MANUAL

FOR PREPARATION OF

REGULATORY SCIENCE MANUSCRIPTS

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PREFACE

The preparation of this manual was stimulated by activities of students participating in regulatory science courses at Georgetown University leading to the publication of many papers in peer-reviewed scientific journals. During the process of preparation of manuscripts several shortcomings were observed causing unnecessary efforts to comply with requirements of publication process. For example, in many cases students provided an email address for a scientific paper instead of proving a reference common in scientific publications.

This manual is supplementary to the *Regulatory Science Manual,* recently prepared for regulatory science students particularly those at Georgetown University. Although it is prepared for students participating in regulatory science courses, it is likely to be useful for many others. Currently there are many books that describe in detail on how to design a study and prepare a manuscript including numerous instructions for authors provided by publishers, and journals. However, based on the experience of students participating in regulatory courses at Georgetown University, in most cases these documents

have been less than useful for inexperienced authors. Due to the problems identified in referencing various documents, tis manual emphasizes the referencing process.

We are hoping that this manual will provide guidance to students, reduce the efforts of authors including the professors and ultimately stimulate publications by students.

INTRODUCTION

The advancement of scientific areas covered by peer-reviewed journals often requires the participation of individuals from multiple disciplines. It is both desirable and necessary to encourage critical assessments of a distinct area of study such as regulatory science. Critical assessments consist of a critical review of a subject, and an assessment of relevant parameters, such as the status of relevant science, technological advancements, regulatory development at national and international levels, usefulness and economics of various options, and societal acceptability of specific proposed or implemented actions. Due to their unique value, journals accept critical assessments not only in the areas covered by the journal, but also in related areas that directly or indirectly impact its areas of coverage.

The emerging regulatory science discipline requires the participation of individuals from multiple disciplines in addressing discipline specific as well as multidisciplinary scientific issues. Studies that attempt to address regulatory science are often referred to as scientific assessment or critical assessment. For the sake of simplicity these or other scientific documents that are

directly useable in the regulatory or any other policy-making process are referred to as regulatory science assessment. For obvious reasons regulatory science assessments may cover advancements in every regulatory science discipline such as pharmacology; toxicology; many environmental protection areas; occupational safety and health; and other scientific and engineering areas. Regulatory science assessments also consider parameters, such as technological advancements, regulatory development at national and international levels, usefulness and economics of various options, and societal acceptability of specific proposed or implemented actions. Due to their unique value, journals accept regulatory science assessments not only in the areas covered by the journal, but also in related areas that directly or indirectly impact their areas of coverage. The key criteria for the acceptability of regulatory science assessments are:

- The area must be distinct and clearly defined.
- The assessment must either cover the entire literature or more likely, a unique segment of the literature.
- The assessment must be critical in that the reader must be told the level of maturity and

reliability of science, as well as the what is reasonable or what is not.

- The manuscript must be of high scientific quality.
- The manuscript must be original requiring that no assessment by the author or anyone else has been published that covers the same subject.

Regulatory science assessments must be well-organized with appropriate headings and subheadings to facilitate the reading of the text. The reader should be led through the field in such a way to permit the reading of a segment of the text without having to read the entire manuscript or a large segment of the manuscript.

STRUCTURE OF REGULATORY SCIENCE MANUSCRIPTS

A study that leads to regulatory science paper starts with the formulation of questions also known as assessments criteria or questions to be answered during the study. During the next step key elements of assessment criteria are used to search the internet. The result of the internet and other search sources lead to the compilation of the existing relevant literature. One of the processes to evaluate the usefulness of the collected information is Metrics for Evaluation of Regulatory Science Claims (MERSC) derived from Best Available Regulatory Science (BARS). Key useful elements of BARS/MRESC for evaluation of literature search are:

Reliability of Scientific Claims

One of the key elements of reliability of regulatory science claims is peer review. Virtually all scientific journals claim to perform peer review before accepting a submitted manuscript to be published. However, there are many published papers that have been retracted based on errors by the authors, editors, or poor manuscript processing. There are also other documents that have been subjected to independent peer review. The

shortcomings of peer review must be considered in assessing the reliability of scientific claims.

Level of Maturity of Regulatory Science Claims

Most published studies that can be used in regulatory science assessment are Evolving Science as described in BARS/MERSC. The application of these studies would require assumptions, judgments, inclusion of default data, and other non-scientific elements. Also, the conclusions included in the publication often are based on speculation. Therefore, it is imperative that the level of maturity of science is considered in regulatory science assessments.

