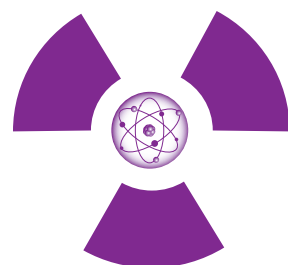


Guide for Laboratories – Identification, Preparation, and Implementation of Core Operations for Radiological or Nuclear Incident Response



EPA 402-R-10-002
www.epa.gov
June 2010
Revision 0

Guide for Laboratories — Identification, Preparation, and Implementation of Core Operations for Radiological or Nuclear Incident Response

**U.S. Environmental Protection Agency
Office of Air and Radiation
Office of Radiation and Indoor Air
National Air and Radiation Environmental Laboratory
Montgomery, AL 36115**



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This report was prepared for the National Air and Radiation Environmental Laboratory of the Office of Radiation and Indoor Air, United States Environmental Protection Agency. It was prepared by Environmental Management Support, Inc., of Silver Spring, Maryland, under contracts 68-W-03-038, work assignment 35, and EP-07-037, work assignments B-33 and I-33, all managed by David Garman. Mention of trade names or specific applications does not imply endorsement or acceptance by EPA.

PREFACE

The need to ensure an adequate laboratory infrastructure to support response and recovery actions following a major radiological or nuclear incident has been recognized by a number of federal agencies. The Integrated Consortium of Laboratory Networks (ICLN), created in 2005 by 10 federal agencies,¹ consists of existing and emerging laboratory networks across the Federal Government. ICLN is designed to provide a national infrastructure with a coordinated and operational system of laboratory networks that will provide timely, high quality, and interpretable results for early detection and effective consequence management of acts of terrorism and other events requiring an integrated laboratory response. It also designates responsible federal agencies (RFAs) to provide laboratory support across response phases for chemical, biological, and radiological agents. To meet its RFA responsibilities, EPA established the Environmental Response Laboratory Network (ERLN) to address chemical, biological, and radiological threats during nationally significant incidents (www.epa.gov/erln/). EPA is the RFA for monitoring, surveillance, and remediation of radiological agents. EPA will share responsibility for overall incident response with the U.S. Department of Energy (DOE).

This document is one of several initiatives by EPA's Office of Radiation and Indoor Air designed to provide guidance to radioanalytical laboratories that will support EPA's response and recovery actions following a radiological or nuclear incident. This guide examines those core operations of federal, state, and commercial radioanalytical laboratories that will be challenged when responding to a radiological incident. Suddenly, a laboratory will be faced with large numbers of radioactive samples collected following a radiological or nuclear incident, such as or a radiological dispersal device (RDD) ("dirty bomb") or the detonation of an improvised nuclear device (IND). These samples will be contaminated with varying levels of radionuclides, and will represent multiple matrices (such as building materials and various types of air filters, as well as more typical environmental matrices). Advance planning by national and regional response teams, as well as by radiological laboratories, will be critical to ensure uninterrupted throughput of large numbers of radioactive samples and the rapid turnaround of results that meet required data quality objectives associated with the protection of human health and the environment.

EPA's responsibilities, as outlined in the *National Response Framework Nuclear/Radiological Incident Annex*, include response and recovery actions to detect and identify radioactive substances and to coordinate federal radiological monitoring and assessment activities.

Detailed guidance on recommended radioanalytical practices can be found in the *Multi-Agency Radiological Laboratory Analytical Protocols Manual* (MARLAP), which provides detailed radioanalytical guidance for project planners, managers, and radioanalytical personnel based on project-specific requirements. MARLAP is available at www.epa.gov/radiation/marlap/index.html. Familiarity with Chapters 2 and 3 of MARLAP will be of significant benefit to users of this guide.

This document is one in a planned series designed to present radioanalytical laboratory personnel, Incident Commanders (and their designees), and other field response personnel with key

¹ Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Homeland Security, Interior, Justice, and State, and the U.S. Environmental Protection Agency.

laboratory operational considerations and likely radioanalytical requirements, decision paths, and default data quality and measurement quality objectives for analysis of samples taken after a radiological or nuclear incident, including incidents caused by a terrorist attack. Documents currently completed or in preparation include:

- *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance – Radionuclides in Water* (EPA 402-R-07-007, January 2008)
- *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance – Radionuclides in Air* (EPA 402-R-09-007, June 2009)
- *Radiological Laboratory Sample Screening Analysis Guide for Incidents of National Significance* (EPA 402-R-09-008, June 2009)
- *Method Validation Guide for Qualifying Methods Used by Radiological Laboratories Participating in Incident Response Activities* (EPA 402-R-09-006, June 2009)
- *Guide for Laboratories – Identification, Preparation, and Implementation of Core Operations for Radiological or Nuclear Incident Response* (EPA 402-R-10-002, June 2010)
- *A Performance-Based Approach to the Use of Swipe Samples in Response to a Radiological or Nuclear Incident* (in preparation)
- *Guide for Radiological Laboratories for the Control of Radioactive Contamination and Radiation Exposure* (in preparation)
- *Radiological Laboratory Sample Analysis Guide for Radiological or Nuclear Incidents – Radionuclides in Soil* (in preparation)

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ACKNOWLEDGMENTS

This guide was developed by the National Air and Radiation Environmental Laboratory (NAREL) of EPA's Office of Radiation and Indoor Air (ORIA). Dr. John Griggs was the project lead for this document. Several individuals provided valuable support and input to this document throughout its development. We wish to acknowledge the external peer reviews conducted by Mr. Sherrod Maxwell, Dr. Daniel Montgomery, Dr. J. Stanley Morton and Dr. Shiyamalie Ruberu, whose thoughtful comments contributed greatly to the understanding and quality of the document. Several excerpts from the Washington State Department of Health Incident Response Plan are included in the appendices, for which we thank Dr. Blaine Rhodes, Director of Environmental Laboratory Sciences, and his staff. Numerous other individuals both inside and outside of EPA provided peer review of this document, and their suggestions contributed greatly to the quality and consistency of the final document. Technical support was provided by Dr. N. Jay Bassin, Dr. Anna Berne, Mr. David Burns, Dr. Carl V. Gogolak, Dr. Robert Litman, Dr. David E. McCurdy, and Mr. Robert Shannon of Environmental Management Support, Inc.

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ACRONYMS, ABBREVIATIONS, UNITS, AND SYMBOLS

(Excluding chemical symbols and formulas)

α	alpha particle
α	probability of a Type I decision error
AAL	analytical action level
ADC	analog-digital converter
ADL	analytical decision level
AIM	acquisition interface module
β	beta particle
β	probability of a Type II decision error
Bq	becquerel (1 dps)
CFR	<i>Code of Federal Regulations</i>
Ci	curie
CoC	chain-of-custody
d	day
DL	discrimination limit
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegration per minute
dps	disintegration per second
DQO	data quality objective
EDD	electronic data deliverable
EPA	United States Environmental Protection Agency
ERC	Emergency Response Center
ERLN	Environmental Response Laboratory Network
γ	gamma ray
g	gram
GC/MS	gas chromatograph/mass spectrometer
GM	Geiger-Muller detector
GPC	gas-proportional counting/counter
Gy	gray
h	hour
HPGe	high-purity germanium [detector]
HVAC	heating, ventilation, air conditioning [system]
ICLN	Integrated Consortium of Laboratory Networks
ICP/AES	inductively coupled plasma/atomic emission spectroscopy
IND	improvised nuclear device (i.e., a nuclear bomb)
IRP	Incident Response Plan
ISO	International Organization for Standardization
k	coverage factor
L	liter
LCS	laboratory control sample
LSC	liquid scintillation counting/counter
μCi	microcurie (10^{-6} Ci)
m	meter

MAPEP	Mixed Analyte Performance Evaluation Program
MARLAP	<i>Multi-Agency Radiological Laboratory Analytical Protocols Manual</i>
MCA	multichannel analyzer
MCB.....	multichannel buffer
mg	milligram (10^{-3} g)
min	minute
MQO	measurement quality objective
MS.....	matrix spike
NaI(Tl)	thallium-activated sodium iodide detector
nCi.....	nanocurie (10^{-9} Ci)
NELAC	National Environmental Laboratory Accreditation Conference
NIM.....	nuclear instrument module
NRC	United States Nuclear Regulatory Commission
PAG.....	protective action guide
pCi.....	picocurie (10^{-12} Ci)
PHA.....	pulse-height analyzer
PIPS®	passivated implanted planar silicon [detector]
PT.....	proficiency testing
QA.....	quality assurance
QC.....	quality control
QAPP	Quality Assurance Project Plan
rad	radiation absorbed dose
RCA	Radiological Control Area
RCRA.....	Resource Conservation and Recovery Act
RDD	radiological dispersal device (i.e., “dirty bomb”)
rem	roentgen equivalent: man
RFA.....	responsible federal agency
RSO.....	Radiation Safety Officer
s	second
SOP	standard operating procedure
Sv	sievert
TAT.....	turnaround time
TNI.....	The NELAC Institute
TSCA	Toxic Substances Control Act
u_{MR}	required method uncertainty
y.....	year

RADIOMETRIC AND GENERAL UNIT CONVERSIONS

To Convert	To	Multiply by	To Convert	To	Multiply by
years (y)	seconds (s)	3.16×10^7	s	y	3.17×10^{-8}
	minutes (min)	5.26×10^5	min		1.90×10^{-6}
	hours (h)	8.77×10^3	h		1.14×10^{-4}
	days (d)	3.65×10^2	d		2.74×10^{-3}
disintegrations per second (dps)	becquerels (Bq)	1	Bq	dps	1
Bq	picocuries (pCi)	27.0	pCi	Bq	3.70×10^{-2}
Bq/kg	pCi/g	2.70×10^{-2}	pCi/g	Bq/kg	37.0
Bq/m ³	pCi/L	2.70×10^{-2}	pCi/L	Bq/m ³	37.0
Bq/m ³	Bq/L	10^{-3}	Bq/L	Bq/m ³	10^3
microcuries per milliliter (μCi/mL)	pCi/L	10^9	pCi/L	μCi/mL	10^{-9}
disintegrations per minute (dpm)	μCi	4.50×10^{-7}	pCi	dpm	2.22
	pCi	4.50×10^{-1}	μCi		2.22×10^6
cubic feet (ft ³)	cubic meters (m ³)	2.83×10^{-2}	m ³	ft ³	35.3
gallons (gal)	liters (L)	3.78	L	gal	0.264
gray (Gy)	rad	10^2	rad	Gy	10^{-2}
roentgen equivalent man (rem)	sievert (Sv)	10^{-2}	Sv	rem	10^2

NOTE: Traditional units are used throughout this document instead of the International System of Units (SI). Conversion to SI units will be aided by the unit conversions in this table.

1. INTRODUCTION

In the event of a radiological or nuclear incident, radiological laboratories will be called upon to perform analyses that will present significant challenges due to the large number of samples across a wide variety of matrices, the radionuclides potentially present, requested turnaround times, and, perhaps most of all, the range of activity levels present or expected. In order to produce defensible data of appropriate quality and meet demands for significantly faster TATs and higher throughput, a laboratory needs to be prepared to deal with issues that it may not face under normal circumstances. The purpose of this guide is to provide an overview of core operational considerations and the changes that should be considered so that a laboratory will be better prepared to transition and adjust to incident-response conditions. It cannot be emphasized enough that such planning is essential for proper and continued operations of the laboratory, for the protection of human health and the environment, and to help ensure the production of data that meet required data quality objectives (DQOs) and measurement quality objectives (MQOs) applicable to an actual response.

Accepting samples taken during a radiological incident response² will impact a laboratory in a number of ways. The radiological and analytical effects of varied and elevated levels of radioactivity associated with these samples have to be addressed. There is also the need for greater flexibility in the quality assurance/quality control (QA/QC) process to assure that the data produced are of appropriate quality. And last, but not least, there will be an increased demand for materials and resources needed by the laboratory to function over a period of time.

The first step in preparing for a radiological or nuclear incident is to develop a Laboratory Incident Response Plan. Chapter 2 of this guide introduces key elements of a Laboratory Incident Response Plan by providing a template for such a plan. The template includes elements such as staffing and additional training considerations; changes to sample handling and processing; changes to the laboratory Radiation Controls Program, including the Radiation Protection Program; enhancements to the laboratory's Quality System; and other changes that need to be anticipated as a laboratory plans and prepares for a response. Chapters 3, 4, and 5 discuss parts of the template in more detail. Appendix A provides excerpts from an actual Laboratory Incident Response Plan that show how modifications to selected laboratory operations can be made.

Chapter 3 addresses some of the issues related to the potential increase in radioactivity and radiation levels as a result of a surge in the number of samples received by a laboratory during an incident response. The necessity for effective controls to manage radiological exposures and radioanalytical contamination is brought into focus. This is done by suggesting enhancements to the existing laboratory Radiation Protection Program designed to minimize the effects of increased radioactivity and radiation levels on laboratory facilities, personnel, and data quality.

² Throughout this guide, "incident response" includes the three phases as defined by EPA:

- **Early (or Emergency) Phase:** The initial reaction to the emergency and can last for a few hours or up to a few days.
- **Intermediate Phase:** This phase initiates when the immediate emergency situation is under control and reliable environmental measurements are available for use as the basis of additional protective actions. This phase may overlap the other two phases and can last from weeks to months.
- **Late (or Recovery) Phase:** This phase begins when recovery actions begin. Recovery actions are designed to reduce radiation levels in the environment to levels acceptable for unrestricted use.

Efficient and safe use of available space is also addressed, by reviewing changes that a laboratory might plan to make to the existing sample and work flow before accepting samples from the incident to continue working safely and produce results quickly. A more detailed discussion of measures that can be taken to minimize or prevent radiological and radioanalytical contamination can be found in *Guide for Radiological Laboratories for the Control of Radioactive Contamination and Radiation Exposure* (in preparation).

Chapter 4 offers guidance on how to determine the most important factors contributing to the quality of data reported during incident response and what enhancements to the existing laboratory Quality System might be advisable to assure that quality of data needed by the Incident Commander (or the designee)³ is sufficient for the intended purpose. This analysis focuses on the effects on the quality of data resulting from the increased volume and activity concentration of the samples that will be received. The discussion in Chapter 4 highlights a range of other practical and operational issues that must be addressed if the laboratory is to optimize throughput and TATs for analyses and at the same time provide assurance that the data produced are of sufficient quality to support the decisions of the response.

Chapter 5 offers guidance on how to evaluate productivity issues related to available and needed resources. Developing a realistic estimate of the number of samples that can be processed in a specific amount of time requires laboratories to carefully examine their work processes so that they can identify limitations and barriers that may prevent them from successfully satisfying the demands and expectations that will be placed upon them. Appendix B offers a simplified example of how to evaluate a laboratory's capacity. The evaluation is meant to identify a laboratory's capacity to analyze samples that could arrive tomorrow (or next week) without much time to make significant changes to operations. It also is designed to identify areas where relatively minor changes might be possible to increase a laboratory's capacity in a targeted area. It should be noted that the example assumes that all of the sample workload results from response to the incident. This simplifies the capacity evaluation, but laboratories should consider what portion of their total capacity will actually need to be reserved for routine work.

Chapter 6 offers a list of additional concerns and issues that a laboratory might have to address when planning for a response to a radiological or nuclear incident. This list should not be considered all-inclusive or complete, but rather it should be viewed as a starting point in the process of evaluating the impact on current laboratory practices and activities of accepting samples during a radiological incident response.

