Introductory Comments:

1. Licensee denotes users of radioactive material and registrant denotes users of electronically-produced ionizing radiation. References to "registrant" were removed from rules dealing only with radioactive material. References to "licensee" were removed from rules dealing only with electronically-produced ionizing radiation.

2. Doses less than 1 rem are changed to their millirem equivalent. For example: ~~0.1 rem~~ 100 millirem.

PART D STANDARDS FOR PROTECTION AGAINST RADIATION

General Provisions

~~Sec.~~ Rule D.1001 - Purpose.

a. ~~Part D~~ This part establishes standards for protection against ionizing radiation resulting from activities conducted ~~pursuant to~~ under licenses or registrations issued by the ~~Agency~~ department. These ~~regulations~~ rules are issued ~~pursuant to the [cite Radiation Control Act, as amended]~~ under Part 135 of 1978 PA 368, as amended, MCL 333.13501 to 333.13538.

b. The requirements of ~~Part D~~ this part are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by a~~ny~~ licensee or registrant so that the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in ~~Part D~~ this part. ~~However, nothing~~ Nothing in ~~Part D~~ this part shall be construed as limiting actions that may be necessary to protect health and safety.

~~Sec.~~ Rule D.1002 - Scope.

~~Except as specifically provided in other Parts of these regulations, Part D~~ This part applies to ~~persons~~ a person licensed or registered by the ~~Agency~~ department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in ~~Part D~~ this part do not apply to doses due to background radiation, to exposure of patients to radiation for ~~the purpose of~~ medical diagnosis or therapy, to exposure from individuals administered radioactive material and released ~~in accordance with [cite appropriate Part G reference~~ under Rule G.40, or to exposure from voluntary participation in medical research programs.

10 CFR 20.1002 does not have "Except as specifically provided in other parts of these regulations."

Rule G.40, "Release of Individuals Containing Radioactive Drugs or Implants" is the Suggested State Regulation's counterpart to 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material."

~~Sec.~~ Rule D.1003 - Definitions.

Definitions will be added later.

~~Sec.~~ Rule D.1004 - Implementation.

Subrules D.1004(a), (b), (c), and (d) have parallel wording in 10 CFR 20.1008(b), (c), (d), and (e), respectively.

a. If the requirements of this part are more restrictive than a license or registration condition established before [effective date of these rules], the licensee or registrant shall comply with this part unless exempted by subrule c. of this rule.

~~a~~b. An~~y~~ existing license or registration condition that is more restrictive than ~~Part D~~ this part remains in force until ~~there is an amendment or renewal of~~ the license or registration is amended or renewed.

~~b~~c. If a license or registration condition exempts a licensee or registrant from a provision of ~~Part D~~ this part in effect ~~on or~~ before [effective date of these ~~regulations~~ rules], it also exempts the licensee or registrant from the corresponding provision of ~~Part D~~ this part.

~~c~~d. If a license ~~or registration~~ condition cites ~~provisions of Part D~~ a provision of 10 CFR Part 20 in effect ~~prior to~~ before [effective date of these ~~regulations~~ rules]~~, which do~~ that does not correspond to ~~any provisions of Part D~~ a provision of this part, the license ~~or registration~~ condition remains in force until ~~there is an~~ a license amendment or renewal ~~of the license or registration that~~ modifies or removes ~~this~~ the condition.

Radiation Protection Programs

~~Sec.~~ Rule D.1101 - Radiation Protection Programs.

a. ~~Each~~ A licensee or registrant shall develop, document, and implement a radiation protection program ~~sufficient to ensure~~ commensurate with the scope and extent of licensed or registered activities that ensures compliance with the provisions of this part. Rule D.2102 ~~for~~ provides recordkeeping requirements relating to these programs.

The phrase “commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part” is the current 10 CFR 20 language.

Many states require radiation machine registrants to have a radiation protection program. The department plans to develop guidance for the various categories of radiation machine registrants and radioactive materials licensees.

Rule D.2102 is “Records of Radiation Protection Programs.”

b. ~~The~~ To the extent practical, a licensee or registrant shall use~~, to the extent practical,~~ procedures and engineering controls based ~~up~~on sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as ~~is~~ reasonably achievable (ALARA).

c. The licensee or registrant shall, at ~~intervals not to exceed 12 months~~ least annually, review the radiation protection program content and implementation.

10 CFR 20.1101(c) is worded "The licensee shall periodically (at least annually) review the radiation protection program content and implementation."

d. To implement the ALARA requirements of ~~D.1101b.~~ subrule b. of this rule and notwithstanding the requirements ~~in~~ of Rule D.1301, a licensee shall establish a constraint on air emissions of radioactive material to the environment, excluding ~~Radon~~ radon-222 and its ~~daughters, shall be established by licensees other than those subject to 10 CFR Part 50.34a of the USNRC regulations, such~~ decay products, so that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent ~~in excess of~~ greater than 0.1 millisievert (10 ~~mrem~~ millirem) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the ~~exceedance~~ occurrence to the department as ~~provided~~ specified in Rule D.2203 and promptly take appropriate corrective action to ensure against recurrence.

10 CFR 50.34a is entitled, "Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors." The state will not be regulating nuclear power reactors so the phrase referring to 10 CFR 50.34a is not applicable and can be removed.

D.1301 is "Dose Limits for Individual Members of the Public." D.2203 is "Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits."

Occupational Dose Limits

~~Sec.~~ Rule D.1201 - Occupational Dose Limits for Adults.

a. ~~The~~ A licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures ~~pursuant to~~ as specified in Rule D.1206, to the following dose limits:

i. An annual limit, which is the more limiting of:

(1) The total effective dose equivalent ~~being equal to~~ of 0.05 Sievert (5 rem); or

(2) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye ~~being equal to~~ of 0.5 Sievert (50 rem).

ii. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are:

(1) A lens dose equivalent of 0.15 Sievert (15 rem); and

(2) A shallow dose equivalent of 0.5 Sievert (50 rem) to the skin of the whole body or to the skin of any extremity.