Areas Outside the Purview of Science

Regulatory science as currently practiced includes many societal objectives such as ideology and supporting the vision of the scientists and regulators to be protective, conservative, and other related actions. The true regulatory science assessment must be as accurate as possible and must provide the regulators the status of science in a manner that a regulator can follow. To be protective or conservative is the task of the regulator and is Outside the Purview of Science.

STRUCTURE OF THE MANUSCRIPT

As discussed above, the regulatory science manuscript is often a critical review of the existing literature. The elements of such a manuscript are as follows:

Title Page

The content of the title page should consist of the title of the review, the name(s) of the author(s), the institution where the work was completed, and the city and country where the institution is located. The title should be as short as possible, but descriptive enough to properly encompass the subject covered.

Abstract

An informative abstract should consist of four parts.

1. **Context and Objectives:** This section, consisting of about 50 words, should describe why the assessment was done and its objectives.
2. **The Assessment:** This section of should indicate what was done.

3. **Results:** This part summarizes the core of the study and describes what was found including a few words on its significance.
4. **Conclusions:** This section should be brief and less than 30 words.

Introduction

The Introduction is a clear statement of the status of science and a discussion of why the assessment was undertaken. It must outline the status of science by describing and referencing cite pertinent literature. A good Introduction tells the reader the "story" of the status of science and closes with a brief outline of the assessment's objective.

Results

The author should summarize the data collected and the statistical treatment of them. The author should also include only relevant data but give enough detail to justify your conclusions. Equations, figures, and tables should be used where necessary, for clarity and conciseness. The same data may be presented in tables or in figures but not in both.

Discussion

When discussing the results Point out the features and limitations of the works should be interpreted. The results of the study should be compared with previous studies. Often the question is raised: Has the problem identified as the objective of the study been solved and what is exactly the contribution resulting from the study? The results and discussion may be presented as two separate sections or one section if it is more logical to do so. Ideally the section Discussion may not include new references or new thoughts, except those resulting from the study. The discussion of the literature belongs in the section Introduction.

Conclusions

Conclusions respond to the phrase "On the basis of this study it can be concluded that..." Conclusions may not repeat information.

Acknowledgment (if necessary)

Acknowledgments should be enough but brief. They should not contain lengthy descriptions.

References

References constitute an important part of every scientific manuscript and should be listed on a separate page. See the following section for detailed instructions on how to format references.

Tables and Figures

All tables and figures should be of high quality and contain appropriate captions. These captions should provide enough information so that the figures can be understood by the reader without him/her having to read the text. Additionally, units and quantities used should be clearly identified. Both tables and figures should be properly numbered by the order that they appear in the review. Avoid grey shading. The document must be submitted as a Word document, not a PDF.

Equations

All equations should be simple and suitable for a multidisciplinary audience. For example, fractions within

fractions, and subscripts within subscripts should be avoided.

Footnotes

Virtually all materials included in t footnotes can be incorporated into the text for the benefit of the readers, editors, and printers. Footnotes should be.

REFERENCING INSTRUCTIONS

Introduction

A reference is the documentation to prove that information alleged to be from a specific source can be verifiably true. Therefore, a properly documented reference is a key to scientific reporting. Much like any other aspect of science, the quality of referencing deviates significantly among scientific journals. Even the most prestigious journals often accept references that are not readily verifiable. This does not excuse the less prestigious journals to follow this mistake and accept unverifiable or ambiguous references. There are several key elements of referencing consisting of

- WHO
- WHAT
- WHERE
- WHEN

The WHO

The WHO is the author of a document. The author can be one or more than one individual who are normally listed in the order of their contribution to the document. On

occasion, some institutions choose to list the authors in alphabetical order. However, this approach is considered less desirable and is mostly done when there are many authors. Note the author WHO interacts with the editor and is normally the first listed author who is referred to as the "Senior author" unless an individual other than the first-listed author is identified as the corresponding author. If there are more than six authors, the first author with the addition of et al. is enough.

The author may also be an organization. The reports of scholarly organizations such as National Academies of Science, Engineering and Medicine (NASEM), National Council on Radiation Protection and Measurements (NCRP), American Society of Mechanical Engineers (ASME), and American Medical Association (AMA)) fall into that category. Included are also official pronouncements of government agencies or private organizations. For these authors, in most cases, the abbreviation of the organization is followed by the spelled- out title. However, a report that is prepared by a staff of an organization does not constitute official pronouncement and thus the organization cannot be listed as the author. If there is no identifiable author, then the author is anonymous. In this case, the word

“Anonymous” is used instead of the author. The anonymous author is also used when a report is prepared by an organization without identifying an author, but the report does not constitute the official pronouncement of an organization or an agency. It is not always easy to recognize if a report is the official pronouncement of an organization or the work of a staff person. In ambiguous cases, the error should be on the side of using anonymous.