³ Throughout this guide, the use of "Incident Commander" refers to the person or that person's designated representative.

2. DEVELOPMENT OF THE LABORATORY INCIDENT RESPONSE PLAN

2.1 Introduction

In the event of a radiological or nuclear incident, laboratories may receive and process radioactive materials with a greater range of activities, including higher activity than is the case during routine operations. Materials with varied and elevated activities may be encountered as samples, standards and tracers required for analyses, sample test sources,⁴ quality control (QC) samples, and waste produced during some analyses. It should also be expected that the number of samples that need to be processed, analyzed, and stored may significantly exceed those during routine operations, and a number of a laboratory's functions, processes, and programs may be affected. Development of a Laboratory Incident Response Plan provides an opportunity for examining those laboratory functions that will be impacted by a response to a radiological or nuclear incident, and for considering solutions to the issues that are anticipated.

In this chapter, key elements of a Laboratory Incident Response Plan are introduced by providing a template for such a plan. The template includes elements such as staffing and additional training considerations; changes to sample handling and processing; changes to the laboratory Radiation Controls Program, including the Radiation Protection Program; enhancements to the laboratory's Quality System; and other changes that need to be anticipated as a laboratory plans and prepares for a response to a radiological or nuclear incident. This template, discussed next, can be used to identify the steps necessary for a laboratory to transition into the incident response mode that supports the needs of the event in a quick, safe, and efficient manner.

2.2 Template for Creating a Laboratory Incident Response Plan

The process of creating a Laboratory Incident Response Plan focuses on examining a laboratory's current practices and procedures and identifying changes that will have to be implemented when incident-response conditions are in effect. The template below is basically a list of factors that most likely will be impacted by the increased flow of samples with potentially higher activities of known/unknown radionuclides. This list is used to create a plan specific to the laboratory, which addresses only those factors that will be changed when preparing for incident response. For some of the factors listed, examples of typical considerations are included. In addition, Appendix A includes examples taken from an actual Incident Response Plan, to illustrate how one laboratory approached the level of detail in the plan that was required for its successful implementation.

There are steps that a laboratory might implement before a response in order to ensure that periodic task requirements do not interfere with the incident response efforts. Changing the laboratory's Quality Manual to specify performance-based recalibration requirements in lieu of schedule-driven (e.g., annual) requirements may minimize the risk that analytical operations will be interrupted during an incident response for routine calibrations. There is often no regulatory

⁴ A "sample test source" is a sample, sample aliquant, or final product of a chemical or a physical process prepared for the purpose of activity determination (ASTM D7282). It is also considered to be the final form in a geometry that will be counted by a radiation detector.

driver for schedule-driven requirements beyond those stated in the laboratory's Quality Manual – a factor that is generally in control of the laboratory. Key quality standards, such as ANSI N42.23, ASTM D7282, and the TNI Standard, do not require recalibration as long as long as QC check control charts indicate acceptable performance. In those cases where there is an external requirement for periodic recalibration, it might be useful to establish a staggered timeline for recalibration of affected instruments so that only a portion of the total instruments of that type is taken out of service at a time. This practice would have an added benefit during routine operations of formalizing the schedule for periodic tasks, which may prevent unintended outages due to unanticipated problems with materials or other logistical considerations.

2.2.1 General Considerations

This section describes those high-level administrative functions of the organization that would be impacted by the laboratory's response to a radiological or nuclear incident, and identifies the changes that would need to take place as the laboratory transitions from normal to incident response conditions. It could address:

- Discussion of chain-of-command during incident response;
- Issues related to security and chain-of-custody; and
- Overview of the operational phases of the response, such as notification, preparation, shift scheduling, emergency work schedule, and return to normal operations.

2.2.2 Staffing and Job Descriptions

This section should identify the augmented or altered responsibilities appropriate to the incident response as well as any job functions that may be temporarily suspended. It should be noted that the incident response could extend over a period of months or even longer, and the planned changes need to take that into account. For example, the consequences of suspending some functions have to be evaluated and a time frame provided regarding how long such a suspension can last before significantly impacting the laboratory. Any additional functions and responsibilities also have to be evaluated in terms of their impact on working schedules so that work proceeds at a sustainable pace and degradation of performance due to overwork, fatigue, or induced stress is minimized. The elements considered in this section may include:

- Additional job functions created because of incident response conditions (such as incident response coordinator)
- Additional job functions added to support tasks that must be performed with increased frequency (e.g., frequency of radiological surveys)
- Changes to job assignments based on sample prioritization and resulting changes to the workload
- Changes to analysts and supervisor schedules to cover all shifts, and temporarily relieve them of any ancillary functions not related to the incident response
- Identification of all job functions to ensure that staffing is adequate to cover them
- Identification of areas where job overlap (one person wearing many hats) may leave essential functions uncovered or without sufficient coverage to satisfy QC requirements

2.2.3 Development of a Quality Assurance Project Plan

The ongoing steps that a laboratory should take to ensure preparedness in the event of a radiological or nuclear incident should be included in a Quality Assurance Project Plan (QAPP)⁵, or other planning document, whose focus would be only those elements of the Laboratory Quality Manual that are relevant to the incident response activities.

This QAPP should carefully define the anticipated quality requirements for incident-related activities and should delineate whether each requirement is supplemental to, or in lieu of, the requirements stated in the Laboratory Quality Manual. Because this QAPP is written in anticipation of a radiological or nuclear incident, it should be generic enough and flexible enough to be easily and quickly adapted to conditions specific to the incident response. Other guides in this series (see Preface) can be used as a source of default values for analytical action levels, required method uncertainty, etc., appropriate to incident response and necessary for the development of a QAPP. Additional discussion of the elements that should be considered in developing an incident response QAPP can be found in Section 4.3.

2.2.4 Incident Response Sample Handling

Each stage of processing an incident response sample is described in terms of changes made to the routine operations of the laboratory because of the nature of the sample. In each case, preparation, lists of additional supplies and equipment, and changes to working conditions should be considered. Concerns related to sample handling may include:

- Sample Receipt and Tracking (Sample Control)
 - Information that may be available prior to samples arriving at the laboratory
 - Information that might be provided in advance of, or delivered along with, the sample shipment, for example:
 - Radiation level based on field survey, color-coded to reflect processing priority, if not stated differently by the Incident Commander
 - Results of any surveys of the sample container
 - Specifics regarding sample matrix, such as type, quantity, location, and date of collection
 - Requested analyses
 - Special requirements for chain-of-custody documentation
 - Current sample login procedure adequate for accepting samples from unexpected sources. For example, a laboratory routinely may be set up only for current clients, and the computerized login procedures may not be adequate for an incident response client.
 - Plan in place for cataloging and storing samples for quick retrieval if needed for re-analysis
- Sample Screening (in preparation for sample prioritization)
 - Equipment calibration – current and suitable for sample geometries to be received
 - Established objectives for sample receipt and associated screening

⁵ Guidance on developing a Quality Assurance Project Plan can be found in EPA QA/G-5 (2002) and other quality documents (www.epa.gov/quality/qa_docs.html).

- Time per sample for screening so that projections for processing can be easily estimated
- Type of radiation screening to be performed and potential radiological/non-radiological interferences that may be present
- Additional documentation required for both the laboratory and the client
- Defined measurement quality objectives (MQOs) for each screening analysis
- Additional considerations for opening sample containers, storage of samples, and disposal of waste transport containers
- Protective packaging to be used for sample containers and samples after screening

Additional information regarding radiological incident response sample screening can be found in *Radiological Laboratory Sample Screening Analysis Guide for Incidents of National Significance* (EPA 2009c).

2.2.5 Incident Response Sample Processing

Depending on how a laboratory is set up to process routine samples, sample processing procedures will also have to be examined and adapted to analyze samples with potentially varied or increased levels of radioactivity. The issues that should be considered include:

- Sample Prioritization
 - Is there a process for sample prioritization?⁶
 - How is the sample prioritization communicated to staff?
- Temporary Storage and Shielding
 - Location of the temporary storage and shielding for higher-activity samples
 - Access control to the temporary storage locations
 - Radiation monitoring of the temporary storage locations
- Sample Preparation
 - Location of preparation areas for incident response samples
 - Alternate sample preparation procedures for higher-activity samples (e.g., use of smaller aliquants, addition of tracers with higher-activity concentration)
 - Additional contamination control measures applied to these samples
 - Changes to the types and levels of appropriate QC samples included with each batch:
 - Laboratory control samples to reflect sample activity levels different from those the laboratory handles routinely
 - Adjusting the level of the matrix spikes to prevent matrix spike failure due to high sample activity vs. low spike level (see discussion in section 4.5.2)
 - Increasing the frequency of duplicates to reflect the complexity of subsampling for samples such as urban matrices that can contain brick-, concrete-, or asphalt-particulates.
- Analytical Separations

⁶ If there is no other information available, a default sample prioritization scheme can be based on sample flow process discussed in *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance – Radionuclides in Water* (EPA 2008) and *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance – Radionuclides in Air* (EPA 2009b).

- Has the laboratory implemented and validated rapid methods to be used in incident response?
- Location of areas in the laboratory for performing analytical separations for samples with potentially higher activity levels
- Additional requirements for screening sample test sources before submitting for counting
- Sample Test Source Counting
 - Increased frequency of instrument background checks
 - Action levels for sample test source activity that will trigger a special (nonscheduled) instrument contamination check or background subtraction count
 - Changes in counting times necessary to meet the MQOs, as the anticipated activity levels change depending on the actual phase of the incident response. Counting times might be reduced for samples with elevated activity, but may need to be increased for samples with activities lower than routine, in order to meet the required MQOs (listed here as an element to be considered, but it could be addressed in the relevant analytical standard operating procedure for incident response).
- Calculations and Recordkeeping
 - Are the calculations performed in accordance with the incident response method?
 - Do the reported values have the correct units?
 - Has the laboratory provided the necessary documentation of sample chain-of-custody within the laboratory?
 - Are the analytical protocols consistent with the incident requirements?
 - Are spreadsheets with appropriate calculations developed to facilitate sample prioritization after sample screening is completed?
- Data Review and Validation
 - Defining responsibilities for additional data review, if required
 - Establishing criteria/checklists to address incident response specific concerns such as looking for interferences not normally encountered (concerns arising from having high-activity levels in samples, presence of fresh fission products that are normally not present in samples; e.g., ^{140}Ba interfering with radiostrontium analysis or ^{210}Po interfering with determination of uranium isotopes via alpha spectrometry)
 - Ensuring that sample preparation/splitting is correctly documented and that appropriate factors are applied in calculations
 - Making sure that the data review requirements completed by the laboratory are as expected
- Results Reporting
 - Non-routine reporting formats or units
 - Boilerplate narratives in place
 - Software in place to facilitate reporting
 - Electronic data deliverable (EDD) production defined
 - Expected turnaround times and were these turnaround times met
- Feedback to and from the Incident Commander
 - Means of communication with the Incident Commander and identification of personnel directly responsible for responding to or implementing any requests from the Incident Commander
- Waste Management

- What are the issues regarding waste generation and management that the laboratory will face as a result of an increased influx of samples or when higher-activity samples are processed? For example:
 - How will the laboratory address labeling and placement of additional waste containers for radioactive materials?
 - Will it be necessary to have a radioactive waste storage area outside of the building confines as a temporary storage area until shipment can be arranged?
 - How will the facility screen normal wastes to ensure that no contaminated materials are inadvertently released?
 - Will the laboratory be prepared to dispose of waste that might contain other regulated constituents (e.g., Resource Conservation and Recovery Act [RCRA] or Toxic Substances Control Act [TSCA]) whose presence may result in creating mixed wastes?
 - Is the laboratory prepared to address potential radiation exposure risks resulting from elevated levels of radioactivity in wastes?
- How can these issues be addressed, and what specific provisions have been made by the laboratory in advance of a radiological or nuclear incident?⁷

For additional information on analyzing samples received during an incident response, see *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance — Radionuclides in Water* (EPA 2008), *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance — Radionuclides in Air* (EPA 2009b), and *Method Validation Guide for Qualifying Methods Used by Radioanalytical Laboratories Participating in Incident Response Activities* (EPA 2009a).

2.2.6 Changes to the Laboratory Radiation Controls Program and Implementation Strategies

The presence of samples and other materials with potentially elevated levels of activity may increase the risk of occupational radiation exposure, impact the quality of data by increasing instrument backgrounds and the risk of cross-contamination among samples and instruments, and become a potential source of contamination. The impact of these effects on laboratory operations and personnel safety can be minimized by developing:

- A new section of the laboratory’s Radiological Controls Program documentation⁸ that addresses issues of laboratory personnel exposed to increased radiation levels arising from a sudden influx of higher-activity samples;
- A program for minimizing *radiological* contamination (i.e., general contamination of the laboratory at levels that pose radiological health and safety concerns); and
- A program for minimizing, detecting, and controlling *radioanalytical* contamination in the laboratory, i.e., uncontrolled spread of radioactivity that leads to sample cross-

⁷ See a more detailed discussion in Chapter 6.

⁸ This documentation may have many different names depending on the type of facility, such as “radiation safety manual,” “radiation protection plan,” or “radiological controls plan.” All of these encompass the hazards of working with ionizing radiation and radioactive materials. This document uses the term “Radiological Controls Program.”

contamination or otherwise negatively impacts radiochemical analysis, so that the data produced are defensible and of appropriate quality.

The existing Radiological Controls Program is generally designed to address routine operations of the laboratory. Changes chosen for increased protection of laboratory personnel and the public as a result of the presence of higher-activity samples should be identified in this section of the Laboratory Incident Response Plan. These changes will depend on the measures already in place, the activity level that the laboratory is able to accept, and the number of additional samples that the laboratory is able to process. A much more detailed discussion of the radiological and radioanalytical controls that might be appropriate is found in the *Guide for Radiological Laboratories for the Control of Radioactive Contamination and Radiation Exposure* (in preparation). A few examples include:

- Identify locations of step-off pads and frisking stations.
- Identify areas of restricted access due to either dose or contamination.
- Adjust receiving protocols to account for inspection and screening of sample shipments as they arrive.
- Manage amount of material in process and storage areas to minimize dose.
- Use dosimetry by all personnel and publicly post the administrative dose limits.
- Post the requirements for personal protective equipment.
- Identify new areas inside the laboratory that will be surveyed and sampled for surface contamination.
- Add dose and contamination monitoring locations outside the laboratory.
- Include procedures or references for facility and personnel decontamination.

2.2.7 Enhancements to the Laboratory Quality System

This section of the Laboratory Incident Response Plan should list and include a brief description of all the incident response procedures and other related analytical procedures. It could also become the area where the laboratory describes experiences with implementing these procedures (i.e., lessons learned). Documenting these experiences may prevent repeating some mistakes, and may serve as a starting point for future investigations or discussions of improvements. While the actual narratives, notes, annotations, and comments need not be included in the Laboratory Incident Response Plan, their location should be identified clearly for future reference. Another element of this section might be a crosswalk comparing routine procedures with incident response procedures to identify the critical differences between them. For example, the same method may be used for sample preparation and chemical separation, and only the sample counting time is changed; this would not require additional training of the analyst. Chapter 4 provides additional details.

