LCB File No. R-084-98

NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption of Regulations Of the Nevada State Health Division

The State Board of Health will hold a public hearing at 9:00 a.m. on December 11, 1998 at the Washoe County District Health Department, Ninth and Wells Streets, Reno, Nevada. The purpose of the hearing is to receive comments from all interested persons regarding the adoption of regulations that pertain to Chapter 459 of the Nevada Administrative Code (NAC).

The proposed amendments and additions pertain to disposal of radioactive waste, medical use of radioactive material, radiation protection, industrial radiography, decommissioning, and reciprocity. The amendments and additions are needed in order to remain consistent with the regulations of the Nuclear Regulatory Commission in accordance with the Governor's signed agreement.

The following information is provided pursuant to the requirements of NRS 2233B.060:

1. The proposed regulations are to remain consistent with the regulations of the Nuclear Regulatory Commission in accordance with the Governor's signed agreement.
2. The proposed regulations address the following issues:
   Disposal of radioactive waste
   Medical use of radioactive material
   Radiation protection
   Industrial radiography
   Decommissioning
   Reciprocal recognition of licenses
3. Anticipated effects on the business which NAC 459 regulations:
   No adverse effects are anticipated as a result of these revisions and additions.
   These revisions allow more flexibility in meeting medical use requirements and financial assurance for decommissioning requirements.
   These regulation revisions will immediately provide greater flexibility for medical use licensees, licensees who require respiratory protection equipment, industrial radiography licensees, and licensees subject to decommissioning requirements.
   No. long term effects are anticipated as a result of these revisions.

The estimated economic effects on the general public are as follows:
   No anticipated adverse effects on or costs to the public are anticipated.

4. Estimated cost to the Health Division for enforcement of the proposed regulation:

No additional cost to the Health Division is anticipated for enforcement of these regulations. These amendments do not establish any new fees or increase any existing fees.

5. The proposed regulations do not overlap or duplicate any other local, state or federal processes or procedures established for public water systems.
6. The proposed regulations do not result in any new fees or increase in any existing fees.

Persons wishing to comment upon the proposed action of the Nevada State Health Division, State Board of Health may appear at the scheduled public hearing or may address their comments, data, views or arguments, in written form, to:

Secretary, State Board of Health
Nevada State Board of Health
Capitol Complex
505 East King Street, Room 201
Carson City, NV 89701-4797

The Nevada State Health Division, State Board of Health must receive written submissions on or before November 20, 1998. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Nevada State Health Division, State Board of Health may proceed immediately to act upon any written submissions.

A copy of this notice and the regulation to be adopted will be on file at the Nevada State Library and Archives, 100 Stewart Street, Carson City, Nevada, for inspection by members of the public during business hours. Additional copies of the notice and the regulation to be adopted will be available at:

Nevada State Health Division
505 East King Street, Room 201
Carson City, Nevada

Nevada State Health Division, Bureau of Health Protection Services
1179 Fairview Drive
Carson City, Nevada

Nevada State Health Division, Bureau of Health Protection Services
620 Belrose Street
Las Vegas, Nevada

And in all counties in which an office of the agency is not maintained, at the main public library, for inspection and copying by members of the public during business hours. This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations, which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request. A reasonable fee may be charged for copies if it is deemed necessary.

Per NRS 233B.064(2), upon adoption of any regulation, the Nevada State Health Division, State Board of Health, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against

its adoption and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice of hearing has been posted at the following locations:

STATE LIBRARY AND ARCHIVES, 100 Stewart Street, Carson City
BUREAU OF HEALTH PROTECTION SERVICES, 1179 Fairview Drive, Carson City
NEVADA STATE HEALTH DIVISION, 505 East King Street, Carson City
LEGISLATIVE COUNSEL BUREAU, 401 South Carson Street, Carson City

NEVADA COUNTY PUBLIC LIBRARIES

Carson City Library, 900 North Roop Street, Carson City

Churchill County Library, 553 S. Maine Street, Fallon

Clark County Library, 1401 E. Flamingo Road, Las Vegas

Douglas County Library, 1625 Library Lane, Minden

Elko County Library, 720 Court Street, Elko

Esmeralda County: Goldfield Public Library, corner of Crook and Ramsey, Goldfield

Eureka Branch Library, 10190 Monroe Street, Eureka

Humboldt County Library, 85 East 5th Street, Winnemucca

Lander County: Battle Mountain Branch Library, 625 Broad Street, Battle Mountain

Lincoln County Library, 63 Main Street, Pioche

Lyon County Library, 20 Nevin Way, Yerington

Mineral County Library, 125 "A" Street, Hawthorne

Nye County: Tonopah Public Library, 171 Central, Tonopah

Pershing County Library, 125 Central, Lovelock

Storey County Library, 95 South "R" Street, Virginia City

Washoe County Library, 301 South Center Street, Reno

White Pine County Library, 950 Campton Street, Ely

LCB File No. R084-98

PROPOSED REGULATION OF THE HEALTH DIVISION

Draft NAC 459 Regulation Revisions

File Name: regrev\98 Reg Revision Final Draft

Authority: NRS 459.030

Chapter 459 of NAC is hereby amended by adding thereto the provision set forth as sections 1 to 37, inclusive, of this regulation.

Section 1 "Person" defined. "Person" means an individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, or another state or political subdivision or agency thereof, and a legal successor, representative, agent or agency of the foregoing, but does not include federal government agencies.

Sec. 2 "Authorized nuclear pharmacist" defined. Authorized nuclear pharmacist means a pharmacist who is:
1. Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;
2. Identified as an authorized nuclear pharmacist on a division, Nuclear Regulatory Commission or agreement state license that authorizes the use of radioactive material in the practice of nuclear pharmacy; or
3. Identified as an authorized nuclear pharmacist on a permit issued by a division, Nuclear Regulatory Commission or agreement state specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy.

Sec. 3 "Medical use" defined. "Medical use" means the intentional internal or external administration of licensed material, the radiation therefrom, or the intentional external administration of radiation from radiation producing machines to patients or human research subjects under the supervision of an authorized user.

Sec. 4 Provisions for research involving human subjects.
A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by an agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its division license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

Sec. 5 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 division, the Nuclear Regulatory Commission or an agreement state, or as allowed in subsection 2 or 3.

2. An individual may receive, possess, use, or transfer radioactive material in accordance with these regulations under the supervision of an authorized user as provided in Section 9, unless prohibited by license condition.

3. An individual may prepare unsealed radioactive material for medical use in accordance with these regulations under the supervision of an authorized nuclear pharmacist or authorized user as provided in Section 9, unless prohibited by license condition.

Sec. 6 Application for license, amendment, or renewal.

1. If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

2. An application for a license for medical use of radioactive material as described NAC 459.247, 459.2481, 459.253, 459.255, and Section 12 must be made by filing an original and one copy of Form NRC - 5, "Application for Radioactive Material License." For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

3. An application for a license for medical use of radioactive material as described in NAC 459.3884 must be made by filing an original and one copy of Form NRC - 5. For guidance in completing the form, refer to the instructions in the most current version of the appropriate Regulatory Guide. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

4. For copies of regulatory guides, application forms, or to submit an application or an amendment request, refer to NAC 459.134.

5. An applicant that satisfies the requirements specified in NAC 459.268 may apply for a Type A specific license of broad scope.

Sec. 7 Notifications.

1. A licensee shall provide to the division a copy of the board certification, the division, Nuclear Regulatory Commission or agreement state license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to NAC 459.381.2.(a) through 459.381.2.(d).

2. A licensee shall notify the division by letter no later than 30 days after:

(a) An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(b) The licensee's mailing address changes.

Sec. 8 Exemptions regarding Type A specific licenses of broad scope.

A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:
(a) The provisions of NAC 459.381.2;
(b) The provisions of NAC 459.381.5 regarding additions to or changes in the areas of use only at the addresses specified in the license;
(c) The provisions of Section 7.1; and
(d) The provisions of Section 7.(2)(a) for an authorized user or an authorized nuclear pharmacist.

Sec. 9 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 Section 6.2 shall:
(a) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;
(b) Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with these regulations 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 permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by Section 5.3, shall:
(a) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written quality management program, as appropriate to that individual's use of radioactive material;
(b) Require the supervised individual to follow the instructions given pursuant to subsection 2.(a) and to comply with these regulations and license conditions; and
(c) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.
3. A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

Sec. 10 Suppliers for sealed sources or devices for medical use.
A licensee may use for medical use only:
1. Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 C.F.R. Part 30 and 10 C.F.R. 32.74 or the equivalent requirements of an agreement state; or
2. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 10 C.F.R. Part 30 or the equivalent requirements of an agreement state.

Sec. 11 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

1. This section does not apply to unit dosages of alpha- or beta- emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to 10 C.F.R. 32.72 or equivalent agreement state requirements.

2. For other than unit dosages obtained pursuant to subsection 1, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:

(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(b) Check each instrument for constancy and proper operation at the beginning of each day of use.

Sec. 12 Use of sealed sources for diagnosis.

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

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

(b) Iodine-125 as a sealed source in a portable imaging device.

2. A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have in his possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Sec. 13 Training for use of sealed sources for diagnosis.

Except as provided in NAC 459.3962, the licensee shall require the authorized user of a sealed source in a device listed in Section 12 to be a physician who:

1. Is certified in:

(a) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(b) Nuclear medicine by the American Board of Nuclear Medicine;

(c) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(d) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

2. Has had 8 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.

Sec. 14 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:
1. Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or
2.(a) Has completed 700 hours in a structured educational program consisting of both:
(1) Didactic training in the following areas:
(I) Radiation physics and instrumentation;
(II) Radiation protection;
(III) Mathematics pertaining to the use and measurement of radioactivity;
(IV) Chemistry of radioactive material for medical use; and
(V) Radiation biology; and
(2) Supervised experience in a nuclear pharmacy involving the following:
(I) Shipping, receiving, and performing related radiation surveys;
(II) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
(III) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
(IV) Using administrative controls to avoid mistakes in the administration of radioactive material;
(V) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and
(b) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Sec. 15 Training for experienced nuclear pharmacists.
A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in Section 14.2.(a) before August 31, 1998, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (Section 14.2.(a)) and recentness of training (NAC 459.3966) to qualify as an authorized nuclear pharmacist.

Sec. 16 ”Principal activities” defined. "Principal activities" means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Sec. 17 “Individual” defined. “Individual” means any human being.

Sec. 18 “Chemical description” defined. “Chemical description” means a description of the principal chemical characteristics of a low-level radioactive waste.

Sec. 19 “Computer-readable medium” defined. “Computer-readable medium” means that the division’s computer can transfer the information from the medium into its memory.

Sec. 20 "Consignee" defined. "Consignee" means the designated receiver of the shipment of low-level radioactive waste.

Sec. 21 "Decontamination facility" defined. "Decontamination facility" means a facility operating under a Nuclear Regulatory Commission or agreement state license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this section, is not considered to be a consignee for LLW shipments.

Sec. 22 "Disposal container" defined. "Disposal container" means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see ``high integrity container''). Note that for some shipments, the disposal container may be the transport package.

Sec. 23 "EPA identification number" defined. "EPA identification number" means the number received by a transporter following application to the Administrator of Environmental Protection Agency as required by 40 C.F.R. part 263.

Sec. 24 "Generator" defined. "Generator" means a licensee operating under a Nuclear Regulatory Commission or agreement state license who (1) is a waste generator or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

Sec. 25 "High integrity container (HIC)" defined. "High integrity container (HIC)" means a container commonly designed to meet the structural stability requirements of NAC 459.830, and to meet U.S. Department of Transportation (DOT) requirements for a Type A package.

Sec. 26 "Land disposal facility" defined. "Land disposal facility" means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive wastes.

Sec. 27 "Package" defined. "Package" means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

Sec. 28 "Physical description" defined. "Physical description" means the items called for on NRC Form 541 to describe a low-level radioactive waste.