The WHAT

The WHAT is the title of the document that, if properly prepared, describes its content. Titles come in a variety of shapes and forms, and a great deal of judgment is necessary to ensure that one is using the correct title. In scientific periodicals, the title is mostly straightforward. Similarly, titles of newspaper articles, regulations, and reports are normally clear. There are, however, documents that do not have a title. In these cases, the document is referenced as “untitled”.

The WHERE

Increasingly certain authors attempt to use the internet address as a reference. However, with minor exceptions the internet address should be used as supplementary

address. Ideally the internet address should be added at the end of each reference including the date (month and year) when internet was accessed. For scientific periodicals, the WHERE is the title of the periodical, the volume, the pages (ideally the beginning and the end), and the year. Some journals start every issue with page 1. In these cases, the issue (number, month, etc.) is also identified.

For books, the WHERE includes the city where the publisher is located and the name of the Publisher. The words: corporation, limited, company, inc., GmbH, Cie, and similar items that describe the legal status of the publisher are deleted unless they are an integral part of the title of the publisher. Reports of many scholarly organizations follow the same approach as a book. Therefore, the style of identifying the location is identical to a book.

For reports prepared by various organizations including government agencies and their contractors, there is a report number that designates the organization and some identifying code. This code precedes the description of the organization. Otherwise, the same rules described for books apply. In these cases, the city (including the two-

letter abbreviation of the state) is followed by the name of the organization.

An issue of concern is a paper published in a volume edited by someone other than the author. This problem is particularly prevalent in proceedings of meetings. In these cases, the word "In" is used to indicate that the author is not the author of the entire volume. After "in", the title of the volume, the name(s) of editor(s) are given. The remainder of the reference is identical to that described for a book.

The WHEN

The description of the WHEN for scientific periodicals was described in the last paragraph under "The WHERE". Most libraries can find an article once the information described in that section is provided to them.

For books, the year of publication is the WHEN, as is for reports. There is often confusion for a report (or proceeding) that states the results of an event, such as a meeting or a symposium that took place at a given date. In most cases, the date and the place of the event is a part of the title and not the WHEN.

Referencing Styles

Although there are several styles of referencing, they can be categorized as follows

1. **Numbering System:** In this system references are numbered as they are mentioned in the text. In the list references are numbered as they are numbered in the text.
2. **Name and Year**: In this system in the text the name of the author and the year of the publication is used. The reference list follows alphabetical. In the text if there are two authors both are mentioned they are mentioned and if they are more than two authors the name of the first author is followed by et al.

Internet as a Reference

Increasingly internet is used as a tool to identify various references. It is imperative to recognize that the internet address alone is not a reference. On occasion the internet address of publications in a scientific journal is added to the traditional referencing process. Although such an approach may simplify finding the text if a reference, in most cases the addition of the internet address is unnecessary. In contrast, it is desirable to include the

internet address of laws, regulations, and many other references.

EXAMPLES

Papers Published in a Scientific Journal

Moghissi AA, Calderone AA, McBride DK, and Jaeger L. Innovation in Regulatory Science: Metrics for Evaluation of Regulatory Science Claims based on Best Available Regulatory Science. *Journal of Regulatory Science*. 5; 50-59: 2017

Moghissi AA, O'Brien J, Stoneham J, Calderone RA, and McBride DK. Regulatory Biomedical Engineering: Application of the Regulatory Science Framework to Biomedical Engineering. *Journal of Biotechnology and Bioengineering* 2; 51-60: 2018

Papers Published in a Scientific Journal in a Foreign Language

Einstein A. Zur Quantentheorie der Strahlung (On the quantum theory of radiation). *Physikalishe Zeitschrift*. 18; 121-128; 1917

Meuleman, M.; Betz, W. Homeopathie Wetenschap of Geloof. (Homeopathy, Science or Belief.) *J. Immunology and Immunopharmacology*. 10: 15-17; 1998 (in Dutch).

Letters, Editorials and Similar Contributions Published in a Scientific Journal

Ames, B.N.; Gold, L.S. Response [to Rall 1991]. *Science* 251: 12-13; 1991.

Anonymous. Editorial. Quackery Quakes. *Journal of American Medical Association*. 184: 652; 1963.

Slovic, P.; Fischhoff, B.; Lichtenstein, S. Rating the risks. *Environment* 21 (3): 14-39; 1979.

Henningfield, J.E. Nicotine medications for smoking cessation. *New England Journal of Medicine*. 333: 1196-1203; 1995.