2.2.8 Assessing and Managing Resources

Complete response to a major radiological or nuclear incident may last as long as a year—or even longer—as the initial efforts to assess the extent and the level of contamination will transition to assessing the remediation and cleanup efforts. Accepting additional samples will result in a significant strain on a laboratory's resources, and not anticipating and preventing

shortages of staff and of materials may result in a complete halt of analytical activities, thus jeopardizing a successful recovery from a radiological or nuclear incident. This section of the Laboratory Incident Response Plan might include the results of the initial assessment of the laboratory's capability and capacity, with a list of options available to remedy the issues identified in the assessments (an example of such an assessment is provided in Appendix B). For example, a procedure might be implemented during incident response to monitor the level of existing supplies more frequently so that shortages of critical materials are anticipated and prevented. A list (including names, telephone numbers, etc.) of vendors that have agreed to stock specific supplies and make them available preferentially could also be included here. Chapter 5 provides additional details.

2.2.9 Appendices

Supporting information should be included here. Examples include:

- Floor plans indicating changes to be made under incident response conditions, such as posting doorways for limited access to minimize movement of samples
- Placement of additional thermoluminescence dosimeters in work areas to monitor worker exposure
- Examples of all additional forms to be used during incident response operation, such as recording results of additional surveys
- Tables of exposure limits, waste disposal limits, and acceptable levels of radioactivity and radiation (specific to the laboratory)
- List of contacts, including vendors, regulatory agencies, and laboratory management; after-hours and emergency numbers should be listed as well, if available.

2.3 Additional Comments on Creating the Laboratory Incident Response Plan

Additional measures implemented during an incident response may require new or expanded administrative, radiological protection, and radioanalytical procedures. These procedures should be developed and tested. All staff responsible for the execution of these procedures should be trained accordingly. If the laboratory needs to develop an approach to certain tasks (e.g., site-specific changes to sample receipt to allow for additional screening and sample segregation, or selection of the laboratory space for processing of high-level samples), it may be helpful to involve appropriate staff, including corporate, government, or other stakeholders, as soon as possible in the process.

A laboratory could begin by conducting a table-top exercise to review an existing procedure, brainstorm proposed changes, and update, retest, and validate the procedure until it addresses the specific concern. Once it appears that a good procedure has been developed, a drill may be conducted to test a manageably small part of the procedure. For example, a drill could focus on processes prior to sample arrival, including who has to be notified and how, who needs to be waiting in the sample receipt area, what equipment will be required for screening, and who documents pre-receipt information. An independent observer should be present to monitor the progress of the drill and provide subsequent feedback. Because the same staff will be involved in both the procedure development and its testing and implementation, their active involvement

assures management that the new, revised, or augmented procedures are appropriate to the task and reflect the needs and operations of the laboratory.

As the process of developing laboratory-specific approaches to incident response continues, testing small, individual components during drills should be followed by exercises that combine several small components. This could be accomplished by conducting a simulated incident response exercise that demonstrates how quickly staff members are able to reorganize the laboratory into low- and high-level activity zones, how well they know their roles and responsibilities, and how quickly they can fully integrate into the incident response mode. Such comprehensive simulated response exercises should be conducted periodically to provide feedback on the adequacy of the existing procedures, level of staff preparedness, and identification of areas that need improvement. These exercises involve everyone in developing improved procedures and corrections to the existing plan.

3. ENHANCEMENTS TO THE RADIOLOGICAL CONTROLS PROGRAM FOR INCIDENT RESPONSE

3.1 Introduction

Every radiological laboratory with a radioactive materials license must implement a Radiation Protection Program that controls and minimizes radiation exposure.⁹ The primary purpose of the Radiation Protection Program is to protect laboratory personnel and the public from the effects of radiation resulting from laboratory activities. This guide assumes that such a program is in place and is designed to address issues related to the routine operations of the laboratory.

In the event of a significant radiological or nuclear incident, however, it is likely that many radiological laboratories will be called upon to perform sample analyses in support of the various response efforts taking place, and that the radioactivity concentrations in these samples may be well in excess of those to which the laboratory is routinely accustomed. The numbers of samples and the overall quantity of sample material are also likely to be significantly increased. In addition, the increased radioactivity levels in the standards and tracers required for analysis, waste produced during analyses, sample test sources, and quality control (QC) samples all will contribute to the increased radioactivity and radiation levels in the laboratory.

Elevated activities in the laboratory may increase the risk of occupational radiation exposure, may impact the quality of data by increasing instrument backgrounds and the possibility of cross-contamination among samples, and may become a potential source of laboratory and environmental contamination. The laboratory should make advance preparations for receiving and handling the samples in order to minimize radiation exposure and radioactive contamination.

Radiological and Radioanalytical Contamination:

This guide refers to both *radiological* and *radioanalytical* contamination.

The general term *radiological contamination* refers to the radioactive contamination of the laboratory facilities or personnel. In some cases, radiological contamination may occur at levels that pose a radiological health and safety concern.

The term *radioanalytical contamination* refers to contamination of the sample material, instrumentation, or laboratory facilities that leads to sample cross-contamination or otherwise negatively impacts radiochemical analyses.

While the laboratory's surveillance and control measures for personnel protection and for the prevention of radioanalytical contamination may frequently overlap, the goals are sufficiently different that they will be discussed separately in this guide whenever the distinction becomes important.

These advance preparations should be clearly outlined in the Radiation Protection Program and in relevant standard operating procedures (SOPs). The advance preparations for a radiological or nuclear incident should include an assessment of the configuration of the laboratory, the resources available for the incident response, and the sample handling and contamination control procedures to be implemented during the incident response. In addition, the laboratory staff should be adequately trained to implement these measures efficiently and effectively during an incident. These preparations, the Radiation Protection Program, the laboratory SOPs, and the necessary training collectively comprise an effective Radiological Controls Program.

⁹ 10 CFR 835.101(for DOE facilities) and 10 CFR 20.1101 (Subpart B and 10 CFR 20 Subparts C (1201-1208) and D (1301 and 1302) or equivalent Agreement State regulations.

An effective Radiation Controls Program should minimize the effects of increased radioactivity and radiation levels on laboratory facilities, personnel, and data quality. This may be accomplished through the development of procedures and practices to:

- Control the radioactive materials being handled in the laboratory. This includes the accurate assessment (screening) of the nature of the material and the establishment of well defined and effective procedures for the physical handling of the material and the movement of the material through the laboratory.
- Actively monitor radiological and radioanalytical contamination and personnel exposure and establish quantitative limits for surface contamination of laboratory benches and work areas, as well as detectors.
- Address the decontamination and shielding of the laboratory personnel, facilities, and equipment when the established quantitative limits are exceeded.

As with all other aspects of the laboratory's incident response activities, a Radiation Controls Program should anticipate the unique challenges associated with various incident scenarios and allow for rapid assessment of, and adjustments to, changing laboratory conditions.

To this end, the laboratory should assign personnel to perform incident response functions within the laboratory for monitoring of contamination and radiation, overview of sectoring the laboratory for high- and low-activity samples, cleanup following a spill or identified contaminated area, and disposal of the radioactive wastes from samples and the analytical process. Examples of some of these functions with some procedural excerpts are shown in Appendix A.

3.2 Radioactive Materials License Issues

Current Nuclear Regulatory Commission (NRC, or Agreement States) Radioactive Materials License requirements should be evaluated in terms of the laboratory's ability to accept and analyze samples with higher-than-normal activity levels or to add new radionuclides. Availability of provisions to increase the inventory limits, if necessary, for incident response should be examined. It should be remembered however, that changes in license may impact other aspects of laboratory operations, such as storage of materials and samples, and may require increased controls (e.g., internal dosimetry, increased contamination monitoring).

3.3 Selecting the Type of Processing Configuration for the Laboratory

Efficient and safe use of available space becomes critical when an influx of samples with potentially elevated activities is anticipated. Any changes that a laboratory plans to make to the existing sample and work flow to continue working safely and produce results quickly and of known quality should be planned in advance and be an integral part of the Radiation Controls Program.

There are several possible approaches for managing the flow of material with varying levels of radioactivity, including:

- (a) The use of separate processing facilities for high- and low-level samples;
- (b) Isolating high- and low-level sample processing areas in the same facility; and
- (c) The use of a single low-level processing area.

The suggestions offered below may be used as a starting point for any changes that an existing laboratory is considering, and should be a part of any new facility planning effort. The actual approach selected by the laboratory will depend on factors such as resources available, the projected intensity of the response effort, and other functions that the laboratory is required to perform.

These suggestions may be considered to be three distinct, “ideal” solutions to a very complex problem. (The discussion below offers only an overview of the topic. Additional information is presented in the *Guide for Radiological Laboratories for the Control of Radioactive Contamination and Radiation Exposure*, in preparation). The specific plan that a laboratory develops may have elements from all three, but in every case, the underlying principle always will be to maintain the separation between high- and low-activity samples. Establishing and maintaining this separation, combined with adding appropriate contamination controls, will assure both the health and safety of the laboratory personnel and the public, and will protect the integrity of the samples and the quality of the analytical results.

Separate processing facilities for high- and low-level samples: The segregation process ideally should occur even before the sample receipt area is reached (i.e., in the field), with high- and low-level samples arriving in separate shipments, or at least in separate shipping containers. Each facility would have its own receipt and screening area, followed by transfer of the samples to a separate high- or low-level processing facility. This is clearly the most resource-intensive solution to the problem, but it affords the greatest degree of separation of high- and low-activity samples. However, implementation of such an approach is probably possible only when a new facility is being designed. For existing laboratories, depending on their size, physical setup, and resources, two other possible alternatives are suggested below.

Isolate high- and low-level processing areas in the same facility: One common sample receipt area can be used for screening and subsequent segregation of samples according to their assessed activity levels. Samples are segregated, prepared, and counted in permanently established high- and low-level processing areas, or in suitable areas that are temporarily assigned for processing high- or low-level samples. The area for high-level samples should be self-contained, equipped with balances, hoods, labware, hotplates, standards, and instrumentation—whatever is required to support work at higher activity levels.

Additional concerns about contamination and cross-contamination, and the impact of radiation on work areas and radioanalytical instrumentation, should drive the design and use of such areas. Issues such as control of access, capability of the air handling system for minimizing air flow between the high- and low-level processing areas, and control of the movement of materials to eliminate the possibility of cross-contamination should be considered.

A laboratory may already have separate facilities for high- and low-activity samples, or may be able to establish a high-level area in the existing space, taking into consideration issues discussed

here. Until incident response work is required, these areas can be used for routine measurements, with standard laboratory controls. However, returning to normal use after high-level samples have been processed requires additional measures to determine and eliminate contamination from the area. These measures and their impact on the routine operations of the laboratory should be considered and defined in the laboratory's Laboratory Incident Response Plan.

Use one low-level processing facility: This option entails having a single dedicated sample receipt screening area to screen and digest each sample, followed by appropriate dilution to produce a solution with activity low enough to be handled in the routine low-level processing area without undue risk of cross-contamination. This is clearly the least expensive option, as far as facility costs are concerned. It is generally the best option for facilities that concentrate on low-activity work and are not able to support a dedicated high-level sample processing facility.

This option would require the augmentation of an existing sample receiving process to allow for screening and subsequent sample dilution to reduce the levels of activity in the aliquant processed in the laboratory itself. The screening and sample preparation and dilution sample-flow design should include measures to minimize the laboratory personnel's exposure to radiation, and measures to minimize the potential of cross-contamination, since this is the only time when samples with disparate levels of radioactivity are present in the same area. For soil samples, laboratories accustomed to handling only low-level samples may use grinding equipment that may not be appropriate for higher-level samples; therefore, equipment should be available for samples suspected of having elevated levels. This also would require additional dedicated screening instrumentation, such as liquid scintillation counters (LSC) or gas-proportional counters (GPC), and perhaps even a high-purity germanium detector (HPGe), all of which might become contaminated if an incident of national significance took place. (See *Radiological Laboratory Sample Screening Analysis Guide for Incidents of National Significance* [EPA 2009c].)

However, this approach is not always effective. Some types of samples, such as soils, cannot be easily subdivided without extensive treatment. Occasionally, radionuclides such as ^{238}Pu may need to be determined at very low levels in samples that contain higher levels of other radionuclides (e.g., natural uranium or ^{137}Cs). A separate screening and high-level sample processing area may still be required in these cases.

4. CHANGES TO THE LABORATORY QUALITY SYSTEM

4.1 Introduction

Laboratory data should be produced under a Quality System (EPA offers guidance on Quality System documents at www.epa.gov/quality/qa_docs.html). A Quality System is a structured and documented management framework that describes the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The purpose of having a Quality System is to provide the client with data of known and documented quality with which to demonstrate regulatory compliance and for other decisionmaking purposes. This system includes a process by which appropriate analytical methods are selected, their capability is evaluated, and their performance is documented. The Quality System is documented in the laboratory's Quality Manual.

Quality Assurance (QA) refers to an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected. It can be thought of as an overall plan and set of processes, including policies, procedures, guidance documents, training programs, procurement specifications, and other laboratory activities and measurements that support the overall quality of the analytical data, and ensure that the needs and expectations of the end-user of the data are fulfilled (MARLAP 2004).

Quality Control (QC) is the overall system of technical activities whose purpose is to measure and control the quality of a process or service so that it meets the needs of the users or performance objectives. It can also be viewed as a subset of quality assurance and is meant to include those aspects of the Quality System program that evaluate specific measurement data, and other output parameters, against defined objectives that are derived in such a way as to ensure that the data meet the requirements of the intended user (MARLAP 2004).

The purpose of this section of the guide is to introduce aspects of QA and QC that may be specific to the laboratory's response to an incident. These aspects of QA and QC supplement the established laboratory Quality System, and no part of this document is intended to supersede established procedures, activities, and practices.

This guide assumes that prior to its participation in the response to a radiological or nuclear incident, each laboratory will have undergone accreditation or approval by a nationally recognized program such as EPA's Drinking Water Certification Program, The NELAC Institute (TNI), or ISO 17025 accreditation, and thus will have the minimum elements of a Quality System in place. This chapter of the guide addresses those aspects of QA/QC that are specific to incident response that may not be included in the laboratory's normal QA plan. The QA elements that need to be reviewed and augmented for incident response include, but are not limited to:

- A Laboratory Quality Manual that provides overall guidance and procedures for all QA and QC activities (see Section 4.2), including prescribed processes for addressing data quality and other laboratory events that do not meet the established acceptance criteria.

- A QAPP for incident response that at minimum (see Section 4.3) considers additional training relevant to radiological or nuclear incident response, anticipated changes to chain-of-custody requirements, expedited corrective actions, appropriate level of method validation of procedures for higher-level samples, and participation in proficiency testing (PT) programs with PT samples similar to those anticipated in the response (see Section 4.3.5).
- Establishing objective and defensible criteria for analytical measurement performance criteria, and ensuring that incident response MQOs are met (see Section 4.4).
- Identifying the types of QC samples that need to be re-evaluated in terms of their frequency and acceptance criteria as a result of the laboratory's analyses of samples with elevated levels of activity (see Section 4.5).

A project involving a radiological or nuclear incident should begin with the laboratory's existing QA and QC requirements, and should address how those functions would change and how the changes are to be implemented. For example, the staffing and approach for data review and its frequency might change from weekly to daily, and the QC charts would have different ranges for the laboratory control samples (LCSs; see Section 4.5.2). These are usually qualitative requirements. QC parameters may be narrowly defined, based on the acceptability of a single measurement or the adherence to a particular procedure.

