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Colorado Department
of Public Health
and Environment

July 27, 2001

Mr. Fred Combs
Deputy Director, Office of State Programs
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Combs,

Attached are the proposed revisions to Part 1 – General Provisions, Part 4 – Standards for Protection Against Radiation, Part 7 – Use of Radionuclides in the Healing Arts, Part 16 – Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies, and Part 19 – Licenses and Radiation Safety Requirements for Irradiators of the Colorado *Rules and Regulations Pertaining to Radiation Control*. The Colorado Board of Health Briefing for these changes is scheduled for August 15, 2001.

The proposed changes to Part 4 are editorial and clarifying changes. The proposed changes to Parts 1, 7, 16, and 19 are included to assure that those Parts of the Regulations will continue to be consistent with the requirements of Part 4. Parts 1, 4, 7, 16, and 19 have been reformatted in their entirety. These format changes have been made to establish a consistent and uniform format throughout the Regulations and do not alter the existing requirements. The Parts will be published in their entirety in order to implement the format changes.

Please direct any questions or comments by August 29, 2001 to Robert Terry at (303) 692-3051 or by e-mail at robert.terry@state.co.us.

Sincerely,

David A. Butcher

David A. Butcher, Director
Laboratory and Radiation Services Division

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Attachments: as stated

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STATEMENT OF BASIS AND PURPOSE AND SPECIFIC STATUTORY AUTHORITY FOR

MODIFICATIONS TO PART 1 GENERAL PROVISIONS

MODIFICATIONS TO PART 4 STANDARDS FOR PROTECTION AGAINST RADIATION

MODIFICATIONS TO PART 7 USE OF RADIONUCLIDES IN THE HEALING ARTS

MODIFICATIONS TO PART 16 RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

MODIFICATIONS TO PART 19 LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

August 15, 2001

Basis and Purpose.

The Colorado Radiation Control Act, Title 25, Article 11, Colorado Revised Statutes 1989 (Act), authorizes the Colorado Department of Public Health and Environment (Department) to develop and conduct programs for the evaluation and control of hazards that are associated with the use of sources of ionizing radiation. Section 25-11-104 of the Act authorizes the state Board of Health to formulate, adopt and promulgate rules and regulations pertaining to radiation control.

In 1968 the State of Colorado entered into an agreement with the federal government whereby the State assumed responsibility from the federal government for the regulation of certain types of radiation and radioactive material. These particular types of radioactive material are called "source," "special nuclear" and "byproduct" material in federal law. In order to maintain its agreement with the federal government, Colorado's radiation regulations must also be compatible with the regulations of the U.S. Nuclear Regulatory Commission (NRC).

This proposed action conforms Parts 1, 7, 16 and 19 of *Rules and Regulations Pertaining to Radiation Control* to minor correcting and clarifying amendments to the requirements in Part 4; and makes changes to Parts 1, 4, 7, 16 and 19 that are needed to maintain Colorado radiation control regulations' compatibility with the regulations of the NRC.

Section 104(2) provides that "all such regulations shall be modeled after and shall be neither more nor less stringent than those proposed by the Conference of Radiation Control Program Directors Inc., . . . under the title of *Suggested State Regulations for Control of Radiation*; except that . . . the board need not maintain such suggested state regulation or may adopt and promulgate such substitute regulation as the case may be."

These changes have not yet been incorporated into the *Suggested State Regulations for Control of Radiation* (SSRCR) published by the Conference of Radiation Control Program Directors, Inc. (CRCPD), but they are believed to be consistent with the changes that CRCPD will eventually incorporate.

As part of the modifications to the Regulations, Parts 1, 4, 7, 16, and 19 will be reformatted in their entirety. These format changes have been made to establish a consistent and uniform format throughout the Regulations. These format changes do not alter the existing requirements. When these regulations are finalized, Parts 1, 4, 7, 16, and 19 will be published in their entirety in order to implement the format changes.

The changes to Part 1 delete two definitions that are modified in Part 4; those modifications are described elsewhere in this Statement of Basis and Purpose.

The changes to Part 4 adopt the wording, in its entirety, that is specified in the Nuclear Regulatory Commission Final Rule: Minor Corrections, Clarifying Changes, and a Minor Policy Change (FR63,141:39477-39483, July 23, 1998), for 10 CFR Part 20, and in the Nuclear Regulatory Commission Final Rule: Transfer for Disposal and Manifests; Minor Technical Conforming Amendment (FR63,182:50127-50128, September 21, 1998), for 10 CFR Part 20, except:

where citations of specific regulations from *Rules and Regulations Pertaining to Radiation Control* are made in place of citations of specific regulations from Title 10 of the *Code of Federal Regulations*;

where *Rules and Regulations Pertaining to Radiation Control* had previously incorporated wording that is specified in the Final Rule;

where wording in *Rules and Regulations Pertaining to Radiation Control* required variation from the wording that is specified in the Final Rule, in order to assure that the meaning would be consistent with the revisions to Title 10 of the *Code of Federal Regulations*; and

where revisions to Title 10 of the *Code of Federal Regulations* that were specified in the final rule apply only to federal regulations that have no equivalent passages in *Rules and Regulations Pertaining to Radiation Control.*

The changes to Parts 7, 16 and 19 adopt the wording, in its entirety, that is specified in the Nuclear Regulatory Commission Final Rule: Minor Corrections, Clarifying Changes, and a Minor Policy Change (FR63,141:39477-39483, July 23, 1998), for 10 CFR Parts 35, 36 and 39, except where citations of specific regulations from *Rules and Regulations Pertaining to Radiation Control* are made in place of citations of specific regulations from Title 10 of the *Code of Federal Regulations.*

Adoption of these proposed changes will make the requirements in *Rules and Regulations Pertaining to Radiation Control* consistent with Title 10 of the *Code of Federal Regulations*, the *Suggested State Regulations for Control of Radiation*, and the requirements of other Agreement States' regulations.

This proposed action deletes two definitions from Part 1 of *Rules and Regulations Pertaining to Radiation Control* for the purpose of eliminating redundancy in the regulations.

In RH 1.4, "Definitions," the following definitions are deleted:

The definition of "High radiation area" is deleted to eliminate redundancy and to eliminate any future need to modify a definition in more than one place in the Regulations. The definition of "High radiation area" is modified in Part 4; that modification and the basis and purpose for the modification are described elsewhere in this Statement of Basis and Purpose.

The definition of "Individual monitoring devices" is also deleted to eliminate redundancy and to eliminate any future need to modify a definition in more than one place in the Regulations. The definition of "Individual monitoring devices" is modified in Part 4; that modification and the basis and purpose for the modification are described elsewhere in this Statement of Basis and Purpose.

This proposed action makes one minor substantive change to Part 4 of *Rules and Regulations Pertaining to Radiation Control*; that change is described in paragraphs 9 – 10 and 13 - 14, that follow. The remaining changes are made for the purpose of improving the clarity of the regulations. A total of thirty-one editorial changes are made to Part 4 of *Rules and Regulations Pertaining to Radiation Control*, described in the following paragraphs 1 through 22:

1. In RH 4.3, "Definitions," clarifying changes and minor corrections are made to the following:

   The definition of "Declared pregnant woman" is revised to specify that the written declaration of pregnancy would be given to the licensee or registrant rather than the employer, unless the employer is also the licensee. This is necessary to ensure that the entity responsible for work assignments involving radiation exposure (the licensee) is aware of the declaration of pregnancy to facilitate timely and appropriate action. The change also specifies that the declaration, as well as associated dose restrictions, remains in effect until it is withdrawn in writing or until the woman is no longer pregnant. The determination that a declared pregnant woman is no longer pregnant should be based on a discussion between the declared pregnant woman and the licensee.

   The definitions of "High radiation area" and "Very high radiation area" are revised to make it clear that these area designations are made solely to note radiation levels from sources external to an individual who may receive the dose.

   The definition of "Individual monitoring devices" is revised to correct the misuse of the term thermoluminescent to describe thermoluminescence dosimeters.

   The term "Lens dose equivalent (LDE)" replaces "Eye dose equivalent (EDE)" to avoid confusion between the initialisms for dose to the lens of the eye and effective dose equivalent (EDE). Department Forms OR-RH-16 and OR-RH-17 were first published in April 1993 using the term "eye dose equivalent (LDE) to the lens of the eye" and require no changes; those forms or their equivalent are required to be used by existing RH 4.10.3.2, by existing RH 4.46.3, RH 4.46.4, RH 4.46.5, and RH 4.46.6; and by existing RH 4.56.2.

2. In RH 4.5, "Radiation Protection Programs," RH 4.5.2, a clarifying change is made:

   The word "practicable" is changed to "practical" to remove the basis for an incorrect perception among some licensees that, by using the word "practicable" in this section, this Department is requiring licensees to use any dose averting technique that is capable of being used even if the technique is unproven or impractical. The definition in Part 1, General Provisions, RH 1.4, "Definitions," for "As low as is reasonably achievable," uses the word "practical," and therefore requires no changes.

3. In RH 4.6.1, "Occupational Dose Limits for Adults," RH 4.6.1.2.1, RH 4.6.3.1, RH 4.8 "Determination of External Dose from Airborne Radioactive Material," RH 4.8.1, RH 4.40, "Records," RH 4.40.2, RH 4.46 "Records of Individual Monitoring Results," RH 4.46.1.1, RH 4.52, "Notification of Incidents,", RH 4.52.1.1.1.2 and RH 4.52.2.1.1.2, clarifying changes are made:

   "Lens dose equivalent" replaces "eye dose equivalent" as described in the changes to definitions in RH 4.3.

4. In RH 4.11, "Planned Special Exposures," RH 4.11.1, a clarifying change is made:

   "Dose estimated to result from the planned special exposure" replaces "higher exposure" to avoid misinterpretation of a criterion for situations in which a planned special exposure (PSE) may be authorized. The new wording makes authorization of a PSE permissible only in situations when it is impractical to use alternatives that might avoid the dose estimated to result from the PSE, or when such alternatives are unavailable.

5. In RH 4.13, "Dose Equivalent to an Embryo/Fetus," RH 4.13.1, RH 4.13.3, RH 4.13.3.2, and RH 4.13.4, clarifying changes are made:

   "Dose equivalent to an embryo/fetus" replaces "dose to an embryo/fetus" to make it clear that the dose limit specifically applies to the dose equivalent, which is the technically correct term that is used to denote effect of dose to an organ.

