2003
RATIONALE FOR REVISIONS

PART D
STANDARDS FOR PROTECTION AGAINST RADIATION

Introduction

This revision to Part D incorporates changes of the revised Part 20 into the *Suggested State Regulations for Control of Radiation.* An accompanying revision to Part A incorporates many of the definitions to Part 20 into the *Suggested State Regulations for Control of Radiation.* Definitions have been added, deleted or amended in Part D to be consistent with the revised Part A where the new or revised terms were used throughout the regulations. Part J was amended to be consistent with the revised 10 CFR Part 19.

Compatibility Requirements

Most of the changes to Part D are compatibility requirements. Compatibility requirements are in an attachment following the draft Parts. The following changes are addressed in this particular update:
60 FR 15649 (Low-Level Waste Shipment Manifest Information & Reporting) eff. date 3/1/98
60 FR 36038 (Radiation Protection Requirements Amended Definitions & Criteria) eff. date 8/14/95
60 FR 48623 (Medical Administration of Radiation & Radioactive Materials) eff. 10/20/95
60 FR 7900 (Freq. of Medical Examination for Use of Respiratory Protection Equip.) eff. date 3/13/95
60 FR 20183 (Standards for Protection Against Radiation; Clarification) eff. date of 4/25/95
61 FR 24669 (Term./Transfer of Licensed Activities: Recordkeeping Requirements) eff. date 6/17/96
61 FR 65120 (Clean Air Act/Resolution of Dual Regulation) eff. date 1/9/97
62 FR 4120 (Criteria for Release of Individuals Administered Radioactive Material) eff. date 5/29/97
62 FR 39058 (Radiological Criteria for license Termination) eff. date 8/20/97
63 FR 39477 (Minor corrections/clarifying changes/minor policy change) eff. date 10/26/98
63 FR 45393 (Minor corrections/clarifying changes/minor policy change) eff. date 10/26/98
63 FR 50127 (Transfer Disposal & Manifests) eff. date 11/20/98
64 FR 54543 (Respiratory Protection & Controls to Restrict Internal Exposure) eff. date 2/2/03
64 FR 55525 (Respiratory Protection & Controls to Restrict Internal Exposure) eff. date 2/2/03

General Provisions

The working group discussed and agreed to renumber the entire Part D to be consistent with all applicable Parts in 10 CFR 20.

In addition to the re-numbering, the following proposed changes are being submitted for review:

D.1001.b. (formerly D.1.b), "in an emergency" was deleted in the last line in order to be consistent with revised 10 CFR 20.1001b.

D.1002 (formerly D.2): language was added to be consistent with 10 CFR 20 after the Release of Patients Administered Radioactive Material change.

D.1003 (formerly D.3):

"Constraint": New definition to be consistent with 10 CFR 20.
"Declared Pregnant Woman": revised to be consistent with 10 CFR 20.
"Dosimetry Processor": revised to be consistent with 10 CFR 20.
"Planned Special Exposure": revised to be consistent with 10 CFR 20.
"Respiratory Protective Device": revised to be consistent with 10 CFR 20.
"Very High Radiation Area": revised to be consistent with 10 CFR 20.

D.1001.b & d (formerly D.101): revised to be consistent with 10 CFR 20.1001

D.1201 (formerly D.201): revised to be consistent with 10 CFR 20.1201

D.1203 (formerly D.203): revised to be consistent with 10 CFR 20.1203

D.1206 (formerly D.206): revised to be consistent with 10 CFR 20.1206

D.1208 (formerly D.208): revised to be consistent with 10 CFR 20.1208

D.1301 (formerly D.301): revised to be consistent with 10 CFR 20.1301

D.1501 (formerly D.501): revised to be consistent with 10 CFR 20.1501

D.1502 (formerly D.502): revised to be consistent with 10 CFR 20.1502

D.1503 (formerly D.503): revised to be consistent with 10 CFR 20.1503

D.1701 (formerly D.701): revised to be consistent with 10 CFR 20.1701

D.1702 (formerly D.702): revised to be consistent with 10 CFR 20.1702

D.1703 (formerly D.703): revised to be consistent with 10 CFR 20.1703

D.1704 (formerly D.704): revised to be consistent with 10 CFR 20.1704

D.1705 (formerly D.705): revised to be consistent with 10 CFR 20.1705

D.1902c (formerly D.902c): revised to allow the words "Grave Danger" to be omitted.

