

SELF ASSESSMENT OF RADIATION-SAFETY PROGRAMS



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Self Assessment of Radiation-Safety Programs

**Recommendations of the
NATIONAL COUNCIL ON RADIATION
PROTECTION AND MEASUREMENTS**

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[For detailed information on the availability of NCRP publications see page 103.]

Preface

During the past two decades the National Council on Radiation Protection and Measurements (NCRP) has published several reports related to operational radiation safety in various occupational and medical settings, including the following reports:

- No. 88, *Radiation Alarms and Access Control Systems*;
- No. 105, *Radiation Protection for Medical and Allied Health Personnel*;
- No. 114, *Maintaining Radiation Protection Records*;
- No. 127, *Operational Radiation Safety Program*;
- No. 134, *Operational Radiation Safety Training*;
- No. 142, *Operational Radiation Safety Program for Astronauts in Low-Earth Orbit: A Basic Framework*;
- No. 144, *Radiation Protection for Particle Accelerator Facilities*;
- No. 145, *Radiation Protection in Dentistry*;
- No. 147, *Structural Shielding Design for Medical X-Ray Imaging Facilities*;
- No. 148, *Radiation Protection in Veterinary Medicine*;
- No. 151, *Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities*;
- and
- No. 157, *Radiation Protection in Educational Institutions*.

This Report provides guidance on establishing a self-assessment program to ensure the timely self identification and correction of deficiencies in a radiation-safety program, and to improve the performance of the program by ensuring that its design and implementation are effective and efficient. Implementing the self-assessment process is an important procedure recommended for all institutions that use radioactive materials or radiation-generating devices. These institutions range from universities or research laboratories using small radioactive sources to large nuclear power plants, nuclear fuel-cycle facilities, and national government laboratories.

The current Report provides guidance for individuals who have the responsibility of developing and implementing a self-assessment program at their institutions. All aspects of an effective

self-assessment program are described, including the identification of responsible individuals, the types and levels of self assessments to be performed, self-assessment planning and techniques, reporting of results, and the implementation and verification of corrective actions identified through a self-assessment process. In addition to supporting a safe working environment, a comprehensive self-assessment program serves to ensure regulatory compliance and conformity of operations with the goals of the radiation-safety program, to establish a workplace safety and continuous improvement culture, and to identify noteworthy practices and exemplary performance by employees working with radioactive materials and sources.

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Contents

Preface	iii
1. Executive Summary	1
2. Introduction	3
2.1 Definition of Self Assessment	3
2.2 Purposes of Self Assessments	4
2.2.1 Ensure a Safe Working Environment	5
2.2.2 Ensure Regulatory Compliance	5
2.2.3 Assess Conformity with the Radiation-Safety Program	6
2.2.4 Reaffirm the Workplace Continuous Improvement Culture	6
2.2.5 Reaffirm an Atmosphere of Caring	6
2.2.6 Identify Noteworthy Practices and Exemplary Performance	7
2.2.7 Demonstrate the Effectiveness of the Program and Identify Areas for Further Evaluation	7
2.2.8 Provide an Opportunity for Learning	7
3. Types of Self Assessment	8
3.1 Performance-Based Self Assessments	8
3.2 Risk-Based Self Assessments	10
3.3 Compliance-Based Self Assessment	12
3.4 Assessment Levels	13
3.4.1 Task-Level Assessments	13
3.4.2 Process-Level Assessments	14
3.4.3 Program-Level Assessments	14
3.5 Formal or Informal Self Assessment	15
4. Responsibilities for Establishing Self-Assessment Programs	17
4.1 Upper Management	17
4.2 Line Management	18
4.3 Radiation-Safety Program Personnel	18
4.4 Workers	19

5. Self-Assessment Program Planning	20
5.1 Establishing the Purpose and Objectives of the Self-Assessment Program	20
5.2 Selecting the Types of Self Assessments to be Performed	20
5.3 Selecting the Program Elements to be Assessed	22
5.4 Establishing the Schedule for the Self-Assessment Program	23
5.5 Establishing the Resources for the Self-Assessment Program	24
5.6 Reviewing and Trending Self-Assessment Results	25
5.7 Reviewing the Self-Assessment Program	25
6. Qualification and Selection of Assessors	27
6.1 Assessors of Radiation-Safety Programs and Processes	27
6.1.1 Experience	28
6.1.2 Knowledge of Area Being Assessed	28
6.1.3 Training and Certification	29
6.2 Assessors of Specific Radiation-Safety Tasks	30
6.2.1 Experience	30
6.2.2 Knowledge of Radiation-Safety-Related Tasks	31
6.2.3 Training and Certification	31
6.3 Independence and Access to Management and Staff	31
6.4 Using In-House Personnel	32
6.5 Self Assessments Supplemented with Outside Contractors or Independent Consultants	33
7. Self-Assessment Methods and Techniques	34
7.1 Evaluation of the Radiation-Monitoring Program Results	34
7.2 Workplace Observations	35
7.3 Interviews of Personnel in the Work Area	36
7.4 Use of Checklists	38
7.5 Document Review	40
7.6 Documentation of Results	40
8. Types of Deficiencies, Response Priorities, and Noteworthy Practices	41
8.1 Identified Deficiencies that Require Routine Response	42
8.2 Identified Deficiencies that Require Timely Response	43
8.3 Identified Deficiencies that Require Prompt Response	43
8.4 Deficiencies that Require Immediate Response	44
8.5 Noteworthy Practices	45

9. Planning an Individual Self Assessment	47
9.1 Schedule for an Individual Self Assessment	48
9.2 Task Assessments	48
9.3 Process, Program Element, and Comprehensive Program Assessments	48
9.3.1 Selecting the Focus of the Assessment	49
9.3.2 Assessment Tools	49
9.4 Responsibilities of Assessment Personnel	50
9.4.1 Team Leader	50
9.4.2 Team Member	51
9.5 Criteria for Assessment	51
9.6 Preassessment Coordination	52
10. Conducting the Self Assessment	53
10.1 Entrance Meeting	53
10.2 Assessment Activities	53
10.3 Daily Team Conferences	54
10.4 Management Briefings	55
10.5 Exit Meeting	55
10.6 Documentation	55
11. Documenting the Self Assessment	57
11.1 Written Reports	57
11.1.1 Title	57
11.1.2 Summary	57
11.1.3 Scope	58
11.1.4 Methodology and Techniques	58
11.1.5 Results	58
11.1.6 Approval	60
11.1.7 Attachments	60
11.2 Communication of Results to Affected Personnel	61
11.3 Reports to Regulators	61
11.4 Note on Legal Considerations	61
12. Documenting Deficiencies and Corrective Actions	63
12.1 Deficiency and Corrective-Action Tracking System	63
12.1.1 Categorization of Deficiencies	63
12.1.2 Regulatory Review	63
12.1.3 Causal Analysis of Deficiencies	64
12.1.4 Isolated or Systemic Deficiencies	64
12.1.5 Development of Corrective Actions	64
12.1.6 Corrective-Action Completion	65
12.1.7 Evaluation of Effectiveness of Corrective Actions	65

