U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH

April 1982
Division 8

DRAFT REGULATORY GUIDE AND VALUE/IMPACT STATEMENT

Task OP 722-4

Contact: J. M. Bell (301) 443-5970

QUALIFICATIONS FOR THE RADIATION SAFETY OFFICER IN A LARGE-SCALE NON-FUEL-CYCLE RADIONUCLIDE PROGRAM

A. INTRODUCTION

Paragraph 30.33(a)(3) of 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," requires that the applicant for a byproduct material[1] license be qualified by training and experience to use radioactive material safely. Paragraphs 33.13(c)(2) and 33.14(b)(1) of 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," require that the applicant for a Type A or Type B broad license for the possession and use of byproduct material appoint a radiological safety officer[2] who is qualified by training and experience in radiation protection. Paragraph 35.11(b) of 10 CFR Part 35, "Human Use of Byproduct Material," requires that an institution applying for a license for human use of byproduct material appoint a medical isotopes committee of at least three members, one of whom should be a person experienced in assay of radioisotopes and protection against ionizing radiations. Paragraph 40.32(b) of 10 CFR Part 40, "Domestic Licensing of Source Material," requires that an applicant for a license to possess and use source material be qualified by training and experience to use the source

[1]"Byproduct material" is defined in paragraph 30.4(d) of 10 CFR Part 30; generally speaking, the term refers to reactor-produced radionuclides.

[2]Professionals responsible for radiation safety are referred to by various titles such as "radiological safety officer," "radiation protection officer," and "radiation safety officer." This guide uses the title "radiation safety officer (RSO)."

[3]"Source material" is defined in paragraph 40.4(h) of 10 CFR Part 40; generally speaking, the term refers to naturally occurring uranium and thorium.

material safely. Application forms for both the byproduct material license and the source material license request a description of the training and experience of the person who will be responsible for the applicant's radiation safety program.

Similarly, paragraph 70.23(a)(2) of 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," requires that the applicant for a license to possess and use special nuclear material[4] be qualified by training and experience to use the material safely, and paragraph 70.22(a)(6) of 10 CFR Part 70 requires that the application contain a description of the technical qualifications, including training and experience, of the applicant and members of its staff to possess and use special nuclear material.

Additionally, paragraph 20.1(c) of 10 CFR Part 20, "Standards For Protection Against Radiation," states that occupational radiation exposure should be kept as low as is reasonably achievable (ALARA). The effective supervision and conduct of the radiation safety program is essential to the effective implementation of ALARA (see Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," and other guides relating to specific types of programs such as Regulatory Guide 8.18, "Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be As Low As Is Reasonably Achievable").

Each program in which radioactive materials are used under a Commission license will have someone responsible for radiation safety and compliance with Commission regulations on radiation safety. In a small program, the responsibility may be assigned to (or assumed by) each individual using radioactive materials. In a medium-size program, the responsibility may be assigned to an individual on a part-time basis with the primary responsibility of that person being in another area of work. In a large program, the many facets of occupational and environmental radiation safety require that the responsibility for the radiation safety program be assigned on a full-time basis to an individual (with a supporting staff, as appropriate) who has professional status in the radiation safety field (e.g., certification by the American Board of Health Physics) and experience commensurate with his or her duties

[4]"Special nuclear material" is defined in paragraph 70.4(m) of 10 CFR Part 70; generally speaking, the term refers to plutonium, uranium-235, and uranium enriched in the isotope 233 or 235.

and responsibilities. This guide describes the qualifications (training and experience) acceptable to the NRC staff for a radiation safety officer (RSO) for a large program involving the use of radioactive materials under a Commission license.

B. DISCUSSION

The individual worker using radionuclides as a tool may find that acquiring the knowledge and developing the practices necessary to ensure that his or her radiation doses are as low as is reasonably achievable demands too much of his or her valuable time. When a number of individuals are working with radioactive materials, it becomes very inefficient for each worker to make the many assessments and decisions related to his or her and the group's radiation safety.[5] In addition, coordination of various activities (e.g., effluent discharges, receipt and distribution of radioactive materials, disposal of radioactive wastes) will be necessary to avoid violation of Commission regulations and to be consistent with good radiation safety practices. In such cases, a person specifically trained in the radiation health sciences and appropriately experienced in applying this training to the management of a radiation protection program becomes invaluable. This person can maintain an awareness of developments in the radiation health sciences and inform workers (e.g., by means of training programs) of the benefits to be derived from recent advances in radiation safety knowledge. His or her knowledge of regulatory requirements and improvements in equipment and radiation safety practices can also be made available to management for its use in making decisions affecting the radiation safety of workers. Also, such a person with experience managing a radiation safety program and with knowledge of the licensee's specific program will be in a position to communicate appropriate

---

[5]In accordance with § 19.12 of 10 CFR Part 19, all workers must receive training commensurate with the radiation safety problems associated with their individual jobs. However, such training will usually not qualify each worker as a radiation safety professional capable of interpreting and applying basic radiation safety standards to such things as the design of procedures, processes, and equipment.

information to management and others (e.g., the public) in an efficient and effective manner when questions arise concerning the radiation safety aspects of the licensee's program.