6. In RH 4.17, "Surveys and Monitoring (General)," RH 4.17.1.2.1, a clarifying change is made:

   "Magnitude and extent of radiation levels" replaces "radiation levels" to clarify the intended meaning that surveys and monitoring are required to evaluate the amount of radiation dose that could be received in an area, across the entire area in which the radiation hazard is present.

7. In RH 4.17, "Surveys and Monitoring (General)," RH 4.17.1.2.3, a simplifying change is made:

   "The potential radiation hazards" replaces "the potential radiological hazards that could be present," to remove redundancy.

8. In RH 4.18, "Conditions Requiring Individual Monitoring of External and Internal Radiation Dose," RH 4.18.1, a clarifying change is made:

   "Occupational exposure to radiation" is modified by the phrase, "from licensed and unlicensed radiation sources under the control of the licensee" to make it clear that a licensee is not required to take into account the contibution to radiation doses from sources of radiation that are not under its control, when determining whether or not individual monitoring of radiation doses is required. Note that occupational dose continues to include dose from licensed and unlicensed material, whether in the possession of the licensee or of another person.

9. In RH 4.18, "Conditions Requiring Individual Monitoring of External and Internal Radiation Dose," RH 4.18.1.2, monitoring requirements for minors are revised:

   The threshold for monitoring the deep dose equivalent (DDE) to minors is increased to 1 mSv (0.1 rem) in a year from 0.5 mSv (0.05 rem) in a year in light of the fact that 1 mSv (0.1 rem) in a year represents the lowest practical monitoring threshold (0.1 – 0.3 mSv, or 0.01 – 0.03 rem, per monitoring period) that can be measured using individual dosimetry monitoring devices. The thresholds for monitoring the lens dose equivalent (LDE) to minors, 1.5 mSv (0.15 rem), and the shallow dose equivalent (SDE), 5 mSv (0.5 rem) to the skin or to the extremities of minors are now stated explicitly and remain unchanged.

10. In RH 4.18, "Conditions Requiring Individual Monitoring of External and Internal Radiation Dose," RH 4.18.1.3, monitoring requirements for minors and declared pregnant women are revised and clarified:

    The threshold for monitoring the deep dose equivalent (DDE) to declared pregnant women is increased to 1 mSv (0.1 rem) during the entire pregnancy from 0.5 mSv (0.05 rem) in a year in light of the fact that 1 mSv (0.1 rem) in a year represents the lowest practical monitoring threshold (0.1 – 0.3 mSv, or 0.01 – 0.03 rem, per monitoring period) that can be measured using individual dosimetry monitoring devices. An embryo/fetus is not expected to receive a dose equivalent to the lens of the eye or a dose equivalent to the skin or to the extremities, other than the dose equivalent that is derived from the deep dose equivalent (DDE) to the pregnant woman.

11. In RH 4.18, "Conditions Requiring Individual Monitoring of External and Internal Radiation Dose," RH 4.18.1.4, a monitoring requirement for minors and declared pregnant women that was previously stated in RH 4.18.1.3 is clarified:

    References to high radiation areas and very high radiation areas are stated more explicitly.

12. In RH 4.18, "Conditions Requiring Individual Monitoring of External and Internal Radiation Dose," RH 4.18.2.1, RH 4.18.2.2, and RH 4.18.2.3, clarifying changes are made:

    Wording is modified to show more clearly that the rationale for monitoring requirements that are described in RH 4.18.2 is parallel and consistent with the rationale for monitoring requirements that are described in RH 4.18.1.

13. In RH 4.18, "Conditions Requiring Individual Monitoring of External and Internal Radiation Dose," RH 4.18.2.2, monitoring requirements for minors are revised:

    The threshold for monitoring the occupational intake of radioactive material by minors and their associated committed effective dose equivalent, is increased to 1 mSv (0.1 rem) in a year from 0.5 mSv (0.05 rem) in a year to make the requirement consistent with the change to RH 4.18.1.2, described in paragraph 9.

14. In RH 4.18, "Conditions Requiring Individual Monitoring of External and Internal Radiation Dose," RH 4.18.2.3, monitoring requirements for minors and declared pregnant women are clarified:

    The threshold for monitoring the occupational intake of radioactive material by declared pregnant women and their associated committed effective dose equivalent, is increased to 1 mSv (0.1 rem) during the entire pregnancy from 0.5 mSv (0.05 rem) in a year to make the requirement consistent with the change to RH 4.18.1.3, described in paragraph 10.

15. In RH 4.29, "Exceptions to posting requirements," RH 4.29.4 is renumbered to RH 4.29.5 and a new exception is inserted at RH 4.29.4:

    RH 4.29.4 now exempts teletherapy rooms in a hospital from posting requirements, as long as access is controlled by the licensee to prevent the exposure of workers, other patients, and members of the public to radiation. This change brings the regulation into conformity with existing licensing practices and eliminates a requirement that needlessly created alarm for patients and their visitors.

16. In RH 4.32, "Procedures for Receiving and Opening Packages," RH 4.32.4, a simplifying change is made:

    In cases when the licensee must immediately notify the final delivery carrier and this Department of an excessive exposure rate or contamination, the notification must be made by telephone; the reference to notification by telegram, mailgram, or facsimile is removed.

17. In RH 4.40, "General Provisions -- Records," RH 4.40.2, a simplifying change is made:

    Reference to "total organ dose equivalent" is removed because it is no longer used in assessing radiation hazards; it has been replaced by the current practice, which includes estimating the total effective dose equivalent and committed effective dose equivalent to the subject.

18. In RH 4.40, "General Provisions -- Records," RH 4.40.2, minor simplifying changes are made:

    Grammar and punctuation are simplified to make the paragraph easier to read.

19. In RH 4.46, "Records of individual monitoring results," RH 4.46.1.2, a clarifying change is made:

    RH 4.46.1.2 refers the reader to RH 4.7 for information regarding compliance with requirements for summation of external and internal doses, in a manner that is consistent with the wording employed by U.S. NRC in 10 CFR 20.2106(a)(2); RH 4.7 does not prescribe circumstances under which intakes of radionuclides must be estimated.

20. In RH 4.46, "Records of individual monitoring results," RH 4.46.1.4, clarifying words are added:

    RH 4.46.1.4 is revised by adding a reference to RH 4.9.1, that requires licensees to take measurements of (1) concentrations of radioactive materials in air in work areas, or (2) quantities of radionuclides in the body, or (3) quantities of radionuclides excreted from the body, or (4) combinations of these measurements in order to determine internal dose when required by RH 4.18 to monitor internal occupational dose. Such determination in effect uses recorded concentrations of radioactive material in air, quantities of radioactive material determined to be in the body or excreta, or any combination of these that would be needed, for assessing the committed effective dose equivalent (CEDE). This information enhances the reliability of the assessments and calculations that are performed and is needed to support the recorded results of the licensee's calculation of CEDE.

    RH 4.46.1.4 refers the reader to RH 4.9.1 and 4.9.3 for information regarding determination of internal exposure. RH 4.9.1 contains requirements for measurements that are made in the assessment of radiation doses, rather than the calculation of radiation doses. RH 4.9.3 states conditions under which the licensee may modify calculations and assessments of committed effective dose equivalent.

21. In RH 4.2, "Scope," an exception to the applicability of the dose limits in Part 4 is added, that was previously understood but never stated:

    RH 4.2 is revised to state that the dose limits in Part 4 do not apply to exposure from individuals who are administered radioactive material and then released in accordance with RH 7.26. The radioactive materials may be either permanent implants or other physical or chemical forms.

22. In RH 4.38, "Scope," RH 4.38.1, RH 4.38.2, RH 4.38,3, and RH 4.38.4, wording is removed that was made obsolete after the reference date of March 1, 1998:

    RH 4.38.1, RH 4.38.2, RH 4.38,3, and RH 4.38.4 is revised by removal of references to Appendix D. Appendix D had previously been removed and reserved.

This proposed action makes no substantive changes to Part 7 of *Rules and Regulations Pertaining to Radiation Control.* Four editorial changes are made to Part 7 of *Rules and Regulations Pertaining to Radiation Control* for the purpose of improving the clarity of the regulations along with five corrections to references in the Regulations:

1. In RH 7.59, "Radiation Surveys for Teletherapy Facilities," RH 7.59.1.2.1, two clarifying changes are made:

    The phrase "radiation levels" is replaced by the more precise phrase "radiation dose rates."

Personnel exposures subject to the limits specified in RH 4.6 are precisely linked to radiation dose rates to "any occupationally exposed individual."

2. In RH 7.59, "Radiation Surveys for Teletharapy Facilities," RH 7.59.1.2.2, two clarifying changes are made:

   The phrase "radiation levels" is replaced by the more precise phrase "radiation dose rates."

   Personnel exposures subject to the limits specified in RH 4.14.1 are precisely linked to radiation dose rates to "any individual member of the public."

3. In RH 7.61, "Modification of Teletherapy Unit or Room Before Beginning a Treatment Program," a clarifying change is made:

   Personnel exposures subject to the limits specified in RH 4.14.1 are precisely linked to radiation dose rates to "any individual member of the public."

4. In RH 7.61, "Modification of Teletherapy Unit or Room Before Beginning a Treatment Program," RH 7.61.1, a correction is made:

   Modifications must be made to assure that radiation doses will not exceed the limits specified in RH 4.14, "Dose Limits for Individual Members of the Public," rather than in RH 4.6, "Occupational Dose Limits for Adults." According to the summary information for the Final Rule, it had always NRC's intent that the modifications that are described in RH 7.61 would be subject to the limit in RH 4.14.1, of 1 mSv (0.1 rem) limit for individual members of the public; a higher annual limit that is specified in RH 4.14.3, of 5 mSv (0.5 rem), would be allowed, subject to prior approval by the licensing agency.

5. Because of previous changes to the Regulations and RH numbers, five references have been corrected in Part 7. These changes occur in RH 7.34.1, RH 7.36.2, RH 7.68, RH 7.69, and RH 7.70.