12.2	Reviewing the Effectiveness of the Deficiency Tracking and Corrective-Action System	65
Appendix A.	Interview Guide for Task Assessments	67
Appendix B.	Examples of Self-Assessment Lines of Inquiry	71
B.1	Adequacy of Worker Training and Qualifications	71
B.1.1	Worker Training	71
B.1.2	Worker Qualifications	72
B.2	“As Low as Reasonably Achievable” Program	74
B.3	Engineered Safety Controls	76
B.3.1	Shielding	76
B.3.2	Ventilation and Filtration Systems	77
B.3.3	Fume Hoods and Glove Boxes	78
B.3.4	Radiation Alarm and Access-Control Systems ..	78
B.3.5	Air-Monitoring Equipment	79
B.3.6	Area-Monitoring Systems	80
B.4	Adequacy of Equipment	80
B.5	Emergency Preparedness	82
B.6	Radiation-Source Accountability and Control	82
B.7	Radiation-Safety Program Software	84
B.8	Worker Attitude Towards Radiation Safety	85
B.9	Environmental Radiation Protection	85
B.10	Radioactive Waste Management	86
B.11	Records	87
Glossary		88
References		90
The NCRP		94
NCRP Publications		103
Index		114

1. Executive Summary

The purpose of this Report is to provide guidance for performing self assessments of radiation-safety programs. The self-assessment process is important for all institutions that use radioactive material or radiation-generating devices. These institutions range from a college using small radioactive sources in the physics department to a large nuclear power plant complex. Of course, the extent and rigor of a self-assessment program will be tailored to the size and complexity of the radiation-safety program at the institution.

Self assessments are a proactive component of an effective radiation-safety program and they should occur at all levels within the institution. Self assessments can identify and correct deficiencies and can improve the performance of the radiation-safety program. The self-assessment process is designed to find and correct deficiencies before they have a negative impact on safety or the institution's activities. Another benefit of the self-assessment program is to encourage worker involvement in improving the radiation-safety program. Finally, an effective self-assessment program can demonstrate to regulators that the risk of radiological activities is being adequately managed and that the institution is committed to safe use of radiation and radioactive material.

Self assessments are planned and controlled internally by an institution. They differ from external reviews, which are generally referred to as inspections, audits or appraisals and are controlled from outside the institution, often by regulatory agencies.

This Report provides guidance for individuals who have the responsibility of developing and implementing a self-assessment program at an institution. It provides information and guidance on the following topics:

- definition and purposes of self assessment;
- types of self assessment (*i.e.*, performance based, risk based, compliance based, task, process and program level, formal and informal);
- responsibilities for establishing self-assessment programs including upper management, line management, the radiation-safety committee (RSC), radiation-safety program personnel including the radiation-safety program manager or radiation-safety officer (RSO), and workers;

- self-assessment program planning for an institution including determining the purpose and type of self assessments, selecting the program elements to be assessed, allocating the necessary resources, and developing a self-assessment program review plan;
- qualification and selection of individuals performing the self assessments;
- self-assessment methods and techniques including evaluation of radiation-safety program survey and monitoring results, workplace observations, interviews, document reviews, checklists, review of metrics, and questionnaires;
- types of deficiencies that can be identified in the self-assessment process, ranging from the minor ones that are most likely to be found to those that are more serious;
- identification of noteworthy practices;
- planning an individual self assessment including the program elements to be assessed, the schedule for performing the self assessment, and the type(s) of self assessment to be used;
- conducting the self assessment including the entrance meeting, performing the assessment activities, daily team conferences, upper management briefings, exit meeting, and documentation;
- documenting the self assessment including writing reports, report approval, communicating the results, and legal considerations; and
- developing corrective-action plans including tracking and resolution of corrective actions and reviewing the effectiveness of the corrective-action program.

2. Introduction

2.1 Definition of Self Assessment

The National Council on Radiation Protection and Measurements (NCRP, 1998) described a radiation-safety program audit as “a deliberate examination of the program to determine if it is effective.” Deliberate examinations of a radiation-safety program that are planned and controlled internally by an institution are referred to as self assessments. In this Report, an institution refers to a management structure and its associated activities conducted in one or more facilities at one or more sites. Examples of institutions include a corporation in the private sector, a government research laboratory, a hospital, a nuclear power plant or other nuclear fuel-cycle facility, and a university.

Specifically, self assessment is the process that an institution uses to critically review its own activities and performance in relation to regulations, standards, internal policy documents, implementing procedures, industry best practices, and goals. In the self-assessment process, the institution determines who will perform the assessment, what radiation-safety program areas will be assessed, and the schedule for the assessment. The institution also controls how and to whom the results are reported. Generally, self-assessment results are maintained internal to the institution. In some cases, the results of the self assessments may be disseminated to regulators and others outside the institution who may benefit from them. The elements of the self-assessment process include:

- establishing an overall self-assessment program plan;
- assigning responsibilities for implementing the self-assessment program;
- identifying the purpose of the self assessment;
- identifying the type of self assessment to be performed (*i.e.*, performance, risk and compliance based);
- identifying the level of the self assessment (*i.e.*, task, process and program);
- determining whether the self assessment will be formal or informal;

- identifying qualified individuals to conduct the self assessment;
- reviewing specific self-assessment methods and techniques (*e.g.*, interviews, checklists, observations, document reviews, review of performance measure results);
- developing an individual self-assessment plan (*e.g.*, areas to be assessed, criteria used for assessment, level of self assessment);
- conducting the self assessment;
- documenting and reporting the results of the self assessment;
- determining the causes of any deficiencies;
- developing corrective actions; and
- implementing and verifying the implementation and effectiveness of corrective actions.

Each of these elements of the self-assessment process is discussed in detail in this Report.

