

Regulating Ionizing Radiation Based on Metrics for Evaluation of Regulatory Science Claims

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Abstract

This article attempts to reconcile differences within the relevant scientific community on the effect of exposure to low levels of ionizing radiation notably the applicability of linear nonthreshold (LNT) process at exposures below a certain limit. This article applies an updated version of Metrics for Evaluation of Regulatory Science Claims (MERSC) derived from Best Available Regulatory Science (BARS) to the arguments provided by the proponents and opponents of LNT. Based on BARS/MERSC, 3 categories of effects of exposure to ionizing radiation are identified. One category (designated as S) consists of reproducible and undisputed adverse effects. A second category (designated as U) consists of areas where the scientific evidence for potential adverse effects includes uncertainties. The scientific evidence in the U category leads to a threshold. In contrast, the scientific foundation of the third category (designated as P) is questionable, as the scientific evidence indicates that adverse effects of the exposure at this level are not only questionable but may be helpful. This article claims that the third area is the domain of policy makers including regulators. This article describes Jeffersonian Principle that categorizes the affected community into specialists, knowledgeable nonspecialists, and the general public. Based on Jeffersonian Principle, the relevant scientific information, particularly the U and P areas, must be translated into a language that at a minimum is understandable to the knowledgeable group. Once this process is completed, the policy makers including regulators may select exposure limits based on their judgment.

Keywords

linear nonthreshold, science vs policy, Best Available Regulatory Science, Jeffersonian Principle

Introduction

There is a long history going back more than a century, of studying the carcinogenic effects of exposure to low levels of ionizing radiation. There are several international organizations such as the International Commission on Radiological Protection (ICRP) and United Nations Scientific Committee on Effects of Atomic Radiation (UNSCEAR) that have provided many reports addressing this important issue. In the United States and other countries, there are scholarly organizations that have also addressed the same issue. In the United States, these organizations include the National Academies (NA) consisting of National Academy of Sciences, National Academy of Engineering, and National Academy of Medicine; and the National Council of Radiation Protection and Measurements (NCRP). Typically, these organizations not only employ but are also supported by individuals with unique distinction and exceptionally recognized scientific accomplishments. Currently, these and many other organizations rely upon the

so-called linear nonthreshold (LNT) process for assessing the consequences of exposure to ionizing radiation. A detailed review of the biological effect of ionizing radiation is beyond the scope of this article. Calabrese¹⁻³ provides an extensive review of the historical evolution of the LNT process. The subject has also been extensively addressed in numerous publications of national and international organizations, including

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UNSCEAR,⁴ ICRP,⁵ NA,⁶ and NCRP.⁷ Although these and many other scholarly organizations explicitly recognize uncertainties associated with potential effects at low doses, they recommend the application of LNT process in societal decisions. A useful chart summarizing dose ranges of exposure to ionizing radiation has been prepared by Metting.⁸

Based on the recommendations of these scholarly organizations, currently, all regulatory agencies in the United States and most other countries use the LNT process for assessing the risk of exposure to ionizing radiation. For example, the regulations of the Environmental Protection Agency (EPA)⁹ permit emissions up to 10 mrem/year (0.1 mSv/year). Although often the existence of beneficial effects of exposure to ionizing radiation (known as hormesis) is recognized, in most cases, the authors of these reports implicitly or explicitly recommend the application of LNT process, based on their desire to be protective. The only scholarly organization that have avoided such an approach is the French equivalent of the NA,¹⁰ suggesting a threshold and thus disagreeing with LNT.

In the last decade or so, many members of the relevant professions increasingly have demanded a reevaluation of the LNT process. There are many publications claiming the usefulness of LNT and many others that represent the opposite view. For example, Calabrese¹¹ refers to the current status of application of LNT as “LNT gate.” There were also exchange of letters between Beyea¹² and Cuttler¹³ highlighting the contested validity of this process. Cuttler claimed that the time has come for regulators to recognize that the application of the LNT process is not only wrong, but that there is evidence that at low levels, ionizing radiation has beneficial effects known as hormesis.¹⁴ In contrast, Beyea claimed that LNT is valid and correctly used for regulating exposure to ionizing radiation. The process described in this article demonstrates that this disagreement is not based on credible scientific process but on the judgment of the authors.

