



**State of Utah
Administrative Rule Analysis
Notice of Proposed Rule/Change**

D.A.R. FILE NUMBER

16182

CODE NUMBER
AGENCY - RULE - SECTION

R 313 - 38 -

Division of Administrative Rules
State Archives Building, State Capitol
Salt Lake City, Utah 84114
Telephone 538-3011

Department: Environmental Quality
Agency: Radiation Control
Address: 168 N 1950 W - P.O. Box 144850
Salt Lake City UT 84114-4850
Contact Person: Craig Jones
Telephone: (801) 536-4250

1. CODE TITLE OF RULE OR SECTION

Radiation Safety Requirements for Wireline Service Operation and Subsurface Tracer Studies

2. REASON FOR AND SUMMARY OF RULE OR CHANGE

The proposed changes incorporate terminology defined in R313-12 or R313-15, add clarity, and reference the authority of the Radiation Control Board and the Executive Secretary to the Board. The proposed change also includes a definition for "irretrievable well logging source".

3. COST OR SAVINGS IMPACT OF RULE - UCA 63-46a-4(3)

STATE BUDGET: NONE
LOCAL GOV'T: NONE
PUBLIC: NONE

4. TYPE OF NOTICE

PROPOSED RULE (NEW AMEND REPEAL) 120-DAY RULE - UCA 63-46a-7
 CHANGE IN PROPOSED RULE (CHANGES PROPOSED RULE FILE NUMBER _____) FIVE-YEAR REVIEW / CONTINUATION

5. JUSTIFICATION FOR 120-DAY RULE CHECKED ABOVE - UCA 63-46a-7(1)

6. RULE AUTHORIZED BY STATE CODE / CONSTITUTION (CITATION): UCA 19-3-104 & 19-3-113
 RULE REQUIRED BY FEDERAL MANDATE (U.S. CODE, CFR, OR FED. REGISTER CITATION):

7. PUBLIC MAY PARTICIPATE IN RULEMAKING BY: (REQUIRED ONLY FOR PROPOSED RULES)

WRITTEN OR ORAL COMMENT PUBLIC HEARING (MAY BE OPTIONAL)
UNTIL: 10/17/94 DATE: PLACE:
TIME:

THIS RULE/CHANGE MAY BECOME EFFECTIVE ON:

10/18/94

NOTE: PUBLIC MAY REQUEST HEARING IN ACCORDANCE WITH UCA 63-46a-5(2)(b)

8. INDEXING INFORMATION

AGENCY NOTE: TEXT MUST BE IN CODE FORMAT

STATE STATUTE CITATION(S): UCA 19-3-104 & 19-3-113

KEY WORD(S): licensing, radioactive material, administrative responsibility, surveys

THE FULL TEXT OF ALL PROPOSED ADMINISTRATIVE RULES OR RULE CHANGES IS PUBLISHED IN THE UTAH STATE BULLETIN UNLESS EXCLUDED BECAUSE OF LENGTH AND SPACE LIMITATION. THE FULL TEXT MAY BE INSPECTED AT THE AGENCY (ADDRESS ABOVE) OR DIVISION OF ADMINISTRATIVE RULES.

9. AUTHORIZATION

William J. Sinclair, Exe. Secretary 08/26/94
AGENCY HEAD OR DESIGNEE DATE
Utah Radiation Control Board

AGENCY

SEND WHITE & YELLOW TO D.A.R., YELLOW WILL BE RETURNED TO AGENCY

10. DIVISION OF ADMINISTRATIVE RULES

RECEIVED BY: NL DATE: 9/1/94 TIME: 9:45
120-DAY RULE EFFECTIVE: N/A LAPSES: N/A
 TOO LONG TO PRINT PAGES: 12



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RECEIVED BY: DATE: TIME:

120-DAY RULE EFFECTIVE: LAPSES:

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Quality Management Program
and Misadministration

56 # 234104

R313 Environmental Quality, Radiation Control.

R313-32. Medical Use of Radioactive Material.

R313-32-1. Purpose and ~~[Scope]~~ Authority.

(1) ~~[This chapter prescribes]~~ The purpose of this rule is to prescribe requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of R313-32 are in addition to, and not in substitution for, other ~~[chapters]~~ sections of R313.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-101 through 19-3-301.

R313-32-2. Definitions.

[(1)] "Authorized user" means a physician, dentist, or podiatrist who is identified as an authorized user on a Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of radioactive material.

[(2)] "Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

[(3)] "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

[(4)] "Dental use" means the intentional external administration of the radiation from radioactive material to human beings in the practice of dentistry in accordance with a license issued by this state.

[(5)] "Dentist" means an individual licensed by this state to practice dentistry.

"Diagnostic clinical procedures manual" means a collection of written procedures that describes each method, other instructions, and precautions, by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

[(6)] "Management" means the chief executive officer or that person's delegate.

[(7)] "Medical institution" means an organization in which several medical disciplines are practiced.

[(8)] "Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by this State.

"Ministerial change" means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgement about whether those requirements should apply in the case at hand.

[(9)] "Misadministration" means the administration of:

(a) ~~[a radiopharmaceutical or radiation from a sealed source other than the one intended;]~~ A radiopharmaceutical dosage greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131:

(i) involving the wrong patient or wrong radiopharmaceutical, or
(ii) when both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 1.11 MBq (30 uCi).

(b) ~~[a radiopharmaceutical or radiation to the wrong patient;]~~ A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

(i) involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or
(ii) when the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(c) ~~[a radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;]~~ A gamma stereotactic radiosurgery radiation dose:

(i) involving the wrong patient or wrong treatment site; or
(ii) when the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose.

(d) [a diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50 percent; A teletherapy radiation dose:

(i) involving the wrong patient, wrong mode of treatment, or wrong treatment site;

(ii) when the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose;

(iii) when the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

(iv) when the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(e) [a therapeutic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 10 percent; or] A brachytherapy radiation dose:

(i) involving the wrong patient, wrong radionuclide, or wrong treatment site, excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site;

(ii) involving a sealed source that is leaking;

(iii) when, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(iv) when the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

(f) [a therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.] A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131, or both:

(i) involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) when the dose to the patient exceeds 0.05 Sv (five rems) effective dose equivalent or 0.5 Sv (50 rems) dose equivalent to any individual organ.

[-(10)—] "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

[-(11)—] "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

[-(12)—] "Podiatric use" means the intentional external administration of the radiation from radioactive material to human beings in the practice of podiatry in accordance with a license issued by this State.

[-(13)—] "Podiatrist" means an individual licensed by this State to practice podiatry.

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

(a) in a written directive; or

(b) either in the diagnostic clinical procedures manual or in an appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

"Prescribed dose" means:

(a) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(b) for teletherapy, the total dose and dose per fraction as documented in the written directive; or

(c) for brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

[-(14)—] "Radiation Safety Officer" means the individual identified as the Radiation Safety Officer on a [Bureau] license issued by the Executive Secretary.

"Recordable event" means the administration of:

(a) a radiopharmaceutical or radiation without a written directive where a written directive is required;

(b) a radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(c) a radiopharmaceutical dosage greater than 1.11 MBq (30 uCi) of either

sodium iodide I-125 or I-131 when both:

(i) the administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage, and

(ii) the difference between the administered dosage and prescribed dosage exceed 555 kBq (15 uCi);

(d) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage;

(e) A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or

(f) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than ten percent of the prescribed dose.

[+15—] "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

[+16—] "Teletherapy physicist" means the individual identified as the teletherapy physicist on a [Bureau—]license issued by the Executive Secretary.

[+17—] "Visiting authorized user" means an authorized user who is not identified as an authorized user on the license of the licensee being visited.

"Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified for brachytherapy containing the following information:

(a) for any administration of quantities greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131: the dosage;

(b) for a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(c) for gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(d) for teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(e) for high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(f) for all other brachytherapy:

(i) prior to implantation: the radionuclide, number of sources, and source strengths; and

(ii) after implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time, or equivalently, the total dose.

R313-32-11. License Required.

(1) A person shall not manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued by the [Bureau]Executive Secretary, the Nuclear Regulatory Commission, or an Agreement State, or as allowed in [~~paragraph (2) of this section~~]R313-32-11(2).

(2) An individual [~~may~~]shall receive, possess, use, or transfer radioactive material in accordance with [Bureau of]the Utah Radiation Control Rules under the supervision of an authorized user as provided in R313-32-25, unless prohibited by license condition.

R313-32-13. License Amendment.

A licensee shall apply for and [~~must~~]receive a license amendment[~~7~~]:

(1) before it receives or uses radioactive material for a clinical procedure permitted under [~~this chapter~~]R313-32 but not permitted by the license issued pursuant to [~~this chapter~~]R313-32;

(2) before it permits anyone, except a visiting authorized user described in R313-32-27 to work as an authorized user under the license;

(3) before it changes Radiation Safety Officers or Teletherapy Physicists;

(4) before it orders radioactive material in excess of the amount, or radionuclide or form different than authorized on the license; and

(5) before it adds to or changes the address or addresses of use identified on the license.

R313-32-14. Notifications.

A licensee shall notify the ~~[Bureau]~~ Executive Secretary by letter within ~~[thirty-]~~ [30+] days when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change, or when the licensee's mailing address changes.

R313-32-18. License Issuance.

The ~~[Bureau]~~ Executive Secretary shall issue a license for the medical use of radioactive material for a term of five years ~~[if]~~ provided the following requirements are met:

(1) ~~[the]~~ The applicant has filed form ~~[BRC-02]~~ DRC-02 "Application for Materials License - Medical" in accordance with the instructions in R313-22-32~~[+]~~.

(2) ~~[the]~~ The applicant has paid any applicable fee as provided in R313-70~~[+]~~.

(3) ~~[the Bureau]~~ The Executive Secretary finds the applicant equipped and committed to observe the safety standards established ~~[by the Bureau]~~ in R313-15 for the protection of the public health and safety.

(4) In addition to the requirements set forth in R313-22-33 a specific license for human use of radioactive material in institutions will be issued if:

(a) the applicant has appointed a radiation safety committee to coordinate the use of radioactive material throughout that institution and to maintain surveillance over the institution's radiation safety program; and

(b) ~~[if]~~ if the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has training and experience in the use of a variety of radioactive materials for a variety of human uses, and meets the training and experience requirements of ~~[this chapter]~~ R313-32.

(5) A specific license for the human use of radioactive material will be issued to an individual physician if ~~[all of]~~ the following are complied with:

(a) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable.

(b) The applicant has training and experience as required by ~~[this chapter]~~ R313-32, in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients.

(c) The application is for use in the applicant's practice in an office outside a medical institution.

(d) The ~~[Bureau]~~ Executive Secretary shall not approve an application by an individual physician or group of physicians for a specific license to receive, possess or use radioactive material on the premises of a medical institution unless:

(i) the use of radioactive material is limited to:

(A) the administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(B) the performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;

(C) the performance of in vitro diagnostic studies;

(D) the calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation;

(ii) the physician brings the radioactive material with him and removes the radioactive material when he departs. ~~[+]~~ The institution cannot receive, possess or store radioactive material other than the amount of material remaining in the patient~~[+]~~; or

(iii) the medical institution does not hold a radioactive material license issued pursuant to the provisions of ~~[subsection (4) of this section]~~ R313-32-18(4).

R313-32-19. Specific Exemptions.

The ~~[Bureau]~~ Board may, upon application of any interested person or upon its own initiative, grant ~~[such]~~ exemptions from the rules in ~~[this chapter]~~ R313-32 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The ~~[Bureau]~~ Board will review requests for exemptions from training and experience

requirements with the assistance of [~~its Technical Advisory Committee~~] the Executive Secretary.

R313-32-20. ALARA Program.

(1) [~~Each~~] The licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.

(2) To satisfy the requirement of [~~paragraph (1) of this section~~] R313-32-20(1) one of the following [~~must~~] shall be implemented:

(a) At a medical institution, management, the Radiation Safety Officer, and [~~all~~] authorized users [~~must~~] shall participate in the program as requested by the Radiation Safety Committee.

(b) For licensees that are not medical institutions, management and [~~all~~] authorized users [~~must~~] shall participate in the program as requested by the Radiation Safety Officer.

(3) The program [~~must~~] shall include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of radioactive material used, occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for [~~all~~] personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that licensees make a reasonable effort to maintain individual and collective occupational doses ALARA.

R313-32-21. Radiation Safety Officer.

(1) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

(2) The Radiation Safety Officer shall:

(a) investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practices and implement corrective actions as necessary;

(b) establish, collect in one binder or file, and implement written policy and procedures for:

(i) authorizing the purchase of radioactive material;

(ii) receiving and opening packages of radioactive material;

(iii) storing radioactive material;

(iv) keeping an inventory record of radioactive material;

(v) using radioactive material safely;

(vi) taking emergency action if control of radioactive material is lost;

(vii) performing periodic radiation surveys;

(viii) performing checks of survey instruments and other safety equipment;

(ix) disposing of radioactive material;

(x) training personnel who work in or frequent areas where radioactive material is used or stored;

(xi) keeping a copy of all records and reports required by the [~~Bureau rules~~] Utah Radiation Control Rules, a copy of these rules, a copy of each licensing request, [~~and~~] license and amendment[s], and written policy and procedures required by the rules;

(c) brief management once [~~each~~] a year on the radioactive material program;

(d) establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure;

(e) establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;

(f) for medical use not at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management; and

(g) for medical use at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

R313-32-22. Radiation Safety Committee.

[Each]The medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material.

(1) [Each]The Committee [must]shall meet the following administrative requirements:

(a) Membership [must]shall consist of at least three individuals and [must]shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(b) The Committee [must]shall meet at least quarterly.

(c) To establish a quorum and to conduct business, at least one-half of the Committee's membership [must]shall be present, including the Radiation Safety Officer and the management's representative.

(d) The minutes of each Radiation Safety Committee meeting [must]shall include:

(i) the date of the meeting;

(ii) members present;

(iii) members absent;

(iv) summary of deliberations and discussions;

(v) recommended actions and the numerical results of all ballots; and

(vi) ALARA program reviews described in R313-32-20.

(e) The Committee [must]shall promptly provide [each member with a copy]the members with copies of the meeting minutes, and retain one copy for the duration of the license.

(2) To oversee the use of licensed material, the Committee [must]shall:

(a) review recommendations on ways to maintain individual and collective doses ALARA;

(b) review, on the basis of safety and with regard to the training and experience standards in R313-32-900 through R313-32-972[~~of this chapter~~], and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or a Teletherapy Physicist before submitting a license application or request for amendment or renewal;

(c) review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under R313-32-31;

(d) review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of [all]personnel working with radioactive material;

(e) review quarterly, with the assistance of the Radiation Safety Officer, [all]incidents involving radioactive material with respect to cause and subsequent actions taken; and

(f) [Review]review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

R313-32-23. Statements of Authority and Responsibilities.

(1) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority, organizational freedom, and management prerogative, to:

(a) identify radiation safety problems;

(b) initiate, recommend, or provide corrective actions; and

(c) verify implementation of corrective actions.

(2) A licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, and retain the current edition of these statements as a record until the [Bureau]Executive Secretary terminates the license.

R313-32-25. Supervision.

(1) A licensee that permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by R313-32-11(2)[~~of this chapter~~] shall:

(a) instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material;

(b) require the supervised individual to follow the instructions of the supervising authorized user, follow the procedures established by the Radiation Safety Officer, and comply with the ~~[Bureau of]~~Utah Radiation Control Rules and the license conditions with respect to the use of radioactive material; and

(c) periodically review the supervised individual's use of radioactive material and the records kept to reflect this use.

(2) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

R313-32-27. Visiting Authorized User.

(1) A licensee may permit ~~[any-]~~visiting authorized ~~[user]~~users to use licensed material for medical use under the terms of the licensee's license for sixty days each year if:

(a) the visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(b) the licensee has a copy of a license issued by the ~~[Bureau]~~Executive Secretary, Nuclear Regulatory Commission, or Agreement State, or a permit issued by the ~~[Bureau]~~Executive Secretary, Nuclear Regulatory Commission or Agreement State broad licensee that is authorized to permit medical use, that identifies the visiting authorized user by name as an authorized user for medical use; and

(c) only those procedures for which the visiting authorized user is specifically authorized by the license or permit are performed by that individual.

(2) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in ~~[paragraph (1) of this section]~~R313-32-27(1).

(3) A licensee shall retain the records specified in ~~[this section]~~R313-32-27 for two years after the visiting authorized user's last use of licensed material, but may discard the records if the visiting authorized user has been listed as an authorized user on the licensee's license.

R313-32-29. Administrative Requirements that Apply to the ~~[Provision]~~Providers of Mobile Nuclear Medicine Service.

(1) The ~~[Bureau]~~Executive Secretary will license mobile nuclear medicine service only in accordance with ~~[-subparts]~~R313-32-100, R313-32-200, and R313-32-500~~[-of this chapter and R313-21-22(8)(b)]~~.

(2) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of radioactive material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for ~~[two]~~three years after the last provision of service.

(3) If a mobile nuclear medicine service provides services that the client ~~[it]~~is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the rules while the mobile nuclear medicine service is under the client's direction.

(4) A mobile nuclear medicine service ~~[may]~~shall not order radioactive material to be delivered directly from the manufacturer or distributor to the client's address of use.

R313-32-31. Radiation Safety Program Changes.

(1) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes in R313-32-13 and R313-32-606~~[-of this chapter. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and addresses; adoption of model radiation safety procedures published in Nuclear Regulatory Commission Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys]~~. A licensee is responsible for assuring that any

change made is in compliance with the requirements of the rules and the license.

(2) A licensee shall retain a record of each change until the license has been renewed or terminated. The record ~~[must]~~ shall include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

R313-32-32. Quality Management Program.

(1) The applicant or licensee shall establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

(a) that, prior to administration, a written directive is prepared for:
(i) teletherapy radiation doses;
(ii) gamma stereotactic radiosurgery radiation doses;
(iii) brachytherapy radiation doses;
(iv) administration of quantities greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131;

(v) therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(b) that the following are exceptions to the written directive:

(i) if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision;

(ii) also, a written revision to an existing written directive may be made for a diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose;
or

(iii) if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive;

(c) that, prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive;

(d) that final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(e) that each administration is in accordance with the written directive;
and

(f) that each unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(2) The licensee shall:

(a) develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

(i) representative samples of patient administrations,

(ii) recordable events, and

(iii) misadministrations to verify compliance with each aspect of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(b) evaluate these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of R313-32-32(1); and

(c) retain records of the review, including the evaluations and findings of the review, in an auditable form for three years.

(3) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(a) assembling the relevant facts including the cause;

(b) identifying what, if applicable, corrective action is required to prevent recurrence; and

(c) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if applicable, was taken.

(4) The licensee shall retain:

(a) a written directive; and

(b) a record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in R313-32-32(1)(a), in an auditable form, for three years after the date of administration.

(5) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the Executive Secretary within 30 days after the modification has been made.

(6)(a) Applicants for a new license, as applicable, shall submit to the Executive Secretary in accordance with R313-12-110 a quality management program as part of the application for a license and implement the program upon issuance of the license by the Executive Secretary.

(b) Existing licensees, as applicable, shall submit to the Executive Secretary in accordance with R313-12-110, prior to March 1, 1995, a written certification that the quality management program has been implemented along with a copy of the program.

R313-32-33. ~~[Records and Reports]~~ Notifications, Reports and Records of Misadministrations.

(1) When a misadministration [~~involves any therapy procedure~~] occurs, the licensee shall notify the [~~Bureau~~] Executive Secretary by telephone no later than the next calendar day after discovery of the misadministration. The licensee shall also notify the referring physician of the affected patient and the patient [~~or a responsible relative (or guardian)~~], unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications [~~must~~] shall be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

(2) Within 15 days after [~~an initial therapy misadministration report to the Bureau~~] discovery of the misadministration, the licensee shall submit a written report, [~~in writing,~~] to the [~~Bureau~~] Executive Secretary and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative [~~(+) or guardian) if either was previously notified by the licensee under paragraph (1) of this section~~] if either were notified by the licensee. The written report [~~must~~] shall include the licensee's name; the [~~referring~~] prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; [~~the~~] actions taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative [~~(+) or guardian(+)~~], and if not, why not; and if the patient was notified, what information was provided to the patient. The report [~~must~~] shall not include the patient's name or other information that could lead to identification of the patient.

~~(3) When a misadministration involves a diagnostic procedure, the Radiation Safety Officer shall promptly investigate its cause, make a record for Bureau review, and retain the record as directed in R313-32-33(4). The licensee shall also notify the referring physician and the Bureau in writing on form R313-32-33 within 15 days if the misadministration involved the use of radioactive material not intended for medical use, administration of a dosage five fold different from the intended dosage, or administration of radioactive material such that the patient is likely to receive an organ dose greater than 2 rem (20.0~~

mSv) or a whole body dose greater than 500 millirem (5.0 mSv). Licensees may use dosimetry tables in package inserts, corrected only for amount of radioactivity administered, to determine whether a report is required.]

~~[-(4) Each]~~ (3) The licensee shall retain a record of each misadministration for ~~[ten]~~ five years. The record ~~[must]~~ shall contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the ~~[event]~~ misadministration, why it occurred, the effect on the patient, and what improvements are needed to prevent recurrence; the actions taken ~~[, if any,]~~ to prevent recurrence.

~~[-(5)]~~ (4) Aside from the notification requirement, nothing in ~~[this section]~~ R313-32-39 affects any rights or duties of licensees and physicians in relation to each other, patients, or responsible relatives (or guardians).

R313-32-49. Suppliers.

A licensee may use for medical use only:

(1) Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the rules in R313-22-33 and R313-22-75(10) through R313-22-75(12) or the equivalent regulations of the Nuclear Regulatory Commission or an Agreement State.

(2) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval by the ~~[Bureau]~~ Executive Secretary pursuant to ~~[R313-22-45]~~ R313-22-39, or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State for the preparation of radiopharmaceuticals for medical use.

(3) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to R313-22-33 or the equivalent regulations of the Nuclear Regulatory Commission or an Agreement State.

R313-32-50. Possession, Use, Calibration, and Check of Dose Calibrators.

(1) A medical use licensee authorized to administer radiopharmaceuticals shall have in its possession a dose calibrator and use it to measure the amount of activity administered to each patient.

(2) A licensee shall:

(a) check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy ~~[the]~~ this requirement ~~[-of this paragraph]~~, the check ~~[must]~~ shall be done on a frequently used setting with a sealed source of not less than ~~[10 microcuries (370.0 kBq)]~~ 370 kBq (ten uCi) of radium-226 or ~~[50 microcuries (1.85 MBq) of any other]~~ 1.85 MBq (50 uCi) for a photon-emitting radionuclide;

(b) ~~[Test]~~ test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within ~~[5]~~ five percent of its stated activity, whose activity is at least ~~[10 microcuries (370.0 kBq)]~~ 370 kBq (ten uCi) for radium-226 and ~~[50 microcuries (1.85 MBq) for any other]~~ 1.85 MBq (50 uCi) for a photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV[-];

(c) ~~[Test]~~ test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be administered to a patient and ~~[10 microcuries (370.0 kBq)]~~ 370 kBq (ten uCi); and

(d) ~~[Test]~~ test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(3) A licensee shall also perform appropriate checks and tests required by ~~[this section]~~ R313-32-50 following adjustment or repair of the dose calibrator.