Self assessments are proactive components of effective radiation-safety program management plans. Self assessments can and should occur at all levels within the institution and they have the potential of engaging everyone as stakeholders in improving the radiation-safety program. Self assessment is an effective tool to evaluate new program elements, new or changed radiological activities, and changes in requirements or regulations.

Self assessments do not include reviews conducted and controlled by individuals external to the institution being assessed. These external reviews are generally referred to as inspections, audits or appraisals. Also, routine renewals of work authorizations that may include a review of hazards, controls and performance are typically not considered part of the self-assessment process. Finally, since self assessments are prospective evaluations of an institution's radiation-safety program, they do not include incident or accident investigations, which are retrospective in nature and have their own formal methodology. For example, the U.S. Department of Energy (DOE, 1997) and the U.S. Nuclear Regulatory Commission (NRC, 1997) provide guidance for performing accident investigations.

2.2 Purposes of Self Assessments

The self-assessment process has two general objectives. The first is the timely self identification and correction of deficiencies or weaknesses in the radiation-safety program. The second is to

improve the performance of the radiation-safety program by ensuring that its design, development and implementation are effective and efficient. The specific purposes of a self assessment are discussed in the following paragraphs.

2.2.1 *Ensure a Safe Working Environment*

One of the most important purposes of a self-assessment program is to identify and correct deficiencies in the radiation-safety program. These deficiencies include unsafe practices, equipment, and working conditions that could lead to incidents and accidents and radiation exposures that are either not as low as reasonably achievable (ALARA) (NCRP, 1998) or over regulatory limits. Examples of the types of deficiencies and severity levels are presented in Section 8.

Self assessments can help eliminate or minimize the possibility of accidents and minimize the impact when accidents occur. Self assessments can help ensure that procedure changes do not inadvertently lessen the established level of safety.

In addition to ensuring a safe working environment, self assessments can help ensure the safety of the public and the protection of the environment.

2.2.2 *Ensure Regulatory Compliance*

All radiation-safety programs must comply with applicable regulations and license conditions. NRC and its Agreement States, DOE, U.S. Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), U.S. Food and Drug Administration (FDA), U.S. Department of Transportation (DOT), Mine Safety and Health Administration (MSHA), and other government agencies issue regulations that may be applicable to a radiation-safety program. Also, states have the authority for regulating the use of accelerators and x-ray machines not covered by federal regulations. All regulations require that radiation exposures be within regulatory limits. NRC and its Agreement States, DOE, EPA, FDA, and the states (for accelerators and x-ray machines) also require that radiation exposures comply with the ALARA principle. The requirements of applicable regulations must be incorporated into top-level policy documents and implemented through procedures, manuals and work documents.

A compliance-based self assessment (Section 3.3) can help evaluate how well the radiation-safety program complies with the applicable regulatory requirements. The purposes of this type of

self assessment are to enhance safety and to identify instances of noncompliance so that preemptive corrective actions can be taken.

2.2.3 *Assess Conformity with the Radiation-Safety Program*

In addition to the regulations, the day-to-day radiation-safety program is based on standards, internal policy documents and manuals, implementing procedures, and goals. It is important to assess whether operations are conducted in conformance with these implementing documents. It is also important to identify areas of the radiation-safety program with insufficient or inadequate implementing guidance.

2.2.4 *Reaffirm the Workplace Continuous Improvement Culture*

Aggressive self assessments can identify opportunities for improvement, including identification of practices that hinder quality improvement, beyond findings of noncompliance. Self assessments can also foster a workplace safety culture that encourages the adoption of best available technology or standards-of-practice and the identification and elimination of nonvalue added activities.

There are a number of management initiatives such as the Baldrige National Quality Program (NIST, 1987), various implementations of total quality management including the International Organization for Standardization standard (ISO, 2008), and the DOE Integrated Safety Management Program (DOE, 2006) that advocate a culture of continuous improvement. Also, NRC (2005) has provided guidance for establishing and maintaining a safety conscious work environment and the International Atomic Energy Agency (IAEA, 2002) has provided guidance in enhancing a safety culture in nuclear facilities.

A culture of continuous improvement is one in which workers are empowered by management to identify and make small changes to processes that result in continuous improvement over time. One method of identifying these small changes is by workers and supervisors conducting self assessments of workplace tasks and processes that they use every day.

2.2.5 *Reaffirm an Atmosphere of Caring*

Self assessments are one opportunity to let employees know they have ready access to their supervisors, the radiation-safety staff, and management. They can serve to reemphasize to staff that they have access to various services and that management is concerned with their well-being.

When employees are empowered to assure their own safety through active participation in self-assessment programs, it can increase their desire to perform their tasks in a better way rather than simply because they are told to do so or to comply with regulations.

In order to foster openness during the self-assessment process, self-critical assessments should be encouraged. The emphasis should be focused on process improvements as opposed to finding fault with personal performance. If the self assessment reveals instances of deliberate or negligent actions by employees, these cases should be referred to management for appropriate action.

2.2.6 *Identify Noteworthy Practices and Exemplary Performance*

In addition to identifying deficiencies in a radiation-safety program, self assessments can help identify noteworthy practices that can be implemented in other program areas as part of a continuous improvement program. Also, self assessments should identify exemplary performance so that the workers can be acknowledged for their efforts. Specific examples of noteworthy practices are presented in Section 8.

2.2.7 *Demonstrate the Effectiveness of the Program and Identify Areas for Further Evaluation*

Self assessment can identify program strengths and systemic weaknesses. Self assessments can help drive strategic decisions about the direction of the program, including priorities, resources, and improvement initiatives. Assessment serves to evaluate overall performance of the program, and provides a method for reporting to stakeholders (*e.g.*, senior management, regulators, and workers).

Weaknesses and vulnerabilities may warrant further oversight and management attention. A single condition can indicate a systemic weakness that can only be determined through evaluation of the extent of the condition. In certain cases, follow-up assessment may be warranted.

2.2.8 *Provide an Opportunity for Learning*

Assessors themselves have the opportunity to learn new elements of the radiation-safety program when they participate in self assessments. This approach can improve interfaces during normal and emergency radiation-protection activities. Peer-to-peer assessment can facilitate the cross-pollination of good practices and increases consistency across a program as appropriate.