10 CFR 20.1201(a)(2) includes "to the skin of the whole body, and to the skin of the extremities."

b. ~~Doses~~ A licensee or registrant shall subtract doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, ~~shall be subtracted~~ from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. ~~See~~ The dose limits for planned special exposures are provided in Rules D.1206e.i. and ii.

c. When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent shall be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the department.

This wording was added to 10 CFR 20.1201(c) and became effective on January 3, 2008.

~~c~~d. The assigned deep dose equivalent ~~and shallow dose equivalent~~ shall be for the ~~portion~~ part of the body receiving the highest exposure. The assigned shallow-dose equivalent shall be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

The specification of the shallow-dose equivalent in a separate sentence in 10 CFR 20.1201(c) became effective on January 3, 2008.

i. ~~The~~ If the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable, the deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements ~~for the purpose of demonstrating~~ to demonstrate compliance with the occupational dose limits~~, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or~~.

ii. When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in ~~D.1502a.v.~~ Rule D.1503, the effective dose equivalent for external radiation shall be determined as follows:

(1) When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation; or

(2) When only one individual monitoring device is used and it is located at the neck ~~(collar)~~ outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in Rule D.1201a., the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

(3) When two individual monitoring devices are worn, ~~both~~ one under the protective apron at the waist and the other outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose

equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

10 CFR 20.1201 does not contain a requirement equivalent to D.1201(d)(ii).

~~d~~e. ~~Derived~~ The derived air concentration (DAC) and annual limit on intake (ALI) values are ~~specified~~ presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. ~~See~~ Requirements for record keeping of individual monitoring results are provided in Rule D.2106.

~~e~~f. In addition to the annual dose limits, ~~the~~ a licensee ~~or registrant~~ shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. ~~See footnote c/ of Appendix B.~~ Requirements for annual limits on intake for uranium are provided in Appendix B.

The reference to registrant was deleted since this subrule only applies to licensees.

~~f~~g. The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person during the current year. ~~See~~ Requirements for determining prior occupational exposure are provided in Rule D.2104.

~~Sec.~~ Rule D.1202 - ~~Compliance with~~ Requirements for Summation of External and Internal Doses.

a. If ~~the~~ a licensee or registrant is required to monitor ~~pursuant to~~ individual occupational dose by both Rules D.1502a. and b., the licensee or registrant shall demonstrate compliance with the dose limits in Rule D.1201 by summing external and internal doses. If ~~the~~ a licensee or registrant is required to monitor individual occupational dose only ~~pursuant to~~ by Rule D.1502a. or only ~~pursuant to~~ by Rule D.1502b., then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses ~~pursuant to~~ by meeting the requirements of Rules D.1202b., c., and d. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits specified in Rule D.1201.

b. ~~Intake by Inhalation.~~ If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

i. The sum of the fractions of the inhalation ALI for each radionuclide; or

ii. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

iii. The sum of the ~~calculated~~ committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. ~~For purposes of this requirement, an~~ An organ or tissue is ~~deemed to be~~ considered significantly irradiated if,

for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

10 CFR 20.1202 has the discussion on significantly irradiated as a footnote.

c. ~~Intake by Oral Ingestion.~~ If the occupationally exposed individual receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee ~~or registrant~~ shall account for this intake and include it in demonstrating compliance with the dose limits in Rule D.1201.

d. ~~Intake through Wounds or Absorption through Skin.~~ The licensee ~~or registrant~~ shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin ~~has been~~ is included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated.

~~Sec.~~ Rule D.1203 - Determination of External Dose from Airborne Radioactive Material.

a. ~~Licensees or registrants shall, when~~ When determining the external dose from airborne radioactive material, a licensee shall include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. ~~See Appendix B, footnotes a/ and b/.~~

The eliminated footnote references are: a/ "Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material. b/ These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 µCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See D.203.)

b. ~~Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when~~ If the airborne radioactive material includes radionuclides other than noble gases or ~~if~~ the cloud of airborne radioactive material is not relatively uniform, airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep-dose equivalent. The determination of the deep dose equivalent to an individual shall be based ~~up~~on measurements using instruments or individual monitoring devices.

~~Sec.~~ Rule D.1204 - Determination of Internal Exposure.

a. ~~For purposes of assessing~~ To assess the dose used to determine compliance with occupational dose equivalent limits, ~~the~~ a licensee ~~or registrant~~ shall, when required ~~pursuant to~~ by Rule D.1502, take suitable and timely measurements of:

i. Concentrations of airborne radioactive materials in ~~air in~~ work areas; or

ii. Quantities of radionuclides in the body; or

iii. Quantities of radionuclides excreted from the body; or

iv. Combinations of these measurements.

b. Unless respiratory protective equipment is used, as provided in Rule D.1703, or the assessment of intake is based on bioassays, the licensee ~~or registrant~~ shall assume that an individual inhales radioactive material at the airborne concentration ~~in which~~ where the individual is present.

c. ~~When~~ If specific information ~~on~~ is known about the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual ~~is known, the~~, a licensee ~~or registrant~~ may:

i. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee ~~or registrant~~ shall document that information in the individual's record; and

ii. ~~Upon~~ With prior approval of the ~~Agency~~ department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size, distribution, or density; and

iii. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. ~~See~~ Requirements for annual limits on intake are provided in Appendix B.

d. If ~~the~~ a licensee ~~or registrant~~ chooses to assess intakes of Class Y material using the measurements ~~given~~ specified in ~~D.1204a.ii. or iii.~~ subrules a.ii or a.iii. of this rule, the licensee ~~or registrant~~ may delay the recording and reporting of the assessments for ~~periods~~ up to 7 months, unless otherwise required by Rules D.2202 or D.2203. This delay ~~permits~~ allows the licensee ~~or registrant~~ to make additional measurements basic to the assessments.