Sec. 29 "Residual waste" defined. "Residual waste" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

Sec. 30 "Shipper" defined. "Shipper" means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

Sec. 31 "Shipping paper" defined. "Shipping paper" means NRC Form 540 and, if required, NRC Form 540A which includes the information required by the U.S. DOT in 49 C.F.R. part 172.

Sec. 32 "Uniform Low-Level Radioactive Waste Manifest or uniform manifest" defined. "Uniform Low-Level Radioactive Waste Manifest or uniform manifest" means the combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

Sec. 33 "Waste collector" defined. "Waste collector" means an entity, operating under a Nuclear Regulatory Commission or agreement state license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

Sec. 34 "Waste description" defined. "Waste description" means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541.

Sec. 35 "Waste generator" defined. "Waste generator" means an entity, operating under a Nuclear Regulatory Commission or agreement state license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a ``waste generator'' if the transfer of low-level radioactive waste from its facility is defined as ``residual waste.''

Sec. 36 "Waste processor" defined. "Waste processor" means an entity, operating under a Nuclear Regulatory Commission or agreement state license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

Sec. 37 "Waste type" defined. "Waste type" means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

NAC 459. 459.0208 is hereby amended to read as follows:

459.0208 "Authorized user" defined. "Authorized user" means a physician [who is identified as an authorized user on a license issued by the State of Nevada, the Nuclear Regulatory

Commission or an agreement state that authorizes the use of radioactive materials in medical procedures.] , dentist, or podiatrist who is:

1. Board certified by at least one of the boards listed in paragraph 1 of NAC 459.3944, 459.3946, 459.3948, 459.3954, Section 13, or 459.3958;

2. Identified as an authorized user on a division, Nuclear Regulatory Commission or agreement state license that authorizes the medical use of radioactive material; or

3. Identified as an authorized user on a permit issued by a division, Nuclear Regulatory Commission or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material.

NAC 459.051 is hereby amended to read as follows:

459.051 "Member of the public" defined. "Member of the public" means [a person in an unrestricted area. The term does not include a person during any period in which that person receives an occupational dose] any individual except when that individual is receiving an occupational dose.

NAC 459.0514 is hereby amended to read as follows:

459.0514 "Misadministration" defined. "Misadministration" means the administration of:

1. A dosage greater than 30 microcuries of sodium iodide containing iodine-125, or iodine-131, if:

(a) The administration is:

(1) To an individual [patient] other than the individual [patient] intended by the prescribing physician; or

(2) Of a radiopharmaceutical other than that intended by the prescribing physician; or

(b) The administered dosage differs from the prescribed dosage by more than 20 percent, and the difference between the administered dosage and the prescribed dosage is more than 30 microcuries;

2. A therapeutic dosage of a radiopharmaceutical other than sodium iodide containing iodine-131, if:

(a) The administration is:

(1) To an individual [patient] other than the individual [patient] intended by the prescribing physician;

(2) Of a radiopharmaceutical other than that intended by the prescribing physician; or

(3) By a route of administration other than that intended by the prescribing physician; or

(b) The administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage;

3. A dose of gamma radiation during stereotactic radiosurgery, if:

(a) The administration is:

(1) To an individual [patient] other than the individual [patient] intended by the prescribing physician; or

(2) At a site other than the site of treatment intended by the prescribing physician; or

(b) The calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

4. A dose of radiation during teletherapy, if:

(a) The administration is:

(1) To an individual [patient] other than the individual [patient] intended by the prescribing physician;

(2) By a mode of treatment other than that intended by the prescribing physician; or

(3) At a site other than the site of treatment intended by the prescribing physician;

(b) The treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

(c) The calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

(d) The calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

5. A dose of radiation during brachytherapy, if:

(a) The administration is:

(1) To an individual [patient] other than the individual [patient] intended by the prescribing physician;

(2) Of a radioisotope other than that intended by the prescribing physician;

(3) At a site other than the site of treatment intended by the prescribing physician, except for permanent implants where seeds planted in the intended site migrate outside that site;

(4) Of a sealed source that leaks; or

(5) Of a temporary implant and one or more sealed sources are not removed upon completion of the procedure; or

(b) The calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose; or

6. A diagnostic dosage of a radiopharmaceutical, other than a quantity that exceeds 30 microcuries of sodium iodide containing iodine-125 or iodine-131, if the effective dose equivalent to the individual [patient] exceeds 5 rems, or the dose equivalent to any organ exceeds 50 rems, and:

(a) The administration is:

(1) To an individual [patient] other than the individual [patient] intended by the prescribing physician;

(2) Of a radiopharmaceutical other than that intended by the prescribing physician; or

(3) By a route of administration other than that intended by the prescribing physician; or

(b) The administered dosage differs from the prescribed dosage.

NAC 459.054 is hereby amended to read as follows:

459.054 "Occupational dose" defined. "Occupational dose" means the dose received by a person:

[1. In a restricted area; or]

[2]1. In the course of employment in which the person's duties involve exposure to radiation [and] or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of a licensee, registrant or any other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has

received, from voluntary participation in medical research programs, or as a member of the public.

NAC 459.065 is hereby amended to read as follows:

459.065 "Public dose" defined. "Public dose" means the dose received by a member of the public from radiation or radioactive material that is released by a licensee, or from another source of radiation [within an unrestricted area] under the control of a licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, or from voluntary participation in medical research programs.

NAC 459.1165 is hereby amended to read as follows:

459.1165 "Written directive" defined. "Written directive" means a written order for the administration of a radiopharmaceutical or radiation to a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation except as specified in subsection 5.(b) which:

1. For the administration of a quantity greater than 30 microcuries of sodium iodide containing iodine-125 or iodine-131, contains the dosage prescribed.
2. For the therapeutic administration of a radiopharmaceutical other than sodium iodide containing iodine-131, contains the radiopharmaceutical, dosage, and route of administration prescribed.
3. For the administration of gamma radiation during stereotactic radiosurgery, contains the target coordinates, collimator size, plug pattern, and total dose prescribed.
4. For the administration of radiation during teletherapy, contains the total dose, dose per fraction, site of treatment, and overall period of treatment prescribed.
5. For the administration of radiation during:

(a) Brachytherapy by remote afterloading at a high dose rate, contains the radioisotope, site of treatment, and total dose prescribed.

(b) Any other brachytherapy, contains:

(1) Before implantation, the radioisotope, number of sources, and source strengths prescribed.

(2) After implantation and before completion of the procedure, the radioisotope, and site of treatment prescribed, and:

(I) The total source strength and time of exposure prescribed; or

(II) The total dose prescribed.

NAC 459.186 is hereby amended to read as follows:

459.186 (See attached page 10a for revised text).

NAC 459.1955 is hereby amended to read as follows:

459.1955 Requirements of applicants: Submission of decommissioning plan and financial assurance.

1. Each applicant for a license authorizing the possession and use of unsealed radioactive materials of half-life greater than 120 days and in quantities [equal or] exceeding 10^5 times the applicable quantities set forth in NAC 459.362 [the following quantities] shall submit a [decommissioning plan and a] plan for financing [the] decommissioning as described in subsection 5[:]. The decommissioning funding plan shall also be submitted when a combination of radionuclides is involved if R divided by 10^5 is greater than one, where R is defined here as the sum of the ratios of the quantity of each radionuclide to the applicable value in NAC 459.362.

[(a) Quantity of radioactive material in unsealed form with a half-life greater than 120 days exceeding 10^3 times and for sealed forms exceeding 10^{10} times the applicable quantity set forth for one isotope in NAC 459.362. Or in the case where a combination of isotopes is involved, when R divided by 10^3 or 10^{10}, as appropriate, is greater than 1. As used in this paragraph, "R" means the sum of the ratios of the quantity of each isotope to the applicable value set forth in NAC 459.362.

(b) Quantity of source material in readily dispersible form exceeding 10 millicuries.

2. The decommissioning plan must include the following:

(a) Drawings of the facility where the radioactive material is located depicting the areas where the radioactive materials are used and stored.

(b) A description of methods and general procedures that will be used for decontamination of the facility, maintaining security during the process of decontamination and for performing surveys to evaluate the progress of decontamination.

(c) The time within which the process of decommissioning will commence after the use of radioactive material is terminated and the expected time within which decommissioning will be completed.]

2. Applicants for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in subsection 4 shall either:

(a) submit a decommissioning funding plan as described in subsection 5; or

(b) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by subsection 4 using one of the methods described in subsection 6. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of subsection 6 shall be submitted to the division before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the division, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements subsection 6.

3.(a) Holders of a specific license issued on or after August 31, 1998, which is of a type described in subsection 1 or 2 shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.

(b) Holders of a specific license issued before August 31, 1998, and of a type described in subsection 1 shall submit, on or before August 31, 1998, a decommissioning

funding plan as described in subsection 5 or a certification of financial assurance for decommissioning in an amount at least equal to $750,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(c) Holders of a specific license issued before August 31, 1998, and of a type described subsection 2 shall submit, on or before August 31, 1998, a decommissioning funding plan as described in subsection 5 or a certification of financial assurance for decommissioning in accordance with the criteria set forth in this section.

(d) A licensee who has submitted an application before August 31, 1998, for renewal of license in accordance with NAC 459.202 shall provide financial assurance for decommissioning in accordance with subsections 1 and 2. This assurance shall be submitted before August 1, 1998.

4. Table of required amounts of financial assurance for decommissioning by quantity of material:

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of radioactive material, as defined in NAC 459.362 in unsealed form. For a combination of radionuclides, if R, as defined in subsection 1 divided by 10^4 is greater than one but R divided by 10^5 is less than or equal to one:	$750,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of radioactive material, as defined in NAC 459.362 in unsealed form. For a combination of radionuclides, if R, as defined in subsection 1 divided by 10^3 is greater than one but R divided by 10^4 is less than or equal to one:	$150,000
Greater than 10^{10} times the applicable quantities of radioactive material, as defined in NAC 459.362 in sealed sources or plated foils. For combination of radionuclides, if R, as defined in subsection 1, divided by 10^{10} is greater than one:	$75,000

[3]5. The plan for financing the decommissioning must contain the following:

(a) An estimate of the costs of decommissioning the facility based on the decommissioning plan;

(b) A description of the method of assuring financing for decommissioning in compliance with subsection 6; [and]

(c) A schedule for adjusting the estimate of costs and associated levels of funding periodically over the life of the facility[.];and

(d) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of subsection 6.

[4]6. Financial assurance for decommissioning must be provided by one or more of the following methods:

(a) Prepayment. Prepayment is the d[D]eposit of the amount of money in cash or liquid assets that would be sufficient to pay the costs of decommissioning before starting operations at the facility, into an account segregated from the licensee's assets and outside the licensee's administrative control. Prepayment [The money or liquid assets] may be [deposited] in the form of a trust, escrow account, government fund, certificate of deposit or deposit of government securities.

(b) Provision of a surety that assures that the costs of decommissioning will be paid should the licensee fail to do so. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in subsection 8. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in subsection 9. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety used to provide financial assurance for decommissioning must contain the following conditions:

(1) The surety must be open-ended or, if written for a specified term, must be renewed automatically unless 90 days or more before the renewal date, the issuer notifies the division, the beneficiary and the licensee of his intention not to renew. [The surety must provide notice of cancellation to the division, the beneficiary and the licensee, not less than 30 days before cancellation of the surety.] The surety must provide that the full-face amount will be paid to the beneficiary automatically before the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the division within 30 days after receipt of notification of the cancellation.

(2) The surety must be payable to a trust established for the costs of decommissioning [the facility]. The trustee and trust must be approved by the division. The division will approve as a trustee an appropriate agency of the state or federal government or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by an agency of the state or federal government. A licensee shall maintain the surety in effect until the division has terminated his license. As used in this paragraph, "surety" means, but is not limited to a trust fund, surety bonds, letters of credit, insurance, other guarantees of performance, or any combination of these or other forms of security approved by the division.