(4) A licensee shall mathematically correct dosage readings for ~~[-any]~~ geometry or linearity errors that exceed ~~[5]~~ ten percent if the dosage is greater than ~~[10 microcuries (370.0 kBq)]~~ 370 kBq (ten uCi) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds ~~[10]~~ ten

percent.

(5) A licensee shall retain a record of each check and test required by ~~[this section]~~ R313-32-50 for three years unless directed otherwise. The records required in ~~[paragraph (2)(a) through (2)(d) of this section must]~~ R313-32-50(2)(a) through (2)(d) shall include:

(a) ~~[For paragraph (2)(a)]~~ for R313-32-50(2)(a), the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check[-];

(b) ~~[For paragraph (2)(b)]~~ for R313-32-50(2)(b), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the signature of the Radiation Safety Officer[-];

(c) ~~[For paragraph (2)(c)]~~ for R313-32-50(2)(c), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer[-]; and

(d) ~~[For paragraph (2)(d)]~~ for R313-32-50(2)(d), the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

R313-32-51. Calibration and Check of Survey Instruments.

(1) A licensee shall calibrate the survey instruments used to show compliance with ~~[this chapter]~~ R313-32 before first use, annually, and following repair. The licensee shall:

(a) calibrate all scales with readings up to ~~[1000 millirem (10.0 mSv)]~~ ten mSv (1000 mrem) per hour with a radiation source;

(b) calibrate two separated readings on each scale that ~~[must]~~ shall be calibrated. The readings ~~[must]~~ shall be separated by 50 percent of the scale reading; and

(c) conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(2) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(3) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.

(4) A licensee shall retain a record of each survey instrument calibration for three years. The record ~~[must]~~ shall include:

(a) a description of the calibration procedure; and

(b) the date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

R313-32-53. Measurement of Radiopharmaceutical Dosages.

A licensee shall:

(1) measure the activity of each radiopharmaceutical dosage that contains more than ~~[10 microcuries (370.0 kBq)]~~ 370 kBq (ten uCi) of a photon-emitting radionuclide before medical use;

(2) measure the activity of each radiopharmaceutical dosage with a desired activity of ~~[10 microcuries (370.0 kBq)]~~ 370 kBq (ten uCi) or less of a photon-emitting radionuclide before medical use to verify that the dosage does not exceed ~~[10 microcuries (370.0 kBq)]~~ 370 kBq (ten uCi); and

(3) ~~[Retain]~~ retain a record of the measurements required by ~~[this section]~~ R313-32-53 for three years. To satisfy this requirement, the record ~~[must]~~ shall contain the following:

(a) generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

- (b) patient's name, and identification number if one has been assigned;
- (c) prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than [~~10 microcuries (370.0 kBq)~~] 370 kBq (ten uCi);
- (d) date and time of the measurement; and
- (e) initials of the individual who made the record.

R313-32-57. Authorization for Calibration and Reference Sources.

[~~Any person~~] Persons authorized by R313-32-11 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

- (1) sealed sources manufactured and distributed by a person licensed pursuant to R313-22-75(12) or equivalent Nuclear Regulatory Commission or Agreement State regulations and that do not exceed [~~15 millicuries (555.0 MBq)~~] 555 MBq (15 mCi) each;
- (2) [~~any~~] radioactive material listed in R313-32-100 or R313-32-200 with a half-life not longer than 100 days in individual amounts not to exceed [~~15 millicuries (555.0 MBq)~~] 555 MBq (15 mCi);
- (3) [~~any~~] radioactive material listed in R313-32-100 or R313-32-200 with a half-life longer than 100 days in individual amounts not to exceed [~~200 microcuries (7.4 MBq) each~~] 7.4 MBq (200 uCi); and
- (4) technetium-99m in individual amounts not to exceed [~~50 millicuries (1.85 GBq)~~] 1.85 GBq (50 mCi).

R313-32-59. Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(1) A licensee in possession of [~~any~~] sealed [~~source~~] sources or brachytherapy [~~source~~] sources shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(2) A licensee in possession of a sealed source shall:

(a) test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(b) test the source for leakage at intervals not to exceed six months or at other intervals approved by the [~~Bureau~~] Executive Secretary, the Nuclear Regulatory Commission or an Agreement State and described in the label or brochure that accompanies the source.

(3) To satisfy the leak test requirements of [~~this section~~] R313-32-59, the licensee must:

(a) take a wipe sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate or wash the source in a small volume of detergent solution and treat the entire volume as the sample;

(b) take teletherapy and other device source test samples when the source is in the "off" position; and

(c) measure the sample so that the leakage test can detect the presence of 185 Bq (0.005 uCi) [~~0.005 microcuries~~] of radioactive material on the sample.

(4) A licensee shall retain leakage test records for five years. The records [~~must~~] shall contain the model number, the serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in becquerels or microcuries, a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer.

(5) If the leakage test reveals the presence of [~~0.005 microcurie (185.0 Bq)~~] 185 Bq (0.005 uCi) or more of removable contamination, the licensee shall:

(a) immediately withdraw the sealed source from use and store it in accordance with the requirements in R313-15 [~~and R313-19~~]; and

(b) file a report within five days of the leakage test with the [~~Bureau~~] Executive Secretary describing the equipment involved, the test results, and the action taken.

(6) A licensee need not perform a leakage test on the following sources:

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

(b) sources containing only radioactive material as a gas;

(c) sources containing [~~100 microcuries (3.7 MBq)~~] 3.7 MBq (100 uCi) or less of beta or gamma-emitting material or [~~10 microcuries (370.0 kBq)~~] 370 kBq (ten uCi) or less of alpha-emitting material;

(d) sources stored and not being used. The licensee shall, however, test each [~~such~~] source for leakage before [~~any~~] use or transfer unless it has been leakage-tested within six months before the date of use or transfer; and

(e) seeds of iridium-192 encased in nylon ribbon.

(7) A licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all [~~such~~] sources in its possession. The licensee shall retain [~~each~~] inventory [~~record~~] records for five years. The inventory records [~~must~~] shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

(8) A licensee in possession of a sealed source or brachytherapy source shall measure the ambient dose rates quarterly in all areas where [~~such~~] sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(9) A licensee shall retain a record of each survey required in [~~paragraph (8) of this section~~] R313-32-59(8) for three years. The record [~~must~~] shall include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area expressed in [~~millirem (uSv)~~] microseverts or millirem per hour, the survey instrument used, and the signature of the Radiation Safety Officer.

R313-32-60. Syringe Shields and Labels.

(1) A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

(2) To identify its contents, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label [~~must~~] shall show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed or the patient's name.

(3) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient.

R313-32-61. Vial Shields and Labels.

(1) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

(2) To identify its contents, a licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical. The label [~~must~~] shall show the radiopharmaceutical name or its abbreviation.

R313-32-70. Surveys for Contamination and Ambient Radiation Exposure Rate.

(1) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(2) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

(3) A licensee shall conduct the surveys required by [~~paragraph (1) and (2) of this section~~] R313-32-70(1) and (2) so as to be able to detect dose rates as low as [~~0.1 millirem per hour (1 uSv/h)~~] one uSv (0.1 mrem) per hour.

(4) A licensee shall establish radiation dose rate trigger levels for the surveys required by [~~paragraphs (1) and (2) of this section~~] R313-32-70(1) and (2). A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

(5) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(6) A licensee shall conduct the survey required by ~~[paragraph (5) of this section]~~ R313-32-70(5) so as to be able to detect contamination on each wipe sample of ~~[2000]~~ 2200 disintegrations per minute, (0.001 uCi or 37 Bq).

(7) A licensee shall establish removable contamination trigger levels for the surveys required by ~~[paragraph (5) of this section]~~ R313-32-70(5). A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the trigger level.

(8) A licensee shall retain a record of each survey for three years. The record ~~[must]~~ shall include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in ~~[millirem (uSv)]~~ microseverts or millirem per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels or curies) per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

R313-32-75. Release of Patients Containing Radiopharmaceuticals or Permanent Implants.

(1) A licensee ~~[may]~~ shall not authorize release from confinement for medical care ~~[any]~~ a patient administered a radiopharmaceutical until either:

(a) the measured dose rate from the patient is less than ~~[5 millirems (50.0 uSv)]~~ 50 uSv (five mrem) per hour at a distance of one meter; or

(b) the activity in the patient is less than ~~[30 millicuries (1.11 GBq)]~~ 1.11 GBq (30 mCi).

(2) A licensee ~~[may]~~ shall not authorize release from confinement for medical care of ~~[any]~~ a patient administered a permanent implant until the measured dose rate from the patient is less than ~~[5 millirems (50.0 uSv)]~~ 50 uSv (five mrem) per hour at a distance of one meter.

R313-32-80. Technical Requirements that Apply to the ~~[Provision]~~ Providers of Mobile Nuclear Medicine Service.

A licensee providing mobile nuclear medicine service shall:

(1) transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(2) bring into each address of use all radioactive material to be used and, before leaving, remove all unused radioactive material and all associated waste;

(3) secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an address of use;

(4) check survey instruments and dose calibrators as described in R313-32-50 and R313-32-51 and check all other transported equipment for proper function before medical use at each address of use;

(5) carry a radiation detection survey meter in each vehicle that is being used to transport radioactive material, and, before leaving a client address of use, survey all radiopharmaceutical areas of use with a radiation detection survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed; and

(6) retain a record of each survey required in ~~[paragraph (5) of this section]~~ R313-32-80(5) for three years. The record ~~[must]~~ shall include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in ~~[millirem (uSv)]~~ microseverts or millirems per hour, the instrument used to make the survey, and the initials of the individual who performed the survey.

R313-32-90. Storage of Volatiles and Gases.

A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container. A licensee shall store a multi-dose container in a fume hood after drawing the first dosage from it.

R313-32-92. Decay-In-Storage.

(1) A licensee may hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of R313-15-1001 if it:

- (a) holds radioactive material for decay a minimum of ten half-lives;
- (b) monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding;
- (c) removes or obliterates all radiation labels; and
- (d) separates and monitors each generator column individually with ~~[all]~~ radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

(2) A licensee shall retain a record of each disposal permitted under ~~[paragraph (1) of this section]~~ R313-32-92(1) for three years. The record ~~[must]~~ shall include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

R313-32-100. Use of Radiopharmaceuticals for Uptake, Dilution and Excretion Studies.

A licensee may use ~~[any]~~ radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

R313-32-120. Possession of Survey Instrument.

A licensee authorized to use radioactive material for uptake, ~~[dilution]~~ dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range ~~[0.1 millirem (1.0 uSv) per hour to 100 millirem (1.0 mSv)]~~ one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour.

R313-32-200. Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.

(1) A licensee may use ~~[any]~~ radioactive material in a diagnostic radiopharmaceutical or ~~[any]~~ generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) ~~[or]~~ approved a "New Drug Application" (NDA) or approved a "Product Licensing Agreement (PLA)".

(2) A licensee shall elute generators and prepare reagent kits in accordance with the manufacturer's instructions.

(3) A licensee may depart from the manufacturer's instructions for eluting generators and preparing reagent kits for which the Food and Drug Administration (FDA) has approved a "New Drug Application" (NDA) by following the directions of an authorized user physician.

(4) R313-32-200 does not relieve a licensee from complying with applicable state, FDA or other federal regulations.

R313-32-204. Permissible Molybdenum-99 Concentration.

(1) A licensee ~~[may]~~ shall not administer to humans a radiopharmaceutical containing more than ~~[0.15 microcurie (5.55 kBq)]~~ 5.55 kBq (0.15 uCi) of molybdenum-99 per ~~[millicurie (37.0 MBq)]~~ 37.0 MBq (one mCi) of technetium-99m.

(2) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each elute or extract.

(3) A licensee that ~~[must]~~ is required to measure molybdenum concentration shall retain a record of each measurement for three years. The record ~~[must]~~ shall include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in ~~[millicuries (MBq)]~~ megabecquerels or millicuries, the measured activity of the molybdenum expressed in ~~[microcuries (kBq)]~~ kilobecquerels or microcuries, the ratio of the measures expressed as ~~[microcuries (kBq)]~~ kilobecquerels or microcuries of molybdenum per ~~[millicurie (MBq)]~~ megabecquerels or millicuries of technetium, the time and date of the measurement, and the initials of the individual who made the

measurement.

R313-32-205. Control of Aerosols and Gases.

(1) A licensee that administers radioactive aerosols or gases shall do so in a room with a system that will keep airborne concentrations within the limits prescribed in R313-15-201(4) and R313-15-301. The system ~~[must]~~ shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(2) A licensee shall administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

(3) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limit as specified in R313-15-201. The calculation ~~[must]~~ shall be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

(4) A licensee shall make a record of the calculations required in ~~[paragraph (2) of this section]~~ R313-32-205(3) that includes the assumptions, measurements, and calculations made and shall retain the record for the duration of use of the area. A licensee shall also post the calculated time and safety measures to be instituted in case of a spill at the area of use.

(5) A licensee shall check the operation of reusable collection systems each month, and measure the ventilation rates available in areas of radioactive gas use each six months. Records of the measurement shall be kept for three years.

R313-32-220. Possession of Survey Instruments.

A licensee authorized to use radioactive material for imaging and localization studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of ~~[0.1 millirem (1.0 uSv) per hour to 100 millirem (1.0 mSv)]~~ one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~[1 millirem (10.0 uSv) per hour to 1000 millirem (10.0 mSv)]~~ ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour.

R313-32-300. Use of Radiopharmaceuticals for Therapy.

(1) A licensee may use any radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.

(2) A licensee may depart from the package insert instructions regarding indications or methods of administration for a radiopharmaceutical for which the Food and Drug Administration (FDA) has approved a "New Drug Application" (NDA), provided that the authorized user physician has prepared a written directive as required by R313-32-32(1).

(3) R313-32-300 does not relieve the licensee from complying with applicable state, FDA and other federal regulations.

R313-32-310. Safety Instruction.

(1) A licensee shall provide radiation safety instruction for ~~[all]~~ personnel caring for the patient receiving radiopharmaceutical therapy and hospitalized for compliance with R313-32-75. To satisfy this requirement, the instruction ~~[must]~~ shall describe the licensee's procedures for:

- (a) patient control;
- (b) visitor control;
- (c) contamination control;
- (d) waste control; and
- (e) notification of the Radiation Safety Officer in case of the patient's death or medical emergency.

(2) A licensee shall keep for three years a list of individuals receiving instruction required by ~~[paragraph (1) of this section]~~ R313-32-310(1), a description of the instruction, the date of instruction, and the name of the

individual who gave the instruction.

R313-32-315. Safety Precautions.

(1) For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with R313-32-75, a licensee shall comply with~~[-all of]~~ the following:

- (a) ~~[Provide]~~provide a private room with a private sanitary facility~~[-];~~
- (b) ~~[Post]~~post the patient's door with a "Caution - Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room~~[-];~~
- (c) ~~[Authorize]~~authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer~~[-];~~
- (d) ~~[Promptly]~~promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of R313-15, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in microseverts or millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey~~[-];~~
- (e) ~~[Either]~~either monitor material and items removed from the patient's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste~~[-];~~
- (f) ~~[Provide]~~provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient~~[-];~~
- (g) ~~[Survey]~~survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room ~~[must]~~shall not be reassigned until removable contamination is less than ~~[200]~~220 disintegrations per minute (.0001 uCi or 3.7 Bq) per 100 square centimeters~~[-];~~ and
- (h) ~~[Measure]~~measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by R313-15-1107 a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(2) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

R313-32-320. Possession of Survey Instruments.

A licensee authorized to use radioactive material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range ~~[0.1 millirem (1.0 uSv) per hour to 100 millirem (1.0 mSv)]~~one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~[1 millirem (10.0 uSv) per hour to 1000 millirem (10.0 mSv)]~~ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour.

R313-32-400. Use of Sources for Brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

- (1) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (2) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (3) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;
- (4) Iridium-192 as seeds encased in nylon ribbon for interstitial and intracavitary treatment of cancer and as seeds for topical treatment of cancer;
- (5) Strontium-90 as a sealed source in an applicator for treatment of

superficial eye conditions;

(6) Iodine-125 as a sealed source in seeds for topical, interstitial and intracavitary treatment of cancer;

~~[(7) Radon 222 as seeds for topical, interstitial, and intercavitary treatment of cancer; and~~

~~(8) Radium 226 as a sealed source in needles and applicator cells for topical, interstitial, and intercavitary treatment of cancer; and]~~

(7) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

R313-32-404. Release of Patients Treated With Temporary Implants.

(1) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee ~~may~~ shall not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

(2) A licensee shall retain a record of patient surveys for three years. Each record ~~must~~ shall include the date of the survey, the name of the patient, the dose rate from the patient expressed as microseverts or millirem per hour and measured at one meter from the patient, the survey instrument used, and the initials of the individual who made the survey.

R313-32-406. Brachytherapy Sources Inventory.

(1) Promptly after removing them from a patient, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

(2) A licensee shall make a record of brachytherapy source use which ~~must~~ shall include:

(a) the names of the individuals permitted to handle the sources;

(b) the number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(c) the number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(3) Immediately after implanting sources in a patient the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

(4) A licensee shall retain the records required in ~~[paragraphs (2) and (3) of this section]~~ R313-32-406(2) and (3) for three years.

~~[(5) Each licensee shall assure that needles or standard medical applicator cells containing radium 226, cesium 137 or cobalt 60 as wire are not opened while in the licensee's possession unless specifically authorized by a license issued by the Bureau.]~~

R313-32-410. Safety Instruction.

(1) The licensee shall provide radiation safety instruction to ~~[all]~~ personnel caring for the patient undergoing implant therapy. To satisfy this requirement, the instruction ~~must~~ shall describe:

(a) size and appearance of the brachytherapy sources;

(b) safe handling and shielding instructions in case of a dislodged source;

(c) procedures for patient control;

(d) procedures for visitor control; and

(e) procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

(2) A licensee shall retain for three years a record of individuals receiving instruction required by ~~[paragraph (1) of this section]~~ R313-32-410(1), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

R313-32-415. Safety Precautions.

(1) For ~~[each patient]~~patients receiving implant therapy, a licensee shall:

(a) ~~[Not]~~not quarter the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirements of R313-15-301(a) at a distance of one meter from the implant~~[-]~~;

(b) ~~[Post]~~post the patient's door with a "Caution - Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room~~[-]~~;

(c) ~~[Authorize]~~authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer~~[-]~~;

(d) ~~[Promptly]~~promptly after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of R313-15, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in ~~[millirem-(uSv)]~~microseverts or millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey~~[-]~~; and

(e) ~~[Provide]~~provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.

(2) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

R313-32-420. Possession of Survey Instrument.

A licensee authorized to use radioactive material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range ~~[0.1 millirem (1.0 uSv) per hour to 100 millirem (1.0 mSv)]~~one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~[1 millirem (10.0 uSv) per hour to 1000 millirem (10.0 mSv)]~~ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour.

R313-32-500. Use of Sealed Sources for Diagnosis.

A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

(1) ~~[Iodine-125]~~iodine-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis~~[-]~~; and

(2) ~~[Iodine-125]~~iodine-125 as a sealed source in a portable imaging device.

R313-32-520. Availability of Survey Instrument.

A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range ~~[0.1 millirem (1.0 uSv) per hour to 100 millirem (1.0 mSv)]~~one uSv (0.1 mrem) per hour to one mSv per hour to (100 mrem) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ~~[1 millirem (10.0 uSv) per hour to 1000 millirem (10.0 mSv)]~~ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour. The instrument ~~[must have been]~~shall be calibrated in accordance with R313-32-51~~[-of this chapter]~~.

R313-32-600. Use of a Sealed Source in a Teletherapy Unit.

The rules and provisions of ~~[this subpart]~~R313-32-600 through R313-32-647 govern the use of teletherapy units for medical use that contain a sealed source of cobalt-60 or cesium-137.

R313-32-605. Maintenance and Repair Restrictions.

Only a person specifically licensed by the ~~[Bureau]~~Executive Secretary, the Nuclear Regulatory Commission, or an Agreement State to perform teletherapy unit maintenance and repair shall:

- (1) install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or
- (2) maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

R313-32-606. License Amendments.

In addition to the changes specified in R313-32-13, a licensee shall apply for and ~~must~~ shall receive a license amendment before:

- (1) making any change in the treatment room shielding;
- (2) making any change in the location of the teletherapy unit within the treatment room;
- (3) using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;
- (4) relocating the teletherapy unit; or
- (5) allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

R313-32-610. Safety Instruction.

(1) A licensee shall post instructions at the teletherapy unit console. To satisfy this requirement, these instructions ~~must~~ shall inform the operator of:

- (a) the procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption; and
- (b) the procedure to be followed if:
 - (i) the operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and
 - (ii) the names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

(2) A licensee shall provide instruction in the topics identified in ~~[paragraph (1) of this section to all]~~ R313-32-610(1) to individuals who operate a teletherapy unit.

(3) A licensee shall retain for three years a record of individuals receiving instruction required by ~~[paragraph (2) of this section]~~ R313-32-610(2), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

R313-32-615. Safety Precautions.

(1) A licensee shall control access to the teletherapy room by a door at each entrance.

(2) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that will:

(a) prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;

(b) turn the primary beam of radiation off immediately when an entrance door is opened; and

(c) prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(3) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

(4) A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(a) A radiation monitor ~~must~~ shall provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source, and ~~must~~ shall be observable by an individual entering the teletherapy room.

(b) A radiation monitor ~~must~~ shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

(c) A radiation monitor ~~must~~ shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for

treatment of patients.

(d) A licensee shall maintain a record of the check required by [~~paragraph (4)(c) of this section~~]R313-32-615(4)(c) for three years. The record [must]shall include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.

(e) If a radiation monitor is inoperable, the licensee shall require~~[-any]~~ individuals entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for ~~[any]~~malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter [must]shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in [~~paragraph (4)(d) of this section~~]R313-32-615(4)(d).

(f) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(5) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

R313-32-620. Possession of Survey Instrument.

A licensee authorized to use radioactive material in a teletherapy unit shall have in its possession either a portable radiation detection survey instrument capable of detecting dose ~~[rate]rates~~ over the range [~~0.1 millirem (1.0 uSv) per hour to 100 millirem (1.0 mSv)~~]one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour ~~[and]or~~ a portable radiation measurement survey instrument capable of measuring dose rates over the range [~~1 millirem (10.0 uSv) per hour to 1000 millirem (10.0 mSv)~~]ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour.

R313-32-630. Dosimetry Equipment.

(1) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions [must]shall be met:

(a) The system ~~[must have been]~~shall be calibrated by the National Institute of [~~Standards~~]Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration [must]shall have been performed within the previous two years and after any servicing that may have affected system calibration.

(b) The system [must]shall have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system [must]shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the National Bureau of Standards or by a calibration laboratory accredited by the AAPM. The intercomparison meeting [must]shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting [must]shall have indicated that the calibration factor of the licensee's system had not changed by more than ~~[2]two~~ percent. The licensee ~~[may]shall~~ not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(2) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with [~~paragraph (1) of this section~~]R313-32-630(1). This comparison [must]shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in [~~paragraph (1) of this section~~]R313-32-630(1).

