UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

August 7, 2008

EPA-SAB-08-010

The Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Review of Draft ***"Multi-Agency Radiation Survey and Assessment of Materials and Equipment (MARSAME) Manual"***

Dear Administrator Johnson:

At the request of EPA's Office of Radiation and Indoor Air, the Science Advisory Board (SAB) Radiation Advisory Committee (RAC), augmented with additional experts (referred herein as the Panel or the SAB MARSAME Review Panel), has completed its review of the ***"Multi-Agency Radiation Survey and Assessment of Materials and Equipment (MARSAME) Manual,"(December 2006 Draft).*** This draft manual was prepared by a multi-agency work group with participation from the U.S. Department of Energy, the U.S. Nuclear Regulatory Commission, the U.S. Department of Defense, and the U.S. Environmental Protection Agency (U.S. EPA). The multi-agency work group has been active since 1995, for some periods with representation from additional federal agencies, to prepare a series of radiological guidance documents, of which this is the third. The preceding documents are entitled ***"Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)"*** and ***"Multi-Agency Radiological Laboratory Analytical Protocols (MARLAP) Manual."*** These manuals were previously reviewed by the RAC, augmented with additional experts.

The MARSAME manual complements MARSSIM (a surface soils radiation survey manual) by providing a process for surveying potentially radioactive material and equipment (M&E). It is a detailed document that provides guidance to determine whether M&E are sufficiently free of radionuclide contamination to be admitted to or removed from a site. Its chapters address the components of a survey plan: initial assessment, input needed for decision making, survey design, survey implementation, and reaching a disposition decision. The manual begins with a road map to help the user navigate the manual, includes a chapter with illustrative examples, and collects pertinent information in seven appendices. Much of its presentation is based on the contents of MARSSIM and MARLAP because M&E surveys often are related to site investigations and utilize laboratory analyses; however, an M&E survey may stand alone.

The SAB found the MARSAME manual to be an admirable cooperative and competently written effort by staff from the several agencies that provides guidance in an important endeavor. The Panel expects the manual to be as widely applied as the two earlier radiological guidance manuals and to contribute significantly to radiation protection for the US population. To assist this endeavor, the Panel presents 37 Recommendations and a Statistical Analysis Appendix in the enclosed review.

The main recommendations are:

- To facilitate application of MARSAME by important users such as project managers and site cleanup specialists who are not radiation protection professionals, support the Manual by holding training courses.
- To improve ease in reading and applying MARSAME, combine in a separate chapter the detailed guidance for hypothesis testing, experimental design, and statistical analysis that is now dispersed throughout the Manual.
- To clarify application of MARSAME guidance, improve the illustrative examples (now mislabeled 'case studies') by replacing them with real case studies, or enhance the illustrative examples with additional information based on real situations.
- To permit realistic design of M&E surveys in response to required action levels, include in MARSAME the pertinent regulations and guidance, and provide an updating mechanism.
- To avoid serious errors in delineating the radioactive contaminants of M&E, provide in MARSAME the same detailed discussion of radionuclides that are categorized as (1) removable from the surface and (2) distributed throughout the material volume as is currently devoted to the category of surface contamination that may be either fixed or removable.
- To expand the range of alternative M&E surveys available in MARSAME – from application of the full content of the Manual to 'no further action needed,' include descriptions of iterative release efforts that may include decontamination efforts and storage for radioactive decay.

Other recommendations concern additional refinements and improvements in content and presentation, including the concept that MARSAME be updated periodically.

The SAB appreciates the opportunity to review this draft manual and hopes that the recommendations provided will enable EPA and cooperating agencies to issue effective guidance for radiological surveys of material and equipment.

The revised MARSAME Manual will be a useful document for EPA and other Federal and State agencies in providing guidance to control transfer of material and equipment that may be contaminated with radionuclides. We look forward to the Agency's response.

Sincerely,

/Signed/	***/Signed/***
Dr. M. Granger Morgan Chair, Science Advisory Board	Dr. Bernd Kahn Chair, Radiation Advisory Committee

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Radiation Advisory Committee (RAC) Augmented for Review of the Multi-Agency Radiation Survey and Assessment of Materials and Equipment (MARSAME) Manual

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Dr. Jonathan M. Links, Professor, Department of Environmental Health Sciences, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

Mr. Bruce A. Napier, Staff Scientist, Radiological Science & Engineering Group, Pacific Northwest National Laboratory, Richland, WA[1]

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[1] Mr. Napier was unable to attend the face-to-face meeting of October 29-31, 2007 and the conference call of March 10, 2008.

Dr. Daniel O. Stram, Professor, Department of Preventive Medicine, Division of Biostatistics and Genetic Epidemiology, Keck School of Medicine, University of Southern California, Los Angeles, CA

Dr. Richard J. Vetter, Head, Radiation Safety Program, Mayo Clinic, Rochester, MN

CONSULTANTS:

Mr. Bruce W. Church, President, BWC Enterprises, Inc., Hurricane, UT

Mr. Kenneth Duvall, Environmental Scientist/Consultant, Washington, D.C.

Dr. Janet A. Johnson, Consultant, Carbondale, CO

Dr. Paul J. Merges, President, Environment & Radiation Specialists, Inc., Loudonville, N.Y.

SCIENCE ADVISORY BOARD STAFF

Dr. K. Jack Kooyoomjian, Designated Federal Officer, 1200 Pennsylvania Avenue, NW, Washington, DC, 20460-0001, Phone: 202-343-9984, Fax: 202-233-0643, or 0645 (kooyoomjian.jack@epa.gov) Messenger/Physical Delivery Address: 1025 F Street, NW, Room 3606, Mail Code 1400F

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Dr. Barton H. (Buzz) Thompson, Jr., Robert E. Paradise Professor of Natural Resources Law at the Stanford Law School and Director, Woods Institute for the Environment Director, Stanford University, Stanford, CA

Dr. Robert Twiss, Professor Emeritus, University of California-Berkeley, Ross, CA

Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Oakland, CA

SCIENCE ADVISORY BOARD STAFF

Mr. Thomas Miller, Designated Federal Officer, 1200 Pennsylvania Avenue, NW 1400F, Washington, DC, Phone: 202-343-9982, Fax: 202-233-0643

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1. EXECUTIVE SUMMARY

The Radiation Advisory Committee (RAC) of the Science Advisory Board (SAB), augmented for this review (also hereinafter referred to as the Panel, or the SAB MARSAME Review Panel) has completed its review of the Agency's draft document entitled ***"Multi-Agency Radiation Survey and Assessment of Materials and Equipment (MARSAME) Manual,"*** Draft Report for Comment, December 2006 (U.S. EPA, 2006; see also the MARSAME Hotlink at http://www.marsame.org). The MARSAME manual presents a framework for planning, implementing, and assessing radiological surveys of material and equipment (M&E). MARSAME supplements the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM; see also the MARSSIM Hotlink at http://epa.gov/radiation/marssim/index.html), and refers to information provided in the Multi-Agency Radiological Laboratory Analytical Protocols (MARLAP) Manual. The MARLAP Hotlink is http://epa.gov/radiation/marlap/index.html.

All manuals were prepared collaboratively by a multi-agency work group comprised of professionals from several pertinent Federal agencies. The three documents, taken together, describe radiological survey programs in great detail and address recommendations to "technical audiences having knowledge of health physics and statistics" for performing such surveys. The manuals are designed to enable effective comparisons of survey measurements of radionuclide concentrations to regulations or guides for accepting or rejecting approval of a program or process. Vocabulary and techniques in MARSAME are carried forward from MARSSIM and MARLAP.

The MARSAME manual complements MARSSIM (a surface-soil radiation survey manual known as the Multi-Agency Survey and Site Investigation Manual) by providing a process for surveying potentially radioactive M&E that may be in nature, commerce, or use when considered for receipt or disposition. It presents an overview of the various aspects of initial assessment, decision inputs, survey design, survey implementation, and assessment of results. Important activities such as hypothesis testing and statistical analysis of measurement reliability are described in considerable detail. A number of illustrative examples, incorrectly termed "case studies," are presented. A road map assists the reader in moving among chapters. Useful information is collected in appendices.

This review of the MARSAME Manual by the SAB was requested by the EPA Office of Radiation and Indoor Air (ORIA). It is based on reading the *MARSAME Draft Report for Comment (December 2006),* presentations by MARSAME multi-agency work group members at the meeting on October 29–31, 2007, and discussions in a series of teleconference meetings held on October 9, 2007, December 21, 2007, and March 10, 2008. A quality review of the Panel's April 24, 2008 draft report was conducted by the chartered SAB on May 29, 2008 in a public teleconference.

The Panel recognizes the magnitude of the effort by the multi-agency work group and the value of its product. The Panel recommends modifications to only a small fraction of this product. Panel recommendations can be summarized in the following broad categories:

- MARSAME guidance is suitable for experienced radiation protection and surveillance staff, but supporting courses should be presented for involved managers and professionals with limited knowledge of health physics or statistics to give them the needed special training and information that they would otherwise have to assimilate by searching through the lengthy MARSSIM and MARLAP documents. (1-3, 3-2, 3-4, C-4)[2]

- Specialized guidance for applying statistical tools for data analysis, experimental design, and hypothesis testing should be separated from the otherwise pervasively non-quantitative guidance for the convenience of the general audience and for acceptance by specialists. This guidance should be in a separate chapter, enhanced in accord with comments in the Appendix to this review. (1b-3, 1c-1, 2a-1, 2a-2, 2c-1, 3-6)[2]

- The incorrectly entitled 'case studies' should be labeled as 'illustrative examples' and their contents should be enhanced to assure realism. (1d-1, 1d-2, 1d-3, 1d-4, 2c-2, 2c-3)[2]

- Known regulations and guidance for meeting M&E action levels in MARSAME should be tabulated or cited by reference, with a mechanism for updating the references. (1b-1, 3-5)[2]

- As much consideration should be given to surveys for radioactive contamination that is removable from the surface and that is dispersed throughout the material volume as is given currently to surface contamination (fixed plus removable) in order to distinguish among the three categories for radiation protection. (1b-2, 2b-3, 2b-4)[2]

- The various alternatives for M&E surveys should be described in sufficient detail to provide a wide choice of options, from no further action needed through minor survey efforts to a major survey that applies the full contents of the MARSAME manual. The options should include iterative M&E release efforts such as decontamination or storage for decay. (1-1, 1-2, 1c-2, C-3)[2]

- Other recommendations are intended to improve the usefulness of various portions of the MARSAME manual, including updating it periodically (1a-1, 1a-2, 1a-3, 2a-3, 2b-1, 2b-2, 3-1, 3-3, 3-7, 3-8, C-1, C-2)[2]

The multi-agency work group clearly has devoted considerable effort to describing the statistical tools. This is important because acceptance of survey measurements depends on their reliability near the action level (AL). Meeting this requirement can only be demonstrated in a statistical framework; for example, the discrimination level (DL) must be below the AL in Scenario A, where the DL is defined to the satisfaction of the surveyor and the regulator in terms of the values for allowable type I error α and the allowable type II error β.

[2] The parenthetical numbers identify recommendations in response to the charge questions.

Because of the importance of clarity in the mathematical support structure, a sub-group of the Panel has prepared a guide to those topics in MARSAME that is collected in Appendix A to this review. This guide is devoted to matters such as survey design, the gray region, the DL, the test significance levels α and β, and hypothesis testing for Scenario A and Scenario B. The guide is intended to present to the multi-agency work group the Panel's view of (1) making this approach readily accessible to persons only generally familiar with statistical analysis, and (2) gaining acceptance by those who are knowledgeable on this topic.