(c) Provision of an external sinking fund in which deposits are made at least annually, coupled with a surety issued in compliance with the provisions of paragraph (b) except that the value of the surety may decrease by the amount being accumulated in the external sinking fund. As used in this paragraph, "external sinking fund" means a fund established and

maintained by setting aside money periodically in an account segregated from the licensee's assets and outside the licensee's administrative control in which the total amount of money to be accumulated before the termination of operation [of the facility] is expected is sufficient to pay the costs of decommissioning. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit or deposit of government securities. The surety or insurance provisions shall be as stated in subsection 6.(b).

(d) If the licensee is a federal, state or local governmental agency, a statement of intent containing an estimate of the costs of decommissioning [the facility] or an amount based on the Table in subsection 4 and an indication that money for decommissioning will be obtained when necessary.

7. Persons licensed under NAC 459.180 through 459.314 shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with NAC 459.198.2 licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records are kept for other purposes, reference to these records and their locations may be used. Information the division considers important to decommissioning consists of the following:

(a) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records shall include any known information on identification of involved nuclides, quantities, forms, and concentrations;

(b) as-built drawings and modification of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations;

(c) except for areas containing only sealed sources, provided the sources have not leaked or no contamination remains after a leak, or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, including all of the following:

(1) all areas designated and formerly designated as restricted areas as defined under NAC 459.090;

(2) all areas outside of restricted areas that require documentation under subsection 7(a);

(3) all areas outside of restricted areas where current and previous wastes have been buried as documented under NAC 459.3673; and

(4) all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under NAC 459.3595; and

(d) records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

8. Criteria relating to use of financial tests and parent company guarantees for providing reasonable assurance of funds for decommissioning.

(a) To pass the financial test refer to in subsection 6.(b), the parent company shall meet one of the following criteria:

(1) The parent company shall have all of the following:

(I) Two of the following three ratios: a ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5;

(II) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates, or prescribed amount if a certification is used;

(III) Tangible net worth of at least $10 million; and

(IV) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates, or prescribed amount if a certification is used; or

(2) The parent company shall have all of the following:

(I) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A or Baa as issued by Moody's;

(II) Tangible net worth at least six times the current decommissioning cost estimate, or prescribed amount if a certification is used;

(III) Tangible net worth of at least $10 million; and

(IV) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates, or prescribed amount if certification is used.

(b) The parent company's independent certified public accountant shall have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the division within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(c)(1) After the initial financial test, the parent company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(2) If the parent company no longer meets the requirements of subsection 8.(a) the licensee shall send notice to the division of intent to establish alternative financial assurance as specified in this paragraph. The notice shall be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

(d) The terms of a parent company guarantee which an applicant or licensee obtains shall provide that:

(I) The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the division. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the division, as evidenced by the return receipts.

(II) If the licensee fails to provide alternate financial assurance as specified in this section within 90 days after receipt by the licensee and the division of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

(III) The parent company guarantee and financial test provisions shall remain in effect until the division has terminated the license.

(IV) If a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the division. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

9. Criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning.

(a) To pass the financial test referred to in subsection 6.(b), a company shall meet all of the following criteria:

(I) Tangible net worth at least ten times the total current decommissioning cost estimate, or the current amount required if certification is used, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor;

(II) Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate, or the current amount required if certification is used, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor; and

(III) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's, or Aaa, Aa, or A as issued by Moody's.

(b) To pass the financial test, a company shall meet all of the following additional requirements:

(I) The company shall have at least one class of equity securities registered under the Securities Exchange Act of 1934;

(II) The company's independent certified public accountant shall have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the division within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test; and

(III) After the initial financial test, the company shall repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(c) If the licensee no longer meets the requirements of subsection 9.(a), the licensee shall send immediate notice to the Division of its intent to establish alternate financial assurance as specified in this section within 120 days of such notice.

(d) The terms of a self-guarantee which an applicant or licensee furnishes shall provide that:

(I) The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the division. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the division, as evidenced by the return receipt.

(II) The licensee shall provide alternative financial assurance as specified in this section within 90 days following receipt by the division of a notice of a cancellation of the guarantee.

(III) The guarantee and financial test provisions shall remain in effect until the division has terminated the license or until another financial assurance method acceptable to the Division has been put in effect by the licensee.

(IV) The licensee shall promptly forward to the Division and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

(V) If, at any time, the licensee's most recent bond issuance ceases to be rated in a category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the Division within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of subsection 9.(a).

(vi) The applicant or licensee shall provide to the Division a written guarantee, a written commitment by a corporate officer, which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Board, the licensee shall set up and fund a trust in the amount of the current cost estimates for decommissioning.

NAC 459.200 is hereby amended to read as follows:

459.200 Expiration and [T]termination of licenses: Notification; submission of report, radiation survey, and proposed plan for completion of decommissioning of sites and separate buildings or outdoor areas.

[1. Except as otherwise provided in subsection 5 and in NAC 459.202, each specific license expires at the end of the day, in the month and year stated in the license.

2. Each licensee shall notify the division immediately in writing and request termination of his license when he terminates all activities involving radioactive materials authorized under the license. The notification and request for termination of the license must include the reports specified in paragraphs (d) and (e) of subsection 3.

3. If the licensee requests termination of the license or does not submit an application for renewal of the license as provided in NAC 459.202, he shall, on or before the expiration date specified on the license:

(a) Terminate his use of radioactive material;

(b) Remove radioactive contamination until the only radiation remaining is background radiation;

(c) Properly dispose of the radioactive material in his possession by transferring it to a person licensed to possess that specific type and quantity of radioactive material;

(d) Submit a report to the division which includes:

(1) The name, address, and telephone number of the person to whom the radioactive material was transferred; and

(2) A copy of a receipt for the radioactive material, signed by the recipient, which contains:

(I) The date the radioactive material was received;

(II) A description of the isotope and the activity for each isotope in the shipment received; and

(III) The license number of the recipient; and

(e) Submit a report of a radiation survey to the division to notify it of the absence of radioactive material or the presence and levels of residual radioactive contamination.

4. If the licensee submits in the report of the radiation survey adequate evidence that no residual radioactive material attributable to activities conducted under the license is detected on the premises, the division, after verification, will notify him that the license is terminated.

5. If, after the radiation survey, detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to the possession of residual radioactive material present as contamination, until the division notifies the licensee in writing that the license is terminated.

6. Each licensee who possesses residual radioactive material after the expiration date specified in the license shall:

(a) Submit to the division a proposed plan for completion of decommissioning the facility where the radioactive material is located. The plan must contain the following information:

(1) A description of activities planned for the decommissioning of the facility;

(2) A description of the methods that will be used to assure protection of employees of the facility and the environment against hazards involving radiation during the decommissioning of the facility;

(3) A description of an additional radiation survey to be performed after the decommissioning of the facility is completed;

(4) The proposed date of commencement of activities for the decommissioning of the facility and the expected date of completion; and

(5) An updated and detailed estimate of the cost for decommissioning the facility, a comparison of that estimate with money set aside for decommissioning the facility, and a plan for assuring the availability of adequate money for payment of the costs of completion of decommissioning the facility.

The proposed plan for completion of decommissioning the facility will be approved by the division if the information therein demonstrates that the decommissioning will be completed as soon as is reasonable and the health and safety of employees of the facility and the public will be adequately protected. Upon approval of the proposed plan for completion of decommissioning, the licensee shall complete decommissioning in accordance with the plan. After the decommissioning of the facility is completed, the licensee shall submit a report of the additional radiation survey and shall certify the disposition of wastes accumulated from the decommissioning of the facility.]

1. A specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under NAC 459.202 no less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the division makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

2. A specific license revoked by the division expires at the end of the day on the date of the division's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by an Order issued by the division.

3. A specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the division notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

([b]a) [L]limit actions involving radioactive material to those related to decommissioning; and [decontamination and other activities related to preparation of the premises for release for unrestricted use.]

([c]b) [C]continue to control entry to restricted areas [on the premises] until they are suitable for release [for unrestricted use and the division notifies him in writing that the license is terminated] so that there is not an undue hazard to public health and safety.

4. Within 60 days of the occurrence of any of the following, a licensee shall provide notification to the division in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release so that there is not an undue hazard to public health and safety, or submit within 12 months of notification a decommissioning plan, if required by subsection 7.(a), and begin decommissioning upon approval of that plan if:

(a) the license has expired pursuant to subsection 1 or 2; or

(b) the licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release because of an undue hazard to public health and safety; or

(c) no principal activities under the license have been conducted for a period of 24 months; or

(d) no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release because of an undue hazard to public health and safety.

5. Coincident with the notification required by subsection 4, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to NAC 459.1955 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to subsection 7.(d)(v).

(a) A licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so on or before August 31, 1998.

(b) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the division.

6. The division may grant a request to extend the time periods established in subsection 4 if the division determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to subsection 4. The schedule for decommissioning set forth in subsection 4 may not commence until the division has made a determination on the request.

7.(a) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the division and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(1) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(2) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(3) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(4) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(b) The division may approve an alternate schedule for submittal of a decommissioning plan required pursuant to subsection 4 if the division determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(c) Procedures such as those listed in subsection 7.(a) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(d) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(1) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(2) a description of planned decommissioning activities;

(3) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(4) a description of the planned final radiation survey; and

(5) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(6) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in subsection 9.

(e) The proposed decommissioning plan will be approved by the division if the information therein demonstrates that the decommissioning will be completed as soon as practical and that the health and safety of workers and the public will be adequately protected.

8.(a) Except as provided in subsection 9, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practical but no later than 24 months following the initiation of decommissioning.

(b) Except as provided in subsection 9, when decommissioning involves the entire site, the licensee shall request license termination as soon as practical but no later than 24 months following the initiation of decommissioning.

9. The division may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if

appropriate, if the division determines that the alternative is warranted by consideration of the following:

(a) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(b) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24- month period;

(c) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(d) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(e) other site-specific factors which the division may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

10. As the final step in decommissioning, the licensee shall:

(a) certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(b) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:

(I) report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters--removable and fixed- - for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(II) specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

11. Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the division determines that:

(a) radioactive material has been properly disposed;

(b) reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(c)(I) a radiation survey has been performed which demonstrates that the premises are suitable for release so that there is not an undue hazard to public health and safety; or

(II) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release so that there is not an undue hazard to public health and safety.

NAC 459.202 is hereby amended to read as follows:

459.202 Renewal of licenses.

1. Applications for renewal of specific licenses must be filed in accordance with NAC 459.236 and, except as otherwise provided in NAC 459.203, must be accompanied by the appropriate fee as prescribed in NAC 459.310.

[2. If a licensee, not less than 30 days before the expiration of his existing license, has filed an application in proper form for a renewal or a new license authorizing the same activities, his existing license will not expire until the application has been finally determined by the division.]

NAC 459.203 is hereby amended to read as follows:

459.203 [Annual f]Payment of Fees for specific licenses.

1. Except as otherwise provided in subsection 2, if the division issues a specific license pursuant to NAC 459.196, the licensee must, for each year his specific license is valid, submit to the division the appropriate fee set forth in NAC 459.310. The annual fee must be received by the division not later than the last day of the month specified in the expiration date of the license.

2. The annual fee and a license renewal application must be received by the division not later than the date on which the license expires. If the fee and application are [is] not received by that date, the licensee must:

(a) Stop all operations involving radioactive materials and place all sources of radiation in storage until they can be transferred to persons authorized to receive them; or

(b) Submit to the division within 5 days after the license expires, an application for renewal of the license accompanied by a fee that is equal to twice the amount of the appropriate fee set forth in NAC 459.310.