(3) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record [must]shall include the date, the model numbers and serial numbers of the instruments that were

calibrated, intercompared, or compared as required by [~~paragraphs (1) and (2) of this section~~]R313-32-630(1) and (2), the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

R313-32-632. Full Calibration Measurements.

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

- (a) before the first medical use of the unit; and
- (b) before medical use under the following conditions:

(i) whenever spot-check measurements indicate that the output differs by more than [5]five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) following replacement of the source or following reinstallation of the teletherapy unit in a new location; or

[~~(ii)~~](iii) following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

- (c) at intervals not exceeding one year.

(2) To satisfy the requirement of [~~paragraph (1) of this section~~]R313-32-632(1), full calibration measurements [~~must~~]shall include determination of:

(a) the output within [~~+3~~]plus or minus three percent for the range of field sizes and for the distance or range of distances used for medical use;

(b) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(c) the uniformity of the radiation field and its dependence on the orientation of the useful beam;

- (d) timer constancy and linearity over the range of use;

(e) on-off error; and

(f) the accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in R313-32-630(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in [~~paragraph (2)(a) of this section~~]R313-32-632(2)(a) may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by [~~paragraph (1) of this section~~]R313-32-632(1) in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-711, and Vol. 11, No. 2, 1984, p. 213.

(5) A licensee shall correct mathematically the outputs determined in [~~paragraph (2)(a) of this section~~]R313-32-632(2)(a) for physical decay for intervals not exceeding one month for cobalt-60 [~~ef~~]or six months for cesium-137.

(6) Full calibration measurement required in [~~paragraph (1) of this section~~]R313-32-632(1) and physical decay corrections required by [~~paragraph (5) of this section~~ must]R313-32-632(5) shall be performed by the licensee teletherapy physicist.

(7) A licensee shall retain a record of each calibration for the duration of the teletherapy unit source. The record [~~must~~]shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer linearity and constancy, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of

the teletherapy physicist.

R313-32-634. Periodic Spot-Checks.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

- (a) timer constancy, and timer linearity over the range of use;
- (b) on-off error;
- (c) the coincidence of the radiation field and the field indicated by the light beam localizing device;
- (d) the accuracy of all distance measuring and localization devices used for medical use;

(e) the output for one typical set of operating conditions measured with the dosimetry system described in R313-32-630(2); and

(f) the difference between the measurement made in [~~paragraph (2)(e) of this section~~]R313-32-634(2)(e) and the anticipated output, expressed as a percentage of the anticipated output (~~[i.e.,]~~ the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by [~~paragraph (1) of this section~~]R313-32-634(1) in accordance with procedures established by the teletherapy physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the teletherapy physicist review the results of each spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for three years.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks for each teletherapy facility once in each calendar month that assure proper operation of:

- (a) electrical interlocks at each teletherapy room entrance;
- (b) electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
- (c) beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;
- (d) viewing systems;
- (e) treatment room doors from inside and outside the treatment room; and
- (f) electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) A licensee shall arrange for prompt repair of any system identified in [~~paragraph (4) of this section~~]R313-32-634(4) that is not operating properly, and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.

(6) A licensee shall retain a record of each spot-check required by [~~paragraphs (1) and (4) of this section~~]R313-32-634(1) and (4) for three years. The record [~~must~~]shall include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

R313-32-636. Safety Checks for Teletherapy Facilities.

(1) A licensee shall promptly check all systems listed in R313-32-634(4) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by [~~R313-32-634(1)~~]R313-32-606(1) through (4).

(2) If the results of the checks required in ~~[paragraph (1) of this section]~~ R313-32-636(1) indicate the malfunction of ~~[any]~~ a system specified in R313-32-634(4), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(3) A licensee shall retain for three years a record of the facility checks following installation of a source. The record ~~[must]~~ shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.

R313-32-641. Radiation Surveys for Teletherapy Facilities.

(1) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by R313-32-606(1) through (4), the licensee shall perform radiation surveys with a portable radiation measurement survey instrument calibrated in accordance with R313-32-51 ~~[of this chapter]~~ to verify that:

(a) ~~[The]~~ the maximum and average dose rates at one 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 millirem (100.0 uSv) per hour and 2 millirem (20.0 uSv)]~~ 100 uSv (ten mrem) per hour and 20 uSv (two mrem) per hour, respectively[-];

(b) ~~[With]~~ 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 the radiation, that:

(i) radiation dose quantities per unit time in restricted areas are not likely to cause personnel exposures in excess of the limits specified in R313-15-201; and

(ii) radiation dose quantities per unit time in unrestricted areas do not exceed the limits specified in R313-15-301.

(2) If the results of the surveys required in ~~[paragraph (1) of this section]~~ R313-32-641(1) indicate any radiation dose quantity per unit time in excess of the respective limit specified in ~~[that paragraph]~~ R313-32-641(1), the licensee shall lock the control in the off position and not use the unit:

(a) except as may be necessary to repair, replace, or test the teletherapy unit shielding or the treatment room shielding; or

(b) until the licensee has received a specific exemption pursuant to R313-12-54.

(3) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record ~~[must]~~ shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microseverts or millirem [-uSv] per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

R313-32-643. Modification of Teletherapy Unit or Room Before Beginning a Treatment Program.

(1) If the survey required by R313-32-641 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by R313-15-301, before beginning the treatment program the licensee shall:

(a) either equip the unit with stops or add additional radiation shielding to ensure compliance with R313-15-301(3);

(b) perform the survey required by R313-32-641 again; and

(c) include in the report required by R313-32-645 the results of the initial survey, a description of the modification made to comply with ~~[paragraph (1)(a) of this section]~~ R313-32-643(1)(a), and the results of the second survey.

(2) As an alternative to the requirements set out in ~~[paragraph (1) of this section]~~ R313-32-643(1), a licensee may request a license amendment under

R313-15-301(3) that authorizes radiation levels in unrestricted areas greater than those permitted by R313-15-301(1). A licensee ~~may~~ shall not begin the treatment program until the license amendment has been issued.

R313-32-645. Reports of Teletherapy Surveys, Checks, Tests and Measurements.

A licensee shall mail a copy of the records required in R313-32-636, R313-32-641, R313-32-643, and the output from the teletherapy source expressed as ~~[roentgens (C/kg)]~~ coulombs/kilogram (roentgens) or ~~[rads (Gy)]~~ gray (rad) per hour at one meter from the source and determined during the full calibration required in R313-32-632 to the ~~[Bureau]~~ Executive Secretary within thirty days following completion of the action that initiated the record requirement.

R313-32-647. Five-Year Inspection.

(1) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(2) This inspection and servicing ~~may~~ shall only be performed by persons specifically licensed to do so by the ~~[Bureau]~~ Executive Secretary, the Nuclear Regulatory Commission, or an Agreement State.

(3) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record ~~must~~ shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

R313-32-900. Radiation Safety Officer.

Except as provided in R313-32-901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in R313-32-21 to be an individual who:

- (1) is certified by:
 - (a) American Board of Health Physics in Comprehensive Health Physics;
 - (b) American Board of Radiology;
 - (c) American Board of Nuclear Medicine;
 - (d) American Board of Science in Nuclear Medicine; ~~[-or]~~
 - (e) Board of Pharmaceutical Specialities in Nuclear Pharmacy; or
 - (f) Canadian Royal College in Nuclear Medicine; or
- (2) has had classroom and laboratory training and experience as follows:
 - (a) 200 hours of classroom and laboratory training that includes:
 - (i) radiation physics and instrumentation;
 - (ii) radiation protection;
 - (iii) mathematics pertaining to the use and measurement of radioactivity;
 - (iv) radiation biology; and
 - (v) radiopharmaceutical chemistry; and
 - (b) one year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a ~~[Bureau]~~ license issued by the Executive Secretary, Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of radioactive material; or
- (3) be an authorized user identified on the licensee's license.

R313-32-901. Training for Experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on a ~~[Bureau]~~ license issued by the Executive Secretary, Nuclear Regulatory Commission or Agreement State ~~[license-]~~ before January 1, 1989, need not comply with the training requirements of R313-32-900.

R313-32-910. Training for Uptake, Dilution, and Excretion Studies.

Except as provided in R313-32-970 and R313-32-971, the licensee shall require the authorized user of a radiopharmaceutical in R313-32-100(1) to be a physician who:

- (1) is certified in:
 - (a) nuclear medicine by the American Board of Nuclear Medicine;

- (b) diagnostic radiology by the American Board of Radiology; ~~or~~
- (c) diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
- (d) nuclear medicine by the Canadian Royal College; or
- (2) has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:
 - (a) 40 hours of classroom and laboratory training that includes:
 - (i) radiation physics and instrumentation;
 - (ii) radiation protection;
 - (iii) mathematics pertaining to the use and measurement of radioactivity;
 - (iv) radiation biology; and
 - (v) radiopharmaceutical chemistry; and
 - (b) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:
 - (i) examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
 - (ii) selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
 - (iii) administering dosages to patients and using syringe radiation shields;
 - (iv) collaborating with the authorized user in the interpretation of [~~radioisotope~~]radionuclide test results; and
 - (v) patient follow-up; or
- (3) has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in ~~[all]the topics identified in [paragraph (2) of this section]~~R313-32-910(2).

R313-32-920. Training for Imaging and Localization Studies.

Except as provided in R313-32-970 or R313-32-971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in R313-32-200(1) to be a physician who:

- (1) is certified in:
 - (a) nuclear medicine by the American Board of Nuclear Medicine;
 - (b) diagnostic radiology by the American Board of Radiology; ~~or~~
 - (c) diagnostic radiology or radiology by the American Osteopathic board of Radiology; or
 - (d) nuclear medicine by the Canadian Royal College; or
- (2) has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:
 - (a) 200 hours of classroom and laboratory training that includes:
 - (i) radiation physics and instrumentation;
 - (ii) radiation protection;
 - (iii) mathematics pertaining to the use and measurement of radioactivity;
 - (iv) radiopharmaceutical chemistry; and
 - (v) radiation biology; and
 - (b) 500 hours of supervised work experience under the supervision of an authorized user that includes:
 - (i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
 - (iii) calculating and safely preparing patient dosages;
 - (iv) using administrative controls to prevent the misadministration of radioactive material;
 - (v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (vi) eluting technetium-99m from generator systems, measuring and testing the elute for molybdenum-99 and alumina contamination, and processing the elute with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(c) 500 hours of supervised clinical experience under the supervision of the authorized user that includes:

(i) examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) administering dosages to patients and using syringe radiation shields;

(iv) collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) patient follow-up; or

(3) has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in ~~[all]~~the topics identified in ~~[paragraph (2) of this section]~~R313-32-920(2).

R313-32-930. Training for Therapeutic Use of Radiopharmaceuticals.

Except as provided in R313-32-970, the licensee shall require the authorized user of radiopharmaceuticals in R313-32-300 to be a physician who:

(1) is certified by:

(a) The American Board of Nuclear Medicine; ~~[-or]~~

(b) The American Board of Radiology in radiology or therapeutic radiology ~~[-]; or~~

(c) The Canadian Royal College; or

(2) has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

and

(iv) radiation biology; and

(b) supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

(i) use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ~~[10]~~ten individuals; and

(ii) use of iodine-131 for treatment of thyroid carcinoma in ~~[3]~~three individuals.

R313-32-932. Training for Treatment of Hyperthyroidism.

Except as provided in R313-32-970, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that includes:

(a) radiation physics and instrumentation;

(b) radiation protection;

(c) mathematics pertaining to the use and measurement of radioactivity;

and

(d) radiation biology[-]; and

(2) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in ~~[10]~~ten individuals.

R313-32-934. Training for Treatment of Thyroid Carcinoma.

Except as provided in R313-32-970, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical

experience as follows:

- (1) 80 hours of classroom and laboratory training that includes:
 - (a) radiation physics and instrumentation;
 - (b) radiation protection;
 - (c) mathematics pertaining to the use and measurement of radioactivity;

and

(d) radiation biology[-]; and

(2) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in [3] three individuals.

R313-32-940. Training for Use of Brachytherapy Sources.

Except as provided in R313-32-970 the licensee shall require the authorized user of a brachytherapy source listed in R313-32-400 for therapy to be a physician who:

(1) is certified in:

- (a) radiology or therapeutic radiology by the American Board of Radiology;
- (b) radiation oncology by the American Osteopathic Board of Radiology;
- (c) radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
- (d) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

(a) 200 hours of classroom and laboratory training that includes:

- (i) radiation physics and instrumentation;
- (ii) radiation protection;
- (iii) mathematics pertaining to the use and measurement of radioactivity;

and

(iv) radiation biology;

(b) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) checking survey meters for proper operation;

(iii) preparing, implanting, and removing sealed sources;

(iv) maintaining running inventories of material on hand;

(v) using administrative controls to prevent the misadministration of radioactive material; and

(vi) using emergency procedures to control radioactive material; and

(c) three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(i) examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(ii) selecting the proper brachytherapy sources and dose and method of administration;

(iii) calculating the dose; and

(iv) post-administration follow-up and review of case histories in collaboration with the authorized user.

R313-32-941. Training for Ophthalmic Use of Strontium-90.

Except as provided in R313-32-970, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in

ophthalmic radiotherapy as follows:

- (1) 24 hours of classroom and laboratory training that includes:
 - (a) radiation physics and instrumentation;
 - (b) radiation protection;
 - (c) mathematics pertaining to the use and measurement of radioactivity;

and

- (d) radiation biology.
- (2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:
 - (a) examination of each individual to be treated;
 - (b) calculation of the dose to be administered;
 - (c) administration of the dose; and
 - (d) follow-up and review of each individual's case history.

R313-32-950. Training for Use of Sealed Sources for Diagnosis.

Except as provided in R313-32-970, the licensee shall require the authorized user of a sealed source in a device listed in R313-32-500 to be a physician, dentist, or podiatrist who:

- (1) is certified in
 - (a) radiology, diagnostic radiology, or therapeutic radiology by the American Board of Radiology;
 - (b) nuclear medicine by the American Board of Nuclear Medicine; or
 - (c) diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
- (2) has had ~~8~~eight hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:
 - (a) radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
 - (b) radiation biology;
 - (c) radiation protection; and
 - (d) training in the use of the device for the uses requested.

R313-32-960. Training for Teletherapy.

Except as provided in R313-32-970, the licensee shall require the authorized user of a sealed source listed in R313-32-600 in a teletherapy unit to be a physician who:

- (1) is certified in:
 - (a) radiology or therapeutic radiology by the American Board of Radiology;
 - (b) radiation oncology by the American Osteopathic Board of Radiology;
 - (c) radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - (d) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
 - (2) is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:
 - (a) 200 hours of classroom and laboratory training that includes:
 - (i) radiation physics and instrumentation;
 - (ii) radiation protection;
 - (iii) mathematics pertaining to the use and measurement of radioactivity;
- and
- (iv) radiation biology[-];
 - (b) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:
 - (i) review of the full calibration measurements and periodic spot checks;
 - (ii) preparing treatment plans and calculating treatment times;
 - (iii) using administrative controls to prevent misadministrations;
 - (iv) implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
 - (v) checking and using survey meters[-]; and
 - (c) ~~Three~~three years of supervised clinical experience that includes one

year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

- (i) examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
- (ii) selecting the proper dose and how it is to be administered;
- (iii) calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and
- (iv) post-administration follow-up and review of case histories.

R313-32-961. Training for Teletherapy Physicist.

The licensee shall require the teletherapy physicist to be an individual who:

(1) is certified by the American Board of Radiology or American Board of Medical Physics in:

- (a) therapeutic radiological physics or radiation oncology physics;
- (b) roentgen ray and gamma ray physics;
- (c) x-ray and radium physics; or
- (d) radiological physics; or

(2) ~~[has completed training and experience as follows:~~

~~(a) bachelor's degree in physics, biophysics, radiological physics, or health physics plus five years of work experience in therapeutic radiological physics; or~~

~~(b) master's degree in physics, biophysics, radiological physics, or health physics plus three years of work experience in therapeutic radiological physics; or~~

~~(c) doctor's degree in physics, biophysics, radiological physics, or health physics plus two years of work experience in therapeutic radiological physics; and~~

~~(3) has completed one year of work experience required by R313-32-961(2) while under the supervision of a therapeutic radiological physicist at a medical institution that includes the tasks listed in R313-32-59, R313-32-632, R313-32-634 and R313-32-641]~~holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in R313-32-59, R313-32-632, R313-32-634 and R313-32-641.

R313-32-970. Training for Experienced Authorized Users.

Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of radioactive material on a [Bureau] license issued by the Executive Secretary, Nuclear Regulatory Commission, or Agreement State license issued before January 1, 1989, who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of R313-32-900 to R313-32-961.

R313-32-971. Physician Training in a Three Month Program.

A physician who, before October 1, 1988, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of R313-32-910 or R313-32-920.

R313-32-972. Recentness of Training.

The training and experience specified in ~~[this subpart must]~~R313-32-972 shall have been obtained within the five years preceding the date of application or the individual ~~[must]~~shall have had related continuing education and experience since the required training and experience was completed.

R313-32-999. Resolution of Conflicting Requirements During Transition Period.

If the rules in [~~this chapter~~]R313-32 conflict with the licensee's radiation safety program as identified in its license, and if that license was approved by the Bureau of Radiation Control, Department of Health, before January 1, 1989, and has not been renewed since January 1, 1989, then the requirements in the license will apply. However, if the licensee exercises its privilege to make minor changes in its radiation safety procedures that are not potentially important to safety under R313-32-31[~~of this chapter~~], the portion changed [~~must~~]shall comply with the requirements of [~~this chapter~~]R313-32. At the time of license renewal and thereafter, these amendments to [~~this chapter~~]R313-32 shall apply.

KEY: radioactive material
[~~1989~~]1994

[~~26-1-27~~]19-3-104
19-3-108

1 R313. Environmental Quality, Radiation Control.

2 R313-25. License Requirements For Land Disposal Of Radioactive Waste - General
3 Provisions.

4 R313-25-1 Purpose and Scope.

5 The rules in this chapter establish procedures, criteria, and terms and
6 conditions upon which the Department issues licenses for the land disposal of
7 wastes received from other persons. The requirements of R313-25 are in addition
8 to, and not in substitution for, other applicable requirements of these rules.
9

10 R313-25-2 Definitions.

11 As used in R313-25, the following definitions apply:

12 "Active maintenance" means significant activity needed during the period
13 of institutional control to maintain a reasonable assurance that the performance
14 objectives in R313-25-19 and R313-25-20 are met. Active maintenance may include
15 the pumping and treatment of water from a disposal unit, the replacement of a
16 disposal unit cover, or other episodic or continuous measures. Active
17 maintenance does not include custodial activities like repair of fencing, repair
18 or replacement of monitoring equipment, revegetation, minor additions to soil
19 cover, minor repair of disposal unit covers, and general disposal site upkeep.

20 "Buffer zone" means a portion of the disposal site that is controlled by
21 the licensee and that lies under the disposal units and between the disposal
22 units and the boundary of the site.

23 "Commencement of construction" means clearing of land, excavation, or other
24 substantial action that could adversely affect the environment of a land disposal
25 facility. The term does not mean disposal site exploration, necessary roads for
26 disposal site exploration, borings to determine foundation conditions, or other
27 preconstruction monitoring or testing to establish background information related
28 to the suitability of the disposal site or the protection of environmental
29 values.

30 "Custodial agency" means an agency of the government designated to act on
31 behalf of the government owner of the disposal site.

32 "Disposal" means the isolation of wastes from the biosphere by placing them
33 in a land disposal facility.

34 "Disposal site" means that portion of a land disposal facility which is
35 used for disposal of waste. It consists of disposal units and a buffer zone.

36 "Disposal unit" means a discrete portion of the disposal site into which
37 waste is placed for disposal. For near-surface disposal, the disposal unit may
38 be a trench.

39 "Engineered barrier" means a man-made structure or device intended to
40 improve the land disposal facility's performance under R313-25.

41 "Hydrogeologic unit" means a soil or rock unit or zone that has a distinct
42 influence on the storage or movement of ground water.

43 "Inadvertent intruder" means a person who may enter the disposal site after
44 closure and engage in activities unrelated to post closure management, such as
45 agriculture, dwelling construction, or other pursuits which could, by disturbing
46 the site, expose individuals to radiation.

47 "Intruder barrier" means a sufficient depth of cover over the waste that
48 inhibits contact with waste and helps to ensure that radiation exposures to an
49 inadvertent intruder will meet the performance objectives set forth in R313-25,
50 or engineered structures that provide equivalent protection to the inadvertent
51 intruder.

52 "Land disposal facility" means the land, buildings and structures, and
53 equipment which are intended to be used for the disposal of radioactive waste [~~s~~
54 ~~into the subsurface of the land~~].

55 "Monitoring" means observing and making measurements to provide data to
56 evaluate the performance and characteristics of the disposal site.

57 "Near-surface disposal facility" means a land disposal facility in which
58 waste is disposed of within approximately the upper 30 meters of the earth's
59 surface.

60 "Site closure and stabilization" means those actions that are taken upon
61 completion of operations that prepare the disposal site for custodial care, and
62 that assure that the disposal site will remain stable and will not need ongoing
63 active maintenance.

64 "Stability" means structural stability.

1 survey control program; methods and areas of waste storage; and methods to
2 control surface water and ground water access to the wastes. The description
3 shall also include a description of the methods to be employed in the handling
4 and disposal of wastes containing chelating agents or other non-radiological
5 substances which might affect meeting the performance objectives of R313-25

6 (7) A description of the disposal site closure plan, including those
7 design features which are intended to facilitate disposal site closures and to
8 eliminate the need for active maintenance after closure.

9 (8) Identification of the known natural resources at the disposal site
10 whose exploitation could result in inadvertent intrusion into the wastes after
11 removal of active institutional control.

12 (9) Descriptions of the kind, amount, classification and specifications
13 of the radioactive material proposed to be received, possessed, and disposed of
14 at the land disposal facility.

15 (10) Descriptions of quality ~~[control programs]~~ assurance programs,
16 tailored to low-level waste disposal, including audit and managerial controls,
17 for the determination of natural disposal site characteristics and for quality
18 control during the design, construction, operation, and closure of the land
19 disposal facility and the receipt, handling, and emplacement of waste.

20 (11) A description of the radiation safety program for control and
21 monitoring of radioactive effluents to ensure compliance with the performance
22 objective in R313-25-19 and monitoring of occupational radiation exposure to
23 ensure compliance with the requirements of R313-15 and to control contamination
24 of personnel, vehicles, equipment, buildings, and the disposal site. The
25 applicant describe procedures, instrumentation, facilities, and equipment
26 appropriate to both routine and emergency operations.

27 (12) A description of the environmental monitoring program to provide data
28 and to evaluate potential health and environmental impacts and the plan for
29 taking corrective measures if migration is indicated.

30 (13) Descriptions of the administrative procedures that the applicant will
31 apply to control activities at the land disposal facility.

32 **R313-25-8 Technical Analyses.**

33 The specific technical information shall also include the following
34 analyses needed to demonstrate that the performance objectives of R313-25 will
35 be met:

36 (1) Analyses demonstrating that the general population will be protected
37 from releases of radioactivity shall consider the pathways of air, soil, ground
38 water, surface water, plant uptake, and exhumation by burrowing animals. The
39 analyses shall clearly identify and differentiate between the roles performed by
40 the natural disposal site characteristics and design features in isolating and
41 segregating the wastes. The analyses shall clearly demonstrate a reasonable
42 assurance that the exposures to humans from the release of radioactivity will not
43 exceed the limits set forth in R313-25-19.

