UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

- - - Date to be Inserted - - -

EPA-SAB-08-XXX

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

Subject: Re Report on Agency Draft entitled ***"Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME),"*** Draft Report for Comment, December 2006

Dear Administrator Johnson:

The Radiation Advisory Committee (RAC) Multi-Agency Radiation Survey and Assessment of Materials and Equipment (MARSAME) Manual Review Panel of the Science Advisory Board has completed its review of ***"Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME)," Draft Report for Comment, December 2006***. The Draft Manual ~~Report~~ was prepared by a multi-agency work group with participation by staff from US DOE, US NRC, US DoD and US EPA. The multi-agency work group has been active since 1995, for some periods with representation from additional 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 Manual (MARLAP)"***. Both manuals underwent this review process. Preparation of at least one more manual is planned.

The MARSAME manual is a well-written document that provides guidance for radiological surveys to determine whether materials and equipment (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 case studies, 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 Review Panel found the MARSAME manual to be an admirable cooperative effort by staff from several agencies to provide guidance in an important endeavor, appropriately detailed and competently written. The Panel expects the manual to be as widely applied as the two earlier radiological guidance manuals, and to have the potential for contributing significantly to maintaining radiation protection for the US population. To assist this endeavor, the Panel presents 30 suggestions and a Statistical Analysis Appendix in the enclosed review.

The main Panel recommendations are:

- Provide training and an additional Appendix to assist important users who are not the radiation protection specialists addressed in the MARSAME manual, such as project managers, in utilizing the manual without having to assimilate the lengthy MARSSIM and MARLAP documents.
- Collect detailed guidance – notably in terms of equations and their development --for statistical analysis, experimental design, and hypothesis testing in a separate chapter and consider enhancing the guidance in accord with comments in the Appendix to this review.
- Because the situations presented as case studies are actually illustrative examples, re-label their descriptive titles and enhance their content to assure realism.
- Give as much consideration to surveys for radioactive contamination that is removable from the surface or that is volumetric as is given currently to undifferentiated surface contamination.
- Present the various alternatives for M&E surveys in sufficient detail to assist the reader in recognizing the existence of 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, and selecting the suitable option.
- Consider non-linear processes such as the option for iterative M&E release efforts embodied in a survey followed by a decontamination effort, followed by a re-survey; or storage for decay followed by re-survey.

Other Panel recommendations concern refinements and improvements in content and presentation.

In summary, the SAB finds the reviewed MARSAME Draft Report to be a potentially useful document for EPA/ORIA as well as other Federal and State agencies for providing guidance to control transfer of M&E that may be contaminated with radionuclides. The MARSAME Panel of RAC appreciates the opportunity to review this draft report and hopes that the suggestions provided will enable EPA and participating agencies to issue effective guidance for radiological surveys of material and equipment. We look forward to your response, particularly to the items highlighted in this letter to you.

Sincerely,

Dr. M. Granger Morgan, Chair
EPA Science Advisory Board

Dr. Bernd Kahn, Chair
Radiation Advisory Committee
MARSAME Review Panel

NOTICE

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U.S. Environmental Protection Agency Science Advisory Board Radiation Advisory Committee (RAC) Multi-Agency Radiation Survey and Assessment of Materials and Equipment (MARSAME) Manual Review Panel

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Mr. Thomas Miller, Washington, DC

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1. EXECUTIVE SUMMARY

The Radiation Advisory Committee (RAC) of the Science Advisory Board (SAB) has completed its review of the Agency's draft document entitled ***"Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME),"*** 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 refer to information provided in the Multi-Agency Radiological Laboratory Analytical Protocols manual (MARLAP; see also the MARLAP Hotlink at http://epa.gov/radiation/marlap/index.html).

All of these manuals were prepared by at multi-agency work group that is a joint effort by staff members of several pertinent Federal agencies. The three documents, taken together, describe radiological survey programs in great detail and address recommendations to competent radiation protection professionals and managers for performing such surveys. The manuals are designed to enable effective comparisons of survey measurements to radionuclide concentrations specified in 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 document goes beyond MARSSIM for surveying possibly radioactive material and equipment (M&E) that may be in nature, in commerce, or in use when considered for receipt or removal. It presents an overview of the various aspects of initial assessment, decision inputs, survey design, survey implementation, and assessment of results. Important aspects, such as hypothesis testing and statistical aspects of measurement reliability are described in considerable detail. A number of illustrative examples, erroneously 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 document by the EPA-SAB Radiation Advisory Committee (RAC) Panel was requested by the EPA Office of Radiation and Indoor Air (ORIA). The review by the RAC's MARSAME Review Panel is based on reading the *MARSAME Draft Report for Comment (December 2006)* and presentations by MARSAME multi-agency work group members at the meeting on October 29–31, 2007 and in a series of teleconference meetings held October 9, 2007, December 21, 2007, and march 10, 2007. The review responds to the set of charge questions posed by ORIA, but also refers to certain other technical items. (NOTE: Add a statement regarding the Quality Review meeting here when this occurs. - - - KJK).

The Panel recognizes the magnitude of the effort by the multi-agency work group and the value of its product; note that the Panel suggestions for modifications address only a small fraction of this product. Most Panel recommendations can be summarized in the following broad categories:

- MARSAME guidance is suitable for experienced radiation protection and surveillance staff, but use by other interested readers, such as managers, will require special training or insertion of additional information for them;

- appropriate advice and information should be added for use of (a) available regulations and technical guidance for the action level (AL), (b) decontamination applied as part of the disposition plan, and (c) measurements to distinguish removable surface contamination and volumetric contamination from fixed surface contamination; and

- specialized guidance for applying statistical tools should be separated from the otherwise pervasively non-quantitative guidance for the convenience of the general audience and for acceptance by specialists.