NAC 459.210 is hereby amended to read as follows:

459.210 Reciprocal recognition of licenses.

1. Subject to the provisions of NAC 459.010 to 459.950, inclusive, any person who holds a specific license from the Nuclear Regulatory Commission or any agreement state issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year provided that:

(a) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(b) The out-of-state licensee notifies the division in writing at least 3 state business days prior to engaging in [such] the proposed activity and receives written permission from the division to proceed with the proposed activity. The notification must indicate the location, period and type of proposed possession and use within the state, and must be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3-day period would impose an undue hardship on the out-of-state licensee, he may apply to the division and obtain written permission to proceed sooner. The division may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in subsection 1;

(c) The out-of-state licensee complies with all applicable regulations of the division and with all the terms and conditions of his licensing document, except any terms and conditions which may be inconsistent with applicable regulations of the division;

(d) The out-of-state licensee supplies such other information as the division may request; and

(e) The out-of-state licensee must not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person:

(1) Specifically licensed by the division or by the Nuclear Regulatory Commission to receive such material; or

(2) Exempt from the requirements for a license for such material under NAC 459.184.

2. Before radioactive materials can be used at a temporary jobsite at any Federal facility, the jurisdictional status of the jobsite must be determined. If the jurisdictional status is not known, the Federal agency should be contacted to determine if the jobsite is under exclusive Federal jurisdiction. A response should be obtained in writing or a record should be made of the name and title of the person at the Federal agency who provided the determination and the date it was provided. Authorization for the use of radioactive materials at jobsites under exclusive Federal jurisdiction shall be obtained either by: (a) filing a NRC Form-241 in accordance with 10 C.F.R. 150.20(b), "Recognition of agreement state Licensees"; or (b) by applying for a specific NRC license.

3. Before radioactive material can be used at a temporary jobsite in another State, authorization shall be obtained from the State if it is an agreement state, or from the NRC for any non-agreement states either by filing for reciprocity or applying for a specific license.

[2]4. Any person who holds a specific license issued by the Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install or maintain a device described in NAC 459.216 within areas subject to the jurisdiction of the licensing body, is hereby granted a general license to install, transfer, demonstrate or maintain such a device in this state provided that:

(a) Such person shall file a report with the division within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report must identify each general licensee to whom such device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device;

(b) The device has been manufactured, labeled, installed and maintained in accordance with applicable provisions of the specific license issued to such person by the Nuclear Regulatory Commission or an agreement state;

(c) Such person must assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that: "Removal of this label is prohibited"; and

(d) The holder of the specific license must furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in NAC 459.216.

[3]5. The division may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to the licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

NAC 459.245 is hereby amended to read as follows:

459.245 Specific licenses: Conditions of and limitations upon medical uses of radioactive material; checks and tests of dose calibrators.

1. A licensee who is authorized for any medical use of radioactive material shall use for medical purposes only:

(a) [Radioactive material] Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued by the Nuclear Regulatory Commission pursuant to 10 C.F.R. Part 30, [and § 32.72, 32.73, or 32.74 of] 10 C.F.R. Part 32.74, or the equivalent regulations of an agreement state.

[(b) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval given by the Nuclear Regulatory Commission pursuant to 32.73 of 10 C.F.R. Part 32, or an agreement state under equivalent regulations for the preparation of radiopharmaceuticals for medical use.]

([c]b) Teletherapy sources manufactured and distributed in accordance with a license issued by the Nuclear Regulatory Commission pursuant to 10 C.F.R. Part 30, or the equivalent regulations of an agreement state.

[(d) Radiopharmaceuticals approved by the United States Food and Drug Administration. A list of these radiopharmaceuticals and changes to the listing are available from the division upon request.]

2. A licensee authorized to use and administer radiopharmaceuticals shall have in his possession a dose calibrator and use it to:

(a) M[m]easure the amount of activity of the photon-emitting radionuclide in each radiopharmaceutical dosage immediately before administration to a patient or human research subject.

(b) Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or a beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 10 C.F.R. 32.72 or equivalent agreement state requirements;

3. A licensee shall retain a record of the measurements required by this section for three years. To satisfy this requirement, the record must contain the:

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

(b) Patient's or human research subject'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 30 microcuries;

(d) Date and time of the measurement; and

(e) Initials of the individual who made the record.

[3]4. 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 requirement of this paragraph, the check must be done on a frequently used setting with a sealed source of not less than 10 microcuries of radium-226 or 50 microcuries of any photon-emitting radionuclide.

(b) 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 to be within 5 percent of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principle photon energy between 100 keV and 500 keV.

(c) 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 or human research subject and 30 microcuries.

(d) 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.

[4]5. A licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator.

[5]6. A licensee shall mathematically correct the dosage reading for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

[6]7. Except as otherwise provided in paragraph (d) of subsection 4, a licensee shall retain a record of each check and test required by this section for at least 3 years unless directed otherwise by the division. The records of the checks and tests required by subsection 4 must include:

(a) For paragraph (a) of subsection 4, 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 person who performed the check;

(b) For paragraph (b) of subsection 4, the model and serial number of the dose calibrator, the model and serial number of each source used, 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] initials of the person who performed the check;

(c) For paragraph (c) of subsection 4, 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] initials of the person who performed the check; and

(d) For paragraph (d) of subsection 4, 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] initials of the person who performed the check.

NAC 459.247 is hereby amended to read as follows:

459.247 Specific licenses: Use of radiopharmaceuticals in studies of uptake, dilution or excretion.

1. A licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material [in a radiopharmaceutical or for diagnostic use in measuring uptake, dilution, or excretion of a substance for which the United States Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" or has approved a "New Drug Application."] prepared for medical use that is either:

(a) Obtained from a manufacturer or preparer licensed pursuant to 10 C.F.R. 32.72 or equivalent agreement state requirements; or
(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in NAC 459.3946, or an individual under the supervision of either as specified in Section 9.

2. A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall have in his possession a portable radiation detection survey instrument capable of detecting dose rates ranging from 0.1 millirem per hour to 100 millirem per hour.

NAC 459.2481 is hereby amended to read as follows:

459.2481 Specific licenses: Use of radiopharmaceuticals, generators, and reagent kits in studies of imaging and localization.

1. A licensee may use for imaging and localization studies any unsealed 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 United States Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" or approved a "New Drug Application."] prepared for medical use that is either:
(a) Obtained from a manufacturer or preparer licensed pursuant to 10 C.F.R. 32.72 or equivalent agreement state regulations; or
(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in NAC 459.3946, or an individual under the supervision of either as specified in Section 9.

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

[3]2. A licensee shall not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

[4]3. A licensee who uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate or extract.

[5]4. A licensee who is required to measure molybdenum concentration pursuant to subsection 4 shall retain a record of each measurement for at least 3 years. The record must include, for each elution or extraction of technetium-99m:

(a) The measured activity of the technetium expressed in millicuries;

(b) The measured activity of the molybdenum expressed in microcuries;

(c) The ratio of the measures expressed as microcuries of the molybdenum per millicurie of the technetium;

(d) The time and date of the measurement; and

(e) The initials of the person who made the measurement.

[6]5. A licensee who is authorized to use radioactive material for imaging and localization studies shall have in his possession a portable radiation detection survey instrument capable of detecting dose rates ranging from 0.1 millirem per hour to 100 millirem per hour and a portable radiation measurement survey instrument capable of measuring dose rates ranging from 1 millirem per hour to 1,000 millirem per hour.

NAC 459.255 is hereby amended to read as follows:

459.255 Specific licenses: Use of radiopharmaceuticals for therapy.

1. A licensee may use any unsealed radioactive material [in a radiopharmaceutical which is used therapeutically and for which the United States Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" or approved a "New Drug Application." The licensee shall comply with the package insert instructions regarding
indications and method of administration] prepared for medical therapy use that is either:

(a) Obtained from a manufacturer or preparer licensed pursuant to 10 C.F.R. 32.72 or equivalent agreement state regulations; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in NAC 459.3946, or an individual under the supervision of either as specified in Section 9.

2. A licensee who is authorized to use radioactive material for radiopharmaceutical therapy shall have in his possession a portable radiation detection survey instrument capable of detecting dose rates ranging from 0.1 millirem per hour to 100 millirem per hour and a portable radiation measurement survey instrument capable of measuring dose rates ranging from 1 millirem per hour to 1,000 millirem per hour.

NAC 459.256 is hereby amended to read as follows:

459.256 Specific licenses: Release of [patients] individuals given radiopharmaceuticals or radioactive implants; conduct of radiation surveys; calculation of total effective dose equivalent; provision of information to limit exposure of other persons to radiation emitted from [patient] individuals; records.

1. A licensee shall not authorize release from confinement for medical care any [patient] individual given a radiopharmaceutical until:

(a) The measured dose rate from the [patient] individual is less than 5 millirems per hour at a distance of one meter; or

(b) The activity in the [patient] individual is less than 30 millicuries.

2. A licensee shall not authorize release from confinement for medical care a [patient] individual given a permanent implant until the measured dose rate from the [patient] individual is less than 5 millirems per hour at a distance of one meter.

3. Immediately after removing the last temporary implant source from a [patient] individual, the licensee shall make a radiation survey of the [patient] individual with a radiation detection survey instrument to confirm that all sources have been removed.

4. A licensee shall not release from confinement for medical care a [patient] individual treated by temporary implant until all sources have been removed.

5. A licensee shall retain a record of the survey of [patients] individuals for at least 3 years. Each record must include:

(a) The date of the survey;

(b) The name of the [patient] individual;

(c) The dose rate from the [patient] individual expressed as millirem per hour and measured at one meter from the [patient] individual;

(d) The identity of the survey instrument used; and

(e) The initials of the person who made the survey.

6. Using the survey data required pursuant to subsection 5, the licensee shall calculate the total effective dose equivalent that a person who resides in the same house as the [patient] individual is likely to receive from the [patient] individual. If the licensee calculates that the total effective dose equivalent to any person from exposure to the released [patient] individual could exceed 100 millirems in 1 year unless certain precautions are taken, the licensee shall provide verbal and written instructions to the [patient] individual, which if carefully followed by the [patient] individual, should limit the exposure of other persons to the radiation emitted from the [patient] individual to less than 100 millirems per year. If the [patient] individual appears to have difficulty in understanding the instructions, the licensee shall contact a member of the family of the [patient] individual, his guardian, or other representative until a person is found who can communicate the meaning of the instructions to the [patient] individual.

7. The licensee shall maintain for at least 3 years the records of a released [patient] individual which must include a copy of the written instructions and the calculated total effective dose equivalent to the person likely to receive the highest dose.

NAC 459.2571 is hereby amended to read as follows:

459.2571 Specific licenses: Written directives required for certain administrations; exceptions.

1. A written directive is required for each:

(a) Administration of a dose of radiation during teletherapy;

(b) Administration of a dose of gamma radiation during stereotactic radiosurgery;

(c) Administration of a dose of radiation during brachytherapy;

(d) Administration of a quantity greater than 30 microcuries of sodium iodide containing iodine-125 or iodine-131; or

(e) Therapeutic administration of a radiopharmaceutical other than sodium iodide containing iodine-131.

2. If a written directive is required for an administration, the prescribing physician shall, before the administration occurs:

(a) Prepare, date, and sign a written directive for the administration, unless:

(1) Because of the emergent nature of the patient's or human research subject's condition, the delay required to prepare the written directive would place the health of the patient or human research subject in jeopardy;

(2) An oral directive for the administration is made and immediately written in the patient's or human research subject's record; and

(3) The prescribing physician prepares, dates, and signs a written directive for the administration within 24 hours after the oral directive is made; or

(b) Date and sign a written revision to an existing written directive for a diagnostic or therapeutic procedure, unless:

(1) Because of the patient's or human research subject's condition, the delay required to prepare the written revision would place the health of the patient or human research subject in jeopardy;

(2) An oral revision of the existing written directive is made and immediately written in the patient's or human research subject's record; and

(3) The prescribing physician signs a revised written directive within 48 hours after the oral revision is made.

NAC 459.2572 is hereby amended to read as follows:

459.2572 Specific licenses: Written program of policies and procedures required; modification of written program; submission of written program with application for license.

1. The holder of a specific license for a medical use of radioactive material shall establish and carry out a written program to ensure that radioactive material and radiation from radioactive material is administered as directed by the prescribing physician. The program must include written policies and procedures to ensure that:

(a) The prescribing physician complies with the provisions of NAC 459.2571.