3. Types of Self Assessment

The primary purpose of a radiation-safety program is to maintain radiation exposures to employees and the public within regulatory limits including a requirement that exposures be maintained ALARA (NCRP, 1998). There are three primary types of self assessment used to assess whether a radiation-safety program is achieving this purpose. They are performance-, risk-, and compliance-based self assessments. Self assessments also vary based on the level at which the assessment occurs (task, process or program) and on the degree of desired formality and rigor. While each primary type is described separately, elements of each may be used, especially when conducting a comprehensive self assessment of a large radiation-safety program. Each type may be used to assess specific aspects of a radiation-safety program element in one or across multiple line organizations in a horizontal slice. The assessment types may also be combined to review radiation safety in a particular line organization in a vertical slice such as waste management or operations in a particular laboratory. The types of self assessment are discussed in the following paragraphs.

3.1 Performance-Based Self Assessments

As defined in this Report, a performance-based self assessment evaluates the overall effectiveness and efficiency of a radiation-safety program. That is, in addition to evaluating compliance with regulations, it takes a broad look at the radiation-safety program (or an element of a radiation-safety program) to assess how well it is performing. This could include assessing how well the ALARA program is implemented, the adequacy of and adherence to internal procedures, the ability to respond to emergencies, the quality and implementation of radiation-safety training, ongoing efforts to improve the radiation-safety program, the quality of the radiation staff and the guidance they provide, and management commitment to and involvement in the radiation-safety program. In summary, a performance-based self assessment evaluates the effectiveness of the radiation-safety program beyond just compliance with regulations.

Specific questions that could be asked in a performance-based assessment concerning radiation-safety program performance include:

- Has there been a history of significant incidents or accidents resulting in overexposure to workers or the public?
- Do occupational radiation doses to workers meet regulatory requirements including ALARA?
- Have there been instances of procedural violations or lack of procedural guidance?
- Do releases of equipment, property, and radioactive material to the environment or other public exposure pathways meet regulatory requirements including ALARA?
- Have performance measures been established and are they being met?
- Are incidents and emergencies responded to properly?
- Are emergency-response exercises executed properly?
- Have there been any near misses?
- Have there been any instances of misplaced, lost or stolen radioactive materials or sources, or radiation-generating devices?
- Do radiation measurements (*e.g.*, personal dosimeters, surveys, air samples, swipes) provide appropriate information to the required levels of sensitivity and accuracy?
- Do engineered controls function as designed?
- Is personal protective equipment (PPE) specified, appropriate, available, in good condition, and utilized properly?

Questions concerning radiation-safety program management:

- Are funding, staffing, and staff qualifications adequate for the radiation-safety program?
- Is adequate training provided so workers can effectively perform their radiation-safety program responsibilities?
- Is management actively involved in evaluating the performance of the radiation-safety program?
- Are radiation-safety program performance goals being met?
- Does management encourage a safety culture and consider safety in performance reviews of staff members?
- Do management and staff act as a team to implement the radiation-safety program?
- Are resources dedicated to implement corrective actions when deficiencies are identified?

- Does management provide the radiation-safety staff sufficient authority and independence to implement the radiation-safety program?
- Is management committed to the continuous improvement of the radiation-safety program?

While an assessor must be familiar with regulations and institutional requirements, in performance-based assessments the assessor's knowledge and experience are essential factors in determining whether the radiation-safety program is performing satisfactorily. Therefore, participants in performance-based assessments must be technically competent in the areas they are assessing. For example, an assessor evaluating a waste management process must be familiar with the potential hazards within the process, waste classification and waste-form requirements; transportation regulations including appropriate packaging, labeling and shielding requirements; and any regulatory guidance from oversight agencies. In addition, it would be very desirable for the assessor to be familiar with other regulations such as security, criticality safety, chemical safety, industrial safety, and industrial hygiene that could impact the radiation-safety program.

The performance-based assessment usually provides the most useful information to management; however, it requires a high level of competence on the part of the assessment team.

3.2 Risk-Based Self Assessments

In this Report, a risk-based self assessment is the evaluation of the radiation-safety program to determine if the radiological risks have been reduced to those deemed acceptable by the institution. These risks could be health risks to workers, the public, or the environment. In addition to the potential health risks of a radiological incident or condition, the potential financial costs of suspending operations, mitigation efforts, adverse public perception, regulatory fines and impacts, and the negative impact on business should be considered.

A risk assessment considers both the consequences of a hazardous incident and the probability that the incident could occur. The radiation-safety program should be designed and implemented to reduce the radiological risk from primary program activities (*e.g.*, nuclear power plant, nuclear-medicine laboratory, particle accelerator) to an acceptable level. If the radiation-safety program is not properly designed or executed, it can result in unacceptable risks to workers, the public, or the environment. For example, the improper

analysis of the contents of a waste-retention tank could result in a significant release to the environment or the improper use of a survey instrument could lead to worker overexposure. Guidance on performing in-depth risk assessments is available in Vesely *et al.* (1981).

In a risk-based self assessment, the questions that should be asked are, “What could go wrong?” and “Have mitigating measures been put in place to keep the risk at acceptable levels if something does go wrong?” It is important that senior management establish expectations and standards for acceptable risk, based on regulatory and other stakeholder considerations.

Specific questions that should be asked in a risk-based assessment are:

- Has the staff identified the potential hazards and determined the probability that hazardous incidents could occur for the various radiological operations? For example: have the risks from a failure of a piece of safety equipment, failure to follow a procedure, or the failure to respond properly in an emergency been identified and adequate backup measures been implemented? Specific examples include the following:
 - If failure of a single interlock could lead to a high hazard situation, have two interlocks in series been installed or have other hazard mitigating measures been implemented?
 - If breach of a filter on a hazardous effluent stack could produce a significant risk to the public, have multiple filters and a filter protection system been provided?
 - If failure of a radiation survey instrument could lead to a significant hazard to workers, what procedures have been implemented to minimize this possibility, and what backup radiation-monitoring techniques have been implemented?
 - If failure to follow a safety procedure could lead to a significant hazard to workers, is there a double check or independent verification built into the procedure to enhance the likelihood that the procedure is followed properly?
 - If the loss of control of a radioactive source could present a significant risk to workers or the public, have adequate controls been implemented to secure the source during storage, transport, change of custody, and handling activities?

- Is there a proper balance between the use of engineered controls and administrative controls?
- Are incidents and near misses evaluated and follow-up actions taken to minimize the possibility of their recurrence?
- Is there an adequate emergency-response program to reduce the consequences from incidents to acceptable levels? If a high-consequence accident is credible, are there sufficient procedures, training plans, and emergency exercise protocols in place?
- Are workers trained adequately to reduce the risk from radiation-safety program-related activities to acceptable levels?
- Are resources, staffing and priorities allocated based on risk?
- Has the ALARA principle been incorporated into operations?