The above items are discussed within the context of the charge questions.

The Multi-agency Work group clearly has devoted considerable effort to describing the statistical tools. This is important because the acceptance of survey measurements depends on their reliability near the action level. Meeting this requirement can only be demonstrated in a statistical framework: the discrimination level (DL) must be below the action level (AL), 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.

Because of the importance of clarity in the mathematical support structure, a sub-group of the Panel has prepared a guide to topics in those portions of MARSAME, 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 (null hypothesis for Scenario A and Scenario B). The guide is intended to present to the Multi-agency Work Group the view of the Panel on making this approach readily accessible to persons only generally familiar with statistical analysis, and also to gain acceptance from those who are knowledgeable on this topic.

2. INTRODUCTION

2.1 Background

The MARSAME document was designed to guide a radiation protection professional through all aspects of radiological surveys of M&E prior to intended receipt or discharge. 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. The presented alternative outcomes are release or interdiction, i.e., acceptance or rejection of M&E transfer.

The document was prepared by staff working together from the following Federal agencies: US EPA, US NRC, US DOE, and US DoD. It is part of a continuing and technically significant effort that began with writing MARSSIM, continued with MARLAP, and anticipates preparation of at least one other manual after MARSAME. 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, and M&E description. 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. The sensitivity of measurements is defined in terms of the discrimination limit (DL), which is attained by selecting suitable radionuclide detectors and conditions of sampling or measurement. The measurement results must be acceptable relative to action levels (AL) and significance levels specified in regulations or other guidance.

The MARSAME document is structured as follows, shown with the relevant charge question (CQ) number:

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 (CG 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 RAC MARSAME Review Panel and is addressed first. The Panel also considered a few related topics, commented in detail on the MARSAME discussion of statistical 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 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*. MARSAME is a supplement to the *"Multi-Agency Radiation Survey and Site Investigation Manual" (MARSSIM*, EPA 402-R-970-016, Rev. 1, August 2000 and June 2001 update). 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 philosophies that form the basis of this manual were developed to be consistent with current Federal limitations, guidelines, and procedures.

The SAB RAC MARSAME Review Panel met in an initial public teleconference meeting on Tuesday, October 9, 2007 to introduce the subject and discuss the charge to the Panel, determine if the review and background materials provided are adequate to respond to the charge questions directed to the SAB's RAC MARSAME Review Panel, and agree on charge assignments for the Panelists. The purpose of the meeting of Monday, October 29 through Wednesday, October 31, 2007 was to receive presentations by the Multi-Agency Work Group staff, deliberate on the charge questions, and draft a report in response to the charge questions pertaining to the draft MARSAME manual. The Panel reviewed the first public draft report dated December 17, 2007 in a December 21, 2007 public conference call. The second public draft report dated February 27, 2008 was reviewed in the March 10, 2008 public conference call. ……………(continue with SAB Quality Review Public meeting, etc. - - - KJK)………..

2.3 EPA Charge to the Panel

The EPA's Science Advisory Board (SAB) conducted the scientific peer reviews of the companion multi-agency documents MARSSIM (EPA-SAB-RAC-97-008, dated September 30, 1997) and MARLAP (EPA-SAB-RAC-03-009, dated June 6, 2003). The Federal agencies participating in those peer reviews found the process used by the SAB to be beneficial in assuring the accuracy and usability of the final manuals. Consequently, two consultations have taken place for MARSAME (EPA-SAB-RAC-CON-03-002, dated February 27, 2003, and EPA-

SAB-RAC-CON-04-001, dated February 9, 2004). On behalf of the four participating Federal agencies, the EPA's Office of Radiation and Indoor Air (ORIA) requested that the SAB conduct this formal technical peer review of the draft MARSAME manual.

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

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. Related responses to individual charge questions, notably for charge questions 1b, 1c, and 2a, are referred to Appendix A.

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 <u>Charge Question 1:</u> ***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 radiation health physics and an understanding of statistics," with further capabilities described in Chapter 1, lines 187 – 194. The following itemized suggestions elaborate on these points.

SUGGESTION 1-1: Separate the discussion that begins in Chapter l, line 49, by creating a sub-section to present clearly the concept of simple alternatives to what may appear to the reader to be a major undertaking. Follow this paragraph 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.

SUGGESTION 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.

SUGGESTION 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 another 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. They are rational and useful for obtaining an IA of the type and magnitude of radioactive contaminants although, because they were not randomly selected, they 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.

SUGGESTION 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.

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

SUGGESTION 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" can be misleading when this description is not clearly defined. 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. As MARSAME states on line 258, 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 admirably clear. The Panel has the following suggestions to benefit the reader:

SUGGESTION 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. To surface contamination regulations in Table E.2 by DOE and Table E.3 by NRC, add – at least by citation -- other regulations, notably those by states and state compacts. Guidance for volumetric contamination clearance is important; a summary such as Table 5.1 of NCRP (2002) from reports of national and international standard-setting groups, should be included here.

SUGGESTION 1b-2: Information that guides input 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 contamination and the subsequent disposition of M&E according to this categorization. For example, consider the DOT regulations that require measurement of removable contamination, and the ALs that respond to potential radiation exposure to persons from removable *vs.* fixed contamination. See also SUGGESTIONS 2b-3 and 1d-3 for discussion of removable radioactive contaminants.

SUGGESTION 1b-3: Certain aspects of the discussion concerning measurement method uncertainty, detection capability, and quantification capability in Chapter 3, lines 567 – 622, takes the MARSAME presentation from broad guidance to specific statistical tutorial. The content of the tutorial raises difficulties for some general readers and questions for some professionals. Consider maintaining the more general tone of MARSAME in these sub-sections while referring to a separate chapter with detailed discussion of statistical aspects as given in SUGGESTIONS 1c-1 and 2a-1. This approach could remove concerns why the MDC is recommended for the MQO in Chapter 3, lines 593 – 597, instead of the 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 approach and helpful. The Disposition Survey Design and Documentation sections are well prepared. Further discussion would be helpful 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, as 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 concept of uncertainty with default significance levels and the resulting gray area and discrimination limits leading to minimum quantifiable concentrations are not so readily assimilated. An extended consideration of the statistical approach has been prepared and is attached to this review as Appendix A.