D.2202 - Notification of Incidents.
D.2203 - Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.

e. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

i. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or

ii. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

f. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

g. ~~When~~ If a mixture of radionuclides in the air exists, a licensee ~~or registrant~~ may disregard certain radionuclides in the mixture if:

i. The licensee ~~or registrant~~ uses the total activity of the mixture ~~in demonstrating~~ to demonstrate compliance with the dose limits specified in Rule D.1201 and ~~in complying~~ complies with the monitoring requirements specified in Rule D.1502b.; and

ii. The concentration of any radionuclide disregarded is less than 10 percent of its DAC; and

iii. The sum of ~~these~~ the percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

h. ~~When determining the committed effective dose equivalent, the following information may be considered:~~

10 CFR 20.1204(h) does not contain the above text, but does contain h.i. and h.ii. below.

i. ~~In order to~~ To calculate the committed effective dose equivalent, ~~the~~ a licensee ~~or registrant~~ may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sievert (5 rem). This assumption may only be made for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent;

ii. ~~For an~~ When the ALI and the associated DAC is determined by the nonstochastic organ dose limit of 0.5 Sievert (50 rem), the stochastic ALI, which is the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sievert (5 rem), ~~that is, the stochastic ALI,~~ is listed in parentheses in Table I of Appendix B. ~~The~~ In this case, the licensee ~~or registrant~~ may~~, as a simplifying assumption,~~ use the stochastic ALIs to determine the committed effective dose equivalent. ~~However, if~~ When the licensee ~~or registrant~~ uses the stochastic ALIs, the licensee ~~or registrant~~ shall also demonstrate that the limit in Rule D.1201a.i.(2) is ~~met~~ not exceeded.

~~Sec.~~ Rule D.1206 - Planned Special Exposures.

A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in Rule D.1201 ~~provided that each of~~ if the following conditions ~~is~~ are satisfied:

a. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical;

b. The licensee or registrant, and employer if the employer is not the licensee or registrant, ~~specifically~~ authorizes the planned special exposure, in writing, before the exposure occurs;

c. Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

i. Informed, in writing, of the purpose of the planned operation; ~~and~~

ii. Informed, in writing, of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

iii. Instructed in the measures to ~~be taken to~~ keep the dose ALARA considering other risks that may be present;

10 CFR 20.1206(c) does not require that the individual who will receive the radiation dose receive written information regarding the planned operation.

Planned special exposures are meant to be deliberate events. In an emergency, Rule D.1001(b), "Nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety," can be invoked to perform lifesaving or other emergency actions.

d. ~~Prior to permitting~~ Before allowing an individual to participate in a planned special exposure, the licensee or registrant ~~ascertains~~ determines prior doses ~~as required by~~ pursuant to Rule D.2104b. ~~during~~ for the lifetime of ~~the individual for~~ each individual involved;

Rule D.2104 - Determination and Records of Prior Occupational Dose.
b. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:
i. The internal and external doses from all previous planned special exposures; and
ii. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

e. Subject to Rule D.1201b., the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

i. The numerical values of any of the dose limits in Rule D.1201a. in any year; and

ii. Five times the annual dose limits in Rule D.1201a. during the individual's lifetime;

f. The licensee or registrant ~~maintains~~ keeps records of ~~the conduct of~~ a planned special exposure ~~in accordance with~~ pursuant to Rule D.2105 and submits a written report ~~in accordance with~~ to the department pursuant to Rule D.2204;

Rule D.2105 is "Records of Planned Special Exposures."
Rule D.2204 is "Reports of Planned special Exposures."

g. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days ~~from~~ after the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling the future occupational dose of the individual pursuant to Rule D.1201a. but shall be included in evaluations required by ~~D.1206~~ subrules d. and e. of this rule.

~~Sec.~~ Rule D.1207 - Occupational Dose Limits for Minors.

The annual occupational dose limits for ~~minors~~ a minor are 10 percent of the annual occupational dose limits specified for an adult worker~~s~~ in Rule D.1201.

~~Sec.~~ Rule D.1208 - Dose Equivalent to an Embryo/Fetus.

a. The licensee or registrant shall ensure that the dose equivalent to ~~an~~ the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 5 millisieverts (~~0.5 rem~~ 500 millirem). ~~See D.2106d. for recordkeeping requirements.~~ Records for doses to the embryo/fetus shall be kept according to Rule D.2106d.

> Rule D.2106 - Records of Individual Monitoring Results.
> d. The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

b. The licensee or registrant shall make efforts to avoid substantial variation~~*/~~ above a uniform monthly exposure rate to a declared pregnant woman ~~so as~~ to satisfy the limit in Rule D.1208a.

> " */ The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.5 millisievert (0.05 rem) to the embryo/fetus be received in any one month." This footnote is being deleted from the rules.

c. The dose equivalent to the embryo/fetus is the sum of:

i. The deep dose equivalent to the declared pregnant woman; and

ii. The dose equivalent ~~resulting~~ to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

> 10 CFR 20.1208(c)(2) includes the phrase "to the embryo/fetus."

d. If the dose equivalent to the embryo/fetus ~~is found to have exceeded 5 millisieverts (0.5 rem), or is within 0.5 millisieverts (0.05 rem) of this dose, by the time~~ has exceeded 4.5 millisieverts (450 millirem), when the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be ~~deemed to be~~ considered in compliance with

~~D.1208a~~ subrule a. of this rule if the additional dose equivalent to the embryo/fetus does not exceed 0.5 millisievert (~~0.05 rem~~ 50 millirem) during the remainder of the pregnancy.