4.2 The Laboratory Quality Manual

A laboratory's Quality Manual documents the management policies, objectives, principles, organizational structure and authority, responsibilities, and accountability of a laboratory to ensure the quality of its product and its utility to the user. This guide assumes that the laboratory has a manual that clearly addresses quality assurance as it is applied to all testing and analytical services on behalf of customers or accrediting organizations for its routine operations, and that the laboratory's management has ensured that it is being implemented appropriately. The manual should specify the management and technical requirements that demonstrate that the laboratory operates a Quality System, is technically competent, and is able to generate valid results. Requirements for a Quality System, and subsequent contents of a Quality Manual depend on the standard used, such as The NELAC Institute (TNI) standard or ISO 17025. These standards define elements of a Quality System that a laboratory might operate under to meet its obligations or accreditation requirements (if applicable).

However, typically the Quality Manual does not address specific QA and QC measures as they relate to the laboratory's participation in the response to an incident (or any other event-specific project). These additional or supplementing measures, including appropriate QC acceptance criteria, corrective actions, or other elements of the laboratory's Quality System that need to be adjusted to meet the anticipated requirements of the response project, should be identified in the QAPP for incident response. The elements of the QAPP for incident response that are considered important to producing defensible and timely results are discussed next.

4.3 The Quality Assurance Project Plan for Incident Response

The ongoing steps that a laboratory should take to ensure preparedness in the event of an incident should be included in a QAPP for incident response,¹⁰ or other planning document, whose focus would be only those elements of the laboratory Quality Manual that are relevant to the incident response activities. This QAPP should define the anticipated quality requirements for incident-related activities and should carefully delineate whether each requirement is supplemental to or substitutes for the requirements stated in the Quality Manual. These additional requirements should include:

- Ongoing cross-training to maintain versatility and technical competence among the existing staff.
- Periodic exercises or drills to evaluate the laboratory's ability to perform anticipated non-routine functions on short notice.
- Periodic review and re-evaluation of a preliminary Laboratory Incident Response Plan that outlines the steps to be taken once an incident has occurred and after more specific information is available.
- Responsibilities of personnel during implementation of incident response activities.
- Procedures for transitioning from routine to incident response operations.
- Implementation of a graded approach to method validation that would facilitate rapid validation of methods that have been modified for response to a radiological or nuclear incident.¹¹
- MQOs applicable to an incident response.¹²
- Analytical procedures to be used.
- Requirements for periodic retraining.
- Requirements for other quality-related tasks, such as instrument background frequency.

An example of a project-specific requirement is to perform method blank analyses, such as air particulate filters (see Section 4.5.2), which are likely to be supplemental to the standard batch- and instrument-QC requirements contained in the laboratory's Quality Manual. At the same time, the acceptance criteria for the incident-related batch or instrument QC may supersede the criteria defined in the Quality Manual.

4.3.1 Incident Response Training

To the extent possible, personnel should be trained on what information would be needed to respond adequately to a radiological or nuclear incident. At a minimum, this might include gathering available information about identities of radionuclides that are likely to be present, the levels of radioactivity expected, physical and chemical properties of the incident-specific radionuclides, and anticipated action levels. Incident-specific MQOs, hazards that may be

¹⁰ Guidance on developing a Quality Assurance Project Plan can be found in EPA QA/G-5 (2002).

¹¹ See *Method Validation Guide for Qualifying Methods Used by Radiological Laboratories Participating in Incident Response Activities* (EPA 2009a) for details.

¹² Default MQOs for water and air matrices may be found in *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance – Radionuclides in Water* (EPA 2008) and *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance – Radionuclides in Air* (EPA 2009b), respectively.

present, and appropriate safety measures should be established and addressed in the training as well.

Laboratory personnel should receive training on the various methods to be employed and should demonstrate proficiency in those methods for which they will be responsible. This should be planned and completed as part of an incident response preparedness program.

In addition, staff should be adequately aware of the Incident Command System anticipated for an event, including planning for continuous communications with the Incident Commander, depending upon the phase of the incident.

4.3.2 Review of Chain-of-Custody Information

While it is unlikely that an environmental radioanalytical laboratory will be involved in the handling of forensic samples for attribution or prosecution purposes, there may still be special chain-of-custody (CoC) requirements for the project. The laboratory should incorporate these requirements into the QAPP.

In addition, large-scale projects may involve many laboratories with different capabilities, and the incident site may contain many distinct zones with highly disparate levels of radioactivity. Careful attention to field CoC protocols, if possible, combined with good communication between the laboratory and the Incident Commander about the expected delivery of samples, may help in the early identification of shipping errors and other handling issues that could compromise the samples or possibly even contaminate the laboratory.

4.3.3 Expedited Corrective Action Procedures

The QAPP should clearly identify procedures and personnel in the laboratory that will address any necessary corrective action in a timely and effective manner. Lines of communication both within the laboratory and with the Incident Commander should be identified and staffed with technically knowledgeable personnel who have the authority to make decisions regarding the data quality and to help formulate corrective action plans, when necessary.

4.3.4 Method Validation Requirements

The QAPP should clearly define the requirements for the validation of newly developed or newly introduced methods in the laboratory that will be used in incident response. It is likely that many routine radioanalytical procedures may be appropriate for incident response. However, the laboratory should validate any of these procedures for use in similar matrices, with varying or higher activities or interference levels. In the absence of specific requirements, the companion guide, *Method Validation Guide for Qualifying Methods Used by Radiological Laboratories Participating in Incident Response Activities* (EPA 2009a) provides detailed guidance on the validation of methods introduced under these circumstances. Key issues, such as uncertainty, method specificity, ruggedness, precision, and bias and detection capability should be addressed.

4.3.5 Proficiency Testing Programs

A laboratory preparing to respond to a radiological incident should participate in regular PT studies that have radionuclides, activity levels, and matrices such as water, air particulate, soils, building materials, and swipes that are relevant to a radiological dispersal device (RDD) incident.¹³ These PT studies can be used to examine specific components of a laboratory's incident-response capabilities, such as turnaround time, suitability of reporting format, contamination control procedures, and analysis of higher-activity samples, to determine the laboratory's capability to respond to an incident of national significance. However, aside from existing PT programs such as DOE's Mixed Analyte Performance Evaluation Program (MAPEP), it is unlikely that appropriate external PT programs will be available prior to, or immediately after, a radiological or nuclear incident. "Appropriate" in this case means that the PT samples are of a similar matrix, with comparable radionuclides and activity levels, as the samples received from the incident. The laboratory may need to assess the availability of PT samples periodically and may consider developing internal PT samples before an event occurs. In any case, using these PT samples routinely allows for initial and ongoing training on all incident response procedures which then become an integral part of the laboratory's operations.

4.3.6 Availability of a Reliable Source of the Target Radionuclide

In developing methods and performing the analyses for the response to an incident, the radionuclide of concern in the incident may not be readily available for method development, instrument calibration, or batch QC purposes. The laboratory should develop clear guidelines for the use of surrogate radionuclides for method development and quality control, and share these with the Incident Commander for his/her approval. The type of radiation and its emission energy, the chemical behavior, and the physical properties of the surrogate should be carefully considered to assure that they are representative of the radionuclide(s) of concern.

4.4 Data Quality Objectives, Analytical Action Levels, Measurement Quality Objectives, and Analytical Decision Levels

DQOs and MQOs can be established using the guidance found in MARLAP and should include an analytical action level (AAL), discrimination limit (DL), gray region, null hypothesis, analytical decision level (ADL), and required method uncertainty u_{MR} at the AAL. It is anticipated that the Incident Commander will provide the laboratory with appropriate DQOs and MQOs. In their absence, default values for DQOs and a procedure for calculating related MQOs are contained in Appendix VI of the *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance – Radionuclides in Water* (EPA 2008).

4.4.1 Data Quality Objectives

The DQO process may be applied to all programs or studies involving the collection of environmental data with objectives that cover decisionmaking activities. When the goal of a study is to support decisionmaking, the DQO process applies systematic planning and statistical

¹³ See *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance — Radionuclides in Water* (EPA 2008) for an example of a list of radionuclides that might be present in an RDD.

hypothesis testing methodology to decide between the alternative actions. DQOs can be developed using the guidance in EPA QA/G-4 (2006).

Laboratory personnel should be familiar with the source or basis for the DQOs, and should have a working knowledge of a directed planning process (MARLAP 2004, Chapter 2) to ensure that any data generated support the decisionmaking process and are within the scope of capabilities of the laboratory.

4.4.2 Analytical Action Levels

An essential part of the DQO process is the specification of a decision rule. This rule, which may be qualitative or quantitative, will contain alternative actions to be taken, depending on whether the analytical measurement result is above or below an AAL. The decision that will be made is expressed in a hypothesis test. The null hypothesis is defined by initially assuming the result is either above or below the AAL. Because analytical data always have some uncertainty associated with them, a decision error may be made, e.g., rejecting the null hypothesis when it is true (a Type I error), or failing to reject the null hypothesis when it is false (a Type II error).

The DQO process will result in a desired limit on the probability of making decision errors. The limit for the probability of making a Type I error (denoted α) is generally specified at the AAL. The probability of making a Type II error (denoted β) is specified at a DL. The DL is a concentration for which the null hypothesis is false, and where it is important to distinguish that concentration from the AAL.

The AAL and DL together bound a gray region in which decision error probabilities are not controlled as tightly as outside of it. The width of the gray region is $\Delta = | \text{AAL} - \text{DL} |$.

4.4.3 Measurement Quality Objectives

Measurement quality objectives specify the analytical data requirements by which a measurement can be assessed to meet the objectives of the project. MQOs generally are quantitative data requirements that evaluate the quality of the measurement against the criteria for which decisions are made using those data.

MARLAP considers the u_{MR} at the AAL to be a fundamental MQO. For decisions about whether a single sample exceeds the AAL, it can be calculated as $u_{MR} \leq \frac{\Delta}{z_{1-\alpha} + z_{1-\beta}}$.¹⁴ Details and refinements for this are given in MARLAP Appendix C or Appendix VI of either *Radiological*

¹⁴ $z_{1-\alpha}$ and $z_{1-\beta}$ are the respective quantiles of the standard normal distribution function. Values of $z_{1-\alpha}$ (or $z_{1-\beta}$) for some commonly used values of α (or β), taken from tables of the cumulative normal distribution (EPA 2009b), are:

α or β	$z_{1-\alpha}$ (or $z_{1-\beta}$)	α or β	$z_{1-\alpha}$ (or $z_{1-\beta}$)
0.001	3.090	0.10	1.282
0.01	2.326	0.20	0.842
0.025	1.960	0.30	0.524
0.05	1.645	0.50	0.000

Laboratory Sample Analysis Guide for Incidents of National Significance – Radionuclides in Water (EPA 2008) or *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance – Radionuclides in Air* (EPA 2009b).

In order to implement the use of the required method uncertainty, the laboratory must have in place an acceptable method for estimating the combined standard uncertainty of each result. MARLAP recommends the method put forth in the *Guide to the Expression of Uncertainty in Measurement* (ISO 1995). No measurement should ever be reported without an associated uncertainty and its coverage factor, k . Simply reporting “counting uncertainty” is incomplete, and for high-activity samples, may result in significantly underestimating the combined standard uncertainty.

4.4.4 Analytical Decision Levels

The AAL is the dividing point that determines a choice between alternative actions. The need to make informed defensible decisions about whether an AAL has been exceeded, with acceptable limits on the probability of a decision error, will drive the quality of the measurements of the parameter being measured.

To limit the probability of a Type I decision error, the measurement result is compared to an ADL.

If the null hypothesis is that the sample exceeds the AAL, the ADL is calculated as $AAL - z_{1-\alpha} u_{MR}$, where u_{MR} is the required method uncertainty at the AAL.¹⁵ Only measurement results less than the ADL will result in rejecting the null hypothesis that the true concentration is greater than the AAL.¹⁶

As an example, let us look at a situation during sample screening, where it may be very important to correctly identify samples that exceed the AAL. Sending a low-level sample to a high-level section of the laboratory is less of a practical problem for the laboratory than risking contamination by processing a high-level sample in a low-level section of the laboratory. In this case, the null hypothesis is that the sample exceeds the AAL, to protect better against the Type I error of incorrectly deciding that the sample is below the AAL when it actually is above the AAL. However, we would like to be sure that if a sample is really below the AAL, it is also correctly identified in order to avoid a Type II error of incorrectly deciding that the sample is above the AAL when it actually is below. For this example, the discrimination level DL is chosen as $DL = 0.5AAL$.

Suppose the AAL is 1 nCi/L activity in the sample. Then the DL is 0.5 nCi/L, and $\Delta = (AAL - DL) = 1.0 - 0.5 = 0.5$. The probability of making a Type I error is set at $\alpha = 5\%$ and the

¹⁵ See MARLAP (2004), Chapter 3, for how to determine the u_{MR} for a project.

¹⁶ Usually the null hypothesis that the sample exceeds the AAL is chosen. However, there may be cases where the null hypothesis is that the sample does *not* exceed the AAL, for which the ADL becomes $AAL + z_{1-\alpha} u_{MR}$, and only measurement results greater than the ADL will result in rejecting the null hypothesis that the true concentration is less than the AAL.

probability of making a Type II error is set at $\beta = 10\%$. Notice that the probability of making a Type I error is smaller than the one for a Type II error, and this reflects the statement made in the previous paragraph about the greater risk associated with the incorrect decision that the sample is below the AAL. Consequently, to minimize that risk, a small (5%) value is chosen for the acceptable Type I error rate, and a larger (10%) value for the acceptable Type II error rate of incorrectly deciding that the sample is above AAL.

From section 4.4.4, we limit the required method uncertainty to $u_{MR} \leq \frac{\Delta}{z_{1-\alpha} + z_{1-\beta}} = 0.5$

nCi/L/(1.645 + 1.282) = 0.17 AAL = 0.17 nCi/L. From Section 4.4, the ADL = AAL - $z_{1-\alpha} u_{MR}$ = 1.0 - (1.645) (0.17 nCi/L) = 0.72 nCi/L. Only measurement results less than the ADL will result in rejecting the null hypothesis that the true concentration is greater than the AAL.

4.5 Quality Control

The basic types of QC samples prepared during the response to a radiological or nuclear incident should be defined explicitly in the QAPP, or may follow the laboratory's default QC practices. In most cases, the types of QC samples will include blank samples, LCSs (i.e., fortified blanks), and duplicate samples. These QC types are not unique to an incident and are not addressed specifically in this guide, except for the issues of event-specific acceptance criteria and the special case of media used to collect samples, such as air filters and swipes.

4.5.1 Incident-Specific Acceptance Criteria

During routine laboratory operations, QC acceptance criteria are frequently used in the form of control limits, which are derived statistically from historical data and which provide expected limits for the performance of a method, based on past performance.

During the response to a nuclear or radiological incident, however, the Incident Commander should specify acceptance criteria (MQOs) appropriate for the DQOs of the project. Using concepts and equations found in MARLAP (Chapters 7 and 18 and Appendices B and C) and the required method uncertainty u_{MR} as the primary MQO, specific criteria can be derived.

The acceptance criteria that will change most significantly are those for the matrix spike (MS) and the LCSs. These specific issues are discussed in Section 4.5.2. The laboratory should ensure that the event-specific acceptance criteria are applied only to incident-related samples, and that other samples unrelated to the incident are not evaluated against the incident-specific acceptance criteria.