44 (2) Analyses of the protection of inadvertent intruders shall demonstrate
45 a reasonable assurance that the waste classification and segregation requirements
46 will be met and that adequate barriers to inadvertent intrusion will be provided.

47 (3) Analysis of the protection of individuals during operations shall
48 include assessments of expected exposures due to routine operations and likely
49 accidents during handling, storage, and disposal of waste. The analysis shall
50 provide reasonable assurance that exposures will be controlled to meet the
51 requirements of R313-15.

52 (4) Analyses of the long-term stability of the disposal site shall be
53 based upon analyses of active natural processes including erosion, mass wasting,
54 slope failure, settlement of wastes and backfill, infiltration through covers
55 over disposal areas and adjacent soils, and surface drainage of the disposal
56 site. The analyses shall provide reasonable assurance that there will not be a
57 need for ongoing active maintenance of the disposal site following closure.

58 **R313-25-9 Institutional Information.**

59 The institutional information submitted by the applicant shall include:

60 (1) A certification by the federal or state agency which owns the disposal
61 site that the agency is prepared to accept transfer of the license when the
62 provisions of R313-25-16 are met and will assume responsibility for institutional
63
64

State of Utah
Administrative Rule Analysis

NOTICE OF NONSUBSTANTIVE RULE CHANGE

Complete and Return to: State of Utah Division of Administrative Rules (DAR) 3120 State Office Building; 450 North Main PO Box 141007 Salt Lake City, UT 84114-1007 Phone: (801) 538-3218, FAX: (801) 538-3844 State E-mail: <i>asitmain.rules</i>	DAR File No.: 17732 Utah Admin. Code Ref.: R313-25 Date Filed: 04/26/96 Time Filed: 09:59 Received by: NL
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Department:	Environmental Quality
Agency:	Radiation Control
Room No., Building:	State of Utah Office Park, Building 2
Street Address:	168 North 1950 West
Mailing Address:	PO Box 144850
City, State ZIP:	Salt Lake City, UT 84114-4850
Contact Person:	Dane Finerfrock
Telephone:	(801) 536-4250
FAX:	(801) 533-4097

1. Title of Rule or Section:
License Requirements for Land Disposal of Radioactive Waste - General Provisions

2. Reason for Change:
Compatibility changes to meet NRC's requirement for Agreement States to adopt compatibility items three years from the effective date.

3. This change is a response to comments by the Administrative Rules Review Committee. Yes No

4. Summary of Change:
Changes are compatibility changes as published by the NRC in 58 Federal Register No. 118, June 22, 1993. R313-25-2: Corrections to the definition of "Land disposal facility;" R313-25-7(10): changes referencing the quality assurance method to be employed.

5. Indexing Information-Keywords (maximum of four):
radiation, radioactive waste disposal

6. Enter filename of the file containing this rule's FULL text (Example: xxx-xxx.wpd). R313-025.732
(All rule text must be in code format.)

A nonsubstantive change becomes effective on the date DAR makes the change in the *Utah Administrative Code*.

AGENCY AUTHORIZATION

Agency Head or Designee: William J. Sinclair, Executive Secretary	Date (mm/dd/yy):	04/26/96
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Low-level Waste Shipping manifest until reporting

R313. Environmental Quality, Radiation Control.

R313-25. License Requirements for Land Disposal of Radioactive Waste - General Provisions.

R313-25-1. Purpose and Scope.

The rules in this chapter establish procedures, criteria, and terms and conditions upon which the Department issues licenses for the land disposal of wastes received from other persons. The requirements of R313-25 are in addition to, and not in substitution for, other applicable requirements of these rules.

R313-25-2. Definitions.

As used in R313-25, the following definitions apply:

"Active maintenance" means significant activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in R313-25-19 and R313-25-20 are met. Active maintenance may include the pumping and treatment of water from a disposal unit, the replacement of a disposal unit cover, or other episodic or continuous measures. Active maintenance does not include custodial activities like repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general disposal site upkeep.

"Buffer zone" means a portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.

"Commencement of construction" means clearing of land, excavation, or other substantial action that could adversely affect the environment of a land disposal facility. The term does not mean disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of environmental values.

"Custodial agency" means an agency of the government designated to act on behalf of the government owner of the disposal site.

"Disposal" means the isolation of wastes from the biosphere by placing them in a land disposal facility.

"Disposal site" means that portion of a land disposal facility which is used for disposal of waste. It consists of disposal units and a buffer zone.

"Disposal unit" means a discrete portion of the disposal site into which waste is placed for disposal. For near-surface disposal, the disposal unit may be a trench.

"Engineered barrier" means a man-made structure or device intended to improve the land disposal facility's performance under R313-25.

"Hydrogeologic unit" means a soil or rock unit or zone that has a distinct influence on the storage or movement of ground water.

"Inadvertent intruder" means a person who may enter the disposal site after closure and engage in activities unrelated to post closure management, such as agriculture, dwelling construction, or other pursuits which could, by disturbing the

site, expose individuals to radiation.

"Intruder barrier" means a sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in R313-25, or engineered structures that provide equivalent protection to the inadvertent intruder.

"Land disposal facility" means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive waste.

"Monitoring" means observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

"Near-surface disposal facility" means a land disposal facility in which waste is disposed of within approximately the upper 30 meters of the earth's surface.

"Site closure and stabilization" means those actions that are taken upon completion of operations that prepare the disposal site for custodial care, and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

"Stability" means structural stability.

"Surveillance" means monitoring and observation of the disposal site to detect needs for maintenance or custodial care, to observe evidence of intrusion, and to ascertain compliance with other license and regulatory requirements.

"Waste" means those low-level radioactive wastes as defined in R313-19-3-102(7) that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as it does in the Low-Level Radioactive Waste Policy Act, Pub.L. 96-573, 94 Stat. 3347; thus, the term denotes radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, waste does not mean byproduct material as defined in 42 U.S.C. 2011(e)(2) of the Atomic Energy Act, uranium or thorium tailings and waste.

"Treatment" means the stabilization or the reduction in volume of waste by a chemical or a physical process.

R313-25-3. Siting Criteria and Pre-licensing Plan Approval for Commercial Radioactive Waste Disposal Facilities.

(1) Persons proposing to construct or operate commercial radioactive waste disposal facilities, including waste incinerators, shall obtain a plan approval from the Executive Secretary before applying for a license. Plans meet the siting criteria and plan approval requirements of R313-25-3 and R313-19-3-105.

(2) The siting criteria and plan approval requirements in R313-25-3 apply to prelicensing plan approval applications.

(3) Treatment and disposal facilities, including commercial radioactive waste incinerators, shall not be located:

(a) within or underlain by:

(i) national, state, and county parks, monuments, and recreation areas; designated wilderness and wilderness study areas; wild and scenic river areas;

(ii) ecologically and scientifically significant natural

areas, including wildlife management areas and habitats for listed or proposed endangered species as designated by federal law;

(iii) 100 year floodplains;

(iv) areas 200 feet from Holocene faults;

(v) underground mines, salt domes and salt beds;

(vi) dam failure flood areas;

(vii) areas subject to landslide, mud flow, or other earth movement, unless adverse impacts can be mitigated;

(viii) farmlands classified or evaluated as "prime", "unique", or of "statewide importance" by the U.S. Department of Agricultural Soil Conservation Service under the Prime Farmland Protection Act;

(ix) areas five miles of existing permanent dwellings, residential areas, and other habitable structures, including schools, churches, and historic structures;

(x) areas five miles of surface waters including intermittent streams, perennial streams, rivers, lakes, reservoirs, and wetlands;

(xi) areas 100 feet of uranium mill tailings;

(xii) areas 1000 feet of archeological sites to which adverse impacts cannot reasonably be mitigated;

(xiii) recharge zones of aquifers containing ground water which has a total dissolved solids content of less than 10,000 mg/l; or

(xiv) drinking water source protection areas designated by the State Drinking Water Committee;

(b) in areas:

(i) above or underlain by aquifers containing ground water which has a total dissolved solids content of less than 500 mg/l and which aquifers do not exceed state ground water standards for pollutants;

(ii) above or underlain by aquifers containing ground water which has a total dissolved solids content between 3000 and 10,000 mg/l when the distance from the surface to the ground water is less than 100 ft.;

(iii) areas, such as areas of extensive withdrawal of water, gas, or oil;

(iv) above or underlain by weak and unstable soils, including soils that lose their ability to support foundations as a result of hydrocompaction, expansion, or shrinkage;

(v) above or underlain by karst terrains.

(4) Incinerators associated with land disposal facilities may not be located above aquifers containing ground water which has a total dissolved solids content below 3000 mg/l. Incinerators not associated with ground disposal facilities shall not be located above aquifers containing ground water which has a total dissolved solids content below 500 mg/l.

(5) Facilities may not be located within a distance to existing drinking water wells and watersheds for public water supplies of one year ground water travel time plus 1000 feet for incinerators and of five years ground water travel time plus 1000 feet for land disposal facilities.

(6) The plan approval application shall include hydraulic conductivity and other information necessary to estimate adequately

the ground water travel distance.

(7) The plan approval application shall include the results of studies adequate to identify the presence of ground water aquifers in the area of the proposed site and to assess the quality of the ground water of all aquifers identified in the area of the proposed site.

(8) The Executive Secretary may require the applicant to conduct vadose zone or other near surface monitoring.

(9) Emergency response and safety.

(a) The plan approval application shall demonstrate the availability and adequacy of emergency services, including medical and fire response. The application shall provide evidence that the applicant has coordinated emergency response plans with local and regional emergency response resources.

(b) The plan approval application shall include plans for responding to emergencies both at the site and those involving the transport of wastes within the state. Details of the proposed emergency response plan shall be given in the plan approval application and will be stipulated in the plan approval and radioactive materials license.

(c) The plan approval application shall show proposed routes for transportation of radioactive wastes within the state. The Executive Secretary will not approve plans that propose radioactive waste transportation routes over roads or bridges where weight restrictions would be exceeded. The Executive Secretary will not approve plans that pose adverse impact or risk of harm to inhabited areas. The plan approval application shall address risks to inhabited areas, including both residential and non-residential areas; the width, condition, and types of roads to be used; roadside development on proposed routes; seasonal and climatic factors which may affect safety; alternate emergency access to the facility; the type, size, and configuration of vehicles proposed to haul wastes; transportation restrictions on proposed routes; and the transportation means and routes available to evacuate the population at risk in the event of accidents, including spills and fires.

(10) Siting Authority. The Executive Secretary recognizes that Titles 10 and 17 of the Utah Code give cities and counties authority for local use planning and zoning. Nothing in R313-25-3 precludes cities and counties from establishing additional requirements as provided by applicable state and federal law.

R313-25-4. License Required.

(1) Persons shall not receive, possess, or dispose of waste at a land disposal facility unless authorized by a license issued by the Executive Secretary pursuant to R313-25 and R313-22.

(2) Persons shall file an application with the Executive Secretary pursuant to R313-22-32 and obtain a license as provided in R313-25 before commencement of construction of a land disposal facility. Failure to comply with this requirement may be grounds for denial of a license and other penalties established by law and rules.

R313-25-5. Content of Application.

In addition to the requirements set forth in R313-22-33, an application to receive from others, possess, and dispose of wastes shall consist of general information, specific technical information, institutional information, and financial information as set forth in R313-25-6 through R313-25-10.

R313-25-6. General Information.

The general information shall include the following:

- (1) identity of the applicant including:
 - (a) the full name, address, telephone number, and description of the business or occupation of the applicant;
 - (b) if the applicant is a partnership, the names and addresses of the partners and the principal location where the partnership does business;
 - (c) if the applicant is a corporation or an unincorporated association;
 - (i) the state where it is incorporated or organized and the principal location where it does business; and
 - (ii) the names and addresses of its directors and principal officers; and
 - (d) if the applicant is acting as an agent or representative of another person in filing the application, the applicant shall provide, with respect to the other person, information required under R313-25-6(1).
- (2) Qualifications of the applicant shall include the following:
 - (a) the organizational structure of the applicant, both offsite and onsite, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;
 - (b) the technical qualifications, including training and experience of the applicant and members of the applicant's staff, to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in R313-25-6(2)(a) shall be provided;
 - (c) a description of the applicant's personnel training program; and
 - (d) the plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling, and disposal operations in a safe manner.
- (3) A description of:
 - (a) the location of the proposed disposal site;
 - (b) the general character of the proposed activities;
 - (c) the types and quantities of waste to be received, possessed, and disposed of;
 - (d) plans for use of the land disposal facility for purposes other than disposal of wastes; and
 - (e) the proposed facilities and equipment; and
- (4) proposed schedules for construction, receipt of waste, and first emplacement of waste at the proposed land disposal facility.

R313-25-7. Specific Technical Information.

The application shall include certain technical information.

The following information is needed to determine whether or not the applicant can meet the performance objectives and the applicable technical requirements of R313-25:

- (1) A description of the natural and demographic disposal site characteristics shall be based on and determined by disposal site selection and characterization activities. The description shall include geologic, geochemical, geotechnical, hydrologic, ecologic, archaeologic, meteorologic, climatologic, and biotic features of the disposal site and vicinity.
- (2) Descriptions of the design features of the land disposal facility and of the disposal units for near-surface disposal shall include those design features related to infiltration of water; integrity of covers for disposal units; structural stability of backfill, wastes, and covers; contact of wastes with standing water; disposal site drainage; disposal site closure and stabilization; elimination to the extent practicable of long-term disposal site maintenance; inadvertent intrusion; occupational exposures; disposal site monitoring; and adequacy of the size of the buffer zone for monitoring and potential mitigative measures.
- (3) Descriptions of the principal design criteria and their relationship to the performance objectives.
- (4) Descriptions of the natural events or phenomena on which the design is based and their relationship to the principal design criteria.
- (5) Descriptions of codes and standards which the applicant has applied to the design, and will apply to construction of the land disposal facilities.
- (6) Descriptions of the construction and operation of the land disposal facility. The description shall include as a minimum the methods of construction of disposal units; waste emplacement; the procedures for and areas of waste segregation; types of intruder barriers; onsite traffic and drainage systems; survey control program; methods and areas of waste storage; and methods to control surface water and ground water access to the wastes. The description shall also include a description of the methods to be employed in the handling and disposal of wastes containing chelating agents or other non-radiological substances which might affect meeting the performance objectives of R313-25.
- (7) A description of the disposal site closure plan, including those design features which are intended to facilitate disposal site closures and to eliminate the need for active maintenance after closure.
- (8) Identification of the known natural resources at the disposal site whose exploitation could result in inadvertent intrusion into the wastes after removal of active institutional control.
- (9) Descriptions of the kind, amount, classification and specifications of the radioactive material proposed to be received, possessed, and disposed of at the land disposal facility.
- (10) Descriptions of quality assurance programs, tailored to low-level waste disposal, including audit and managerial controls, for the determination of natural disposal site characteristics and for quality control during the design, construction, operation, and closure of the land disposal facility and the receipt, handling,

and emplacement of waste.

(11) A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in R313-25-19 and monitoring of occupational radiation exposure to ensure compliance with the requirements of R313-15 and to control contamination of personnel, vehicles, equipment, buildings, and the disposal site. The applicant shall describe procedures, instrumentation, facilities, and equipment appropriate to both routine and emergency operations.

(12) A description of the environmental monitoring program to provide data and to evaluate potential health and environmental impacts and the plan for taking corrective measures if migration is indicated.

(13) Descriptions of the administrative procedures that the applicant will apply to control activities at the land disposal facility.

(14) A description of the facility electronic recordkeeping system as required in R313-25-33.

R313-25-8. Technical Analyses.

The specific technical information shall also include the following analyses needed to demonstrate that the performance objectives of R313-25 will be met:

(1) Analyses demonstrating that the general population will be protected from releases of radioactivity shall consider the pathways of air, soil, ground water, surface water, plant uptake, and exhumation by burrowing animals. The analyses shall clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes. The analyses shall clearly demonstrate a reasonable assurance that the exposures to humans from the release of radioactivity will not exceed the limits set forth in R313-25-19.

(2) Analyses of the protection of inadvertent intruders shall demonstrate a reasonable assurance that the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided.

(3) Analysis of the protection of individuals during operations shall include assessments of expected exposures due to routine operations and likely accidents during handling, storage, and disposal of waste. The analysis shall provide reasonable assurance that exposures will be controlled to meet the requirements of R313-15.

(4) Analyses of the long-term stability of the disposal site shall be based upon analyses of active natural processes including erosion, mass wasting, slope failure, settlement of wastes and backfill, infiltration through covers over disposal areas and adjacent soils, and surface drainage of the disposal site. The analyses shall provide reasonable assurance that there will not be a need for ongoing active maintenance of the disposal site following closure.

R313-25-9. Institutional Information.

The institutional information submitted by the applicant shall include:

(1) A certification by the federal or state agency which owns the disposal site that the agency is prepared to accept transfer of the license when the provisions of R313-25-16 are met and will assume responsibility for institutional control after site closure and for post-closure observation and maintenance.

(2) Evidence, if the proposed disposal site is on land not owned by the federal or a state government, that arrangements have been made for assumption of ownership in fee by the federal or a state agency.

R313-25-10. Financial Information.

This information shall demonstrate that the applicant is financially qualified to carry out the activities for which the license is sought. The information shall meet other financial assurance requirements of R313-25 .

R313-25-11. Requirements for Issuance of a License.

A license for the receipt, possession, and disposal of waste containing radioactive material will be issued by the Executive Secretary upon finding that:

(1) the issuance of the license will not constitute an unreasonable risk to the health and safety of the public;

(2) the applicant is qualified by reason of training and experience to carry out the described disposal operations in a manner that protects health and minimizes danger to life or property;

(3) the applicant's proposed disposal site, disposal design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and post-closure institutional control, are adequate to protect the public health and safety as specified in the performance objectives of R313-25-19;

(4) the applicant's proposed disposal site, disposal site design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and post-closure institutional control are adequate to protect the public health and safety in accordance with the performance objectives of R313-25-20;

(5) the applicant's proposed land disposal facility operations, including equipment, facilities, and procedures, are adequate to protect the public health and safety in accordance with R313-15;

(6) the applicant's proposed disposal site, disposal site design, land disposal facility operations, disposal site closure, and post-closure institutional control plans are adequate to protect the public health and safety in that they will provide reasonable assurance of the long-term stability of the disposed waste and the disposal site and will eliminate to the extent practicable the need for continued maintenance of the disposal site following closure;

(7) the applicant's demonstration provides reasonable assurance that the requirements of R313-25 will be met;

(8) the applicant's proposal for institutional control

provides reasonable assurance that control will be provided for the length of time found necessary to ensure the findings in R313-25-11(3) through (6) and that the institutional control meets the requirements of R313-25-28.

(9) the financial or surety arrangements meet the requirements of R313-25.

R313-25-12. Conditions of Licenses.

(1) A license issued under R313-25, or a right thereunder, may not be transferred, assigned, or disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to a person, unless the Executive Secretary finds, after securing full information, that the transfer is in accordance with the provisions of the Radiation Control Act and Rules and gives his consent in writing in the form of a license amendment.

(2) The Executive Secretary may require the licensee to submit written statements under oath.

(3) The license will be terminated only on the full implementation of the final closure plan, including post-closure observation and maintenance, as approved by the Executive Secretary.

(4) The licensee shall submit to the provisions of the Act now or hereafter in effect, and to all findings and orders of the Executive Secretary. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to, or by reason of rules, and orders issued in accordance with the terms of the Act and these rules.

(5) Persons licensed by the Executive Secretary pursuant to R313-25 shall confine possession and use of the materials to the locations and purposes authorized in the license.

(6) The licensee shall not dispose of waste until the Executive Secretary has inspected the land disposal facility and has found it to conform with the description, design, and construction described in the application for a license.

(7) The Executive Secretary may incorporate, by rule or order, into licenses at the time of issuance or thereafter, additional requirements and conditions with respect to the licensee's receipt, possession, and disposal of waste as the Executive Secretary deems appropriate or necessary in order to:

(a) protect health or to minimize danger to life or property;

(b) require reports and the keeping of records, and to provide for inspections of licensed activities as the Executive Secretary deems necessary or appropriate to effectuate the purposes of the Radiation Control Act and Rules.

(8) The authority to dispose of wastes expires on the expiration date stated in the license. An expiration date on a license applies only to the above ground activities and to the authority to dispose of waste. Failure to renew the license shall not relieve the licensee of responsibility for implementing site closure, post-closure observation, and transfer of the license to the site owner.

R313-25-13. Application for Renewal or Closure.

(1) An application for renewal or an application for closure under R313-25-14 shall be filed at least 90 days prior to license expiration.

(2) Applications for renewal of a license shall be filed in accordance with R313-25-5 through 25-10. Applications for closure shall be filed in accordance with R313-25-14. Information contained in previous applications, statements, or reports filed with the Executive Secretary under the license may be incorporated by reference if the references are clear and specific.

(3) If a licensee has filed an application in proper form for renewal of a license, the license shall not expire unless and until the Executive Secretary has taken final action to deny application for renewal.

(4) In evaluating an application for license renewal, the Executive Secretary will apply the criteria set forth in R313-25-11.

R313-25-14. Contents of Application for Site Closure and Stabilization.

(1) Prior to final closure of the disposal site, or as otherwise directed by the Executive Secretary, the licensee shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the disposal site closure plan included in the original license application submitted and approved under R313-25-7(7). The plan shall include the following:

(a) additional geologic, hydrologic, or other data pertinent to the long-term containment of emplaced wastes obtained during the operational period;

(b) the results of tests, experiments, or other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media, or other tests, experiments, or analyses pertinent to the long-term containment of emplaced waste within the disposal site;

(c) proposed revision of plans for:

(i) decontamination or dismantlement of surface facilities;

(ii) backfilling of excavated areas; or

(iii) stabilization of the disposal site for post-closure care.

(d) Significant new information regarding the environmental impact of closure activities and long-term performance of the disposal site.

(2) Upon review and consideration of an application to amend the license for closure submitted in accordance with R313-25-14(1), the Executive Secretary shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives of R313-25 will be met.

R313-25-15. Post-Closure Observation and Maintenance.

The licensee shall observe, monitor, and carry out necessary maintenance and repairs at the disposal site until the site closure is complete and the license is transferred by the Executive Secretary in accordance with R313-25-16. The licensee shall remain responsible for the disposal site for an additional five years.

The Executive Secretary may approve closure plans that provide for shorter or longer time periods of post-closure observation and maintenance, if sufficient rationale is developed for the variance.

R313-25-16. Transfer of License.

Following closure and the period of post-closure observation and maintenance, the licensee may apply for an amendment to transfer the license to the disposal site owner. The license shall be transferred when the Executive Secretary finds:

(1) that the disposal site was closed according to the licensee's approved disposal site closure plan;

(2) that the licensee has provided reasonable assurance that the performance objectives of R313-25 have been met;

(3) that funds [~~and necessary records~~] for care and records required by R313-25-33(4) and (5) have been [~~will be~~] transferred to the disposal site owner;

(4) that the post-closure monitoring program is operational and can be implemented by the disposal site owner; and

(5) that the Federal or State agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under R313-25-11(8) will be met.