AL, IL, KS, LA, MS, ND, NE, NH, NC, NY, OR, SC, TN, TX, and WA use the phrase "4.5 millisieverts (0.45 rem) or more," NRC has a Management Directive for its own employees that reads "If the dose to the declared pregnant employee has already exceeded 0.45 rem at the time of the declaration, the dose for the remainder of the pregnancy must be limited to 0.05 rem."

Radiation Dose Limits for Individual Members of the Public

~~Sec.~~ Rule D.1301 - Dose Limits for Individual Members of the Public.

a. ~~Each~~ A licensee or registrant shall conduct operations so that:

i. The total effective dose equivalent to ~~individual members~~ a member of the public from the licensed or registered operation does not exceed 1 millisievert (~~0.1 rem~~ 100 millirem) in a year, ~~exclusive of the~~ excluding dose contributions from:

(1) ~~background~~ Background radiation,

(2) ~~from any medical~~ Medical administrations the individual has received,

(3) ~~from exposure~~ Exposure to individuals administered radioactive material and released ~~in accordance with [cite appropriate reference from Part G of these regulations],~~ pursuant to Rule G.40,

(4) ~~from voluntary~~ Voluntary participation in medical research programs, and

(5) ~~from the~~ The licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with Rule D.2003;~~**/ and~~

Separating 10 CFR 20(a)(i) into parts makes it easier to read.

The footnote is being deleted. " **/ Retrofit shall not be required for locations within facilities where only radiation machines existed prior to [the effective date of these regulations] and met the previous requirements of 5 millisievert (0.5 rem) in a year."

Rule D.2003 is "Disposal by Release into Sanitary Sewerage."

ii. The dose in any unrestricted area from external sources of radiation, ~~exclusive of~~ excluding the dose contributions from ~~patients~~ individuals administered radioactive material and released ~~in accordance with [cite appropriate reference to Part G of these regulations]~~ pursuant to Rule G.40, does not exceed 0.02 millisievert (~~0.002 rem~~ 2 millirem) in any one hour; ~~and~~

The following definitions from 10 CFR 20 may assist in understanding the physical locations where some rules will apply:

"Restricted area" means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

"Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee.

The International Atomic Energy Agency (IAEA), the International Commission of Radiological Protection (ICRP), and the National Council on Radiation Protection and Measurements (NCRP) do not use or define the terms "restricted area" or "unrestricted area." They define "controlled area" as follows:

A defined area in which specific protection measures and safety provisions are or could be required for controlling normal exposures or preventing the spread of contamination during normal working conditions, and preventing or limiting the extent of potential exposures. (IAEA and ICRP)

A limited-access area in which the occupational exposure of personnel to radiation or to radioactive material is under the supervision of an individual in charge of radiation protection. This definition implies that access, occupancy, and working conditions are controlled for radiation protection purposes. (NCRP)

In addition, the NCRP defines an "uncontrolled area" as "any space not meeting the definition of controlled area."

The 10 CFR 20 definition of "restricted area" approximates the "controlled area" definition of these national and international radiation advisory organizations. The 10 CFR 20 definition of "controlled area" would be considered an "uncontrolled area" internationally and by the x-ray users in the United States.

~~iii. The total effective dose equivalent to individual members of the public from infrequent exposure to radiation from radiation machines does not exceed 5 millisievert (0.5 rem).~~

Since Rule D.1301a.iii. addresses machine-generated radiation, 10 CFR 20 does not have this provision. Eighteen states do not have Rule D.1301a.iii. Many of the states that have this subrule restrict its use to radiation machines installed before January 1, 1994 that have not had significant changes in the operation since the machines were installed.

b. If ~~the~~ a licensee or registrant ~~permits~~ allows members of the public to have access to ~~restricted~~ controlled areas, the dose limits for members of the public continue to apply to those individuals.

10 CFR 20.1301(b) has "controlled areas." The NRC cited Wisconsin for using "restricted"

instead of “controlled” in their draft rules.

~~(~~c~~)~~ Notwithstanding ~~paragraph~~ subrule (a)(~~1~~ i) of this ~~section~~ rule, a licensee may ~~permit~~ allow a visitor~~s~~ to an individual who cannot be released, ~~under § 35.75~~ pursuant to Rule G.40, to receive ~~a~~ an annual radiation dose greater than ~~0.1 rem (1 mSv)~~ 1 millisievert (100 millirem) if:

~~(1)~~i The annual radiation dose received does not exceed ~~0.5 rem (5 mSv)~~ 5 millisieverts (500 millirem); and

~~(2)~~ii The authorized user, as defined in ~~10 CFR Part 35~~ Part G, has determined before the visits that ~~it~~ the visits ~~is~~ are appropriate.

Rule D.1301c. is not included in the most recent version of SSR Part D. The base text was taken from 10 CFR 20.1301(c) that became effective on October 24, 2002. The redline/strikethrough are suggested changes from the 10 CFR 20.1301(c) text.

d. A licensee may request an exemption under Rule D.2301 for a visitor functioning as a caregiver to an individual who cannot be released, pursuant to Rule G.40, to receive an annual radiation dose greater than 5 millisieverts (500 millirem).

The NRC has issued a Regulatory Issue Summary (RIS) 2006-18, “Requesting Exemption From the Public Dose Limits for Certain Caregivers of Hospital Patients,” August 31, 2006, that discusses the NRC exemption protocol for a licensee to request that a caregiver be allowed to receive more than 5 but less than 20 millisieverts (500 to 2,000 millirem) in a year. The RIS also discusses the possibility that a caregiver may, in rare instances, receive more than 20 millisieverts (2,000 millirem) in a year. The RIS states that the NRC decided not to proceed with rulemaking on this issue. The RIS is available on the NRC ADAMS website as Accession Number ML061940204.

We plan to issue a similar guidance document when Michigan becomes an Agreement State.

