



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

DEC 12 2003

THE ADMINISTRATOR

Dr. William H. Glaze  
Chair, Science Advisory Board  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, D.C. 20460

Dear Dr. Glaze:

Thank you for providing me with a copy of the Science Advisory Board Radiation Advisory Committee Review Panel's report, *Review of the Multi-Agency Radiological Laboratory Analytical Protocols Manual* (EPA-SAB-RAC-03-009).

I am pleased that the Panel applauded the MARLAP work group's collaborative effort and its common sense approach to voluntary implementation of government programs and guidelines. I am also pleased that the Panel found the manual to be a well-conceived, comprehensive work that will serve as a valuable reference for project planners, managers, and radioanalytical laboratories supporting both federal and state radiation program needs.

Enclosed you will find the MARLAP work group's response to the Panel, which details the steps being taken to address the Panel's comments and recommendations.

On behalf of the MARLAP work group, please extend my thanks to the members of the Panel for their work on this important issue and for their thoughtful review of the manual.

Sincerely,

A handwritten signature in black ink that reads "Michael O. Leavitt".

Michael O. Leavitt

Enclosure

## MARLAP Workgroup Responses to EPA-SAB-RAC-03-009

### Charge Question #1: Effectiveness and Clarity of the Overall Approach in Part I

*Comments and Responses based on EPA-SAB-RAC-03-009 Cover letter, Page 2 and Section 7 Summary of Findings and Recommendations.*

**SAB Report 7.2.2 (a):** The Manual should undergo a thorough technical edit, the main objectives of which should be to (1) remove the considerable amount of redundancy; (2) ensure internal consistency among the chapters in presentation style and formatting; (3) make wider and more consistent use of effective techniques for presenting information; (4) proofread all references, equations, tables, figures, and examples; and (5) reduce the use of acronyms.

**MARLAP Workgroup Response:** The MARLAP Manual is currently undergoing a thorough technical edit to address the objectives mentioned above. The MARLAP Workgroup appreciates the editorial review comments provided in Appendix D of EPA-SAB-RAC-03-009.

**SAB Report 7.2.2 (b):** Provide a well-written Executive Summary using clear, simple text, and figures to unify the document and show the linkages among the chapters.

**MARLAP Workgroup Response:** An Executive Summary that provides an overview of the MARLAP Manual and shows the linkages of the chapters and appendices will be added to the manual.

**SAB Report 7.2.2 (c):** A good overview figure is needed at the outset, a figure that lays out the entire planning process and shows the interrelationships among steps.

**MARLAP Workgroup Response:** An overview figure has been added to Chapter 1 *Introduction to MARLAP* to illustrate the iterative MARLAP process and the interrelationships of the various steps of the process.

**SAB Report 7.2.2 (d):** More examples should be included in the Manual to illustrate the planning process and the graded approach, so as to bring these to life for the reader. A variety of clearly presented and realistic scenarios will be critical to the success of MARLAP and should emphasize the potential benefits of planning and using a graded approach.

**MARLAP Workgroup Response:** The MARLAP Workgroup agrees that realistic examples will aid in the implementation of the MARLAP Manual. The workgroup is currently developing examples that illustrate the MARLAP Process as outlined in the manual. The examples along with a “MARLAP Roadmap” will be published in a separate volume.

**SAB Report 7.2.2 (e):** To address the concern that regulatory agencies may try to apply the entire MARLAP process to situations and organizations for which a full-scale effort would not be

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appropriate, the Panel suggests the inclusion of more explicit guidance on how to scale back the process to a level appropriate to the decision under consideration.

**MARLAP Workgroup Response:** Additional language has been added to emphasize the graded approach discussed in the MARLAP Manual. The additional language emphasizes the need to ensure that the level of effort and resources expended on a project should be commensurate with the decision under consideration.

**SAB Report 7.2.2 (f):** Figures and tables should be designed so as to reinforce the text, or to help reduce the need for lengthy discussions. In particular, the very nonlinear and iterative nature of the planning process should be indicated by feedback loops in figures to more clearly convey the sense of the process of continual reassessing and fine-tuning the objectives and approaches.