The study leading to the preparation of this article was the result of the development of a new regulatory science program at Georgetown University. That program covers all scientific disciplines, rather than the current programs that cover areas regulated by the Food and Drug Administration (FDA). In 2 previous articles, Moghissi et al^{15,16} attempted to apply regulatory science approach to the LNT process. This article expands the coverage of those articles by using the assessment systems described in the next section to identify the respective roles of the relevant scientific community, the regulators, and the affected community. A key element of the process is the communication of relevant science to the affected community and others such as legislators.

Assessment Process

The assessment process used in this article is based on regulatory science¹⁷ and consists of updated version¹⁸ of the process described in previous by Moghissi et al.^{17,18} Briefly, one of the key elements or tools of regulatory science is the Best Available Science (BAS) and Metrics for Evaluation of Scientific

Claims (MESC). Due to the unique nature and complexity of regulatory science, the BAS/MESC system evolved and improved. The recent reevaluation of BAS/MESC to regulatory science issues such as LNT resulted in retitling the BAS to Best Available Regulatory Science (BARS) and MESC to Metrics for Evaluation of Regulatory Science Claims (MERSC). Figure 1 shows the updated process. Although certain segments of the BARS/MERSC were described in previous publications including the article by Moghissi et al,¹⁷ for the sake of clarity, the entire process is summarized as follows:

Five principles constitute the foundation BARS: The Open-Mindedness and Skepticism Principles imply that the scientific community and the regulators must be open-minded and must consider new claims, but those who make a claim must provide evidence on the validity of their claim. The Scientific Rules Principle addresses processes, methods, and approaches in scientific research, development, and publications. The Ethical Rules Principle is particularly relevant to the evaluation of the LNT process and will be discussed later in this article. Finally, the Reproducibility Principle implies that ultimate proof of a scientific claim must be reproducible by those who have the necessary competency and relevant research tools and facilities.

Three pillars are derived from BARS principles and constitute MERSC. The pillar on reliability of regulatory science identifies 4 categories consisting of personal opinions, gray literature and peer-reviewed and consensus-processed scientific claims. Note that gray literature refers to reports prepared by various organizations that have not been subjected to independent peer review. The pillar on classification of regulatory science identifies 3 groups consisting of proven, evolving, and borderline science. Finally, the pillar on areas outside the purview of science implies that science may not include ideology, belief, or any other societal objectives.

Key Sections of BARS/MERSC Applicable to LNT Evaluation

The following key areas of BARS/MERSC that are critical in evaluating the LNT are briefly addressed.

Truthfulness. One of the key elements of Ethical Rules Principle of BARS is truthfulness. Although the desirability of truthfulness is universally accepted, it is not uncommon that many organizations exaggerate or minimize the impact of an agent, an action, or a situation.

Communicability. Another element of Ethical Rules Principle is communicability requiring that regulatory science claim be translated into in language that is understandable by the affected communities. The Jeffersonian Principle described below is a key tool for implementation of communicability.

Transparency. Regulatory science, including LNT, is predictive in nature and inherently includes uncertainties. The Ethical Rules Principle requires that all assumptions, judgments,