The specific radiological risk will depend on the specific program activity. However, the level of acceptable risk should be consistent throughout an organization. The objective of a risk-based self assessment is to ensure that radiological risks have been identified and mitigating controls have been implemented to reduce the risks to an acceptable level.

3.3 Compliance-Based Self Assessment

Stalnaker (1996) describes self assessments as an effective way for a safety program to achieve a level of performance that can withstand external scrutiny.

All radiological protection programs must satisfy applicable regulatory requirements and license or permit conditions. The regulations that apply to a radiation-safety program are determined by the type of operation; the size, complexity and potential radiological hazards associated with a program; and the regulatory agency that has jurisdiction. As noted in Section 2.2.2, the regulations are issued by NRC and its Agreement States, the states (for accelerators and x-ray machines), DOE, EPA, OSHA, FDA, DOT, MSHA, and other government agencies. These requirements should be incorporated in top-level policy documents and reflected in implementing procedures.

As defined in this Report, a compliance-based self assessment evaluates whether a radiation-safety program complies with regulatory requirements and license or permit conditions. This process first requires the identification of the applicable radiation-safety regulations including license requirements. Next, it requires a review of the radiation-safety program to evaluate whether all regulations and other external requirements (*e.g.*, contractual,

permits, registrations) are being met. Since a compliance-based self assessment focuses solely on compliance with regulations, it is typically less comprehensive than a performance-based assessment (Section 3.1) and may not be a valid assessment of the overall safety program.

Finally, there should be a process in place to bring the program into compliance with new regulatory requirements. This can be a particularly challenging process when an institution has facilities at more than one site and involves different state regulatory agencies.

3.4 Assessment Levels

Self assessments can be performed at the task, process or program level. The level of assessment depends on management support for the self-assessment process, the culture or institutional attitude toward continuous improvement, and on the experience of workers. The more receptive the institution is to continuous improvement, the more advantageous it is to perform self assessments at the task level. The more experienced the work force, the more likely work units or teams can perform assessments of their work processes and tasks with a reduced need for specialized assessors.

3.4.1 *Task-Level Assessments*

A task is a work activity that has a definite beginning and ending, consists of two or more steps, and leads to a product, service or decision. Examples include:

- entering radioactive material into a glove box;
- placement and wearing of external dosimeters;
- surveying when workers exit potentially-contaminated areas; and
- labeling of radioactive-waste containers.

Task-level assessments examine work controls and verify that the work controls are being implemented effectively. Task-level assessments are often called “job observations.”

Typically, a single assessor performs a task-level assessment. Depending on the knowledge and experience of the assessor, the assessment can simply verify compliance with written procedures. If a more experienced assessor conducts the assessment, the assessor may ensure that all work controls were implemented during a specific task to control the associated hazards or look for opportunities for improvement of task performance. Such “floor-level”

assessments should include evaluation of other workplace hazards and controls if practicable, and they are an opportunity for open conversation about individual concerns and program issues.

3.4.2 *Process-Level Assessments*

A process is a series of actions that are taken to achieve a desired result and usually will include multiple tasks. Examples of processes are:

- management of radioactive materials in a glove-box environment (entry, removal, inventory and handling techniques);
- issuance, retrieval and processing of external dosimeters;
- egress of a worker from a contaminated area to an uncontaminated area; and
- radioactive-waste storage and/or shipment.

The process-level assessment focuses on whether the component tasks and procedures are appropriate, the performance objectives are being met, and whether the process complies with the appropriate regulations and requirements. The process-level assessment also reviews management's commitment to providing the appropriate leadership and support systems to implement the processes. For example:

- Are adequate resources provided for external dosimeters and dosimeter processing equipment?
- Is proper equipment for surveying workers and checking for contamination in the workplace available and in use?
- Is there an adequate radioactive-waste storage area and is adequate waste monitoring equipment provided?
- Do personnel receive adequate training, including basic radiation concepts, regulations, the use of radiation survey instrumentation, and the radiation-safety procedures used at the institution?

3.4.3 *Program-Level Assessments*

A program is the integration of a set of processes and other activities that are planned, initiated and managed in a coordinated way to achieve desired results. Program-level assessments are very important because they address primary elements of the radiation-safety program and because problems can occur in hand-offs/connections between processes within a program. Examples of program-level assessments are:

- glove-box operations, including management of materials, ventilation and filtration, fire protection, maintenance, and emergency power;
- external radiation dosimetry program;
- contamination control program;
- radioactive waste-management program;
- PPE program, including the proper use of respiratory protection; and
- sealed-source safety and security program including receipt, use, inventory, storage and disposal.

The conduct of program-level assessments can answer the following questions:

- Are the radiation-safety program components properly established and implemented?
- Are the elements that establish the radiation-safety program adequately integrated?
- Are the appropriate leadership and support systems provided to enable the implementation of the programs?
- Are changes in programmatic operations adequately evaluated and appropriate safety controls implemented?

A specific example of a program-level assessment is the review of a researcher's new use of radioactive materials or radiation-generating device to ensure that hazards are adequately addressed and any process changes are evaluated. Another example is an assessment after a change in regulatory requirements to ensure that the requirements are addressed by all program elements.

Because of their scope and complexity, a team typically conducts program-level assessments. Program-level assessments generally have formal assessment criteria, are characterized by their thoroughness, and are often performed on a regular frequency.

3.5 Formal or Informal Self Assessment

In general, the degree of formality and rigor of a self-assessment program should be based on the degree of risk associated with the radiological activities and the size and complexity of the radiation-safety program. For example, the self assessment of the radiation-safety program for a nuclear power plant will be very formal and very rigorous; that for a small campus laboratory using only small check sources much less so.

Typically, formal self assessments are highly structured and have well-defined assessment criteria. Formal self assessments can

be initiated internally to address questions discussed in Sections 3.1 to 3.3, performed as a good practice, may be an element of an institution-wide assessment program, or they may be required by regulations. Formal self assessments should be performed periodically on all functional areas of the radiation-safety program. As a general rule, program- and process-level assessments are formal in nature.

Informal self assessments are by definition less rigorous than formal self assessments. They can be performed by managers or supervisors to familiarize themselves with an aspect of the radiation-safety program, to evaluate a question or concern raised by an employee, or to review a new radiological activity or minor program change. Task-level assessments are typically informal in nature.

