Working Guidelines and Procedures for Preparation of ORD Scientific and Technical Assessment Reports (STAR)

Office of Research and Development
U.S. Environmental Protection Agency
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ATTACHMENT

WORKING GUIDELINES
FOR
PREPARATION OF ORD
SCIENTIFIC AND TECHNICAL ASSESSMENT REPORTS
(STAR)

OFFICE OF PROGRAM INTEGRATION
OFFICE OF RESEARCH AND DEVELOPMENT
ENVIRONMENTAL PROTECTION AGENCY

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1. INTRODUCTION AND OBJECTIVES

The assessment of known available data on major pollutants of concern to EPA is one of the major functions of the Office of Research and Development. Whether the data are generated by EPA through in-house efforts or through grants or contracts, or by other research institutions, ORD has a responsibility, as the Agency's technical arm, for assessing the information available to determine its validity and significance. The purpose of Scientific and Technical Assessment Reports (STARs) is to assist the Agency in complying with the statutory directives for which it is responsible, in accordance with the Assistant Administrator's memorandum of August 15, 1974. This is a two-fold requirement on the part of ORD, which involves the close interaction between our professional staff and: 1) the Program Offices in developing various standards, guidelines, regulations, and technical reports, and 2) the Office of General Counsel in defending, as a result of possible litigation, those same standards, guidelines, regulations and technical reports. The importance of the Reports, therefore, cannot be overestimated.

Although the key characteristics desired for STARs are explained in the Assistant Administrator's memorandum, it may be useful to briefly summarize them here:

- Assessment, not just summarization of knowledge on each

pollutant.

- o Multi-media, not single media in scope.
- o Objective assessment without recommendations.
- o Dose-response relationships, not effects thresholds.

The objectives of these Working Guidelines and Procedures are to establish a uniform set of procedures and a standardized outline, to the extent practical, for the preparation of ORD STARs. These guidelines and procedures supercede all previous ones and with the exceptions noted in the next paragraph will be used in the preparation of ORD assessment-type documents.

It is recognized that there are likely to be many cases where special circumstances will make the standardized outline impractical and where it will create more difficulties than it will resolve. In those cases where it is possible to anticipate this, special detailed outlines will be prepared. This is likely to be the case when specific legislative requirements must be met (as in the case of criteria documents) or when the documents report on terminated research. In still other circumstances, the inappropriateness of the outline will become evident only during the actual preparation of a section of a document. In that case those responsible for the section should proceed with a more useful structure of their section and notify the OPI Coordinator if the change is sufficiently major so as to make the revised section incompatible with sections being prepared by other

laboratories. It is hoped that in this way the outline will prove to be more of a guide, and hopefully an aid, to those preparing assessment documents rather than a set of restrictions on their activities.

In writing STARs, it is important to keep the English as simple and straightforward as possible consistent with maintaining the precision necessary. Professional jargon should be avoided whenever possible. Where possible, the English should be understandable to a decision maker in a program office who may not have technical training in the particular specialized field being discussed.

2. STANDARDIZED DOCUMENT OUTLINE

As discussed in the introduction, the standardized document outline to be presented in this section is intended to be more a guide and an aid to those preparing assessment documents than a set of restrictions on their activities. The outline has been annotated in an attempt to indicate the type of information or questions which should be considered in preparing each module. Additional sub-headings may be used as appropriate.

DOCUMENT OUTLINE

ABSTRACT

Required by EPA regulations. 200 words or less. Will be prepared by the report assembly organization.

PREFACE

The preface should state the objective of the document and acknowledge contributions by the principal authors. It should also explain why the report has been prepared and the relation of the document to other

similar documents. The preface should be brief and prepared by the report assembly organization.

TABLE OF CONTENTS

Will be prepared by the report assembly organization and carry the heading CONTENTS. First order headings should be listed in upper case; second order headings should be listed using upper and lower case style with the first letter of the first word capitalized. Third order headings (also in upper and lower case style) may be included if done uniformly throughout the report and if they are numbered in the report. Section and subsection numbers should precede the title. The first line of all titles should have a uniform indentation from the left margin. Extra space should be left between sections.