2. INTRODUCTION

2.1 Background

The MARSAME Manual (U.S. EPA, 2006b) was designed to guide a radiation protection professional through all aspects of radiological surveys of M&E prior to intended receipt or appropriate disposition. It is written sufficiently broadly to pertain to all types of M&E. Cited as examples are metals, concrete, tools, trash, equipment, furniture, containers of material, and piping, among others. Release or interdiction, i.e., acceptance or rejection of M&E transfer, are the alternate outcomes of the survey.

The draft document for review was prepared collaboratively by staff working together from the following Federal agencies: the U.S. Environmental Protection Agency (US EPA), the U.S. Nuclear Regulatory Commission (US NRC), the U.S. Department of Energy (US DOE), and the U.S. Department of Defense (US DoD). It is part of a continuing and technically significant effort that began with writing MARSSIM (U.S. EPA./SAB,1997; U.S. EPA, 2000 and 2001), continued with MARLAP (U.S. EPA./SAB, 2003a.; U.S. EPA, 2004), and anticipates preparation of at least one other manual after MARSAME for sub-surface radiation surveys and characterization. The methodology and associated vocabulary in MARSAME follow those of the preceding manuals, although a few aspects of MARSAME are distinct. Notably, MARSAME may be connected to MARSSIM and MARLAP as part of a site survey, or stand by itself in considering the transfer of M&E to or from a site.

Survey guidance in the MARSAME manual and its predecessors is based on the Data Quality Objectives (DQO) process to design the best survey with regard to disposition option, action level (AL), and M&E type. The Data Life Cycle (DLC) supports DQO by carrying suitable information through the planning, implementation, assessment, and decision stages of the program. The data are collected, evaluated, and applied in terms of Measurement Quality Objectives (MQO) established with statistical concepts of data uncertainty and Minimum Quantifiable Concentrations (MQC). The sensitivity of measurements is defined in terms of the discrimination limit (DL), which is is attained by selecting suitable radionuclide detectors and conditions of sampling and measurement. The measurement results must be acceptable relative to action levels and significance levels specified in regulations or guidance.

The MARSAME document is structured as follows, shown with the relevant charge question (CQ) number (See Section 2.3 for the charge questions):

Acronyms and Abbreviations
Symbols, Nomenclature, and Notations
Conversion factors
Road Map (CQ 3)
Chapter 1, Introduction and overview (CQ 1)
Chapter 2, Initial assessment of M&E (CQ 1a)
Chapter 3, Identify inputs for the decision (CQ 1b)
Chapter 4, Survey design (CQ 1c)

Chapter 5, Implementation of disposition surveys (CQ 2a)
Chapter 6, Assess the results of the disposition survey (CQ 2b)
Chapter 7, Case studies (CQ 1d and 2c)
7 Appendices (CQ 3)
References
Glossary

Response to the charge questions was the primary purpose of the Panel and is addressed first. The Panel also considered a few related topics, commented in detail on the MARSAME discussion of statistical and operational aspects, and suggested minor corrections.

2.2 Review Process and Acknowledgement

The U.S. EPA's Office of Radiation and Indoor Air (ORIA), on behalf of the Federal Agencies participating in the development of the draft MARSAME Manual, requested the SAB to provide advice on the draft document entitled *"Multi-Agency Radiation Survey and Assessment of Materials and Equipment (MARSAME) Manual," Draft Report for Comment, December 2006* (U.S. EPA. 2006b.; also numbered as NUREG-1575, Supp. 1; EPA 402-R-06-002; and DOE/EH-707). MARSAME is a supplement to the *"Multi-Agency Radiation Survey and Site Investigation Manual"* (MARSSIM; U.S. EPA, 2000 and 2001; also numbered as NUREG-1575, rev. 1; EPA 402-R-97-016, Rev. 1; and DOE/EH-0624, Rev. 1). The SAB Staff Office announced this advisory activity and requested nominations for technical experts to augment the SAB's Radiation Advisory Committee (RAC) in the Federal Register (72 FR 11356; March 13, 2007).

MARSAME was developed collaboratively by the Multi-Agency Work Group (60 FR 12555; March 7, 1995) and provides technical information on approaches for planning, conducting, evaluating, and documenting radiological surveys to determine proper disposition of materials and equipment (M&E). The techniques, methodologies, and principles that form the basis of this manual were developed to be consistent with current Federal limits, guidelines, and procedures.

The Panel met in an initial public teleconference meeting on Tuesday, October 9, 2007. The meeting was intended to introduce the subject and discuss the charge to the Panel, determine if the review and background materials provided were adequate to respond to the charge questions directed to the Panel, and agree on charge assignments for the Panelists. A public meeting was scheduled on Monday, October 29 through Wednesday, October 31, 2007, to receive presentations by the multi-agency work group, consider the charge questions, and draft a report in response to the charge questions pertaining to the draft MARSAME manual. The Panel discussed the first public draft report (December 17, 2007), in a December 21, 2007 public conference call. The Panel discussed it's second public draft report (February 27, 2008) in the March 10, 2008 public conference call. The April 24, 2008 draft report was provided for a public quality review teleconference meeting of the chartered Board on May 29, 2008. This report incorporates suggestions made by the chartered SAB.

2.3 EPA Charge to the Panel

The EPA's Science Advisory Board (SAB) previously conducted the scientific peer reviews of the companion multi-agency documents MARSSIM (U.S. EPA/SAB, 1997; EPA-SAB-RAC-97-008, dated September 30, 1997) and MARLAP (U.S. EPA/SAB, 2003b.; EPA-SAB-RAC-03-009, dated June 10, 2003). The Federal agencies participating in those peer reviews considered the process used by the SAB to be beneficial in assuring the accuracy and usability of the final manuals. Subsequently, two consultations took place for MARSAME (U.S. EPA/SAB, 2003a; EPA-SAB-RAC-CON-03-002, dated February 27, 2003, and U.S. EPA/SAB, 2004; EPA-SAB-RAC-CON-04-001, dated February 9, 2004). These are now being followed by a request from EPA ORIA on behalf of the four participating Federal agencies that the SAB conduct this formal technical peer review of the draft MARSAME manual.

The following charge questions were posed to the SAB MARSAME Review Panel (U.S. EPA, 2007b):

1) The objective of the draft MARSAME is to provide an approach for planning, conducting, evaluating, and documenting environmental radiological surveys to determine the appropriate disposition for materials and equipment with a reasonable potential to contain radionuclide concentration(s) or radioactivity above background. Please comment on the technical acceptability of this approach and discuss how well the document accomplishes this objective. In particular, please

a) Discuss the adequacy of the initial assessment process as provided in MARSAME Chapter 2, including the new concept of sentinel measurement (a biased measurement performed at a key location to provide information specific to the objectives of the Initial Assessment).

b) Discuss the clarity of the guidance on developing decision rules, as provided in MARSAME Chapter 3.

c) Discuss the adequacy of the survey design process, especially the clarity of new guidance on using Scenario B, and the acceptability of new scan-only and in-situ survey designs, as detailed in MARSAME Chapter 4.

d) Discuss the usefulness of the case studies in illustrating new concepts and guidance, as provided in MARSAME Chapter 7.

2) The draft MARSAME, as a supplement to MARSSIM, adapts and adds to the statistical approaches of both MARSSIM and MARLAP for application to radiological surveys of materials and equipment. Please comment on the technical acceptability of the statistical methodology considered in MARSAME and note whether there are terminology or application assumptions that may cause confusion among the three documents. In particular, please

a) Discuss the adequacy of the procedures outlined for determining measurement uncertainty, detectability, and quantifiability, as described in MARSAME Chapter 5.

b) Discuss the adequacy of the data assessment process, especially new assessment procedures associated with scan-only and in-situ survey designs, and the clarity of the information provided in Figures 6.3 and 6.4, as detailed in MARSAME Chapter 6.

c) Discuss the usefulness of the case studies in illustrating the calculation of measurement uncertainty, detectability, and quantifiability, as provided in MARSAME Chapter 7.

3) The draft MARSAME includes a preliminary section entitled Roadmap as well as seven appendices. The goal of the Roadmap is to assist the MARSAME user in assimilating the information in MARSAME and determining where important decisions need to be made on a project-specific basis. MARSAME also contains appendices providing additional information on the specific topics. Does the SAB have recommendations regarding the usefulness of these materials?

3. RESPONSE TO THE STATISTICS ELEMENTS OF THE CHARGE QUESTIONS

Detailed discussions of statistical analysis related to experimental design and hypothesis testing permeate the otherwise non-mathematical guidance for M&E surveys. The Panel response and comments specifically addressed to statistical analysis are compiled in Appendix A rather than scattering them throughout this review. Appendix A consists of an introduction that describes the view of the Panel, followed by specific reviewer responses based on these reviews. All related responses to individual charge questions, notably for charge questions 1b, 1c, and 2a, are referred to Appendix A.

The Panel recommends that topics presented in Appendix A be included as a separate chapter that appears early in the MARSAME manual. This will serve to consolidate many of the important statistical concepts that now are now scattered throughout several chapters. The first-time user will then become familiar with statistical considerations that are the backbone for the MARSAME process.

MARSAME contains many suggested equations for designing and interpreting survey procedures (e.g., Tables 5.1, 5.2). The equations are derived from sound statistical principles, but can lead to incorrect conclusions if the underlying assumptions in the derivations are not satisfied. Not every equation needs to be derived in detail, but the assumptions and sampling requirements to implement specific equations should be thoroughly identified and explained.

Classical hypothesis testing procedures require specification of a null hypothesis and values of α and β that quantify boundaries for type I and type II errors. The selection of these values provides a measure of tolerance for uncertainty and assurance that the ultimate goals relating to risk are satisfied. The existing discussion in Chapter 4 is too vague to provide guidance on how these values should be selected and should either be more specific or -- if this is considered to be beyond the scope of MARSAME – refer to sources of detailed guidance on the selection of α and β.

In the design of disposition surveys, the manual discusses determination of measurement uncertainty, detectability, and quantifiability in terms of MQO requirements. These MQO values should be organized and presented for individual types, such as *in situ*, scan only, or MARSSIM survey types.

4. RESPONSE TO CHARGE QUESTION 1: PROVIDING AN APPROACH FOR PLANNING, CONDUCTING, EVALUATING AND DOCUMENTING ENVIRONMENTAL RADIOLOGICAL SURVEYS TO DETERMINE THE APPROPRIATE DISPOSITION FOR MATERIALS AND EQUIPMENT

4.1 Charge Question 1: ***The objective of the draft MARSAME is to provide an approach for planning, conducting, evaluating, and documenting environmental radiological surveys to determine the appropriate disposition for materials and equipment with a reasonable potential to contain radionuclide concentration(s) or radioactivity above background. Please comment on the technical acceptability of this approach and discuss how well the document accomplishes this objective.***

The MARSAME manual impresses the Panel as an excellent technical document for guiding an M&E survey. Regarding CQ 1, the Panel recommends greater detail in describing the "alternate approaches or modification" for applying MARSAME, as discussed in Chapter 1, lines 50 – 56. For example, the option of decontaminating the M&E as part of the process when considering alternate actions appears to be missing. The Panel also recommends making the manual more accessible to interested non-specialists, notably project managers and other decision makers. Such non-specialists generally are not included in the intended "technical audience having knowledge of health physics and an understanding of statistics," with further capabilities also described in Chapter 1, lines 187 – 194. The following itemized recommendations elaborate on these points.

RECOMMENDATION 1-1: Create a sub-section for the discussion that begins in Chapter l, line 49, to present clearly the concept of simple alternatives to what may appear to the reader to be a major undertaking. Also, in lines 103-111 further define 'release' *vs*. 'interdiction' to clarify the distinction between the terms. Follow these paragraphs with sufficient detail and references to later chapters to assure the reader that when M&E is reasonably expected to have little or no radioactive contamination, it can be processed without excessive effort under the MARSAME system. One approach identified subsequently is applying standard operating procedures (SOP's). Categorization as non-impacted or as class 3 M&E based on historical data also can lead to an appropriately simple process.