Workers can also provide input to the self-assessment process based on their work experiences. An effective radiation-safety program involves regular feedback from workers based on their experiences working directly with the radiation source. When faced with potential radiation hazards that they feel are not adequately addressed, workers should communicate the problem to their supervisor or a radiation-safety staff member. Often the workers themselves can offer effective suggestions to eliminate the hazard or reduce it to an acceptable level.

All self assessments should be documented. A formal self assessment should be documented in a comprehensive report commensurate with the length and complexity of the assessment. An informal self assessment might be documented in a supervisor's logbook. More information about documenting self assessments is provided in Section 11.

Finally, it is absolutely essential that any findings of serious or imminently dangerous safety situations as defined in Section 8 be resolved with appropriate urgency regardless of the means of identification. Severe and imminent threats typically require that, at a minimum, the activity be stopped and that management be notified immediately.

4. Responsibilities for Establishing Self-Assessment Programs

4.1 Upper Management

Institutional managers are responsible for providing a safe workplace and for promoting a safety culture among all workers. A self-assessment program is an important tool for fulfilling this responsibility. Thus, it is important that upper management of an institution understands and appreciates the goals and benefits of self-assessment programs. As discussed in Section 2.2, one of the most important purposes of self-assessment programs is to enhance the health and safety of workers and the public and to protect the environment. Another benefit of self-assessment programs is to ensure that the institution is in compliance with all applicable laws and regulations regarding protection of workers, members of the public, and the environment. An effective self-assessment program will facilitate the continuous improvement of a radiation-safety program.

Several federal regulatory agencies, including DOE (2008a), EPA (2000), NRC (2008a; 2008b), and OSHA (2000) and many state and local agencies either require or highly recommend self assessments as a part of their regulatory framework. In some cases, the regulatory agency will refrain from issuing a citation or lessen a penalty for violations that have been identified through a self-assessment program provided the violation has been corrected and appropriate steps have been taken to prevent its recurrence. The regulatory agency may also require self reporting of the violation.

Therefore, it is important that upper management strongly and visibly support an institution's self-assessment program by providing the necessary resources of adequately trained assessors, time, and equipment to conduct the self-assessment program and to promptly correct violations or other deficiencies that are identified. Although upper management is responsible for sponsoring the self-assessment program, radiation-safety program personnel are typically tasked with planning and conducting the self assessments.

Upper management should also ensure that the findings of the self-assessment program are brought directly to them for their information and, as appropriate, follow-up action.

4.2 Line Management

Line managers have the responsibility to understand and support the purposes of self assessments and the potential benefits to their operational units. They should understand that it is not the purpose of the self-assessment program to find fault or fix blame, but rather to aid in the early identification and correction of deficiencies and to improve processes so they run more safely and efficiently. In addition, line managers should:

- be familiar with the procedures that are used in the development and execution of self assessments (line managers often have primary responsibility for participating in assessments and for executing corrective actions for their areas of responsibility);
- ensure that those they supervise are encouraged and afforded the opportunity to participate in the development of self-assessment plans (e.g., the development of checklists); and
- encourage those they supervise to participate in the self-assessment process and ensure that they participate fully without any fear of recrimination for their participation and input.

4.3 Radiation-Safety Program Personnel

Typically, the radiation-safety program manager or the RSO has the responsibility for developing, implementing and maintaining the self-assessment program. NCRP (1998) specified that auditing the effectiveness of a radiation-safety program is a responsibility of the radiation-safety advisory organization. At many institutions, a RSC provides oversight for the radiation-safety program and would provide input to the planning of the self-assessment plan.

Elements of the self-assessment program (*e.g.*, conducting the self assessment, compiling the findings, and preparing the self-assessment report) are often delegated to radiation-safety staff members. Guidance on developing a self-assessment program plan is provided in Section 5. Guidance on developing individual self-assessment plans is provided in Section 9. Guidance on preparing the self-assessment report is provided in Section 11 of this Report.

With input from workers and managers, radiation-safety program personnel should develop self-assessment tools specific to the institution they are assessing. Guidance on specific self-assessment methods and techniques is provided in Section 7 of this Report.

Radiation-safety program personnel (or management) should communicate the results of the self assessment and identify corrective actions that have been taken or are planned. Lessons learned from the self assessment should be communicated to the remainder of the institution.

Radiation-safety personnel often have responsibility for implementing corrective actions in response to assessment findings.

4.4 Workers

As discussed in Section 4.1, managers and supervisors are responsible for providing a safe workplace. However, as stated in NCRP (1998), ultimately workers are responsible for their own safety.

It is important that workers understand the self-assessment program and process and the benefits that are associated with it. This understanding will require that workers be informed about the self-assessment program through meetings, training classes, and/or written material, as appropriate.

Individuals who are given privileges to use radioactive material or radiation-generating equipment have a responsibility to perform self assessments of their work areas and activities. They should periodically review handling procedures and techniques and whether they are following good safety practices. This will help to ensure that everyone using radiation sources is working in a safe manner and not placing their privileges in jeopardy. Individuals may occasionally request an independent assessment of their work areas. A member of the radiation-safety staff could perform such an assessment.

Workers may be given the responsibility to perform task and process-level self assessments and they may be asked by management to participate in the development and implementation of the self-assessment program. It is important that each worker fulfill the self-assessment responsibilities to which he or she is assigned. Workers should understand that only by their full participation in the self-assessment program can the full potential of the program be realized.

Finally, as discussed in Section 3.5, an effective radiation-safety program involves feedback from workers on a regular basis. Workers should communicate any concerns regarding radiation safety to their supervisor or a radiation-safety staff member. Often the workers can offer useful suggestions to eliminate a hazard or reduce it to an acceptable level.

5. Self-Assessment Program Planning

An individual self assessment is generally performed within the framework of an overall self-assessment program. Frequently, in larger institutions, the radiation-safety self-assessment program is likely to be part of an institution-wide performance improvement program that addresses a wide variety of topics such as operations, maintenance, training, and other safety disciplines. Management should require the self-assessment program plan to be comprehensive and that individual assessments are organized and conducted in a cost-effective, efficient manner. Institutional management, the radiation-safety staff, a quality-assurance organization, or a combination thereof can establish a self-assessment program.

Self-assessment program plans should be developed to the level of rigor and detail necessary to ensure adequate review of the radiation-safety program being assessed. Smaller institutions will generally have smaller scope radiation-safety programs, and self-assessment program planning will likewise be less complex.