4.5.2 Sample-Related Quality Control

The frequency and acceptance criteria for sample QC may be different for an incident response than for normal operations. Processing of samples that have activity elevated above samples normally encountered will present contamination control issues for samples, reagents, sample processing equipment, and sampling collection media (such as filters and charcoal cartridges). For example, the frequency of routine blank sample analysis may need to be increased to reflect different activity levels, and the need to monitor and minimize the impact of cross-contamination

on the results. Two types of laboratory blank samples, as defined in MARLAP (Glossary and Section 18.4.1), should be distinguished:

- *Reagent blank* – Consists of the analytical reagent(s) in the procedure (without the *target analyte* or sample matrix), introduced into the analytical procedure at the appropriate points and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps.
- *Method blank* – A *sample* assumed to be essentially *target analyte*-free that is carried through the radiochemical preparation, analysis, mounting, and measurement process in the same manner as a routine sample of a given matrix.

A reagent blank is a commonly used quality control sample used to evaluate absolute bias (i.e., positive or negative bias to the analytical measurement that results from reagents or other sources of bias intrinsic to the method). Typically, one reagent blank is included in every batch. However, an additional blank might be added when, due to the large quantities of reagents used during incident response, more than one lot of chemicals or reagents is needed to complete processing of samples in a batch.

Examples of method blanks would include clean, unused particulate air filters, or a portion of clean quartz sand of similar quantity to that of the sample aliquant. Where possible, use of method blanks as batch quality control samples is the most ideal situation since method blanks most closely match the actual matrix of the samples under analysis. Use of method blanks, however, may complicate the QC evaluation of the blank since they may contain naturally occurring radionuclides of interest. For example, natural uranium is commonly present in readily measurable concentrations in glass fiber filters and in quartz sand which would interfere with uranium or gross alpha/beta analyses. In such cases, it may be preferable to rely on a reagent blank as a batch quality control blank. If the use of a method blank is deemed important, each lot of material to be used as a surrogate (blank) matrix should be characterized for the radionuclides of interest prior to its initial use and the data generated from the initial characterization used to establish acceptance criteria for evaluating the acceptability of batch method blanks.

It also may be of interest to the project to obtain an accurate measurement of the background activity of analytes of interest in sample collection media (e.g., glass fiber filters). The QAPP for incident response should address periodic re-evaluation of interfering native constituents each time the lot or manufacturer of sampling media changes. Similarly, it is suggested that a field blank (or “trip blank”) be analyzed as a sample to evaluate contamination that might result from sample acquisition in the field and subsequent transport to the laboratory.

Two other routine quality control samples, as defined in MARLAP, that are used include:

- *Laboratory control sample* – A standard material of known composition or an artificial *sample* (created by fortification of a clean material similar in nature to the sample), which is prepared and analyzed in the same manner as the sample. In an ideal situation, the result of an analysis of the *laboratory control sample* should be equivalent to (give 100 percent of) the *target analyte* concentration or *activity* known to be present in the fortified sample or standard material. The result normally is expressed as *percent recovery*.

- *Matrix spike* – An *aliquant* of a *sample* prepared by adding a known quantity of *target analytes* to a specified amount of matrix and subjected to the entire analytical procedure to establish if the method or procedure is appropriate for the analysis of the particular matrix.

Both of these will need to have the activity increased to be commensurate with the activity of the samples being analyzed. As an example, a laboratory normally adds 10 pCi of ^{90}Sr to its matrix spike for water samples. If the expected concentration of ^{90}Sr is 300 pCi/L, the amount of spike added needs to be increased so that the measured value associated with the matrix spike is not obscured by the actual sample activity measurement uncertainty. In this example, a 5% uncertainty in the 300-pCi/L sample activity is 15 pCi/L. This is greater than the amount of the routine spike of 10 pCi/L, and any conclusions based on the results of the analysis of this matrix spike will be meaningless.

The LCS and MS will need to have increased activity so that they can reflect the method's capability to accurately determine higher concentrations of the radionuclide. Many methods rely on chemical separations that use techniques such as microprecipitation, ion exchange, or solvent extraction. Increased quantities of the radionuclide being processed by the analysis may compromise the quality of the sample test source needed for an adequate spectrum, or exceed the capacity of the technique or method to carry the radionuclide through the analysis.

Another routine quality control sample is the duplicate. From MARLAP:

- *Duplicates* – Two equal-sized samples of the material being analyzed, prepared, and analyzed separately as part of the same batch, used in the laboratory to measure the overall *precision* of the sample measurement process, beginning with laboratory sub-sampling of the field *sample*.

This sample is very important from the perspective that the method is reproducible on a sample of the same exact matrix, that it is a measure of the adequacy of the estimation of the combined standard uncertainty, and that laboratory sub-sampling has not compromised obtaining a representative portion of the sample for analysis. Given the variability and complexity of incident-response matrices, effective subsampling may be more of a challenge than when routine samples are being processed. If there is a concern regarding the potential lack of reproducibility because of a difficult matrix, it might be advisable to increase the frequency of duplicates, followed by immediate review of the results, so that any detected problems can be addressed promptly.

There are additional considerations when preparing LCSs in certain situations. Very often the methods that have been developed and routinely used in a laboratory focus on the analysis of the single radionuclide and may not have been validated when other radionuclides that are orders of magnitude higher in concentration are present. Thus, a LCS may need to contain not only the radionuclide of interest, but also another radionuclide expected to have a much higher concentration in the samples and also known to be an interferent in the separation and counting of the radionuclide of interest.

Quality control charts that reflect the project-related acceptance criteria will need to be established. This may be achieved by using the MQO for the required method uncertainty, u_{MR} . Specific equations identifying acceptance criteria (based on that required method uncertainty) for duplicate, blanks, laboratory control, and matrix spike samples are also found in MARLAP.

4.5.3 Instrument-Related Quality Control

Many laboratories count instrument backgrounds for a much longer period of time than the associated samples. During the response to a radiological or nuclear incident, it may be possible to shorten background count times as long as they are still longer than the longest count time for samples counted on that detector. This should not affect data quality because some of the samples will have significantly higher count rates than the background for the radionuclides of interest. Reducing background count times will create additional instrument capacity for the counting of samples while ensuring that data quality is not compromised. On a routine basis, a longer background count should be performed on each instrument to monitor the detector for low-level contamination. However, the frequency with which this is done will be very low compared to the short-term checks. It actually may be advisable to increase the frequency of the short-term checks to monitor for possible contamination resulting from counting higher-activity samples. These quality checks for the instruments may also be put into separate control charts since the acceptance criteria for an out of specification result may end up being different when analysis is performed on much higher-activity samples.

Finally, it may be useful to check an instrument for gross contamination by swiping sections of the counting chamber and counting the swipes on a complementary detection instrument. For example, a swipe of the inside of a gamma spectrometry cave may be taken and analyzed for gross alpha and beta by gas proportional counting to identify the presence of non-gamma emitting (or low-energy emitting) radionuclides that could pose contamination and cross-contamination concerns. If such checks are to be conducted, however, it is very important that long background checks and background subtraction counts be measured before and after the swipes are taken. This is because swiping the chamber could add, remove, or redistribute contamination and prevent contamination from being identified as having compromised the sample counts, or even change the activity in a background subtraction count.

4.5.4 Tracking and Trending Quality Control Charts

In general, the approach to evaluating quality control charts during an incident response needs to differ from routine operations with several changes that reflect changes to the analytical process as a result of the incident response. It may be necessary to establish quality control charts for methods not routinely used, or to reflect modification made to methods, and different activity levels being processed, or to address project-related acceptance criteria. For example, if an incident-specific method is used that varies from routine sample analysis, a separate control chart is needed to allow performance of that method to be assessed apart from routine sample work. Similarly, if the activity level of spiked control samples such as the LCS or MS may vary from that of routine operation, it is important to set up separate control charts because performance at those activity levels may vary from routine. Similarly, if a tolerance chart is used to track a

method against project-specific acceptance criteria, a specific control chart will be needed for this purpose.

The frequency of analyzing control samples probably also will increase during incident response. This is especially the case with blanks which need to be run at increased frequency due to an increased risk of cross-contamination that accompanies running samples of higher activity than normal. Similarly, the general approach to instrument QC checks may vary, and background checks may need to be run more frequently because of increased concerns about cross-contamination from samples of higher activity than normal. Finally, batches of samples may be run at significantly higher frequencies than normal, and the frequency of trending of the charts should be increased accordingly to ensure that bias and trends are promptly identified and corrective actions taken in a timely manner.

5. IDENTIFYING NEEDS AND OPTIMIZING RESOURCES FOR INCIDENT RESPONSE

5.1 Introduction

Because a radiological or nuclear incident will occur without warning, advance planning is vital. Large numbers of samples and as-quick-as-possible turnaround times will be the rule. The increased levels of throughput will likely continue at unprecedented levels for many months, or even longer. Planning to rapidly transition from normal operations to incident response operations will help ensure that laboratories are ready to provide optimal support for an incident response. Because such planning generally focuses on maximizing laboratory efficiency, such planning often will also benefit the laboratory's routine operations.

Delays in obtaining critical items, such as tracers, standards, or columns, may also be responsible for temporary or longer-term disruption of production. Critical physical resources also include longer-term, more expensive items such as radioanalytical instrumentation and major laboratory equipment, as well as smaller items ranging from minor laboratory equipment to expendable supplies (e.g., disposable gloves), labware, reagents, and standards.

Laboratories should develop a plan that ensures instrumentation, laboratory equipment, and supplies can be maintained at levels needed to support current and changing production needs and which proactively address details associated with transitioning from routine operations to incident response operations. This section will address several such areas.

This guide does not address personnel issues specifically, since that is beyond its scope. However, it should be pointed out that both the capacity and the capability incident response assessment has to include considerations such as the number of available staff and the extent of available cross-training to ensure redundancy in all areas.

5.2 Documenting Capabilities and Estimating Capacity for Incident Response at the Laboratory

An incident of national significance could create a sudden and very intense demand for a particular capability or set of capabilities. Having previously identified capabilities and capacities¹⁷ allows the laboratory to initially make more realistic commitments regarding the type and number of samples that can be analyzed for particular parameters.

As part of planning for an incident response, a laboratory should define its capabilities and estimate its capacity to analyze certain combinations of radionuclides and matrices. This will establish a quantitative basis for planning to manage physical resources during an incident response. It is recognized that capacity evaluations may need to take different forms to best reflect the needs and unique aspects of the particular laboratory and questions at hand. Evaluations may seek to place an upper bound on a laboratory's capacity by identifying discrete points in the analytical process that limit a laboratory's capacity to perform a certain test or analyze a

¹⁷ The laboratory's capabilities must be based on validated methods. A laboratory should not assume that a method can be developed and validated quickly, in response to the needs of an event.

specific-sample matrix. For example, sufficient instrumentation and preparation space, procedures, and staff may be available for processing soil samples, but a relative lack of equipment for grinding soils may drastically limit the total number of soil samples that can be processed. Appendix A provides an example of one possible matrix-based approach to estimating capacity and identifying key factors that pose limits to a laboratory's capacity.

The laboratory, as part of its incident response planning, should develop contingency plans for adding equipment, or making targeted changes to the facility and its operations, that will ensure that it can maintain the physical resources needed to manage a smooth transition to incident response operations, and which would allow it to very rapidly and economically expand its capacity for a set of capabilities.¹⁸

5.3 Increasing Laboratory Capacity Without Adding Instrumentation

If the laboratory has not invested in additional radioanalytical instrumentation prior to the incident, it may have problems obtaining new instrumentation in an expedient manner following the incident. Demand will likely outstrip limited supply, and instruments may not be widely available until after they are needed most. Anticipating this likely situation, the laboratory can explore alternative strategies for increasing capacity using current instrumentation.

One strategy involves evaluating instrument use and implementing measures to identify under-utilization. Such measures may be as straightforward as staffing uncovered shifts to provide additional capacity. Screening potential high-activity samples before counting may identify cases where shorter counting times will satisfy MQOs (while minimizing the risk of contaminating detectors). Throughput also may be increased by optimizing QC frequency by processing full batches of samples. If the laboratory Quality Manual and SOPs are flexibly and thoughtfully written, QC protocols can be structured to reflect current needs for an instrument. For example, the laboratory may be able to meet MQOs with shortened sample count times. Because laboratories generally count backgrounds for much longer than the associated samples, it may be possible to shorten background subtraction count times and periodic background checks to match the counting times for samples, thereby “creating” additional instrument capacity for the counting of samples, while ensuring that data quality is not compromised.

Another approach, however, involves additional advanced planning but will have the most significant impact on increased sample throughput, not only for incident response operations but potentially for routine operations as well. Since the count time needed to obtain results of a specified uncertainty is roughly proportional to the inverse square of the size of the sample processed, if methods can be modified to increase the size of the sample aliquant, count times can be decreased and a marked impact on laboratory throughput achieved without having to procure new instrumentation. Of course, this requires that more robust sample preparation and chemical separation methods be used. Depending on the incident scenario and the radionuclides being measured, sequential methods may contribute to time saving and thus increased capacity. The laboratory should always remember that if it chooses to make significant changes in

¹⁸ Quite apart from the topic of incident response, such an exercise could identify areas where improvements could be of immediate benefit to the laboratory's routine operations.

methods or protocols, it is important that the methods be formally validated prior to use to demonstrate that they will be capable of meeting project MQOs.

5.4 Adding (Non-Radioanalytical) Equipment During Incident Response

There is less chance that non-radioanalytical laboratory equipment will be as difficult to obtain after an incident, as will radioanalytical equipment. It may be possible to identify areas where additional capabilities would be needed following an incident. A laboratory may determine that it can quickly expand capabilities by adding non-radioanalytical equipment after an incident. This may allow the laboratory to quickly increase its productivity. New capabilities may be added, or pinch-points that detract from laboratory capacity may be addressed by expanding existing capabilities. This would require that specifications be written, plans developed, arrangements for installing equipment made, methods developed, procedures written, and staff trained on new equipment.

It might be possible to plan and make tentative arrangements with vendors in advance, so that they will be able to secure equipment. For example, the laboratory in its Incident Response Plan may make arrangements to conditionally rush order and rapidly deploy equipment when the need arises. Plans should consider that, especially when major equipment is to be installed, this may need to occur while the laboratory is working. Any plan should consider this and consider how to minimize negative impacts on production. For example, sketches of the proposed changes to the laboratory layout and the placement of the additional equipment could be included. SOPs could be written flexibly enough that they apply to both old and new equipment, should it be added.

Table 1 lists examples of typical major and minor non-radioanalytical equipment and supplies whose resupply a laboratory may choose to consider prior to an incident. Anticipating the need for these materials and planning for their acquisition and deployment prior to an incident response can significantly improve the laboratory's capabilities and capacity. Of course, any complete list would be specific to a given laboratory's operations and could be much longer.

Table 1 – Typical Examples of Major and Minor Non-Radioanalytical Equipment

Major Laboratory Equipment	Minor Laboratory Equipment
<ul style="list-style-type: none"> • Hoods • Glove boxes • Drying ovens • Muffle furnaces • Grinding equipment (e.g., paint shaker ball mills) • Balances • Centrifuges • Specialty glassware such as radon emanation or tritium distillation apparatus • Microwave digestion apparatus 	<ul style="list-style-type: none"> • Infrared lamps (for drying planchets) • Pipettes, fixed and variable volume • Replacement parts • Sieves • Vortex mixers • Water bath • Hot blocks • Hot plates • Filtration apparatus (filter stands, manifolds) • Vacuum supply (e.g., filtering, emanation apparatus) • Chromatography apparatus • Vacuum boxes or peristaltic pumps for ion exchange and extraction chromatography

5.5 Supplies

Estimating capacity for an analysis is a difficult endeavor since estimates of capacity depend on a large number of factors. The picture is further complicated since analytical demands change from day-to-day, and varying mixes of analyses compete for a common set of resources. In order to estimate the amount of supplies that are needed to ensure continued support to an incident response, it is important to estimate the capacity of the laboratory to run the analyses in question. This was discussed earlier in this chapter (see Section 5.2). Once some estimates for a realistic maximum throughput have been made, the average expendables used for each analysis can be estimated.