RECOMMENDATION 1-2: Insert a sub-section in Chapter 1 and in appropriate subsequent chapters to consider various degrees of M&E decontamination as part of the available options associated with a MARSAME survey. Storage for radioactive decay can be an option for decontamination.

RECOMMENDATION 1-3: Insert a paragraph after Chapter 1, line 196, to address use by persons less skilled professionally than defined in a preceding paragraph. Reference to Appendices B, C, and D, would be helpful for such persons. Adding an appendix that includes portions of the MARSSIM Roadmap and Chapters 1 and 2 could provide suitable background information without requiring that all of MARSSIM be read. Presentation of training courses for managers and other generalists with responsibility for MARSAME radiation surveys would be most helpful.

4.2 <u>Charge Question 1a:</u> ***Discuss the adequacy of the initial assessment process as provided in MARSAME Chapter 2, including the new concept of sentinel measurement (a biased measurement performed at a key location to provide information specific to the objectives of the Initial Assessment).***

The initial assessment (IA) process is useful as described. That many measurements made throughout the MARSAME process could be biased should be obvious to the radiation protection and survey professional. Additional information sources cited below could be helpful.

Sentinel measurements, as described for the IA process of MARSAME have been widely applied, although not necessarily designated by that name. They are rational and useful for obtaining an IA of the type and magnitude of radioactive contaminants although they may not have been randomly selected and, hence, are biased by definition. These measurements and their applicability and limitations are well described in the document, and their use is clear. In fact, wider application appears practical.

RECOMMENDATION 1a-1: Add to the information sources in Chapter 2, lines 104 – 115, the files (inspection reports, incident analyses, and compliance history) maintained by currently and formerly involved regulatory agencies. Discussion with agency staffs, especially their inspectors, also could be fruitful.

RECOMMENDATION 1a-2: The listing of complexity attributes in Table 2.1 could include Toxic Substances Control Act (TSCA) materials and hazardous waste.

RECOMMENDATION 1a-3: In Chapter 1, lines 253 – 259, MARSAME should recognize that sentinel measurements are important because they may represent the entire historical record available for IA. Moreover, the measurements may have been so well planned that considering them "limited data" is misleading without a clear definition of terms. Sentinel measurements are particularly useful to evaluate assumptions based on process knowledge. In Chapter 2, lines 277 – 280, design of a preliminary survey for radioactive contaminants to fill knowledge gaps often depends on the availability of data from sentinel measurements. In some instances, the physical shape of the M&E may limit further survey to sentinel measurements. On the other hand, the MARSAME Manual draft, line 258, is correct in stating that sentinel measurements should not be used alone to justify categorization of M&E as non-impacted, especially when geometric or non-homogeneity limitations in radiation detection are suspected.

4.3 <u>Charge Question 1b:</u> *Discuss the clarity of the guidance on developing decision rules, as provided in MARSAME Chapter 3.*

This chapter, devoted to developing decision rules, is very useful. The decision rules are clear. The Panel has the following recommendations concerning (1) distinction among surface removable, surface fixed, and volumetric radioactive contamination; (2) presentation of regulations and guidance that address these contaminant forms; and (3) the mathematically complex aspects of measurement method uncertainty, detection capability, and quantification capability. With regard to the latter, Chapter 3, lines 567 – 622 takes the MARSAME presentation from broad guidance to specific statistical tutorial, which raises difficulties for some general readers and questions for some professionals.

RECOMMENDATION 1b-1: The regulations or guidance for radionuclide clearance that define the action levels (AL) discussed in Chapter 3, lines 118 – 120, and listed in Appendix E should be sufficiently inclusive to apply to the usual M&E handled by users with regard to both non-fixed (removable) surface contamination and volumetric (distributed throughout the material) contamination. Tabulate or cite all other known pertinent regulations and guides for this purpose. To the non-fixed surface contamination regulations included in Table E.2 by DOE and Table E.3 by NRC, add the Department of Transportation regulation (U.S. DOT, 49CFR173.443), and guides by states such as New Jersey (State of New Jersey, 2007) and Nevada (State of Nevada, 2001). Include guidance for volumetric contamination clearance, summarized in Table 5.1 of NCRP (2002) from reports of national and international standard-setting groups.

RECOMMENDATION 1b-2: Information that guides decisions for radioactively contaminated M&E, listed in Chapter 3, lines 141 – 147, should include measurements of removable *vs.* fixed surface contamination to match the distinctions specified in Tables E.2 and E.3. Insert sub-sections that discuss the implications of planning for and responding to measurement of removable *vs.* fixed and surface *vs.* volumetric radioactive contamination and the subsequent disposition of M&E according to this categorization (see also RECOMMENDATIONS 2b-3 and 1d-3 for discussion of removable radioactive contaminants).

RECOMMENDATION 1b-3: Maintain the more general tone of MARSAME throughout Chapter 3 while moving detailed discussions of statistical aspects to a separate chapter (see also RECOMMENDATIONS 1c-1 and 2a-1). This approach could remove concerns such as why the Minimum Detectable Concentration (MDC) is recommended for the Measurement Quality Objective (MQO) in Chapter 3, lines 593 – 597, instead of the Minimum Quantifiable Concentration (MQC), and how item #1 differs from item #3 on lines 609 – 617.

4.4 <u>Charge Question 1c:</u> *Discuss the adequacy of the survey design process, especially the clarity of new guidance on using Scenario B. and the acceptability of new scan-only and in-situ survey designs, as detailed in MARSAME Chapter 4.*

With the exception of Section 4.2, Statistical Decision Making, Chapter 4 is easily understood by the general reader. Classification of M&E is an effective and helpful process.

The Disposition Survey Design and Documentation sections are well prepared. Further discussion would help in addressing problems associated with complex geometric or non-homogeneous distributions of the radioactive contamination relative to the detector. These are of particular interest when using scanning or *in situ* detection methods, and could be demonstrated effectively in the illustrative example concerning rubble disposal of Section 7.3.

Regarding statistical decision making, the concepts of hypothesis testing and uncertainty *per se* are readily understood. However, the aspects of uncertainty with default significance levels and the resulting gray area and discrimination limits (DL) leading to minimum quantifiable concentrations (MQC) are not so readily assimilated. Extensive consideration of the statistical approach is attached to this review as Appendix A.

RECOMMENDATION 1c-1: In the organization of MARSAME, instead of the current mixture of general guidance about surveillance with detailed presentations of statistical matters, retain in each chapter only a brief and less detailed discussion of statistics. Collect the mathematical discussion in a separate chapter, as proposed above. Chapter 19, Measurement Statistics, in MARLAP should serve as example. The separation will serve both the specialist in statistics, who will appreciate the exposition in the newly added chapter, and readers with less training in statistics who can follow the general import of the MARSAME approach in the existing chapters.

RECOMMENDATION 1c-2: The MARSAME manual has emphasized disposition options that, after identification and segregation, lead directly to the disposition survey. Conditioning of the M&E, such as vacuuming, wiping down, chemical etching, and other forms of decontamination should be encouraged for meeting disposition options (see also RECOMMENDATION 1-2). Preliminary measurements are useful for this purpose. The MARSAME manual should provide more detail on these approaches and encourage them as an As Low As Reasonably Achievable (ALARA) policy.

4.5 <u>Charge Question 1d:</u> *Discuss the usefulness of the case studies in illustrating new concepts and guidance, as provided in MARSAME Chapter 7.*

Case studies can be immensely beneficial for clarifying the MARSAME process and guiding the user, but members of the multi-agency work group informed the Panel that Chapter 7 does not contain case studies but rather invented illustrative examples. The latter usually are not as instructive as case studies because they lack the element of reality, but can be helpful if created carefully to represent actual situations.

RECOMMENDATION 1d-1: Delete or replace the example for Standard Operating Procedure (SOP) use in Section 7.2. Given the good discussion in Section 3.10 for improving an SOP within the MARSAME framework, the example of applying SOP's at a nuclear power station appears to contribute little.

RECOMMENDATION 1d-2: The example in Section 7.3 of mineral processing of concrete rubble is instructive, but the reader should be informed that many more measurement results than those listed in Table 7.3 are obtained under actual conditions and must be evaluated before making decisions. The radionuclide concentrations reported in Chapter 7, lines 213 – 214, should be confirmed as typical values or replaced by such values, because readers may apply them as default values. For the same reason, the AL taken from a U.S. Nuclear Regulatory Commission document (NUREG-1640;U.S. NRC, 2003) should be identified as a specific selection, not a general limit. Inserting boxes with interpretive comments would help the reader to understand the process used for illustration and the logic leading to the decisions.

RECOMMENDATION 1d-3: Insert an introductory statement to place in context the length of the 21-page example devoted in Section 7.4 to a simple baseline survey of a rented front loader, to avoid discouraging the reader from applying it. This statement should explain that these details are needed to describe the survey process, but that the actual work is brief. This survey provides an opportunity to present the benefit of sentinel measurements and the comparison of removable with fixed surface contamination. An actual case history undoubtedly would show these and also contain a table of survey measurements.

RECOMMENDATION 1d-4: Include in each of the illustrative example headings a statement that they are demonstrating the MARSAME process.

5. RESPONSE TO CHARGE QUESTION 2: COMMENTS ON THE STATISTICAL METHODOLOGY CONSIDERED IN MARSAME

5.1 Charge Question # 2: ***The draft MARSAME, as a supplement to MARSSIM, adapts and adds to the statistical approaches of both MARSSIM and MARLAP for application to radiological surveys of materials and equipment. Please comment on the technical acceptability of the statistical methodology considered in MARSAME and note whether there are terminology or application assumptions that may cause confusion among the three documents.***

MARSAME contains tables and text that carefully compare the three documents and identify consistencies and differences. To Panel members familiar with the three documents, application of the statistical methodology in MARSAME appears to match that used in MARSSIM and MARLAP.

The statistical methodology applied in MARSAME is acceptable and not confusing when all three documents are read. Application of comments in Appendix A to this report and consolidation of the mathematical aspects of MARSAME in a single chapter as recommended below should enhance use of MARSAME.

A shift appears to have occurred from use of the Data Quality Objective (DQO) terminology of MARSSIM to the Measurement Quality Objective (MQO) of MARSAME, but the principle is understandable. Clearly, MARSAME has close connections to MARSSIM in surveys of M&E at MARSSIM sites. The manual also addresses M&E that is to be moved onto or from a site for various reasons, including - - but not necessarily - - processing and surveying the site subject to MARSSIM.

5.2 Charge Question # 2a: ***Discuss the adequacy of the procedures outlined for determining measurement uncertainty, detectability, and quantifiability, as described in MARSAME, Chapter 5.***

The presentation for determining uncertainty, detectability, and quantifiability in Chapter 5, as well as aspects of this discussion in Chapters 4 and 6, follows the well-developed path in MARSSIM and MARLAP and is essential to the disposition survey planner. The Panel believes that the outlined procedures are adequate, but that correct application by the user requires (1) previous reading of MARSSIM and MARLAP, and (2) the expertise and knowledge specified in Chapter 1, lines 189 – 194.

RECOMMENDATION 2a-1: Enable the reader to understand the topics in Chapter 5 more clearly by separating the entire mathematically detailed statistical exposition in a chapter that could be entitled “Review of Experimental Design and Hypothesis Testing.” Appendix G can be included in this chapter. The chapter can be placed before Chapter 4. All sections currently in Chapters 4 – 6 that discuss generalized aspects of these topics, including measurement uncertainty, detectability, and quantifiability, can be kept in place; reference should be made to the technical discussions, equations, and tables in the new chapter.