SUGGESTION 1c-1: Consider maintaining the same level of generalized guidance that pervades most of MARSAME in brief sub-sections that address statistical matters. Collect the mathematical discussion in a separate chapter, as proposed in SUGGESTION 2a-1. Chapter 19, Measurement Statistics, of 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 MASAME approach in the existing chapters.

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. Although the Panel was informed by members of the Multi-agency Work Group that Chapter 7 contains not case studies but invented illustrative examples, these also can be helpful if created carefully to represent actual situations.

SUGGESTION 1d-1: Delete or replace the example for Standard Operating Procedures (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.

SUGGESTION 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 for application. 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 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.

SUGGESTION 1d-3: An introductory statement should place in context the sheer length of the 21-page example in Section 7.4 of the baseline survey of a rented front loader to avoid discouraging its application. The introduction 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 ~~S~~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.

SUGGESTION 1d-4: Each of the illustrative example headings would benefit from inclusion of 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 <u>Charge Question # 2:</u> ***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 to the extent observable over the existing wide range of applications.

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 comprehensible. It is clear that MARSAME has close connections to MARSSIM in surveys of M&E that is located 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 <u>Charge Question # 2a:</u> ***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. The Panel believes 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.

SUGGESTION 2a-1: Enable the reader to understand the topics in Chapter 5 more clearly by separating the entire mathematically detailed statistical exposition in MARSAME to 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 or after Chapter 6. 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.

SUGGESTION 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.

5.3 <u>Charge Question # 2b:</u> ***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 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, but minor changes are proposed (see revised Figures below).

The Panel emphasizes the importance of distinguishing among contamination that is (1) removable on the surface, (2) fixed to the surface, or (3) volumetric in all MARSAME chapters. Regarding the first item, 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. The Panel understands the reluctance of Multi-agency Working Group members, expressed in our meetings, to include in MARSAME a survey process that is as poorly defined with regard to reproducibility – i.e., relation of the wipe test result to the area concentration of a radionuclide -- but considers ignoring the wipe test to be unrealistic and potentially misleading.

SUGGESTION 2b-1: In Fig. 6.3 (revision attached), 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 …."

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

SUGGESTION 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.

SUGGESTION 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) 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 include difficulties in characterizing the depth of volumetrically distributed radionuclides and quantifying radionuclides that emit no gamma rays.