The simplest way to start is by analyzing the SOPs for use of various supplies, reagents, standards, and other equipment. A list of typical supplies could include but is not limited to:

- Reagents
- Standards
- Carriers
- Resins
- Chromatography supplies
- Disposable labware
- Centrifuge tubes
- Pipette tips
- Transfer pipettes
- Filters, such as cellulose, glass fiber, polypropylene, etc.
- Digestion vessels
- Sample labels
- Sample containers
- Waste containers and drums
- Swipes
- Others that may be specific to the laboratory's methods

While some supplies have a relatively long shelf-life and may be used without concern of expiration, others such as reagents, standards, and resins may have expiration dates assigned by the manufacturer, or should have expiration dates established at the laboratory that will limit the use of these items to a specific time, and which will also tend to limit the total inventory maintained at any given time.

It is important to account for all supplies needed for batch QC (frequency varies based on batch size), rework, preparation, cleanup, waste (e.g., assume that only 80 to 90% of standards or reagents are fully utilized), and any periodic operations needed to continue running samples, such as calibrations, backgrounds, validation activities, or standards verification activities. The average rate of use for expendable supplies, equipment, reagents, and standards for operation at maximum production levels should be calculated.

The second step involves projecting realistic restocking time for critical expendables in the post-incident context. It is important to identify potential critical supply-chain shortfalls that could unexpectedly delay restocking of supplies. Vendors should be contacted and inquiries made whether they keep enough stock on hand to address a run on supplies in the case of an emergency. It could be assumed, as an example, that 30 to 40 laboratories will be placing orders to meet similar needs calculated above. If a routine vendor does not maintain sufficient supply, other vendors could be called on as back-ups if they can provide the same or at least equivalent items. However, substituting items might impact method performance, and there may be procurement restrictions on using non-approved vendors. Single-source suppliers for items, such as specialty glassware, instrument replacement parts, and extraction chromatography supplies, may not be able to maintain large stocks of items, and they may routinely produce to meet standing orders from a customer. There are alternatives or strategies that might be used to secure the supply of expendables. For example, it may be possible to obtain an agreement from a vendor to maintain more stock (perhaps even at a discounted price) if it has contractual assurances that the laboratory plans on procuring the item in question from the vendor over a longer period of time.

5.6 Major Radioanalytical Instrumentation

Radioanalytical instrumentation represents a longer term investment that contributes to an upper bound on a laboratory's analytical throughput. Assuming that a laboratory's physical layout already includes areas dedicated to sample preparation and chemical separation of potentially elevated activity level samples, acquiring additional instrumentation is the next most effective measure for increasing absolute analytical capacity. The relatively small size of the radioanalytical instrumentation market, however, will likely complicate attempts to obtain radioanalytical instrumentation after a national emergency. Although the demand for instrumentation will spike, manufacturing capacity for new instruments is typically tied to routine levels of demand. Even if instrument manufacturers work to accommodate increased demand by ramping up production, practical limitations such as the availability of trained, qualified personnel and the dependence on contractor supply relationships mean that significant increases in production will possibly occur after they are most needed. Limitations in the supply chain and the availability of four major types of radioanalytical instrumentation in use at environmental radiochemistry laboratories will be addressed in more detail in Table 2 and in the subsections below.

5.6.1 Alpha Spectrometers

Instrumentation: Alpha spectrometers represent a relatively small niche in the radioanalytical instrumentation market. Currently, there are only two producers of alpha spectrometers worldwide. Total annual production is estimated in the range of 600 to 700 alpha spectrometers with routine delivery times of 1 to 4 months, depending on currently available parts in stock. Alpha spectrometry systems are manufactured on demand after receipt of an order. Financial considerations, however, limit the number of excess parts maintained in stock for building alpha spectrometry systems. Parts on hand at any point in time may be sufficient to build no more than a total of 20 to 30 chambers per manufacturer. After critical manufacturing parts are exhausted, production of new units must stop until specialty contractors resupply the manufacturers. At that point, production will move forward, limited by the established capacity for manufacturing the units (trained personnel, facilities) and the resupply of critical components.

Table 2 – Availability of Radioanalytical Instrumentation Following a Radiological or Nuclear or Incident

Laboratory Instrument Type	Component	Number of Vendors in U.S. (Globally)	Typical Lead Time	Post-Incident Availability and Delivery Time	Time After Delivery Until Productive	Comments*
Alpha Spectrometry Systems	Chamber Detector Electronics	2(2)	30-120 days	Extremely limited availability. Delivery 9-12 mo. and beyond.	Days to weeks	World-wide production is ~600-700 chambers/yr. Systems exclusively built to order – parts on-hand limit immediate production to < 50–100 chambers. Perhaps 1/3 of available production will go to environmental labs. After ~6 months for ramp-up, additional combined production may reach ~25-50 chambers/month.
	Software		1-2 weeks	Yes	Weeks to months	
Gamma Spectrometry System	Detector Electronics	2(2)	60-90 days	Very limited availability.	Days to weeks	Perhaps 30-40 detectors in stock at any time. Shortage of electronics will immediately limit delivery to less than ~10 complete systems. After 3-6 months ramp-up, production for new systems will be ~20-30 units/month/ manufacturer. Shields generally are built to order and are a second limiting factor. After 3-6 months ramp-up, output of shields may reach ~5–10/week.
	Shield		3-12 mo.	Delivery 6-9 mo. and beyond.		
	Software		1-2 weeks	Yes	Days	
Low Background Gas Flow Proportional Counters	Complete system	3(4)	2-3 mo.	Limited availability. Delivery 3-12 mo. And beyond.	Weeks	Stock of completed instruments is probably ~1 per manufacturer. Limited parts are maintained in stock and will delay ramp-up. After 3-6 months ramp-up, production will peak at ~1 unit/ week/manufacturer. At this point, however, the limiting factor shifts from supply to on-site support for set-up and repair of instruments.
Liquid Scintillation Spectrometry System	Complete system	2(3)	1-2 mo.	Good availability. Delivery 30-90 days and beyond.	Days to weeks	Relatively significant production capability due to market demand in biotech research (25-35 units/mo). On-site installation may present itself as limiting to overall expansion in the availability of new instrumentation.

*Support to install all instruments likely will be problematic after an incident but is not considered here. Information in the table on the production and availability of various instrumentation types presented in the following sections is based on information obtained during 2008 in interviews with present and former representatives of major radioanalytical instrument manufacturers, including Ametek Ortec, Canberra, Gamma Products, Perkin Elmer Life Sciences, Protean Instrument Corporation, and Target Instruments.

Following an incident involving alpha-emitting radionuclides, the short- and mid-term availability of alpha spectrometry systems will be poor, and delivery times may extend to a year and beyond. Additionally, it is estimated that only about one-third of total production of alpha spectrometers will be available for environmental testing after a radiological or nuclear incident due to urgent demands for bioassay testing. Thus, it seems reasonable that perhaps only 200 to 250 additional alpha spectrometry chambers would become available over the first year after an event. Given the longer term sales outlook, it seems unlikely that instrument manufacturers will be inclined to expand production capabilities significantly beyond current levels.

Maintenance, Repairs, Spare Parts, and Consumables: In developing their incident response plan, laboratories may wish to consult with manufacturers for recommendations for spare parts and to discuss options and expectations for major maintenance should this be needed. Laboratories may evaluate their needs and resources, and plan to maintain a supply of spare parts on hand to facilitate minor repairs that are simple to complete on-site. Such parts might include:

- Charged particle detectors (PIPS[®]/ruggedized alpha detectors)
- Modular electronic components (e.g., amplifier, analog-digital converter (ADC), pulse-height analyzer (PHA), multichannel analyzer/multichannel buffer/acquisition interface module (MCA/MCB/AIM), bias supply)
- Stand-alone alpha spectrometers (e.g., integral amplifier and electronics as appropriate)
- Replacement cables (appropriate type, impedance, resistance, etc.)
- Replacement chamber shelves
- Gaskets or O-rings for chambers and vacuum manifold
- Vacuum pumps
- Vacuum pump oil demisters

Although silicon-charged particle detectors (i.e., alpha spectrometry detectors) are not inexpensive, keeping spare detectors on hand (e.g., 10% of total installed capacity) will allow the laboratory to immediately replace contaminated or defective detectors. Following an incident with alpha emitters, detectors will likely be hard to obtain while contractors resupply the manufacturer with detector-grade silicon and needed parts for manufacturing. Being able to continue operations with a minimum of down-time, however, is not only vital, it will also quickly repay the cost of any replacement detectors. If a detector is contaminated with short-lived radionuclides, it need not be disposed of, but rather can be taken out of service for a period of time until the contamination decays to levels that permit reuse.

When dealing with an alpha spectrometry system based on modular electronics, keeping spare electronic components and supplies on hand will facilitate rapid troubleshooting of electronic components and also provide replacements for defective components, thus saving time. Some alpha spectrometry systems are constructed in group units (two, eight, etc.) with much of the electronics and vacuum system integrated into a single spectrometer. While these units offer some degree of operational simplicity, they may not lend themselves to on-site troubleshooting and service that is as rapid as is the case for highly modular units. Thus, when service is required, the entire multiple detector unit will potentially have to be taken off-line and returned to the factory resulting in a significant loss of production capability. Clarifying and potentially

negotiating terms for major repairs in advance will both inform the laboratory's maintenance planning and help streamline repairs should these become necessary. The laboratory will significantly minimize interruptions in operations by putting a service contract in place with the instrument manufacturer to guarantee rapid turnaround times for phone, on-site, and factory troubleshooting and service. Laboratories should evaluate their needs and resources, and plan to maintain a supply of critical consumable supplies that need to be maintained for alpha spectrometry. Some possibilities for such a list could include:

- Microprecipitation filters
- Sample mounting disks
- Microprecipitation filter funnels
- Disks for electroplating
- Electroplating cell supplies
- Storage containers for sample test sources (e.g., Petri dishes or envelopes)
- Mixed alpha calibration standards
- Vacuum pump oil filters
- Ion exchange and solid-phase extraction chromatography resins

5.6.2 High-Purity Germanium Gamma Spectrometers

Instrumentation: Analogous to alpha spectrometers, currently there are only two producers of high-purity germanium (HPGe) gamma spectrometry systems in the world. While it is estimated that after an incident, gamma detection instrumentation will be more readily available than alpha spectrometers, obtaining new HPGe systems following an incident will be nevertheless problematic. Stocks of HPGe detectors available on a routine basis are estimated to be fewer than about 40 detector units. Initial supplies of complete gamma spectrometry systems, however, will be limited by the availability of supporting electronics and counting shields to about 5 to 10 complete systems. After a period of 2 to 4 months required for production ramp-up, it is projected that approximately 20 to 40 systems can be produced per month, and that turnaround times for delivery could likely extend months and beyond, depending on demand. Laboratories should also be aware that there are limitations regarding cross-platform compatibility of equipment, especially in the case of associated electronics. While this is generally less of a concern than in the case of alpha spectrometry, it will still tend to limit laboratories to buying instrumentation from the manufacturer of gamma spectrometry equipment and software already installed at the laboratory.

Maintenance, Repairs, Spare Parts, and Consumables: The considerations here are similar to those discussed for alpha spectrometers. The laboratory should consult with the manufacturer regarding spare parts as well as expectations for major maintenance. Laboratories should evaluate needs and resources, and maintain a supply of spare parts on hand to facilitate minor repairs that are simple to complete on-site. These might include:

- Modular electronic components
- Spare nuclear instrument module (NIM) bin/NIM power supply (many ADCs require 6-volt power)
- Replacements for cables (appropriate impedance or resistance for the application)

- Grounding straps
- Volt meter
- Dewar stands and insulators (to isolate potential electrical noise pickup/ground loops)
- Dewar collar replacements
- Liquid nitrogen fill lines and fittings
- Oscilloscope
- Entrance window protector caps (for extended range detectors)
- Sample positioning jigs (also called geometry stands)
- Sample carriers for automatic sample changers

When dealing with modular electronics, keeping spare electronic components and supplies on hand will greatly facilitate rapid troubleshooting of electronics problems and provide replacements for defective components, thus eliminating time lost waiting for repairs or replacements. If major service is required for defective spectrometry equipment, units must often be returned to the factory. Clarifying and potentially negotiating terms for major repairs in advance will inform the laboratory's maintenance planning and also streamline repairs should these become necessary. The laboratory can significantly minimize interruptions in operations by putting a service contract in place with the instrument manufacturer to guarantee rapid turnaround times for phone, field, and factory troubleshooting and service.

Laboratories should evaluate needs and resources, and plan to maintain stocks of critical consumable supplies for gamma spectrometry. Some possibilities could include:

- Containers for all calibrated geometries (e.g., Marinelli beakers, bottles, vials, planchets, etc.)
- Plastic spill protection (to cover detector and inside of cave)
- Calibration standards
- Liquid standards, radionuclide mix for custom standards, and QC samples
- Liquid nitrogen

5.6.3 Low-Background Gas Flow Proportional Counters

Instrumentation: Short- to mid-term supplies of low-background gas proportional counters will be limited following a radiological or nuclear incident. Although there are currently three manufacturers that regularly supply the U.S. market (four world-wide), the overall size of the market is still relatively small. Manufacturers generally have no more than one instrument of any one type immediately available. After current supplies are exhausted, three to four months will be needed to ramp up production to a level of about one detector system per manufacturer per week. Thus, if 30 laboratories need to acquire one multi-detector unit each, it is estimated that the minimum time elapsed between the order and delivery of the final units would be in the range of 10 to 14 weeks. One further complicating factor will be having sufficient service personnel available to install new equipment. This could extend delivery times by an additional month or longer.

Maintenance, Repairs, Spare Parts, and Consumables: Although there are similarities to alpha and gamma spectrometers, gas flow proportional counters generally rely less on modular

electronics than do alpha or gamma spectrometers. The effect of this is twofold. First, shared electronics for multiple detector units are more expensive and sometimes more difficult to troubleshoot on-site. Second, it is often less economically feasible to maintain components in reserve that can be used for troubleshooting and rapid field repairs. Thus, the likelihood that components will need to be sent back to the factory is greater than with highly modular alpha or gamma spectrometry equipment.

Laboratories should evaluate needs and resources, and maintain a supply of spare parts on hand to facilitate minor repairs that are simple to complete in the field. These might include:

- Replacement windows for detectors
- Carrier plates and inserts of various depths (as calibrated)
- P-10 gas lines, plastic tubing and fittings
- Amplifier
- Detector replacement (particularly valuable for single detector units)
- High-voltage power supply

Clarifying and potentially negotiating terms for major repairs in advance will inform the laboratory's maintenance planning and also streamline repairs should these become necessary. The laboratory can minimize interruptions in operations significantly by putting a service contract in place with the instrument manufacturer to guarantee rapid turnaround times for phone, field, and factory troubleshooting and service.