This proposed action makes no substantive changes to Part 16 of *Rules and Regulations Pertaining to Radiation Control.* A single editorial change is made to Part 16 of *Rules and Regulations Pertaining to Radiation Control* for the purpose of improving the clarity of the regulations:

In RH 16.8, "Radiation Survey Instruments," RH 16.8.1, a clarifying change is made:

The phrase "maintain sufficient ... radiation survey instruments" is replaced by the simpler phrase "keep a ... radiation survey instrument," and the operating capabilities of the instrument are described more clearly and succinctly.

In addition, two footnotes have been changed to Part 16 to reflect the new Division name and address.

This proposed action makes no substantive changes to Part 19 of *Rules and Regulations Pertaining to Radiation Control.* A single editorial change is made to Part 19 of *Rules and Regulations Pertaining to Radiation Control* for the purpose of improving the clarity of the regulations:

In RH 19.8, "Access control," RH 19.8.7, a simplifying change is made:

The posting requirements for entrances to radiation rooms of panoramic irradiators are prescribed by reference to RH 4.28, "Posting Requirements," rather than by detailed wording.

Specific Statutory Authority. These rules are promulgated pursuant to the following statute:

Colorado Radiation Control Act, Title 25, Article 11, Colorado Revised Statutes 1989 (Act).

Alternative Rules Considered and Why Rejected.

Procedure SA-2000 of the NRC Office of State and Tribal Programs requires timely action to incorporate these changes in Colorado's radiation control regulations as a matter of compatibility with NRC. Within limitations, the Colorado radiation control program has flexibility in adopting changes that are made by NRC. This proposed rulemaking adopts the changes as specified by NRC, without the use of alternative rules, because the rationale for the changes that were made by NRC is fully compatible with current operations and established precedents that guide this program.

Major Factual and Policy Issues Encountered.

The Colorado Board of Health has previously adopted provisions conforming to revisions by the U.S. Nuclear Regulatory Commission (NRC) in 10 CFR Parts 20, 35, 36 and 39.

REGULATORY ANALYSIS FOR

MODIFICATIONS TO PART 1
GENERAL PROVISIONS

MODIFICATIONS TO PART 4
STANDARDS FOR PROTECTION AGAINST RADIATION

MODIFICATIONS TO PART 7
USE OF RADIONUCLIDES IN THE HEALING ARTS

MODIFICATIONS TO PART 16
RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

MODIFICATIONS TO PART 19
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

August 15, 2001

1. **A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.**

The minor revisions to Parts 1 and 4 of *Rules and Regulations Pertaining to Radiation Control* will affect all Colorado radioactive material licensees and registrants.

	Class	Number
Radioactive materials licensees	Total	334
Radiation machine registrants	Total	4800
Service companies	Total	122
Qualified inspectors	Total	55

The minor revisions to Part 7 of *Rules and Regulations Pertaining to Radiation Control* will affect Colorado radioactive material licensees who use radionuclides in the healing arts and who possess and use a teletherapy unit or room.

	Class	Number
Licensees who use radionuclides in the healing arts and who possess and use a teletherapy unit or room	Licensees who use radionuclides in the healing arts Licensees who have a teletherapy unit	73 1

The minor revisions to Part 16 of *Rules and Regulations Pertaining to Radiation Control* will affect Colorado radioactive material licensees who engage in wireline operations and/or subsurface tracer studies.

	Ownership	Number
Licensees who engage in wireline operations and/or subsurface tracer studies	Private	10

The minor revisions to Part 19 of *Rules and Regulations Pertaining to Radiation Control* will affect Colorado radioactive material licensees who possess panoramic irradiators.

	Ownership	Number
Licensees who possess panoramic irradiators	Private	3

2. **To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.**

Quantitative:

All of the Colorado licensees, service companies, qualified inspectors (QIs) and registrants who are affected by Parts 1 and 4 will be impacted by this change. No cost is associated with this rule change, and there may be some reduction in burden to the licensee. However, any reduction is likely to be small. Changes to requirements for shipping manifests for low-level radioactive waste will have no economic impact at all. Only one of the 73 Colorado licensees who are affected by Part 7 will be impacted by this change. No cost is associated with this rule change, and there may be some reduction in burden to the licensee. However, any reduction is likely to be small.

All 10 of the Colorado licensees who are affected by Part 16 will be impacted by this change. No cost is associated with this change, and there will be a minor reduction in burden to the licensees. However, any reduction is likely to be small.

All 3 of the Colorado licensees who are affected by Part 19 will be impacted by this change. No cost is associated with this change, and there may be some reduction in burden to the licensee. However, any reduction is likely to be small.

Qualitative:

The changes to Part 1 help to assure that the regulations will not be duplicative or inconsistent. There is no tangible benefit to the licensees and registrants; the benefit to the regulatory program is that the future costs of updating the regulations will be slightly reduced by having fewer passages in the regulations that will require reconciliation with future changes.

The changes to Part 4 clarify regulations that were previously subject to misunderstanding, and simplify the use of the regulations as a benchmark for good practice among users of radioactive materials and radiation-generating machines. Costs of correcting errors in applications for use of radioactive materials and radiation generating machines, and of correcting items of noncompliance, should thereby be reduced.

The change to Part 7 waives posting requirements in teletherapy rooms in hospitals and may thereby eliminate the unsettling effects that the signs may have on patients. This change may therefore have a beneficial, though intangible, effect on teletherapy patients. There would be no decrease in safety because the safety precautions in Part 7 are considered by the NRC to be adequate to protect individuals from inadvertent exposure to radiation.

The change to Part 16 eliminates the requirement for written incident reports and allows licensees to submit incident reports by telephone. The change is consistent with the federal Paperwork Reduction Act of 1995.

The change to Part 19 makes the posting requirements that are specified for panoramic irradiators conform to the posting requirements that are specified in Part 4 for high or very high radiation areas. Licensees who are in compliance with the Part 4 posting requirements are also in compliance with the revised Part 19 posting requirements.

3. **The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.**

Incremental costs or cost savings from the changes to Parts 1, 4, 7, 16 and 19 are expected to be negligible. The number of criteria that inspectors must evaluate at the time of inspection, in making a determination of compliance with the requirements of Parts 7 and 19, will be slightly reduced. The number of reports that licensees must submit to this Department in order to conform to the requirements of Part 16, will be reduced.

No other federal, state or local agency will be affected by this change.

4. **A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.**

There will be no benefits or savings to the state or to Colorado or its licensees if this change is not adopted.

As stated in the responses to questions 2 and 3, the change is not expected to increase costs to either licensees or the Department.

5. **A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.**

The purpose of the proposed change is to simplify and reduce the requirements that are imposed on the licensees. There are no less costly or intrusive means to achieve the purpose of this change.

6. **A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.**

The advantages to Colorado licensees of conforming with the federal regulations in this case outweigh the no action alternative.

7. **To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.**

The analysis for the proposed changes to Parts 1 and 4 is based on the current number of Colorado licensees (334) and registrants (4800).

The analysis for the proposed changes to Part 7 is based on the current number of Colorado licensees who use radionuclides in the healing arts, and who possess and use, or are likely in the foreseeable future to possess and use, a teletherapy unit or room (1).

The analysis for the proposed change to Part 16 is based on the current number of Colorado licensees who engage in wireline operations and/or subsurface tracer studies (10).

The analysis for the proposed change to Part 19 is based on the current number of Colorado licensees who possess panoramic irradiators (3).

PART 1

GENERAL PROVISIONS

RH 1.4 Definitions. As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain part will be found in that part.

~~"High radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates.~~

~~"Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these regulations, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.~~

PART 4

STANDARDS FOR PROTECTION AGAINST RADIATION

RH 4.1 Purpose.

4.1.1 Part 4 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Department. These regulations are issued pursuant to the 25-11-101 CRS, 1988.

4.1.2 The requirements of Part 4 are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so 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 4. However, nothing in Part 4 shall be construed as limiting actions that may be necessary to protect health and safety.

RH 4.2 Scope. Except as specifically provided in other parts of these regulations, Part 4 applies to persons licensed or registered by the Department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part 4 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 RH 7.26, or to EXPOSURE FROM voluntary participation in medical research programs.

RH 4.3 Definitions. As used in Part 4:

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

"Background radiation" means radiation from cosmic sources; naturally occurring radioactive material, including radon, except as a decay product of source or special nuclear material; and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include radiation from radioactive materials regulated by the Department.

"Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days , and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

"Constraint" (dose constraint) means a value above which specified licensee actions are required.

"Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

"Declared pregnant woman" means a woman who has voluntarily informed ~~her employer~~ THE LICENSEE OR REGISTRANT, in writing, of her pregnancy and the estimated date of conception. THE DECLARATION REMAINS IN EFFECT UNTIL THE DECLARED PREGNANT WOMAN WITHDRAWS THE DECLARATION IN WRITING OR IS NO LONGER PREGNANT.

"Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits: (1) release of the property for unrestricted use and termination of the license: or (2) release of the property under restricted conditions and termination of the license.

"Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B.

"Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

"Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

"Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

"HIGH RADIATION AREA" MEANS AN AREA, ACCESSIBLE TO INDIVIDUALS, IN WHICH RADIATION LEVELS FROM RADIATION SOURCES EXTERNAL TO THE BODY COULD RESULT IN AN INDIVIDUAL RECEIVING A DOSE EQUIVALENT IN EXCESS OF 1 mSv (0.1 rem) IN 1 HOUR AT 30 CENTIMETERS FROM THE RADIATION SOURCE OR 30 CENTIMETERS FROM ANY SURFACE THAT THE RADIATION PENETRATES.

'INDIVIDUAL MONITORING DEVICES (INDIVIDUAL MONITORING EQUIPMENT) MEANS DEVICES DESIGNED TO BE WORN BY A SINGLE INDIVIDUAL FOR THE ASSESSMENT OF DOSE EQUIVALENT SUCH AS FILM BADGES, THERMOLUMINESCENCE DOSIMETERS (TLDs), POCKET IONIZATION CHAMBERS, AND PERSONAL ("LAPEL") AIR SAMPLING DEVICES.

"Inhalation class" (see "Class").

"LENS DOSE EQUIVALENT" ("LDE") APPLIES TO THE EXTERNAL EXPOSURE OF THE LENS OF THE EYE AND IS TAKEN AS THE DOSE EQUIVALENT AT A TISSUE DEPTH OF 0.3 CENTIMETER (300 mg/cm^2).