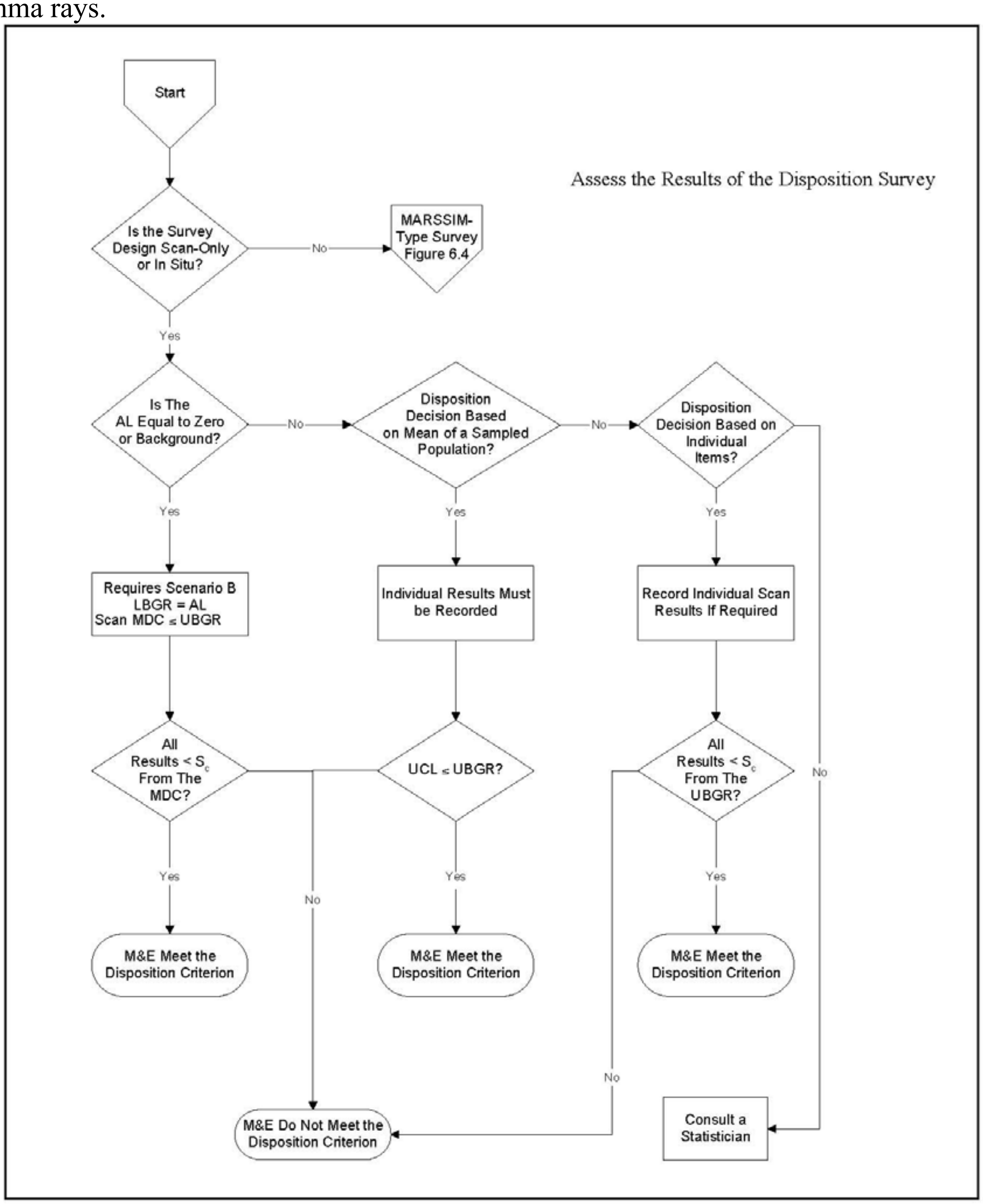

Figure 6.3 Interpretation of Survey Results for Scan-Only and In Situ Surveys

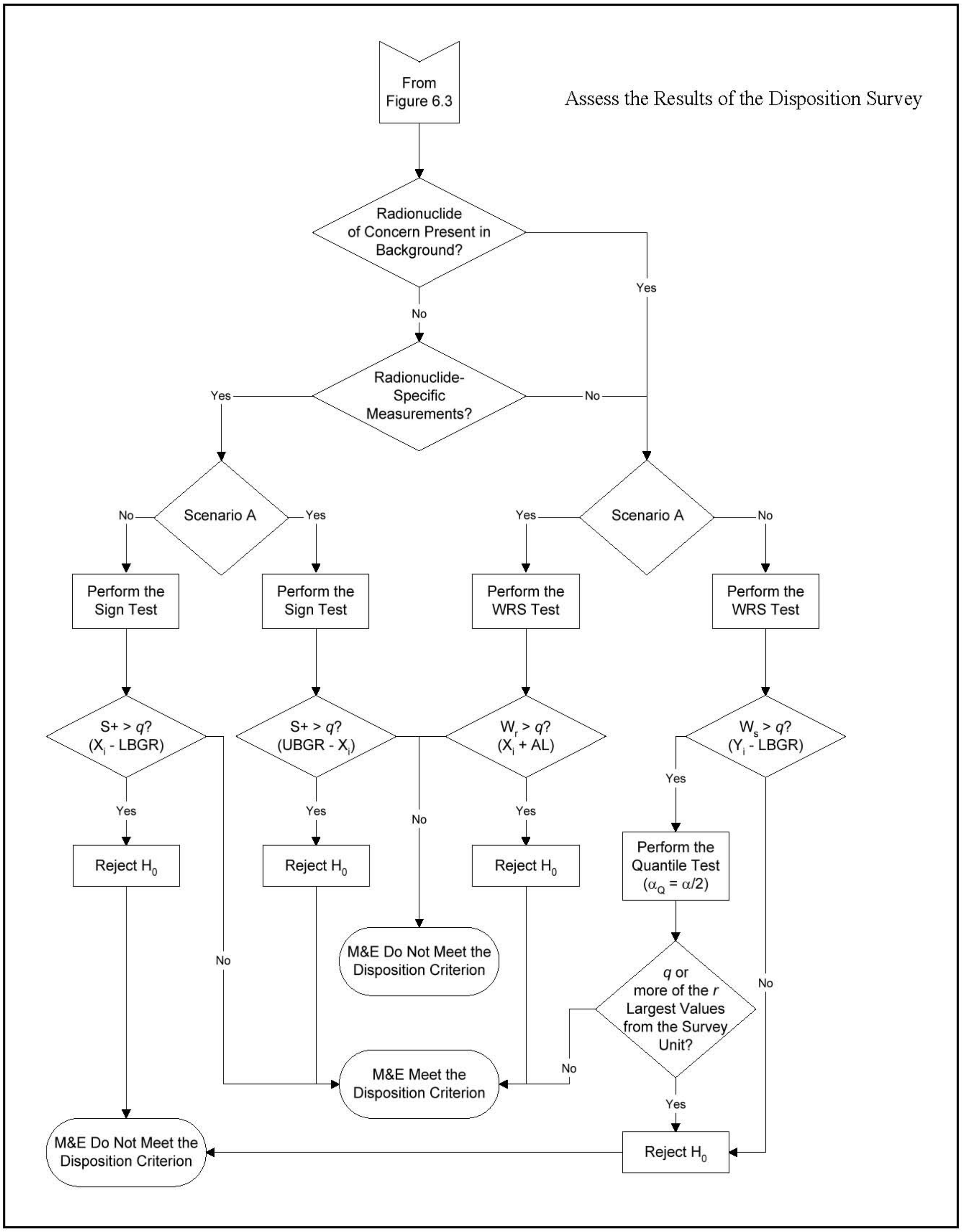

Figure 6.4 Interpretation of Results for MARSSIM-Type Surveys

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 Charge question 1d, case studies are invaluable in guiding the user through complex operations. 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 – 565, 682 – 689, and 1133 -1150. For discussions related to uncertainty, refer to Appendix A.

SUGGESTION 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.

SUGGESTION 2c-2: Use illustrative examples to illustrate any MARSAME guidance that the Multi-agency Working Group considers difficult to follow. These may include approximating uncertainty (see Chapter 5), demonstrating distinctions such as interdiction *vs.* release, and applying scenarios A *vs.* B.

SUGGESTION 2c-3: Use the illustrative example in Sections 7.4 and 7.5 to demonstrate the benefit of wipe tests to determine 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

Charge Question 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?***

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 suggestions are intended to enhance their use.

SUGGESTION 3-1: Roadmap Figure 1 connects the MARSAME chapters in terms of the Data Life Cycle. Is it possible to draw 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.