R313-25-17. Termination of License.

(1) Following the period of institutional control needed to meet the requirements of R313-25-11, the licensee may apply for an amendment to terminate the license.

(2) This application will be reviewed in accordance with the provisions of R313-22-32.

(3) A license shall be terminated only when the Executive Secretary finds:

(a) that the institutional control requirements of R313-25-11(8) have been met;

(b) that additional requirements resulting from new information developed during the institutional control period have been met; [~~and~~]

(c) that permanent monuments or markers warning against intrusion have been installed [~~-~~]; and

(d) that records required by R313-25-33(4) and (5) have been sent to the party responsible for institutional control of the disposal site and a copy has been sent to the Executive Secretary immediately prior to license termination.

R313-25-18. General Requirement.

Land disposal facilities shall be sited, designed, operated, closed, and controlled after closure so that reasonable assurance exists that exposures to individuals do not exceed the limits stated in R313-25-19 and 25-22.

R313-25-19. Protection of the General Population from Releases of Radioactivity.

Concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants or animals shall not result in an annual dose

exceeding an equivalent of 25 millirems (0.25 mSv) to the whole body, 75 millirems (0.75 mSv) to the thyroid, and 25 millirems (0.25 mSv) to any other organ of any member of the public. Reasonable efforts should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

R313-25-20. Protection of Individuals from Inadvertent Intrusion.

Design, operation, and closure of the land disposal facility shall ensure protection of any individuals inadvertently intruding into the disposal site and occupying the site or contacting the waste after active institutional controls over the disposal site are removed.

R313-25-21. Protection of Individuals During Operations.

Operations at the land disposal facility shall be conducted in compliance with the standards for radiation protection set out in R313-15 of these rules, except for release of radioactivity in effluents from the land disposal facility, which shall be governed by R313-25-19. Every reasonable effort should be made to maintain radiation exposures as low as is reasonably achievable, ALARA.

R313-25-22. Stability of the Disposal Site After Closure.

The disposal facility shall be sited, designed, used, operated, and closed to achieve long-term stability of the disposal site and to eliminate, to the extent practicable, the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring, or minor custodial care are required.

R313-25-23. Disposal Site Suitability Requirements for Land Disposal - Near-Surface Disposal.

(1) The primary emphasis in disposal site suitability is given to isolation of wastes and to disposal site features that ensure that the long-term performance objectives are met.

(2) The disposal site shall be capable of being characterized, modeled, analyzed and monitored.

(3) Within the region where the facility is to be located, a disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the disposal facility to meet the performance objectives of R313-25.

(4) Areas shall be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives of R313-25.

(5) The disposal site shall be generally well drained and free of areas of flooding or frequent ponding. Waste disposal shall not take place in a 100-year flood plain, coastal high-hazard area or wetland, as defined in Executive Order 11988, "Floodplain Management Guidelines."

(6) Upstream drainage areas shall be minimized to decrease the amount of runoff which could erode or inundate waste disposal units.

(7) The disposal site shall provide sufficient depth to the

water table that ground water intrusion, perennial or otherwise, into the waste will not occur. The Executive Secretary will consider an exception to this requirement to allow disposal below the water table if it can be conclusively shown that disposal site characteristics will result in molecular diffusion being the predominant means of radionuclide movement and the rate of movement will result in the performance objectives being met. In no case will waste disposal be permitted in the zone of fluctuation of the water table.

(8) The hydrogeologic unit used for disposal shall not discharge ground water to the surface within the disposal site.

(9) Areas shall be avoided where tectonic processes such as faulting, folding, seismic activity, vulcanism, or similar phenomena may occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of R313-25 or may preclude defensible modeling and prediction of long-term impacts.

(10) Areas shall be avoided where surface geologic processes such as mass wasting, erosion, slumping, landsliding, or weathering occur with sufficient such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of R313-25, or may preclude defensible modeling and prediction of long-term impacts.

(11) The disposal site shall not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives of R313-25 or significantly mask the environmental monitoring program.

R313-25-24. Disposal Site Design for Near-Surface Land Disposal.

(1) Site design features shall be directed toward long-term isolation and avoidance of the need for continuing active maintenance after site closure.

(2) The disposal site design and operation shall be compatible with the disposal site closure and stabilization plan and lead to disposal site closure that provides reasonable assurance that the performance objectives will be met.

(3) The disposal site shall be designed to complement and improve, where appropriate, the ability of the disposal site's natural characteristics to assure that the performance objectives will be met.

(4) Covers shall be designed to minimize, to the extent practicable, water infiltration, to direct percolating or surface water away from the disposed waste, and to resist degradation by surface geologic processes and biotic activity.

(5) Surface features shall direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance in the future.

(6) The disposal site shall be designed to minimize to the extent practicable the contact of water with waste during storage, the contact of standing water with waste during disposal, and the contact of percolating or standing water with wastes after disposal.

R313-25-25. Near Surface Land Disposal Facility Operation and Disposal Site Closure.

(1) Wastes designated as Class A pursuant to R313-15-307 of these rules shall be segregated from other wastes by placing them in disposal units which are sufficiently separated from disposal units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives of R313-25. This segregation is not necessary for Class A wastes if they meet the stability requirements of R313-15-308(2).

(2) Wastes designated as Class C pursuant to R313-15-307 shall be disposed of so that the top of the waste is a minimum of five meters below the top surface of the cover or shall be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.

(3) Except as provided in R313-25-1(1), only waste classified as Class A, B, or C shall be acceptable for near-surface disposal. Wastes shall be disposed of in accordance with the requirements of R313-25-25(4) through 11.

(4) Wastes shall be emplaced in a manner that maintains the package integrity during emplacement, minimizes the void spaces between packages, and permits the void spaces to be filled.

(5) Void spaces between waste packages shall be filled with earth or other material to reduce future subsidence within the fill.

(6) Waste shall be placed and covered in a manner that limits the radiation dose rate at the surface of the cover to levels that at a minimum will permit the licensee to comply with all provisions of R313-15-105 at the time the license is transferred pursuant to R313-25-16.

(7) The boundaries and locations of disposal units shall be accurately located and mapped by means of a land survey. Near-surface disposal units shall be marked in such a way that the boundaries of the units can be easily defined. Three permanent survey marker control points, referenced to United States Geological Survey or National Geodetic Survey control stations, shall be established on the site to facilitate surveys. The United States Geological Survey or National Geodetic Survey control stations shall provide horizontal and vertical controls as checked against United States Geological Survey or National Geodetic Survey record files.

(8) A buffer zone of land shall be maintained between any buried waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in R313-25-26(4) and take mitigative measures if needed.

(9) Closure and stabilization measures as set forth in the approved site closure plan shall be carried out as the disposal units are filled and covered.

(10) Active waste disposal operations shall not have an adverse effect on completed closure and stabilization measures.

(11) Only wastes containing or contaminated with radioactive material shall be disposed of at the disposal site.

(12) Proposals for disposal of waste that are not generally

acceptable for near-surface disposal because the wastes form and disposal methods shall be different and, in general, more stringent than those specified for Class C waste, may be submitted to the Executive Secretary for approval.

R313-25-26. Environmental Monitoring.

(1) At the time a license application is submitted, the applicant shall have conducted a preoperational monitoring program to provide basic environmental data on the disposal site characteristics. The applicant shall obtain information about the ecology, meteorology, climate, hydrology, geology, geochemistry, and seismology of the disposal site. For those characteristics that are subject to seasonal variation, data shall cover at least a 12-month period.

(2) During the land disposal facility site construction and operation, the licensee shall maintain an environmental monitoring program. Measurements and observations shall be made and recorded to provide data to evaluate the potential health and environmental impacts during both the construction and the operation of the facility and to enable the evaluation of long-term effects and need for mitigative measures. The monitoring system shall be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

(3) After the disposal site is closed, the licensee responsible for post-operational surveillance of the disposal site shall maintain a monitoring system based on the operating history and the closure and stabilization of the disposal site. The monitoring system shall be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

(4) The licensee shall have plans for taking corrective measures if the environmental monitoring program detects migration of waste which would indicate that the performance objectives may not be met.

R313-25-27. Alternative Requirements for Design and Operations.

The Executive Secretary may, upon request or on his own initiative, authorize provisions other than those set forth in R313-25-24 and 25-26 for the segregation and disposal of waste and for the design and operation of a land disposal facility on a specific basis, if it finds reasonable assurance of compliance with the performance objectives of R313-25.

R313-25-28. Institutional Requirements.

(1) Land Ownership. Disposal of waste received from other persons may be permitted only on land owned in fee by the Federal or a State government.

(2) Institutional Control. The land owner or custodial agency shall conduct an institutional control program to physically control access to the disposal site following transfer of control of the disposal site from the disposal site operator. The institutional control program shall also include, but not be limited to, conducting an environmental monitoring program at the disposal site, periodic surveillance, minor custodial care, and

other equivalents as determined by the Executive Secretary, and administration of funds to cover the costs for these activities. The period of institutional controls will be determined by the Executive Secretary, but institutional controls may not be relied upon for more than 100 years following transfer of control of the disposal site to the owner.

R313-25-30. Applicant Qualifications and Assurances.

The applicant shall show that it either possesses the necessary funds, or has reasonable assurance of obtaining the necessary funds, or by a combination of the two, to cover the estimated costs of conducting all licensed activities over the planned operating life of the project, including costs of construction and disposal.

R313-25-31. Funding for Disposal Site Closure and Stabilization.

(1) The applicant shall provide assurances prior to the commencement of operations that sufficient funds will be available to carry out disposal site closure and stabilization, including:

(a) decontamination or dismantlement of land disposal facility structures, and

(b) closure and stabilization of the disposal site so that following transfer of the disposal site to the site owner, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance, and monitoring are required. These assurances shall be based on Executive Secretary approved cost estimates reflecting the Executive Secretary approved plan for disposal site closure and stabilization. The applicant's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.

(2) In order to avoid unnecessary duplication and expense, the Executive Secretary will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of Federal or other State agencies or local governmental bodies for decontamination, closure, and stabilization. The Executive Secretary will accept these arrangements only if they are considered adequate to satisfy the requirements of R313-25-31 and if they clearly identify that the portion of the surety which covers the closure of the disposal site is clearly identified and committed for use in accomplishing these activities.

(3) The licensee's financial or surety arrangement shall be submitted annually for review by the Executive Secretary to assure that sufficient funds will be available for completion of the closure plan.

(4) The amount of the licensee's financial or surety arrangement shall change in accordance with changes in the predicted costs of closure and stabilization. Factors affecting closure and stabilization cost estimates include inflation, increases in the amount of disturbed land, changes in engineering plans, closure and stabilization that have already been accomplished, and other conditions affecting costs. The financial

or surety arrangement shall be sufficient at all times to cover the costs of closure and stabilization of the disposal units that are expected to be used before the next license renewal.

(5) The financial or surety arrangement shall be written for a specified period of time and shall be automatically renewed unless the person who issues the surety notifies the Executive Secretary; the beneficiary, the site owner; and the principal, the licensee, not less than 90 days prior to the renewal date of its intention not to renew. In such a situation, the licensee shall submit a replacement surety within 30 days after notification of cancellation. If the licensee fails to provide a replacement surety acceptable to the Executive Secretary, the beneficiary may collect on the original surety.

(6) Proof of forfeiture shall not be necessary to collect the surety so that, in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above shall be clearly stated on surety instruments.

(7) Financial or surety arrangements generally acceptable to the Executive Secretary include surety bonds, cash deposits, certificates of deposit, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combinations of the above or other types of arrangements as may be approved by the Executive Secretary. Self-insurance, or an arrangement which essentially constitutes self-insurance, will not satisfy the surety requirement for private sector applicants.

(8) The licensee's financial or surety arrangement shall remain in effect until the closure and stabilization program has been completed and approved by the Executive Secretary, and the license has been transferred to the site owner.

R313-25-32. Financial Assurances for Institutional Controls.

(1) Prior to the issuance of the license, the applicant shall provide for Executive Secretary approval, a binding arrangement, between the applicant and the disposal site owner that ensures that sufficient funds will be available to cover the costs of monitoring and required maintenance during the institutional control period. The binding arrangement shall be reviewed annually by the Executive Secretary to ensure that changes in inflation, technology, and disposal facility operations are reflected in the arrangements.

(2) Subsequent changes to the binding arrangement specified in R313-25-32(1) relevant to institutional control shall be submitted to the Executive Secretary for prior approval.

R313-25-33. Maintenance of Records, Reports, and Transfers.

(1) Licensees shall maintain records and make reports in connection with the licensed activities as may be required by the conditions of the license or by the rules and orders of the Executive Secretary.

(2) Records which are required by these rules or by license conditions shall be maintained for a period specified by the appropriate rules or by license condition. If a retention period is not otherwise specified, these records shall be maintained and

transferred to the officials specified in R313-25-33(4) as a condition of license termination unless the Executive Secretary otherwise authorizes their disposition.

(3) Records which shall be maintained pursuant to R313-25 may be the original or a reproduced copy or microfilm if this reproduced copy or microfilm is capable of producing copy that is clear and legible at the end of the required retention period.

(4) Notwithstanding R313-25-33(1) through (3), copies of records of the location and the quantity of wastes contained in the disposal site shall be transferred upon license termination to the chief executive of the nearest municipality, the chief executive of the county in which the facility is located, the county zoning board or land development and planning agency, the State Governor, and other state, local, and federal governmental agencies as designated by the Executive Secretary at the time of license termination.

(5) Following receipt and acceptance of a shipment of waste, the licensee shall record the date that the shipment is received at the disposal facility, the date of disposal of the waste, a traceable shipment manifest number, a description of any engineered barrier or structural overpack provided for disposal of the waste, the location of disposal at [in] the disposal site, the condition of the waste packages as received, discrepancies between the materials listed on the manifest and those received, the volume of any pallets, bracing, or other shipping or onsite generated materials that are contaminated, and are disposed of as contaminated or suspect materials, and evidence of leakage or damaged packages or radiation or contamination levels in excess of limits specified in U.S. Department of Transportation and Executive Secretary regulations or rules. The licensee shall briefly describe repackaging operations of the waste packages included in the shipment, plus other information required by the Executive Secretary as a license condition.

(6) Licensees authorized to dispose of waste received from other persons shall file a copy of their financial report or a certified financial statement annually with the Executive Secretary in order to update the information base for determining financial qualifications.

(7)(a) Licensees authorized to dispose of waste received from other persons, pursuant to R313-25, shall submit annual reports to the Executive Secretary. Reports shall be submitted by the end of the first calendar quarter of each year for the preceding year.

(b) The reports shall include:

(i) specification of the quantity of each of the principal contaminants released to unrestricted areas in liquid and in airborne effluents during the preceding year;

(ii) the results of the environmental monitoring program;

(iii) a summary of licensee disposal unit survey and maintenance activities;

(iv) a summary, by waste class, of activities and quantities of radionuclides disposed of;

(v) instances in which observed site characteristics were significantly different from those described in the application for a license; and

(vi) other information the Executive Secretary may require.

(c) If the quantities of waste released during the reporting period, monitoring results, or maintenance performed are significantly different from those predicted, the report shall cover this specifically.

(8) In addition to the other requirements in R313-25-33, the licensee shall store, or have stored, manifest and other information pertaining to receipt and disposal of radioactive waste in an electronic recordkeeping system.

(a) The manifest information that must be electronically stored is:

(i) that required in Appendix G of 10 CFR 20.1001 to 20.2402, 1997 ed., which is incorporated into these rules by reference, with the exception of shipper and carrier telephone numbers and shipper and consignee certifications; and

(ii) that information required in R313-25-33(5).

(b) As specified in facility license conditions, the licensee shall report the stored information, or subsets of this information, on a computer-readable medium.

R313-25-34. Tests on Land Disposal Facilities.

Licensees shall perform, or permit the Executive Secretary to perform, any tests the Executive Secretary deems appropriate or necessary for the administration of the rules in R313-25, including, but not limited to, tests of;

(1) wastes;

(2) facilities used for the receipt, storage, treatment, handling or disposal of wastes;

(3) radiation detection and monitoring instruments; or

(4) other equipment and devices used in connection with the receipt, possession, handling, treatment, storage, or disposal of waste.

R313-25-35. Executive Secretary Inspections of Land Disposal Facilities.

(1) Licensees shall afford to the Executive Secretary, at reasonable times, opportunity to inspect waste not yet disposed of, and the premises, equipment, operations, and facilities in which wastes are received, possessed, handled, treated, stored, or disposed of.

(2) Licensees shall make available to the Executive Secretary for inspection, upon reasonable notice, records kept by it pursuant to these rules. Authorized representatives of the Executive Secretary may copy and take away copies of, for the Executive Secretary's use, any records required to be kept pursuant to R313-25.

KEY: radiation, radioactive waste disposal

[1993]1998

Notice of Continuation May 1, 1997

19-3-104

19-3-108

State of Utah
Administrative Rule Analysis

8. Compliance Costs for Affected Persons ("Person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an agency):

None.

9. This rule is authorized or mandated by state law, and implements or interprets the following state and federal laws.

State Code or Constitution Citations (Required): Sections 19-3-104 and 19-3-108

Federal Citations (Optional):

10. This Filing Adds or Updates an Incorporated Reference (Submit a Copy to DAR):

Yes No

(Reference Title and Date of Issue or Edition): 10 CFR 20.1001 to 20.2402, 1997 ed.

11. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the *Utah State Bulletin*. See Section 63-46a-5 and Rule R15-1 for more information.)

Comments Will Be Accepted Until 5:00 p.m. on (mm/dd/yy): 12/31/97

A Public Hearing (Optional) Will Be Held on (mm/dd/yy):

at (Time):

at (Place):

12. This Filing May Become Effective on (mm/dd/yy):

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To the agency: Information requested on this form is required by Sections 63-46a-4, 5, 6, and 10. Incomplete forms may be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency Head or Designee: William J. Sinclair, Executive Secretary
(Please Include Title)

Date (mm/dd/yy): 11/15/97

effective date 3/20198

60 FR 15649

Low-Level Waste Shipment manifest
information and Reporting

R313. Environmental Quality, Radiation Control.

R313-15. Standards for Protection Against Radiation.

R313-15-1. Purpose, Authority and Scope.

(1) R313-15 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses issued by the Executive Secretary. These rules are issued pursuant to Sections 19-3-104(3) and 19-3-104(6).

(2) The requirements of Rule R313-15 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 Rule R313-15. However, nothing in Rule R313-15 shall be construed as limiting actions that may be necessary to protect health and safety.

(3) Except as specifically provided in other sections of these rules, Rule R313-15 applies to persons licensed or registered by the Executive Secretary to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Rule R313-15 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 Section R313-32-75, or to exposure from voluntary participation in medical research programs.

R313-15-2. Definitions.

"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 of 10 CFR 20.1001 to 20.2402, 199[3] ed., which is incorporated by reference.

"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 ten days, for Class W, Weeks, from ten to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.

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

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

"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 rules, 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 of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference.

"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).

"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.

"Inhalation class", refer to "Class".

"Labeled package" means a package 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 49 CFR 172.436 through 440, 199[3]7 ed. 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 49 CFR 173.421 through 424, 199[2]7 ed.

"Lung class", refer to "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 rules, "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~~ employees 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."

"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 rules, "probabilistic effect" is an equivalent term.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of five Gy (500 rad) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. 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:

TABLE
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(1)
Whole Body	1.00(2)

(1) 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

(2) 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.

R313-15-3. Implementation.

(1) Any existing license or registration condition that is more restrictive than Rule R313-15 remains in force until there is an amendment or renewal of the license or registration.

(2) If a license or registration condition exempts a licensee or registrant from a provision of Rule R313-15 in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of Rule R313-15.

(3) If a license or registration condition cites provisions of Rule R313-15 in effect prior to January 1, 1994, which do not correspond to any provisions of Rule R313-15, 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.

R313-15-101. Radiation Protection Programs.

(1) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Rule R313-15. See Section R313-15-1102 for recordkeeping requirements relating to these programs.

(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 that are as low as is reasonably achievable (ALARA).

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

(4) To implement the ALARA requirements of Subsection R313-15-101(2), and notwithstanding the requirements in Section R313-15-301, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees or registrants 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 mSv (10 mrem) per year from these emissions. If a licensee or registrant subject to this requirement exceeds this dose constraint, the licensee or registrant shall report the exceedance as provided in Section R313-15-1203 and promptly take appropriate corrective action to ensure against recurrence.

R313-15-201. Occupational Dose Limits for Adults.

(1) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to Section R313-15-206, to the following dose limits:

(a) An annual limit, which is the more limiting of:

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

(ii) 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 0.50 Sv (50 rem).

(b) The annual limits to the lens of the eye, to the skin, and to the extremities which are:

(i) An eye dose equivalent of 0.15 Sv (15 rem), and

(ii) A shallow dose equivalent of 0.50 Sv (50 rem) to the skin or to any extremity.

(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 Subsections R313-15-206(5)(a) and R313-15-206(5)(b).

(3) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:

(a) 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

(b) When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in Subsection R313-15-502(1)(d), the effective dose equivalent for external radiation shall be determined as follows:

(i) When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in Subsection R313-15-201(1), the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

(ii) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are [~~presented~~]specified in Table I of Appendix B of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference, and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See Section R313-15-1107.

(5) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to ten milligrams in a week in consideration of chemical toxicity. See footnote 3, of Appendix B of 10 CFR 20.1001 to 20-2402, 199[3]7 ed., which is incorporated by reference.

(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 Subsection R313-15-205(5).

R313-15-202. Compliance with Requirements for Summation of External and Internal Doses.

(1) If the licensee or registrant is required to monitor pursuant to both Subsections R313-15-502(1) and R313-15-502(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 Subsection R313-15-502(1) or only pursuant to Subsection R313-15-502(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 Subsections R313-15-202(2), R313-15-202(3) and R313-15-202(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.

(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:

(a) The sum of the fractions of the inhalation ALI for each radionuclide, or

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

(c) 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 ten percent of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

(3) Intake by Oral Ingestion. If the occupationally exposed individual [~~also~~] receives an intake of radionuclides by oral ingestion greater than ten 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) 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 Subsection R313-15-202(4).

R313-15-203. Determination of External Dose from Airborne Radioactive Material.

(1) Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See footnotes 1 and 2 of Appendix B of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference.

(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.

R313-15-204. Determination of Internal Exposure.

(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, when required pursuant to Section R313-15-502, take suitable and timely measurements of:

(a) Concentrations of radioactive materials in air in work areas; or

(b) Quantities of radionuclides in the body; or

- (c) Quantities of radionuclides excreted from the body; or
- (d) Combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in Section R313-15-703, 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.

(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:

(a) 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

(b) Upon prior approval of the Executive Secretary, 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

(c) 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 of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference.

(4) If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in Subsections R313-15-204(1)(b) or R313-15-204(1)(c), the licensee or registrant may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by Section R313-15-1202 or Section R313-15-1203. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

(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:

(a) The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference, for each radionuclide in the mixture; or

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

(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.

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

(a) The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in Section R313-15-201 and in complying with the monitoring requirements in Subsection R313-15-502(2), and

(b) The concentration of any radionuclide disregarded is less than ten percent of its DAC, and

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

(8) When determining the committed effective dose equivalent, the following information may be considered:

(a) 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.