LIST OF FIGURES

Should list all figures that appear in the report by figure number, title, and page number. The title should be in upper and lower case style, with the first letter capitalized. The first line of all titles should have a uniform indentation from the left margin. Will be prepared by report assembly organization.

LIST OF TABLES

Should list all tables that appear in the report by table number, title, and page number. The title should be upper and lower case style, with the first letter capitalized. The first line of all titles should have a uniform indentation from the left margin. Will be prepared by report assembly organization.

LIST OF ABBREVIATIONS AND SYMBOLS

Will be prepared by report assembly organization. All abbreviations used in the text should be listed alphabetically and the full word(s) listed to the right using a uniform indentation.

LIST OF CHEMICAL FORMULAS

Will be prepared by report assembly organization. All chemical formulas mentioned in the text should be listed alphabetically with their full name listed to the right using a uniform indentation.

1. SUMMARY AND CONCLUSIONS

Each primary, module development organization will prepare a separate sub-section on summary and conclusions to the specific module of the outline for which it is responsible. The report assembly organization will use these contributions in preparing this section.

1.1 SUMMARY

An executive summary in which the most important points, from the standpoint of decision-making, included in each major section are presented in concise and simple language. The summary should contain no information which is not supported in the rest of the document.

1.2 CONCLUSIONS

The conclusions should concisely assess the degree of knowledge of various aspects of the problems posed by the pollutant, what critical data gaps may exist, the extent of the problem posed by the pollutant, and the range of possibilities available for doing something about it. There would be nothing in the conclusions that is not clearly based on data in the report. Although significant gaps in knowledge should be noted, no recommendations should be made as to whether future research

should be carried out to fill them. There should also be no recommendations as to what action, if any, the Agency should take with respect to the pollutant.

2. POLLUTANT CHARACTERIZATION

2.1 CHEMICAL AND PHYSICAL PROPERTIES

A discussion of the chemical and physical properties of the pollutant to be discussed in the report that may be significant with regard to uses, sampling and analysis, transport and transformation, effects, and control technology. This section should discuss why these properties are important. Include the basic chemical formulae in the case of compounds as well as a diagram of compound structure. Emphasize compounds which may be of concern, whether or not they exist naturally in the environment, their associations, stability, solubility, etc.

2.2 MEASUREMENT TECHNIQUES

This sub-section should discuss two questions: can the pollutant be measured and how well? These questions should be addressed with respect to ambient levels in air, water, and land materials (soil, sediments, etc.), and concentrations in food receptors such as plants, animals, and man, in food consumed by animals and man, and in effluent emissions from pollution sources. In each case, these two questions should be answered in terms of assessing the techniques available for sampling and the preparation and analysis of samples for the more promising techniques. Shortcomings of each technique should be discussed. It is also appropriate to assess the availability of instruments and of standard reference materials for instrument calibration and to assess the quality assurance status of the method described. Additionally, for the methods described, it is appropriate to indicate the working range and recommended technique, and equivalent techniques if no standard reference technique has been established. Particular attention should be paid to the relationship of what is measured by the analytical method to the form the pollutant takes in the various media and on those techniques used to obtain data presented in other modules of the same document. Where possible, quantitative values for precision, accuracy, etc., should be stated. Interference should be discussed specifically, as well as other problems related to obtaining reliable data. Discussion of procedures should not be repeated; simply reference previous paragraphs.

3. ENVIRONMENTAL OCCURRENCE AND TRANSPORT

Where possible it would be useful to include somewhere in this section a figure that conveys an idea as to the total cycle that the pollutant goes through from source to receptor including approximate ranges of concentrations in each medium and the exchange rates and mechanisms between media and sub-media, where important.

3.1 CONCENTRATIONS

An assessment of available data on observed concentrations in air, water, land materials, plants, animals, man, and food for animals and man should be presented. Characteristic patterns in space and time for both short- and long-term changes should be emphasized. Dates of data collection should be included, as well as confidence limits (quantiative or subjective), measurement methods, and averaging times. Significant gaps in the data and changes in measurement methods during the period of record should be noted. If the term "trace" is used it should be defined.