SUGGESTION 3-2: Would it be possible to assist project managers by highlighting major operational decision points in the roadmaps?

SUGGESTION 3-3: 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.

SUGGESTION 3-4: Insert a table with AL guidance for volumetric radionuclide contamination in Appendix E (see SUGGESTION 1b-1).

SUGGESTION 3-5: Either move Appendix G into the new chapter on experimental design and hypothesis testing or indicate its relation to that new chapter.

SUGGESTION 3-6: Move the Glossary to the front to join the tables of acronyms and of symbols.

7. SUGGESTIONS BEYOND THE CHARGE

SUGGESTION C-1: Discuss decisions leading to selecting the degree of confidence, embedded in the choice of significance level α and β values, in a section of Chapter 3. Selection may be a matter of the acceptable uncertainty specified by the agency that sets the AL.

SUGGESTION C-2: Discuss the impact of survey cost, needed skills, needed instruments, and length of time on the MARSAME effort in a section of Chapter 2. Brief projects obviously need different designs than lengthy ones. Discuss requirement and program for data retention, especially in long projects and when contractors replace each other.

SUGGESTION C-3: Discuss in a section in Chapter 6 the options to be considered and pursued when the plan proposed initially for M&E transfer must be rejected because of the observed contaminants.

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

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U.S. NRC. 2003. ***"Radiological Assessment for Clearance of Materials from Nuclear Facilities,"*** Nuclear Regulatory Commission (NRC), Office of Nuclear Regulatory Research, Washington, DC, NUREG-1640, Vols. 1-4, June 2003

Web-based Citations and Hotlinks

(e.g., Provided current relevant operational hotlinks below. May need more work - - -KJK)

MARSSIM: http://epa.gov/radiation/marssim/index.html

MARSAME: http://www.marsame.org

MARLAP: http://epa.gov/radiation/marlap/index.html

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

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

The general problem of design of 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 this can be manipulated (by changing counting times or performing repeated measurements of the same dose 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 having 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 materials that are to be measured. This distribution can often be well characterized by a standard deviation σ_S which we may call the sampling standard distribution;

(3) Deciding upon the number of samples, N, from the distribution of dose 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 the type I error (α) allowed, which may be controlled by the regulator or other guidance; the MARSAME manual should review the issues involved in specifying an acceptable type I error rate as well as any historical guidance – e.g., 1% or 5% -- that are typically applied;

(6) determining with fixed Δ and α the power $1 - \beta$ to reject the null hypothesis in favor or 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 1 error and power, given the instrument's measurement error properties and the sampling dose 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 excess radionuclide level is less than AL. In Scenario 2 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. The MARSAME manual should note that the interplay between α and 1 – β. 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.

When a single measurement is taken, the variance of that measurement will be equal to $\sigma_M^2 + \sigma_S^2$. 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 for example). 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 standard deviation of 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, however, there may be inherent biases in measurement instruments so that some or all of the measurement error is shared for all measurements.

When sampling variability is present (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, for example, to imperfect calibration (as in the "measured efficiency" of a monitor discussed in several places in the document). Generally, as more and more measurements are taken, the contribution of the sampling variance to the variance of the mean disappears, whereas some or all of the contribution of the measurement error may remain. The special case when 100 percent of a potentially contaminated material is measured may be regarded as the limit when $N \rightarrow \infty$. Again, some or all of the measurement error variance may still remain.

For most situations covered by 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 however 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 document, 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 detectable limit DL depend upon the power, type I error rate, and the standard error of the estimate σ. *One of the confusing aspects of the MARSAME document 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, the 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 is (for fixed power and type I error) dependent 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 levels to a "critical value" (termed S_c in the report) 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 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 section 4 would be more comprehensible if it consistently referred back to the suggested introduction to experimental design and hypothesis testing.

Section 4.1.1.2 gives a suggestion 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 in this report are illustrated for the first time in Figures. 4.2 and 4.3 of MARSAME. It is unfortunate that even though the concepts shown of the figures all relate to net radioactivity, are termed a "level", "value" or "limit." This could cause confusion and possibly be misinterpreted 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.

Suggestions 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.

As mentioned above, the Action Level 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 Action Level. Rather, each sample is compared with the Critical Value shown in the Figures. This insures that the probability for rejecting the null hypothesis, when it is true, will not exceed α. The Discrimination Limit 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-β). 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-β.

The intent of section 5.5 would be made more clear 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. It appears, however, that 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} is apparently referring 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} be estimating 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?