(b) Before each administration occurs, the identity of the patient or human research subject is verified, by two or more methods, as the person named in the written directive for the administration.

(c) The final plan of treatment and related calculations for any brachytherapy, teletherapy or stereotactic radiosurgery by gamma radiation are in accordance with the written directive for the administration.

(d) Each administration is made in accordance with the written directive for the administration.

(e) Any unintended deviation from a written directive is identified and evaluated, and appropriate action taken.

2. The licensee may modify the program established pursuant to subsection 1 to increase the efficiency of the program if:

(a) The modification will not result in a decrease in the efficiency of the program; and

(b) He provides the division with a copy of the modification within 30 days after the modification is made.

3. An applicant for a specific license for a medical use of radioactive material shall submit to the division, as part of his application for such a license, a written program that complies with the requirements of subsection 1.

NAC 459.2573 is hereby amended to read as follows:

459.2573 Specific licenses: Mandatory review and evaluation of written program. A licensee shall:

1. Develop a procedure for and, at intervals not to exceed every 12 months, conduct a review of the program he establishes pursuant to NAC 459.2572. Each review must include an evaluation of:

(a) A representative sample of administrations to patients or human research subjects;

(b) All recordable events; and

(c) All misadministrations, in which he was involved since the most recent review, to verify compliance with all aspects of the program.

2. Evaluate each review to determine the effectiveness of the program and, if necessary, modify the program so that it complies with the requirements of NAC 459.2572.

NAC 459.2575 is hereby amended to read as follows:

459.2575 Specific licenses: Notifications and reports of medical misadministrations; medical care for individual [patient].

1. A licensee involved in a misadministration shall:

(a) No later than the next calendar day after he discovers the misadministration, notify the division of the misadministration by telephone.

(b) No later than 24 hours after he discovers the misadministration, notify the referring physician of the misadministration.

(c) No later than 24 hours after he discovers the misadministration, notify the individual [patient], or a relative or guardian responsible for the individual [patient], of the misadministration, except that:

(1) He is not required to provide that notification without first consulting with the referring physician or if the referring physician personally informs him that:

(I) The referring physician will provide the notification; or

(II) Based upon the medical judgment of the referring physician, such a notification would be harmful.

(2) He is not required to provide that notification within 24 hours if:

(I) The referring physician, individual [patient], relative or guardian cannot be reached within that time; and

(II) He provides that notification as soon as possible thereafter.

(d) Within 15 days after he discovers the misadministration, submit to the division a written report of the misadministration. The report must state:

(1) The name of the licensee;

(2) The name of the prescribing physician;

(3) A brief description of the misadministration;

(4) The reason the misadministration occurred;

(5) The effect of the misadministration on the individual [patient];

(6) Any corrective action taken to prevent a recurrence; and

(7) Whether the licensee notified the individual [patient], or a relative or guardian responsible for the individual [patient], of the misadministration and:

(I) If not, the reason for not doing so; or

(II) If so, the information provided to the individual [patient], relative or guardian.

The report must not include the name of the individual [patient] or any other information that could lead to the identification of the individual [patient].

(e) Within 15 days after he discovers the misadministration, submit to any individual [patient], relative or guardian who received notification of the misadministration pursuant to paragraph (c), a written report of the misadministration. The report must consist of:

(1) A copy of the report submitted to the division pursuant to paragraph (d); or

(2) A brief description of the misadministration and the possible effects on the individual [patient], and a statement that the report submitted to the division pursuant to paragraph (d) may be obtained from the licensee.

2. A licensee shall not delay any appropriate medical care for a individual [patient], including any remedial care required as a result of a misadministration, because of any delay required to carry out this section.

3. Except for the specific requirements of this section regarding notification, nothing in this section affects the respective rights and duties of any licensee or physician with regard to each other, any individual [patient], or any relative or guardian responsible for any individual [patient].

NAC 459.2576 is hereby amended to read as follows:

459.2576 Specific licenses: Records of written directives, administrations and misadministrations. A licensee shall:

1. Retain a copy of each written directive with which he is involved for at least 3 years following the date of administration.

2. Prepare a record of each administration of a dosage of a radiopharmaceutical or dose of radiation:

(a) In which he is involved; and

(b) For which a written directive is required,

and retain the record for at least 3 years following the date of administration in a form that can be audited.

3. Prepare a record of each review the licensee conducts pursuant to [section 9] NAC 459.2573 of this regulation, which includes the evaluation and findings of each review, and retain the record for at least 3 years in a form that can be audited.

4. Prepare a record of the relevant facts regarding, and any corrective action taken to prevent the recurrence of, a recordable event in which the licensee is involved, and retain the record for at least 3 years in a form that can be audited.

5. Prepare, and retain for at least 5 years, a record of each misadministration in which the licensee is involved. The record must contain:

(a) The name of each person involved in the misadministration, including the [patient] individual who received the misadministration, the referring physician, the prescribing physician and any allied health personnel;

(b) The social security number or other number identifying the [patient] individual, if one has been assigned; and

(c) A brief description of:

(1) The misadministration;

(2) The reason the misadministration occurred;

(3) The effect of the misadministration on the [patient] individual;

(4) Any corrective action necessary to prevent a recurrence; and

(5) Any corrective action taken to prevent a recurrence.

NAC 459.282 is hereby amended to read as follows:

459.282 Manufacture and distribution of devices. An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear

material, to persons generally licensed under NAC 459.216 or equivalent regulations of the Nuclear Regulatory Commission or an agreement state will be approved if:

1. The applicant satisfies the general requirements of NAC 459.238;

2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions and potential hazards of the device to provide reasonable assurance that:

(a) The device can be safely operated by persons not having training in radiological protection;

(b) Under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of 1 year a dose in excess of 10 percent of the limits specified in NAC 459.325;

(c) In an accident such as fire or explosion, associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

(1) Whole body, head and trunk, active blood-forming organs, gonads or lens of eye. .. . . . . 15 rems

(2) Hands and forearms, feet and ankles, localized areas of skin averaged over areas no larger than 1 square centimeter. . . . . 200 rems

(3) Other organs. . . . . 50 rems

3. Each device bears a durable, legible, clearly visible label or labels approved by the division which contain in a clearly identified and separate statement:

(a) Instructions and precautions necessary to assure safe installation, operation and maintenance of the device.

Documents such as operating and service manuals may be identified in the label and used to provide this information;

(b) The requirement, or lack of requirement, for leak testing, or for testing any on-and-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity and date of determination of the quantity; and

(c) The information called for in the following statement, in the same or substantially similar form:

> The receipt, possession, use and transfer of this device model, serial number, are subject to a general license or the equivalent and the regulations of the Nuclear Regulatory Commission of a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercises of regulatory authority. This label must be maintained on the device in a legible condition. Removal of this label is prohibited.

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.....

(Name of manufacturer or distributor)

(d) The model, serial number and name of manufacturer or distributor may be omitted from the label required by this subsection if the information is specified elsewhere and labeling is affixed to the device.

NAC 459.300 is hereby amended to read as follows:

459.300 Manufacture, [and] preparation, or transfer for commercial distribution of radiopharmaceuticals for medical use.

1. An application for a specific license to manufacture, [and] prepare, or transfer for commercial distribut[e]ion radiopharmaceuticals containing radioactive material for use by persons licensed for medical use pursuant to NAC 459.240, 459.242, or 459.258, or by persons authorized under a license issued by the Nuclear Regulatory Commission or any other agreement state will be approved if:

[1](a). The applicant satisfies the general requirements specified in NAC 459.238;

[2](b). The applicant submits evidence that the applicant is at least one of the following:

([a]1) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer; [The radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, as a new drug application approved by the Food and Drug Administration, a biologic product license issued by the administration, or a "Notice of Claimed Investigational Exemption for a New Drug" that has been accepted by the administration; or]

([b]2) Registered or licensed with a state agency as a drug manufacturer [The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Services Act];

(3) Licensed as a pharmacy by a State Board of Pharmacy; or

(4) Operating as a nuclear pharmacy within a medical institution.

[3](c). The applicant submits information on the radionuclide, chemical and physical form, [packaging including] the maximum activity per [package] vial, syringe, generator, or other container of the radiopharmaceutical and shielding provided by the packaging of the radioactive material [which is] to show it is appropriate for safe handling and storage of radiopharmaceuticals by medical use licensees; and

[4](d). The applicant satisfies the following labeling requirements:

([a]1) [The]A label affixed to each [package] transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of the radiopharmaceutical [contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the division for distribution to persons licensed for

medical use pursuant to NAC 459.240, 459.242, or 459.258, or under equivalent licenses of the Nuclear Regulatory Commission or an agreement state. The labels, leaflets, or brochures required by this section are in addition to the labeling required by the Food and Drug Administration and they may be separate from or, with the approval of the administration, may be combined with the labeling required by the administration.] to be transferred for commercial distribution. The label must include the radiation symbol and the words ``CAUTION, RADIOACTIVE MATERIAL'' or ``DANGER, RADIOACTIVE MATERIAL''; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radiopharmaceuticals with a half life greater than 100 days, the time may be omitted.

(2) A label is affixed to each syringe, vial, or other container used to hold a radiopharmaceutical to be transferred for commercial distribution. The label must include the radiation symbol and the words ``CAUTION, RADIOACTIVE MATERIAL'' or ``DANGER, RADIOACTIVE MATERIAL'' and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. A licensee described by subsection 1.(b)(3) or (4):

(a) May prepare radiopharmaceuticals for medical use, as defined in Section 3, provided that the radiopharmaceutical is prepared by either an authorized nuclear pharmacist, as specified in subsection 2.(b) and 2.(c), or an individual under the supervision of an authorized nuclear pharmacist as specified in Section 2.

(b) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(1) This individual qualifies as an authorized nuclear pharmacist as defined in Section 2,

(2) This individual meets the requirements specified in Section 14.(b) and NAC 459.3966 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(3) This individual is designated as an authorized nuclear pharmacist in accordance with subsection 2.(c).

(c) The actions authorized in subsection 2.(a) and 2.(b) are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist (as defined in NAC 459.062) as an authorized nuclear pharmacist if the individual is identified as of August 31, 1998, as an “authorized user'' on a nuclear pharmacy license issued by the division, the Nuclear Regulatory Commission or an agreement state.

(e) Shall provide to the division a copy of each individual's certification by the Board of Pharmaceutical Specialties, the division, Nuclear Regulatory Commission or agreement state license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to subsection 2.(b)(1) and 2.(b)(3), the individual to work as an authorized nuclear pharmacist.

3. A licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceuticals. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radiopharmaceuticals prior to transfer for commercial distribution. In addition, the licensee shall:

(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(b) Check each instrument for constancy and proper operation at the beginning of each day of use.

4. Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radiopharmaceuticals.

NAC 459.314 is hereby amended to read as follows:

459.314 Transportation: Preparation of radioactive material.

1. No licensee may deliver any radioactive material to a carrier for transport, unless:

(a) The licensee complies with the applicable requirements of the regulations, appropriate to the mode of transport of the Department of Transportation [relating to the packing of radioactive material and to the monitoring, marking and labeling of those packages];

(b) The licensee has established procedures for opening and closing a package in which radioactive material is transported to provide safety to and ensure that prior to the delivery to a carrier for transport, each package is properly closed for transport; and

(c) Prior to delivery of a package to a carrier for transport, the licensee must assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

2. For the purpose of subsection 1, a licensee who transports his own licensed material as a private carrier is considered to have delivered such material to a carrier for transport.

3. Subsection 1 does not apply to the transportation of licensed material, or to the delivery of licensed material to a carrier for transport, where the transportation is subject to the regulations of the Postal Service.