Lung class" (see "Class").

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "Deterministic effect" is an equivalent term.

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection Report, ICRP Publication 23, "Report of the Task Group on Reference Man."

"Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee=s control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Part 4 of these regulations.

"Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

"Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations, "probabilistic effect" is an equivalent term.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels FROM RADIATION SOURCES EXTERNAL TO THE BODY could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation or 1 METER from any surface that the radiation penetrates.[1]

[1]At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

"Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a]
Whole Body	1.00[b]

[a] 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

[b] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

RH 4.4 Implementation.

4.4.1 Any existing license or registration condition that is more restrictive than Part 4 remains in force until there is an amendment or renewal of the license or registration.

4.4.2 If a license or registration condition exempts a licensee or registrant from a provision of Part 4 in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of revised Part 4.

4.4.3 If a license or registration condition cites provisions of Part 4 in effect prior to January 1, 1994, which do not correspond to any provisions of Part 4, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

RADIATION PROTECTION PROGRAMS

RH 4.5 Radiation Protection Programs.

4.5.1 Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Part 4. See RH 4.41 for recordkeeping requirements relating to these programs.

4.5.2 The licensee or registrant shall use, to the extent ~~practicable~~ PRACTICAL, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and ~~public~~ doses TO MEMBERS OF THE PUBLIC that are as low as is reasonably achievable (ALARA).

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

4.5.4 To implement the ALARA requirements of RH 4.5.2 and notwithstanding the requirements in RH 4.14 of this part, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees, such 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 0.1 millisevert per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in RH 4.53.2 and promptly take appropriate corrective action to ensure against recurrence.

OCCUPATIONAL DOSE LIMITS

RH 4.6 Occupational Dose Limits for Adults.

4.6.1 The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to RH 4.11, to the following dose limits:

4.6.1.1 An annual limit, which is the more limiting of:

4.6.1.1.1 The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

4.6.1.1.2 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 0.5 Sv (50 rem).

4.6.1.2 The annual limits to the lens of the eye, to the skin, and to the extremities which are:

4.6.1.2.1 ~~An eye~~ A LENS dose equivalent of 0.15 Sv (15 rem), and

4.6.1.2.2 A shallow dose equivalent of 0.5 Sv (50 rem) to the skin or to any extremity.

4.6.2 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 RH 4.11.5.1 and 4.11.5.2.

4.6.3 The assigned deep dose equivalent and shallow dose equivalent ~~shall~~ MUST be for the ~~portion~~ PART of the body receiving the highest exposure. ~~determined as follows:~~

4.6.3.1 ~~The deep dose equivalent, eye dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating 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~~ 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 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.

~~4.6.3.2 Reserved.~~

4.6.4 Derived air concentration (DAC) and annual limit on intake (ALI) values are 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 RH 4.46.

4.6.5 Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

4.6.6 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. See RH 4.10.3.1 and 4.10.5.

RH 4.7 Compliance with Requirements for Summation of External and Internal Doses.

4.7.1 If the licensee or registrant is required to monitor pursuant to both RH 4.18.1 and 4.18.2, the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to RH 4.18.1 or only pursuant to RH 4.18.2, 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 RH 4.7.2, 4.7.3 and 4.7.4. 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.

4.7.2 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:

4.7.2.1 The sum of the fractions of the inhalation ALI for each radionuclide, or

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

4.7.2.3 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 organ or tissue is deemed to be 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_{50}, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

4.7.3 Intake by Oral Ingestion. If the occupationally exposed individual also 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 limits.

4.7.4 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 included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to RH 4.7.4.

RH 4.8 Determination of External Dose from Airborne Radioactive Material.

4.8.1 Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, ~~eye~~ LENS dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B TO Part 4, footnotes 1 and 2.

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

RH 4.9 Determination of Internal Exposure.

4.9.1 For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, when required pursuant to RH 4.18, take suitable and timely measurements of:

4.9.1.1 Concentrations of radioactive materials in air in work areas; or

4.9.1.2 Quantities of radionuclides in the body; or

4.9.1.3 Quantities of radionuclides excreted from the body; or

4.9.1.4 Combinations of these measurements.

4.9.2 Unless respiratory protective equipment is used, as provided in RH 4.24, 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 the individual is present.

4.9.3 When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee or registrant may:

4.9.3.1 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

4.9.3.2 Upon prior approval of the 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

4.9.3.3 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 Appendix B.

4.9.4 If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in RH 4.9.1.2 or 4.9.1.3, the licensee or registrant may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by RH 4.52 or 4.53. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

4.9.5 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:

4.9.5.1 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

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

4.9.6 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.

4.9.7 When a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if:

4.9.7.1 The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in RH 4.6 and in complying with the monitoring requirements in RH 4.18.2, and

4.9.7.2 The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

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

4.9.8 When determining the committed effective dose equivalent, the following information may be considered:

4.9.8.1 In order to calculate the committed effective dose equivalent, the 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 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

4.9.8.2 For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in RH 4.6.1.1.2 is met.

RH 4.10 Determination of Prior Occupational Dose.

4.10.1 For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to RH 4.18, the licensee or registrant shall:

4.10.1.1 Determine the occupational radiation dose received during the current year; and

4.10.1.2 Attempt to obtain the records of lifetime cumulative occupational radiation dose.

4.10.2 Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

4.10.2.1 The internal and external doses from all previous planned special exposures; and

4.10.2.2 All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

4.10.2.3 All lifetime cumulative occupational radiation dose.

4.10.3 In complying with the requirements of RH 4.10.1, a licensee or registrant may:

4.10.3.1 Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

4.10.3.2 Accept, as the record of lifetime cumulative radiation dose, an up-to-date Department Form OR-RH-16, Cumulative Occupational Exposure History, or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

4.10.3.3 Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

4.10.4 Record of Exposure History.

4.10.4.1 The licensee or registrant shall record the exposure history, as required by RH 4.10.1, on Department Form OR-RH-16, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Department Form OR-RH-16 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Department Form OR-RH-16 or equivalent indicating the periods of time for which data are not available.

4.10.4.2 Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the Regulations in Part 4 in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on Department Form OR-RH-16 or equivalent before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

4.10.5 If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

4.10.5.1 In establishing administrative controls pursuant to RH 4.6.6 for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

4.10.5.2 That the individual is not available for planned special exposures.

4.10.6 The licensee or registrant shall retain the records on Department Form OR-RH-16 or equivalent until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Department Form OR-RH-16 or equivalent for 3 years after the record is made.

RH 4.11 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 RH 4.6 provided that each of the following conditions in RH 4.11.1 through 4.11.7 is satisfied:

4.11.1 The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the ~~higher exposure~~ DOSE ESTIMATED TO RESULT FROM THE PLANNED SPECIAL EXPOSURE are unavailable or impractical.

4.11.2 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.

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

4.11.3.1 Informed of the purpose of the planned operation; and

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

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

4.11.4 Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by RH 4.10.2 during the lifetime of the individual for each individual involved.

4.11.5 Subject to RH 4.6.2, 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:

4.11.5.1 The numerical values of any of the dose limits in RH 4.6.1 in any year; and

4.11.5.2 Five times the annual dose limits in RH 4.6.1 during the individual's lifetime.

4.11.6 The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with RH 4.45 and submits a written report in accordance with RH 4.54.

4.11.7 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 the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to RH 4.6.1 but shall be included in evaluations required by RH 4.11.4 and 4.11.5.

RH 4.12 Occupational Dose Limits for Minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in RH 4.6.

RH 4.13 Dose EQUIVALENT to an Embryo/Fetus.

4.13.1 The licensee or registrant shall ensure that the dose EQUIVALENT to an embryo/fetus during the entire pregnancy, due to THE occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See RH 4.46 for recordkeeping requirements.

4.13.2 The licensee or registrant shall make efforts to avoid substantial variation[2] above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in RH 4.13.1.

4.13.3 The dose EQUIVALENT to an embryo/fetus ~~shall be taken as~~ IS the sum of:

4.13.3.1 The deep dose equivalent to the declared pregnant woman; and

4.13.3.2 The dose EQUIVALENT to the embryo/fetus RESULTING from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

4.13.4 If ~~by the time the woman declares pregnancy to the licensee or registrant,~~ the dose EQUIVALENT to the embryo/fetus ~~has~~ IS FOUND TO HAVE exceeded ~~4.5 mSv (0.45 rem)~~ 5 mSv (0.5 rems), OR IS WITHIN 0.5 mSv (0.05 rems) OF THIS DOSE, BY THE TIME THE WOMAN DECLARES THE PREGNANCY TO THE LICENSEE OR REGISTRANT, the licensee or registrant shall be deemed to be in compliance with RH 4.13.1 if the additional dose EQUIVALENT to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

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[2] 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 mSv (0.05 rem) to the embryo/fetus be received in any one month.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

RH 4.14 Dose Limits for Individual Members of the Public.

4.14.1 Each licensee or registrant shall conduct operations so that:

4.14.1.1 The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 milliSievert (0.1 rem) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with RH 7.26, from voluntary participation in medical research programs, and from the dose contribution from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with RH 4.35, and

4.14.1.2 The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with RH 7.26, does not exceed 0.02 milliSievert (0.002 rem) in any one hour.

4.14.2 Reserved.

4.14.3 A licensee, registrant, or an applicant for a license or registration may apply for prior Department authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem). This application shall include the following information:

4.14.3.1 Demonstration of the need for and the expected duration of operations in excess of the limit in RH 4.14.1; and

4.14.3.2 The licensee's or registrant's program to assess and control dose within the 5 mSv (0.5 rem) annual limit; and

4.14.3.3 The procedures to be followed to maintain the dose ALARA.

4.14.4 In addition to the requirements of Part 4, a licensee or registrant subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

4.14.5 The 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.

RH 4.15 Compliance with Dose Limits for Individual Members of the Public.

4.15.1 The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in RH 4.14.

4.15.2 A licensee or registrant shall show compliance with the annual dose limit in RH 4.14 by:

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

4.15.2.2 Demonstrating that:

4.15.2.2.1 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 of Appendix B; and

4.15.2.2.2 If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

4.15.3 Upon approval from the Department, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II, 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.