Fig. A-1. Scenario A

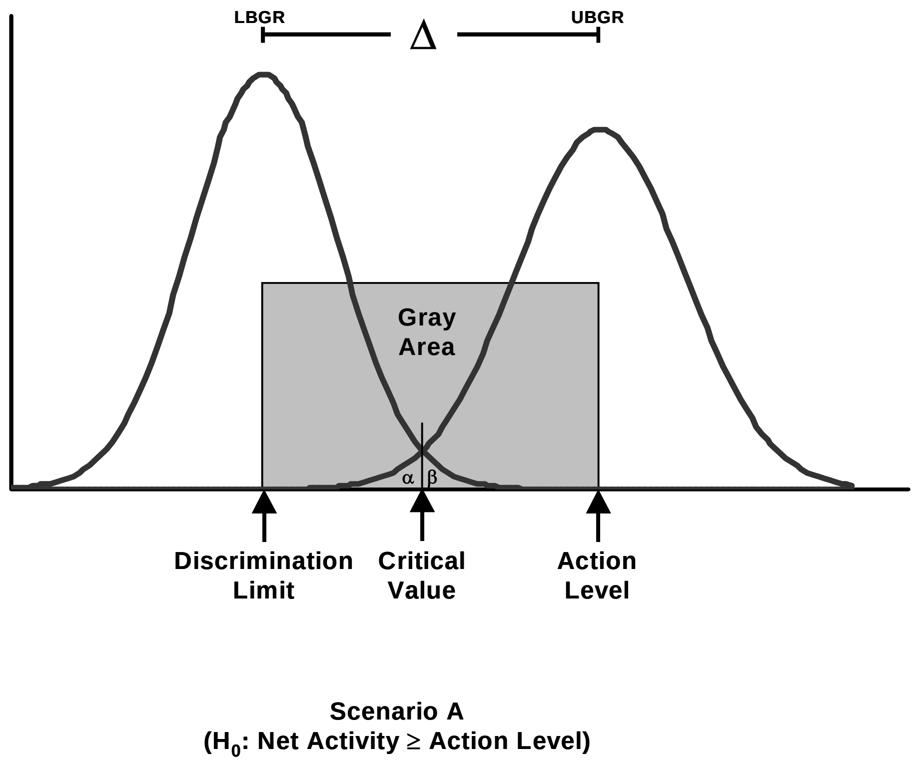
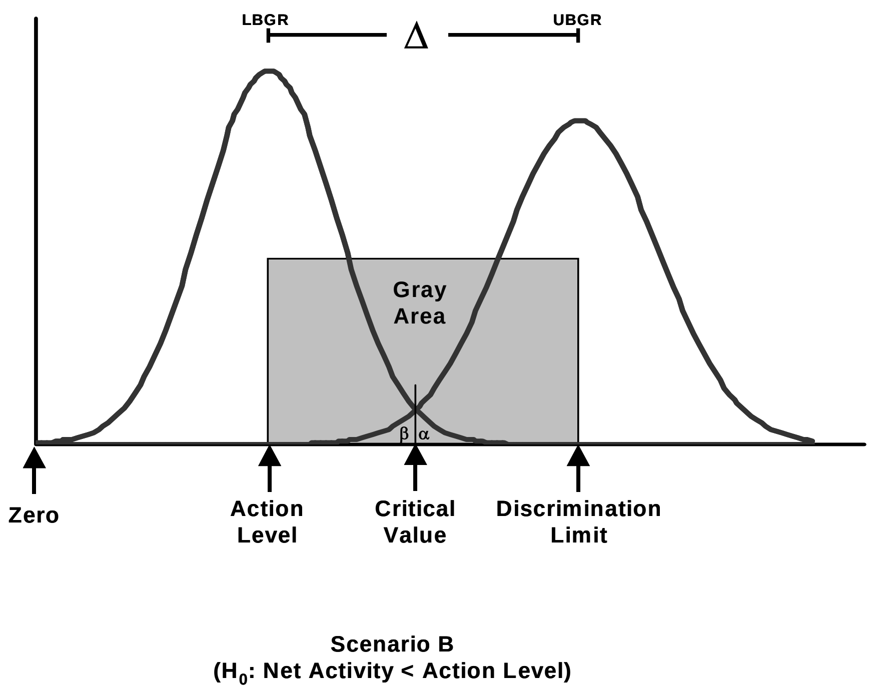


Fig. A-2. Scenario B



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 is now referring to the error in measurement-background rather than just the error in the measurement itself. At other points in the document σ_m seems to refer rather to the variance of just the measurement.

Table 5.1 shows details of the calculation of a critical value specialized to radiation counters with Poisson errors in estimating both the background radioactivity level and the level of radioactivity in the measured M&E. Use of the Stapleton formulae seems to be giving an improvement correcting for non-normality of the Poisson distribution for small count times. It would be helpful here to note clearly that the MDC is the value of S_c for rejecting the null hypothesis (scenario B) of no excess radiation above background, i.e. by referring back to the suggested introduction to experimental design and hypothesis testing.

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, but 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 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 $1-\beta$. 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 Discrimination Limit. 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 (Curie) 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.

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, $1-\beta$, as a function of the increasing amounts of radioactivity above background.

The blue curve represents the simulation for paired samples and the red curve 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 $\beta = 0.01$ when background is a constant. The two curves are identical when the excess radioactivity corresponds to S_c and therefore $\beta = 0.5$. The vertical line corresponds to the value of MDC obtained from equation 5.2.1. Note that the MDC, $(1-\beta) = 0.95$, obtained from the simulation with constant value for background is smaller than when using the assumption of paired samples.

