PART I

RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

Sec. I.1 - Purpose and Scope.

a. This Part establishes procedures for the registration [or licensing] and the use of particle accelerators.

b. In addition to the requirements of this Part, all registrants [or licensees] are subject to the requirements of Parts A, B, [C,] D, and J of these regulations. Registrants [and licensees] engaged in industrial radiographic operations are subject to the requirements of Part E of these regulations, and registrants [and licensees] engaged in the healing arts are subject to the requirements of Parts F and G of these regulations. Registrants [or licensees] whose operations result in the production of radioactive material are subject to the requirements of Part C of these regulations.

Registration [or License] Procedure

Sec. I.2 - Registration [or License] Requirements. No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration [or license] issued pursuant to Part[s] B [or C] of these regulations.

Sec. I.3 - General Requirements for the Issuance of a Registration [or License] for Particle Accelerators. In addition to the requirements of Part[s] B [or C] of these regulations, a registration [or license] application for use of a particle accelerator will be approved only if the Agency determines that:

a. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this Part and Parts D and J of these regulations in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

c. The issuance of the registration [or license] will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in Section I.4;

d. The applicant has appointed a radiation safety officer;

e. The applicant and the applicant's staff has substantial experience in the use of particle accelerators and training sufficient for application to its intended uses;

f. The applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the Agency; and

g. The applicant has an adequate training program for operators of particle accelerators.

Sec. I.4 - Human Use of Particle Accelerators. In addition to the requirements of Part B of these regulations, a registration [or license] for use of a particle accelerator in the healing arts will be issued only if:

a. The applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator whenever deemed necessary by the Agency. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation;

b. The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and

c. The individual designated on the application as the user is a physician.

Radiation Safety Requirements for the Use of Particle Accelerators

Sec. I.5 - Reserved.

Sec. I.6 - Limitations.

a. No registrant [or licensee] shall permit any individual to act as an operator of a particle accelerator until such individual:

   i. Has been instructed in radiation safety and shall have demonstrated an understanding thereof;

   ii. Has received copies of and instruction in this Part and the applicable requirements of Parts D and J of these regulations, pertinent registration [or license] conditions and the registrant's [or licensee's] operating and emergency procedures, and shall have demonstrated understanding thereof; and

   iii. Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

b. The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is

c. deemed necessary to minimize danger to public health and safety or property.

Sec. I.7 - Shielding and Safety Design Requirements.

a. A qualified expert, acceptable to the Agency, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

b. Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with Sections D.101 and D.105 of these regulations.

Sec. I.8 - Particle Accelerator Controls and Interlock Systems.

a. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

b. Each entrance into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.

c. Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.

d. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

e. When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.

f. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

Sec. I.9 - Warning Devices.

a. Each location designated as high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

b. Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas.

c. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with Section D.203 of these regulations.

Sec. I.10 - Operating Procedures.

a. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

b. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

c. All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the Agency.

d. Electrical circuit diagrams of the accelerator and the associated safety interlock systems shall be kept current and maintained for inspection by the Agency and shall be available to the operator at each accelerator facility.

e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

   i. Authorized by the radiation safety committee or radiation safety officer;

   ii. Recorded in a permanent log and a notice posted at the accelerator control console; and

   iii. Terminated as soon as possible.

f. A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

Sec. I.11 - Radiation Monitoring Requirements.

a. There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been appropriately calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and repair.

b. A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the Agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

c. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring

d. devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

e. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

f. Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.

g. Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.

h. All surveys shall be made in accordance with the written procedures established by a qualified expert, acceptable to the Agency, or the radiation safety officer.

i. Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the Agency.

Sec. I.12 - Ventilation Systems.

a. Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Part D, Appendix A, Table I of these regulations.

b. A registrant [or licensee], as required by Section D.106 of these regulations, shall not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in Part D, Appendix A, Table II of these regulations, except as authorized pursuant to Section D.302 or Paragraph D.106b. of these regulations. For purposes of Paragraph I.12b., concentrations may be averaged over a period not greater than one year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.

1988
Rationale for Revisions

Part I
Radiation Safety Requirements for Particle Accelerators

There were no major amendments to Part I for this edition of Volume I (Ionizing Radiation) of the Suggested State Regulations for Control of Radiation (SSRCR). The Technical Review Committee made some editorial changes to Part I for consistency with regulatory language and with the other Parts of the SSRCR (e.g., revision of certain provisions with "and/or" as part of the sentence structure).