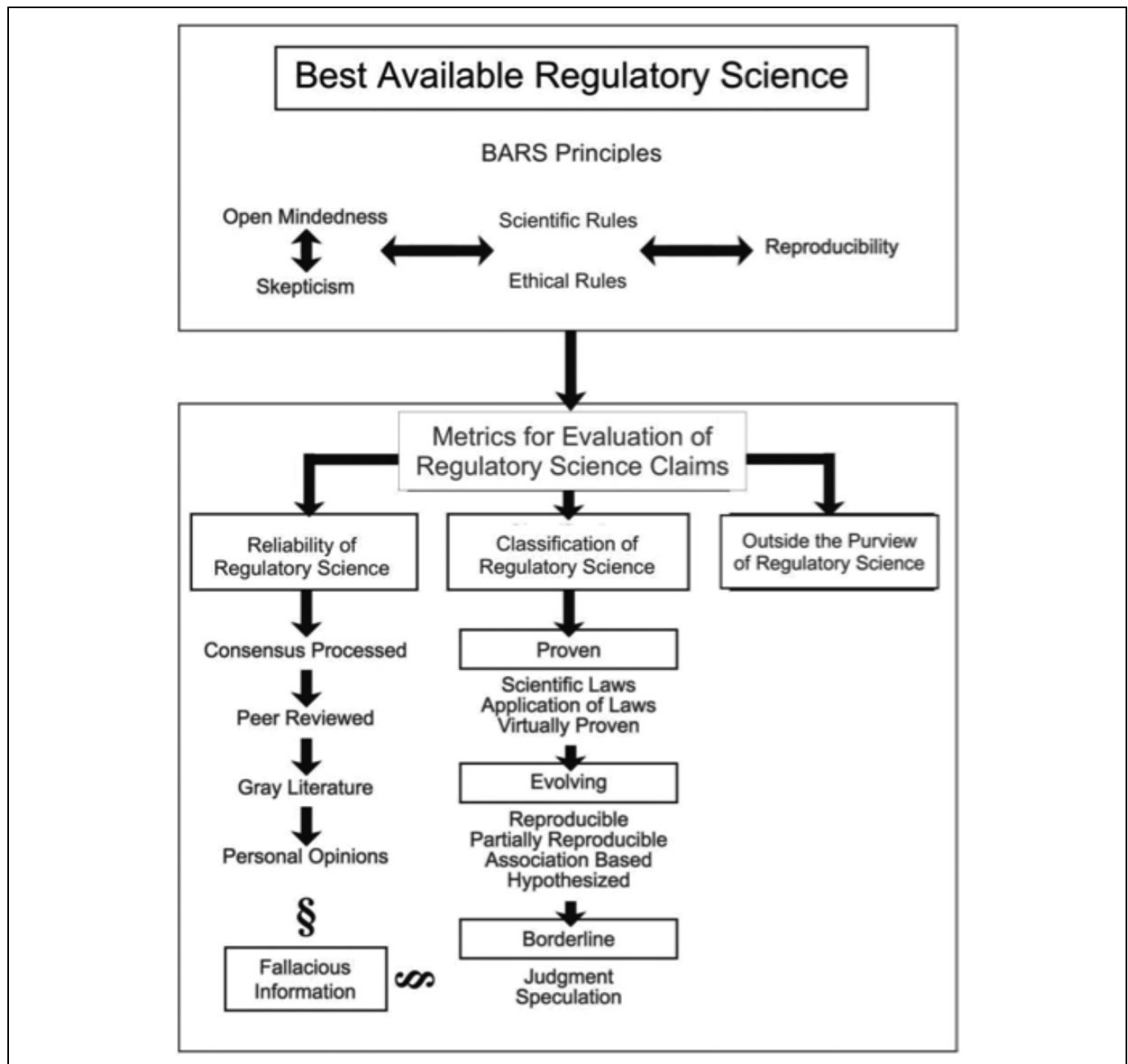


Figure 1. Structure of BARS and MERSC. BARS indicates Best Available Regulatory Science; MERSC, Metrics for Evaluation of Regulatory Science Claims.

inclusion of default data, or any other issue that led to a conclusion must be identified and provided to the affected community.

Scientific ethics. The relevant ethical requirements are extensively addressed by regulations, guides, and international agreements. In addition, as reported by Moghissi et al,¹⁸ scientific ethics includes regulatory science ethics. One of the key elements of scientific ethics is as follows:

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.

Jeffersonian Principle. William Ruckelshaus, the founding administrator of the EPA, introduced the Jeffersonian Principle.¹⁹ Thomas Jefferson, the third president of the United States, recognized the significance of providing information to the public by stating “If we think [the people are] not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion by education.” As described by Diamond,²⁰ there

are those who disagree with Jeffersonian Principle and occasionally claim that members of the public are “stupid.” Based on the Jeffersonian Principle, the regulatory science process categorizes the affected community as follows:

Specialists. This group consists of individuals who, based on their education and experience, have sufficient knowledge to understand specific scientific subjects.