(b) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.50 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 of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference. 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 Subsection R313-15-201(1)(a)(ii) is met.

R313-15-205. Determination of Prior Occupational Dose.

(1) For each individual [~~who may enter the licensee's or registrant's restricted or controlled area and is~~] likely to receive, in a year, an occupational dose requiring monitoring pursuant to Section R313-15-502, the licensee or registrant shall:

(a) Determine the occupational radiation dose received during the current year; and

(b) Attempt to obtain the records of [~~lifetime~~] cumulative occupational radiation dose. A licensee or registrant may accept, as the record of cumulative radiation dose, an up-to-date form DRC-05 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.

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

(a) The internal and external doses from all previous planned special exposures; and

(b) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual [~~and~~].

~~[(c) All lifetime cumulative occupational radiation dose.]~~

(3) In complying with the requirements of Subsection R313-15-205(1), a licensee or registrant may:

(a) 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

~~[(b) Accept, as the record of lifetime cumulative radiation~~

~~dose, an up-to-date form DRC-05 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]~~

~~[(c)](b)~~ Obtain reports of the individual's dose equivalents 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, other electronic media 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) ~~[(a)]~~ The licensee or registrant shall record the exposure history, as required by Subsection R313-15-205(1), on form DRC-05, or other clear and legible record, of all the information required on that form.

(a) 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 form DRC-05 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 form DRC-05 or equivalent indicating the periods of time for which data are not available.

(b) For the purpose of complying with this requirement, ~~[(L)]~~ 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 rules in Rule R313-15 in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on form DRC-05 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.

(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:

(a) In establishing administrative controls under Subsection R313-15-201(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

(b) That the individual is not available for planned special exposures.

(6) The licensee or registrant shall retain the records on form DRC-05 or equivalent until the Executive Secretary terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing form DRC-05 or equivalent for three years after the record is made.

R313-15-206. 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 Section R313-15-201 provided that each of the following conditions is satisfied:

(1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.

(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.

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

(a) Informed of the purpose of the planned operation; and

(b) 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

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

(4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by Subsection R313-15-205(2) during the lifetime of the individual for each individual involved.

(5) Subject to Subsection R313-15-201(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:

(a) The numerical values of any of the dose limits in Subsection R313-15-201(1) in any year; and

(b) Five times the annual dose limits in Subsection R313-15-201(1) during the individual's lifetime.

(6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with Section R313-15-1106 and submits a written report in accordance with Section R313-15-1204.

(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 Subsection R313-15-201(1) but shall be included in evaluations required by Subsections R313-15-206(4) and R313-15-206(5).

R313-15-207. Occupational Dose Limits for Minors.

The annual occupational dose limits for minors are ten percent of the annual occupational dose limits specified for adult workers in Section R313-15-201.

R313-15-208. Dose to an Embryo/Fetus.

(1) The licensee or registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed five mSv (0.5 rem). See Section R313-15-1107 for recordkeeping

requirements.

(2) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in Subsection R313-15-208(1).

(3) The dose to an embryo/fetus shall be taken as the sum of:

(a) The [deep dose equivalent to the] dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman; and

(b) The dose that is most representative of the dose to the embryo/fetus from external radiation, that is, in the mother's lower torso region. [radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.]

(i) If multiple measurements have not been made, assignment of the highest deep dose equivalent for the declared pregnant woman shall be the dose to the embryo/fetus, in accordance with Subsection R313-15-205(3); or

(ii) If multiple measurements have been made, assignment of the deep dose equivalent for the declared pregnant woman from the individual monitoring device which is most representative of the dose to the embryo/fetus shall be the dose to the embryo fetus. Assignment of the highest deep dose equivalent for the declared pregnant woman to the embryo/fetus is not required unless that dose is also the most representative deep dose equivalent for the region of the embryo/fetus.

(4) If by the time the woman declares pregnancy to the licensee or registrant, the dose to the embryo/fetus has exceeded 4.5 mSv (0.45 rem) the licensee or registrant shall be deemed to be in compliance with Subsection R313-15-208(1) if the additional dose to the embryo/fetus does not exceed 0.50 mSv (0.05 rem) during the remainder of the pregnancy.

R313-15-301. Dose Limits for Individual Members of the Public.

(1) Each licensee or registrant shall conduct operations so that:

(a) [The] Except as provided in Subsection R313-15-301(1)(c), the total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one mSv (0.1 rem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Section R313-32-75, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with Section R313-15-1003[-]; and

(b) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with Section R313-32-75, does not exceed 0.02 mSv (0.002 rem) in any one hour[-]; and

(c) The total effective dose equivalent to individual members of the public from infrequent exposure to radiation from radiation machines does not exceed 5 mSv (0.5 rem) in a year.

(2) If the licensee or registrant permits members of the

public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

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

(a) Demonstration of the need for and the expected duration of operations in excess of the limit in Subsection R313-15-301(1); and

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

(c) The procedures to be followed to maintain the dose ALARA.

(4) The Executive Secretary 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.

R313-15-302. Compliance with Dose Limits for Individual Members of the Public.

(1) The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in Section R313-15-301.

(2) A licensee or registrant shall show compliance with the annual dose limit in Section R313-15-301 by:

(a) 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

(b) Demonstrating that:

(i) 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 of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference; and

(ii) If an individual were continu[ally]ously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.50 mSv (0.05 rem) in a year.

(3) Upon approval from the Executive Secretary, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference, 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.

R313-15-401. Testing for Leakage or Contamination of Sealed Sources.

(1) The licensee or registrant in possession of any sealed source shall assure that:

(a) Each sealed source, except as specified in Subsection R313-15-401(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 six months before transfer to the licensee or registrant.

(b) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the Executive Secretary, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

(c) Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the Executive Secretary, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

(d) 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.

(e) 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 uCi) 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.

(f) 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 uCi) 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.

(g) 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 uCi) of a radium daughter which has a half-life greater than four days.

(2) A licensee or registrant need not perform tests for leakage or contamination on the following sealed sources:

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

(b) Sealed sources containing only radioactive material as a gas;

(c) Sealed sources containing 3.7 MBq (100 uCi) or less of beta or photon-emitting material or 370 kBq (ten uCi) or less of alpha-emitting material;

(d) Sealed sources containing only hydrogen-3;

(e) Seeds of iridium-192 encased in nylon ribbon; and

(f) 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 six months before the date of use or transfer.

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

(4) Test results shall be kept in units of becquerel or microcurie and maintained for inspection by representatives of the Executive Secretary. Records of test results for sealed sources shall be made pursuant to Section R313-15-1104.

(5) The following shall be considered evidence that a sealed source is leaking:

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

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

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

(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 Rule R313-15.

(7) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to Section R313-15-1208.

R313-15-501. Surveys and Monitoring - General.

(1) Each licensee or registrant shall make, or cause to be made, surveys that:

(a) Are necessary for the licensee or registrant to comply with Rule R313-15; and

(b) Are necessary under the circumstances to evaluate:

(i) Radiation levels; and

(ii) Concentrations or quantities of radioactive material;

and

(iii) The potential radiological hazards that could be present.

(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, except when a more frequent interval is specified in another applicable part of these rules or a license condition.

(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 Section R313-15-201, with other applicable provisions of these rules, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

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

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

R313-15-502. 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 Rule R313-15. As a minimum:

(1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

(a) Adults likely to receive, in one year from sources external to the body, a dose in excess of ten percent of the limits in Subsection R313-15-201(1); and

(b) Minors and declared pregnant women likely to receive, in one year from sources external to the body, a dose in excess of ten percent of any of the applicable limits in Sections R313-15-207 or R313-15-208; and

(c) Individuals entering a high or very high radiation area; and

(d) Individuals working with medical fluoroscopic equipment.

(i) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to Subsection R313-15-208(1), shall be located under the protective apron at the waist.

(A) If an individual monitoring device worn by a declared pregnant woman has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem), the value to be used for determining the dose to the embryo/fetus, pursuant to Subsection R313-15-208(3)(a) for radiation from medical fluoroscopy, may be the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the potential overestimation of dose recorded by the monitoring device because of the overlying tissue of the pregnant individual. This correction shall be performed by a radiation safety officer of an institutional radiation safety committee, a qualified expert approved by the Board, or a representative of the Executive Secretary.

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

(iii) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to Subsection R313-15-201(3)(b), it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. Note: The second individual monitoring device is required for a declared pregnant woman.

(2) Each licensee or registrant shall monitor, to determine compliance with Section R313-15-204, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(a) Adults likely to receive, in one year, an intake in excess of ten percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference; and

(b) Minors and declared pregnant women likely to receive, in one year, a committed effective dose equivalent in excess of 0.50 mSv (0.05 rem).

R313-15-503. Location of Individual Monitoring Devices.

Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with Subsection R313-15-502(1) wear individual monitoring devices as follows:

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

(2) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to Subsection R313-15-208(1), shall be located at the waist under any protective apron being worn by the woman.

(3) An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with Subsection R313-15-201(1)(b)(i), shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye.

(4) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with Subsection R313-15-201(1)(b)(ii), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

R313-15-601. Control of Access to High Radiation Areas.

(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:

(a) 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 one mSv (0.1 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or

(b) 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

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

(2) In place of the controls required by Subsection R313-15-601(1) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) The licensee or registrant may apply to the Executive Secretary for approval of alternative methods for controlling access to high radiation areas.

(4) The licensee or registrant shall establish the controls required by Subsections R313-15-601(1) and R313-15-601(3) in a way that does not prevent individuals from leaving a high radiation area.

(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 rules of the U.S. Department of Transportation provided that:

(a) The packages do not remain in the area longer than three days; and

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

(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 Rule R313-15 and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

(7) The 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 Section R313-15-601 if the registrant has met all the specific requirements for access and control specified in other applicable sections of these rules, such as, Rule R313-36 for industrial radiography, Rule R313-28 for x rays in the healing arts, Rule R313-30 for therapeutic radiation machines, and Rule R313-[44]35 for [particle accelerators] industrial use of x-ray systems.

R313-15-602. Control of Access to Very High Radiation Areas.

(1) In addition to the requirements in Section R313-15-601, 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 five Gy (500 rad) or more in one hour at one 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.

(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 Subsection R313-15-602(1) if the registrant has met all the

specific requirements for access and control specified in other applicable sections of these rules, such as, Rule R313-36 for industrial radiography, Rule R313-28 for x rays in the healing arts, Rule R313-30 for therapeutic radiation machines, and Rule R313-[44]35 for [particle accelerators] industrial use of x-ray systems.

R313-15-603. Control of Access to Very High Radiation Areas -- Irradiators.

(1) Section R313-15-603 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Section R313-15-603 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 a high levels of radiation in an area that is accessible to any individual.

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

(a) Each entrance or access point shall be equipped with entry control devices which:

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

(ii) 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 one mSv (0.1 rem) in one hour; and

(iii) 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 one mSv (0.1 rem) in one hour.

(b) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by Subsection R313-15-603(2)(a):

(i) 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 one mSv (0.1 rem) in one hour; and

(ii) 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.

(c) 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:

(i) 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 one mSv (0.1 rem) in one hour; and

(ii) 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.

(d) 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.

(e) 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 Subsections R313-15-603(2)(c) and R313-15-603(2)(d).

(f) 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 shall be installed in the area and which can prevent the source of radiation from being put into operation.

(g) 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.

(h) 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 one mSv (0.1 rem) in one hour.

(i) The entry control devices required in Subsection R313-15-603(2)(a) shall be tested for proper functioning. See Section R313-15-1110 for recordkeeping requirements.

(i) 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

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

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

(j) 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.

(k) 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 automatically to prevent loose radioactive material from being carried out of the area.

(3) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of Subsection R313-15-603(2) which will be used in a variety of positions or in locations, such as open fields or forests, that make it [~~impracticable~~]impractical to comply with certain requirements of Subsection R313-15-603(2), such as those for the automatic control of radiation levels, may apply to the Executive Secretary for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in Subsection R313-15-603(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) The entry control devices required by Subsections R313-15-603(2) and R313-15-603(3) shall be established in such a way that no individual will be prevented from leaving the area.

R313-15-701. Use of Process or Other Engineering Controls.

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

R313-15-702. Use of Other Controls.

When it is not [~~practicable~~]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 or registrant shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

- (1) Control of access; or
- (2) Limitation of exposure times; or
- (3) Use of respiratory protection equipment; or
- (4) Other controls.

R313-15-703. Use of Individual Respiratory Protection Equipment.

(1) If the licensee or registrant uses respiratory protection equipment to limit intakes pursuant to Section R313-15-702:

(a) Except as provided in Subsection R313-15-703(1)(b), the licensee or registrant 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.

(b) [~~if~~]The licensee or registrant [~~wishes to~~]may 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, provided the licensee or registrant [shall submit] has submitted to the Executive Secretary and the Executive Secretary has approved 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.

(c) The licensee or registrant shall implement and maintain a respiratory protection program that includes:

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

(ii) Surveys and bioassays, as appropriate, to evaluate actual intakes; and

(iii) Testing of respirators for operability immediately prior to each use; and

(iv) 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

(v) Determination by a physician prior to initial fitting of respirators, and [~~at least~~]either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is [~~physically~~]medically [~~able~~]fit to use the respiratory protection equipment.

(d) The licensee or registrant shall issue a written policy statement on respirator usage covering:

(i) The use of process or other engineering controls, instead of respirators; and

(ii) The routine, nonroutine, and emergency use of respirators; and

(iii) The length of periods of respirator use and relief from respirator use.

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

(f) The licensee or registrant 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.

(2) When estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to Section R313-15-702, provided that the following conditions, in addition to those in Subsection R313-15-

703(1), are satisfied:

(a) The licensee or registrant selects respiratory protection equipment that provides a protection factor, specified in Appendix A of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference, 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 of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference. However, if the selection of respiratory protection equipment with a protection factor greater than the ~~[peak concentration]multiple defined in the preceding sentence~~ is inconsistent with the goal specified in Section R313-15-702 of keeping the total effective dose equivalent ALARA, the licensee or registrant 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.

(b) The licensee or registrant shall obtain authorization from the Executive Secretary before assigning respiratory protection factors in excess of those specified in Appendix A of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference. The Executive Secretary may authorize a licensee or registrant to use higher protection factors on receipt of an application that:

(i) Describes the situation for which a need exists for higher protection factors, and

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

(c) In an emergency, the licensee or registrant 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.

(d) The licensee or registrant shall notify the Executive Secretary in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either Subsections R313-15-703(1) or R313-15-703(2).

R313-15-801. Security and Control of Licensed or Registered[Stored] Sources of Radiation.

~~[The licensee or registrant shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in controlled or unrestricted areas.]~~

R313-15-802. Control of Sources of Radiation not in Storage.

~~(1) The licensee or registrant shall control and maintain constant surveillance of licensed or registered radioactive~~

~~material that is in a controlled or unrestricted area and that is not in storage or in a patient.~~

~~(2) The registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.]~~ (1) The licensee or registrant shall secure licensed or registered radioactive material from unauthorized removal or access.

(2) The licensee or registrant shall maintain constant surveillance, and use devices or administrative procedures to prevent unauthorized use of licensed or registered radioactive material that is in an unrestricted area and that is not in storage.

(3) The registrant shall secure registered radiation machines from unauthorized removal.

(4) The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

R313-15-901. Caution Signs.

(1) Standard Radiation Symbol. Unless otherwise authorized by the Executive Secretary, the symbol prescribed by 10 CFR 20.1901, 199[3]7 ed., which is incorporated by reference, shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

(a) Cross-hatched area is to be magenta, or purple, or black, and

(b) The background is to be yellow.

(2) Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of 10 CFR 20.1901a, 199[3]7 ed., which is incorporated by reference, 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.

(3) Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in Rule R313-15, the licensee or registrant 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.

R313-15-902. Posting Requirements.

(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."

(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."

(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) 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."

(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 ten times the quantity of such material specified in Appendix C of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL."

R313-15-903. Exceptions to Posting Requirements.

(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 eight hours, if each of the following conditions is met:

(a) 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 Rule R313-15; and

(b) The area or room is subject to the licensee's or registrant's control.

(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to Section R313-15-902 provided that the patient could be released from ~~[confinement]~~licensee control pursuant to Section R313-32-75.

(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) 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.

R313-15-904. Labeling Containers and Radiation Machines.

(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.

(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.

(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.

R313-15-905. Exemptions to Labeling Requirements.

A licensee or registrant is not required to label:

(1) Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference; or

(2) Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference; or

(3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Rule R313-15; or

(4) Containers when they are in transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation; or

(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

(6) Installed manufacturing or process equipment, such as piping and tanks.

R313-15-906. Procedures for Receiving and Opening Packages.

(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 Section R313-19-4 and Subsection R313-19-100(19), shall make arrangements to receive:

(a) The package when the carrier offers it for delivery; or

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

(2) Each licensee or registrant shall:

(a) Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in Section R313-12-3; and

(b) Monitor the external surfaces of a labeled 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 Section R313-19-4 and Subsection R313-19-100(19); and

(c) 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.

(3) The licensee or registrant shall perform the monitoring required by Subsection R313-15-906(2) as soon as [practicable]practical after receipt of the package, but not later than three 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 three hours from the beginning of the next working day if it is received after working hours.] or if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged. If a package is received after working hours, and has no evidence of degradation of package integrity, the package shall be monitored no later than three hours from the beginning of the next working day.

(4) The licensee or registrant shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Executive Secretary when:

(a) Removable radioactive surface contamination exceeds the limits of Subsection R313-19-100(13)(h); or

(b) External radiation levels exceed the limits of Subsections R313-19-100(13)(i) and R313-19-100(13)(j).

(5) Each licensee or registrant shall:

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

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

(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 Subsection R313-15-906(2), but are not exempt from the monitoring requirement in Subsection R313-15-906(2) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

R313-15-1001. Waste Disposal - General Requirements.

(1) A licensee or registrant shall dispose of licensed or registered material only:

(a) By transfer to an authorized recipient as provided in Section R313-15-1006 or in Rules R313-21, R313-22, or R313-25, or to the U.S. Department of Energy; or

(b) By decay in storage; or

(c) By release in effluents within the limits in Section R313-15-301; or

(d) As authorized pursuant to Sections R313-15-1002, R313-15-1003, R313-15-1004, or R313-15-1005.

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

(a) Treatment prior to disposal; or

(b) Treatment or disposal by incineration; or

(c) Decay in storage; or

(d) Disposal at a land disposal facility licensed pursuant to Rule R313-25; or

(e) Storage until transferred to a storage or disposal

facility authorized to receive the waste.

R313-15-1002. Method for Obtaining Approval of Proposed Disposal Procedures.

A licensee or registrant or applicant for a license or registration may apply to the Executive Secretary for approval of proposed procedures, not otherwise authorized in these rules, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

(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

(2) An analysis and evaluation of pertinent information on the nature of the environment; and

(3) The nature and location of other potentially affected facilities; and

(4) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in Rule R313-15.

R313-15-1003. Disposal by Release into Sanitary Sewerage.

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

(a) The material is readily soluble, or is readily dispersible biological material, in water; and

(b) The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in one 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 of 10 CFR 20.1001 to 20.2402, 199[3] ed., which is incorporated by reference; and

(c) If more than one radionuclide is released, the following conditions shall also be satisfied:

(i) The licensee or registrant shall determine the fraction of the limit in Table III of Appendix B of 10 CFR 20.1001 to 20.2402, 199[3] ed., which is incorporated by reference, 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 of 10 CFR 20.1001 to 20.2402, 199[3] ed., which is incorporated by reference; and

(ii) The sum of the fractions for each radionuclide required by Subsection R313-15-1003(1)(c)(i) does not exceed unity; and

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

(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in Subsection R313-15-1003(1).

R313-15-1004. 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]~~ form and concentration specified in Section R313-15-1005 or as specifically approved by the Executive Secretary pursuant to Section R313-15-1002.

R313-15-1005. Disposal of Specific Wastes.

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

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

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

(2) A licensee or registrant shall not dispose of tissue pursuant to Subsection R313-15-1005(1)(b) in a manner that would permit its use either as food for humans or as animal feed.

(3) The licensee or registrant shall maintain records in accordance with Section R313-15-1109.

R313-15-1006. Transfer for Disposal and Manifests.

(1) ~~[The r] Requirements of Section R313-15-1006 and Appendix F and G of 10 CFR 20.1001 to 20.2402, 199[3]7 ed. [which is incorporated by reference,]~~

(a) The requirements of Section R313-15-1006 and Appendix F and G of 10 CFR 20.1001 to 20.2402, 1997 ed., which are incorporated into these rules by reference, are designed to:

(i) control transfers of low-level radioactive waste [intended for disposal at a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.] by any waste generator, waste collector, or waste processor licensee, as defined in Appendix F or G in 10 CFR 20.1001 to 20.2402, 1997 ed., who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in Section R313-25-2;

(ii) establish a manifest tracking system; and

(iii) supplement existing requirements concerning transfers and recordkeeping for those wastes.

(b) Beginning March 1, 1998, all affected licensees must use Appendix G of 10 CFR 20.1001 to 20.2402, 1997 ed., which is incorporated into these rules by reference. Prior to March 1, 1998, a low-level waste disposal facility operator or its regulatory authority may require the shipper to use Appendix F or Appendix G of 10 CFR 20.1001 to 20.2402, 1997 ed. Licensees using Appendix F shall comply with Subsection R313-15-1006(2)(a). Licensees using Appendix G shall comply with Subsection R313-15-1006(2)(b).

(2) Shipment of Radioactive Waste.

(a) Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified

in Section I of Appendix F of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference.

(b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded information to the intended consignee in accordance with Appendix G to 10 CFR 20.1001 to 20.2402, 1997 ed., which is incorporated into these rules by reference.

(3) Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix F or G, as appropriate, of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference. See Subsection R313-15-1006(1)(b) to determine the appropriate Appendix.

(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 F or G, as appropriate, of 10 CFR 20.1001 to 20.2402, 199[3]7 ed., which is incorporated by reference. See Subsection R313-15-1006(1)(b) to determine the appropriate Appendix.

R313-15-1007. Compliance with Environmental and Health Protection Rules.

Nothing in Sections R313-15-1001, R313-15-1002, R313-15-1003, R313-15-1004, R313-15-1005, or R313-15-1006 relieves the licensee or registrant from complying with other applicable Federal, State and local rules governing any other toxic or hazardous properties of materials that may be disposed of pursuant to Sections R313-15-1001, R313-15-1002, R313-15-1003, R313-15-1004, R313-15-1005, or R313-15-1006.

R313-15-1008. Classification and Characteristics of Low-Level Radioactive Waste.

(1) Classification of Radioactive Waste for Land Disposal

(a) Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration shall be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration shall be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

(b) Classes of waste.

(i) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste shall meet the minimum requirements set forth in Subsection R313-15-1008(2)(a). If Class

A waste also meets the stability requirements set forth in Subsection R313-15-1008(2)(b), it is not necessary to segregate the waste for disposal.

(ii) Class B waste is waste that shall meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste shall meet both the minimum and stability requirements set forth in Subsection R313-15-1008(2).

(iii) Class C waste is waste that not only shall meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste shall meet both the minimum and stability requirements set forth in Subsection R313-15-1008(2).

(c) Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in Table I, classification shall be determined as follows:

(i) If the concentration does not exceed 0.1 times the value in Table I, the waste is Class A.