**MARLAP Workgroup Response:** Several sections of text have been eliminated or shortened where figures or tables concisely present the material. Feedback loops have been added to several figures to emphasize the iterative and nonlinear nature of the MARLAP Process.

**SAB Report 7.2.2 (g):** An appendix containing good examples of process outputs (e.g., DQOs and Statements of Work) for projects differing in scope and complexity would be helpful.

**MARLAP Workgroup Response:** The examples the MARLAP Workgroup is currently developing will include examples of process outputs (e.g., DQOs, MQOs, etc.) for a fairly large complex project and for a small project that is more limited in scope.

### Charge Question #2: Technical Accuracy of the Guidance in Part II

*Comments and Responses based on EPA-SAB-RAC-03-009 Cover letter, Page 2 and Section 7 Summary of Findings and Recommendations*

**SAB Report 7.3.2 (a):** The Panel strongly supports the initiation and maintenance of a teaching program and the implementation of a web site to enhance dissemination of guidance on issues related to MARLAP.

**MARLAP Workgroup Response:** The MARLAP Workgroup agrees that training is essential to the implementation of the guidance in the MARLAP Manual. The workgroup is currently considering several training vehicles such as traditional classroom training, interactive internet-based training, self-paced computer modules, etc. The type and frequency of training offered will depend on a number of factors including resource availability.

**SAB Report 7.3.2 (b):** Restructuring some of the chapters in Part II could add clarity and usefulness to the document by providing more consistency in the level of detail, employing a more logical order of presentation, and inserting appropriate cross-references between chapters to reduce confusion and repetition. Discussion of limited value should be deleted, with the reader

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referred to specific publications (e.g., special matrices and radionuclide behavior in the environment).

**MARLAP Workgroup Response:** The MARLAP Workgroup agrees that restructuring some of the chapters in Part II will improve the presentation and usefulness of the manual. The material in Chapter 15 *Nuclear Counting Instrumentation* and Chapter 16 *Instrument Calibration and Test Source Preparation* has been reorganized and combined into a single chapter resulting in a more logical presentation with less repetition. The order of the Part II chapters has been changed to be more consistent with the analytical process in a radioanalytical laboratory. Additional cross-references between chapters have been added to improve linkages among related topics.

**SAB Report 7.3.2 (c):** Although the Panel agrees that the laboratory must report values “as measured” when below the limit of detection—or even negative through subtraction of background—presentations of the data annotated with qualitative indicators of non-detectability or less-than notation may be desirable to include in reports to the lay public and to decision makers. The Manual should address this issue and attempt to find a solution that would maximize lay understanding while minimizing the potential for misuse.

**MARLAP Workgroup Response:** Additional language has been added to emphasize that the recommendation in the manual to report values “as measured” is intended for the laboratories generating the data. Language has also been added which recommends that project planners and managers decide how laboratory results are to be communicated to all interested and affected parties during project planning. The MARLAP Workgroup believes that this is best decided on a case-by-case basis by individuals familiar with the specific project rather than on the basis of a general rule.

**SAB Report 7.3.2 (d):** The federal MARLAP Workgroup has provided guidance on laboratory analyses with the intent of ensuring that the uncertainties in their results do not contribute significantly to the overall uncertainty of the decision process, including those from the sampling design and those from translating risk-reduction policy goals to action levels. This intent should be further clarified in the Manual, and the issue of tradeoffs between sampling coverage and laboratory precision should also be discussed.

**MARLAP Workgroup Response:** Since the basic goal of the MARLAP Manual is to provide guidance to ensure the generation of radioanalytical laboratory data of known quality appropriate for its intended use, the discussions on uncertainty in the manual have focused on analytical uncertainties with the goal of keeping these uncertainties manageable when compared to other sources of uncertainties such as sampling uncertainties. Additional language has been added to show the possible tradeoffs of the various major sources of uncertainty for a project relative to the tolerable overall uncertainty of the decision process.