This section discusses factors that should be considered in developing a self-assessment program plan. Guidance for planning individual self assessments is provided in Section 9 of this Report.

5.1 Establish the Purpose and Objectives of the Self-Assessment Program

The purposes for performing self assessments are discussed in Section 2.2. In preparing a self-assessment program plan, Section 2.2 should be reviewed to aid in determining the overall objectives of the self-assessment program. In general, a self-assessment program will include most or all of the objectives listed in Section 2.2, but program planners may choose to focus on one or more of the objectives based on past experience and/or plans for improving the radiation-safety program. The objectives of the self-assessment program should be documented in the program plan.

5.2 Selecting the Types of Self Assessments to be Performed

Program planners should review the types and levels of self assessments discussed in Section 3 of this Report. Although an

individual self assessment might emphasize a specific assessment type (*i.e.*, performance, risk or compliance based), a self assessment typically includes elements of more than one assessment type. For example, a performance-based self assessment could identify that the contents of a waste-retention tank were being improperly analyzed. Then a compliance-based assessment would be used to determine if the release of the contents of the waste-retention tank was above regulatory limits. Regardless of assessment type used, they all have the same purpose, which is to improve the radiation-safety program as discussed in Section 2.2.

The specific mix of self-assessment types selected would normally be a function of the institution and the purposes of the self-assessment program that were identified in Section 5.1. Using a mix of self-assessment types will likely provide the most comprehensive evaluation of the overall performance of a radiation-safety program.

Typically, a combination of short-term and in-depth program, process, and task-level self assessments will provide a good overview of the radiation-safety program. Task-level assessments might consist of radiation-safety staff members or first-line supervisors observing a task or activity being performed by health-physics technicians or radiation workers, while a process-level assessment might examine a radiological work process performed by a team of radiation workers. A program-level assessment might be an assessment in a specific topical area, such as the implementation of regulatory requirements for an internal dosimetry program. Also, the implementation of the radiation-safety program by a specific line organization, such as a maintenance department, could also be examined using performance-, risk- and compliance-based assessment techniques.

Choosing the type of self assessment for an individual self assessment should consider several factors, which are contained in the following list. Suggested assessment types are given in parentheses after each factor, although the actual assessment type (or mix of types) will depend on the specific circumstances.

- Is it a regularly scheduled self assessment? (*performance, risk, compliance*)
- Have there been incidents involving unnecessary radiation exposure to workers? (*performance, compliance*)
- Have there been an unusual number of contamination incidents or loss of control of radioactive material? (*performance*)
- Have there been an unusual number of near misses that could have resulted in a radiological incident or accident? (*performance, risk*)

- Has there been an increase in noncompliance citations by a regulatory agency or is a compliance inspection scheduled for the near future? (*compliance*)
- Have the radiological risks been adequately assessed by the radiation-safety program? (*risk*)
- Have workers expressed concerns about a potential radiation hazard that in their view is not adequately addressed by the radiation-safety program? (*performance, risk*)
- Has the workload increased significantly since the last self assessment? (*performance, risk*)
- Is there a new or changed process, radiological operation, or requirement? (*performance, risk, compliance*)
- Is there a known or suspected vulnerability at a specific facility or within a process that warrants a review? (*risk*)
- Is there a corrective action or process improvement that warrants effectiveness evaluation? (*performance*)
- Are there specific performance issues identified by previous assessments, events, performance indicators, management, or regulators that warrant focused assessment? (*performance*)

5.3 Selecting the Program Elements to be Assessed

A radiation-safety program consists of program elements that are dependent on the extent and complexity of the radiological activities at the institution. The self-assessment program plan should determine the set of program elements that need to be included in the self-assessment program and should be comprehensive in nature. The following is a list of radiation-safety program elements that may be applicable to the radiation-safety program at a specific institution:

- radiation-safety program management/leadership;
- ALARA program;
- internal/external radiation dosimetry programs;
- radiation-safety training program;
- radiological-survey program;
- radiological-instrumentation program;
- radioactive-material receipt and shipment program;
- solid and liquid radioactive waste-control program;
- effluent release and environmental-monitoring program;
- engineered safety-control program, including radiation-shielding design and configuration control;
- radiological work planning and control program;

- contamination control, including hot-particle control program;
- radioactive-material/source security, accountability and control program;
- emergency-response program;
- radiation-generating device program;
- radiological posting and labeling;
- PPE program, including the proper use of respiratory protection;
- medical x-ray/nuclear-imaging program;
- radiation therapy program;
- document control and record retention program;
- RSO and RSC responsibilities;
- regulatory compliance program, including licensing and permits; and
- facility design and maintenance.

Once the appropriate assessment topics have been identified, they should be prioritized. Priority should be given to those program elements which are identified as having the highest risk, their past performance was less than adequate, or there have been significant changes in the program. Program areas having the highest risk can be identified through review of performance indicator data, previous assessment results, worker feedback, near misses, etc. It is also useful to review industry lessons learned or known regulatory agency or external assessor focus areas. In addition to the risk of radiological consequences of failure, the risk of adverse public perception, and operational or regulatory/compliance impacts should be considered.

5.4 Establishing the Schedule for the Self-Assessment Program

Self-assessment plans should be developed to cover a logical time interval. The time interval could be annual as required by NRC (2008a), or some longer cycle [*e.g.*, 3 y, as required by DOE (2008a) and NRC (2008c)]. In general, self assessments should be conducted at frequencies commensurate with the hazards involved. The overall schedule and frequency of self assessments is generally determined by institutional management.

All program elements in the radiation-safety program should be examined during the self-assessment cycle. Small programs may cover all program elements in a single assessment or a single year. Larger programs will generally require a longer assessment cycle

(*e.g.*, up to 3 y) to examine all program elements in sufficient detail. Regulatory requirements (*e.g.*, NRC, 2008a) for an annual review of a radiation-safety program can generally be satisfied by a comprehensive self-assessment program. The self-assessment program schedule should allow adequate time for preparation, performance (including document reviews and field work), analysis, and documentation of results. With demonstrated positive performance in a given program area, the frequency and/or duration of self assessments in specific program elements may be decreased.

Job observations or assessments of individual or multiple tasks should occur more frequently than process or program element assessments because these assessments have the potential to reduce individual exposures or intakes of radioactive material. Emphasizing task-level assessments helps ensure that appropriate attention is focused on day-to-day safe conduct of work. Processes are typically assessed more frequently than program elements but less frequently than job observations to ensure that the appropriate requirements and safety precautions are addressed and that processes are achieving their intended purposes.