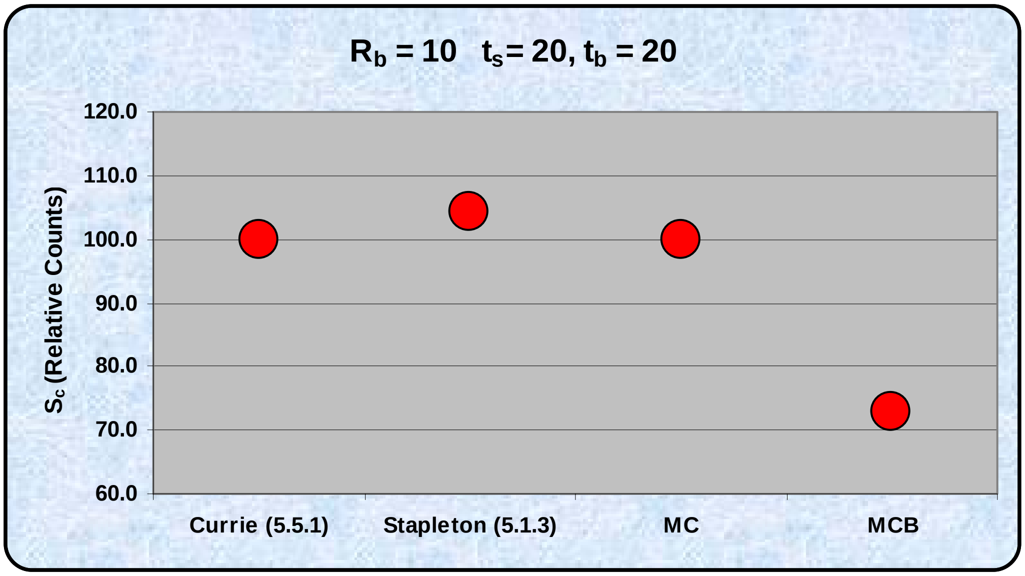


Fig. A-3. Comparison of S_c

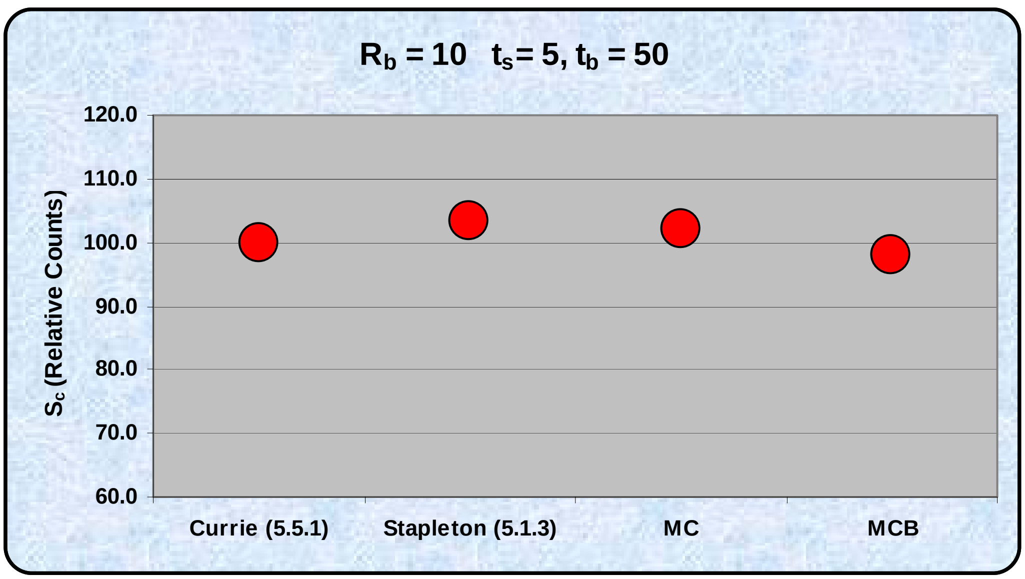


Fig. A-4. Comparison of S_c for longer background counting period

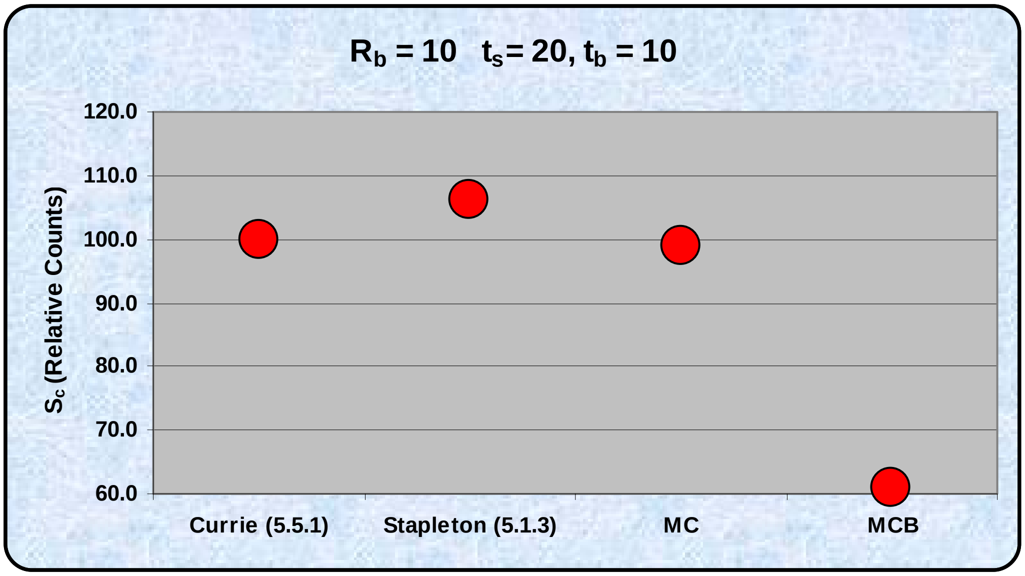


Fig. A-5. S_c for a briefer background counting period

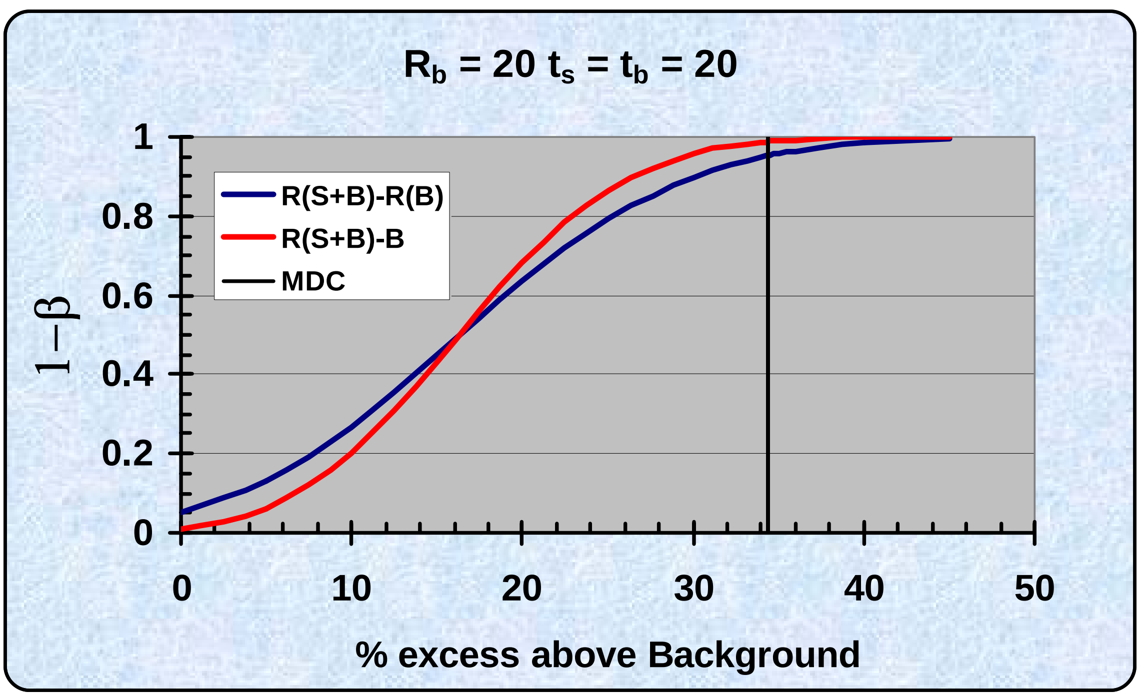


Fig. A-6. 1-β as function of % excess count above background

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 formula 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.

Section 6.2.3. Lines 215-224) 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" if not interpreted carefully (i.e. if one did a standard test such as Wilcoxan or t-test) 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 using the observed data alone. Specifically the sample standard deviation would underestimate the true measurement standard deviation σ if there is a shared uncertainty (such as errors in the estimate of counting efficiency) incorporated in σ_M.

The suggestion (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? Was this what was being meant by the (confusing) discussion in 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 very 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 document is assuming that such shared errors are small enough to be ignorable then 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 out when the background is subtracted from the level measured in the M&E. If this is what is meant then this 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

(This template has been modified, but some terms are still not defined. It is intended that we should use only those terms that are applicable to the subject content being discussed. - - - KJK)

A	Scenario A
AL	Action Limit (or Level)
α	Alpha (Type I error)
AM	Arithmetic Mean
AR	Absolute Risk
β	Beta (Type II error)
B	Scenario B
Bq	Bequerels
Bq/m^2	Bequerels/ Square meter
Bq/m^3	Bequerels/Cubic meter
$1-\beta$	Specified Value (1 minus Beta)
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
Co	Chemical symbol for cobalt (^{60}Co isotope)
CQ	Charge Question (CQ1, CQ 2, CQ3,)
Δ	Difference =Alternative – Null value) also the Detectable Difference
DFO	Designated Federal Officer
DL	Discrimination Limit (or Level)
DLC	Data Life Cycle
DoD	Department of Defense (U.S. DoD)
DOE	Department of Energy (U.S. DOE)
DQO	Data Quality Objective(s)
EAR	Excess Absolute Risk
EPA	Environmental Protection Agency (U.S. EPA)