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### Charge Question #3: Guidance on Measurement Statistics

*Comments and Responses based on EPA-SAB-RAC-03-009 Cover letter, Page 2 and Section 7 Summary of Findings and Recommendations*

**SAB Report 7.4.2 (a):** Many of the terms used in the measurement statistics chapter may be commonly employed in the jargon of laboratory science, but these terms are confusing when read by statisticians. Statements should be included to inform statisticians, who are likely to get involved, that many of the terms used are not directly translatable to corresponding statistical parameters or concepts with which statisticians may be more familiar.

**MARLAP Workgroup Response:** In response to the Panel's recommendation, the MARLAP workgroup has added the following language to Chapter 19:

The terminology and notation used by the *GUM* [*Guide to the Expression of Uncertainty in Measurement*] and this chapter may be unfamiliar or confusing to readers who are familiar with statistics but not metrology. Metrology (the science of measurement) uses the language and methods of probability and statistics, but adds to them its own terms, symbols, and approximation methods.

**SAB Report 7.4.2 (b):** The Panel recommends that the distinctions and connections between uncertainty and variability be discussed early in the section on measurement statistics.

**MARLAP Workgroup Response:** In response to the Panel's recommendation, the MARLAP workgroup has added a note emphasizing that Chapter 19 focuses on the uncertainty of laboratory measurements, not on variability in the field, whose importance to decision-makers is discussed in Appendix C.

**SAB Report 7.4.2 (c):** The terminology and notation throughout Chapter 19 should clearly indicate the approximate nature of most calculations and clearly state whether a formula is an approximation when it is first introduced. It should also indicate the conditions under which each approximation would or would not be valid. If MARLAP intends to suggest a preferred method, it should be clearly stated, along with recommendations for situations when one of the other methods is preferable. For example, Attachment 19D should provide recommendations regarding which of formulae A, B, C, the Stapleton approximation, or the exact test are preferred and under what conditions.

**MARLAP Workgroup Response:** Although the approximate nature of the calculations was already noted in parts of the chapter, the MARLAP workgroup has added additional language to this effect. The workgroup had originally renamed the equation that the GUM calls the "law of propagation of uncertainty" to the "uncertainty propagation formula," with the intent of reducing its perceived status from "law" to merely "formula," but in response to the Panel's recommendation, the workgroup has gone further and identified it as the "first-order uncertainty propagation formula." Furthermore, clarifications have been added to eliminate confusion about the use of

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“equal signs” (=) and “approximation signs” ( $\approx$ ). For example, the following language has been added:

Equation 19.11 is commonly used to *define* the combined standard uncertainty, but note that the combined standard uncertainty is only an approximation of the true standard deviation of the output estimate, and sometimes other definitions provide better approximations (e.g., see Section 19.4.5.1).

Additional recommendations have been added to the chapter on detection decisions. The recommendations regarding the various approximations (A, B, C, and Stapleton) now describe more explicitly the conditions under which each approximation may be preferred.

**SAB Report 7.4.2 (d):** The Manual should incorporate discussion on the use of Monte Carlo analysis as an alternative means for estimating total uncertainties. Given recent advances in desktop computers and work stations, computational restrictions on the use of Monte Carlo methods are no longer a concern. In this case, however, the user needs to be reminded that assumptions about parameter distributions are critical.

**MARLAP Workgroup Response:** The MARLAP Workgroup agrees that a discussion on the use of Monte Carlo analysis as an alternative means for estimating uncertainties should be included in the manual. Chapter 19 now includes references on the subject of Monte Carlo analysis as well as the following language:

An alternative to uncertainty propagation is the use of computerized Monte Carlo methods to propagate not the uncertainties of input estimates but their distributions. Given assumed distributions for the input estimates, the method provides an approximate distribution for the output estimate, from which the combined standard uncertainty or an uncertainty interval may be derived. The joint working group responsible for the GUM is reported to be developing new guidance on the use of such methods. Monte Carlo methods may be particularly useful when the distribution of the result is not approximately normal. However, these methods are most effective when the model can be formulated in terms of independent input estimates.

During subsequent revisions of the manual, the workgroup will reexamine the status of the new guidance mentioned above.