The need for an individual responsible for and in charge of radiation safety is dictated more by the nature of the program than by the amount of radioactivity involved. If there is a well-established routine for the use of radioactive materials under essentially invariant conditions, the individual users of radioactive materials will usually not require the services of a full-time radiation safety expert. Problems likely to occur can usually be foreseen and written instructions can be provided for coping with these problems, including timely consultations with appropriately trained persons.

For example, the large amount of activity in a teletherapy machine incorporating a multi-kilocurie radiation source has the potential for causing serious injury if not used in accordance with established procedures. But because the procedures for the safe use of such machines for patient treatment are well established, the contained radiation source should not present an undue hazard when used in accordance with those procedures and in conjunction with an adequate machine-servicing program and periodic audits by a radiation safety professional. A much smaller amount of activity, however, may present a much greater potential hazard because of the form of the material being used (i.e, liquids, gases, or finely divided solids) or changes in the conditions of use (e.g., equipment and facilities, training of personnel) from project to project. In such cases, there will be a requirement for frequent evaluations of the many variable factors affecting worker health and safety and for decisions to be made by a qualified professional on the basis of these evaluations.

This regulatory guide is intended to provide guidance on the qualifications of the radiation safety officer for a "large" program in which radioactive materials are to be used under a Commission license. The term "large" is applied to a program in which the combination of the number of workers involved, the amount or form of the radioactive material, and the conditions of its use call for a full-time professional in that position. An important characteristic of a large program is licensee flexibility. Such flexibility may relate, for example, to the types and amounts of radionuclides used; the type, location, and method of use; the types and frequency of measurements; or the delegation of responsibility and authority for the use of radioactive

materials. Within the limits of flexibility of the license, the licensee has the prerogative and responsibility to make decisions that have a major effect on the health and safety of its workers and that are necessary to maintain compliance with Commission regulations. Competency in the radiation safety field is basic to making and implementing such decisions. Such flexibility is not limited to "broad" licenses issued under the provisions of 10 CFR Part 33.

A large program may have any or all of the following characteristics:

1. In-house calibration of radiation survey, monitoring, and measurement instruments.

2. The use of multiple chemical and physical forms of multiple radionuclides for various purposes.

3. Program flexibility with regard to the use of radionuclides, their chemical and physical form, and the uses to be made of such radionuclides.

4. The need for accurate detection, identification, and measurement of radioactivity in various types of effluents (gas, liquid, solid) containing varying amounts of different radionuclides and for evaluation of these effluents against Commission regulatory requirements and limitations.

5. The need for radioactive effluent treatment by filtration, absorption, adsorption, holdup, etc.

6. The need for the selection, evaluation, design, fabrication, maintenance, and use of radioactive effluent treatment systems.

7. The need for the selection, evaluation, and maintenance of radiation measurement and analysis equipment.

8. A potential for the contamination of facilities, equipment, and personnel accompanied by the need to control such contamination (including airborne contamination), decontaminate personnel and equipment, and evaluate

possible internal dose (including determination of the need for bioassays and interpretation of bioassay results).

9. The need for emergency planning.

10. The need for the selection, evaluation, maintenance, and use of respiratory protective equipment.

11. The need for the selection, maintenance, evaluation, and use of protective clothing.

12. The need for the selection, evaluation, design, fabrication, maintenance, and testing of process control and confinement systems such as gloveboxes and hoods.

13. The need for the selection, evaluation, design, maintenance, and testing of sealed radiation sources and the devices in which they are to be used.

14. The need for the evaluation, selection, design, fabrication, maintenance, and use of facilities and equipment for the collection, treatment, packaging, and disposal of radioactive waste and for developing related radiation safety procedures.

15. The need for training all personnel who will work with or be exposed to radioactive material or its radiation.

16. The need for monitoring, measuring, and evaluating radiation levels associated with all phases of the receipt, use, and disposal of radioactive materials.