The RIS does not specifically define a caregiver, but does state the following: “Caregivers are usually members of the patient’s family, or someone close to the family or the patient. They do not include hospital staff, who are considered to be occupationally exposed individuals subject to occupational dose limits that are much higher than the limits for members of the public. The role of caregivers often involves close contact with the patient, sometimes for prolonged periods of time, with the result that the radiation doses they receive may be much higher than the dose limit that would normally apply to members of the public.” We plan to define “caregiver” in the definitions.

~~d~~e. For individuals other than those covered in subrules c. and d. of this rule, a ~~A~~ licensee, registrant, or an applicant for a license or registration may ~~apply for prior Agency~~ request authorization from the department to operate up to an annual dose limit for an individual member of the public of 5 millisievert~~s~~ (~~0.5 rem~~ 500 millirem). ~~This application~~ The request shall include the following information:

i. Demonstration of the need for and the expected duration of operations in excess of the limit in ~~D.1301a.~~ subrule a of this rule; and

ii. ~~The~~ A description of the licensee's or registrant's program to assess and control dose within the 5 millisieverts (~~0.5 rem~~ 500 millirem) annual limit; and

iii. The procedures to be followed to ~~maintain~~ keep the dose ~~ALARA~~ as low as reasonably achievable.

The first phrase is added to this subrule to clarify the relationship between subrules c, d, and e.

~~d. In addition to the requirements of Part D, a licensee or registrant subject to the provisions of the Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.~~

The deleted subrule d. immediately above this box is only required for states licensing uranium mills.

~~e~~f. The ~~Agency~~ department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

~~Sec.~~ Rule D.1302 - Compliance with Dose Limits for Individual Members of the Public.

a. ~~The~~ A licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in Rule D.1301.

10 CFR 20.1302(a) includes the phrases “as appropriate” and “and controlled.”

b. A licensee or registrant shall show compliance with the annual dose limit in Rule D.1301 by:

i. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual who is likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

ii. Demonstrating that:

(1) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table ~~II~~ 2 of Appendix B to this part; and

(2) ~~If an individual were continuously present in an unrestricted area, the~~ The dose from external sources of radiation would not exceed 0.02 millisievert (~~0.002 rem~~ 2 millirem) in an hour and 0.5 millisievert (~~0.05 rem~~ 50 millirem) in a year if an individual were continuously present in an unrestricted area.

c. Upon approval from the ~~Agency~~ department, the licensee or registrant may adjust the effluent concentration values in ~~Appendix B Table II~~ Table 2 of Appendix B to this part, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

~~**Testing for Leakage or Contamination of Sealed Sources**~~

~~**Sec. D.1310 - Testing for Leakage or Contamination of Sealed Sources.**~~

The SSR includes this rule in Part D but the NRC regulations and many states have specific leak test requirements for specific uses in different parts of the rules. We will follow their lead and not include this rule here.

10 CFR 20 has Subpart E, "Radiological Criteria for License Termination" located here in the regulations. The Suggested State Regulations have moved these rules to Part O, "Decommissioning." 20.1401 General provisions and scope. 20.1402 Radiological criteria for unrestricted use. 20.1403 Criteria for license termination under restricted conditions. 20.1404 Alternate criteria for license termination. 20.1405 Public notification and public participation. 20.1406 Minimization of contamination.

Surveys and Monitoring

~~Sec.~~ Rule D.1501 - General.

a. ~~Each~~ A licensee or registrant shall make, or cause to be made, surveys that:

i. ~~Are necessary for the licensee or registrant to comply with Part D; and~~ May be necessary to demonstrate compliance with the rules in this part; and

ii. Are ~~necessary~~ reasonable under the circumstances to evaluate:
(1) The magnitude and extent of radiation levels; and
(2) Concentrations or quantities of radioactive material; and
(3) The potential radiological hazards.

10 CFR 20.1501 has "may be" and "the rules in this" and "reasonable".

b. ~~The~~ A licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated ~~at intervals not to exceed 12 months~~ annually for the radiation measured, ~~except when a more frequent interval is specified in another applicable Part of these regulations or a license condition~~ except as otherwise specified in another part of these rules or in a license or registration condition.

10 CFR 20.1501 has “periodically” instead of “at intervals not to exceed 12 months.” 10 CFR 20.1501 does not have “except when a more frequent interval is specified in another applicable Part of these regulations or a license condition.”

c. ~~All~~ This subrule applies to personnel dosimeters, ~~except for direct and indirect reading pocket ionization chambers and those~~ including dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that ~~are used by licensees and registrants~~ a licensee or registrant uses to comply with Rule D.1201, with other applicable provisions of these ~~regulations~~ rules, or with conditions specified in a license or registration. This subrule does not apply to direct and indirect reading pocket dosimeters and electronic personal dosimeters. Personnel dosimeters shall be processed and evaluated by a dosimetry processor that:

i. ~~Holding~~ Holds a current personnel dosimetry accreditation from the ~~National Voluntary Laboratory Accreditation Program~~ national voluntary laboratory accreditation program of the ~~National Institute of Standards and Technology~~ national institute of standards and technology; and

ii. ~~Approved~~ Is approved in this accreditation process for the type of radiation or radiations included in the ~~National Voluntary Laboratory Accreditation Program~~ national voluntary laboratory accreditation program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

10 CFR 20.1501 does not require extremity dosimeters to be accredited by the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP does accredit extremity dosimetry programs. Looking at the information on the NVLAP website, it appears that the commercial dosimetry services used in Michigan are accredited for their extremity dosimeters. 10 CFR 20.1501 has “the extremities” instead of “any extremity.” To make it easier to read, the text of subrule c. has been separated into three sentences.

~~d. The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.~~

Subrule d. is not included in 10 CFR 20.