D.1903 (formerly D.903): revised to be consistent with 10 CFR 20.1903

D.2006 (formerly D.1006): revised to be consistent with 10 CFR 20.2006

D.2007 (formerly D.1007): revised to be consistent with 10 CFR 20.2007

D.2101 (formerly D.1101): revised to be consistent with 10 CFR 20.2101

D.2104 (formerly D.1104): removed potential requirement for transfer of records to the Agency.

D.2104 (formerly D.205): revised to be consistent with 10 CFR 20.2104

D.2106 (formerly D.1106): revised to be consistent with 10 CFR 20.2101

D.2202 (formerly D.1202): revised to be consistent with 10 CFR 20.2202

D.2203 (formerly D.1203): revised to be consistent with 10 CFR 20.2203

D.2205 (formerly D.1205): revised to be consistent with 10 CFR 20.2205

D.2208 (formerly D.1208): the working group wanted to make the distinction between working days and calendar days as implied.

APPENDIX A: revised to be consistent with 10 CFR Appendix A

APPENDIX C: revised quantity of C-14 requiring labeling to be consistent with 10 CFR Appendix C

APPENDIX D: deleted when Appendix G became final in 1998.

APPENDIX E: moved to become an attachment to Appendix G

APPENDIX F: deleted when decommissioning rule became final

APPENDIX G: new appendix to be consistent with 10 CFR Appendix G

Matters for Future Consideration

1. The Working Group is considering changing the definition of calendar quarter as follows: "Calendar quarter means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him for determining calendar quarters except at the beginning of a year." The change needed is to allow licensees or registrants to begin their year at times other than January as is allowed by the Nuclear Regulatory Commission's definition of "quarter." Note: The term quarter is used with residential quarters in the SSRCR.

2. The Working Group (WG) is considering changing the 0.3 multiplicative factor in the version of D.1201c.ii.(2), which may be higher than necessary, to 0.2, which might be more appropriate, pending recommendations of the National Council on Radiation Protection (NCRP) and Measurements. The WG is also looking at revising the 25% criterion to a value more usable and meaningful by the licensee after reviewing any recommendations from NCRP.

3. The Working Group is considering the selection of an attenuation factor for use for pregnant fluoroscopists, for use in D.1208.

4. The Working Group is considering a method for monitoring personnel eye doses when protective eyewear is worn for use in D.1201.

5. In reference to D.1501c. on accreditation of dosimetry processors by the National Voluntary Laboratory Accreditation Program, the Working Group is considering the matters regarding accident-level accreditation, electronic dosimetry and revising the text to eliminate pocket dosimeters per the previous version of the SSR.

6. The Working Group is considering clarifying the expression "proper visual, communication, and other special capabilities" in D.1703a.vi.

7. The Working Group is considering revising D.2201a. as follows:

a. Telephone Reports. Each licensee or registrant shall report to the Agency by telephone each stolen, lost, or missing source of radiation immediately after its absence becomes known to the licensee or registrant. This requirement does not apply to sources of radiation that are not required to be licensed or registered.

8. The Working Group recommended that specific information required in the report of lost waste shipments in Section III.(e)(2) of Appendix D should be developed.

9. The Working Group is considering removing the bracketed section in D.1202.b.iii to remain consistent with 10 CFR 20.1202. This is currently not in 10 CFR 20. This holds a compatibility designation of “A”.

10. The Working Group is considering deleting the wording in D.1801c and adding radiation machines to the list of items a licensee or registrant shall secure from unauthorized removal or access.

11. The Working Group is considering moving sections D.1603 and D.2109 as they pertain only to irradiators and we now have a Part Q, which was written strictly for irradiators. The Group will work closely with the Part Q working group to make this transition.

12. The Working Group is considering amending the decay in storage section (D.2001) to allow decay in storage for any isotope with a half-life of less than 120 days. The WG will work with the SR-6 (Part G) group to combine the decay in storage provision in Part G to that in Part D.