Matters for Future Consideration

1. Specifications should be provided for the frequency, accuracy, precision, and traceability of calibrations.

2. In reference to Paragraph I.8(c), whether both the interlocks and their indicators of status should be required to be on the same independent circuits should be reviewed and appropriate changes made.

1982
Rationale for Revisions

Part I
Radiation Safety Requirements for Particle Accelerators

Introduction

Since publishing of the 1978 revision of the Suggested State Regulations for Control of Radiation (SSRCR), several comments were received requiring consideration for amendment. Additionally, several editorial amendments were made to clarify the intent of the regulation.

Specific Changes

1. Reference to Part C was included in brackets in the second line of Paragraph I.1(b), the third line of Section I.2, and third line of Section I.3 to be consistent with the use of the terms license or licensee in brackets.

2. The insertion of the word "safety" in front of the word "interlock" was included to clarify which interlocks were being referenced.

3. The words "acceptable to" have been inserted, replacing the phrase "specifically approved by" to preclude unnecessary documentation of authorizations as to who is a qualified expert.

Specific Provisions

I.1(b) Purpose and Scope. The last sentence was amended by the substitution of the phrase "whose operations result" for the word "engaged" clarifying that licensing may be required where radioactive material may have been produced incidental to the main purpose of use.

I.5 General Provisions (1978 SSRCR). This item was deleted in its entirety as being non-substantive when considered in context of the other Parts of the SSRCR and Paragraph I.1(b). The item is held "reserved" for future use and to denote an intentional deletion.

I.6(b) Limitations. The phrase "protect health and" was deleted as superfluous and to make the language consistent with the other Parts of the SSRCR.

I.9 Warning Devices. The requirement for "flashing or rotating" warning lights in Paragraph I.9(a) has been deleted to be consistent with other Parts of the SSRCR. The requirement of Paragraph I.9(b) to be discernible in "all radiation areas" has been deleted to be consistent with other Parts of the SSRCR.

I.11 Radiation Monitoring Requirements. The requirements of Paragraph I.11(c) have been revised to be consistent with Section I.9 and other Parts of the SSRCR. The language of Paragraph I.11(h) was modified to be consistent with the other Parts of the SSRCR regarding inspection of records by the Agency.

I.12(b) Ventilation Systems. The word "uncontrolled" was replaced by the word "unrestricted" due to the presence of a definition for the term in Part A and for consistency with other Parts of the SSRCR. Also, the ALARA phraseology was used rather than the ALAP terminology used in the past.

Matters for Future Consideration

1. Specifications should be provided for the frequency, accuracy, precision, and traceability of calibrations.

2. In reference to Paragraph I.8(d) in the 1978 SSRCR (Paragraph I.8(c) in the 1982 SSRCR), whether both the interlocks and their indicators of status should be required to be on the same independent circuits should be reviewed and appropriate changes made. There was inadequate time available for consideration of necessary changes to implement this comment for the 1982 SSRCR.

1978
Rationale for Revisions

Part I
Radiation Safety Requirements for Particle Accelerators

Introduction

A number of editorial and format changes were made in Part I to be consistent with other Parts of the Suggested State Regulations for Control of Radiation (SSRCR). The other specific changes from Part I of the 1974 SSRCR and their rationale are as indicated below.

Specific Provisions

I.3(b) General Requirements for the Issuance of a Registration. In paragraph (b) of Section I.3, the words "or existing" were added following the word "proposed" to read as follows: "The applicant's proposed or existing equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property". The rationale for this change was included in a comment received which indicated that the facility will predate the regulations in some cases. Therefore, statements about existing facilities are needed as well as reference to proposed equipment, facilities, etc.