3.2 TRANSFORMATION AND TRANSPORT MECHANISMS

This sub-section should assess the state of knowledge of chemical, physical, and biological processes in both natural and man-made (such as those arising from disposal and recycling) systems including removal mechanisms and rates when known, transport within and between media, residence times, etc., in air, water (including running, standing, ground marine and estuarine), and soil environments. Knowledge of mechanisms that influence visibility and climate should be assessed. The biological discussion should include food chain transfer as well as biological magnification. To the extent possible, this section should be concerned with the total environmental cycle and the principal mechanisms that have an impact upon environmental loading, as well as the extent to which environmental observations confirm the implications of process information. Knowledge of the following biological processes in fresh surface and marine waters should be assessed where relevant: degradation by algae, bacteria, fungi, and other hetrotrophic populations; microbial transformation (product formation); effects on growth; and incorporation and storage (bioaccumulation). In the case of biological processes in groundwater, degradation as a result of interaction with soil microorganisms and transformation should be assessed. The following chemical processes should be discussed in surface waters: fast (equilibrium conditions) and slow (kinetics) reactions and transformations foz both chemical and photochemical processes. The

following physical processes should be assessed in the case of fresh surface waters: mass transport and dispersion, adsorption, sedimentation, solution, diffusion, and exchange (substrate-water-air-water). The same physical processes should be assessed in the case of marine environments except for the addition of density (salinity) gradients and currents. In the case of physical processes in groundwaters, infiltration and retention rates should be assessed. Chemical processes in air and on surfaces (such as photo-degradation) should be discussed. If relevant, assess the role that other pollutants may have in the transformation of the subject pollutant in the various media in which they come together.

4. ENVIRONMENTAL EXPOSURE AND UNDESIRABLE EFFECTS

Although this section is organized in such a way that each species or group of species would have to be discussed under four different headings, each STAR Committee should carefully consider whether it may prove more efficient and understandable to subdivide this section by groups of species, such as plants, animals, and man or non-human and human, and then to discuss consecutively each of the four subjects of the subsections shown below for each group. If this is done, non-human groups should, in general, be discussed prior to man, the ultimate receptor.

4.1 MECHANISMS OF EXPOSURE

This section is concerned with assessing the mechanisms operating at anatomical and physiological interfaces. The discussion of animals should include respiratory, body surface, and digestive tract routes. Plants should include epidermal, root, and stomatal systems. Materials should include mechanisms relating to undesirable effects, such as corrosion. Mechanisms may be chemical, physical, or biological.

4.2 MECHANISMS OF RESPONSE

In this sub-section, consider the receptor's normal handling of the constituent being reviewed. Include uptake, distribution, metabolism, and excretion. Include information on retention sites and times and on response to various retention levels. Background information necessary to make judgments concerning potential problems should be included along with nutritional requirements if applicable.

4.3 UNDESIRABLE EFFECTS

Identify and describe undesirable effects of the pollutant involved on plants, animals, materials, man, weather and climate, visibility in air, land materials, and water use (including aesthetic uses). Effects on ecosystems as well as effects on individuals and populations should be included when appropriate. This discussion should be structured in such a way that these undesirable effects can be scaled against the level of environmental contamination. In the case of the effects on plants, animals, materials, and man, the discussion should include the results of both laboratory and field studies. Detailed treatment of individual experiments or studies is not necessary; results should be emphasized. Information regarding experimental design should be included if appropriate. A discussion of reversibility or irreversibility should specifically be included. Synergistic effects of the pollutant, if any, with other pollutants commonly found with it should be assessed. The discussion should include proved, suspected, and possible effects, but clearly distinguish among them. The major gaps and uncertainties in our ability to predict or measure the effects should be assessed.

4.4 ENVIRONMENTAL EXPOSURE

The purpose of the sub-section is to assess the possible exposure levels (i.e., the accessability of the pollutant and the combined exposure) of various receptors and the probability that the receptors will actually be subjected to these levels. These exposures may come through a number of routes, all of which should be discussed where relevant. These routes include air, water, food (in the case of man and animals), land materials, occupational activities (in man) and special routes (man) such as smoking, cosmetics, and pharmaceuticals.