RECOMMENDATION 2a-2: Consider the comments made in Appendix A concerning the topics of experimental design, hypothesis testing, and the statistical aspects of uncertainty in preparing the separate chapter suggested above.

RECOMMENDATION 2a-3: Move the discussion on setting MQOs, in Sections 5.5 thru 5.9, to Chapter 4 on Survey Design. Organize a summary or guide that focuses on the procedures for setting MQOs and for determining uncertainty, MDC, and MQC. The ability to set Measurement Quality Objectives (MQOs) is an important element of the MARSAME process, but the discussion involving the implementation of MQOs in the design of the three survey types may confuse the reader. Aspects of implementation are immersed in details defining, explaining, and deriving theoretical concepts

5.3 Charge Question # 2b: *Discuss the adequacy of the data assessment process, especially new assessment procedures associated with scan-only and in-situ survey designs, and the clarity of the information provided in Figures 6.3 and 6.4.*

The data assessment process is appropriate, carefully presented, and thoroughly explored. The advice is pertinent and the examples are helpful.

The Panel discusses statistical considerations in Appendix A. The information presented in Figures 6.3 and 6.4 is clear (See Figures 1 and 2, below), but minor changes, shown in the following two revised Figures are proposed.

The Panel noted above the importance of distinguishing in all MARSAME chapters among contamination that is (1) removable from the surface, (2) fixed to the surface, or (3) volumetric. Smear surveys (wipe tests) are an integral part of an M&E survey because of the potential radiation dose from removable radionuclides that can spread from M&E surfaces and be inhaled and ingested. Removable surface contamination is included in DOE regulations in Table E.2 and NRC regulations in Table E.3, as well as DOT regulations and International Atomic Energy Agency (IAEA) guidance. Multi-agency working group members expressed reluctance about including in MARSAME a survey technique that they consider to be poorly reproducible for defining the removable radionuclide amount per area. The Panel response is that insufficiently discussing wipe tests is unrealistic and misleading. Each type of measurement has its own uncertainty. A reasonable approach is to begin with the instruction in U.S. DOT 49CFR173.443 “wiping an area of 300 cm^2 … with an absorbent material … using moderate pressure” that “sufficient measurements shall be taken in the most appropriate locations to yield a representative assessment” and then provide guidance on defining and controlling variability.

RECOMMENDATION 2b-1: In Fig. 6.3 (See Figure 1 below, which reworks Fig. 6.3), clarify the distinction of a MARSSIM-type survey by moving “Start” to immediately above the decision point “Is the Survey Design Scan-only or *In situ*?” and then connecting this to an inserted decision diamond “Is the AL equal to zero or background?”. A “yes” leads to “Requires scenario B …” and a “no” leads to “Disposition Decision Based on Mean ….”

RECOMMENDATION 2b-2: In Fig. 6.4 (See Figure 2 below, which reworks Fig. 6.4), for a more consistent presentation, insert a decision diamond after both "Perform the Sign Test" and "Perform the WRS Test" that says "Scenario A," followed by a "yes" or "no" leading to the two "Scenario A" and "Scenario B" branches at both locations.

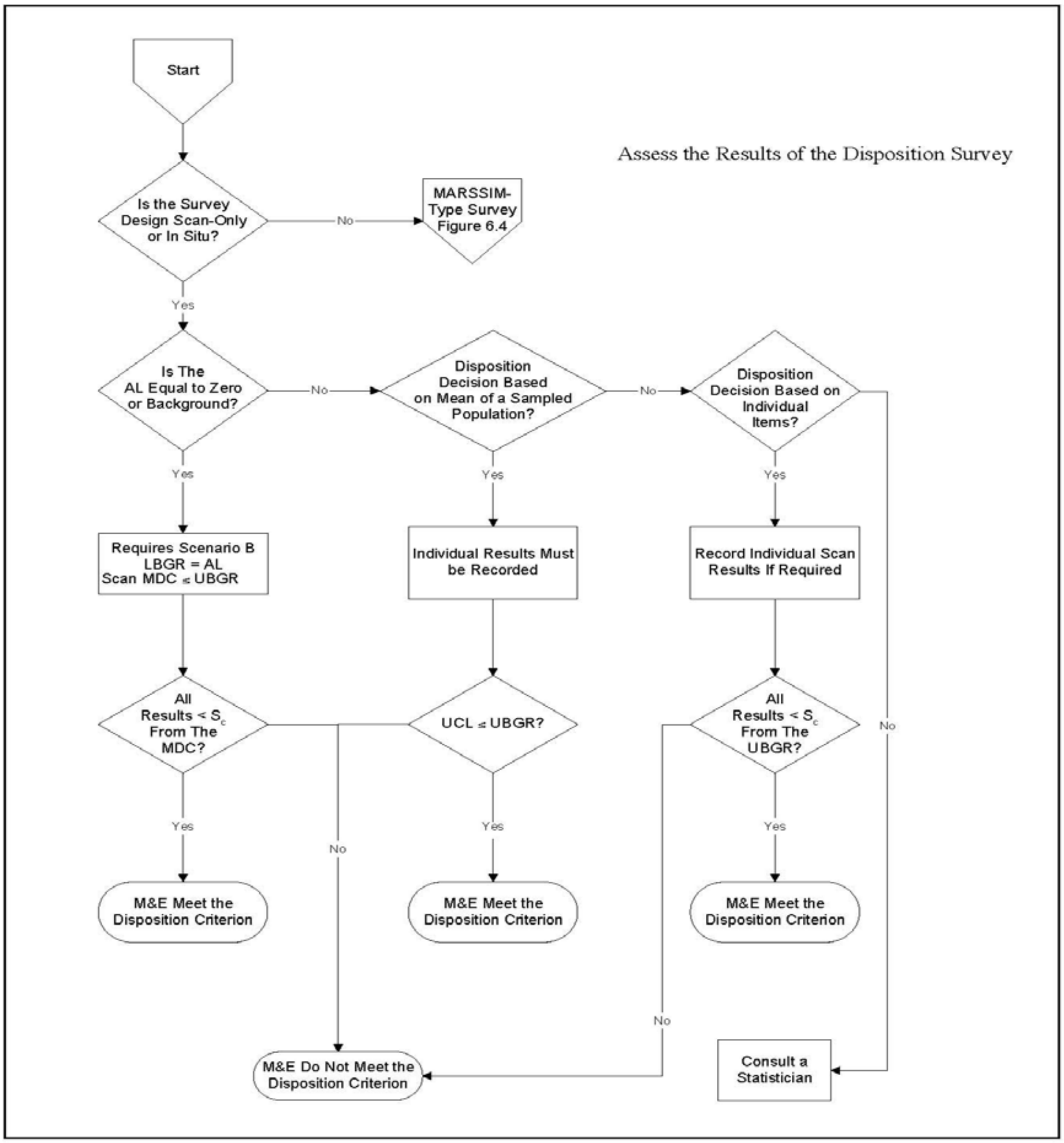

Figure 1 – Suggested Changes for Figure 6.3 from MARSAME Manual for Interpretation of Survey Results for Scan-Only and In-Situ Surveys

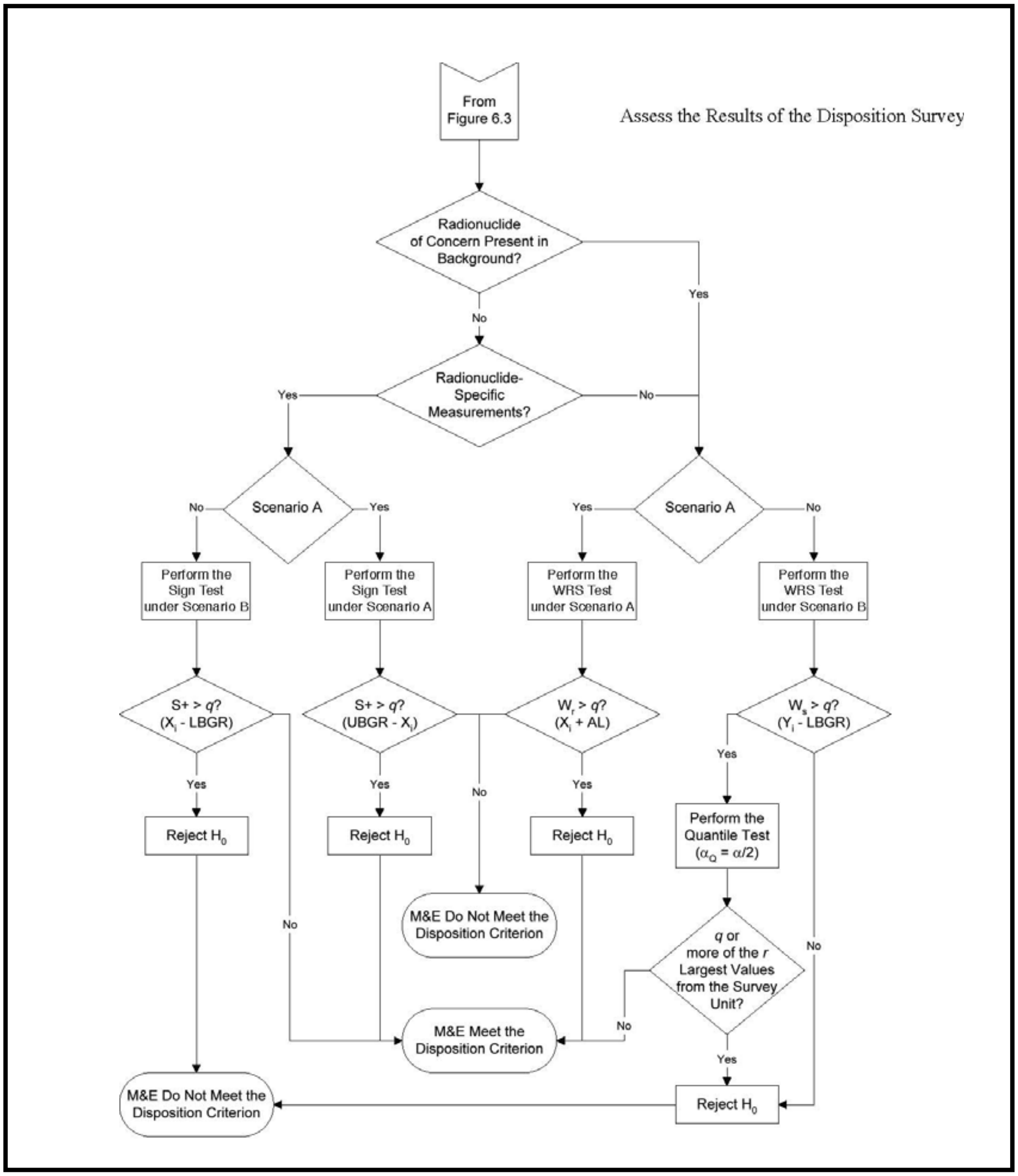

Figure 2 – Suggested Changes for Figure 6.4 from MARSAME Manual for Interpretation of Results for MARSSIM-Type Surveys

RECOMMENDATION 2b-3: To counteract the discomfort of Multi-agency working group members with the qualitative aspect of wipe tests, the MARSAME manual could recommend evaluations of the removable radionuclide fraction measured by wipe test for the surveyed M&E. These evaluations can include, for example, sequential smears at a given location at the M&E, or smears at adjoining locations performed with different material and pressure, by different persons, and for different radionuclides. Refer to State of Nevada (2001) and State of New Jersey (2007) for a description of the process, to Rademacher and Hubbell (2008) pp. 10, 16 for an application to radiological monitoring, and to U.S. EPA (2007a) for more general applications of the wipe test.