Laboratories should evaluate needs and resources, and plan to maintain stocks of critical consumable supplies for gas flow proportional counters. Some possibilities could include:

- P-10 gas
- Snap rings or other filter mounting supplies for all calibrated configurations
- Prepared efficiency or self-absorption calibration standards
- Liquid standards and reagents for preparing efficiency or self-absorption standards with short shelf-life (due to decay/ingrowth)
- Planchets for all calibrated configurations

5.6.4 Liquid Scintillation Counters

Instrumentation: Short-term availability of liquid scintillation counting instrumentation will likely be better for liquid scintillation counters than the other major instrumentation types used for radiochemical analysis. Although there are only three suppliers of laboratory liquid scintillation counters, these instruments are commonly used in biological and pharmaceutical research, and thus the market for liquid scintillation counters is much larger than for other low-level radioanalytical instruments. Based on information received from one supplier of liquid scintillation counters, approximately 30 liquid scintillation counters would be available each month, without need to modify production rates. Allowing for production from the other producer, presumably 35 to 50 units could be produced per month prior to expanding production capabilities. Thus, delivery times for scintillation counters are projected to range from weeks to

months. One limiting factor could be the installation of new equipment since only a fixed number of service personnel are available for setting up equipment at laboratories.

Maintenance, Repairs, Spare Parts, and Consumables: Liquid scintillation counters are single detector instruments. They are highly integrated and thus do not lend themselves to extensive troubleshooting or repair by the user. On the other hand, there is almost never a need to return them to the factory for service. Once on-site, service personnel can generally repair an instrument in several hours. If parts are needed, these can generally be obtained from the factory within 24 to 48 hours (depending on shipping options available for the time of day and the location). Thus there is relatively little utility in maintaining spare parts for these instruments.

By the same token, however, clarifying and negotiating terms for major repairs in advance will not only assist the laboratory's maintenance planning but also likely be the only option for ensuring that service will be available in a timely manner. Putting a service contract in place with the instrument manufacturer will optimize rapid turnaround times for phone, field, and factory troubleshooting and service.

Evaluating needs and resources and planning to maintain stocks of critical consumable supplies for liquid scintillation counters, on the other hand, will help prevent interruptions in production operations. Some possibilities could include:

- Sample racks
- Scintillation vials
- Scintillation cocktails (for all methods to be used)
- Reagents and quenching agents for preparing quench curves
- Liquid radionuclide standards for preparing efficiency standards and quench curves

5.7 Managing Supplies for Incident Response

Laboratories generally maintain sufficient inventory of supplies to support routine needs. Planning ahead will help ensure that the laboratory will have sufficient supplies to accommodate demand. The plan should evaluate the routine demand for supplies as well as the demand for supplies that would arise as a result of a radiological or nuclear incident. The challenge is that one cannot know when an incident might occur or which analyses will be required. The cost of maintaining inventory, and in some cases shelf-life restrictions, encourages laboratories to minimize supplies on hand, with mechanisms in place to restock supplies on a just-in-time basis. However, a plan should be in place to allow for transition between routine and incident response operations. This plan should balance inventory levels for routine and maximum capacity with shelf-life limitations and economic concerns (e.g., cost of maintaining inventory).

In order to ensure that sufficient supplies are available to support an incident response, an estimate of the supply “burn rates” at maximum throughput has to be obtained first. Based on the maximum throughput values determined, and estimates of time needed to resupply, the levels of inventory that would be needed to ensure continued operations can be projected for the time needed to resupply. Weighing ongoing routine operational needs with financial considerations will allow a laboratory to determine whether routine inventory can be maintained at levels to

ensure continued operations until new stocks arrive. If not, and if there is no funding available to stockpile critical supplies, the resupply limitations should be documented in the Incident Response Plan along with projected supply “burn rates” at maximum throughput. In the case of an incident, the plan can then specify that the Incident Commander is promptly notified about supply concerns so that he/she can help facilitate the resupply effort.

5.8 Reagents, Resins, Carriers, and Standards for Incident Response

Reagents, resins, carriers, and standards all play critical roles in the analytical process. Also, a significant amount of time may be required to procure some of the materials, and to prepare solutions and verify the integrity of these solutions. These materials and the time needed for their preparation and verification should be taken into account when estimating the quantities of supplies that will be needed to maintain operations during an incident response.

It should be noted that in the case of an incident response, processing higher-activity samples will require tracer solutions and QC solutions that match the levels of activity being processed in the laboratory. Thus, the amount of activity needed in standards will exceed that used for routine samples. Appendix A includes an example of preparing laboratory supplies for incident response.

6. MISCELLANEOUS LABORATORY INCIDENT RESPONSE PREPARATION ISSUES

A variety of additional concerns relative to the laboratory's security, documentation, data handling and reporting, and staffing should be addressed when the laboratory is planning and preparing for a radiological incident response.

Security: Additional security measures may be needed if samples have increased chain-of-custody requirements (e.g., legal, forensic) or need to be safeguarded against theft as potential materials for an RDD.

Data handling and reporting: A significant increase in the number of samples may challenge the ability of the laboratory to handle the flow of information as the samples are logged in, processed, and analyzed; results are calculated and evaluated; and the reports are prepared. It may be advisable to consult an information technology specialist to evaluate the existing system of data handling and recommend changes where appropriate and feasible. Such evaluation and resulting improvements will benefit the laboratory in the long run even when operating under routine conditions. Examples of issues that should be addressed are:

- Can the current system of sample receipt handle large influx of samples?
- Is there a system in place to clearly identify samples and the results of screening that create more than one stream of samples through the laboratory?
- Does the laboratory have a system in place, such as a Laboratory Information Management System, that collects data, performs calculations, and prepares required reports?
- Are any changes to the current verification and validation procedures required?
- Will these changes require additional staff and/or additional training for the existing staff?
- What reporting format(s) is supported by the laboratory, and is it aligned with requirements set forth by the authorities/organizations/agencies that will be accepting these reports during the incident response?

Human resources: The Laboratory Incident Response Plan should identify changes in the responsibilities and additional job functions created as a result of the laboratory's participation in the incident response (see Section 2.2.2). However, such a plan is most likely written in terms of job functions and responsibilities, and not in terms of names of specific staff members. The laboratory management, when creating actual staffing plans for the incident response, should take into account individual situations of the current staff, and plan to provide support in those areas that might significantly interfere with their work performance during the response (e.g., daycare, eldercare, medical restrictions, transportation, and dietary needs).

Waste management: Even when routine waste is managed according to established procedures, additional considerations arise when the influx of samples increases significantly or when high-activity samples are analyzed. While questions such as those listed below may function as a starting point and can be considered and addressed in advance of the incident, other issues may be identified only during the incident response and may require real-time coordination with appropriate federal and state agencies, waste brokers, and disposal facilities to ensure satisfactory

outcomes to the issues encountered. In any case, a laboratory's review of the questions should generate discussions and proposed solutions for as many elements as possible.

- What will be the potential volume of stored waste? What additional waste storage containers may be needed?
- If different or new methods of analysis are used during an incident response, will the composition and character of waste differ from routine? Are procedures in place to accommodate the differences (e.g., revised sampling protocols, appropriate storage containers, increased frequency of monitoring)?
- Will the new wastes generated in the incident response samples be chemically compatible with each other and existing waste forms?
- How will the level of residual contamination in the waste change, and how will it impact handling and disposal?
- How will the stored waste be monitored? For which radionuclides are there validated methods for sampling and monitoring the waste forms?
- How and where will the waste be stored? Is it remote from occupied areas? What kind of shielding, monitoring, and security will be provided?
- Have disposal options been identified for all types of waste that will be produced?
- Are waste brokers, and treatment, storage, and disposal sites able to accept all wastes produced (considering activity levels; radionuclides, including radiotracers and carriers normally used in the routine methods; mixed hazardous or toxic wastes)?
- Are export permits needed to allow disposition of waste?
- Will disposal be timely enough to ensure that regulation-driven time frames for RCRA-regulated wastes (including mixed waste) can be met?
- How will the laboratory's radioactive materials inventory system (as required by the NRC license) be updated to track activity contained in wastes?
- Will disposal be timely enough to ensure that radioactive material license possession limits are not exceeded (given that material will accumulate more quickly)?

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APPENDIX A: EXCERPTS FROM AN ACTUAL LABORATORY INCIDENT RESPONSE PLAN

Incident response changes routine functions of all personnel. New or more detailed responsibilities need to be assigned to specific personnel so that each area of response has a “caretaker.” In addition to new assignments and more detailed functions, procedural modifications can occur that deal specifically with incident response, particularly with samples of elevated activity that can easily contaminate the laboratory environment.

The different sections of this appendix identify excerpts from an actual Incident Response Plan that show how these modifications to laboratory operations are made. They are presented as examples and are not intended to be complete or appropriate for all laboratories. Mention of brand names or trademarked equipment does not constitute endorsement or approval by EPA.

A1. Initial Laboratory Preparation

Laboratory work flow and access controls will be modified to restrict access to areas from the clean side into the contaminated or radiologically controlled areas and vice versa. One of the main starting points is sample receipt. The use of checklists for a function like this is very important. The checklist easily identifies the planned strategic functions for setting up the laboratory and other areas. The checklists do not have to be performed in sequence and may contain optional materials or actions that can be determined “Not Applicable” by the responsible party. Identified here are two examples: one for the sample receiving area and one for the sample preparation room. In each case, the specifics for an individual laboratory have been used as an example.

Example A1.1 Sample Receiving Station

The sample receiving station is a Radiological Control Area (RCA); a personnel survey/decontamination form is required for entry or exit. Ribbon barriers mark the boundaries of the station at both ends. A piece of plastic sheeting is used to cover the area of ground where samples may be placed during processing. Vehicle approach to the receiving station is controlled by ... *[fill in controls like signage, cones, etc.]*. Access to the area is limited by ... *[fill in methods like barricades, signage, etc.]*.

PREPARATION OF THE SAMPLE RECEIVING STATION

Use the following checklist to make changes when setting up for incident response:

- ☐ 1. Apply plastic sheeting to the ground in the sample receiving area where samples may be placed during processing.
- ☐ 2. Place stanchions around the outside receiving area, and connect them with ribbons. Post “Radiation Area” signs on each leg of this barrier. If bad weather is expected, erect a small tent. If operations are expected to occur in darkness, erect a set of halogen work lights.
- ☐ 3. Place a table or cart just outside the door to be used for sample processing and to hold survey meters and consumable supplies such as gloves, wipes, bags, and tape.

- ☐ 4. Place a barrier ribbon across the walkway to the main building area and post a “Radiation Area” sign at the barrier. This is the RCA boundary.
- ☐ 5. Set up two large garbage cans with liners in the hall inside the RCA boundary. One is labeled “Radioactive Disposable,” and the other one is labeled “Radioactive Washable.”
- ☐ 6. Set up a photocopier or scanner in the hall outside the RCA boundary.
- ☐ 7. Secure a step-off pad to the floor in the hall just outside the RCA boundary.
- ☐ 8. Place a cart, or other appropriate carrier, in the hall just outside the RCA boundary for sample transport.
- ☐ 9. Perform and document an area survey prior to the arrival of samples using an area survey/decontamination form.

Example A1.2 Sample Preparation Room

The sample preparation room is where samples are opened and processed for analysis. It is a Radiological Control Area; a personnel survey/decontamination form is required for transfer of materials in and out of this room. The laboratory includes workbenches, tables, a chemical fume hood, a sink, a gross gamma detector (NaI[Tl]), and computer workstation. The laboratory has three distinct working zones: the fume hood area where samples will be opened and processed, the sink area where equipment will be cleaned, and the desk/gamma screening area where clerical work will be performed. Within these three zones, there are seven specific areas in which samples may be placed as they progress through processing.

PREPARATION OF THE SAMPLE PREPARATION ROOM

- ☐ 1. Remove all items that are not expected to be used during the emergency. Items that will not be used but are to remain should be covered with plastic sheeting.
- ☐ 2. Line the floor of the room with plastic sheeting in areas where sample processing will take place.
- ☐ 3. Cover shelving with plastic sheeting. Leave one or two shelves open for storage. Clear them of objects and line them with plastic.
- ☐ 4. Cover bench tops and tables with an absorbent liner
- ☐ 5. Place a barrier ribbon across the door to the laboratory at a height that allows people wearing personal protective equipment to step over it.
- ☐ 6. Post “Radiation Area” and “Authorized Personnel Only” signs outside the door.
- ☐ 7. Place a step-off pad in the hallway just outside the barrier.
- ☐ 8. Line a small table with absorbent material and place it outside the RCA boundary, next to the step-off pad. This table will hold a survey meter and personnel survey/decontamination forms.
- ☐ 9. Place three large garbage cans with liners in the laboratory. Label one “Radioactive Disposable” and another “Radioactive Washable.” Place “Caution Radioactive Materials” signs on both of these garbage cans. Label the third “Clean Garbage.”
- ☐ 10. Label the work areas as follows:
 - A **Area 1** Sample receiving area. Workbench, nearest the door. Samples are placed here as they are brought into the lab.

- | | | |
|---|-----------------------------|--|
| B | Area 2 | Sample processing bench top. Workbench, nearest the fume hood. Air and water samples are processed here. Double-line with absorbent paper. |
| C | Area 3 | Sample processing fume hood. All other sample types are processed here. Double-line with absorbent paper. |
| D | Area 4 | Gamma screening. Gamma detector in southeast corner of room (to the right of the door on entering). Samples requiring a 1-minute screen are counted here, then taken to Area 2 or 3. |
| E | Table 1 | This table holds supplies for sample processing. |
| F | Table 2 | Prepared samples are placed here to await transport. |
| G | Intermediate Storage | Used to hold additional processed samples if needed. |
- ☐ 11. Arrange supplies in the work zones in such a way as to minimize the possibility of contamination prior to use.
 - ☐ 12. Perform and document an area survey prior to the arrival of samples, using an area survey/decontamination form.

A2. Contamination Control Oversight

During routine operations, this will usually be the sole responsibility of the Radiation Safety Officer (RSO). During an incident response, the RSO will require sustained assistance to manage the stepped up frequency of monitoring and controls and associated paperwork. The personnel assigned to this support function will need to have their specific responsibilities identified, and be trained for those responsibilities and separate procedures to guide them in performing those tasks. The description of a survey team and an excerpt of a procedure are included here as examples. Note that the procedural excerpt has numbered steps indicating that these are to be followed sequentially.

A.2.1 Survey Team

Survey teams will be formed and assigned as needed. Staff members on duty but not assigned to a specific work area (except the runner) will normally be the first choice. Sample receiving teams may be designated a survey team following closeout of receiving operations provided the next receiving team is on duty. Survey teams will not be designated in the event of short staffing. Responsibilities of the survey team are to:

1. Be on call through the RSO and/or Emergency Response Center (ERC).
2. Conduct area contamination surveys as directed by the RSO.
3. Take wipes in areas of suspected contamination.
4. Analyze wipes using survey meters, gross alpha/beta counters, or liquid scintillation counters, or deliver them to the sample preparation room for gamma spectral analysis, as directed by the RSO.
5. Perform decontamination and cleanup as directed by the RSO.
6. Assist with personnel surveys and decontamination as needed.
7. Place and collect area dosimeters as directed by the RSO.
8. Complete appropriate documentation for above activities.