I.3(e) General Requirements for the Issuance of a Registration. In paragraph (e) of Section I.3, the phrase "and training sufficient for application to its" was added after the words "particle accelerators" to read as follows: "The applicant and/or the applicant's staff has substantial experience in the use of particle accelerators and training sufficient for application to its intended uses." The rationale for this change is based on a concern expressed by a commenter that requiring "substantial experience in the use of particle accelerators for the intended uses" (emphasis added) could prevent the development of new facilities or new applications. With the rewording of this paragraph, training would be required for the intended uses; however, the particle accelerator experience required would not need to be specific for the intended use and could be obtained generally in other areas. Therefore, with specific particle accelerator training in the intended use area, a registration could be issued whereby personnel could obtain experience in that use area on the job as long as they had other substantial particle accelerator experience. This revised approach then should not tend to hinder development of new applications of particle accelerators.

I.10(b) Operating Procedures. In paragraph (b) of Section I.10, the following sentence was deleted: "Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam on and off." The rationale for deletion of this first sentence is that it is unduly restrictive and appears to prohibit beam turn on and turn off by users or by data-taking computers, which are normal modes of operation for research accelerators. As pointed out by a commenter, the meaning of this paragraph is adequately given by the second sentence alone which remains as the entire paragraph in the revision as follows: "The safety interlock system shall not be used to turn off the accelerator beam except in an emergency."

I.11(d) Radiation Monitoring Requirements. In paragraph (d) of Section I.11, the word "quarterly" has been replaced by the phrase "at intervals not to exceed one year and after each servicing and repair". Paragraph (d) now reads as follows: "All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair." The rationale for this change is based on experience which indicates that the permanently installed area monitors are generally more reliable than portable monitoring equipment and do not necessarily require calibration on a quarterly basis. Annual calibration of area monitoring equipment at particle accelerator facilities appears to be adequate.

I.12(a) Ventilation Systems. In paragraph (a) of Section I.12, the provision from the 1974 SSRCR was deleted and the following new sentence was included as a replacement: "Means shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Part D, Appendix A, Table I of these regulations." The rationale for this change is that there are other acceptable and commonly used methods of handling airborne radioactive material. Ventilation may be required if personnel are to be entering the area. However, in other situations, it may be preferable to seal and isolate the area in which the activity is present for some time after its production. This practice can be employed when the dominant activities are short lived. The new provision has been qualified by indicating that it refers to situations where personnel may be entering the area. In addition, more flexibility is allowed by reference to keeping exposure of personnel to airborne radioactive material within limits of Part D, without specifying the exact methods which must be used.

Matters for Future Consideration

1. In the next revision of the SSRCR, it is suggested that the Part I Working Group include in Section I.4 a reference to Section F.9 on X-Ray and Electron Therapy Systems with Energies of One MeV and Above.

2. It is suggested that the Working Groups for Part I and Part A consider the possibility of defining the term "calibration" as used in Paragraph I.11(h) and other provisions for inclusion in the next revision of the SSRCR.

3. The Working Groups for Part I, Part A, and Part F should consider developing a definition of "interlock" related to its use in Part I (e.g., Sections I.8 and I.10), Part F, and in other Parts for the next revision of the SSRCR (Note definition of "interlock" in Section F.2 of this revision of the SSRCR).

1974
Rationale for Revisions

Part I
Radiation Safety Requirements for Particle Accelerators

Introduction

It has been estimated that there are over 1,200 particle accelerators in use in the United States. These machines are employed for a variety of purposes, including radiation therapy, production of radionuclides, teaching, and research. Several hundred particle accelerators are being used for medical purposes and are becoming increasingly popular in medicine. A particular type of accelerator, the "Linac," is gaining widespread acceptance in medical therapy, and is therefore increasing in number.

Two particular aspects of the present situation are especially important in evaluation of the hazards associated with particle accelerators. First, many of these machines are capable of producing extremely high levels of radiation, and therefore, if a radiation accident occurs, injuries may be quite severe. Second, particle accelerators have advanced to the stage where they are no longer confined to research applications. Small units for industrial and medical use are now commercially available to persons whose technical background may not equip them to properly assess the hazards associated with their operation.

Due to the great variety of particle accelerators in existence, their complexity and the vast spectrum of uses for which they are employed, maintaining radiation safety at these facilities is a particularly difficult task. In addition, a single machine may be used for a variety of purposes such as research, teaching, and therapy. Regulations governing the design and operation of particle accelerators must therefore be sufficiently broad in scope to include the variety of types and uses of these machines, yet sufficiently specific to insure radiation safety.