~~Sec.~~ Rule D.1502 - Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

~~Each~~ A licensee or registrant shall monitor ~~exposures~~ occupational exposure from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of ~~Part D. As~~ this part. ~~At a minimum:~~

a. ~~Each~~ A licensee or registrant shall monitor occupational exposure to radiation from ~~licensed and unlicensed radiation~~ sources of radiation under ~~its~~ the control of the licensee or registrant and shall supply and require the use of individual monitoring devices by:

10 CFR 20.1502 has “the control of the licensee” instead of “its control.”

i. ~~Adults~~ Each adult likely to receive, in 1 year from sources of radiation external to the body, a dose ~~in excess of~~ greater than 10 ~~percent~~ % of the limits ~~in~~ specified in Rule D.1201a.; and

ii. ~~Minors~~ Each minor likely to receive, in 1 year from sources of radiation external to the body, a deep dose equivalent ~~in excess of~~ greater than 1 millisievert (~~0.1 rem~~ 100 millirem), a lens dose equivalent ~~in excess of~~ greater than 1.5 millisieverts (~~0.15 rem~~ 150 millirem), or a shallow dose equivalent to the skin or to the extremities ~~in excess of~~ greater than 5 millisieverts (~~0.5 rem~~ 500 millirem); and

iii. ~~Declared~~ Each declared pregnant ~~women~~ woman likely to receive during the entire pregnancy, from ~~radiation~~ sources of radiation external to the body, a deep dose equivalent ~~in excess of~~ greater than 1 millisievert (~~0.1 rem~~ 100 millirem); and

iv. ~~Individuals entering~~ Each individual who enters a high or very high radiation area;

~~v. Individuals working with medical fluoroscopic equipment.~~

~~(1) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to D.1208a., shall be located under the protective apron at the waist.~~

~~(2) An individual monitoring device used for lense dose equivalent shall be located at the neck (collar), or an unshielded location closer to the eye, outside the protective apron.~~

~~(3) When only 1 individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to D.1201c.ii., it shall be located at the neck (collar) outside the protective apron. When a second individual monitoring device is used for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.~~

The deleted subrule D.1502v. requirement will be included in Part F,”Diagnostic X-Rays and Imaging Systems in the Healing Arts.” The deleted subrule D.1502v(1), (2) and (3) requirements are included in Rule D.1503.

v. Each individual for whom personnel monitoring is specifically required under other parts of these rules pertaining to specific uses of sources of radiation.

This subrule v. is in the current “Ionizing Radiation Rules” as Rule 222(1)(e). Subrule v. is not in 10 CFR 20.1502 nor is it in the SSR. This subrule simply reminds the reader that other parts of the rules may specifically require personnel monitoring notwithstanding subrules i through iv.

b. ~~Each~~ As specified in Rule D.1204, a licensee ~~or registrant~~ shall monitor~~, to determine compliance with D.1204,~~ the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

i. Adults likely to receive, in 1 year, an intake ~~in excess of~~ greater than 10 ~~percent~~ % of the applicable ~~ALI~~ annual limit on intake in Table I, Columns 1 and 2, of Appendix B~~;~~. ~~and~~

ii. Minors likely to receive, in 1 year, a committed effective dose equivalent ~~in excess of~~ greater than 1 millisievert (~~0.01 rem~~ 100 millirem).

iii. Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent ~~in excess of~~ greater than 1 millisievert (~~0.1 rem~~ 100 millirem).

In subrule b.ii., the correct conversion from 1 millisievert is 100 millirem. 10 CFR 20.1502(b)(3) has “effective.”

~~Sec.~~ Rule D.1503 - Location of Individual Monitoring Devices.

Rule D.1503 is not included 10 CFR 20 or in the rules of several states.

~~Each~~ If Rule D.1502a or other Parts of these rules require occupational dose monitoring for an individual, the licensee or registrant shall ensure that ~~individuals who are required to monitor occupational doses in accordance with D.1502a. wear~~ the individual wears an individual monitoring device(s) as follows:

a. An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck ~~(collar)~~;

b. An individual monitoring device used ~~for monitoring~~ to monitor the dose to an embryo/fetus of a declared pregnant woman, pursuant to Rule D.1208a., shall be ~~located~~ worn at the waist under any protective apron being worn by the woman;

c. An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with Rule D.1201a.ii.(1), shall be ~~located~~ worn at the neck ~~(collar)~~, outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

d. An individual monitoring device used for monitoring the dose to the skin of the extremities, to demonstrate compliance with Rule D.1201a.ii.(2), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

Since Rule D.1201a.ii.(2) refers to “skin of the extremities,” the additional words were added to this subrule.

Control of Exposure from External Sources in Restricted Areas

~~Sec.~~ Rule D.1601 - Control of Access to High Radiation Areas.

a. ~~The~~ A licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following control features:

   i. A ~~control~~ device that, upon entry into the area, causes the ~~level of~~ radiation level to be reduced below ~~that~~ the level ~~at which~~ where an individual ~~might~~ could receive a deep dose equivalent of 1 millisievert (~~0.1 rem~~ 100 millirem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or

   ii. A ~~control~~ device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

   iii. ~~Entryways that are locked~~ Locked entryways, except ~~during periods~~ when access to the area~~s~~ is required, with positive control over each individual entry.

b. In place of the controls required ~~by D.1601a.~~ for a high radiation area~~, the~~ by subrule a. of this rule, a licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

c. ~~The~~ A licensee ~~or~~ , registrant, or applicant for a license or registration may apply to the ~~Agency~~ department for approval of alternative methods for controlling access to high radiation areas.

d. ~~The~~ A licensee or registrant shall establish the controls required by ~~D.1601a.~~ subrules a. and ~~D.1601c.~~ c. of this rule in a way that does not prevent individuals from leaving a high radiation area.

e. ~~The~~ A licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled ~~in accordance with the regulations of the Department of Transportation provided that~~ according to U.S. department of transportation regulations if:

   i. The packages do not remain in the area longer than 3 days; and

   ii. The dose rate at 1 meter from the external surface of a~~ny~~ package does not exceed 0.1 millisievert (~~0.01 rem~~ 10 millirem) per hour.

f. The licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material~~,~~ ~~provided that there~~ if:

   i. Personnel are ~~personnel in attendance~~ present who ~~are taking~~ will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material ~~in excess of~~ greater than the limits established ~~limits in Part D~~ in this part; and ~~to operate~~

ii. The licensee or registrant operates within the ~~ALARA~~ as low as reasonably achievable provisions of the licensee's or registrant's radiation protection program.