RECOMMENDATION 2b-4: Insert sub-sections in all chapters to address implementation and assessment of survey processes to distinguish between surface and volumetric contamination (i.e., measurement after surface cleaning or observing the effect of counting geometry) and between removable and fixed surface contamination (i.e., wipe test results compared to total surface activity). These types of contamination are described in Chapter 1, lines 127 – 152, but their implications should be considered throughout the MARSAME manual. Concerns in measuring volumetric contamination include characterizing non-uniformly distributed radionuclides and quantifying radionuclides that emit no gamma rays.

5.4 <u>Charge Question # 2c:</u> *Discuss the usefulness of the case studies in illustrating the calculation of measurement uncertainty, detectability, and quantifiability as provided in MARSAME chapter 7.*

As stated in the response to CQ 1d, case studies are invaluable in guiding the user through complex operations. A useful case study discussion with references is available in ITRC (2008). The illustrative examples given instead of case studies in MARSAME lack the realistic data accumulation that permits estimation of uncertainty. Excessively detailed derivations of equations for calculation are shown in Chapter 7, lines 579 – 628, 658 – 665, 682 – 689, and 1133 – 1150. For discussions related to uncertainty, refer to Appendix A.

RECOMMENDATION 2c-1: Move the detailed derivations, including partial derivatives, identified above to the newly added separate chapter recommended for discussion of experimental design and hypothesis testing.

RECOMMENDATION 2c-2: Use illustrative examples to demonstrate any MARSAME guidance that the multi-agency work group considers difficult to follow. These may include approximating uncertainty (see Chapter 5), distinctions such as interdiction *vs.* release, and applying scenarios A *vs.* B.

RECOMMENDATION 2c-3: Use Sections 7.4 and 7.5 to illustrate the benefit of wipe tests for determining removable radioactive surface contaminants. Experience suggests that the contaminant usually is in this form on M&E such as earth-moving equipment.

6. RESPONSE TO CHARGE QUESTION 3: RECOMMENDATIONS PERTAINING TO THE MARSAME ROADMAP AND APPENDICES

<u>**Charge Question 3:**</u> ***The draft MARSAME includes a preliminary section entitled Roadmap as well as seven appendices. The goal of the Roadmap is to assist the MARSAME user in assimilating the information in MARSAME and determining where important decisions need to be made on a project-specific basis. MARSAME also contains appendices providing additional information on the specific topics. Does the SAB have recommendations regarding the usefulness of these materials?***

The Roadmap is crucial in guiding the reader through a document as complex as MARSAME. The appendices are useful in various ways, such as providing information compilations and statistical tables, and avoiding the need to seek this information in MARSSIM and MARLAP. Also necessary to the reader are the acronyms and abbreviations; symbols, nomenclature, and notations; and glossary. The following Recommendations are intended to enhance their use.

RECOMMENDATION 3-1: Roadmap Figure 1 connects the MARSAME chapters in terms of the Data Life Cycle. Consider establishing an analogous connection with Roadmap Figures 2, 3, 5, 6, 7, and 8. At present, the only Roadmap figures connected to each other are Fig. 2, 3, and 4, and 7 with 8.

RECOMMENDATION 3-2: Consider assisting project managers by highlighting major operational decision points in the roadmaps.

RECOMMENDATION 3-3: The roadmap should ensure that the primary components of the process are identified, their relationship to one another is depicted, and the boundaries of application are well-defined, in accord with the DQO process. Figure 3 provided below could be used in the MARSAME roadmap to illustrate application of the DQO process in the MARSAME manual. Realize also that the DQO process is iterative, so that, as in the case of MARSSIM, the MARSAME program should have the potential to improve and update the manual.

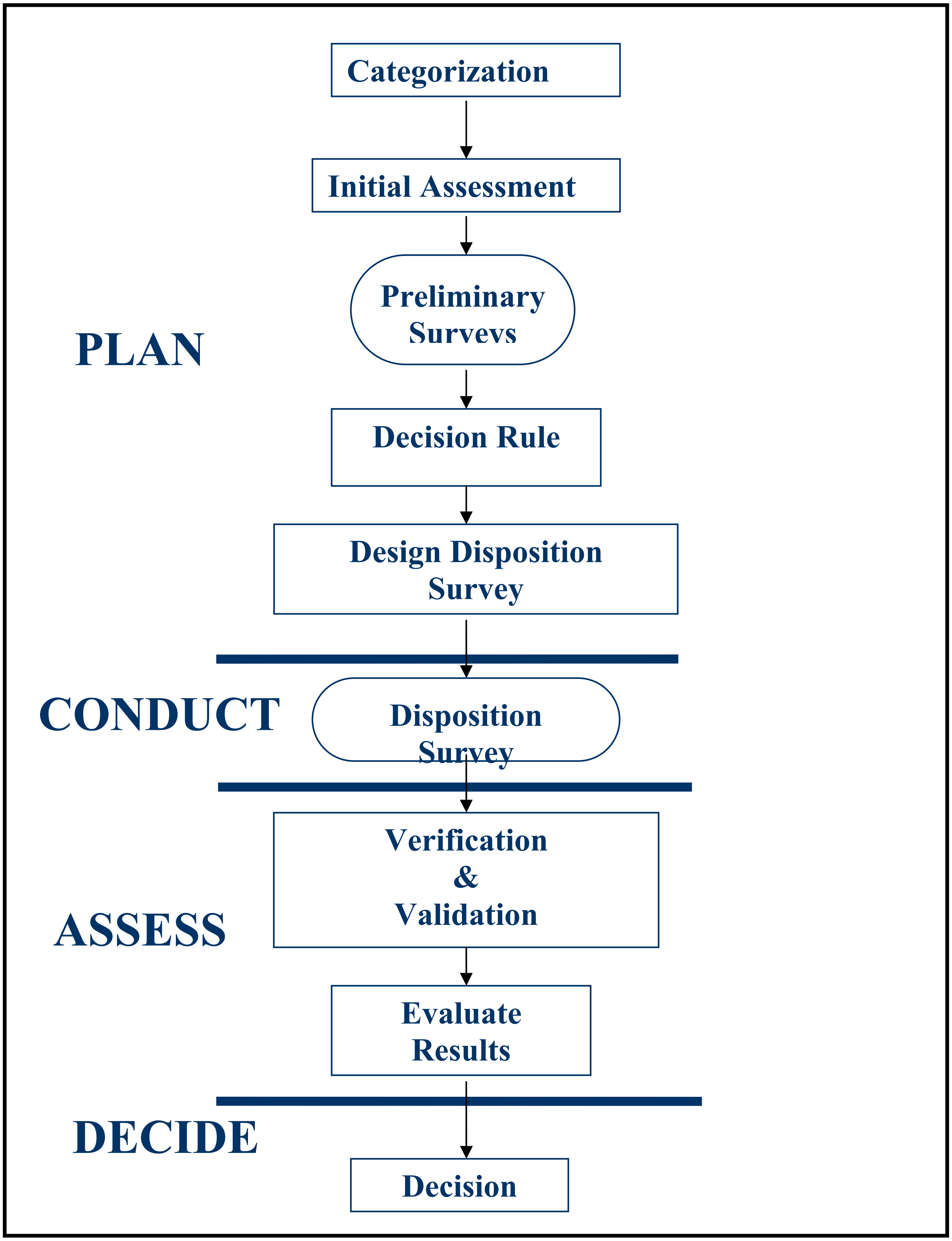

Figure 3 – The MARSAME Process

RECOMMENDATION 3-4: Indicate in the body of the text that Appendices B, C, and D are useful overviews of the environmental radiation background, sources of radionuclides, and radiation detection instruments, respectively, for managers and generalists; they may be too general for the experienced health physicist to whom the manual is addressed.

RECOMMENDATION 3-5: Insert a table with action level (AL) guidance for volumetric radionuclide contamination in Appendix E (see RECOMMENDATION 1b-1).

RECOMMENDATION 3-6: Either move Appendix G into the new chapter on experimental design and hypothesis testing or indicate its relation to that new chapter.

RECOMMENDATION 3-7: Move the Glossary to the front to join the tables of acronyms and of symbols.

RECOMMENDATION 3-8: Expand the definition of 'Interdiction' in the glossary to clarify its application to receiving or disposing of M&E.

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7. RECOMMENDATIONS BEYOND THE CHARGE

RECOMMENDATION C-1: In Chapter 3, discuss in the recommended separate chapter on statistics any decisions leading to selecting the degree of confidence, embedded in the choice of significance level α and β values. Selection may be a matter of the acceptable uncertainty specified by the agency that sets the action level.

RECOMMENDATION C-2: In Chapter 2, discuss the impact of survey cost and needed skills, instruments, and time on the MARSAME effort. Brief projects obviously need different designs than lengthy ones. Discuss requirement and program for data retention, especially in long projects and when contractors are replaced.

RECOMMENDATION C-3: In Chapter 6, discuss the options to be considered and pursued when the plan proposed initially for M&E transfer is rejected because of the observed contaminant levels.

RECOMMENDATION C-4: Provide an additional Appendix that summarizes topics in MARSSIM and MARLAP that are important to the MARSAME manual but are insufficiently described in it, or at least give page references to the earlier documents. Such topics may include aspects of quality assurance (e.g., validation and verification of results), data reliability affected by sample dimensions, measurement frequency, and detector characteristics. Consider also the effect of non-random variability in measurement (e.g., fluctuating geometry or monitor movement rate).

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APPENDIX A – STATISTICAL ANALYSIS – AN INTRODUCTION TO EXPERIMENTAL DESIGN AND HYPOTHESIS TESTING WITH SPECIFIC COMMENTS ON STATISTICS

A-1 An Introduction to Experimental Design and Hypothesis Testing:

The general problem of designing a survey of the sort described in the MARSAME document involves the following issues:

(1) Understanding the error properties of the measurement instrument and how they can be manipulated (by changing counting times or performing repeated measurements of the same radionuclide quantity, for example). Generally the measurement error can be well characterized by its standard deviation $\sigma_{M.}$ This value may be a constant (all measurements have the same standard deviation) or it may vary with radiation level (as in the behavior of an idealized radiation counter);

(2) Understanding the distribution of radionuclides in the population of equipment or material that is to be measured. This distribution can often be well characterized by a standard deviation σ_S which we may call the sampling standard deviation;

(3) Deciding upon the number of samples, N, from the distribution of radionuclide concentration that will be used in the detection problem;

(4) Specifying the null and alternative hypotheses to be examined; the symbol Δ represents the quantity of excess radionuclides equal to the difference between the null and the alternative hypothesis values;

(5) Specifying values of α and β that quantify acceptable limits for type I and type II errors;

(6) Determining, with fixed Δ and α, the power $1 - \beta$ to reject the null hypothesis in favor of the alternative.

From a statistical standpoint, designing an experiment means finding values of the sample size N and the detectable difference Δ that will control type I error and power, given the instrument's measurement error properties and the sampling radionuclide concentration distribution.

In MARSAME, the null and alternative hypotheses generally concern the true difference in radionuclide levels between a potentially contaminated material or piece of equipment and the appropriate background reference. In Scenario A, the null hypothesis is that the M&E is at least as radioactive (over background) as some number called AL (the action level), and the alternative is that the true exess radionuclide level is less than AL. In Scenario B the null hypothesis is that the M&E is at the action level (which usually equals the background in scenario B) and the alternative hypothesis is that the M&E is over the AL. These scenarios are further discussed below. The MARSAME manual should note the interplay between α and $1 - \beta$. For a fixed study design, power can be defined only in terms of α since power is the probability of rejecting the null hypothesis at a given α. (Note that terminology used here follows the MARSAME Glossary and list of Symbols, Nomenclature and Notations.)