The assessment of receptor risks might be treated analogously to a time and motion concept, that is, by considering the buildup of body burden or effect from various environmental (and other) exposures and what proportion is presented by each exposure. Include population density aspect, location of source, receptor location and activities, and chance of contact.

If possible, the exposure estimates presented, summarized, or cited in this subsection should be sufficiently quantitative so as to make it possible to calculate the benefit estimates in Section 6.1. If insufficient data exist to present such calculations, then a qualitative estimate should be prepared. Exposure estimates should be determined for a range of potential control levels, ideally, the same ones considered in Section 5.2, and including the case of no further

control. In some cases, it may be more convenient to put this discussion at the beginning of Section 6.

5. SOURCES AND CONTROLLABILITY

5.1 SOURCES

This sub-section should include a discussion of both current and projected sources of the pollutant from both natural and man-made sources. In the case of natural sources, the section should discuss what they are, how they are distributed geographically, and what their expected contribution is to the total emissions and to the ambient level. In the case of man-made sources, include in addition production, uses, and emission factors and distinguish between stationary and mobile sources. If available, process material balance studies should be cited. At this point in our discussion, we should be concerned with quantitative estimates of the man-made contribution to ambient levels of the pollutant in air, water, biological, and land materials. The discussion should include the processing of raw materials as a source of the pollutant. In discussing the current and projected sources of the pollutant, the impact of existing and planned reductions resulting from current environmental regulations should be identified.

5.2 CONTROL TECHNOLOGY AND CONTROLLABILITY

For each major source listed in Section 5.1 assess the potential for control by all methods; if it can be controlled, assess the availability and effectiveness of technology and/or administrative measures available to do so, the cost of achieving a range of reduced ambient levels, such as those considered in Section 4.4, their applicability, and whether their use generates other pollution problems in the same media. Distinguish between control measures already in use as a result of existing environmental regulations, those planned or expected to be used, and untried and unplanned measures.

5.3 UNDESIRABLE INTERMEDIA EFFECTS OF PRINCIPAL CONTROL MEASURES

Some or all of the control measures discussed in Section 5.2 may create other pollution problems in the same or other media. The existence, extent, and possible solutions to such problems should be discussed for a range of control alternatives.

6. OVERVIEW, BENEFITS, AND INSTITUTIONAL PROBLEMS OF CONTROL

6.1 ECONOMIC BENEFITS FROM CONTROL

To the extent possible, this sub-section should describe the total benefits to the nation, various regions, and income groups from a variety of potential control levels, in that order of importance. This information should be quantitative and expressed in dollars to the extent warranted by the reliability of the data, although quantitative statements expressed in other units (e.g., deaths avoided, hospital days not required, etc.) or even qualitative statements should be made if sufficiently reliable data are not available. Emphasis should be placed on national economic benefits over a range of potential control levels, such as those considered in Sections 4.4 and 5.2, and including the case of complete control.

6.2 SOCIETAL/INSTITUTIONAL CONSTRAINTS ON CONTROL

The intent of this section is to assess the major institutional and societal constraints on the implementation of the potential control measures discussed in Section 5 in order to reach the control levels discussed in Section 6.1. Since the relative difficulty of applying various control measures should be discussed in Section 6.3, this sub-section should be devoted to an analysis of any difficulties likely to

be encountered in implementing each of the various control measures discussed in Section 5. For each administrative or physical control measure described there, the analysis should ascertain whether there exists any Federal legislative authority for carrying out the measure, what the major difficulties of so doing would be, and whether there would be any other (non-legislative) implementation problems of carrying out the measure including administrative problems given current EPA, state, and local policies.

6.3 OVERVIEW

This sub-section should provide an overview assessment of how serious the health, ecological, and materials damage threats posed by the pollutant are and how serious the technological, economic, and institutional/societal problems of control may be. The discussion of how serious the problem is should include both the current situation and projections to the year 2000 if possible. The institutional discussion, unlike that in Section 6.2, should describe the relative difficulty of a range of reasonable control measures, including that of the lowest cost measure. In making this overview assessment, particular attention should be given to the quality and certainty of key information and its relevance to regulatory decisions that the Agency may face.