10 CFR 20.1601 has “will take” instead of “are taking.” 10 CFR 20 and SSR Part D have this as one sentence but it has been separated for clarity.

g. The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in Rule D.1601 if the licensee or registrant ~~has met~~ meets all the specific requirements for access and control specified in other applicable ~~Parts~~ parts of these ~~regulations~~ rules~~, such as, Part E for industrial radiography, Part F for X-rays in the healing arts, and Part I for particle accelerators~~.

Subrule g. is not included 10 CFR 20 or in the rules of several states.

~~Sec.~~ Rule D.1602 - Control of Access to Very High Radiation Areas.

a. ~~In addition to~~ Besides the requirements in Rule D.1601, ~~the~~ a licensee or registrant shall institute additional measures to ensure that an individual ~~is not able to~~ cannot gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 gray (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic X-ray systems are the only source of radiation, or to non-self-shielded irradiators.

10 CFR 20.1602 has “additional.”

b. ~~The~~ A licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in ~~D.1602a.~~ subrule a of this rule if the licensee or registrant ~~has met~~ meets all the specific requirements for access and control specified in other applicable ~~Parts~~ parts of these ~~regulations~~ rules~~, such as, Part E for industrial radiography, Part F for X-rays in the healing arts, and Part I for particle accelerators~~.

10 CFR 20 and some states do not have this subrule.

~~Sec.~~ Rule D.1603 - Control of Access to Very High Radiation Areas – Irradiators.

Rule D.1603 will be included in Part Q “Licensing and Radiation Safety Requirements for Irradiators.”

Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

~~Sec.~~ Rule D.1701 - Use of Process or Other Engineering Controls.

~~The~~ To the extent practical, the licensee ~~or registrant~~ shall use~~, to the extent practical,~~ process or other engineering controls, such as~~,~~ containment, decontamination, or ventilation, to control the airborne concentrations of radioactive material ~~in air~~.

For those devices such as high-energy accelerators or cyclotrons that could produce appreciable concentrations of airborne radioactive material, a registration condition requiring process or other engineering controls will be added to the registration.

~~Sec.~~ Rule D.1702 - Use of Other Controls.

a. When it is not ~~practicable~~ practical to apply process or other engineering controls to control the airborne concentrations of radioactive material ~~in air~~ to values below those that define an airborne radioactivity area, ~~the~~ a licensee ~~or registrant~~ shall, consistent with ~~maintaining~~ keeping the total effective dose equivalent ~~ALARA~~ as low as reasonably achievable, increase monitoring and limit intakes of radioactive material by one or more of the following ~~means~~:

   i. Control ~~of~~ access; ~~or~~

   ii. Limit~~ation of~~ exposure times; ~~or~~

   iii. Use ~~of~~ respiratory protection equipment; or

   iv. ~~Other~~ Establish other controls.

10 CFR 20.1702 has “practical” instead of “practicable.”

b. If ~~the~~ a licensee performs an ALARA analysis to determine whether ~~or not~~ respirators ~~should be used~~ are necessary, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

10 CFR 20.1702 has “consider safety factors other than radiological factors. The licensee should”

~~Sec.~~ Rule D.1703 - Use of Individual Respiratory Protection Equipment.

If the licensee ~~or registrant uses~~ assigns or allows the use of respiratory protection equipment to limit ~~intakes pursuant to D.1702~~ the intake of radioactive material:

10 CFR 20.1703 has “assigns or permits the use of” instead of “uses” and “the intake of radioactive material” instead of “intakes.”

a. ~~Except as provided in D.1703a.ii., the~~ The licensee ~~or registrant~~ shall use only respiratory protection equipment ~~that is~~ tested and certified by the ~~National Institute for Occupational Safety and Health~~ national institute for occupational safety and health except as otherwise noted in this part;

10 CFR 20.1703 has “The” instead of “Except as provided in D.1703a.ii.”
10 CFR 20.1703 also has “except as otherwise noted in this part.”

b. ~~If the~~ A licensee ~~or registrant wishes to~~ may use respiratory protection equipment that ~~has not been tested or certified by the National Institute for Occupational Safety~~ the national institute for occupational safety and health has not tested or certified, or for which there is no schedule for testing or certification, if the licensee ~~shall submit an application to~~ has submitted and the department has approved a request to authorize the ~~Agency for authorized~~ use of ~~this~~ the equipment, except as otherwise ~~noted~~ provided in this ~~Part~~ part. The ~~application must~~ request shall include ~~evidence~~ documentation, based on testing by the licensee or on other reliable test information, that the material and performance characteristics of the equipment ~~are capable of providing~~ can provide the proposed degree of protection under the anticipated conditions of use~~. This must be demonstrated either by the licensee's or registrant's testing or on the basis of reliable test information~~;

10 CFR 20.1703 has “provided” instead of “otherwise noted” near the end of the first sentence.

c. ~~The~~ A licensee ~~or registrant~~ shall implement and maintain a respiratory protection program that includes:

i. Air sampling sufficient to identify ~~the~~ a potential hazard, permit proper equipment selection, and estimate doses;

ii. Surveys and bioassays, as necessary, to evaluate actual intakes;

iii. Testing of respirators for operability ~~(~~ including user seal ~~check~~ checks for face sealing devices and functional ~~check~~ checks for ~~others~~ other devices ~~)~~ immediately ~~prior to~~ before each use; ~~and~~

iv. Written procedures regarding:

(1) Monitoring, including air sampling and bioassays;

(2) Supervision and training ~~or~~ of respirator users;

(3) Fit testing;

(4) Respirator selection;

(5) Breathing air quality;

(6) Inventory and control;

(7) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(8) Recordkeeping; and

(9) Limitations on periods of respirator use and relief from respirator use.

v. Determination by a physician that the individual user is medically fit to use the respiratory protection equipment ~~before~~:

(1) ~~The~~ Before the initial fitting of a face sealing respirator;

(2) Before the first field use of a non-face sealing respirator~~s~~, and

(3) Either every 12 months thereafter, or periodically at a frequency determined by a physician.

vi. Fit testing, with a fit factor ≥ greater than or equal to 10 times the ~~APF~~ assigned protection factor for negative pressure devices, and a fit factor ≥ greater than or equal to 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face sealing respirators and ~~periodically~~ annually thereafter ~~at a frequency not to exceed 1 year~~. Fit testing ~~must~~ shall be performed with the facepiece operating in the negative pressure mode.

d. ~~The~~ A licensee ~~or registrant~~ shall advise each respirator user that the user may leave the area at any time for relief from respirator use ~~in the event of~~ if there is an equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other condition~~s~~ that might require ~~such~~ relief.

e. ~~The~~ A licensee ~~or registrant~~ shall ~~also consider limitations appropriate to~~ use respiratory protection equipment within the equipment manufacturer's expressed limitations for the type and mode of use. When selecting respiratory devices, the licensee ~~or registrant~~ shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. ~~The~~ A licensee ~~or registrant~~ shall use the equipment ~~in such a way~~ so as not to interfere with the proper operation of the respirator.

f. Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection ~~device~~ devices and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby ~~persons must be~~ rescue personnel shall:

i. Be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. ~~The standby rescue persons shall observe~~

ii. Observe or otherwise maintain continuous communication with the workers ~~(~~ through visual, voice, signal line, telephone, radio, or other suitable means ~~), and be~~,

iii. Be immediately available to ~~assist them in case of a failure of~~ help workers if the air supply fails or for any other reason that requires relief from distress. ~~A~~

iv. Be immediately available in sufficient ~~number of standby rescue persons must be immediately available to assist~~ numbers to help all users of this type of equipment and to provide effective emergency rescue if needed.

10 CFR 20 and the SSR have subrule f. as one paragraph. The text was divided into i. through iv. for clarity.

g. Atmosphere-supplying respirators ~~must~~ shall be supplied with respirable air of grade D quality or better as defined by ~~the~~ ANSI/Compressed Gas Association ~~in publication~~ G-7.1-2004, "Commodity Specification for Air," ~~1997~~ and included in the regulations of the ~~Occupational Safety and Health Administration~~ occupational safety and health administration in 29 CFR 1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include:

i. Oxygen content ~~(v/v) of 19.5-23.5%~~ between 19.5% and 23.5% by volume;

ii. ~~Hydrocarbon (condensed)~~ Condensed hydrocarbon content of 5 milligrams per cubic meter of air or less;

iii. Carbon ~~Monoxide (CO)~~ monoxide content of 10 ~~ppm~~ parts per million or less;

iv. Carbon ~~Dioxide~~ dioxide content of 1,000 ~~ppm~~ parts per million or less; and

v. Lack of noticeable odor.

ANSI/CGA G-7.1 was revised in 2004.

h. ~~The~~ A licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the ~~face-facepiece~~ seal between the face and facepiece or the valve function, and that are under the control of the respirator wearer, are ~~present~~ between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

10 CFR 20.1703 has "respirator."

i. ~~In~~ When estimating the dose to individuals from an intake of airborne radioactive material~~s~~, the concentration of airborne radioactive material ~~in the air that is~~ inhaled when respirators are worn is initially assumed to be the ambient concentration in air, without ~~the~~ respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value ~~must~~ shall be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

~~Sec.~~ Rule D.1704 – ~~Further~~ Additional Restrictions on the Use of Respiratory Protection Equipment.

The ~~Agency~~ department may impose restrictions in addition to the provisions of Rules D.1702 and D.1703, and Appendix A of this ~~Part, in order~~ part, to:

a. Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials ~~consistent with maintaining~~ to keep the total effective dose equivalent ~~ALARA~~ as low as reasonably achievable; and

b. Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

10 CFR 20.1704 has “airborne.”

~~Sec.~~ Rule D.1705 – Application for use of Higher Assigned Protection Factors.

~~The~~ A licensee ~~or registrant~~ shall obtain authorization from the ~~Agency~~ department before ~~using assigned~~ assigning respiratory protection factors ~~in excess of~~ greater than those specified in Appendix A. The ~~Agency~~ department may authorize a licensee ~~or registrant~~ to use higher assigned protection factors on receipt of an application that:

a. Describes the situation for which a need exists for higher protection factors; and

b. Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

~~Storage~~ Security and Control of ~~Licensed or Registered~~ Sources of Radiation

~~Sec.~~ Rule D.1801 - Security and Control of ~~Licensed or Registered~~ Sources of Radiation.

10 CFR 20.1801 is titled, “Security of Stored Material.”

a. ~~The~~ A licensee ~~or registrant~~ shall secure licensed ~~or registered~~ radioactive material stored in a controlled or unrestricted area from unauthorized removal or access.

b. ~~The~~ A licensee ~~or registrant~~ shall control and maintain constant surveillance~~, and use devices or administrative procedures to prevent unauthorized use~~ of licensed ~~or registered~~ radioactive material ~~that is~~ in ~~an~~ a controlled or unrestricted area and ~~that is~~ not in storage.

~~c. The registrant shall secure registered radiation machines from unauthorized removal.~~

~~d~~c. ~~The~~ A registrant shall use devices, ~~or~~ administrative procedures, or both to prevent unauthorized use or removal of ~~registered~~ radiation machines.