When a single measurement is taken, the variance of that measurement will equal $\sigma_M^2 + \sigma_S^2$. In some cases the sampling distribution and thus σ_S may be irrelevant to a MARSAME survey; for example, there may be no spatial variability (when there is only 1 level of radiation relevant to a small item). An important issue is how the error properties of the instrument behave when repeated measurements of the same equipment item or same portion of material are taken. For some measuring instruments, it may be reasonable to assume that the average of N measurements of the same unit will have standard deviation equal to $\frac{\sigma_M}{\sqrt{N}}$. This will be the case in an idealized radiation counter, since performing additional measurements on the same sampling unit (item) is equivalent to increasing the count times for that unit. In other cases, inherent biases in measurement instruments may result in a measurement error shared by all measurements.

When sampling variability occurs (so that σ_S is not zero), the variance of the mean of a random sample of N measurements of will have variance somewhere in the range $\frac{\sigma_M^2 + \sigma_S^2}{N}$ to $\sigma_M^2 + \frac{\sigma_S^2}{N}$. The first of these corresponds to measurement errors that are completely unshared and the second corresponding to measurement errors that are completely shared due to imperfect calibration (for example, in the "measured efficiency" of a monitor discussed in several places in the manual). Generally, as more measurements are taken, the contribution of the sampling variance to the variance of the mean tends to disappear, whereas some or all of the contribution of the measurement error may remain. The special case when 100% of a potentially contaminated material is measured may be regarded as the limit when $N \to \infty$. Again, some or all of the measurement error variance may still remain.

For most situations in MARSAME, the null hypothesis concerns the difference between background levels and the level of contamination of the M&E. Table 5.1 (in the current document) gives some special formulae used when counts in time follow a Poisson distribution (so that the variability of the counts of both background and the item of interest depends on counting time and radiation level). In general, the variance of the difference between sampled radioactivity and the estimate of background will require special investigation as a part of the survey design.

For simplicity, it is useful to denote the standard deviation of measurement minus background as σ, which refers to the standard deviation of the estimate (often termed the standard error) obtained from the entire measurement method (involving either single readings, multiple readings, scans of some or all of the material, etc.). This σ can be a relatively complicated function of the underlying measurement and sampling variability (which must include the uncertainties in the estimate of background) that may require careful study to quantify properly.

Once σ is determined, the power, 1-β, of a study will depend upon two other parameters, (1) the type I error rate α and (2) the size of the assumed true difference Δ. If the standard error of the estimate, σ, is the same for all radiation levels being measured, then the ratio Δ/σ determines power for a given value of α (otherwise a more complicated expression is used, as in Table 5.1 of MARSAME). For known σ, we may specify the "detectable difference Δ" by fixing both the type I error α and the power 1-β and solving for Δ. In the MARSAME manual, this detectable difference Δ is called the width of the "gray region." (Differences less than this Δ are only detectable with power less than the required 1-β and hence are "gray.") If the action level, AL, is defined to be the upper bound of the "gray region," then the lower bound (AL-detectable difference Δ) is called the "discrimination limit" (DL). Note that implicitly the detectable difference Δ and the DL depend upon the power, type I error rate, and the standard error of the estimated σ. *One of the confusing aspects of the MARSAME manual is that the DL is introduced long before the concept of power or type I error*.

The two scenarios (A and B) considered in the report both assume that the null hypothesis is at the action level, but differ in the direction of the alternative hypothesis and generally in the value of AL. Under scenario A, the alternative hypothesis is that the radiation level is less than the action level (which is the upper limit above background to be allowed) whereas under scenario B the alternative hypothesis is that the radiation level is greater than the action level (which is typically set to background). *Under scenario A the M&E is only deemed to be safe for release if the null hypothesis is rejected, whereas under scenario B the M&E is safe for release if the null hypothesis is* ***not*** *rejected.*

If under scenario A, for example, the true value of the radionuclide level (or level above background) is less than or equal to DL then the survey will have power 1-β to reject the null hypothesis that the true value is equal to the AL with type I error α. Under scenario B, if the value of true contamination-background is *greater* than the detectable difference Δ, then the study will again have power 1-β to reject this null hypothesis at type I error rate α. Assuming that the standard error of the estimate σ, does not depend upon the radiation levels being measured, the formula for the "detectable" Δ, given α, σ and power 1-β is

$$\text{Detectable difference } \Delta = (Z_{1-\beta} + Z_{1-\alpha})\sigma \qquad (1)$$

Where $Z_{1-\beta}$ and $Z_{1-\alpha}$ are the corresponding critical regions for the standard normal random variable. A somewhat more complicated formulae for Δ is needed when σ is not independent of radiation level as in Table 5.1; however, formulae (1) gives a useful (conservative) approximation to the detectable difference if we choose σ to be at its maximum likely value for either the null or alternative hypothesis.

In general, use of equation (1) for the detectable difference Δ requires that the estimate of contamination (measurement – background) be approximately normally distributed. For radiation counters with long count times and large values of N (when there is sampling variability as well as measurement variability), this assumption is usually quite appropriate. Because the width of Δ (for fixed power and type I error) depends on σ, it is important that an instrument or measurement technique (and sampling fraction for spatially distributed contamination) is selected which is sensitive enough (provides small enough σ) so that the detectable Δ meets requirements (for example so that the DL is not set to be too small in Scenario A, or that the upper range of the gray region is not set too high above background in Scenario B).

In some situations (non-normal distributions, short count times), the detectable Δ will be larger than described in equation (1) and more specialized statistical analysis may be needed. Such techniques as segregation according to likely level of contamination may improve the accuracy of equation (1), as will longer count times.

Hypothesis testing (accepting or rejecting the null hypothesis) involves comparing an estimate of contamination level to a "critical value" (termed S_c in the manual) which allows us to decide whether the observed estimate is consistent with the null value (at a certain type I error level) after taking account of the variability (i.e., σ) of the measurement. For Scenario A, this value is equal to $S_c = AL - Z_{1-\alpha}\ \sigma$, and for Scenario B it is $S_c = AL + Z_{1-\alpha}\ \sigma$. By definition, power is the probability, as computed under the alternative hypothesis, of rejecting the null hypothesis; that is, the probability that the observed estimate is less than (for scenario A) or greater than (for scenario B) the critical value S_c.

If the normality of the estimate is in doubt, then other approaches to hypothesis testing may be needed. For example, while for long count times the Poisson distribution can be approximated as normal for the purpose of hypothesis testing, for short count times, specialized formulae (see Section 5.7.1) may be needed to give a better approximation to the distribution of (measured-baseline) for an idealized radiation counter.

A-2 Specific Comments:

Section 3.8.1 describes "Measurement Method Uncertainty" but in somewhat more vague terms than above. The intent of this section could be better understood in reference to the suggested introduction to experimental design and hypothesis testing.

All of Chapter 4 would be more comprehensible if it consistently referred back to the suggested introduction to experimental design and hypothesis testing.

Section 4.4.1.2 gives a recommendation for how much of an impacted material should be scanned: it is not clear to what the σ value now refers (eq 4-1). This appears to be the measurement error standard deviation σ_M rather than the total standard deviation of the measurement method (measurement method uncertainty). Presumably, this is giving a recommendation that will keep the total measurement method uncertainty bounded for a given level of measurement error (σ_M).

The statistical concepts described earlier MARSAME are illustrated for the first time in Figures. 4.2 and 4.3. It is unfortunate that even though the concepts shown in the figures all relate to net radioactivity, they are termed "level," "value" or "limit." This could cause misinterpretation by someone who is preparing to establish a survey design. An expansion of these figures to include several additional parameters with some supplemental text would be helpful.

Recommendations for scenario A and B are presented in Figs. A-1 and A-2. These embellished Figures with some additional text should also eliminate the need to repeat this information in Chapter 5, as in Figs. 5.2, 5.3, 5.4.

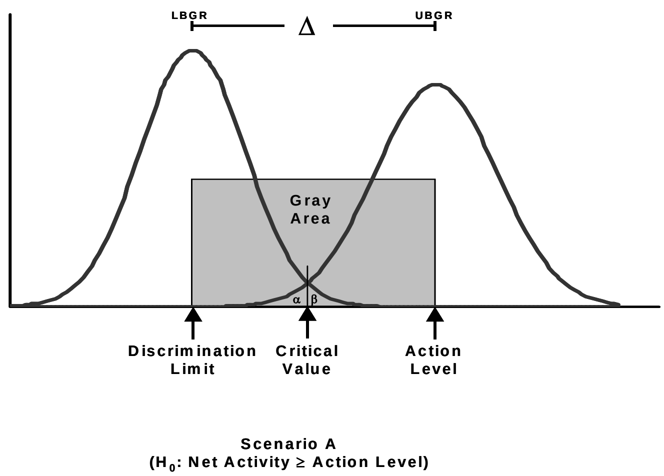

Figure A-1. Scenario A

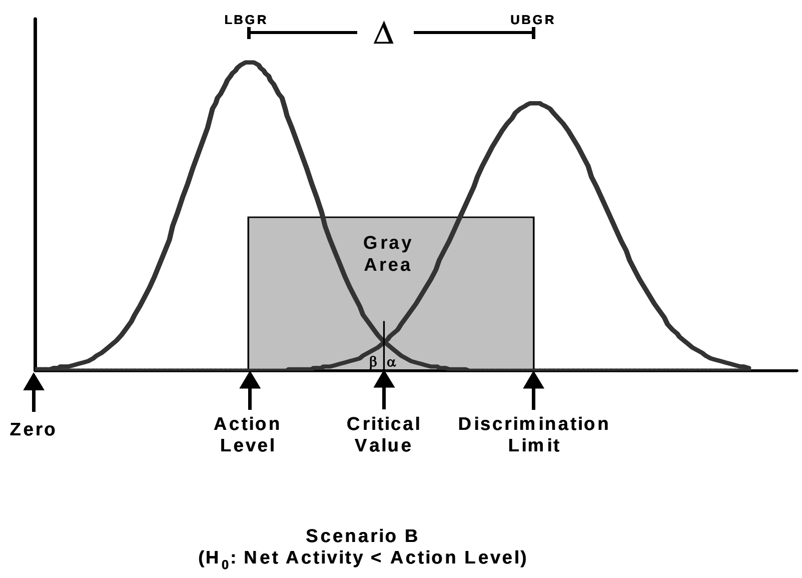

Figure A-2. Scenario B

As mentioned above, the Action Level (AL) for net excess radioactivity is used in defining the null hypothesis. However, the decision on accepting the null hypothesis is not based on the numerical value of net radioactivity at the AL. Rather, each sample is compared with the Critical Value shown in the Figures. This ensures that the probability for rejecting the null hypothesis, when it is true, will not exceed α. The Discrimination Limit (DL) is the net radioactivity in the sample where the probability of accepting the null hypothesis, when it is false, is β (i.e., the power for rejecting the null hypothesis is $1-\beta$). The Gray area is the region of net radioactivity in the sample where the statistical power to reject the null hypothesis, when it is false, is less than $1-\beta$.

Application of Measurement Quality Objectives (MQOs) discussed in Section 5.5 is an operational aspect of the MARSAME process. MQOs are part of the Data Quality Objectives process (DQOs) used as a platform for both the MARSSIM and MARSAME process. Use of MQOs was not incorporated into the MARSSIM process, so it maintains a unique role to MARSAME. The application of MQOs is fairly new to Decommissioning planning. It was employed in MARLAP in 2004 for laboratory-based measurements and now has been extended to field measurements in MARSAME. The Guide to the Expression of Uncertainty in Measurement (GUM), which forms the basis for much of the conceptual and statistical framework of MQOs, was published by the International Standards Organization (ISO) and the National Institute of Standards and Technology (NIST) in 1995 and 1994, respectively. The topic of MQOs may be unfamiliar to many users of the MARSAME. For this reason, it is important to provide a sound basis for the operational and statistical aspects of its use.