4.15.4 Rooms or areas in which diagnostic x-ray systems are the only source of radiation shall demonstrate compliance with RH 4.15.2.1 after construction of a new x-ray facility, after modification or renovation of an existing x-ray facility, or installation or a new x-ray machine in an existing x-ray facility when there is a change in primary beam orientation, or a change in primary shielding due to the modification or renovation of a facility, or where there is a projected increase in the x-ray workload from that which was used for a prior x-ray shielding design.

4.15.5 Facilities using only dental intraoral or panoramic machines in single occupancy rooms are exempt from the requirements of RH 4.15.2.1.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

RH 4.16 Testing for Leakage or Contamination of Sealed Sources.

4.16.1 The licensee or registrant in possession of any sealed source shall assure that:

4.16.1.1 Each sealed source, except as specified in RH 4.16.2, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee or registrant. Sources that indicate contamination in excess of 185 Bq (0.005 microcuries) shall not be put into use.

4.16.1.2 Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals approved by the Department, after evaluation of information specified by RH 3.12.12.4 and 3.12.12.5 of these regulations, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

4.16.1.3 Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals approved by the Department, after evaluation of information specified by RH 3.12.12.4 and 3.12.12.5 of these regulations, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

4.16.1.4 For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use.

4.16.1.5 Tests, and evaluations of tests, for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 µCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

4.16.1.6 The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 µCi) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.

4.16.1.7 Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 µCi) of a radium daughter which has a half-life greater than 4 days.

4.16.2 A licensee or registrant need not perform test for leakage or contamination on the following sealed sources:

4.16.2.1 Sealed sources containing only radioactive material with a half-life of less than 30 days;

4.16.2.2 Sealed sources containing only radioactive material as a gas;

4.16.2.3 Sealed sources containing 3.7 MBq (100 µCi) or less of beta or photon-emitting material or 370 kBq (10 µCi) or less of alpha-emitting material;

4.16.2.4 Sealed sources containing only hydrogen-3;

4.16.2.5 Seeds of iridium-192 encased in nylon ribbon; and

4.16.2.6 Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.

4.16.3 Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Department, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

4.16.4 Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Department.

4.16.5 The following shall be considered evidence that a sealed source is leaking:

4.16.5.1 The presence of 185 Bq (0.005 µCi) or more of removable contamination on any test sample.

4.16.5.2 Leakage of 37 Bq (0.001 µCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

4.16.5.3 The presence of removable contamination resulting from the decay of 185 Bq (0.005 µCi) or more of radium.

4.16.6 The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Part.

4.16.7 Reports of test results for leaking or contaminated sealed sources shall be made pursuant to RH 4.58.

SURVEYS AND MONITORING

RH 4.17 General.

4.17.1 Each licensee or registrant shall make, or cause to be made, surveys that:

4.17.1.1 Are necessary for the licensee or registrant to comply with Part 4; and

4.17.1.2 Are necessary under the circumstances to evaluate:

4.17.1.2.1 ~~Radiation~~ THE MAGNITUDE AND EXTENT OF RADIATION levels; and

4.17.1.2.2 Concentrations or quantities of radioactive material; and

4.17.1.2.3 The potential radiological hazards. ~~that could be present.~~

4.17.2 The 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 for the radiation measured unless otherwise noted in these regulations.

4.17.3 All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those 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 to comply with RH 4.6, with other applicable provisions of these regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

4.17.3.1 Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

4.17.3.2 Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

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

RH 4.18 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part 4. As a minimum:

4.18.1 Each licensee or registrant shall monitor occupational exposure to radiation FROM LICENSED AND UNLICENSED RADIATION SOURCES UNDER THE CONTROL OF THE LICENSEE and shall supply and require the use of individual monitoring devices by: --

4.18.1.1 Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in RH 4.6.1; ~~and~~

4.18.1.2 Minors ~~and declared pregnant women~~ likely to receive, in 1 year from RADIATION sources external to the body, a DEEP dose EQUIVALENT in excess of ~~10 percent of any of the applicable limits in RH 4.12 or 4.13~~ 1mSv (0.1 rem), A LENS DOSE EQUIVALENT IN EXCESS OF 1.5 mSv (0.15 rem), OR A SHALLOW DOSE EQUIVALENT TO THE SKIN OR TO THE EXTREMITIES IN EXCESS OF 5 mSv (0.5 rem); ~~and~~

4.18.1.3 ~~Individuals entering a high or very high radiation area.~~DECLARED PREGNANT WOMEN LIKELY TO RECEIVE DURING THE ENTIRE PREGNANCY, FROM RADIATION SOURCES EXTERNAL TO THE BODY, A DEEP DOSE EQUIVALENT IN EXCESS OF 1mSv (0.1 rem);[2] AND

4.18.1.4 INDIVIDUALS ENTERING A HIGH RADIATION AREA OR A VERY HIGH RADIATION AREA. ~~Reserved.~~

4.18.2 Each licensee or registrant shall monitor, to determine compliance with RH 4.9, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

4.18.2.1 Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in Table I, Columns 1 and 2, of Appendix B TO Part 4, ~~; and~~

4.18.2.2 Minors ~~and declared pregnant women~~ likely to receive, in 1 year, a committed effective dose equivalent in excess of ~~0.5 mSv (0.05 rem).~~ 1 mSv (0.1 rem), AND

4.18.2.3 ~~Minors and~~ DECLARED PREGNANT WOMEN LIKELY TO RECEIVE DURING THE ENTIRE PREGNANCY, A COMMITTED EFFECTIVE DOSE EQUIVALENT IN EXCESS OF 1 mSv (0.1 rem).

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

RH 4.19 Control of Access to High Radiation Areas.

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

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

4.19.1.2 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

4.19.1.3 Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

4.19.2 In place of the controls required by RH 4.19.1 for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

4.19.3 The licensee or registrant may apply to the Department for approval of alternative methods for controlling access to high radiation areas.

4.19.4 The licensee or registrant shall establish the controls required by RH 4.19.1 and 4.19.3 in a way that does not prevent individuals from leaving a high radiation area.

4.19.5 The 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 U.S. Department of Transportation provided that:

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

4.19.5.2 The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

4.19.6 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 are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in Part 4 and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

4.19.7 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 RH 4.19 if the licensee or registrant has met all the specific requirements for access and control specified in other applicable parts of these regulations, such as, Part 5 for industrial radiography, Part 6 for x-rays in the healing arts, and Part 9 for particle accelerators.

RH 4.20 Control of Access to Very High Radiation Areas.

4.20.1 In addition to the requirements in RH 4.19, the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (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.

4.20.2 The 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 RH 4.20.1 if the registrant has met all the specific requirements for access and control specified in other applicable parts of these regulations, such as, Part 5 for industrial radiography, Part 6 for x-rays in the healing arts, and Part 9 for particle accelerators.

RH 4.21 Control of Access to Very High Radiation Areas -- Irradiators.

4.21.1 Section RH 4.21 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Section RH 4.21 does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

4.21.2 Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

4.21.2.1 Each entrance or access point shall be equipped with entry control devices which:

4.21.2.1.1 Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

4.21.2.1.2 Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

4.21.2.1.3 Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in 1 hour.

4.21.2.2 Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by RH 4.21.2.1:

4.21.2.2.1 The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

4.21.2.2.2 Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

4.21.2.3 The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

4.21.2.3.1 The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

4.21.2.3.2 Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

4.21.2.4 When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

4.21.2.5 Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of RH 4.21.2.3 and 4.21.2.4.

4.21.2.6 Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

4.21.2.7 Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

4.21.2.8 Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.

4.21.2.9 The entry control devices required in RH 4.21.2.1 shall be tested for proper functioning. See RH 4.49 for recordkeeping requirements.

4.21.2.9.1 Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

4.21.2.9.2 Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

4.21.2.9.3 The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

4.21.2.10 The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

4.21.2.11 Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to automatically prevent loose radioactive material from being carried out of the area.

4.21.3 Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of RH 4.21.2 which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of RH 4.21.2, such as those for the automatic control of radiation levels, may apply to the Department for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in RH 4.21.2 At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

4.21.4 The entry control devices required by RH 4.21.2 and 4.21.3 shall be established in such a way that no individual will be prevented from leaving the area.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

RH 4.22 Use of Process or Other Engineering Controls. The licensee shall use, to the extent practical, process or other engineering controls, such as, containment or ventilation, to control the concentrations of radioactive material in air.

RH 4.23 Use of Other Controls. When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

4.23.1 Control of access; or

4.23.2 Limitation of exposure times; or

4.23.3 Use of respiratory protection equipment; or

4.23.4 Other controls.

RH 4.24 Use of Individual Respiratory Protection Equipment.

4.24.1 If the licensee uses respiratory protection equipment to limit intakes pursuant to RH 4.23:

4.24.1.1 Except as provided in RH 4.24.1.2, the licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

4.24.1.2 If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

4.24.1.3 The licensee shall implement and maintain a respiratory protection program that includes:

4.24.1.3.1 Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

4.24.1.3.2 Surveys and bioassays, as appropriate, to evaluate actual intakes; and

4.24.1.3.3 Testing of respirators for operability immediately prior to each use; and

4.24.1.3.4 Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and

4.24.1.3.5 Determination by a physician prior to initial fitting of respirators, and either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment.

4.24.1.4 The licensee shall issue a written policy statement on respirator usage covering:

4.24.1.4.1 The use of process or other engineering controls, instead of respirators; and

4.24.1.4.2 The routine, nonroutine, and emergency use of respirators; and

4.24.1.4.3 The length of periods of respirator use and relief from respirator use.

4.24.1.5 The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

4.24.1.6 The licensee shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.

4.24.2 When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to RH 4.23, provided that the following conditions, in addition to those in RH 4.24.1, are satisfied:

4.24.2.1 The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the multiple defined in the preceding sentence is inconsistent with the goal specified in RH 4.23 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

4.24.2.2 The licensee shall obtain authorization from the Department before assigning respiratory protection factors in excess of those specified in Appendix A. The Department may authorize a licensee to use higher protection factors on receipt of an application that:

4.24.2.2.1 Describes the situation for which a need exists for higher protection factors, and

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

4.24.3 In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

4.24.4 The licensee shall notify the Department in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either RH 4.24.1 or 4.24.2.

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

RH 4.25 Security of Stored Sources of Radiation. The licensee shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in unrestricted areas.

RH 4.26 Control of Sources of Radiation not in Storage.