FR	Federal Register
FGR-13	Federal Guidance Report 13
GM	Geometric Mean
GMC	Geometric Mean Coefficient
GSD	Geometric Standard Deviation
Gy	gray, SI unit of radiation absorbed dose (1Gy is equivalent to 100 rad in traditional units)
H	Chemical symbol for Hydrogen (^{3}H isotope)
H_o	Hypothesis??
HPGE	High Purity Germanium ??
IA	Initial Assessment
IAEA	International Atomic Energy Agency
∞	Infinity
I	Chemical symbol for Iodine (^{131}I isotope)
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements, Inc.
k	Coverage Factor for Uncertainty (see Statistical Appendix A p. 32) ??

keV	kiloelectron Volts
LBGR	Lower Bound Gray Region
MARLAP	Multi-Agency Laboratory Analytical Protocols
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 ??
MCB	Measurement Background Uncertainty
MDC	Measurement Data Uncertainty
MQC	Measurement Quality Uncertainty
MQO	Measurement Quality Objectives
mSv	milli-Sievert
N	The Sample Size (N measurements, for instance)
NaI	Sodium Iodide Detectors
NAS	National Academy of Sciences (U.S. NAS)
NCRP	National Council on Radiation Protection and Measurements
NRC	Nuclear Regulatory Commission (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
Pu	Chemical symbol for Plutonium (^{239}Pu Isotope)
QA	Quality Assurance
QC	Quality Control
QA/QC	Quality Assurance/Quality Control
R_b	Radiation Background ??
RAC	Radiation Advisory Committee (U.S. EPA/SAB/RAC)
SAB	Science Advisory Board (U.S. EPA/SAB)
SOP	Standard Operating Procedures
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)
Φ_{mr}	The relative upper bound of the estimated measurement method uncertainty μ_{mr},
t_b	Background Time Period
t_s	Sample Time Peiod
Type I	Error
Type II	Error
Tl-208	Chemical symbol for Thallium (^{208} Tl Isotope)
TSCA	Toxic Substances Control Act
u	Uncertainty (e.g., $u_{c)}$, and
μ_{mr}	Estimated Measurement Method Uncertainty
φ	Uncertainty (e.g., $\varphi_{MR)}$

UBGR	Upper Bound Gray Region
US	United States
WLM	Working Level Months
WRS	Wilcoxen Rank Sum Statistical Test
y_O	Estimate of Zero Order Output Quantity; also Minimum Detectible Concentration ??
Z	Critical Regions (e.g., $Z_{1-\alpha}$, or $Z_{1-\beta}$)

APPENDIX C –MARSAME TYPOS AND CORRECTIONS

(To be moved to a memo from report to a memo from the RAC MARSAME Review Panel DFO to the Multi-Agency Work Group via the ORIA Staff Office - - - KJK)

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)

End of Document