A.2.2 Area Wipe Sampling – A Procedure

The laboratory will be processing samples that have significantly higher levels of radioactivity in them than the laboratory is accustomed to handling. Therefore, it is imperative that every effort be made to restrict the possible spread of contamination. A wipe test in conjunction with area surveys is a tool in this effort. The standard 100-cm² wipe area will be used when documenting that a laboratory area has been successfully checked for contamination or decontaminated.

Wipe samples may be analyzed using either a count rate meter or the laboratory's instrumentation. The initial wipe analysis will typically be looking for gamma-emitting contamination. This should be followed by analysis for gross alpha and beta contamination. Use the following instructions (note that these should be performed in sequence, as indicated):

1. Place a clean glove on the hand that will be used to take the wipe.
2. For wipes to be analyzed with either a survey meter, or by gross alpha/beta counting, use a prepared smear material. For wipes to be analyzed by liquid scintillation, use a filter paper that is translucent to the wavelength of light emitted by the fluor in the cocktail.
3. Wipe the suspected contamination location by estimating the 100-cm² area. If the area is larger than about 2 ft², at least two wipe samples should be taken.
 - If the wipe is taken on a bagged sample, wipe the entire bag.
 - If the wipe is to be taken from a piece of equipment, wipe the area where contamination is suspected.
 - If the wipe is from a laboratory area such as the floor or benchtop, wipe the area of suspected contamination. Ensure that the bounds of the contaminated area are determined.
4. Using a count rate survey meter equipped with a Geiger-Muller detector (GM) (or other appropriate probe), count wipes in a low-background area. If the meter shows counts in excess of twice background, the wipe is considered contaminated.
5. After each wipe has been analyzed, the wipe and glove should be disposed of simultaneously. These items shall be placed into either the radioactive or the non-radioactive waste container as appropriate.
6. Occasionally survey the hand used to take the wipe to assure that no contamination is present.
7. If using the laboratory instrumentation to analyze the wipe sample, follow the normal standard operating procedure(s) for the instrument specified.
8. Document the results using an area survey/decontamination form.

A3. Supplies and Equipment Checklists

A reserve supply of materials that are necessary for incident response should be purchased, used, and restocked on a routine basis so that a rolling stock of materials is established.

The following checklist is a starting point for such supplies; each laboratory should add or delete items from this list to fit its needs.

- ☐ 1. Nitric acid, concentrated, 4 1-gallon bottles
- ☐ 2. Hydrochloric acid, concentrated, 4 1-gallon bottles
- 3. Resin columns for separations (TEVA, UTEVA, SrSpec, Bio-Rad cation and anion resins) 100 g each or 100 individual columns
- 4. Specific procedure reagents:
 - a. ☐ $\text{BaCl}_2 \cdot 2\text{H}_2\text{O}$, 1 500-g bottle
 - b. ☐ TiCl_3 , 1 1500-mL bottle
 - c. ☐ NdF_3 , 1 50-g bottle
 - d. ☐ $\text{Sr}(\text{NO}_3)_2$, 1 100-g bottle
 - e. Tracer solutions:
 - i) ☐ ^{232}U (high and low activity)
 - ii) ☐ ^{85}Sr (low activity; supplier identified for rapid delivery of high activity)
 - iii) ☐ ^{242}Pu (high and low activity)
- ☐ 5. Liquid scintillation cocktail, 2 1-gallon containers
- ☐ 6. Reserve telephone for contaminated area
- ☐ 7. Survey meter with appropriate probe for wipes (GM/ α/β)
- ☐ 8. Prepared smears, or equivalent wipe material
- ☐ 9. Industrial vertical cutter/mixer
- ☐ 10. Top-loading balance (0–1,500 g \times 0.01 g)
- ☐ 11. Contamination film for balance surface that can be peeled off (like Parafilm): 2 rolls
- ☐ 12. Trowels, spatulas, plastic spoons, and tampers (assorted-5 each)
- ☐ 13. Scissors, two or more pair
- ☐ 14. Razor blades, razor box knife, or scalpel
- ☐ 15. Forceps, assorted types and sizes, including large blunt-nosed
- ☐ 16. 4-mil plastic sheeting, 2 rolls
- ☐ 17. Versi-Dry[®] or equivalent absorbent paper, 4 rolls
- ☐ 18. Handi-Mat[®], or equivalent plastic bench cover
- ☐ 19. Masking, label, packaging, or cellophane tape
- ☐ 20. Hot plate, small, one per work station
- ☐ 21. Heat gun, heat tape, or hair dryer
- ☐ 22. Marking pens
- ☐ 23. Laboratory Nitrile gloves, 12 pair

- ☐ 24. Laboratory poly-gloves, disposable, 15 boxes
- ☐ 25. 4-liter and 1-liter Marinelli beakers, 50 each
- ☐ 26. Polypropylene containers with lids, in 100-mL (Falcon[®] #4014), 400-mL (Hi-Plas[®] LT-309-16), and 800-mL sizes
- ☐ 27. 2-inch and 4-inch stainless steel planchets, 1,000 each
- ☐ 28. 3.5-inch plastic Petri dishes, 500 each
- ☐ 29. 47-mm 0.45- μ m filters, 1,000
- ☐ 30. Clear plastic bags, 1.5 mil, in small and medium sizes
- ☐ 31. Large plastic garbage bags, 4 boxes
- ☐ 32. Paper towels, 15 rolls
- ☐ 33. Sorting trays, 5 each
- ☐ 34. Wash bottles containing chelating detergent solution, one per work station
- ☐ 35. Dishwashing detergent, anionic, 2 gallons
- ☐ 36. Assorted dishwashing brushes
- ☐ 37. Spill kit
- ☐ 38. Hand soap
- ☐ 39. Calculators, one per work station

Completed: _____ Date: ____/____/____

A4. Incident Response Procedures

In addition to enhanced normal procedures and ensuring that supplies are stocked, there may be special incident response analytical procedures that are not normally performed. An example of such a procedure is shown here for measurement of gross radioactivity on surface deposition samples mounted on adhesive paper.

Example: Preparation of Deposition Samples on Adhesive Media During an Incident Response

SUMMARY

This procedure is used to prepare deposition samples that have been collected on adhesive media such as tape for analysis by gross alpha/beta counting, alpha spectrometry, or gamma spectroscopy during an incident response. Such samples may be collected from plume fallout in an effort to identify the nuclides involved in an event, to determine their ratios, and possibly to provide a semi-quantitative assessment of levels.

This procedure is performed in the sample preparation room, which has been properly prepared as a Radiological Control Area (RCA).

QUALITY CONTROL

1. A match between sample information listed on the sample tag and the laboratory report sheet will be performed.

REAGENTS

1. De-ionized water

EQUIPMENT

1. 5cm stainless steel planchets
2. 3.5-inch plastic Petri dishes (Falcon #1029 or equivalent)
3. Stiff card stock, $\sim 1.5" \times 2"$, ~ 30 -40
4. Hemostats or large, blunt-nosed forceps
5. Scalpel, razor blade, cork borer, or similar cutting tools
6. Paper, Bench-Kote[®], or similar disposable work surface
7. Cellophane tape
8. Nu-Con[®] smears, or equivalent wipe material
9. Count rate survey meter with GM, or appropriate probe
10. Scissors
11. Fine-tipped indelible markers
12. Ruler with both inch and millimeter scales
13. 47-mm porcelain crucible lid (Coors size[®] 17-K)
14. Hot plate

It is expected that adhesive media deposition samples will arrive at the laboratory inside plastic bags, with the sample material sandwiched between the adhesive side of the media and the bag in which it has been placed. The bag must be opened and the adhesive media disengaged from its container, then secured onto an appropriate mount with the adhesive facing upward.

PROCEDURE

1. At a workbench, carefully open the sample bag(s).
2. If the sample is to be analyzed by gamma spectroscopy only, proceed to Step 5.
3. Using hemostats or blunt-nosed forceps, remove the adhesive media from the container by carefully peeling back the envelope or protective covering.
4. Place the media, adhesive side up, onto a clean paper.
5. Cut a circular piece of the media ~ 47 mm in diameter using a scalpel, razor blade, or appropriate tool.
6. Mount the 47-mm piece of media in a counting geometry:

- a. If the sample will be analyzed only by alpha spectrometry, mount the media adhesive side up onto a piece of stiff card-stock. Use a small piece of cellophane tape to secure it at both ends. Record the laboratory number on the card.
- b. If the sample will be analyzed by gross alpha/beta counting or gamma spectrometry, mount the media adhesive side up in a planchet, labeled with the laboratory number.
 - Use a small piece of tape or O-ring to secure it.
 - Wipe the outside of the planchet with a clean paper towel that has been moistened with de-ionized water.
7. Measure the length and width (or radius) of the mounted sample. Record these measurements, calculate the area, and list it as the sample size on the laboratory report sheet.
8. Wipe the outer sides and bottom of the planchet, or the bottom and ends of the card-stock, with a prepared smear.
9. Count the wipe with a survey meter. If surface contamination is evident, change gloves and re-mount the sample on a clean holder.
10. If surface contamination is not evident, place the mounted sample into a 4-inch plastic Petri dish.
11. Count the sample with a survey meter, probe ½-inch away from the media, and record the count rate on the laboratory sheet.
12. Place the lid on the Petri dish, write a “C” on the lid with a fine-tipped indelible marker, and send the sample along with its Laboratory Report Sheet to the counting room.

APPENDIX B: LABORATORY CAPACITY-LIMITING FACTOR ANALYSIS

Table B1 is a simplified example of one approach that could be used to evaluate a laboratory's capacity. The evaluation is meant to identify a laboratory's capacity to analyze samples that could arrive tomorrow (or next week) without much time to make significant changes to operations. It also is designed to identify areas where relatively minor tweaks might be possible that would increase a laboratory's capacity in a targeted area.

The methodology for the evaluation is relatively simple. An assumption can be made first of an infinite demand for a test/matrix combination, thus providing effectively a continuous stream of incoming samples. Next, by assuming that all available resources will be concentrated on that test/matrix combination, the limiting steps in the process that bound the maximum absolute capacity for that test can be identified. For each test/matrix combination, estimates are made of the maximum throughput possible for that step in the process based on the incident-specific MQOs. These MQOs may be those found in *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance—Radionuclides in Water* (EPA 2008) or *Radiological Laboratory Sample Analysis Guide for Incidents of National Significance—Radionuclides in Air* (EPA 2009b), or may be developed by the laboratory. This permits the capacity-limiting step in the production process to be identified. The throughput estimate based on this capacity-limiting step can then be used to judge the quantity of operational resources needed to maintain throughput at this maximum. Clearly, laboratories do not generally operate at their absolute maximum over a longer period of time. During an incident response, however, they may be asked to do exactly that for a given set of capabilities. Of course, this evaluation will be only as realistic as the individual estimates the laboratory is able to make about its capacity.

The first column in the example shows the areas for which throughput estimates are to be made. To be realistic, the analysis should include every part of the process. Mapping the laboratory's process might be a good way to populate this column. It may be advisable (and quicker) to start with relatively fewer (larger) areas and then to subdivide those areas if it becomes obvious that more detail is needed to permit a realistic analysis. The laboratory will also notice that certain functions are common to multiple tests (e.g., receiving a soil sample is the same regardless of the analysis to be performed) and that these functions will need to be evaluated only once and may be then applied to multiple analyses.

The second column ("Current Maximum – Samples/Day") is used to evaluate the current maximum capacity using available resources and staff. It is common to find that staff very often (but not always) turns out to be the limiting factor to a laboratory's capacity. This reflects current needs more than it does the laboratory's potential to perform in a given area. This step in the evaluation will be most realistic if the laboratory realistically takes known competing demands for resources into account. For example, if there is a base load of analyses that the laboratory assumes will always be present and must be performed and will thus compete for resources with the analysis in question, a portion of the preparation space and equipment, the instrument time, or the trained personnel will not be available for other purposes. Only the unused resources should be considered to be available for this analysis. These estimates of capacity should be for a longer-term surge (e.g., months to a year in duration). It is important to avoid double counting personnel or other resources. The simplest way to do this is to consider exactly which resources

could be allocated to a given area over the long term without having other work go undone. It could be assumed, for example, that a facility is 100% cross-trained. Allocating 100% of the staff to a single task would prevent any other task from being completed for the next year. Instead, it is important to make sure that all tasks from receiving of samples to transmission of the report to the Incident Commander are covered.

The third column (“Max. Samples/Day – Not Staff Limited”) looks beyond current staffing limitations to the absolute potential for throughput given the facility, equipment, instrumentation, and procedures. The same considerations discussed above apply here, except that the restraint of staff has been removed. Some of the subcategory results may seem extremely (absurdly) high. For example, one might be able to aliquant many more samples than one could ever process. This is not a concern, however. Since the point of this exercise is to look for the limiting factor(s), a large number indicates that the step is not limiting. By the same token, there is no real reason to spend a lot of time estimating factors that are obviously not going to be limiting.

Table B1 – Example Laboratory Factor Analysis

Area/Operation	Am-241 in Soil			Sr-90 in Soil			Pu-239/40 in Water			Sr-90 in Water		
	Current Maximum (Samples/day)	Max. samples/day – not staff limited	Limiting?	Current Maximum (Samples/day)	Max. samples/day – not staff limited	Limiting?	Current Maximum (Samples/day)	Max. samples/day – not staff limited	Limiting?	Current Maximum (Samples/day)	Max. samples/day – not staff limited	Limiting?
Receipt/Log-in	170	320	Staff/Work stations	n/a	170	Staff/Work stations	n/a	170	Staff/Work stations	n/a	170	Staff/Work stations
Rad Screen Prep	75	240	Staff/Hoods	20	240	Hood	20	240	Hood	20	240	Hood
Rad Screen Count	120	120	Count time	20	120	Count	20	120	Count	20	120	Count
Sample prep	25	75	Staff/Grinding	25	75	Staff/Grinding	40	60	Filtering	40	60	Filtering
Digestions	48	144	Staff/Microwave vessels	84	252	Staff/Microwave vessels	n/a	n/a	n/a	n/a	n/a	n/a
Separations	50	150	Staff/Vacuum Box	20	50	Cation exchange bench space	20	50	Centrifuge	20	50	Cation exchange bench space
Source Prep	80	240	Staff/Vac. manifold	40	240	Hotplate evaporation	80	240	Staff/Vac. manifold	20	240	Hotplate evaporation
Counting	96	144	Count time	16	108	Instrument	96	144	Count time	16	108	Instrument
Calculation/Review	160	400	Staff/Work stations	20	400	Work stations	160	400	Staff/Work stations	20	400	Work stations
Reporting/Review	120	400	Staff/Copy scanning	120	400	Staff/Copy scanning	120	400	Staff/Copy scanning	120	400	Staff/Copy scanning

Once all of the areas for the analysis/matrix combination have been completed, it will pay to look back at the entries and ask whether they are realistic. The lowest value(s) for all of the areas and operations for an analysis is the limiting value(s). A question should be asked whether these numbers make sense. Another consideration might be whether there may be areas that should

have been included in the analysis but were omitted. Competition for any of these factors might potentially require re-evaluation or adjustment of the results. There might be a need to group factors differently, or to break factors into subcategories to help understand what is truly limiting. Common sense should be used to assess the results, and make adjustments as deemed realistic.

Once the limiting point is identified, it can be used to support planning purposes. The limiting factors should also be evaluated to determine whether taking action to address one or more limiting factors could rapidly and economically increase capacity for the test in question in the case of an incident – or even for current operations.



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