4.26.1 The licensee shall control and maintain constant surveillance of licensed or registered radioactive material that is in an unrestricted area and that is not in storage or in a patient.

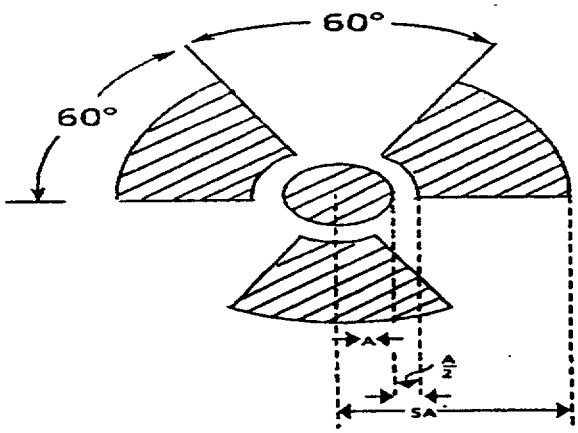
4.26.2 The registrant shall maintain control of radiation machines that are in an unrestricted area and that are not in storage.

RH 4.27 Caution Signs.

4.27.1 Standard Radiation Symbol. Unless otherwise authorized by the Department, the symbol prescribed by RH 4.27 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.



4.27.2 Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of RH 4.27.1, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

4.27.3 Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in Part 4, the licensee shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

RH 4.28 Posting Requirements.

4.28.1 Posting of Radiation Areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

4.28.2 Posting of High Radiation Areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

4.28.3 Posting of Very High Radiation Areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

4.28.4 Posting of Airborne Radioactivity Areas. The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

4.28.5 Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding 10 times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

RH 4.29 Exceptions to Posting Requirements.

4.29.1 A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours, if each of the following conditions is met:

4.29.1.1 The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in Part 4; and

4.29.1.2 The area or room is subject to the licensee's or registrant's control.

4.29.2 Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to RH 4.28 provided that the total effective dose equivalent to individual members of the public from the patient does not exceed 1 milliSievert (0.1 rem) in a year.

4.29.3 A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

4.29.4 ROOMS IN HOSPITALS OR CLINICS THAT ARE USED FOR TELETHERAPY ARE EXEMPT FROM THE REQUIREMENT TO POST CAUTION SIGNS UNDER RH 4.28 IF --

4.29.4.1 ACCESS TO THE ROOM IS CONTROLLED PURSUANT TO RH 7.52; AND

4.29.4.2 PERSONNEL IN ATTENDANCE TAKE NECESSARY PRECAUTIONS TO PREVENT THE INADVERTENT EXPOSURE OF WORKERS, OTHER PATIENTS, AND MEMBERS OF THE PUBLIC TO RADIATION IN EXCESS OF THE LIMITS ESTABLISHED IN THIS PART.

4.29.5 A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

RH 4.30 Labeling Containers and Radiation Machines.

4.30.1 The licensee or registrant shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

4.30.2 Each licensee or registrant shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

4.30.3 Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

RH 4.31 Exemptions to Labeling Requirements. A licensee or registrant is not required to label:

4.31.1 Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C; or

4.31.2 Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B; or

4.31.3 Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Part 4; or

4.31.4 Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation;[4] or

[4]Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.

4.31.5 Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

4.31.6 Installed manufacturing or process equipment, such as piping and tanks.

RH 4.32 Procedures for Receiving and Opening Packages.

4.32.1 Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in RH 17.2 and Appendix A of Part 17 of these regulations, shall make arrangements to receive:

4.32.1.1 The package when the carrier offers it for delivery; or

4.32.1.2 The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

4.32.2 Each licensee or registrant shall:

4.32.2.1 Monitor the external surfaces of a labeled[5] package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in RH 1.4 of these regulations; and

4.32.2.2 Monitor the external surfaces of a labeled[5] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in RH 17.2 and Appendix A to Part 17 of these regulations; and

4.32.2.3 Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

4.32.3 The licensee or registrant shall perform the monitoring required by RH 4.32.2 as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

4.32.4 The licensee or registrant shall immediately notify the final delivery carrier and the Department by telephone, ~~and by telegram, mailgram, or facsimile if:~~ WHEN --

4.32.4.1 Removable radioactive surface contamination exceeds the limits of RH 17.15.8 of these regulations; or

[5]Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440.

4.32.4.2 External radiation levels exceed the limits of RH 17.15.9 and 17.15.10 of these regulations.

4.32.5 Each licensee or registrant shall:

4.32.5.1 Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

4.32.5.2 Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

4.32.6 Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a work site are exempt from the contamination monitoring requirements of RH 4.32.2, but are not exempt from the monitoring requirement in RH 4.32.2 for measuring radiation levels that ensures that the source is still properly lodged in its shield.

WASTE DISPOSAL

RH 4.33 General Requirements.

4.33.1 A licensee or registrant shall dispose of licensed or registered material only:

4.33.1.1 By transfer to an authorized recipient as provided in RH 4.38 or in Parts 3, 14, or 18 of these regulations, or to the U.S. Department of Energy; or

4.33.1.2 By decay in storage; or

4.33.1.3 By release in effluents within the limits in RH 4.14; or

4.33.1.4 As authorized pursuant to RH 4.34, 4.35, 4.36 or 4.37.

4.33.2 A person shall be specifically licensed or registered to receive waste containing licensed or registered material from other persons for:

4.33.2.1 Treatment prior to disposal; or

4.33.2.2 Treatment or disposal by incineration; or

4.33.2.3 Decay in storage; or

4.33.2.4 Disposal at a land disposal facility pursuant to Part 14 of these regulations or as authorized under Parts 3 or 18 of these regulations; or

4.33.2.5 Storage until transferred to a storage or disposal facility authorized to receive the waste.

RH 4.34 Method for Obtaining Approval of Proposed Disposal Procedures. A licensee or registrant or applicant for a license or registration may apply to the Department for approval of proposed procedures, not otherwise authorized in these regulations, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

4.34.1 A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and

4.34.2 An analysis and evaluation of pertinent information on the nature of the environment; and

4.34.3 The nature and location of other potentially affected facilities; and

4.34.4 Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in Part 4.

RH 4.35 Disposal by Release into Sanitary Sewerage.

4.35.1 A licensee or registrant may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:

4.35.1.1 The material is readily soluble, or is readily dispersible biological material, in water; and

4.35.1.2 The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table III of Appendix B; and

4.35.1.3 If more than one radionuclide is released, the following conditions must also be satisfied:

4.35.1.3.1 The licensee or registrant shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table III of Appendix B; and

4.35.1.3.2 The sum of the fractions for each radionuclide required by RH 4.35.1.3.1 does not exceed unity; and

4.35.1.4 The total quantity of licensed or registered radioactive material that the licensee or registrant releases into the sanitary sewerage in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined.

4.35.2 Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in RH 4.35.1.

RH 4.36 Treatment or Disposal by Incineration. A licensee or registrant may treat or dispose of licensed or registered material by incineration only in the amounts and forms specified in RH 4.37 or as specifically approved by the Department pursuant to RH 4.34.

RH 4.37 Disposal of Specific Wastes.

4.37.1 A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:

4.37.1.1 1.85 kBq (0.05 µCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

4.37.1.2 1.85 kBq (0.05 µCi), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

4.37.2 A licensee or registrant shall not dispose of tissue pursuant to RH 4.37.1.2. in a manner that would permit its use either as food for humans or as animal feed.

4.37.3 The licensee or registrant shall maintain records in accordance with RH 4.48.

RH 4.38 Transfer for Disposal and Manifests.

4.38.1 The requirements of RH 4.38 and Appendix G~~, or Appendix D if prior to March 1, 1998,~~ are designed to control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this part, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes. ~~Beginning March 1, 1998, all affected licensees must use Appendix G. Prior to March 1, 1998, a disposal facility operator or its regulatory authority may require the shipper to use Appendix D or Appendix G.~~

4.38.2 Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility shall document the information required on the uniform low-level radioactive waste manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G~~, or each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility prior to March 1, 1998, shall be accompanied by a shipment manifest as specified in Section I of Appendix D~~.

4.38.3 Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix G ~~or Appendix D as appropriate in accordance with RH 4.38.1~~.

4.38.4 Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix G ~~or Appendix D as appropriate in accordance with RH 4.38.1~~.

RH 4.39 Compliance with Environmental and Health Protection Regulations. Nothing in RH 4.33, 4.34, 4.35, 4.37 or 4.38 relieves the licensee or registrant from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to RH 4.33, 4.34, 4.35, 4.37 or 4.38.

RECORDS

RH 4.40 General Provisions.

4.40.1 Each licensee or registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by Part 4.

4.40.2 The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part 4~~, such as,~~ (e.g., total effective dose equivalent, ~~total organ dose equivalent,~~ shallow dose equivalent, ~~eye~~ LENS dose equivalent, deep dose equivalent,~~ or~~ committed effective dose equivalent).

4.40.3 The licensee or registrant shall be consistent in their use of SI or special units. The licensee or registrant shall not change the units used on records required by Part 4 except at the beginning of the calendar year or with Department approval.

RH 4.41 Records of Radiation Protection Programs.

4.41.1 Each licensee or registrant shall maintain records of the radiation protection program, including:

4.41.1.1 The provisions of the program; and

4.41.1.2 Audits and other reviews of program content and implementation.

4.41.2 The licensee or registrant shall retain the records required by RH 4.41.1.1 until the Department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by RH 4.41.1.2 for 3 years after the record is made.

RH 4.42 Records of Surveys.

4.42.1 Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by RH 4.17 and 4.32.2. The licensee or registrant shall retain these records for 3 years after the record is made.

4.42.2 The licensee or registrant shall retain each of the following records until the Department terminates each pertinent license or registration requiring the record:

4.42.2.1 Records of the results of surveys to determine the dose from external sources of radiation and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

4.42.2.2 Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

4.42.2.3 Records showing the results of air sampling, surveys, and bioassays required pursuant to RH 4.24.1.3.1 and 4.24.1.3.2; and

4.42.2.4 Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

4.42.3 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form OR-RH-16 or equivalent, or shall make provision with the Department for transfer to the Department.

RH 4.43 Records of Tests for Leakage or Contamination of Sealed Sources.

