ENGINEERING

A detailed description of the application of regulatory engineering discipline is far beyond the scope of this

document. However, it should be recognized that there are numerous areas that are common to all regulatory engineering disciplines. Some of the more general categories of Regulatory Engineering are:

- Legislative support
- Regulatory development and comment
- Guidance development
- Licensing and permit application development and review/approval
- Regulation compliance and enforcement
- Litigation and support
- Remedial action oversight
- Education and teaching

Therefore, it is imperative to ensure that:

1. Uncertainties, judgments, and the inclusion of default data and similar areas in the decision process are clearly and unambiguously identified.

2. Regulatory Engineering decisions should exclude areas outside the purview of best available regulatory engineering and if not excluded, their inclusion must not only be justified but their details are identified and described.

3. Best engineering practices and ethics should be continuously used. These should include engineering economic in the decision process.

4. Personal preferences and outside influences should be limited in engineering decisions.

5. Undue economic influences should not “cloud” engineering input or decisions.

Finally, if probably performed, the application of the three phases would move the level of maturity of MEREC. In order words the process would improve the reproducibility of applied engineering.

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ABOUT THE AUTHORS:

A Alan Moghisi

Alan Moghissi is President of the Institute for Regulatory Science, and an adjunct professor at Georgetown University School of Medicine. Dr Moghissi has served as senior manager at Environmental Protection Agency He is a fellow of ASME and was associated with several universities. He is an honorary member of the National Council on Radiation Protection and Measurements; and an Academic Councilor of the Russian Academy of Engineering. He is a former Councilor of the University of Puebla (UPAEP) Mexico; and a Commissioner of UNESCO. He is the recipient of many awards including the Distinguished Service Award of the EPA. He also managed over 300 independent peer reviews and scientific assessments for the US Congress and government agencies at federal, state, and local levels. Alan Moghissi received his education in Zurich, Switzerland at the University of Zurich and Federal Institute of Technology (ETH) and the Karlsruhe Institute of Technology in Germany, where he received a doctorate degree in physical chemistry.

Arnold Feldman

Arnold Feldman is ASME Fellow and AIChE Senior Member with Bachelor in Chemical Engineering from New Mexico State University. Before beginning regulatory work, he served in a variety of engineering and production positions at industrial facilities. He Then became the Environmental Manager at a large chemical plant in Illinois for Olin Corporation where he was responsible for overall compliance of the plant. Since then he has held numerous positions in the environmental field with a heavy concentration on compliance monitoring, remedial programs, training and assistance for a wide range of heavy industrial facilities concentrating on waste issues. Arnold started JJDS Environmental in 2000, a full service Environmental, Quality, and Safety consulting firm that is dedicated to balancing legal requirements and cost. He is currently semi-retired and spends most of his time volunteering for ASME.