To summarize, the frequency for conducting individual self assessments depends on the program self-assessment cycle, the type of institution, the frequency at which certain tasks and processes are performed, deficiencies found during prior self assessments, the safety performance of the institution, and the desires and expectations of management. The frequency should be documented in the self-assessment program plan.

5.5 Establishing the Resources for the Self-Assessment Program

When planning the self-assessment program, it is important to make sure that adequate resources are available to meet the established assessment schedule. Self assessments can be performed by in-house staff, and potentially supplemented by outside personnel, including consultants or assessors available under reciprocal arrangements with other institutions. There is some benefit to mixing the use of in-house staff and outside personnel to provide familiarity with internal operations and an independent look at radiation-safety program elements. Similarly, self assessments may be conducted by the line or facility organizations, radiation-safety staff, or a combination of the three.

If the line or facility organizations perform self assessments, they are more likely to take ownership of their performance in implementing the radiation-safety program. If radiation-safety staff members perform self assessments, they can provide in-depth

subject matter expertise in the functional program elements being assessed. In many cases, a cross-functional team can be used to provide both the subject matter expertise and operational viewpoints. However, when an assessor has direct responsibility for program or regulatory compliance in the area being assessed, consideration should be given for the need to be self critical. The training and qualifications of the self-assessment staff are discussed in Section 6.

5.6 Reviewing and Trending Self-Assessment Results

Self-assessment results should be collectively reviewed to provide a picture of overall performance of the radiation-safety program. One useful tool in determining if the self-assessment program is meeting its intended objectives is the development and ongoing review of performance measures. Trending of performance measures provides useful analytical information for determining both the effectiveness of the performance improvement process or declining performance in a specific program area. This allows management to focus resources on problem areas that could lead to significant incidents.

Examples of performance measures include:

- average and collective occupational dose;
- number of contamination incidents;
- number of medical x rays that have to be repeated because of an error in technique;
- number of personnel exposures exceeding regulatory or administrative limits; and
- number of radiation survey instruments not calibrated at required intervals.

The collective review and analysis of self-assessment results and performance trends should be documented in periodic reports. These reports should clearly identify both areas of positive performance improvements and any areas in which performance is declining and need additional resources or focus. One of the key indicators for self assessment effectiveness is the frequency of repeated deficiencies. If these are occurring in a specific program element, management should identify the underlying causes of declining performance, and develop corrective actions to improve that performance (see Section 12.1.3 for guidance in performing a causal analysis for deficiencies).

5.7 Reviewing the Self-Assessment Program

The self-assessment program itself should be reviewed periodically to ensure that it is providing value and meeting its objectives.

Management should periodically review the overall self-assessment program to ensure that it is both useful and effective. Effectiveness reviews should examine whether areas for improvement are being identified, real performance improvements are realized, and potential problems identified before being revealed by accidents or through external audits or inspections. The assessment program should be revised as necessary to be responsive to the needs of both the radiation-safety organization and senior management.

Trending of assessment results should be used to feedback into the assessment program when planning for the next assessment cycle. If one program element is performing at a high level, assessment activities in that area may be reduced during the next self-assessment cycle. If trending indicates an area of concern is emerging, then more assessment activities should be focused and planned for that program element.

6. Qualification and Selection of Assessors

The quality of a self-assessment program will depend in large part on the qualifications of the assessors. In this Report, qualifications refer to formal academic and other training, certification in a radiation-safety-related discipline, knowledge of the activities being assessed, and relevant experience. The qualifications that an assessor should have are related to the type of self assessment they are performing. As described in Section 3.4, self assessments can be performed at the program, process or task level. Assessors who are qualified to evaluate the overall radiation-safety program may not have sufficient qualifications to assess performance of specific radiation-safety tasks at the facility. Conversely, assessors who are adequately qualified to evaluate performance of specific tasks may not have sufficient knowledge or experience to assess the overall radiation-safety program.

In general, individuals performing program- and process-level assessments should have a higher level of qualifications than individuals performing task-level assessments. Qualifications for assessing radiation-safety programs and processes are described in Section 6.1. Qualifications for assessing radiation-safety-related tasks are described in Section 6.2.

6.1 Assessors of Radiation-Safety Programs and Processes

Individuals tasked with assessing radiation-safety programs and processes should have the following qualifications:

- understanding of the self-assessment process including its purposes (Section 2.2), the types of self assessment (Section 3), assessment techniques (Section 7), and end products (Sections 11 and 12);
- knowledge of and experience with the specific radiation-safety program area(s) they are asked to assess;
- familiarity with the policies, procedures and instructions related to the facility's radiation-safety program;

- knowledge of facility operations that require radiation-safety support and industry accepted good practices for implementing radiation safety within those areas of operation;
- training and experience appropriate for the specific elements of the radiation-safety program being assessed;
- independence from pressures within the facility that might bias their assessment results; and
- knowledge of the applicable or relevant and appropriate regulatory requirements for the facility.

Many of these qualifications are described in more detail in Sections 6.1.1 to 6.1.3.

6.1.1 *Experience*

It is desirable to have assessors with prior experience performing self assessments of radiation-safety programs or processes. However, this may not be achievable within a small institution. Individuals having experience with self assessments of functional areas other than radiation safety can be incorporated into the radiation-safety self-assessment team. Regardless of the assessors' previous experience with self assessments of programs or processes other than radiation safety, the assessors should be trained in the requirements specific to the radiation-safety program or process at the subject facility. Although personnel experienced in performing self assessments may not be available when the self-assessment program is initiated, an experienced cadre of assessors can be developed over time. Finally, while assessments should largely be led by experienced personnel, the participation of individuals having lesser experience can bring new perspectives to the activity and may provide candidates for being assessors in the future.

It is particularly valuable to have experienced assessors reviewing the qualitative aspects of a radiation-safety program (*e.g.*, are funding, staffing, and staff qualifications adequate?). These qualitative aspects typically require more judgment than reviewing the more quantitative aspects of the program (*e.g.*, are regulatory dose limits being met?).

Two of the most important qualities of an assessor, which are often enhanced by experience, are having the ability to ask probing questions and identify systemic, program-level issues (while avoiding focusing on items of little value).

6.1.2 *Knowledge of Area Being Assessed*

Detailed knowledge by the assessors of specific day-to-day operations that require radiation-safety support and oversight at the