17. The need for controlling the ordering, receipt, distribution, and disposal of all radioactive materials.

18. The need for maintaining records necessary for compliance with Commission regulations and license conditions.

19. The need for selecting, evaluating, distributing, and maintaining personnel monitoring devices and interpreting monitoring results from them.

20. The need for continual overall surveillance of the radiological health aspects of the use of radioactive materials, including the analysis and reporting of surveillance results to appropriate management.

21. The need for written, formalized rules, instructions, and procedures for procurement, disposal, and safe handling of radioactive materials.

22. The need for evaluating, from a radiation safety standpoint, proposed work with radioactive materials in accordance with an established review process.

23. The need for determining the adequacy, from a radiation safety standpoint, of the training and experience of individuals proposing to work with radioactive materials.

24. The need for effective communication to public and private groups of the implications of the proposed use of radioactive materials and the licensee's radiation safety program.

25. The need for proper packaging and transport of radioactive materials.

The RSO in a large program will need a basic technical knowledge sufficient to understand, in general, the majority of the work being done with radioactive materials under his or her responsibility. However, every RSO cannot be an expert in every field that may be associated with the creation or solution of radiation safety problems. It will be necessary, in many instances, for the RSO to consult experts in such specific fields as criticality control, bioassay, and biochemistry to supplement his or her own knowledge and ability. It is important that the RSO have a background of training and experience and

a maturity of judgment sufficient to recognize the need for expert assistance at an early stage in the development of potential radiation safety problems involving disciplines outside his or her area of expertise.

Also, it is apparent that the effectiveness of an RSO is highly dependent upon the effectiveness of his or her communication with those working with radioactive materials, those working directly for the RSO, and upper-level management. The last group may well be the most important since the value of the RSO's radiation safety assessments and recommendations will be realized only if implemented with the full support of upper-level management.

The RSO should be supported by adequate staff, facilities, and equipment and should hold a position within the licensee's organizational structure providing direct access to the licensee's upper-level management.

C. REGULATORY POSITION

The scope and depth of training and experience of any individual responsible for a radiation safety program under a Commission license should be commensurate with the duties and responsibilities of the position.

The possession of professional standing, a rich background of knowledge and experience, and peer-group recognition of an individual are not necessarily sufficient for every situation. It is important that a person being proposed as an RSO for a particular program have a background of successful experience in a radiation safety program (or programs) similar to that for which he or she is being proposed. It is not necessary that an individual gain experience in a large program, but, nevertheless, the experience should be derived from work in a program (or programs) in which the work with radioactive materials and the radiation safety problems are similar in kind and scope to those in the program for which he or she is being considered as an RSO. The applicant's RSO candidate should have the knowledge and ability necessary to respond effectively to the radiation safety needs of the applicant's program and should possess the characteristics identified in Appendix A to this guide that are applicable to the program.

A radiation safety officer under a Type A broad license (see § 33.13 of 10 CFR Part 33) or comparable limited specific license (issued under 10 CFR Part 30, Part 40, or Part 70) will be considered to possess the characteristics in Appendix A applicable to the licensee's program if the RSO possesses one of the combinations of training and experience in Table 1.

Table 1

COMBINATIONS OF TRAINING AND EXPERIENCE FOR A RADIATION SAFETY OFFICER

	Formal Education and Certification		Experience
A.	Bachelor's degree in health physics or radiological health.	A.	Four years of applied health physics experience in a program with radiation safety problems similar to those in the program to be managed.
B.	Bachelor's degree in a physical science or a biological science with a physical science minor, and one year of graduate work in health physics.	B.	Same as above
C.	Master's degree in health physics or radiological health.	C.	Three years of applied health physics experience in a program with radiation safety problems similar to those in the program to be managed.
D.	Doctor's degree in health physics or radiological health.	D.	Two years of applied health physics experience in a program with radiation safety problems similar to those in the program to be managed.
E.	Comprehensive certification by the American Board of Health Physics.	E.	Same as above

If the applicant believes that a person who does not meet any of the training and experience combinations in Table 1 is qualified to act as the radiation safety officer in its program, the applicant may submit a description of the training and experience of the person in question with supporting justification for using the individual as the radiation safety officer and relating the specific qualifications of the individual to the demands of the position. In doing so, the applicant should consider each of the characteristics listed in Appendix A and specifically demonstrate that the candidate radiation safety officer possesses the characteristics applicable to its program. In addition, should the applicant feel that any of the criteria of Appendix A are not applicable to its program, the basis for its position regarding each such characteristic should be explained.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants regarding the NRC staff's plans for using this regulatory guide.