Records of tests for leakage or contamination of sealed sources required by RH 4.16 shall be kept in units of becquerel or microcurie and maintained for inspection by the Department for 5 years after the records are made.

RH 4.44 Records of Prior Occupational Dose.

4.44.1 The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in RH 4.10 on Department Form OR-RH-16 or equivalent until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Department Form OR-RH-16 or equivalent for 3 years after the record is made.

4.44.2 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form OR-RH-16 or equivalent, or shall make provision with the Department for transfer to the Department.

RH 4.45 Records of Planned Special Exposures.

4.45.1 For each use of the provisions of RH 4.11 for planned special exposures, the licensee or registrant shall maintain records that describe:

4.45.1.1 The exceptional circumstances requiring the use of a planned special exposure; and

4.45.1.2 The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

4.45.1.3 What actions were necessary; and

4.45.1.4 Why the actions were necessary; and

4.45.1.5 What precautions were taken to assure that doses were maintained ALARA; and

4.45.1.6 What individual and collective doses were expected to result; and

4.45.1.7 The doses actually received in the planned special exposure.

4.45.2 The licensee or registrant shall retain the records until the Department terminates each pertinent license or registration requiring these records.

4.45.3 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form OR-RH-16 or equivalent, or shall make provision with the Department for transfer to the Department.

RH 4.46 Records of Individual Monitoring Results.

4.46.1 Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to RH 4.18, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994 need not be changed. These records shall include, when applicable:

4.46.1.1 The deep dose equivalent to the whole body, ~~eye~~ LENS dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; ~~and~~

4.46.1.2 The estimated intake of radionuclides~~, when required by~~ (SEE RH 4.7); ~~and~~

4.46.1.3 The committed effective dose equivalent assigned to the intake of radionuclides; ~~and~~

4.46.1.4 The specific information used to ASSESS AND calculate the committed effective dose equivalent pursuant to RH 4.9.1 AND RH 4.9.3, AND WHEN REQUIRED BY RH 4.18; ~~and~~

4.46.1.5 The total effective dose equivalent when required by RH 4.7; and

4.46.1.6 The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

4.46.2 Recordkeeping Frequency. The licensee or registrant shall make entries of the records specified in RH 4.46.1 at intervals not to exceed 1 year.

4.46.3 Recordkeeping Format. The licensee or registrant shall maintain the records specified in RH 4.46.1 on Department Form OR-RH-17, Occupational Exposure Record for a Monitoring Period, in accordance with the instructions for Department Form OR-RH-17, or in clear and legible records containing all the information required by Department Form OR-RH-17.

4.46.4 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.

4.46.5 The licensee or registrant shall retain each required form or record until the Department terminates each pertinent license or registration requiring the record.

4.46.6 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form OR-RH-16 or equivalent, or shall make provision with the Department for transfer to the Department.

RH 4.47 Records of Dose to Individual Members of the Public.

4.47.1 Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See RH 4.14.

4.47.2 The licensee or registrant shall retain the records required by RH 4.47.1 until the Department terminates each pertinent license or registration requiring the record.

RH 4.48 Records of Waste Disposal.

4.48.1 Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to RH 4.34, 4.35, 4.36, 4.37, Part 14 of these regulations, and disposal by burial in soil, including burials authorized before December 30, 1985.

4.48.2 The licensee or registrant shall retain the records required by RH 4.48.1 in accordance with RH 3.15.4 until the Department terminates each pertinent license or registration requiring the record.

RH 4.49 Records of Testing Entry Control Devices for Very High Radiation Areas.

4.49.1 Each licensee or registrant shall maintain records of tests made pursuant to RH 4.21.2.9 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

4.49.2 The licensee or registrant shall retain the records required by RH 4.49.1 for 3 years after the record is made.

RH 4.50 Form of Records. Each record required by Part 4 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in Department-approved electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

REPORTS

RH 4.51 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

4.51.1 Telephone Reports. Each licensee or registrant shall report to the Department by telephone as follows:

4.51.1.1 Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; or

4.51.1.2 Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix C that is still missing.

4.51.1.3 Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

4.51.2 Written Reports. Each licensee or registrant required to make a report pursuant to RH 4.51.1 shall, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

4.51.2.1 A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

4.51.2.2 A description of the circumstances under which the loss or theft occurred; and

4.51.2.3 A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

4.51.2.4 Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

4.51.2.5 Actions that have been taken, or will be taken, to recover the source of radiation; and

4.51.2.6 Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

4.51.3 Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

4.51.4 The licensee or registrant shall prepare any report filed with the Department pursuant to RH 4.51 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

RH 4.52 Notification of Incidents.

4.52.1 Immediate Notification. Notwithstanding other requirements for notification, each licensee or registrant shall notify the Department as soon as possible but not later than 4 hours after the discovery of an event:

4.52.1.1 Involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

4.52.1.1.1 An individual to receive:

4.52.1.1.1.1 A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

4.52.1.1.1.2 ~~An eye~~ A LENS dose equivalent of 0.75 Sv (75 rem) or more; or

4.52.1.1.1.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or

4.52.1.1.2 The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

4.52.1.2 That prevents immediate protective actions necessary to avoid exposures to radiation and/or radioactive materials that could exceed regulatory limits, or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

4.52.2 Twenty-Four Hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Department:

4.52.2.1 Each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

4.52.2.1.1 An individual to receive, in a period of 24 hours:

4.52.2.1.1.1 A total effective dose equivalent exceeding 0.05 Sv (5 rem); or

4.52.2.1.1.2 ~~An eye~~ A LENS dose equivalent exceeding 0.15 Sv (15 rem); or

4.52.2.1.1.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or

4.52.2.1.2 The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

4.52.2.2 An unplanned contamination event that:

4.52.2.2.1 Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

4.52.2.2.2 Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Part 4 for the material; and

4.52.2.2.3 Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

4.52.2.3 An event in which equipment is disabled or fails to function as designed when:

4.52.2.3.1 The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and/or radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident; and

4.52.2.3.2 The equipment is required to be available and operable when it is disabled or fails to function during the event; and

4.52.2.3.3 No redundant equipment is available and operable to perform the required safety function.

4.52.2.4 An event that requires unplanned medical treatment at a medical facility of an individual who's body or clothing is contaminated with spreadable radioactive material.

4.52.2.5 An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

4.52.2.5.1 The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Part 4 for the material; and

4.52.2.5.2 The damage affects the integrity of the licensed material or its container.

RH 4.53 Preparation and Submission of Reports.

4.53.1 Reports made by licensees or registrants in response to the requirements of RH 4.52, must be made as follows:

4.53.1.1 Licensees or registrants shall make the reports required by RH 4.52.1 and 4.52.2 to the Department by telephone~~, and by telegram, mailgram, or facsimile~~. To the extent that the information is available at the time of notification, the information provided in these reports must included:

4.53.1.1.1 The caller's name and call back telephone number;

4.53.1.1.2 A description of the event including date and time;

4.53.1.1.3 The exact location of the event;

4.53.1.1.4 The isotopes, quantities, and chemical and physical form of the licensed material involved; and

4.53.1.1.5 Any personnel radiation exposure data available.

4.53.1.2 Each licensee or registrant who makes a report required by RH 4.52.1 or 4.52.2 shall submit a written follow-up report to the Department pursuant to RH 4.53.3 within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made.

4.53.1.3 The provisions of RH 4.52 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to RH 4.54.

4.53.2 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits.

In addition to the notification required by RH 4.52, each licensee or registrant shall submit a written report to the Department within 30 days after learning of any of the following occurrences:

4.53.2.1 Incidents for which notification is required by RH 4.52; or

4.53.2.2 Doses in excess of any of the following:

4.53.2.2.1 The occupational dose limits for adults in RH 4.6; or

4.53.2.2.2 The occupational dose limits for a minor in RH 4.12; or

4.53.2.2.3 The limits for an embryo/fetus of a declared pregnant woman in RH 4.13; or

4.53.2.2.4 The limits for an individual member of the public in RH 4.14; or

4.53.2.2.5 Any applicable limit in the license or registration; or

4.53.2.2.6 The ALARA constraints for air emissions established under RH 4.5.4.

4.53.2.3 Levels of radiation or concentrations of radioactive material in:

4.53.2.3.1 A restricted area in excess of applicable limits in the license or registration; or

4.53.2.3.2 An unrestricted area in excess of 10 times the applicable limit set forth in Part 4 or in the license or registration, whether or not involving exposure of any individual in excess of the limits in RH 4.14; or

4.53.2.4 For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

4.53.3 Contents of Written Reports.

4.53.3.1 Each report required by RH 4.53.1.2 or 4.53.2 shall include the following, as appropriate:

4.53.3.1.1 A description of the event, including the possible cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

4.53.3.1.2 The exact location of the event;

4.53.3.1.3 The isotopes, quantities, and chemical and physical form of the licensed material involved;

4.53.3.1.4 Date and time of the event;

4.53.3.1.5 The results of any evaluations or assessments, including:

4.53.3.1.5.1 Estimates of each individual's dose;

4.53.3.1.5.2 The levels of radiation and concentrations of radioactive material involved;

4.53.3.1.5.3 The cause of the elevated exposures, dose rates, or concentrations; and

4.53.3.1.5.4 Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license or registration conditions.

4.53.3.2 Each report filed pursuant to RH 4.53 shall include for each occupationally overexposed individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in RH 4.13, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

RH 4.54 Reports of Planned Special Exposures. The licensee or registrant shall submit a written report to the Department within 30 days following any planned special exposure conducted in accordance with RH 4.11, informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by RH 4.45.

RH 4.55 Reserved.

RH 4.56 Reports of Individual Monitoring.

4.56.1 This section applies to each person licensed or registered by the Department to:

4.56.1.1 Possess or use sources of radiation for purposes of industrial radiography pursuant to Parts 3 and 5 of these regulations; or

4.56.1.2 Receive radioactive waste from other persons for disposal pursuant to Part 14 of these regulations; or

4.56.1.3 Possess or use at any time, for processing or manufacturing for distribution pursuant to Part 3 or 7 of these regulations, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity[a]	
	Ci	Gbq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium- 99m	1,000	37,000

[a] The Department may require as a license condition, or by rule, regulation, or order pursuant to RH 1.9, reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

4.56.2 Each licensee or registrant in a category listed in RH 4.56.1 shall submit an annual report to the Department of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by RH 4.18 during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use Department Form OR-RH-17 or equivalent or Department-approved electronic media containing all the information required by Department Form OR-RH-17.