(ii) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in Table I, the waste is Class C.

(iii) If the concentration exceeds the value in Table I, the waste is not generally acceptable for land disposal.

(iv) For wastes containing mixtures of radionuclides listed in Table I, the total concentration shall be determined by the sum of fractions rule described in Subsection R313-15-1008(1)(g).

TABLE I

Concentration

Radionuclide	curie/cubic meter(1)	nanocurie/gram(2)
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
Tc-99	3	
I-129	0.08	
Alpha emitting transuranic radionuclides with half-life greater than five years		100
Pu-241		3,500
Cm-242		20,000
Ra-226		100

NOTE: (1) To convert the Ci/m³ values to gigabecquerel (GBq)/cubic meter, multiply the Ci/m³ value by 37.

(2) To convert the nCi/g values to becquerel (Bq)/gram, multiply the nCi/g value by 37.

(d) Classification determined by short-lived radionuclides.

If the waste does not contain any of the radionuclides listed in Table I, classification shall be determined based on the concentrations shown in Table II. However, as specified in Subsection R313-15-1008(1)(f), if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

(i) If the concentration does not exceed the value in Column 1, the waste is Class A.

(ii) If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.

(iii) If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.

(iv) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

(v) For wastes containing mixtures of the radionuclides listed in Table II, the total concentration shall be determined by the sum of fractions rule described in Subsection R313-15-1008(1)(g).

TABLE II

Radionuclide	Concentration, Column 1	curie/cubic meter(1)	
		Column 2	Column 3
Total of all radio- nuclides with less than 5-year half- life	700	(2)	(2)
H-3	40	(2)	(2)
Co-60	700	(2)	(2)
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

NOTE: (1) To convert the Ci/m³ value to gigabecquerel (GBq)/cubic meter, multiply the Ci/m³ value by 37.

(2) There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

(e) Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table I and some of which are listed in Table II, classification shall be determined as follows:

(i) If the concentration of a radionuclide listed in Table I is less than 0.1 times the value listed in Table I, the class shall be that determined by the concentration of radionuclides listed in

Table II.

(ii) If the concentration of a radionuclide listed in Table I exceeds 0.1 times the value listed in Table I, but does not exceed the value in Table I, the waste shall be Class C, provided the concentration of radionuclides listed in Table II does not exceed the value shown in Column 3 of Table II.

(f) Classification of wastes with radionuclides other than those listed in Tables I and II. If the waste does not contain any radionuclides listed in either Table I or II, it is Class A.

(g) The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits shall all be taken from the same column of the same table. The sum of the fractions for the column shall be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m³ (50 Ci/m³) and Cs-137 in a concentration of 814 GBq/m³ (22 Ci/m³). Since the concentrations both exceed the values in Column 1, Table II, they shall be compared to Column 2 values. For Sr-90 fraction, $50/150 = 0.33.$, for Cs-137 fraction, $22/44 = 0.5$; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

(h) Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

(2) Radioactive Waste Characteristics

(a) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

(i) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of ~~[Part D]~~ Rule R313-15, the site license conditions shall govern.

(ii) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

(iii) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

(iv) Solid waste containing liquid shall contain as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent of the volume.

(v) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

(vi) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons

transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Subsection R313-15-1008(2)(a)(viii).

(vii) Waste shall not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.

(viii) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20 degrees celsius. Total activity shall not exceed 3.7 TBq (100 Ci) per container.

(ix) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent [~~practicable~~]practical the potential hazard from the non-radiological materials.

(b) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

(i) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

(ii) Notwithstanding the provisions in Subsections R313-15-1008(2)(a)(iii) and R313-15-1008(2)(a)(iv), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5 percent of the volume of the waste for waste processed to a stable form.

(iii) Void spaces within the waste and between the waste and its package shall be reduced to the extent [~~practicable~~]practical.

(3) Labeling. Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Subsection R313-15-1008(1).

R313-15-1101. Records - General Provisions.

(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 Rule R313-15.

(2) Notwithstanding the requirements of Subsection R313-15-1101(1), when recording information on shipment manifests, as required in Subsection R313-15-1006(2), information must be recorded in SI units or in SI units and the special units specified

in Subsection R313-15-1101(1).

~~[(2)](3)~~ The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Rule R313-15, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

R313-15-1102. Records of Radiation Protection Programs.

(1) Each licensee or registrant shall maintain records of the radiation protection program, including:

(a) The provisions of the program; and

(b) Audits and other reviews of program content and implementation.

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1102(1)(a) until the Executive Secretary terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by Subsection R313-15-1102(1)(b) for three years after the record is made.

R313-15-1103. Records of Surveys.

(1) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by Section R313-15-501 and Subsection R313-15-906(2). The licensee or registrant shall retain these records for three years after the record is made.

(2) The licensee or registrant shall retain each of the following records until the Executive Secretary terminates each pertinent license or registration requiring the record:

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

(b) 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

(c) Records showing the results of air sampling, surveys, and bioassays required pursuant to Subsections R313-15-703(1)(c)(i) and R313-15-703(1)(c)(ii); and

(d) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

R313-15-1104. Records of Tests for Leakage or Contamination of Sealed Sources.

Records of tests for leakage or contamination of sealed sources required by Section R313-15-401 shall be kept in units of becquerel or microcurie and maintained for inspection by the Executive Secretary for five years after the records are made.

R313-15-1105. Records of Prior Occupational Dose.

For each individual who is likely to receive in a year an occupational dose requiring monitoring pursuant to Section R313-15-502, ~~[(F)]~~ the licensee or registrant shall retain the records of

prior occupational dose and exposure history as specified in Section R313-15-205 on form DRC-05 or equivalent until the Executive Secretary terminates each pertinent license requiring this record. The licensee or registrant shall retain records used in preparing form DRC-05 or equivalent for three years after the record is made.

R313-15-1106. Records of Planned Special Exposures.

(1) For each use of the provisions of Section R313-15-206 for planned special exposures, the licensee or registrant shall maintain records that describe:

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

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

(c) What actions were necessary; and

(d) Why the actions were necessary; and

(e) What precautions were taken to assure that doses were maintained ALARA; and

(f) What individual and collective doses were expected to result; and

(g) The doses actually received in the planned special exposure.

(2) The licensee or registrant shall retain the records until the Executive Secretary terminates each pertinent license or registration requiring these records.

R313-15-1107. Records of Individual Monitoring Results.

(1) Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to Section R313-15-502, 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:

(a) The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

(b) The estimated intake of radionuclides, see Section R313-15-202; and

(c) The committed effective dose equivalent assigned to the intake of radionuclides; and

(d) The specific information used to calculate the committed effective dose equivalent pursuant to Subsection R313-15-204(3); and

(e) The total effective dose equivalent when required by Section R313-15-202; and

(f) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

(2) Recordkeeping Frequency. The licensee or registrant shall make entries of the records specified in Subsection R313-15-1107(1) at intervals not to exceed one year.

(3) Recordkeeping Format. The licensee or registrant shall maintain the records specified in Subsection R313-15-1107(1) on form DRC-06, in accordance with the instructions for form DRC-06, or in clear and legible records containing all the information required by form DRC-06.

(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.

(5) The licensee or registrant shall retain each required form or record until the Executive Secretary terminates each pertinent license or registration requiring the record.

R313-15-1108. Records of Dose to Individual Members of the Public.

(1) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See Section R313-15-301.

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1108(1) until the Executive Secretary terminates each pertinent license or registration requiring the record. Requirements for disposition of these records, prior to license termination, are located in Section R313-12-51 for activities licensed under these rules.

R313-15-1109. Records of Waste Disposal.

(1) Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to Sections R313-15-1002, R313-15-1003, R313-15-1004, R313-15-1005, Rule R313-25, and disposal by burial in soil, including burials authorized before January 28, 1981.

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1109(1) until the Executive Secretary terminates each pertinent license or registration requiring the record.

R313-15-1110. Records of Testing Entry Control Devices for Very High Radiation Areas.

(1) Each licensee or registrant shall maintain records of tests made pursuant to Subsection R313-15-603(2)(i) on entry control devices for very high radiation areas. These records shall include the date, time, and results of each such test of function.

(2) The licensee or registrant shall retain the records required by Subsection R313-15-1110(1) for three years after the record is made.

R313-15-1111. Form of Records.

Each record required by Rule R313-15 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 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.

R313-15-1201. Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

(1) Telephone Reports. Each licensee or registrant shall report to the Executive Secretary by telephone each stolen, lost, or missing source of radiation immediately after its absence becomes known to the licensee or registrant. This requirement does not apply to sources of radiation that are not required to be licensed or registered. ~~[as follows:]~~

~~[(a) 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 of 10 CFR 20.1001 to 20.2402, 1993 ed., which is incorporated by reference, under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas;~~

~~(b) 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 ten times the quantity specified in Appendix C of 10 CFR 20.1001 to 20.2402, 1993 ed., which is incorporated by reference, that is still missing.~~

~~(c) Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.]~~

(2) Written Reports. Each licensee or registrant required to make a report pursuant to Subsection R313-15-1201(1) shall, within 30 days after making the telephone report, make a written report to the Executive Secretary setting forth the following information:

(a) 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;

(b) A description of the circumstances under which the loss or theft occurred; and

(c) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

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

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

(f) 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.

(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) The licensee or registrant shall prepare any report filed with the Executive Secretary pursuant to Section R313-15-1201 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

R313-15-1202. Notification of Incidents.

(1) Immediate Notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(a) An individual to receive:

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

(ii) An eye dose equivalent of 0.75 Sv (75 rem) or more; or

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

(b) 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.

(2) Twenty-Four Hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Executive Secretary 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:

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

(i) A total effective dose equivalent exceeding 0.05 Sv (five rem); or

(ii) An eye dose equivalent exceeding 0.15 Sv (15 rem); or

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

(b) 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.

(3) The licensee or registrant shall prepare each report filed with the Executive Secretary pursuant to Section R313-15-1202 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(4) Licensees or registrants shall make the reports required by Subsections R313-15-1202(1) and R313-15-1202(2) to the Executive Secretary by telephone, telegram, mailgram, or facsimile to the Executive Secretary.

(5) The provisions of Section R313-15-1202 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 Section R313-15-1204.

R313-15-1203. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits.

(1) Reportable Events. In addition to the notification required by Section R313-15-1202, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(a) Incidents for which notification is required by Section R313-15-1202; or

(b) Doses in excess of any of the following:

(i) The occupational dose limits for adults in Section R313-15-201; or

(ii) The occupational dose limits for a minor in Section R313-15-207; or

(iii) The limits for an embryo/fetus of a declared pregnant woman in Section R313-15-208; or

(iv) The limits for an individual member of the public in Section R313-15-301; or

(v) Any applicable limit in the license or registration; or

(vi) The ALARA constraints for air emissions established under Subsection R313-15-101(4); or

(c) Levels of radiation or concentrations of radioactive material in:

(i) A restricted area in excess of applicable limits in the license or registration; or

(ii) An unrestricted area in excess of ten times the applicable limit set forth in Rule R313-15 or in the license or registration, whether or not involving exposure of any individual in excess of the limits in Section R313-15-301; or

(d) 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.

(2) Contents of Reports.

(a) Each report required by Subsection R313-15-1203(1) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(i) Estimates of each individual's dose; and

(ii) The levels of radiation and concentrations of radioactive material involved; and

(iii) The cause of the elevated exposures, dose rates, or concentrations; and

(iv) 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.

(b) Each report filed pursuant to Subsection R313-15-1203(1) 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 Section R313-15-208, 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.

(3) All licensees or registrants who make reports pursuant to Subsection R313-15-1203(1) shall submit the report in writing to the Executive Secretary.

R313-15-1204. Reports of Planned Special Exposures.

The licensee or registrant shall submit a written report to the Executive Secretary within 30 days following any planned special exposure conducted in accordance with Section R313-15-206, informing the Executive Secretary that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Section R313-15-1106.

R313-15-1205. Reports to Individuals of Exceeding Dose Limits.

When a licensee or registrant is required, pursuant to the provisions of Sections R313-15-1203 or R313-15-1204, to report to the Executive Secretary any exposure of an identified occupationally exposed individual, or an identified member of the public, to sources of radiation, the licensee or registrant shall also provide a copy of the report submitted to the Executive Secretary to the individual. This report shall be transmitted at a time no later than the transmittal to the Executive Secretary.

R313-15-1207. Notifications and Reports to Individuals.

(1) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in Rule R313-18.

(2) When a licensee or registrant is required pursuant to Section R313-15-1203 to report to the Executive Secretary 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 Executive Secretary, and shall comply with the provisions of Rule R313-18.

R313-15-1208. Reports of Leaking or Contaminated Sealed Sources.

If the test for leakage or contamination required pursuant to Section R313-15-401 indicates a sealed source is leaking or contaminated, a report of the test shall be filed within five days with the Executive Secretary describing the equipment involved, the test results and the corrective action taken.

R313-15-1301. 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 his activities, notify the Executive Secretary in writing of intent to vacate. When deemed necessary by the Executive Secretary, the licensee shall decontaminate the premises in such a manner as the Executive Secretary may specify.

KEY: radioactive material, contamination, waste disposal, safety
[1993]1998 19-3-104
19-3-108

State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE OR CHANGE

The agency identified below in box 1 provides notice of proposed rule or change pursuant to Utah Code Subsections 63-46a-4(2) and (4). Please address questions regarding information on this notice to the agency. The full text of all rule filings is published in the *Utah State Bulletin* unless excluded because of space constraints. The full text of all rule filings may also be inspected at the Division of Administrative Rules.

State of Utah Division of Administrative Rules (DAR) 4120 State Office Building; 450 North Main Box 141007 Salt Lake City, UT 84114-1007 Phone: (801) 538-3218, FAX: (801) 538-1773 State E-mail: <i>asdomain.asitmain.rules</i>	DAR File No.: <hr/> Utah Admin. Code Ref. (R No.): R313-15 <hr/> Date Filed: <hr/> Time Filed: <hr/> Received by:
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1. Department: Environmental Quality
 Agency: Radiation Control
 Room No., Building: State of Utah Office Park, Bldg. 2
 Street Address: 168 North 1950 West
 Mailing Address: PO Box 144850
 City, State ZIP: Salt Lake City, UT 84114-4850
 Contact Person: Craig Jones
 Telephone: (801) 536-4250
 FAX: (801) 533-4097
 Internet E-mail: *cjones@deq.state.ut.us*

(Interested persons may inspect this filing at the above address or at DAR between 8:00 a.m. and 5:00 p.m. on business days.)

2. Title of Rule or Section (catchline):
 Standards for Protection Against Radiation

3. Type of Notice:

Proposed Rules	<input type="checkbox"/>	New	<input type="checkbox"/>	Amendment	<input type="checkbox"/>	Repeal
	<input type="checkbox"/>	Repeal and Reenact				

Other Rule Types Change in Proposed Rule (Changes Original Proposed Rule File No.: 20235)

4. Purpose of or Reason for the Filing:
 The reason for filing this change in a proposed rule is to act upon comments received during a public comment period.

5. This filing is a response to comments by the Administrative Rules Review Committee. Yes No

6. Summary of the Filing:
 The citation listed in R313-15-208(3)(b)(i) was found to be incorrect. This filing corrects the error. Public comments on the changes proposed for R313-15-1201(1) were not in favor of the proposal. Therefore, the original text will remain as the regulatory requirement. A change to the year of the Code of Federal Regulations is being made so that there is consistency throughout R313-15.

NOTICE OF PROPOSED RULE OR CHANGE

7. Cost or Savings Impact of Filing:

State Budget: No impact
 Local Government: No impact
 Other Persons (Aggregate Impact): No impact

8. Compliance Costs for Affected Persons ("Person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an agency):

No compliance costs.

9. This rule is authorized or mandated by state law, and implements or interprets the following state and federal laws.

State Code or Constitution Citations (Required): 19-1-201

Federal Citations (Optional):

10. This Filing Adds or Updates an Incorporated Reference (Submit a Copy to DAR):

Yes No

(Reference Title and Date of Issue or Edition):

11. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the *Utah State Bulletin*. See Section 63-46a-5 and Rule R15-1 for more information.)

Comments Will Be Accepted Until 5:00 p.m. on (mm/dd/yy): 3/17/98

A Public Hearing (Optional) Will Be Held on (mm/dd/yy):

at (Time):

at (Place):

12. This Filing May Become Effective on (mm/dd/yy):

3/20/98

13. Indexing Information - Keywords (maximum of four, in lower case):

radioactive material, contamination, waste disposal, safety

14. Indexing Information - Affected Industries (two-digit SIC codes):

13, 33, 39, 80, 87, 89

15. Attach a WordPerfect document containing this filing's text (filename):

R313-15.txt

To the agency: Information requested on this form is required by Sections 63-46a-4, 5, 6, and 10. Incomplete forms may be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency Head or Designee: (Please Include Title)	William J. Sinclair, Executive Secretary	Date (mm/dd/yy):	1/30/98
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60 FR 28323 (6/30/98)

Performance Requirements for
Radiography Equipment - Part 34
effective date 12/12/97

R313. Environmental Quality, Radiation Control.

[R313-36. ~~Special Requirements for Industrial Radiographic Operations.~~

~~R313-36-1. Purpose and Scope.~~

~~The rules in R313-36 prescribe requirements for the issuance of licenses and establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography. The requirements of R313-36 are in addition to, and not in substitution for, the other requirements of these rules. The rules in R313-36 apply to all licensees or registrants who use sources of radiation for industrial radiography. Except for those rules of R313-36 clearly applicable only to sealed radioactive sources, both radiation machines and sealed radioactive sources are covered by R313-36.~~

~~R313-36-2. Definitions.~~

~~As used in R313-36:~~

~~(1) "Cabinet radiography" means industrial radiography employing radiation machines conducted in an enclosure or cabinet so shielded that every exterior location meets the conditions specified in R313-15-301.~~

~~(2) "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed "cabinet") which, independently of existing architectural structure except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals, and similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.~~

~~(3) "Collimator" means a device used to limit the size, shape and direction of the primary radiation beam.~~

~~(4) "Enclosed radiography" means industrial radiography employing radiation machines conducted in an enclosed cabinet or room and includes cabinet radiography and shielded room radiography.~~

~~(5) "Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods utilizing sources of radiation. Industrial radiography as used in R313-36 does not include well logging operations.~~

~~(6) "Permanent radiographic installation" means a shielded installation or structure designed or intended for radiography employing a radiographic exposure device and in which radiography is regularly performed.~~

~~(7) "Personal supervision" means supervision by a radiographer such that the radiographer is physically present at the radiography site and in such proximity that communication can be maintained and immediate assistance given as required. When a radiographer's assistant is using or handling sources of radiation, the radiographer must maintain direct surveillance.~~

~~(8) "Radiographer" means any individual who performs or personally supervises industrial radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of these rules and all license conditions.~~

~~(9) "Radiographer's assistant" means any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools, or radiation survey instruments in industrial radiography.~~

~~(10) "Radiographer instructor" means any individual who has been authorized by the Executive Secretary to provide instruction to radiographer assistant in accordance with these rules.~~

~~(11) "Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.~~

~~(12) "Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.~~

~~(13) "Shielded-room radiography" means industrial radiography conducted in a room so shielded that radiation levels at every location on the exterior meet the limitations specified in these rules.~~

~~(14) "Storage area" means any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.~~

~~(15) "Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and meets all application requirements of the U.S. Department of Transportation.~~

R313-36-11. License Issuance.

~~(1) A specific license for use of sealed sources in industrial radiography will be issued if all of the following are complied with:~~

~~(a) The applicant will have an adequate program for training radiographers and radiographer's assistants and submits to the Executive Secretary a schedule or description of such program which specifies the:~~

~~(i) initial training;~~

~~(ii) periodic training;~~

~~(iii) on-the-job training;~~

~~(iv) means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with Utah Radiation Control rules and licensing requirements, and the operating and emergency procedures of the applicant; and~~

~~(v) means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of the ability to comply with the operating and emergency procedures of the applicant.~~

~~(b) The applicant submits to the Executive Secretary and complies with satisfactory written operating and emergency procedures (described in R313-36-32 of these rules);~~

~~(c) The applicant has established and submits to the Executive Secretary a description of its inspection program adequate to ensure that its radiographers and radiographers' assistants follow the Utah Radiation Control Rules and the applicant's operating and emergency procedures. The inspection program must:~~

~~(i) include observation of the performance of each radiographer and radiographers' assistant during an actual radiographic operation at intervals not to exceed three months;~~

~~(ii) provide that, if a radiographer or a radiographers' assistant has not participated in a radiographic operation for more than three months since the last inspection, that individual's performance must be observed and recorded the next time the individual participates in a radiographic operation; and~~

~~(iii) include the retention of inspection records on the performance of radiographers or radiographers' assistants for three years.~~

~~(d) The applicant submits to the Executive Secretary a description of the applicant's overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program.~~

~~(e) The applicant conducting leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the Executive Secretary a description of such procedures including:~~

~~(i) instrumentation to be used;~~

~~(ii) method of performing tests, e.g., points on equipment to be smeared and method of taking smear; and~~

~~(iii) pertinent experience of the person who will perform the tests.~~

~~(f) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.~~

~~R313-36-20. Performance Requirements for Radiographic Equipment.~~

~~10 CFR 34.20 and 34.21, 1993 ed., which is incorporated by reference with the following exception: substitute R313-19-100 for the reference to 10 CFR Part 71.~~

~~R313-36-21. Equipment Control.~~

~~(1) Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.~~

~~(2) Radiographic exposure devices, source changers, or transport containers that contain radioactive material may not be stored in residential locations. This rule does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with R313-36-23 and if the vehicle does not constitute a permanent storage location.~~

R313-36-22. Locking of Radiographic Exposure Devices.

(1) Each source of radiation shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source and shall be locked at all times except when under the direct surveillance of a radiographer or radiographer assistant. In addition, during radiographic operations the sealed source assembly shall be locked in the shielded position each time the source is returned to that position.

(2) Each sealed source storage container and source changer shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers shall be kept locked when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

(3) Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to assure that the sealed source is in the shielded position.

R313-36-23. Storage Precautions.

locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.

R313-36-24. Radiation Survey Instruments.

(1) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by R313-36. Instrumentation required by R313-36-24 shall have a range such that 2 milliroentgens (5.16×10^{-7} C/kg) per hour through 1 roentgen (2.58×10^{-4} C/kg) per hour can be measured.

(2) Each radiation survey instrument shall be calibrated: (a) at energies appropriate for use and at intervals not to exceed three months and after each instrument servicing; (b) such that accuracy within ± 20 percent can be demonstrated; and (c) at two points located approximately 1/3 and 2/3 of full-scale on each scale for linear scale instruments; at midrange of each decade, and at two points of at least one decade for logarithmic scale instruments; and at appropriate points for digital instruments.

(3) Records shall be maintained of these calibrations for two years after the calibration date for inspection by representatives of the Executive Secretary.

R313-36-25. Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources.

(1) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized

to do so by the Executive Secretary, the U.S. Nuclear Regulatory Commission, or an Agreement State.