This guide has been released to encourage public participation in its development. Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method to be described in the active guide reflecting public comments will be used in the evaluation of license applications docketed after the implementation date to be specified in the active guide. Implementation by the NRC staff will in no case be earlier than six months following publication of this draft guide.

After the issuance of the active guide, the NRC staff intends to recommend that all affected licensees consider modifying their basis for selection of a radiation safety officer so that it is consistent with the recommendations contained in the guide.

APPENDIX A

CHARACTERISTICS FOR QUALIFYING A RADIATION SAFETY OFFICER CANDIDATE

1. Ability to communicate clearly, both verbally and in writing.

2. Knowledge of mathematics, physics, chemistry, and biology sufficient to understand health protection standards, theories, and practices.

3. Knowledge of current standards, guides, and reports published by various organizations (e.g., the International Commission on Radiological Protection; the National Council on Radiation Protection and Measurements; the United Nations Scientific Committee on the Effects of Atomic Radiation; the National Academy of Sciences, National Research Council Advisory Committee on the Biological Effects of Ionizing Radiations; and the American National Standards Institute) and the ability to understand, interpret, and effectively apply them.

4. Knowledge of applicable NRC regulations, regulatory guides, and NUREG-series reports and ability to understand and effectively apply them.

5. Knowledge and ability sufficient to operate instruments used in the program for measuring radiation and radioactive materials and to interpret the resulting measurements.

6. Knowledge and ability sufficient to perform calibrations of instruments used in the program for measuring radiation and radioactive materials.

7. Knowledge and ability sufficient to select radiation and radioactive materials measuring instruments appropriate to their proposed use in the program.

8. Knowledge and ability sufficient to evaluate the need for shielding and to determine the types and amounts of shielding required.

9. Knowledge and ability sufficient to calculate radioactive decay, buildup, and secular and transient equilibrium.

10. Knowledge and ability sufficient to calculate internal and external radiation doses.

11. Knowledge of personnel monitoring devices and the ability to select the proper device for a specific application.

12. Knowledge and ability sufficient to manage or conduct a radiation protection training program for facility personnel.

13. Knowledge and ability sufficient to recognize and anticipate existing and potential radiation safety problems.

14. Knowledge and ability sufficient to recognize potential criticality problems and to take appropriate and timely action with respect to such problems.

15. Knowledge of current radioactive effluent treatment methods, equipment, and procedures and ability to effectively use them.

16. Knowledge and ability sufficient to recognize the potential for contamination associated with work with radioactive materials, to control contamination, and to decontaminate equipment, facilities, and personnel.

17. Knowledge and ability sufficient to prepare a facility emergency plan and to conduct or manage the conduct of operations in accordance with the plan.

18. Knowledge and ability sufficient to evaluate, select, and maintain and effectively use and supervise the use of respiratory protective equipment.

19. Knowledge and ability sufficient to evaluate, select, and maintain and effectively use and supervise the use of protective clothing.

20. Knowledge and ability sufficient to evaluate, design, test, maintain, and supervise the maintenance (from the radiation safety standpoint) of process control and confinement systems such as gloveboxes and hoods.

21. Knowledge and ability sufficient to evaluate, select, design, maintain, and test sealed sources of radiation and devices in which the sources are to be used.

22. Knowledge and ability sufficient to evaluate, select, and design and effectively use, maintain, and supervise the use and maintenance of radioactive waste collection, treatment, packaging, and disposal equipment and facilities and to prepare related radiation safety procedures.

23. Working knowledge of transport regulations and requirements as they apply to the transport of radioactive materials.

24. Knowledge and ability sufficient to conduct a bioassay program.

25. Knowledge and ability (including a maturity of judgment developed from appropriate radiation safety program experience in work situations similar to that of the program for which he or she is a candidate radiation safety officer) sufficient to manage effectively the applicant's radiation safety program.

DRAFT VALUE/IMPACT STATEMENT

1. THE PROPOSED ACTION

1.1 Description

Large-scale radionuclide programs, such as Type A broad license programs, licensed by the NRC are conducted under the guidance of an individual or individuals assigned the responsibility by management to ensure that operating personnel adhere to good radiation safety practices and radiation safety regulations. Such persons have various titles such as "Radiological Safety Officer" and "Radiation Safety Officer" (RSO).

The proposed action will provide guidance on qualifications (training and experience) acceptable to the NRC staff for such individuals.