Books

Stare, F.J.; Olson, R.E.; Whelan, E.M. Balanced nutrition beyond the cholesterol scare. Holbrook, MA: Bob Adams; 1989.

Chapters in a Book

Barnard, R.C. The emerging regulatory dilemma. In: Nicholson, W.J., ed. Management of Assessed Risk for Carcinogens. New York, NY: *New York Academy of Science*; 106-111; 1981.

Papers Published in Proceedings of a Meeting

Food and Drug Administration Records, Record Group 88. Washington, DC: Natl. Arch.; 1910. https://www.archives.gov/research/guide-fed-records/groups/088.html Accessed July 2018

Swedjemark, G. A. Exposure of the Swedish population to radon daughters. Berglund, B.; Lindvall, T., eds. Proc. 3rd international conference on indoor air quality and climate. Stockholm: *Swedish Council for Building Research;* 2:37-43; 1984.

Papers Presented in a Meeting

AMA (American Medical Association). Council on Scientific Affairs; Report: C (A-93) [Thermography]. Presented to the AMA House of Delegates Annual Meeting. AMA Chicago; June 13-17, 1993.

Reports

FDA (Food and Drug Administration) Annual Reports, 1050-1974. Washington, DC: Gov. Print. Off.; 1976.

Ainsworth CC et al. Re-concentration of radioactive material released to sanitary sewers in accordance with 10 CFR Part 20. NUREG/CR-6289.

Washington, DC: U. S. Nuclear Regulatory Commission; 1994. https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/full-text.html Accessed July 2018

CDRH (Center for Devices and Radiological Health). FDA update on the safety of Silicone gel-filled breast implant. Silver spring MD, Food and Drug Administration 2011. https://www.fda.gov/downloads/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/breastimplants/ucm260090.pdf Accessed April 2018

Articles in Newspapers

Schneider, K. New view calls environmental policy misguided. N.Y. Times; March 21, 1993. https://www.nytimes.com/1993/03/21/us/new-view-calls-environmental-policy-misguided.html Accessed July 2018

Laws

(USC) U. S. Code. The Low-Level Waste Policy Act. PL-95-573;December1980**.** http://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title42-chapter23-divisionA-subchapter1&saved=%7CVGhlIExvdy1MZXZlbCBXYXN0ZSBQb2xpY3kgQWN0%7CdHJlZXNvcnQ%3D%7CdHJ1ZQ%3D%3D%7C4%7Ctrue%7Cprelim&edition=prelim Accessed July 2018

(USC) U. S. Code. The Clean Air Act and its subsequent Amendments. 42 U. S. C. 7401-7626.

http://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title42-chapter85&saved=%7CVGhlIENsZWFuIEFpciBBY3QgYW5kIGl0cyBzdWJzZXF1ZW50IEFtZW5kbWVudHM%3D%7CdHJlZXNvcnQ%3D%7CdHJ1ZQ%3D%3D%7C30%7Ctrue%7Cprelim&edition=prelim Accessed July 2018

(USC) U. S. Code. Solid Waste Disposal Act 42 U. S. C. 6901 et-seq. http://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title42-chapter82-subchapter1&saved=%7CU29saWQgV2FzdGUgRGlzcG9zYWwgQWN0%7CdHJlZXNvcnQ%3D%7CdHJ1ZQ%3D%3D%7

C69%7Ctrue%7Cprelim&edition=prelim Accessed July 2018

Judicial Decisions

Supreme Court of the US. *Daubert v. Merrell Dow.* 509 U.S. 579; 1993. https://www.supremecourt.gov/opinions/boundvolumes/509bv.pdf Accessed July 2018

Regulations

EPA (U.S. Environmental Protection Agency). Guidelines for carcinogenic risk assessment. Federal Register

51: 33992-24117; 1986. https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf Accessed July 2018

EPA (U.S. Environmental Protection Agency). Proposed plan for ROD amendment, Colorado Avenue subsite, Hastings ground water contamination site, Hastings, Adams County, Nebraska. Kansas City, KS: Region VII, Environmental Protection Agency; 1998. https://semspub.epa.gov/work/07/180008.pdf Accessed July 2018

Documents Dealing with Governmental and Similar Activities

CPFGA (California Peach and Fig Growers Association). Telegram to Secretary of Agriculture Arthur M. Hyde. October 8, 1929. Fig file 1929. Records of the Office of the Secretary of Agriculture, Record Group 16. Washington, DC: National Archives; 1930.

(ITRC) Interstate Technology and Regulatory Cooperation Fact Sheet. http://www.westgov.org/itrc. Accessed July 2018.