NAC 459.320 is hereby amended to read as follows:

459.320 Purpose; applicability; reasonable effort required.

1. NAC 459.320 to 459.374, inclusive, establish standards for protection against radiation hazards. It is the purpose of those sections to control the receipt, possession, use, disposal and transfer of licensed or registered sources of radiation by any licensee or registrant in such a manner that the total dose to a person, including exposures to licensed or unlicensed or registered or unregistered sources of radiation, whether in the possession of the licensee, registrant or any other person, but not including exposure to radiation from natural background sources or medical diagnosis and therapy, does not exceed the standards of radiation protection prescribed in those sections. Those sections will not be construed as limiting actions that may be necessary to protect the health and safety of the public.

2. Except as otherwise specifically provided, NAC 459.320 to 459.374, inclusive, apply to all licensees or registrants. Those sections do not limit the intentional exposure of [patients] individuals to radiation [for the purpose of medical diagnosis or therapy] for any medical administration the individual has received or the intentional exposure of persons to radiation who are voluntarily participating in programs for medical research.

3. In addition to complying with the requirements set forth in NAC 459.320 to 459.374, inclusive, a licensee or registrant shall make every reasonable effort to maintain exposures and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable.

NAC 459.349 is hereby amended to read as follows:

459.349 Precautionary procedures: Use of individual respiratory protective devices.

1. If a licensee uses respiratory protective devices to limit intakes as required pursuant to NAC 459.347, he shall comply with the following requirements:

(a) Except as otherwise provided in paragraph (b), the licensee shall use only a respiratory protective device that is tested and certified, or has had certification extended, by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

(b) If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorization to use that equipment. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. The evidence must be acquired from testing the equipment or based on information obtained from other reliable tests that have been performed on the equipment.

(c) The licensee shall carry out a program for respiratory protection that includes:

(1) A sampling of the air that is sufficient to identify any potential hazard, permit the proper selection of equipment and estimate exposures;

(2) Surveys and bioassays, as appropriate, to evaluate actual intakes;

(3) Testing respiratory protective devices for operability immediately before each use;

(4) Written procedures regarding the selection, fitting, issuance, maintenance and testing of respiratory protective devices, including procedures for:

(I) Testing for operability immediately before each use;

(II) The supervision and training of personnel;

(III) Recordkeeping; and

(IV) Monitoring, including sampling air and bioassays; and

(5) The determination by a physician before the initial fitting of respiratory protective devices, and [at least] either once every 12 months [after the initial fitting] thereafter or periodically at a frequency determined by a physician, that each user is [physically able] medically fit to use the respiratory protective device.

(d) The licensee shall issue a written statement of policy regarding the use of respiratory protective devices that includes:

(1) The use of process or other engineering controls, instead of respiratory protective devices;

(2) The routine, nonroutine and emergency use of respiratory protective devices; and

(3) The length of use of respiratory protective devices, and relief from such use.

(e) The licensee shall advise each user of a respiratory protective device that the user may leave the area at any time if:

(1) The device malfunctions;

(2) He suffers physical or psychological distress;

(3) There is a failure of communication or a failure to comply with procedural requirements;

(4) There is a significant deterioration in the operating conditions; or

(5) There are any other conditions that might require relief from use of the device.

(f) The licensee shall use respiratory protective devices within the manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication and other special capabilities when needed.

2. When estimating the exposure of persons to airborne radioactive materials, the licensee may make allowance for respiratory protective devices used to limit intakes pursuant to NAC 459.347, if the following conditions, in addition to those specified in subsection 1, are satisfied:

(a) The licensee selects a respiratory protective device that provides a protection factor, as specified in appendix A, which is greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in column 3 of table I of appendix B. If the selection of a respiratory protective device with a protection factor greater than the [peak concentration] multiple defined in the preceding sentence is inconsistent with the requirement specified in NAC 459.347 for keeping the total effective dose equivalent as low as is reasonably achievable, the licensee may select a respiratory protective device with a lower protection factor only if such a selection would result in a total effective dose equivalent that is as low as is reasonably achievable. The concentration of radioactive material in the air that is inhaled when the respiratory protective device is worn may be initially estimated by dividing the average concentration in the 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 must be used. If the exposure is later found to be less than initially estimated, the corrected value may be used.

(b) A licensee shall obtain authorization from the division before assigning respiratory protection factors in excess of those specified in appendix A. The division may authorize a licensee to use higher protection factors upon receipt of an application that:

(1) Describes the situation for which a need exists for higher protection factors; and

(2) Demonstrates that the respiratory protective device provides these higher protection factors under the proposed conditions of use.

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

4. The licensee shall notify the division in writing at least 30 days before the date that a respiratory protective device is first used pursuant to subsection 1 or 2.

NAC 459.3625 is hereby amended as follows:

459.3625 General requirements for preparation and retention of records.

1. Each licensee and registrant shall use the units curie, rad, rem and roentgen, including multiples and subdivisions thereof, to prepare the records required by NAC 459.010 to 459.950, inclusive, and shall clearly indicate the units of all quantities entered on those records.

2. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by NAC 459.010 to 459.950, inclusive.

3. A discontinuance or curtailment of the activities of a licensee or registrant does not relieve that licensee or registrant of the responsibility for retaining all records required by NAC 459.010 to 459.950, inclusive. A licensee or registrant may request the division to retain such records. An acceptance of the records by the division relieves the licensee or registrant of subsequent responsibility only in respect to their retention as required by this section.

4. Not withstanding the requirements of subsection 1, when recording information on shipment manifests, as required in 459.823, information must be recorded in the International System of Units (SI) or in SI and units as specified in subsection 1.

NAC 459.365 is hereby amended to read as follows:

459.365 Records of prior occupational doses [received by persons entering restricted areas].

1. For each person [who enters the restricted area of a licensee or registrant and is] likely to receive, in 1 year, an occupational dose requiring monitoring pursuant to NAC 459.339, the licensee or registrant shall:

(a) Determine the occupational dose received by that person during the current year; and

(b) Attempt to obtain the records of the lifetime cumulative occupational radiation dose received by that person.

2. Before permitting a person to participate in a planned special exposure, the licensee or registrant shall determine:

(a) The internal and external doses received by that person from all previous planned special exposures;

(b) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the person; and

(c) All lifetime cumulative occupational doses.

3. To comply with the requirements of subsection 1, a licensee or registrant may:

(a) Accept, as a record of the occupational dose that the person received during the current year, a signed written statement from the person, or from his most recent employer for work involving exposure to radiation, that discloses the nature and the amount of any occupational dose that the person received during the current year.

(b) Accept, as the record of the lifetime cumulative dose received by a person, a current form regarding history of cumulative occupational exposure, signed by the person and countersigned by:

(1) An appropriate official of the most recent employer of the person for work involving exposure to radiation; or

(2) The current employer of the person, if the person is not employed by the licensee or registrant.

(c) Obtain reports regarding the dose equivalent of a person from his most recent employer for work involving exposure to radiation, or the current employer of the person if he is not

employed by the licensee or registrant, by telephone, telegram, facsimile, electronic media or letter. The licensee or registrant shall request a written verification of the data if the authenticity of the transmitted report cannot be established.

4. A licensee or registrant shall record the history of exposure of each person, as required by subsection 1, on a form regarding history of cumulative occupational exposure, and shall include all the information required by that form. The form must show each period in which the person received occupational exposure to radiation or radioactive material and must be signed by that person. For each period for which the licensee or registrant obtains a report, the licensee or registrant shall use the dose shown in the report in preparing the form regarding history of cumulative occupational exposure. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on the form regarding history of cumulative occupational exposure indicating the periods for which data is not available.

5. Licensees and registrants are not required to reevaluate the separate dose equivalents received from sources of radiation outside the body and committed dose equivalents or intakes of radionuclides received from radioactive material taken into the body that are assessed before the effective date of this regulation. Histories of occupational exposure obtained and recorded on the form regarding history of cumulative occupational exposure before the effective date of this regulation may be used in the absence of specific information regarding the intake of radionuclides by the person.

6. If the licensee or registrant is unable to obtain a complete record of the current and previously accumulated occupational dose of a person, the licensee or registrant shall:

(a) In establishing administrative controls pursuant to subsection 6 of NAC 459.325 for the current year, assume that the allowable limits for the person are reduced by 1.25 rems for each quarter for which records were unavailable and the person was engaged in activities that could have resulted in occupational exposure; and

(b) Assume that the person is not available for planned special exposures.

7. The licensee or registrant shall retain the records on the form regarding history of cumulative occupational exposure until the division terminates each license or registration requiring the records. The licensee or registrant shall retain each record used in preparing the form regarding history of cumulative occupational exposure for at least 3 years after that record is made.

NAC 459.3605 is hereby amended to read as follows:

459.3605 Disposal of waste: Release into sanitary sewerage.

1. Except as otherwise provided in subsection 2, a licensee may discharge licensed radioactive material into sanitary sewerage only if each of the following conditions is satisfied:

(a) The material is readily soluble in water, or is readily dispersible biological material in water.

(b) The quantity of all radioactive material that the licensee releases into the sanitary sewerage in 1 month divided by the average monthly volume of water released into the sanitary sewerage by the licensee does not exceed the concentration of radioactive material listed in table 3 of appendix B.

(c) The total quantity of all radioactive material that the licensee releases into the sanitary sewerage in 1 year does not exceed 5 curies of hydrogen-3, 1 curie of carbon-14 [or] and 1 curie of all other radioactive materials combined.

(d) If more than one radionuclide is released:

(1) The licensee determines the fraction of the limits in table 3 of appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sanitary sewerage by the concentration of that radionuclide listed in table 3 of appendix B; and

(2) The sum of the fractions for each radionuclide required by subparagraph (1) does not exceed unity.

2. Excreta from persons undergoing medical diagnosis or therapy with radioactive material is not subject to the limitations contained in subsection 1.

NAC 459.3695 is hereby amended to read as follows:

459.3695 Report of certain incidents.

1. Each licensee and registrant shall immediately report to the division each event involving a source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause:

(a) A person to receive:

(1) A total effective dose equivalent of 25 rems or more;

(2) An eye dose equivalent of 75 rems or more; or

(3) A shallow-dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rads or more.

(b) The release of radioactive material, inside or outside a restricted area, in a manner in which, had a person been present for 24 hours, the person could have received an intake of radiation that is five times the annual limit on intake for occupational exposure. The provisions of this paragraph do not apply to an area where personnel are not normally stationed during routine operations.

2. Except as otherwise provided in NAC 459.369, each licensee and registrant shall, within 24 hours after discovery, report to the division each event involving the 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:

(a) A person to receive, in a period of 24 hours:

(1) A total effective dose equivalent exceeding 5 rems;

(2) An eye dose equivalent exceeding 15 rems; or

(3) A shallow-dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rems.

(b) The release of radioactive material, inside or outside a restricted area, in a manner in which, had a person been present for 24 hours, the person could have received an intake of radiation that is in excess of one [five times the] annual limit on intake for occupational exposure. The provisions of this paragraph do not apply to an area where personnel are not normally stationed during routine operations.

3. The licensee or registrant shall prepare each report filed with the division pursuant to this section so that the names of persons who have received exposure are stated in a separate and detachable portion of the report.

4. Licensees or registrants shall make the reports required by subsections 1 and 2 to the division by telephone, telegram, mailgram or facsimile.

5. The provisions of this section do not apply to doses that result from planned special exposures, if such doses are within the limits for planned special exposures and are reported pursuant to NAC 459.371.

NAC 459.381 is hereby amended to read as follows:

459.381 Conditions which require amendment to license. A licensee possessing a license authorizing the use of radioactive materials in medical procedures must apply for and receive an amendment to his license before he:

1. Receives or uses any radioactive material for a clinical procedure not specifically permitted by the license.

2. Permits any person to work as an authorized user or authorized nuclear pharmacist under the license[.] except an individual who is:

(a) An authorized user certified by the organizations specified in paragraph (a) of NAC 459.3944, 459.3946, 459.3948, 459.3954, Section 12, or 459.3958;

(b) An authorized nuclear pharmacist certified by the organization specified in paragraph (a) of Section 14;

(c) Identified as an authorized user or an authorized nuclear pharmacist on a Nuclear Regulatory Commission or agreement state license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or

(d) Identified as an authorized user or an authorized nuclear pharmacist on a permit issued by a Nuclear Regulatory Commission or agreement state specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

3. Changes radiation safety officers or teletherapy physicists.

4. Orders radioactive material:

(a) In excess of the amount authorized by the license;

(b) In a form different than authorized by the license; or

(c) Not authorized by the license.