4.56.3 The licensee or registrant shall file the report required by RH 4.56.2, covering the preceding year, on or before April 30 of each year.

RH 4.57 Notifications and Reports to Individuals.

4.57.1 Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in RH 10.4 of these regulations.

4.57.2 When a licensee or registrant is required pursuant to RH 4.53 to report to the Department any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Department, and shall comply with the provisions of RH 10.4.1 of these regulations.

RH 4.58 Reports of Leaking or Contaminated Sealed Sources. The licensee or registrant shall file a report within 5 days with the Department if the test for leakage or contamination indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

ADDITIONAL REQUIREMENTS

RH 4.59 Vacating Premises. Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the licensee's or registrant's activities, notify the Department in writing of intent to vacate. When deemed necessary by the Department, the licensee shall decontaminate the premises in such a manner as the Department may specify.

RH 4.60 Permissible Levels of Radioactive Material in Uncontrolled Areas.

4.60.1 Plutonium. Contamination of the soil in excess of 2.0 disintegrations per minute (0.03 Bq) of plutonium per gram of dry soil or square centimeter of surface area (0.01 microcurie [370 Bq] per square meter) presents a sufficient hazard to the public health to require the utilization of special techniques of construction upon property so contaminated. Evaluation of proposed control techniques shall be available from the Department of Health upon request.

RH 4.61 Radiological Criteria For License Termination.

4.61.1 The criteria in this section apply to the decommissioning of facilities licensed under Parts 3, 5, 7,14, 16, and 19 of these regulations. For low-level waste disposal facilities licensed under Part 14, the criteria apply only to the ancillary surface facilities that support radioactive waste disposal activities.

4.61.1.1 The criteria in this section do not apply to uranium and thorium recovery facilities already subject to Appendix A of Part 18; uranium solution extraction facilities; sites which have been decommissioned and the license terminated prior to July 1, 1999; or sites which have submitted a decommissioning plan prior to July 1, 2000 and have received Department approval of that decommissioning plan prior to July 1, 2001.

4.61.1.2 When calculating the TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE expected within the first 1000 years after decommissioning. In accordance with RH 1.5.1, the Department may authorize the licensee to exclude dose contributions from the inhalation of radon and its decay products when calculating TEDE.

4.61.1.3 Determination of dose and residual radioactivity levels which are as low as reasonably achievable (ALARA) must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

RH 4.61.2 Radiological Criteria For Unrestricted Use.

A site will be considered acceptable for license termination under conditions of unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 0.25 mSv per year (25 mrem/y), including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA.

RH 4.61.3 Radiological Criteria For Restricted Use.

A site will be considered acceptable for license termination under restricted conditions if:

4.61.3.1 The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of RH 4.61.2 would result in net public or environmental harm or were not being made because the residual levels of contamination associated with restricted conditions are ALARA;

4.61.3.2 The licensee has made provisions for durable, legally enforceable institutional controls which provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.25 mSv per year (25 mrem/y); and

4.61.3.3 Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is ALARA and would not exceed either: 1 mSv per year (100 mrem/y); or 5 mSv per year (500 mrem/y), provided the licensee demonstrates that further reductions in residual radioactivity necessary to comply with the 1 mSv per year (100 mrem/y) value of this paragraph are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm.

4.61.4 Alternate Criteria For License Termination.

4.61.4.1 The Department may terminate a license using alternate criteria greater than the dose criterion of RH 4.61.2 or RH 4.61.3.2, if:

4.61.4.1.1 The licensee has performed an analysis for possible sources of exposure to radiation which provides assurance that public health and safety would continue to be protected, and that it is unlikely the TEDE to an average member of the critical group from all radiation that is distinguishable from background radiation, other than medical, would be more than 1 mSv per year (100 mrem/y);

4.61.4.1.2 The licensee has employed, to the extent practical, restrictions on site use which minimize exposures at the site in accordance with the provisions of RH 4.61.3; and

4.61.4.1.3 The licensee has reduced doses to levels which are ALARA.

Part 7

USE OF RADIONUCLIDES IN THE HEALING ARTS

RH 7.34 Control of Aerosols and Gases.

7.34.1 A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by RH ~~4.4~~ 4.6 and RH ~~4.7~~ 4.14 of these regulations.

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SPECIFIC REQUIREMENTS FOR THE USE OF RADIOPHARMACEUTICALS FOR THERAPY

RH 7.36 Use of Unsealed Radioactive Material for Therapeutic Administration. A licensee may use for therapeutic administration any unsealed radioactive material that is either:

7.36.1 Obtained from a manufacturer or preparer licensed pursuant to RH 3.12.10 or equivalent NRC, Agreement State or Licensing State requirements; or

7.36.2 Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in RH ~~7.67~~ 7.68, or an individual under the supervision of either as specified in RH 7.10.

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RH 7.59 Radiation Surveys for Teletherapy Facilities.

7.59.1 Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by RH 7.50.1 through RH 7.50.4, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with RH 7.17 to verify that:

7.59.1.1 The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 10 millirems (100 uSv) per hour and 2 millirems (20 uSv) per hour, respectively; and

7.59.1.2 With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

7.59.1.2.1 Radiation ~~levels~~ DOSE RATES in restricted areas are not likely to cause ~~personnel exposures~~ ANY OCCUPATIONALLY EXPOSED INDIVIDUAL TO RECEIVE A DOSE in excess of the limits specified in RH 4.6 of these regulations; and

7.59.1.2.2 Radiation ~~levels~~ DOSE RATES in CONTROLLED OR unrestricted areas ~~do not exceed~~ ARE NOT LIKELY TO CAUSE ANY INDIVIDUAL MEMBER OF THE PUBLIC TO RECEIVE A DOSE IN EXCESS OF the limits specified in RH 4.14.1 of these regulations.

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RH 7.61 Modification of Teletherapy Unit or Room Before Beginning a Treatment Program. If the survey required by RH 7.59 indicates that ~~an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by RH 4.14.1 of these regulations, before beginning the treatment program the licensee shall:~~ ANY INDIVIDUAL MEMBER OF THE PUBLIC IS LIKELY TO RECEIVE A DOSE IN EXCESS OF THE LIMITS SPECIFIED IN RH 4.14.1 OF THESE REGULATIONS, THE LICENSEE SHALL, BEFORE BEGINNING THE TREATMENT PROGRAM:

7.61.1 Either equip the unit with stops or add additional radiation shielding to ensure compliance with ~~RH 4.6.1~~ RH 4.14 of these regulations;

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RH 7.68 Training for Therapeutic Use of Unsealed Radioactive Material. Except as provided in RH ~~7.74~~ 7.75, the licensee shall require the authorized user of a radiopharmaceutical listed in RH 7.36 for therapy to be a physician who:

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RH 7.69 Training for Therapeutic Use of Brachytherapy Sources. Except as provided in RH ~~7.74~~ 7.75, the licensee shall require the authorized user using a brachytherapy source specified in RH 7.42 for therapy to be a physician who:

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RH 7.70 Training for Ophthalmic Use of Strontium-90. Except as provided in RH ~~7.74~~ 7.75, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

PART 16

RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

RH 16.8 Radiation Survey Instruments.

16.8.1 The licensee or registrant shall ~~maintain sufficient~~ KEEP A calibrated and operable radiation survey ~~instruments~~ INSTRUMENT CAPABLE OF DETECTING BETA AND GAMMA RADIATION at each field station AND TEMPORARY JOBSITE to make ~~physical~~ THE radiation surveys ~~as~~ required by this part and by ~~RH 4.15, 4.17 and 4.18~~ PART 4 of these regulations. TO SATISFY THIS REQUIREMENT, THE RADIATION SURVEY INSTRUMENT ~~Instrumentation shall~~ MUST be capable of measuring ~~0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 50 milliroentgens (12.9 microcoulombs/kg) per hour.~~ 0.001 mSv (0.1 mrem) PER HOUR THROUGH AT LEAST 0.5 mSv (50 mrem) PER HOUR. ~~Survey instruments acquired before the effective date of this part and capable of measuring 0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 20 milliroentgens (5.16 microcoulombs/kg) per hour also satisfies this requirement.~~

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16.12.3 Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations after December 30, 1986 shall be certified by the manufacturer, or other testing organization acceptable to the Department, as meeting the sealed source performance requirements for oil well-logging as contained in the American National Standard N43.6 "Classification of Sealed Radioactive Sources," (formerly N542, ANSI/NBS 126) in effect on December 30, 1985. [1]

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[1] A certified copy of the referenced material is available for public inspection during normal business hours at the ~~Radiation Control Division~~ LABORATORY AND RADIATION SERVICES DIVISION, ~~4300 Creek Drive South, Building B, First Floor~~ 8100 LOWRY BOULEVARD, Denver, Colorado. Certified copies of the referenced material will be provided at cost upon request ~~from the Radiation Control Division~~ at the following mailing address: Director, ~~Radiation Control Division~~ LABORATORY AND RADIATION SERVICES DIVISION, ~~RCD-DO-B1, Colorado Department of Health, 4300 Cherry Creek Drive South~~ 8100 LOWRY BOULEVARD, Denver, Colorado, ~~80222-1530~~ 80230-6928.

****

16.25.4.2.8 an appropriate warning, depending on the specific circumstances of each abandonment. 3/

3/ Appropriate warnings may include: (a) "Do not drill below plug- back depth"; (b) "Do not enlarge casing"; or (c) "Do not re-enter the hole", followed by the words, "before contacting the Colorado Department of Health, ~~Radiation Control Division~~ LABORATORY AND RADIATION SERVICES DIVISION.

PART 19

LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

19.8.7 Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must ~~have a sign bearing the radiation symbol and the words, "CAUTION (OR DANGER) RADIOACTIVE MATERIAL".~~ BE POSTED AS REQUIRED BY RH 4.28. ~~Panoramic irradiators must also have a sign stating "GRAVE DANGER, VERY HIGH RADIATION AREA", but the sign~~ RADIATION POSTINGS FOR PANORAMIC IRRADIATORS MUST COMPLY WITH THE POSTING REQUIREMENTS OF RH 4.28, EXCEPT THAT SIGNS may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

STATE OF COLORADO

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