General Approach

The following approach has been applied in attempting to deal with the above situation:

1. Registration of particle accelerator facilities. The registration mechanism will enable state radiation control authorities to assess the qualifications of individuals seeking to operate particle accelerators.

2. Registration requirements for specific uses. Individuals seeking to operate particle accelerators for a specific use such as medical therapy are subject to additional requirements necessitated by the special hazards associated with this activity.

3. Design requirements. General requirements for shielding, interlocks and warning devices are outlined. Responsibility for application of these requirements to specific situations rests with the state radiation control authority.

4. Operating procedure requirements. General requirements for operating procedures, including radiation surveys and maintenance of monitoring equipment are stated. An effort has been made to simplify the document by referring to other Parts of the Suggested State Regulations for Control of Radiation (SSRCR). This is necessary because provisions dealing with such areas as registration procedures, records and violations must be uniform throughout the regulations. References to these other Parts are included at points in the document where they apply.

Specific Provisions

I.1 Purpose and Scope. The definition of the term "particle accelerator" is included in Part A with other definitions of relevance to the regulations. The definition is intended to exclude medical diagnostic x-ray units from the scope of this Part. It should be noted that users of particle accelerators for production of radioactive material must apply for a radioactive material license in accordance with Part C. Additional requirements such as detailed operating procedures and qualifications were not deemed possible or appropriate.

I.2 Registration Requirements. The intent here is that users or those responsible for the operation of particle accelerators be registered with the appropriate state radiation control authority. The procedures for the registration of particle accelerator facilities are included in Part B, as particle accelerators are considered radiation machines. Provisions dealing with exemptions, expirations, renewals and changes are included in Part A and/or Part B.

I.3 General Requirements for Registration. Particle accelerators are now commercially available to persons whose background may not equip them to properly assess the hazards associated with these units. Therefore, general requirements are designated on use of these radiation machines.

I.4 Human Use of Particle Accelerators. Individuals designated as users of particle accelerators on humans are required to have substantial training and experience in deep therapy techniques or in their use to treat humans. Also, a particle accelerator facility intended for use in the healing arts normally should maintain individuals with relatively divergent backgrounds in fields such as engineering, physical sciences and medicine c its staff. In order to insure proper use of a facility when humans are deliberately exposed to radiation all programs must be evaluated by a medical committee, as determined necessary by the Agency.

I.6 Limitations. Additional requirements concerning posting of written operating and emergency instructions are stated in Section I.11.

I.7 Shielding and Safety Design Requirements. It would have been desirable to include equipment specifications similar to those stated for therapeutic x-ray units and teletherapy equipment. However, due to

the variety of particle accelerators, their complexity and the vast spectrum of uses for which they are employed, this is not possible.

I.8 Particle Accelerator Controls and Interlock Systems. The American National Standards Institute's (ANSI) definition of an interlock as "a device which shuts down a machine under conditions of system malfunction or barrier penetration" applies to this section. Interlocks provided at entrances to target room areas are required to shut down the machine under conditions of barrier penetration. They should be such as to prevent entrance when high radiation intensities are present in these areas.

I.8(c) Particle Accelerator Controls and Interlock Systems. The intent of Paragraph (c) of this Section is to prevent immediate production of radiation when an interlock to a high radiation area has been tripped. When an individual must return to the main control console to resume operation he is removed from the hazardous area.

I.8(d) Particle Accelerator Controls and Interlock Systems. The intent of Paragraph (d) is to prevent a malfunction in one interlock from interfering with the operation of another. A scram button or emergency cutoff switch is required in all high radiation areas, and the accelerator cannot be restarted without resetting this switch.

I.10 Operating Procedures. Because the operating and safety systems must interface at some point it is impossible to keep them totally separate. However, operators should not use the safety system for routinely turning the machine on and off. It is not necessary that a state agency be notified every time a safety interlock is intentionally bypassed. However, such procedures should be authorized by the radiation safety committee and/or radiation safety officer and recorded in the log. State radiation control authorities will be able to assess the safety of such procedures during inspections.

I.11 Radiation Monitoring Requirements. Yearly calibration of portable monitoring equipment and quarterly calibration of area monitoring equipment is required. These calibrations should be sufficiently accurate to insure adequate personnel protection. The intent was to make the Paragraph I.11(c) provision rather rigorous.