Some SAB MARSAME Review Panel comments, in the text and in this Appendix, specifically address the theoretical foundations of the underlying statistical assumptions used in the mathematical relationships and equations. Other panel comments address the application of MQOs from an operational standpoint. The identification of MQOs for certain types of measurement cases and survey designs may be confusing to readers unfamiliar to MQO applications. Considerable detail in the manual is provided on defining, explaining, and deriving the relevant theoretical concepts. The writers of the MARSAME manual should ensure that operational information on the implementation of MQOs is not too deeply embedded within the theoretical discussion. More distinction should be placed on information applicable to identifying performance characteristics, setting MQOs, and selecting appropriate measurement methods. Effective use of the manual relies on the reader to be able to apply MQOs to their specific measurement problem.

A summary or guide that organizes the measurement uncertainty, detectability, and quantifiability requirements for each of the three types of MARSAME surveys, including In-Situ, Scan-only, and MARSSIM-type, would be beneficial to the user. The guide would collect information on the selection of MQOs, which may be scattered throughout the chapter, into one coherent presentation for ready reference. The guide would be useful for designing MARSAME disposition surveys, training activities and for reference when regulators evaluate the measurement requirements of disposition survey plans.

The presentation of statistical formulations and derivations can be quite detailed and extensive and, if not properly balanced with the operational aspects of the guidance, may detract from the clear presentation of the guidance to the target audience. It is important to recognize that the manual is written for those directing and implementing the process, interpreting results, and making decisions. The operational aspects of the guidance address this broad audience directly; however, there is an audience concerned with the scientific and technical soundness of the procedures and the rigor for which the process is founded. An appropriate balance between the presentation of the operational aspects and the statistical foundations of the guidance is paramount.

The intent of Section 5.5 would be made clearer as dealing with the factors that impact the measurement error uncertainty σ as described in more general terms in the suggested review of experimental design and hypothesis testing. Apparently, however, σ_M (the standard deviation of a single measurement not taking into account spatial distribution of materials or the variability of the background) is being confused with the overall σ (total measurement method uncertainty taking these factors into account). It is Δ / σ, not Δ / σ_M, that determines the overall power of the experiment. The document should clearly differentiate these two σ 's.

Section 5.5.1 lines 289-293 seems to be confusing σ_M with σ_s. It is σ_s that, generally speaking, can be decreased by improving scan coverage (not σ_M if this includes "shared" error terms such as the "variance of measured efficiency"). The new terminology u_{MR} apparently refers either to an estimate of the measurement error uncertainty σ_M or to overall σ but this is not made clear in this section (and the requirement that $u_{MR} \leq \sigma_s/3$ makes no sense if σ_S can be reduced to 0 by improving scan coverage).

The comments on line 302-303 seem to require that u_{MR} estimates the overall σ. Example 2 is confusing because the requirement that u_{MR} be a factor of 10 times smaller than Δ seems to assume that u_{MR} is an estimate of σ_M rather than the overall uncertainty σ (this would be a very stringent requirement indeed). Here one needs to focus not just on σ_M but rather on the total variability including σ_S. If σ_s can be reduced to zero by scanning all of a material why is such a stringent requirement made on σ_M?

Line 360 introduces new and not clearly defined uncertainties (u_c and φ_{MR}). Example 5 is unclear, and needs to be tied to some general design or hypothesis testing principles – it just comes out of thin air as it stands.

Section 5.6 is a good description of addressing measurement uncertainty σ_M in certain special cases. One thing that could be clarified is that σ_M now refers to the error in measurement - background rather than just the error in the measurement itself. At other points in the manual, σ_M seems to refer rather to the variance of just the measurement.

All determinations of excess radioactivity are based on the difference between a sample with an unknown amount of radioactivity, and an appropriate control that may contain radioactivity not related to the source of contamination. MARSAME does not provide very much information on how to characterize properly the "background" radiation contained in controls or "reference samples."

Tables 5.1 and 5.2 list equations to determine critical values, S_c. A sample is considered to contain radioactivity in excess of the control if the "net" result is greater than the S_c. The value of S_c is based on the probability that the net result of a sample with no excess radioactivity that will exceed S_c, is equal to α (i.e., false positive). This is, in effect, an example of Scenario

B described in Chapter 4. This is expanded in Table 5.2 to the minimum detectable value, S_D. It is the smallest value of net radioactivity, MDC, that will yield an observed measurement greater than S_c with a statistical power of 1-β. That is, the probability that a sample containing exactly the MDC will be less than S_c is β (i.e., false negative).

The equations in Tables 5.1 and 5.2 are used throughout MARSAME as examples for estimating critical values S_c and MDC. These equations are based on the Poisson assumption for counting statistics and distribution of the difference between two random numbers that are Poison distributed. In effect, this implies that an independent measurement of a control is paired with each measurement of a sample. S_c is based on the distribution of two random numbers selected from the same distribution of background.

Although the equations are correct, it is not common to measure a control for every sample of unknown contamination. This process of comparing paired samples is rare. Generally, an estimate of background radioactivity is established, and subtracted from every sample to estimate the "net" count.

Tables 5.1 and 5.2 are used throughout MARSAME without any reference to any assumptions that were used to derive the equations. There could be serious implications in decisions relating to the presence of radioactivity using S_c and hypothesis testing using MDC as the DL. On the other hand, for most cases these equations might be satisfactory. It will be important for the MARSAME manual to clarify this, and to provide more details on how to measure and characterize "background" in controls that are used to determine "net" activity.

Some examples are shown below. For this case, equations 5.1.1 (Currie) and 5.1.3 (Stapleton) were used to compute S_c. A Monte Carlo model was used to estimate S_c for paired samples from the true background distribution (MC) and also for a constant background, equal to the true mean, that was subtracted from a random sample of background (MCB). For these cases, $\alpha = \beta = 0.05$. Fig. A-3 is for the case where the sample time t_s and the background time t_b are equal and yield a mean count of 200. The abscissa is normalized to the value of S_c obtained from the Currie equation.

This illustrates that S_c obtained from 5.1.1 does indeed come from a distribution of paired samples which is simulated in MC. However the value for S_c obtained by subtracting a constant value equivalent to the mean value of background, MCB, is actually about 30% lower than S_c from the equations.

Fig. A-4 is for the case where the sample time t_s is 5 and the background time t_b is 50. For this case, the background is estimated with greater precision because t_b is large. With a constant background to estimate background, the value of S_c is similar to that obtained from the equations in Table 5.1; however both MCB and the Currie equation yield a value of S_c that is somewhat lower that that obtained from paired samples (MC) by Monte Carlo simulation.

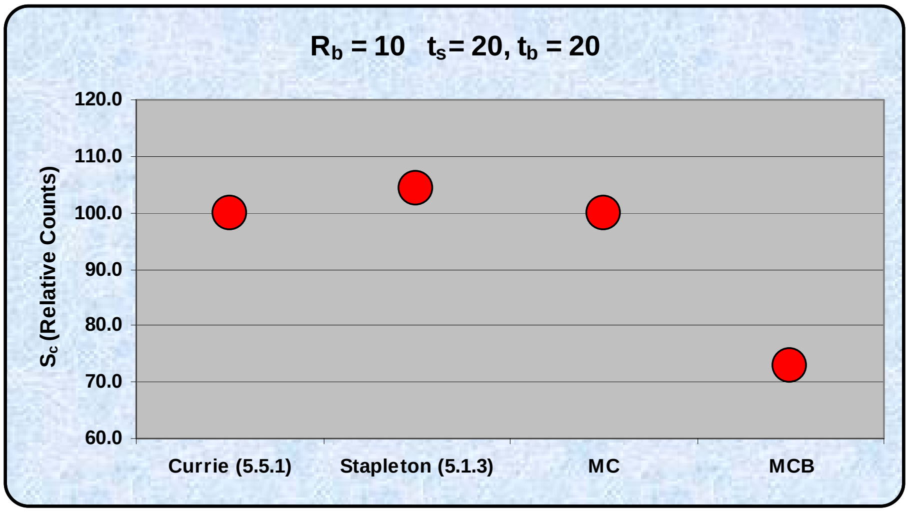

Figure A-3. Comparison of S_c

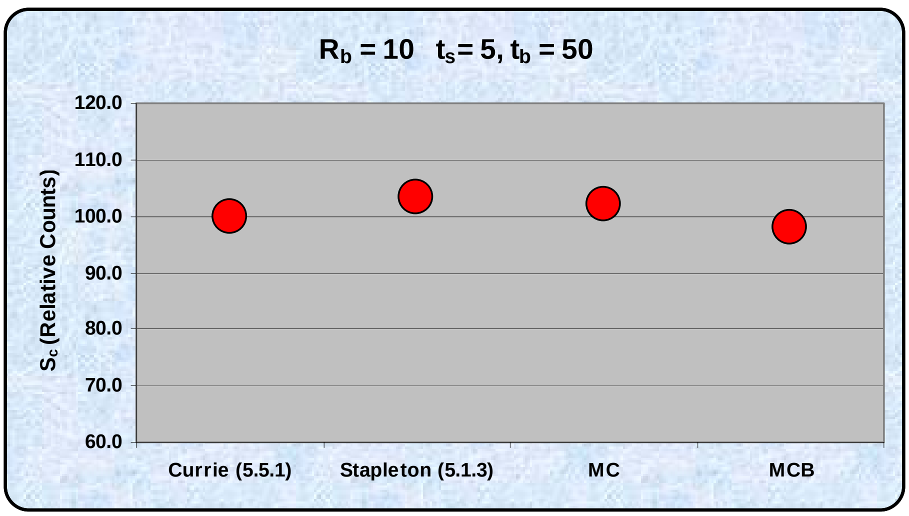

Figure A-4. Comparison of S_c for longer background counting period

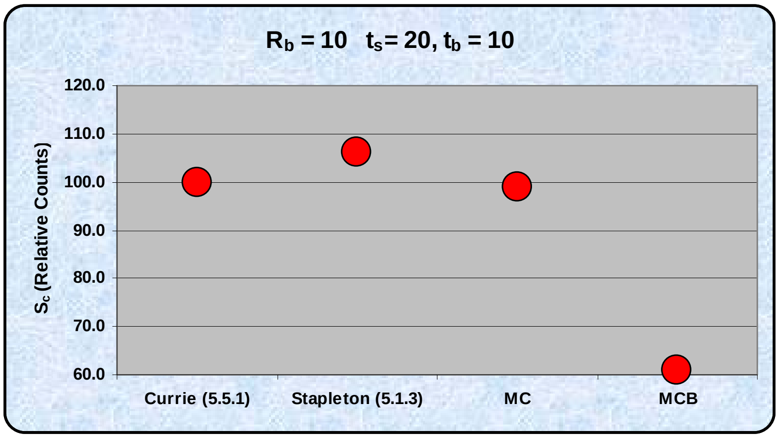

Figure A-5. S_c for a briefer background counting period

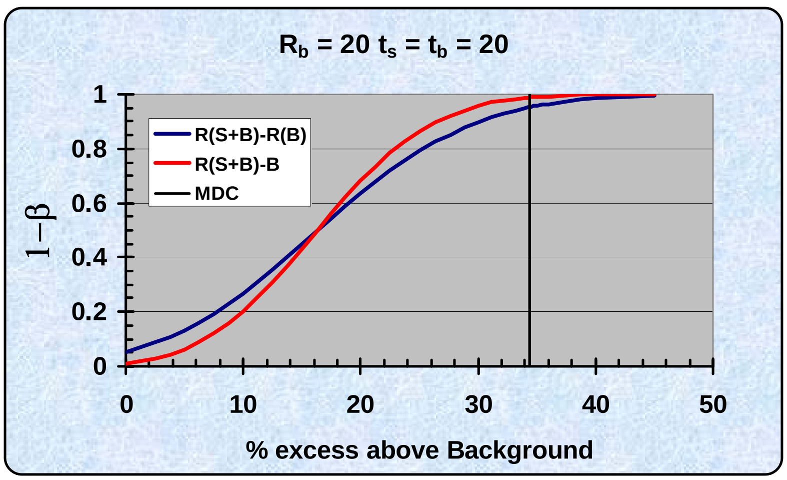

Figure A-6. 1-β as function of % excess count above background

Fig. A-5 is for the case where t_s is twice the value of t_b. Values obtained for S_c using the Currie equation are close to the value from the Monte Carlo simulation for paired samples, but the estimate of S_c using constant value of background is low by about 40%.