~~(2) Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 month period prior to the transfer, the sealed source shall not be put into use until tested and results obtained.~~

~~(3) The leak test shall be capable of detecting the presence of 0.005 microcurie (185.0 Bq) of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to R313-36-11(1)(e). Records of leak test results shall be kept in units of microcuries (kBq) and maintained for inspection by representatives of the Executive Secretary for two years after the leak test is performed or until the sealed source is transferred or disposed of, whichever comes first.~~

~~(4) Any test conducted pursuant to paragraphs (2) and (3) of R313-36-25 which reveals the presence of 0.005 microcurie (185.0 Bq) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with the Utah Radiation Control Rules. Within 5 days after obtaining results of the test, the licensee shall file a report with the Executive Secretary describing the involved equipment, the test results, and the corrective action taken.~~

~~(5) A sealed source which is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag at least one inch square bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger - Radioactive Material - Do Not Handle - Notify Civil Authorities if Found."~~

~~R313-36-26. Quarterly Inventory.~~

~~Each licensee shall conduct a quarterly physical inventory to account for all sealed sources received or possessed. The records of the inventories shall be maintained for three years from the date of inventory for inspection by representatives of the Executive Secretary and shall include the quantities and kinds of radioactive material, the location of sealed sources, and the date of the inventory, device model, serial number and sealed source serial number.~~

~~R313-36-27. Utilization Logs.~~

~~(1) Each licensee or registrant shall maintain current logs, which shall be kept available for inspection by representatives of the Executive Secretary for two years from the date of the recorded event at the address specified in the license, showing for each source of radiation the following information:~~

~~(a) a description (or make and model number) of each source of radiation or storage container in which the sealed source is~~

located:

~~(b) the identity of the radiographer to whom assigned;~~
~~(c) locations where used and dates of use;~~
~~(d) the date each source of radiation is removed from storage and returned to storage.~~

~~(2) The requirements of R313-36-27(1) shall not apply in industrial radiography utilizing sources of radiation in enclosed interlocked rooms which are not occupied during radiographic operations, which are equipped with interlocks such that the source of radiation will not operate unless all openings are securely closed and which is so shielded that every location on the exterior meets conditions specified in R313-15-301.~~

~~(3) A separately identified utilization log is not required if the equivalent information is available in records of the licensee or registrant and available at the address specified in the license or registration.~~

~~R313-36-28. Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Storage Containers and Source Changers.~~

~~(1) The licensee or registrant shall conduct a program for inspection and maintenance of radiation machines, radiographic exposure devices, storage containers and source changers at intervals, not to exceed three months or prior to first use thereafter to assure proper functioning of components important to safety. Records of these inspections and maintenance shall be kept for three years.~~

~~(2) The licensee or registrant shall check for obvious defects in radiation machines, radiographic exposure devices, storage containers, and source changers prior to use each day the equipment is used.~~

~~(3) If any inspection conducted pursuant to R313-36-28(1) reveals damage to components critical to radiation safety, the device shall be removed from service until repairs have been made.~~

~~(4) Any maintenance performed on radiographic exposure devices and accessories shall be in accordance with the manufacturer's specifications.~~

~~R313-36-29. Special Requirements for Permanent Radiographic Installation.~~

~~Permanent radiographic installations having high radiation area entrance controls of the types described in R313-15-601(1)(b) and (c) and R313-15-601(2), or where the high radiation area is locked to protect against unauthorized or accidental entry, shall also meet the following special requirements:~~

~~(1) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation to which R313-36-29 applies shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be actuated by radiation whenever the source is exposed. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed.~~

~~(2) The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use. If~~

~~a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by representatives of the Executive Secretary for three years from the date of the event.~~

~~R313-36-30. Special Requirements for Enclosed Radiography.~~

~~(1) Systems for enclosed radiography designed to allow admittance of individuals during x-radiation generation shall:~~

~~(a) comply with all applicable requirements of R313-36 and R313-15-301 of these rules; and~~

~~(b) be evaluated at intervals not to exceed one year to assure compliance with the applicable requirements as specified in R313-36-30(1)(a). Records of these evaluations shall be maintained for inspection by representatives of the Executive Secretary for a period of three years after the evaluation.~~

~~(2) Cabinet x-ray systems designed to exclude individuals during x-radiation are exempt from the requirements of R313-36 except that:~~

~~(a) Operating personnel must be provided with either a film badge or a thermoluminescent dosimeter and reports of the results must be maintained for inspection by representatives of the Executive Secretary.~~

~~(b) No registrant shall permit any individual to operate a cabinet x-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subparagraph shall be maintained for inspection by representatives of the Executive Secretary until disposition is authorized by the Executive Secretary.~~

~~(c) Tests for proper operation of high radiation area control devices or alarm systems, where applicable, must be conducted at the beginning of each day of use and recorded.~~

~~(d) The registrant shall perform an evaluation, at intervals not to exceed one year, to determine compliance with R313-15-301. Records of these evaluations shall be maintained for inspection by representatives of the Executive Secretary for a period of three years after the evaluation.~~

~~R313-36-31. Limitations - Personnel Radiation Safety Requirements for Radiographers and Radiographers' Assistant.~~

~~(1) No licensee or registrant shall permit any individual to act as a radiographer as defined in R313-36 until such individual has complied with all of the following:~~

~~(a) been instructed in the subjects outlined in R313-36-100;~~

~~(b) received copies of and instruction in the rules contained in R313-36 and the applicable sections of appropriate license(s), and the licensee's or registrant's operating and emergency procedures, and shall have demonstrated understanding thereof;~~

~~(c) demonstrated competence to use the source of radiation, related handling tools, and radiation survey instruments which will be employed in the individual's assignment;~~

~~(d) demonstrated understanding of the instructions in this paragraph by successful completion of written tests and a field~~

~~examination on the subjects covered.~~

~~(2) No licensee or registrant shall permit any individual to act as a radiographer's assistant as defined in R313-36 until such individual has complied with all of the following:~~

~~(a) received copies of and instruction in the licensee's or registrant's operating and emergency procedures;~~

~~(b) demonstrated competence to use under the personal supervision of the radiographer the sources of radiation, related handling tools, and radiation survey instruments which will be employed in the individual's assignment;~~

~~(c) demonstrated understanding of the instructions in this paragraph by successfully completing a written or oral test and a field examination on the subjects covered;~~

~~(d) records of the above training including copies of written tests and dates of oral tests and field examinations shall be maintained for three years.~~

~~(3) Each licensee or registrant shall maintain, for inspection by representatives of the Executive Secretary, records of training and testing which demonstrate that the requirements of R313-36-31(1) and (2) are met.~~

~~(4) Each licensee or registrant shall conduct an internal audit program to ensure that the radioactive material license conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer and radiographer's assistant. These internal audits shall be performed at least quarterly, and each radiographer shall be audited at least quarterly. Records of internal audits shall be maintained for inspection by representatives of the Executive Secretary for three years from the date of the audit.~~

~~R313-36-32. Operating and Emergency Procedures.~~

~~The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:~~

~~(1) the handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in R313-15 "Standards for Protection Against Radiation;"~~

~~(2) methods and occasions for conducting radiation surveys;~~

~~(3) methods for controlling access to radiographic areas;~~

~~(4) methods and occasions for locking and securing sources of radiation;~~

~~(5) personnel monitoring and the use of personnel monitoring equipment including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;~~

~~(6) transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation;~~

~~(7) minimizing exposure of individuals in the event of an accident;~~

~~(8) the procedure for notifying proper personnel in the event of a theft, loss, over exposure or accident involving sources of radiation;~~

~~(9) maintenance of records;~~

~~(10) the inspection and maintenance of radiographic exposure devices, source changers, storage containers and radiation machines.~~

~~R313-36-33. Personnel Monitoring Control.~~

~~10 CFR 34.33, 1993 ed., which is incorporated by reference with the following exception: substitute "Executive Secretary" for the reference to "Commission".~~

~~R313-36-41. Security - Precautionary Procedures in Radiographic Operations.~~

~~(1) During each radiographic operation, the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in R313-12, except:~~

~~(a) where the high radiation area is equipped with a control device or alarm system as described in R313-15-601(1)(a), (b) or (c); or~~

~~(b) where the high radiation area is locked to protect against unauthorized or accidental entry.~~

~~(2) When not in operation or when not under direct surveillance, portable radiation exposure devices shall be physically secured to prevent removal by unauthorized personnel.~~

~~R313-36-42. Posting.~~

~~Notwithstanding any provisions in paragraph R313-15-903, areas in which radiography is being performed or in which a radiographic exposure device is being stored shall be conspicuously posted and access to the area shall be controlled as required by R313-15-902(1) and (2).~~

~~R313-36-43. Radiation Surveys and Survey Records.~~

~~(1) At least one calibrated and operable radiation survey instrument as described in R313-36-24 shall be available and used at each site where radiographic exposures are made, and at the storage area, as defined in R313-36-2, whenever a radiographic exposure device, a storage container, or source is being placed in storage.~~

~~(2) A physical radiation survey shall be made after each radiographic exposure utilizing radiographic exposure devices or sealed sources of radioactive material to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall include the guide tube.~~

~~(3) A physical radiation survey shall be made whenever a radiographic exposure device is placed in a storage area, as defined in R313-36-2, to determine that the sealed source is in its shielded position. The entire circumference of the radiographic exposure device must be surveyed.~~

~~(4) A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off".~~

~~(5) A physical radiation survey shall be made of the boundary~~

of the restricted area during radiographic operations not employing shielded room radiography. The maximum survey reading at the boundary shall be recorded. The records shall indicate approximate distance from source to boundaries, whether or not the exposed source is collimated and any occupied areas with exposure levels greater than $2 \text{ millirentgens } (5.16 \times 10^{-7} \text{ C/kg})$ in any hour during radiographic operations.

(6) A record of the storage survey required in paragraph (3) shall be made and retained for three years when that storage survey is the last one performed in the work day. Records required by paragraph (4) shall be maintained for two years after completion of the survey.

R313-36-44. Supervision of Radiographer's Assistant:

Whenever a radiographer's assistant uses radiographic exposure devices, uses sealed sources or related source handling tools, or conducts radiation surveys required by R313-36-43(2), (3), or (4) to determine that the sealed source has returned to the shielded position after an exposure, he shall be under the personal supervision, as defined in R313-36-2(4), by a radiographer. The personal supervisor shall include (1) the radiographer's personal presence at the site where the sealed sources are being used; (2) the ability of the radiographer to give immediate assistance if required; and (3) the radiographer to observe the performance of his/her assistant during the operations referred to in R313-36-44.

R313-36-45. Records Required at Temporary Job Sites:

Each licensee or registrant conducting industrial radiography at a temporary site shall have the following records available at that site for inspection by representatives of the Executive Secretary:

(1) appropriate license;

(2) operating and emergency procedures;

(3) applicable rules;

(4) survey records required pursuant to R313-36-43 for the period of operation at the site;

(5) daily pocket dosimeter records for the period of operation at the site; and

(6) the latest instrument calibration and leak test record for specific devices in use at the site.

R313-36-46. Specific Requirements for Radiographic Personnel Performing Industrial Radiography:

(1) At a job site, the following shall be supplied by the licensee or registrant:

(a) at least one operable, calibrated survey instrument;

(b) a current whole body personnel monitor (TLD or film badge) for each individual;

(c) an operable, calibrated pocket dosimeter with a range of zero to at least 200 millirentgens ($5.16 \times 10^{-5} \text{ C/kg}$) for each worker; and

(d) the appropriate barrier ropes and signs.

(2) Industrial radiographic operations shall not be performed if any of the items in R313-36-46 are not available at the job site.

~~or are inoperable.~~

~~(3) Each licensee or registrant shall provide as a minimum two person crews when sources of radiation are used at temporary job sites.~~

~~(4) No individual other than a radiographer or a radiographer assistant who is under the personal supervision of a radiographer instructor shall manipulate controls or operate equipment used in industrial radiographic operations.~~

~~(5) During an inspection by representatives of the Executive Secretary, the representatives of the Executive Secretary may terminate an operation if any of the items in R313-36-46 are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.~~

~~(6) No individual shall act as a radiographer instructor unless such individual:~~

~~(a) has met the requirements of R313-36-31;~~

~~(b) has one year of documented experience as an radiographer; and~~

~~(c) has been named as a radiographer instructor on the license issued by the Executive Secretary.~~

~~R313-36-50. Prohibitions.~~

~~Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the Executive Secretary.~~

~~R313-36-100. The Training of Radiographers.~~

~~The training of radiographers shall include at least the following:~~

~~(1) Fundamentals of radiation safety:~~

~~(a) characteristics of ionizing radiation;~~

~~(b) units of radiation dose and quantity of radioactivity;~~

~~(c) hazards of exposure to radiation;~~

~~(i) radiation protection standards;~~

~~(ii) biological effects of radiation dose;~~

~~(d) levels of radiation from sources of radiation;~~

~~(e) methods of controlling radiation dose;~~

~~(i) working time;~~

~~(ii) working distances; and~~

~~(iii) shielding.~~

~~(2) Radiation detection instrumentation to be used:~~

~~(a) use of radiation survey instruments;~~

~~(i) operation;~~

~~(ii) calibration;~~

~~(iii) limitations;~~

~~(b) survey techniques;~~

~~(c) use of personnel monitoring equipment;~~

~~(i) film badges;~~

~~(ii) pocket dosimeters; and~~

~~(iii) thermoluminescent dosimeters.~~

~~(3) Radiographic equipment to be used:~~

~~(a) remote handling equipment;~~

- ~~(b) radiographic exposure devices and sealed sources;~~
- ~~(c) storage containers; and~~
- ~~(d) operation and control of x-ray equipment.~~
- ~~(4) The requirements of pertinent federal and state rules.~~
- ~~(5) The licensee's or registrant's written operating and emergency procedures.~~
- ~~(6) Case histories of radiography accidents.]~~

R313-36. Special Requirements for Industrial Radiographic Operations.

R313-36-1. Purpose and Authority.

(1) The rules in R313-36 prescribe requirements for the issuance of licenses and establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(3) and 19-3-104(6).

(3) The requirements of R313-36 are in addition to, and not in substitution for, the other requirements of these rules.

R313-36-2. Scope.

(1) The requirements of R313-36 shall apply to licensees using radioactive materials to perform industrial radiography.

(2) The requirements of R313-36 shall not apply to persons using electronic sources of radiation to conduct industrial radiography.

R313-36-3. Clarifications or Exceptions.

For purposes of R313-36, 62 FR 28963 to 28973, May 28, 1997, is incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following 10 CFR sections: "34.1", "34.5", "34.8", "34.11", "34.121", and "34.123";

(2) The exclusion of "10 CFR 34.45(a)(9)";

(3) The exclusion of the following 10 CFR references within 10 CFR 34: "21", "30.7", "30.9", and "30.10";

(4) The exclusion of "offshore" in 10 CFR 34.3 definition for "offshore platform radiography";

(5) The substitution of the following wording:

(a) "Utah Radiation Control Rules" for the reference to:

(i) "Commission's regulations", except as stated in R313-36-3(5)(f);

(ii) "Federal regulations"; and

(iii) "NRC regulations";

(b) "Executive Secretary" for the reference to "Commission", except as stated in 10 CFR 34.20 and R313-36-3(5)(c)(iv);

(c) "Executive Secretary, U.S. Nuclear Regulatory Commission, or an Agreement State" for references to:

(i) "NRC or an Agreement State";

(ii) "Commission or by an Agreement State";

(iii) "Commission or an Agreement State"; and

(iv) "Commission" in 10 CFR 34.43(a)(2);

(d) "License" for reference to "NRC license(s)";

(e) In 10 CFR 34.27(d), "reports of test results for leaking or contaminated sealed sources shall be made pursuant to R313-15-

1208.", for reference to the following statements:

(i) "A report must be filed with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, within 5 days of any test with results that exceed the threshold in this subsection, describing the equipment involved, the test results, and the corrective action taken."; and

(ii) "A copy of the report must be sent to the Administrator of the appropriate Nuclear Regulatory Commission's Regional Office listed in appendix D of 10 CFR part 20 of this chapter "Standards for Protection Against Radiation.";

(f) In 10 CFR 34.27(d), "R313-15-401(6)" for the reference to "Commission regulations";

(g) In 10 CFR 34.89, " a U.S. Nuclear Regulatory Commission or an Agreement State" for the reference to "the Agreement State";

(h) In 10 CFR 34.101(a), "Executive Secretary" for the following wording:

(i) "U.S. Nuclear Regulatory Commission, Division of Industrial and Medical Nuclear Safety, Washington, D.C. 20555-0001, with a copy to the Director, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001";

(i) In 10 CFR 34.101(c), "Executive Secretary" for the reference to "appropriate NRC regional office listed in 10 CFR 30.6(a)(2) of this chapter";

(j) In Item 12, Section I of Appendix A to 10 CFR 34, "Executive Secretary, the U.S. Nuclear Regulatory Commission and other independent certifying organizations and/or Agreement States" for the reference to "Commission and other independent certifying organizations and/or Agreement States";

(k) In Item 1, Section II of Appendix A to 10 CFR 34, "equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations" for the reference to "equivalent Agreement State regulations"; and

(l) In Item 2(c), Section II of Appendix A to 10 CFR, "a Utah, U.S. Nuclear Regulatory Commission, or an Agreement State licensee" for the reference to "an Agreement State or a NRC licensee";

(6) The substitution of the following R313 references for specific 10 CFR references:

(a) "R313-12-55(1)" for reference to "10 CFR 34.111";

(b) "R313-15" for the reference to "10 CFR 20";

(c) "R313-15-601(1)(a)" for the reference to "10 CFR 20.1601(a)(1)";

(d) "R313-15-902" for the reference to "10 CFR 20.1902";

(e) "R313-15-903" for the reference to "10 CFR 20.1903";

(f) "R313-15-1203" for the reference to "10 CFR 20.2203";

(g) "R313-18" for the reference to "10 CFR 19";

(h) "R313-19-30" for the reference to "10 CFR 150.20";

(i) "R313-19-50" for the reference to "10 CFR 30.50";

(j) "R313-19-100" for the reference to "10 CFR 71", "10 CFR 71.5", and "49 CFR 171 to 173";

(k) "R313-22-33" for the reference to "10 CFR 30.33"; and

(l) "R313-36" for the reference to "10 CFR 34"; and

(7) The substitution of the following dates:

(a) In 10 CFR 34.42(d) and 10 CFR34.43(a)(2) , "June 27, 1999" for the date "May 28, 1999."

(b) In 10 CFR 34.43(h) , "June 27, 1998" for the date "May 28, 1998."

KEY: industry, radioactive material, licensing, surveys

[~~1994~~]1997

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Notice of Continuation May 15, 1997

19-3-108

R313. Environmental Quality, Radiation Control.**R313-36. Special Requirements for Industrial Radiographic Operations.****R313-36-1. Purpose and Authority.**

(1) The rules in R313-36 prescribe requirements for the issuance of licenses and establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(3) and 19-3-104(6).

(3) The requirements of R313-36 are in addition to, and not in substitution for, the other requirements of these rules.

R313-36-2. Scope.

(1) The requirements of R313-36 shall apply to licensees using radioactive materials to perform industrial radiography.

(2) The requirements of R313-36 shall not apply to persons using electronic sources of radiation to conduct industrial radiography.

R313-36-3. Clarifications or Exceptions.

For purposes of R313-36, 62 FR 28963 to 28973, May 28, 1997, is incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following 10 CFR sections: "34.1", "34.5", "34.8", "34.11", "34.121", and "34.123";

(2) The exclusion of "10 CFR 34.45(a)(9)";

(3) The exclusion of the following 10 CFR references within 10 CFR 34: "21", "30.7", "30.9", and "30.10";

(4) The exclusion of "offshore" in 10 CFR 34.3 definition for "offshore platform radiography";

(5) The substitution of the following wording:

(a) "Utah Radiation Control Rules" for the reference to:

(i) "Commission's regulations", except as stated in R313-36-3(5)(f);

(ii) "Federal regulations"; and

(iii) "NRC regulations";

(b) "Executive Secretary" for the reference to "Commission", except as stated in 10 CFR 34.20 and R313-36-3(5)(c)(iv);

(c) "Executive Secretary, U.S. Nuclear Regulatory Commission, or an Agreement State" for references to:

(i) "NRC or an Agreement State";

(ii) "Commission or by an Agreement State";

(iii) "Commission or an Agreement State"; and

(iv) "Commission" in 10 CFR 34.43(a)(2);

(d) "License" for reference to "NRC license(s)";

(e) In 10 CFR 34.27(d), "reports of test results for leaking or contaminated sealed sources shall be made pursuant to R313-15-1208.", for reference to the following statements:

(i) "A report must be filed with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory

Commission, Washington, DC 20555-0001, within 5 days of any test with results that exceed the threshold in this subsection, describing the equipment involved, the test results, and the corrective action taken."; and

(ii) "A copy of the report must be sent to the Administrator of the appropriate Nuclear Regulatory Commission's Regional Office listed in appendix D of 10 CFR part 20 of this chapter "Standards for Protection Against Radiation.";

(f) In 10 CFR 34.27(d), "R313-15-401(6)" for the reference to "Commission regulations";

(g) In 10 CFR 34.89, " a U.S. Nuclear Regulatory Commission or an Agreement State" for the reference to "the Agreement State";

(h) In 10 CFR 34.101(a), "Executive Secretary" for the following wording:

(i) "U.S. Nuclear Regulatory Commission, Division of Industrial and Medical Nuclear Safety, Washington, D.C. 20555-0001, with a copy to the Director, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001";

(i) In 10 CFR 34.101(c), "Executive Secretary" for the reference to "appropriate NRC regional office listed in 10 CFR 30.6(a)(2) of this chapter";

(j) In Item 12, Section I of Appendix A to 10 CFR 34, "Executive Secretary, the U.S. Nuclear Regulatory Commission and other independent certifying organizations and/or Agreement States" for the reference to "Commission and other independent certifying organizations and/or Agreement States";

(k) In Item 1, Section II of Appendix A to 10 CFR 34, "equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations" for the reference to "equivalent Agreement State regulations"; and

(l) In Item 2(c), Section II of Appendix A to 10 CFR, "a Utah, U.S. Nuclear Regulatory Commission, or an Agreement State licensee" for the reference to "an Agreement State or a NRC licensee";

(6) The substitution of the following R313 references for specific 10 CFR references:

(a) "R313-12-55(1)" for reference to "10 CFR 34.111";

(b) "R313-15" for the reference to "10 CFR 20";

(c) "R313-15-601(1)(a)" for the reference to "10 CFR 20.1601(a)(1)";

(d) "R313-15-902" for the reference to "10 CFR 20.1902";

(e) "R313-15-903" for the reference to "10 CFR 20.1903";

(f) "R313-15-1203" for the reference to "10 CFR 20.2203";

(g) "R313-18" for the reference to "10 CFR 19";

(h) "R313-19-30" for the reference to "10 CFR 150.20";

(i) "R313-19-50" for the reference to "10 CFR 30.50";

(j) "R313-19-100" for the reference to "10 CFR 71", "10 CFR 71.5", and "49 CFR 171 to 173";

(k) "R313-22-33" for the reference to "10 CFR 30.33"; and

(l) "R313-36" for the reference to "10 CFR 34"; and

(7) The substitution of the following dates:

(a) In 10 CFR 34.42(d) and 10 CFR 34.43(a)(2) , "June 27,

1999" for the date "May 28, 1999."

(b) In 10 CFR 34.43(h), "June 27, 1998" for the date "May 28, 1998."

KEY: industry, radioactive material, licensing, surveys

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