5. Adds to or changes:

(a) Any address of use;

(b) Any area of use; or

(c) Any restricted area.

NAC 459.3824 is hereby amended to read as follows:

459.3824 Committee on radiation safety: Meetings; quorum; minutes; duties; records of minor changes in procedures for radiation safety.

1. If established, a committee on radiation safety shall meet at least quarterly, and:

(a) A quorum consisting of at least one-half of the membership of the committee, including the radiation safety officer and a representative of management, must be present to conduct a meeting.

(b) The minutes of each meeting must be recorded and include the following information:

(1) The date of the meeting;

(2) Names of members present;

(3) Names of members absent;

(4) Summary of deliberations and discussions;

(5) Recommended actions and the numerical results of all ballots; and

(6) Any reviews made of the program for radiation safety and on the adequacy of the program to keep radiation exposures as low as is reasonably achievable.

(c) Promptly provide each member with a copy of the minutes of the meeting and retain one copy for the duration of the license of the licensee.

2. To oversee the use of radioactive material, the committee shall:

(a) Review recommendations on ways to maintain individual and collective doses of radiation as low as is reasonably achievable;

(b) Review, on the basis of safety and with regard to required training and experience, standards provided in NAC 459.394 to 459.3966 and Sections 13 through 15, inclusive, and approve or disapprove any person who is to be listed as an authorized user, an authorized nuclear pharmacist, the radiation safety officer, or a teletherapy physicist before submitting an application for a license or a request for the amendment or renewal thereof;

(c) Review, pursuant to 459.381.2.(a) through 2.(d), on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allow that individual to work as an authorized user or authorized nuclear pharmacist;

([c]d) Review on the basis of safety and approve with the advice and consent of the radiation safety officer and a representative of management, or disapprove, minor changes in the procedures for radiation safety that are not potentially important to safety and that were described in the application for a license, or the renewal or amendment thereof;

([d]e) Review quarterly, with the assistance of the radiation safety officer, a summary of the records of the occupational dose of all personnel working with radioactive material;

([e]f) Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material to determine the cause of the incidents and recommend subsequent actions to be taken; and

([f]g) Review annually, with the assistance of the radiation safety officer, the program for radiation safety.

3. A licensee shall retain a record of each change made pursuant to paragraph (d) of subsection 2 until his license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new procedures for radiation safety, the reason for the change, a summary of the matters concerning radiation safety that were considered before making the change, and, if applicable, the signatures of the chairman of the committee on radiation safety, the radiation safety officer, and the representative of management.

NAC 459.383 is hereby amended to read as follows:

459.383 Syringes containing radioactive material.

1. A licensee shall keep syringes that contain radioactive material to be administered to patients or human research subjects in a radiation shield.

2. Each syringe that contains a radiopharmaceutical or each radiation shield which contains such a syringe must be conspicuously labeled by the licensee to identify its contents. The label must identify the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the name of the patient or human research subject.

3. A licensee shall require each person who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient or human research subject.

NAC 459.3841 is hereby amended to read as follows:

459.3841 Radiation surveys of areas used for preparation, administration, or storage of radiopharmaceuticals or waste of radiopharmaceuticals; records.

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

2. A least once each week a licensee shall survey with a radiation detection survey instrument all areas where radiopharmaceuticals or the waste of radiopharmaceuticals are stored.

3. A licensee shall conduct the surveys required pursuant to subsections 1 and 2 to detect dose rates as low as 0.1 millirem per hour.

4. A licensee shall:

(a) Establish limits for rates of radiation dosage for the surveys required by subsections 1 and 2; and

(b) Require the person who performs the survey to notify the radiation safety officer immediately if the [rate of dosage] dose rate measured exceeds the established limit.

5. Once each week a licensee shall make a radiation survey for removable radioactive contamination in all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

6. A licensee shall conduct the surveys required by subsection 5 to detect a minimum radioactive contamination level on each wipe sample of 2000 disintegrations per minute.

7. A licensee shall:

(a) Establish limits for removable radioactive contamination for the surveys required by subsection 5; and

(b) Require the person who performs the survey to inform the radiation safety officer immediately if the amount of radioactive contamination measured exceeds the established limit.

8. A licensee shall retain a record of each survey for at least 3 years. Each record must include:

(a) The date of the survey;

(b) A plan drawing of each area surveyed;

(c) The limits established for levels of radiation or radioactive contamination for each area;

(d) The detected radiation level at several points in each area expressed in millirems per hour and the removable radioactive contamination level at several points in the area expressed in disintegrations per minute per 100 square centimeters;

(e) The identity of the survey instruments used to make the survey and to analyze the wipe samples; and

(f) The initials of the person who performed the survey.

NAC 459.3861 is hereby amended to read as follows:

459.3861 Duties of licensee for patient or human research subject receiving radiopharmaceutical therapy; records.

1. A licensee shall, for each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with NAC 459.256:

(a) Provide a private room with a private sanitary facility.

(b) Post on the outside of the door to the room a sign bearing the radiation symbol and the words "RADIOACTIVE MATERIALS," and post a note on the door or in the chart of the patient or human research subject describing where and how long visitors may stay in the room of the patient or human research subject.

(c) Authorize visits by persons under 18 years of age only on a [patient-by-patient] case-by-case basis with the approval of the authorized user after he has consulted with the radiation safety officer.

(d) Promptly after administration of the dosage, measure the [rate of dosage] dose rate in the contiguous restricted and unrestricted areas with a radiation survey instrument to demonstrate compliance with the prescribed [rates of dosage] dose rates for those areas. The licensee shall retain a record of each survey for at least 3 years. Each record must include:

(1) The time and date of the survey;

(2) A plan drawing of the area or list of points surveyed;

(3) The measured dose rate at several points expressed in millirems per hour;

(4) The identity of the survey instruments used to make the survey; and

(5) The initials of the person who performed the survey.

(e) Either monitor material and items removed from the room of the patient or human research subject to determine that their radioactivity cannot be distinguished from background radiation with a radiation detection instrument set on its most sensitive scale and with no interposed shielding, or handle the items removed from the room of the patient or human research subject as radioactive waste.

(f) Provide the patient or the human research subject 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 or the human research subject.

([f]g)Survey the patient's or human research subject's room and private sanitary facility with a radiation detection instrument for removable contamination before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters.

([g]h) Measure the thyroid burden of each person who helped prepare or administer a dosage of iodine-131 within 3 days after administering the dosage. The licensee shall retain a record of the measurement which must also contain the date of measurement, the name of the person

whose thyroid burden was measured, and the initials of the person who made the measurements, until the division authorizes disposition.

([h]i) Notify the radiation safety officer immediately if the patient or human research subject dies or has a medical emergency.

NAC 459.3864 is hereby amended to read as follows:

459.3864 Tests for leakage, physical inventories, and radiation surveys of certain sources and areas of storage of certain sources; records.

A licensee in possession of a sealed source, a brachytherapy source, except one containing iridium- 192 encased in nylon, or a teletherapy source, shall:

1. Test every source for leakage and report in accordance with the provisions of NAC 459.307 each source that is leaking. In the case of radium sources the leak test must be capable of detecting the escape of radon at the rate of 0.001 microcurie per 24 hours. If the leak test on a radium source detects the escape of radon at the rate of 0.001 microcurie or more in 24 hours, the source must be considered to be leaking.

2. Conduct a physical inventory of all sealed sources in his possession, except any teletherapy source in teletherapy units, at least [once each quarter] quarterly. The licensee shall retain each inventory record for at least 5 years. The records of inventory must contain the model number of each source, the serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, and the signature of the radiation safety officer.

3. At least [once each quarter] quarterly, conduct with a radiation detection instrument a survey of all areas where sealed sources are stored to determine ambient dose rates. This requirement is not applicable to teletherapy sources in teletherapy units. 4. Retain a record of each survey required in subsection 3 for at least 3 years. Each record must include:

(a) The date of the survey;

(b) A plan drawing of the area that was surveyed;

(c) The measured dose rate at several points in each area expressed in millirems per hour;

(d) The identity of the survey instrument used; and

(e) The signature of the radiation safety officer.

NAC 459.3871 is hereby amended to read as follows:

459.3871 Brachytherapy sources: Return to storage area; radiation survey after use; records.

1. A licensee shall, after removing brachytherapy sources from a patient or human research subject, promptly return the 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 the use of brachytherapy sources, which must include:

(a) The names of the persons permitted to handle the sources;

(b) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the patient or human research subject and room number, the number and activity of the sources in storage after the removal, and the initials of the person who removed the sources from storage; and

(c) The number and activity of the sources returned to storage, the time and date they were returned to storage, the patient's or human research subject's name and room number, the

number and activity of the sources in storage after the return, and the initials of the person who returned the sources to storage.

3. Immediately after implanting sources in a patient or human research subject a licensee shall make a radiation survey of the patient or human research subject 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 for at least 3 years the records required by subsections 2 and 3.

NAC 459.3875 is hereby amended to read as follows:

459.3875 Implant therapy: Instruction for persons caring for patient or human research subject; records regarding instruction.

1. A licensee shall provide instruction on radiation safety to all persons caring for a patient or human research subject undergoing implant therapy. To satisfy this requirement, the instruction must describe:

(a) The size and appearance of the brachytherapy sources;

(b) Procedures for the safe handling of, and instructions for shielding in case of, a dislodged source;

(c) Procedures for patient or human research subject control;

(d) Procedures for visitor control; and

(e) Procedures for notifying the radiation safety officer if the patient or human research subject dies or has a medical emergency.

2. A licensee shall retain for at least 3 years a record of persons receiving instruction required by subsection 1, a description of the instruction, the date of instruction, and the name of the person who gave the instruction.

NAC 459.3881 is hereby amended to read as follows:

459.3881 Implant therapy: Duties of licensee regarding patient or human research subject. A licensee shall, for each patient or human research subject receiving implant therapy:

1. Ensure that the patient or human research subject is not placed in the same room with another patient or human research subject who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirements of NAC 459.335 at a distance of 1 meter from the implant.

2. Post on the outside of the door to the room of the patient or human research subject a sign bearing the radiation symbol and the words "RADIOACTIVE MATERIALS," and post a note on the door or in the chart of the patient or human research subject describing where and how long visitors may stay in the room of the patient or human research subject.

3. Authorize visits by persons under 18 years of age only on a [patient-by-patient] case-by-case basis with the approval of the authorized user after he has consulted with the radiation safety officer.

4. Promptly after implanting the brachytherapy sources, survey the [rate of dosage] dose rate in contiguous restricted and unrestricted areas with a radiation survey instrument to demonstrate compliance with the limits of radiation specified for those areas. The licensee shall retain a record of each survey for at least 3 years. Each record must include:

(a) The time and date of the survey;

(b) A plan drawing of each area surveyed;
(c) The measured [rate of dosage] dose rate at several points expressed in millirems per hour;
(d) The identity of the survey instruments used to make the survey; and
(e) The initials of the person who performed the survey.
5. Provide the patient or human research subject with radiation safety guidance that will help to keep the radiation dose to household members and the public as low as reasonably achievable before releasing the individual if the individual was administered a permanent implant.
[5]6. Notify the radiation safety officer immediately if the patient or human research subject dies or has a medical emergency.