Fig. A-6 shows an example of the statistical power, 1-β, as a function of the increasing amounts of radioactivity above background. The curve starting on the ordinate at a statistical power, 1-β, of 0.05 represents the simulation for paired samples and the curve starting at the origin represents the simulation when a constant value of background is subtracted from the sample to form the net value. Without excess radioactivity, β for the paired samples is 0.05 and β = 0.01 when background is a constant. The two curves are identical when the excess radioactivity corresponds to S_c and therefore β = 0.5. The vertical line corresponds to the value of MDC obtained from equation 5.2.1. Note that the MDC, (1-β) = 0.95, obtained from the simulation with constant value for background is smaller than when using the assumption of paired samples.

MARLAP provides additional modifications to estimating S_c when the Poisson approximation may not be satisfied. However, it is not clear that the concerns relating to the process of measuring controls or reference materials have been eliminated.

Many equations have been suggested for designing and interpreting survey procedures in MARSAME. The equations are derived from sound statistical principles. They can lead to incorrect conclusions if the underlying assumptions in the derivations are not satisfied. The Panel does not recommend that each equation be derived in detail, but suggests that the assumptions and sampling requirements needed to properly implement equations be documented in MARSAME.

Section 5.8, Determining Measurement Quantifiability is a complicated way of saying that σ must be small enough (and hence Δ / σ large enough) for the measurement method to have good power to reject the null hypothesis that the level of radioactivity is at the AL for a reasonable Δ (width of the gray region). It also must give a reasonably narrow confidence limit for the estimated value, i.e. where the width of the confidence limit is small compared to the value of the AL.

One complication that is explicitly dealt with in the definition of the MQC is that the measurement method uncertainty, i.e. σ, generally will depend upon the (unknown) true level of radioactivity itself – for example a perfect counter has Poisson variance equal to its mean. Thus the MDC is just the value, y0, of the radioactivity level for which the ratio, $k=y0/\sigma$, is large (the manual recommends k=10). If y0 is small relative to the action limit (between 10-50 percent of the AL is recommended), then it is clear that (1) the detectable Δ will be small with respect to the action limit (i.e. the DL will be close to the AL) and (2) confidence limits around an estimated value of radioactivity will be narrow relative to the value of the AL. Saying this clearly improves the intelligibility of this section.

Section 5.8.1 would be more intelligible if it first noted that it is giving a computation of the MDC, y0, for a fixed k by a formulae for σ that takes account of several factors which are combined into this one σ. These factors are the length of the reading time for the source, the length of reading time for the background, the true value of the background reading, and an estimate of the variance of a "shared" measurement error term, i.e. the measured efficiency of the monitor.

Section 6.2.1 has some confusing aspects: as described earlier, the gray region is defined in terms of the power and type I error of the test with a measurement method of total standard deviation σ. Sentences like "Clearly MDCs must be capable of detecting radionuclide concentrations or levels of radioactivity at or below the upper bound of the gray region" seem tautological if the gray region is defined in terms of detection ability; specifically in terms of power, type 1 error, and σ.

Lines 215-224 of Section 6.2.3 confuse by the statements about how individual measurement results can be utilized for scan-only measurements. The statement that "if disposition decisions will be made based on the mean of the logged data, an upper confidence level for the mean is calculated and compared to the UBGR," must be interpreted carefully. If one did a standard test such as Wilcoxan or t-test) one would ignore any uncertainty component resulting from variability in the measurement process (i.e. measurement error shared by all measurements that constitute the scan). Only if σ_M has no shared components (or if they are very small) would it make sense to do a standard statistical test of the observed data alone. Specifically, the sample standard deviation would underestimate the true measurement standard deviation σ if a shared uncertainty (such as errors in the estimate of counting efficiency) is incorporated in σ_M.

The recommendation (line 60) that for MARSSIM type surveys the sample standard deviation can be used to generate a power curve also implicitly assumes that no shared measurement error components exist. But this contradicts the conclusion of line 223-224 that "Measuring 100% of the M&E accounts for spatial variability but there is still an uncertainty component resulting from variability in the measurement process." In fact, all the discussion of selecting and performing a statistical test, and drawing conclusions in the rest of Section 6 seems to be implicitly assuming that there are no shared errors from measurement to measurement. Is this the intention? If this was the intention, clarify the confusing discussion in Section 5.5.1, lines 289-293. For example, even if all measurements are less than the action level, this might not really be enough information to conclude that the M&E meet the disposition criterion.

Suppose all measurements are only somewhat less than the action level but it is also known that the counting efficiency was not well estimated. Ignoring the uncertainty in the counting efficiency could lead to the wrong conclusion in this case, if the uncertainty in the counting efficiency is indeed "shared error" over all the measurements. In many places in this document, errors in counting efficiency or other apparently shared measurement errors are mentioned (as on line 223-224), but this issue seems to be ignored in most of Section 6. If the manual assumes that such shared errors are small enough to be ignored, this should be stated explicitly. (See also footnote 4 on page 6-17).

One possible resolution is to assume that the measurement of background has exactly the same "shared" uncertainties (counter efficiencies, etc.) as does the measurement of the radioactivity level in the M&E. In this case, the shared uncertainties will be subtracted when the background is subtracted from the level measured in the M&E. If this is meant, then it should be stated clearly (and this should be highlighted in the any initial "review of experimental design and hypothesis testing" when discussing the various components included in σ).

APPENDIX B –ACRONYMS AND ABBREVIATIONS

A	Scenario A for hypothesis testing
AL	Action Limit (or Level)
ALARA	As Low As Reasonably Achievable
α	Maximum acceptable probability for Type I error rate (alpha)
AM	Arithmetic Mean
β	Maximum acceptable probability for Type II error rate (Beta)
B	Scenario B for hypothesis testing
$1-\beta$	Numerical value of the statistical power to reject the null hypothesis when it is true
CFR	Code of Federal Regulations
CON	Consultation
CQ	Charge Question (CQ1, CQ 2, CQ3)
Δ	Difference (Alternative – Null hypothesis), also the Detectable Difference
DFO	Designated Federal Officer
DL	Discrimination Limit (also Discrimination Level)
DLC	Data Life Cycle
DoD	Department of Defense (U.S. DoD)
DOE	Department of Energy (U.S. DOE)
DOT	Department of Transportation (U.S. DOT)
DQO	Data Quality Objective
EH	Environmental Safety and Health (U.S. DOE/EH)
EPA	Environmental Protection Agency (U.S. EPA)
FR	Federal Register
GUM	Guide to the Expression of Uncertainty in Measurement
H_o	Null Hypothesis
IA	Initial Assessment
IAEA	International Atomic Energy Agency
ISO	International Standards Organization
ITRC	Interstate Technology & Regulatory Council
k	Coverage Factor for Uncertainty
LBGR	Lower Bound of the Gray Region
MARLAP	Multi-Agency Laboratory Analytical Protocols (Manual)
MARSAME	Multi-Agency Radiation Survey and Assessment of Materials and Equipment (Manual)
MARSSIM	Multi-Agency Survey and Site Investigation Manual
M&E	Materials and Equipment
MC	True Background Distribution
MCE	Random Sample of Background
MDC	Minimum Detectable Concentration
MQC	Measurement Quality Uncertainty (also Minimum Quantifiable Concentrations)
MQO	Measurement Quality Objective(s)
N	The Sample Size (N measurements, for instance)
NCRP	National Council on Radiation Protection and Measurements
NHSRC	National Homeland Security Research Center

NIST	National Institute of Standards and Technology
NRC	Nuclear Regulatory Commission (U.S. NRC)
NUREG	NRC NUclear REGulatory Guide (U.S. NRC)
OAR	Office of Air and Radiation (U.S. EPA/OAR)
ORIA	Office of Radiation and Indoor Air (U.S. EPA/OAR/ORIA)
PAG	Protective Action Guide
pdf	Portable Document Format
q	critical value for statistical tests
QA	Quality Assurance
QC	Quality Control
QA/QC	Quality Assurance/Quality Control
R_b	Mean Background Count Rate
RAC	Radiation Advisory Committee (U.S. EPA/SAB/RAC)
rev	Revision
SAB	Science Advisory Board (U.S. EPA/SAB)
σ	Standard deviation
σ_M	Standard Deviation of Measurement Error
σ_S	Standard Deviation of Sampling Distribution
S_c	Critical Value
SI	International System of Units (from NIST, as defined by the General Conference of Weights & Measures in 1960)
SOP	Standard Operating Procedure
Φ_{mr}	The relative upper bound of the estimated measurement method uncertainty μ_{mr},
t_B	Background Time
t_S	Sample Time
TSCA	Toxic Substances Control Act
Type I	Type I error is rejecting the null hypothesis when it is true
Type II	Type II error is failing to reject the null hypothesis when it is false
μ_{mr}	Estimated Measurement Method Uncertainty
φ	Uncertainty (e.g., φ_{MR})
UBGR	Upper Bound of the Gray Region
UCL	Upper Control Limit
US	United States
W_r	Adjusted Reference Measurement (WRS test)
W_s	Sum of the Ranks of the Sample Measurements (WRS test)
WRS	Wilcoxon Rank Sum Test
y0	Estimate of Zero Order Output Quantity; also Minimum Detectible Concentration
Z	Critical Regions (e.g., $Z_{1-\alpha}$, or $Z_{1-\beta}$, that is, quantile of the standard normal distribution)

APPENDIX C – TYPOS AND CORRECTIONS

xxix line 504 power?
522 delete one (
xxxi 561 delete one)
567 delete one (
xxxiv 671 Technetium (sp.)
xxxv 676 delete (duplicates 675)
1-3 80 change “activity concentrations” to “area activity” or leave as is but change “Bq/m^2” to “Bq/m^3” and add “and area activity (Bq/m^2)
3-9 194 non-radionuclide-specific (insert dash)
4-5 Figure 4.1a replace second “Large” by “Much Larger”
Figure 4b. replace second “Small” by “Equally Small or Smaller”
5-21 523 value in denominator should be 0.4176 (see line 527)
527 plus should be behind square root of 87
5-53 1148 delete 2nd period
6-6 142 insert “to” behind “likely”
6-11 280 insert “that” behind “determine”
6-13 329 insert “that” behind “demonstrate”
6-23 474 and 482 critical value in symbols table is not in italics (italicized k is coverage factor)
7-10 210 Tl-208 should be beta/gamma, not just beta, with gamma-ray energy in next column
B-6 151 maximize, not minimize
D-9 219 what does “varies” mean?
D-36 849 for LS spectrometer, insert (alpha) on first line of column 2 and (gamma) for the HPGE and NaI detectors
F-1 26 delete (FRER)