Attachment

Rationale for Proposed Changes to Regulations for Individuals Working in Medical Fluoroscopy
(10/30/92)

Medical fluoroscopic procedures involve exposures of operators and ancillary personnel to scattered x rays and occasionally to primary beam x-rays. Special fluoroscopic procedures are surgical in nature and frequently involve operator irradiation times an order of magnitude larger than routine fluoroscopic procedures. Personnel who perform or assist in fluoroscopic special procedures commonly have collar monitor deep dose equivalent values well in excess of those for routine fluoroscopy, and these annual dose equivalent values are likely to be in excess of 5 rem (0.05 Sv) for full-time angiographers and interventionalists who wear their monitors properly. These values, under the present regulations, cause frequent "overexposure incidents," when in fact the associated effective dose equivalent (H_E) is much lower. *ICRP Publication No. 35* (1982) states:

> In particular, the following advice applies in medical radiology, where the use of lead aprons is common. If a single dosimeter is used it should be worn outside the apron, usually high on the trunk. The recorded result will provide information on the dose equivalent to the skin, eye, and unshielded parts of the body (though not necessarily to the hands) but will overestimate the effective dose equivalent. When the recorded values indicate annual totals approaching dose limits for effective dose equivalent or when realistic estimates of effective dose equivalent are needed as in the optimization of protection, this over-estimation may be unacceptable. Two dosimeters should then be used, one over and one under the protective apron. The interpretation of the combined results will have to depend on the local irradiation conditions and any regulatory requirements.

The proposed changes to the SSRCR presented in D.201c.ii define procedures by which H_E can be determined for special procedures fluoroscopists for whom the current method of overestimating H_E is unacceptable, while excluding personnel who may be working in routine fluoroscopic or radiographic procedures. They also allow the current monitoring system to be used to estimate the eye dose equivalent in D502a.iv(1) and the H_E for routine fluoroscopists in D.201c.ii(1).

Determination of Effective Dose Equivalent for Medical Fluoroscopists

Meinhold has presented the need for reporting personnel doses for external radiation in terms of H_E [Health Physics (1989) 56:4, 570]. Although revisions to 10 CFR Part 20 use the weighting factors recommended by *ICRP Publication No. 26* (1977) and *NCRP Report No. 91* (1987) for the determination of H_E for personnel exposure to internal radiation sources, the Nuclear Regulatory Commission revisions do not yet include the use of the H_E concept for exposure to external radiation sources, because of a lack of "specific recommendations for the use of weighting factors for external dose" [Federal Register (May 21, 1991) 56, 23369]. Nuclear Regulatory Commission regulations apply to exposures from most licensed radioactive sources; but exposures to machine-produced x-rays are not under purview of the Nuclear Regulatory Commission, therefore, such exposures were not explicitly addressed in its rule making for amended Part 20. In the case of the medical fluoroscopy work environment, the situation has been well defined by Faulkner and Harrison in their paper "Estimation of Effective Dose Equivalent to Staff in Diagnostic Radiology." This paper

presents extensive data relating the H_E determined for a Rando phantom "operator" in fluoroscopy as a function of individual monitoring devices worn at unshielded collar and shielded waist locations, for various fluoroscopic peak tube potentials and apron thicknesses [Physics in Medicine and Biology (1988) 33:1, 83-91]. Although these extensive data are determined with the configuration of the x-ray tube over the x-ray table, a related paper by Wøhni and Stranden [Health Physics (36:1,71-73)] allows comparisons between the x-ray tube positioned over and underneath the x-ray table.

The data of Faulkner and Harrison have been further analyzed and reduced by Webster, who has proposed a method of combining data from two individual monitoring devices as a good estimate of H_E [Health Physics (1989) 56:4, 568-9]. This method is given in proposed regulation D.201c.ii(2) for fluoroscopists for whom the recorded deep dose equivalent values indicate annual totals approaching or exceeding the conservative regulation, as recommended by *ICRP Publication No. 35*, quoted above. Specifically, Webster's equation requires the use of deep dose equivalent values for a shielded waist monitor (W) and an unshielded collar monitor (C) to determine H_E with modifying factors which were derived from Faulkner and Harrison's paper:

$H_E = 0.04C + 1.5W.$

The difference between H_E and the "whole body" deep dose equivalent values currently required for fluoroscopists is given as an example. *NCRP Report No. 57* states:

> Exposure of the face and neck will exceed the exposure recorded under the apron by factors between 6 and 25.