Knowledgeable nonspecialists. This group is of significance as it includes individuals who have sufficient education and experience to comprehend scientific claims, provided they are written in language that is understandable to members of this group. For example, mathematical equations must be described in words; unique terminologies, vocabulary, abbreviations, acronyms, and any unique processes must be described in a language that a knowledgeable individual can follow. Members of this group include educated individuals, most policy makers, and others with sufficient background knowledge to follow scientific issues that are written for this group.

Others. Originally, the Jeffersonian Principle was intended to address the needs of all citizens, regardless of their education. Ideally, the process described for knowledgeable individuals should be appropriately modified to also cover this group.

Application of Assessment Tools

The primary task of this study was to evaluate the existing literature on LNT with the objective to categorize various claims using BARS/MESC system and Jeffersonian Principle.

Assessment of Level of Maturity of Various Segments of LNT

The literature includes several studies that identified level of maturity of science used in the LNT process. Two statements are of particular significance as follows:

The first statement originated from Health Physics Society (HPS), a key professional society dedicated to radiation protection²¹ by identifying major needs for revision of regulating exposure to ionizing radiation. According to HPS, “Linearity at low dose may be rejected for a number of specific cancers . . .” and “Underlying dose–response relationships at molecular levels appear mainly nonlinear.” Similarly, HPS suggests that “Considerable uncertainties remain for stochastic effects of radiation exposure between 100 mSv and 1000 mSv . . .”

The second statement originated from the French equivalent of the NA,¹⁰ suggesting a threshold and thus disagreeing with LNT.

Inclusion of Areas Outside the Purview of Science in Scientific Assessments

The support for the LNT by NA, NCRP, ICRP, and many other scholarly organizations is based on the shortage of reliable

scientific information at levels below 100 mSv. As described by Calabrese^{1,2,3,4} and other authors, the reason for choosing LNT is that the authors wanted to be “conservative” or “protective.” The fundamental flaw in such an approach is the confusion between the role of the scientific community and the role of regulators and other policy makers. The scientific community must provide the regulators with accurate scientific information including the level of maturity of each scientific issue. It is the task of the regulators to consider the level of maturity of each scientific item and be protective in their decisions if the needed scientific information is less than adequate. The distinction between the respective roles of the scientific community and the policy makers can be shown by the following example: A scientific assessment that is performed in countries such as Saudi Arabia, Israel, Iran, United States, Russia, China, or Brazil should be identical. In contrast, policy including regulatory decisions derived from scientific assessment is likely to depend upon the many factors such as the culture and tradition of the country.

Health Effects of Exposure at Low Levels of Ionizing Radiation

Several studies have been performed attempting to determine the effects of exposure to low levels of ionizing radiation including those published in this journal. Hendry et al²² provided a comprehensive review of studies dealing with global areas with naturally occurring elevated levels of ionizing radiation with the primary objective to determine how epidemiological studies can be conducted to evaluate effects of exposure to low levels of ionizing radiation. Tao et al²³ analyzed cancer mortality in Yangjiang, China, where the average annual exposure to background radiation was about 6.4 mSv/year, as compared to 2.4 mSv/year in the control area. A study by Cuttler et al²⁴ suggests beneficial effects of exposure to ionizing radiation below 700 mGy/year. The comprehensive study found a slightly smaller level of occurrence of cancer mortality in the high exposure area as compared to the control area, although the difference was statistically insignificant.

Results

The application of BARS/MERSC system provides the opportunity to evaluate the scientific data to categorize health effects of ionizing radiation. In the first step, the level of maturity of scientific foundation of LNT must be identified that ranges across multiple classifications, from Proven to Speculation in Borderline Regulatory Science. In the next step, the inclusion of societal objectives including ideology, religious beliefs, or any other nonscientific objective in LNT-related scientific assessments or other regulatory science assessments should be identified. As stated above, the role of the scientific community is to provide regulators and other policy makers with the level of maturity and reliability of regulatory science claims. Once the level of maturity of science enters Borderline Regulatory Science, the task of the scientific community is to