**SAB Report 4.4.2 (e):** The steps used for each statistical estimate should be clearly laid out in chronological order so that users of MARLAP will know how to begin and how to progress through the estimation process. After each estimation procedure is outlined, it should be followed by a numerical example in which each step is worked out with data values typical of radiological assays.

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**MARLAP Workgroup Response:** Additional examples have been added to the manual which clearly outline the steps for the estimation procedure.

**SAB Report 7.4.2 (f):** The potential use of Bayesian analysis should be explored, particularly as a way to address the problem of negative values resulting from background-corrected laboratory data.

**MARLAP Workgroup Response:** While the MARLAP Workgroup finds the use of Bayesian analysis intriguing, the workgroup does not believe there is adequate time to evaluate the use of Bayesian analysis and have the approach independently reviewed for inclusion in the manual at this time. However, the workgroup will consider this recommendation again during subsequent revisions to the manual.

**SAB Report 7.4.2 (g):** The current statistical examples seem to imply that the combined uncertainties associated with radiological measurements are small, particularly when compared to uncertainties often encountered in field sampling. Examples of scenarios where one source of uncertainty may dominate and how this situation should be handled would be useful.

**MARLAP Workgroup Response:** In response to the Panel's recommendation, the workgroup has added examples with larger uncertainties. Overall, there are many examples now, and some of these are paired examples, where assumptions are varied to illustrate their effects on the uncertainty.

Historically, many radiochemists assumed either that radiation "counting uncertainty" was the dominant component of their measurement uncertainty or that the total measurement uncertainty was negligible in comparison to field-sampling uncertainties, and therefore a more complete evaluation of the laboratory measurement uncertainty was unnecessary. The intent of the workgroup is to show that which uncertainty components are dominant depends on circumstances and may vary from sample to sample, and that laboratories should consider all potentially significant sources of uncertainty, not just the counting uncertainty.

### Charge Question #4: Overall Integration and Implementation Issues

*Comments and Responses based on EPA-SAB-RAC-03-009 Cover letter, Page 3 and Section 7 Summary of Findings and Recommendations*

**SAB Report 7.5 (a):** The Panel believes that scenarios and training will be critical to the success of MARLAP, by illustrating the planning process, driving home the potential benefits of the process, and "bringing it to life" for the user community. The Panel recommends that role-playing exercises be part of the user training courses.

**MARLAP Workgroup Response:** The MARLAP Workgroup agrees that training and example scenarios will be critical to implementing the guidance in the MARLAP Manual. As previously

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noted, the workgroup is currently developing examples and evaluating several possible vehicles for training. The workgroup will make every effort to incorporate role-playing exercises in the training. The exact nature of the training offered will depend on many factors including resource availability.

**SAB Report 7.5 (b):** The Panel recommends that the MARLAP Workgroup meet with the MARSSIM Workgroup to find out the lessons learned by this team over the last couple years for developing well-designed training courses.

**MARLAP Workgroup Response:** The MARLAP Workgroup agrees that taking “lessons learned” from the MARSSIM Workgroup’s experience in designing and implementing training courses and applying them to the development and implementation of MARLAP training courses would be beneficial. The MARLAP Workgroup has had some discussions with the MARSSIM Workgroup on training ideas and issues and will continue the dialogue.

**SAB Report 7.5 (c):** The Panel recommends that the MARLAP Workgroup take advantage of the training sessions to obtain user feedback not only on the effectiveness of training but also on MARLAP itself. Users may be able to identify requirements in MARLAP that are infeasible or counterproductive or, by contrast, identify additions to MARLAP that would result in data products better suited to the needs of specific decisions.

**MARLAP Workgroup Response:** The MARLAP Workgroup agrees that training sessions will provide an excellent forum for receiving feedback on the MARLAP Manual and the workgroup will develop a mechanism to solicit and adequately capture feedback on the manual as part of the training session.

**SAB Report 7.5 (d):** It might be useful to devote a short section early in the Manual to showing how the MARSSIM and MARLAP processes are integrated for decisions regarding the cleanup of radioactively contaminated sites.