Therefore, an unshielded collar badge deep dose equivalent of C equal to 1 rem (0.01 Sv) in one month (a large value for routine fluoroscopists, but not uncommon for special procedures fluoroscopists), would be associated with a shielded waist badge deep dose equivalent of W equal to 40--167 mrem (0.4--1.67 mSv). Using Webster's equation, the H_E for that month is calculated to be

$H_E = 0.04\ (1000) + 1.5\ (40 \text{ to } 167)$ mrem; = 40 + (60 to 250) mrem; = 100 to 290 mrem.

This H_E annualizes to 1.2--3.48 rem (12--34.8 mSv), significantly below the limit of 5 rem (0.05 Sv). The annual dose equivalent to the eye is calculated to be 12 rem (0.12 Sv), also below the limit of 15 rem (0.15 Sv). A fluoroscopist with an annual collar monitor deep dose equivalent of 12 rem (0.12 Sv) would therefore be expected to have an annual H_E of less than 3.5 rem (35 mSv).

It should be noted that wearing two personal monitoring devices has at least two drawbacks, i.e., the individual may confuse wearing the monitors and inconsistently wear them in the same locations[1/]; and the cost of monitors is doubled. Fluoroscopy personnel who perform or assist in routine fluoroscopic or radiographic procedures do not receive doses sufficiently high to warrant the expense and potential confusion of wearing two badges in order to require a more accurate determination of H_E.

[1/] *Color-coding holders is helpful in minimizing this problem; "yellow belly" for the waist badge is reasonably straightforward! Also using two different types of monitors, such as film and TLD, may be helpful.*

Consistent with *ICRP Publication No. 35*, quoted above, D.201c.ii.(1) allows an overestimate of H_E for some fluoroscopists to be determined from one individual monitoring device, because the overestimate is not burdensome. The criterion to allow calculation of H_E based on the unshielded neck monitor by use of a 0.3 multiplication factor in D.201c.ii(1) is set at 25 percent of the dose limit for the purpose of separating personnel who work in special procedures from personnel who work in routine fluoroscopic or radiographic procedures. The proposed methodology is derived from *NCRP Report No. 57* by using the most conservative value and setting W = C/6 in Webster's equation for H_E. H_E then becomes approximately equal to the unshielded collar badge deep dose equivalent multiplied by 0.3. Comparison of this factor with the data presented in the papers of Faulkner and Harrison, and Wøhni and Stranden indicate that this factor is conservatively low; however, the factor of 0.3 is not believed to be burdensome for the following two reasons:

1. When the collar monitor is used to monitor the dose to the lens of the eye, and the annual lens dose equivalent is limited to 15 rem (0.15 Sv), then the annual effective dose equivalent will not exceed 5 rem (0.05 Sv) annually. In this case, the lens dose equivalent becomes the limitation, rather than the effective dose equivalent.

2. The effective dose equivalent may be estimated by a single collar monitor, but a more accurate estimate is made with both the collar and waist monitors. If a more accurate estimate of H_E is desired, this second option should be used. Therefore, until the National Council on Radiation Protection and Measurements provides definitive guidance for determining H_E, this conservative multiplicative factor of 0.3 may be used when a single collar monitor is worn.

Unlike routine fluoroscopists, special procedures fluoroscopists are likely to have annual collar badge values in excess of 5 rem (0.05 Sv) when they wear their monitors according to current regulations. Since the number of individuals who perform or assist in these types of procedures is much smaller than those in routine fluoroscopy, permitting better training and supervision, both the likelihood of confusing two monitors and the excess costs are minimized. Wearing two monitors has the added benefit of concurrently monitoring gonad dose as well as the dose to a potential embryo/fetus. If these data are needed for personnel in this higher-dose work environment, they are readily available. However, it is proposed that wearing two monitors be <u>required</u> only for declared pregnant women in fluoroscopy so that actual <u>measured</u> values underneath the apron are documented, rather than coarse estimates [D502a.iv(3)].