1.2 Need

Commission regulations require, and license application forms request descriptions of, radiation protection provisions, including qualified RSOs. With the exception of nuclear power plants, guidance relating RSO qualifications to the characteristics of large-scale programs licensed by NRC has not been published. However, the review of license applications has established the need for guidance in this area.

Although applicants may be aware of the need for appropriately qualified individuals to manage their radiation safety programs, many applicants do not know what the NRC considers appropriate training and experience for qualified RSOs who manage a program such as one that might be conducted under a Type A broad license. Hence, a great deal of time and effort is being consumed in corresponding with individual applicants about this matter.

1.3 Value/Impact

1.3.1 NRC

The proposed action should improve applicant-NRC communications and the overall effectiveness of both the applicant and the application reviewer by

providing guidance for determining the acceptability of individuals as RSOs for large-scale non-fuel-cycle programs.

Use of this guidance should significantly reduce the time and effort expended by NMSS in reviewing applications and corresponding with applicants.

1.3.2 Other Government Agencies

A significant value/impact will not accrue to any other Federal agency, unless that agency happens to be an applicant. A definite benefit will accrue to Agreement States that adapt the guide to their own use.

1.3.3 Industry

The availability of guidance with respect to RSO qualifications should result in greater uniformity in the review of license applications and the expenditure of less time and effort by applicants in meeting licensing requirements and in selecting individuals to serve as RSOs. Any changes in health physics programs resulting from the publication of the guidance would most probably be in the direction of upgrading their quality. Such upgrading may result in increased costs to the applicant. However, it is expected that such costs would be offset by improvements in health physics programs resulting in reductions in exposure to radiation and radioactive materials.

Educational institutions and professional groups that participate in the training of individuals who are to serve as RSOs or that establish RSO qualification standards may also benefit from use of the guidance.

1.3.4 Public

No significant direct impact on the public is foreseen. A likely benefit is the reduction in occupational exposures and effluent releases brought about through the knowledge of better qualified RSOs.

1.4 Decision

It is concluded that guidance should be furnished on acceptable training and experience for RSOs within large-scale non-fuel-cycle programs.

2. TECHNICAL APPROACH

2.1 Technical Alternatives

No reasonable technical alternatives to the recommended action were identified.

3. PROCEDURAL APPROACH

3.1 Procedural Alternatives

RES procedures that may be used to effect the proposed action include publication of:

1. A regulation
2. A regulatory guide
3. An ANSI Standard, endorsed by a regulatory guide
4. A branch position
5. A NUREG-series report
6. Guidance on RSO qualifications included in existing and future guides pertaining to licensing of various types of programs.

3.2 Discussion of Procedural Alternatives

A NUREG-series report is not a viable alternative since the guidance will include position statements. ANSI is not developing a standard on the subject, and, because of the time (more than 3 years) normally required for completion of an ANSI standard, this alternative is not considered acceptable. The matter does not seem to be of sufficient importance to justify issuance of a regulation. A branch position may be a viable alternative, but lacks the desired impact.

The most effective form for publishing the guidance is a regulatory guide or guides. The insertion of piecemeal guidance into existing guides, guides in process, and future guides would tend to confuse the applicant and delay guides presently in preparation. A single, new guide incorporating guidance

with respect to qualifications for an RSO responsible for large-scale programs will present all pertinent information in one document, thereby avoiding confusion. In addition, preparation of a single, separate guide will be more efficient from the standpoint of accommodating comments in the internal NRC review and concurrence process than would several guide revisions. A guide will also provide a mechanism for public review and comment.

3.3 Decision on Procedural Approach

A regulatory guide should be prepared.

4. STATUTORY CONSIDERATIONS

4.1 NRC Authority

The Commission's authority to issue this guide is derived from the Atomic Energy Act of 1954, as amended, through the Commission's regulations.

4.2 Need for NEPA Assessment

The proposed action is not a major action as defined by paragraph 51.5(a)(10) of 10 CFR Part 51 and does not require an environmental impact statement.

5. RELATIONSHIP TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

This action will result in a guide that will supplement other guides related to radiation safety. When this guide is completed, appropriate revision of existing and in-process guides affected by the guidance will be made.

6. SUMMARY AND CONCLUSIONS

A regulatory guide on RSO qualifications for large-scale non-fuel-cycle programs should be prepared and issued.

119406002001 1 QPSAS8
US NRC REGION I
R J BORES
631 PARK AVENUE
REGION I
KING OF PRUSSIA PA 19406