**MARLAP Workgroup Response:** Additional language has been added to Chapter 1 *Introduction to MARLAP* that emphasizes the complementary nature of the MARSSIM and MARLAP manuals. While the MARSSIM Manual focuses on radiation surveys for compliance demonstration, the guidance in the MARLAP Manual is broader in scope and can be used to support any project that requires laboratory radioanalytical data for decision-making. Therefore, the workgroup is reluctant to devote an entire section to discussing the integration of the MARSSIM and MARLAP processes for compliance demonstration. The workgroup believes that this would serve to detract from the broad scope of applicability of the MARLAP Manual. As designed the MARLAP Manual supports the MARSSIM approach or any other sound approach for decision-making that relies on radioanalytical data.

**SAB Report 7.5 (e):** It would be useful to show, perhaps through a table of connections, how the MARLAP Manual interfaces with, augments, or replaces existing guidance on radiochemical analyses.

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**MARLAP Workgroup Response:** The guidance on radiochemical analyses that the MARLAP Workgroup is aware of is generally in the form of compilations of specific radiochemical methods. Several examples of these method compilations are listed in Table 4 of EPA-SAB-RAC-03-009. Since the MARLAP process is based on a performance-based approach to method selection, compilations of radiochemical methods serve as a pool of potential methods to select from using a performance-based approach. Additional language has been added to Chapter 6 *Selection and Application of an Analytical Method* to emphasize the role of compilations of methods in a performance-based approach.

**SAB Report 7.5 (f):** Although it is outside the scope of the Panel's charge, the Panel recommends that each of the authoring organizations seek to establish a time frame for reviewing and revising the radiochemical method resources issued by their organizations to fully reflect the MARLAP guidance. Otherwise, a mixed message will be sent to the user community: on the one hand, advocating the right way to do radiochemical analyses, while on the other hand likely legally requiring the usage of radiochemical methods that follow outdated practices.

**MARLAP Workgroup Response:** The MARLAP Manual is a guidance document that promotes a performance-based approach for radiochemical method selection. The manual acknowledges that there are instances when certain methods are required by regulations. With the exception of the analysis of drinking water samples for compliance monitoring, required methods are relatively rare for projects requiring radioanalytical data. The MARLAP Workgroup will continue to promote and support the full implementation of a performance-based approach.

**SAB Report 7.5 (g):** The MARLAP agencies may need to stimulate a new generation of such experts through scholarships, fellowships, research grants, teaching grants, or other means in order to implement MARLAP as envisioned. A decline in fundamental nuclear research, in the number of nuclear degree-granting programs and in the number of nuclear research reactors on campus facilities, as well as a decline in research support that would encourage faculty to study the nuclear science field have all contributed to a decline in the pool of nuclear scientists and radioanalytic specialists. To the best of our knowledge, there is no nuclear science program today for generally trained scientists and particularly for radioanalytical personnel. This issue is being further explored by the SAB's RAC in a proposed self-initiated study on the broad topic of education and training related to guidance developed by EPA and multi-agency work groups.

**MARLAP Workgroup Response:** The MARLAP Workgroup agrees that there is a need to offset the trend towards a diminishing pool of available experts. As the MARLAP Workgroup develops and implements training and receives feedback on the manual, the workgroup will also solicit feedback on this topic from the agencies involved in the training.

**SAB Cover Letter:** The MARLAP document should be maintained as a "living document" and involve an iterative process whereby user suggestions can be incorporated into future revisions.

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***MARLAP Workgroup Response:*** The workgroup intends to use a variety of mechanisms to continue to obtain feedback on the MARLAP Manual and plans to make revisions to the manual based on comments received and “lessons learned” from implementation by its users.

**SAB Cover Letter:** The success of this and a previous multi-agency effort (i.e., MARLAP and MARSSIM) in addressing complex multi-disciplinary environmental issues leads us to recommend that multi-agency approach be extended to other EPA activities.

***EPA Response:*** EPA will continue to look for appropriate opportunities for using a multi-agency approach for addressing complex environmental issues.

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