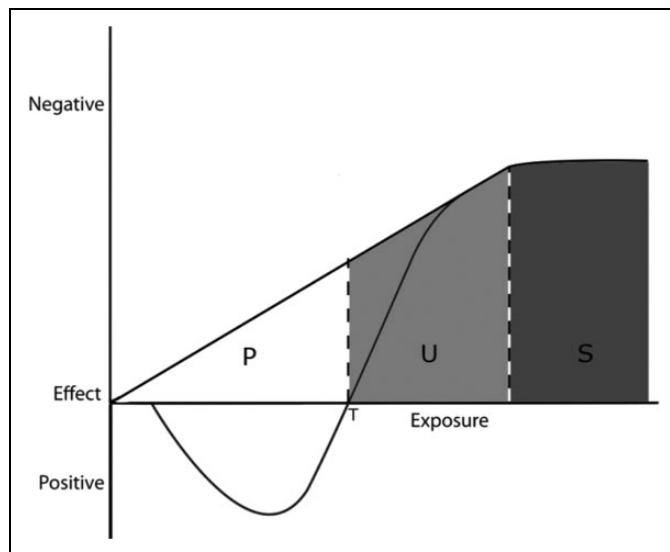


Figure 2. Conceptual description of LNT. LNT indicates linear nonthreshold.

identify what is known and what is unknown and to provide the results of the assessment to the policy makers. Addressing societal objectives is the domain of policy makers and regulators.

Using the statement by HPS²⁵ and the chart prepared by Metting,⁸ the exposure to ionizing radiation can be categorized into 3 groups as shown in Figure 2.

Category 1

This category, designated as S, consists of exposure at 1000 mSv or higher. There is sufficient scientific evidence indicating mortality and other adverse consequences as a result of exposure in this category. Using the BARS/MERSC system, the S area is Proven or Reproducible Evolving Regulatory Science.

Category 2

The area covered by the 2 ends and designated as U consists of exposure between 100 mSv and 1000 mSv. The biological knowledge in this area is limited, but there is reasonable scientific evidence that there is potential risk for adverse consequences of exposure in this region. The point where the vertical curve meets the horizontal line would constitute threshold (T). Based on BARS/MERSC, the area designated as U would qualify as Partially Reproducible Evolving Regulatory Science.

Category 3

The area designated as P is fundamentally based on policy and is the primary area of interest of this article. Based on BARS/MERSC, this category is at best Borderline Regulatory Science consisting of judgment or speculation.

Hormesis

There is evidence that results of new research will require the modification of Figure 2. In this case, based on BARS/MERSC, the area claiming positive health consequences would be placed in Partially Reproducible Evolving Science.

Discussion

This article does not attempt to justify or deny the right of policy makers including the regulators to set up exposure limits. Regulators interpret the legal requirements and may decide the limits that are acceptable in their judgment. The legal process provides opportunities for all groups and individuals including the scientific community to challenge the judgment of regulators. Instead, this article attempts to separate the respective roles of the scientific community versus the responsibility of policy makers. As described above, if exposure at 6.4 mSv/year²² does not cause an adverse effect, obviously setting up a limit at 0.1 mSv/year is not based on science but the desire of regulators to use their policy target. Similarly, as described by Moghissi et al,¹⁷ given the limit of 0.1 mSv/year, how would the regulators tolerate natural exposure at Denver, Colorado, at 1 mSv/year or at Albuquerque, New Mexico, at 1.4 mSv/year. Would it not be logical to evacuate the residents of the 2 cities or any other area where the exposure exceeds the legal limits.

Clearly, in the areas designated as S and U in Figure 2, the scientific community must provide the regulators with sufficient information to develop regulations. In contrast, in the area designated as P, the role of the scientific community is to identify what is known and the existence of contradictory information. In this case, once the necessary information is provided to the knowledgeable group (see Jeffersonian Principle), it is the regulator that must derive societal consequences of scientific judgment or speculation. It is critical to recognize that being protective, conservative, or prudent is outside the purview of science and is the domain of policy makers.

Subsequent to the completion of this article, a new study by Calabrese was published that updated the historic events leading to the adoption of LNT by virtually all regulatory organizations.

Conclusion

There is a need for reassessment of the regulatory process as applied to ionizing radiation. The initial application of LNT process was based on lack of available knowledge. Exposures below 100 mSv (shown in Figure 2 as P) do not necessarily cause harm and may be beneficial. The regulators may have the legal right to identify appropriate exposure limits. However, they may not imply that their decision is based on science, as is currently the case.

Declaration of Conflicting Interests

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