It is recognized that the monitor worn underneath the apron almost certainly provides an overestimate of the dose received by the embryo/fetus. However, a specific dose reduction factor depends on the individual and the work environment, and a universal dose reduction factor is not recommended without the advice of a qualified expert. Because nearly all personnel have monthly shielded waist monitor values of less than 50 mrem (0.5 mSv), the embryo/fetus dose assessment for specific individuals will be required only in rare circumstances [Brateman L., <u>24th Annual National Conference on Radiation Control</u>, CRCPD Publication 92-5 (1992) 277-9].

Proposed regulation D.201c.ii(1) allows the cumulative H_E for special procedures fluoroscopists to be determined when data are available for only the collar monitor. With the use of a multiplicative factor of 0.3 applied to the unshielded collar badge deep dose equivalent value, an estimate of H_E can be obtained for that portion of the year when only the collar monitor was worn, and this value can then

be summed with values of H_E determined from two monitors when two monitors are worn. Because this provision is applicable only for the situation in which personnel receive large reported doses, it does not apply to personnel who work part-time in radiography and fluoroscopy, who routinely receive lower reported annual doses than 1250 mrem (12.5 mSv): for this group, the use of the 0.3 factor is inappropriate because of the mixed work environment in which a portion of the reported dose might have been received as a whole body dose. In addition, since the current regulations are not burdensome for this group, this practice is consistent with *ICRP Publication No. 35*.

Protective aprons are worn to shield the gonads and a major portion of the trunk and bone marrow of the individual. Therefore, an individual assisting in fluoroscopic procedures with his/her back to the x-ray beam needs to wear appropriate shielding to cover the back, as well as the front, of the chest, abdomen and pelvis, to limit the dose to these organs and tissues. This policy also ensures adequate protection in the case of a declared pregnant woman. Aprons of 0.25 to 0.6 millimeters of lead equivalence were used in the derivation of H_E by Webster in his equation, because these aprons are in common usage. Therefore, F.3a.i(5b) is expanded to provide the appropriate monitoring conditions for the assumptions underlying D.201c.ii.

Proposed modifications to Parts D and F address in particular the monitoring of occupational doses from medical fluoroscopy, and proposed modifications to Part F include the relocation of personnel monitoring issues to Part D. Therefore, F.3a.i.(10) is revised so as to include all of the appropriate sections of Part D, and F.3a.i.(10)(a) is replaced by D.502a.iv and D.201c. Because the requirements for wearing protective aprons in fluoroscopy are included in Part F, and the proposed regulation for locating monitors for determining occupational doses is included in Part D, the definition of protective apron is added to Part A, in accordance with the Conference of Radiation Control Program Directors "Policies and Procedures for the Preparation and Publication of the *Suggested State Regulations* Style Manual."

Conclusion and Summary

Physicians who perform special fluoroscopic procedures frequently receive doses to the head and eyes, which are greater than 5 rem (0.05 Sv) per year. Current regulations consider the largest of these values as the "whole body" dose equivalent, even though the gonads and most of the trunk are shielded by aprons, which provide large protective factors. The incorporation of the recently-revised 10 CFR Part 20 into the SSRCR will exclude the present fallback position of allowing a 5(N-18) rem lifetime whole body dose equivalent for these individuals, and an untenable regulatory situation is likely to occur rapidly. It is already the case that, because the enforcement of current regulations requires frequent censure of personnel performing special fluoroscopic procedures, many personnel do not comply with existing requirements (i.e., wearing unshielded collar badges which have values reported as "whole body" doses). Changing the regulations to these proposed will result in a much more accurate assessment of risk from occupational exposure to radiation and will allow personnel who perform special fluoroscopic procedures to utilize the more up-to-date International Council on Radiation Protection and National Council on Radiation Protection and Measurements effective dose equivalent concept, while continuing to allow adequate regulatory oversight over this specialized work environment.

These proposed regulations are seen as an improvement over existing x-ray regulations and provide a conservative estimate of x-ray exposures in medical fluoroscopy without being unduly restrictive, burdensome and costly. It is extremely important that these changes be incorporated before

unnecessary regulatory problems are created -- that is, incorporated concurrent with the revisions to the SSRCR, which include the Nuclear Regulatory Commission Part 20 modifications.