NAC 459.3895 is hereby amended to read as follows:

459.3895 Teletherapy: Posting of instructions at unit; instruction for operators of unit; records regarding instruction.
1. A licensee shall post instructions at the teletherapy unit console which inform the operator of:
(a) The procedure to be followed to ensure that only the patient or human research subject is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;
(b) The procedure to be followed if the operator is unable to turn the primary beam of radiation off with controls outside the treatment room or if any other abnormal operation occurs; and
(c) The names and telephone numbers of the authorized users and the radiation safety officer to be contacted immediately if the teletherapy unit or console operates abnormally.
2. A licensee shall provide instruction concerning the information specified in subsection 1 to all persons who operate a teletherapy unit.
3. A licensee shall retain for at least 3 years a record of all persons receiving instruction pursuant to subsection 2, which must include:
(a) A description of the instruction;
(b) The date of instruction; and
(c) The name of the person who gave the instruction.

NAC 459.3901 is hereby amended to read as follows:

459.3901 Teletherapy: General requirements for room and protection of persons entering room; records.
1. A licensee shall control access to the room for teletherapy by a door at each entrance.
2. A licensee shall equip each entrance to the room for teletherapy with an electrical interlock system that will:
(a) Prevent the operator from turning the primary beam of radiation on unless the entrance door for each treatment room 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 entrance doors to the treatment room are closed and the beam on-off control is reset at the console.

3. A licensee shall equip each entrance to the room for teletherapy with a light that indicates the condition of the beam.

4. A licensee shall install in each room for teletherapy a permanent radiation monitor which must:

(a) Be capable of continuously monitoring the status of the beam of radiation.

(b) Provide visible notice of a malfunction of the teletherapy machine that results in an exposed or partially exposed source, and must be observable by a person entering the room for teletherapy.

(c) Be equipped with a back-up power supply separate from the power supply to the teletherapy unit. The back-up power supply may be a battery system.

(d) Be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for the treatment of patients or human research subjects.

5. A licensee shall maintain a record for at least 3 years of the checks required by paragraph (d) of subsection 4. The record must include:

(a) The date of each check;

(b) A notation that the monitor indicates when its detector is and is not exposed; and

(c) The initials of the person who performed each check.

6. If a radiation monitor is inoperable, a licensee shall require each person 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 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 subsection 5.

7. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

8. A licensee shall construct or equip each room for teletherapy to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

NAC 459.394 is hereby amended to read as follows:

459.394 Qualifications of radiation safety officer. Except as otherwise provided in NAC 459.3942, a licensee shall require the person fulfilling the responsibilities of the radiation safety officer as provided in NAC 459.3821:

1. To be certified by one of the following organizations:

(a) The American Board of Health Physics, in Comprehensive Health Physics;

(b) The American Board of Radiology;

(c) The American Board of Nuclear Medicine;

(d) The American Board of Science, in Nuclear Medicine; [or]

(e) The Board of Pharmaceutical Specialties, in Nuclear Pharmacy;

(f) The American Board of Medical Physics in radiation oncology physics;

(g) The Royal College of Physicians and Surgeons of Canada in nuclear medicine;

(h) The American Osteopathic Board of Radiology; or

(i) The American Osteopathic Board of Nuclear Medicine; or

2. To have classroom and laboratory training and experience as follows:

(a) At least 200 hours of classroom and laboratory training that included:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology; and

(5) Radiopharmaceutical chemistry; and

(b) At least 1 year of full-time experience as a radiation safety technologist at a medical institution under the supervision of the person identified as the radiation safety officer on a license issued by the State of Nevada, the Nuclear Regulatory Commission, or an agreement state that authorizes the medical use of radioactive material; or

3. To be an authorized user on the license of the licensee.

NAC 459.3944 is hereby amended to read as follows:

459.3944 Qualifications of authorized user of radiopharmaceutical in uptake, dilution, or excretion studies. Except as otherwise provided in NAC 459.3962 and 459.3964, a licensee shall require the authorized user of a radiopharmaceutical in uptake, dilution, or excretion studies to be a physician who:

1. Is certified in one of the following specialties:

(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;

(d) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(e) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

2. Has received classroom and laboratory training in basic radioisotope techniques applicable to the use of prepared radiopharmaceuticals, and has the following supervised clinical experience:

(a) At least 40 hours of classroom and laboratory training that included:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology; and

(5) Radiopharmaceutical chemistry; and

(b) At least 20 hours of supervised clinical experience under the supervision of an authorized user which included:

(1) Examining [persons] patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(2) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(3) Administering dosages to patients or human research subjects and using radiation shields for syringes;

(4) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(5) Patient or human research subject follow-up; or

3. Has successfully completed a 6-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 which included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in subsection 2.

NAC 459.3946 is hereby amended to read as follows:

459.3946 Qualifications of authorized user of radiopharmaceutical, generator, or reagent kit in imaging or localization studies. Except as otherwise provided in NAC 459.3962 and 459.3964, a licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in imaging or localization studies to be a physician who:

1. Is certified in one of the following specialties:

(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 Royal College of Physicians and Surgeons of Canada; or

(e) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

2. Has received classroom and laboratory training in basic techniques for handling radioisotopes applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, and has the following supervised work experience and supervised clinical experience:

(a) At least 200 hours of classroom and laboratory training that included:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiopharmaceutical chemistry; and

(5) Radiation biology;

(b) At least 500 hours of supervised work experience under the supervision of an authorized user that included:

(1) Ordering, receiving, and safely unpacking radioactive materials and performing related radiation surveys;

(2) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(3) Calculating and safely preparing dosages for patients or human research subjects;

(4) Using administrative controls to prevent the misadministration of radioactive material;

(5) Using procedures to contain safely radioactive material which has spilled and using proper procedures for decontamination; and

(6) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(c) At least 500 hours of supervised clinical experience under the supervision of an authorized user that included:

(1) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(2) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(3) Administering dosages to patients or human research subjects and using radiation shields for syringes;

(4) Collaborating with authorized user in the interpretation of results of the radioisotope test; and

(5) Patient or human research subject follow-up; or

3. Has successfully completed a 6-month program for training in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and which included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in subsection 2.

NAC 459.3948 is hereby amended to read as follows:

459.3948 Qualifications of authorized user of radiopharmaceuticals in therapeutic [procedures] use of unsealed radioactive material. Except as otherwise provided in NAC 459.3962, a licensee shall require an authorized user of radiopharmaceuticals in therapeutic procedures to be a physician who:

1. Is certified by one of the following organizations:

(a) The American Board of Nuclear Medicine;

(b) The American Board of Radiology in radiology, [or] therapeutic radiology, or radiation oncology; [or]

(c) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(d) The American Osteopathic Board of Radiology after 1984; or

2. Has received classroom and laboratory training in basic radioisotope techniques applicable to the use of therapeutic radiopharmaceuticals, and has the following supervised clinical experience:

(a) At least 80 hours of classroom and laboratory training that included:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user at a medical institution which included:

(1) The use of iodine-123 or iodine-131 for diagnosis of thyroid function and the use of iodine-131 for treatment of hyperthyroidism or cardiac dysfunction in at least 10 persons; and

(2) The use of iodine-131 for treatment of thyroid carcinoma in at least three persons.

NAC 459.3954 is hereby amended to read as follows:

459.3954 Qualifications of authorized user of brachytherapy source in therapy procedures. Except as otherwise provided in NAC 459.3962, a licensee shall require an authorized user of a brachytherapy source in therapy procedures to be a physician who:

1. Is certified in one of the following specialties:

(a) Radiology, [or] therapeutic radiology, or radiation oncology 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 an active practice of therapeutic radiology, who has received classroom and laboratory training in basic techniques for the handling of radioisotopes applicable to the therapeutic use of brachytherapy sources, and who has the following supervised work experience and supervised clinical experience:

(a) At least 200 hours of classroom and laboratory training which included:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology;

(b) At least 500 hours of supervised work experience under the supervision of an authorized user at a medical institution which included:

(1) Ordering, receiving, and safely unpacking radioactive material and performing related radiation surveys;

(2) Checking survey meters for proper operation;

(3) Preparing, implanting, and removing sealed sources;

(4) Maintaining accurate inventories of brachytherapy sources;

(5) Using administrative controls to prevent the misadministration of radioactive material; and

(6) Using procedures for emergencies to control radioactive material; and

(c) At least 3 years of supervised clinical experience that included at least 1 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 at least an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that included:

(1) Examining persons and reviewing their case histories to determine their suitability for brachytherapy treatment and any limitations or contraindications;

(2) Selecting the proper brachytherapy sources and dose and method of administration;

(3) Calculating the dose; and

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

NAC 459.3958 is hereby amended to read as follows:

459.3958 Qualifications of authorized user of sealed source in teletherapy unit. Except as otherwise provided in NAC 459.3962, a licensee shall require an authorized user of a sealed source in a teletherapy unit to be a physician who:

1. Is certified in one of the following specialties:

(a) Radiology, [or] therapeutic radiology or radiation oncology 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, who has received classroom and laboratory training in basic techniques for the handling of radioisotopes applicable to the use of a sealed source in a teletherapy unit, and who has the following supervised work experience and supervised clinical experience:

(a) At least 200 hours of classroom and laboratory training that included:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology;

(b) At least 500 hours of supervised work experience under the supervision of an authorized user at a medical institution which included:

(1) Reviewing the full calibration measurements and periodic spot checks;

(2) Preparing treatment plans and calculating treatment times;

(3) Using administrative controls to prevent misadministrations;

(4) Implementing procedures for emergencies to be followed in the event of the abnormal operation of a teletherapy unit or console; and

(5) Checking and using survey meters; and

(c) At least 3 years of supervised clinical experience that included at least 1 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 at least an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution which included:

(1) Examining persons and reviewing their case histories to determine their suitability for teletherapy treatment and any limitations or contraindications;

(2) Selecting the proper dose and how it is to be administered;

(3) Calculating the teletherapy doses and collaborating with the authorized user in the review of the progress of patients or human research subjects and consideration of the need to modify originally prescribed doses as warranted by the reaction of patients or human research subjects to radiation; and

(4) Post-administration follow-up and review of case histories.

NAC 459.396 is hereby amended to read as follows:

459.396 Qualifications of teletherapy physicist. A licensee shall require the teletherapy physicist to be a person who:

1. Is certified by the American Board of Radiology in:

(a) Therapeutic radiology physics;

(b) Roentgen ray and gamma ray physics;

(c) X-ray and radium physics; or

(d) Radiological physics; or

2. Is certified by the American Board of Medical Physics in radiation oncology physics; or

[2]3. Holds a master's or doctorate degree in physics, biophysics, radiological physics, or health physics, and has completed at least 1 year of full-time training in therapeutic radiological physics and at least an additional 1 year of full-time work experience under the supervision of a teletherapy physicist at a medical institution that included the tasks stated in NAC 459.3864, 459.3914, 459.3917, and 459.3924.

NAC 459.3966 is hereby amended to read as follows:

459.3966 Time requirement for training and experience of applicant to become authorized user. The training and experience specified in NAC 459.394 to 459.396, inclusive, must have been obtained within the [5] 7 years immediately preceding the date of application of the person to become an authorized user on a license, or the person must have had related continuous education and experience since the required training and experience was completed

NAC 459.418 is hereby amended to read as follows:

459.418 "Coefficient of variation" defined. "Coefficient of variation," abbreviated as "C," means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C \text{ (Coefficient of Variation)} = \frac{S}{\bar{X}} = \frac{1}{\bar{X}} \left[\sum_{i=1}^{n} \frac{(Xi - \bar{X})^2}{n - 1} \right]^{1/2}$$

where

s = Estimated standard deviation of the population.

$\bar{X}$ = Mean value of observations in sample.
Xi = ith observation in sample.
n = Number of observations in sample.

NAC 459.713 is hereby amended to read as follows:

459.713 Equipment control: Radiographic exposure devices and associated equipment.
1. A radiographic exposure device in which a sealed source of radioactive material is used and any associated equipment must comply with the requirements set forth in the American National Standards, Inc., Standard N43.9-1991, entitled "For Gamma Radiography - Specifications, Design and Testing of Apparatus," which is hereby adopted by reference. The publication may be purchased from the American National Standards Institute, Inc., 11 West 42nd Street, New York, New York 10036, for the price of $43 per copy.
2. Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiographic equipment

components. Upon review, the division may find this an acceptable alternative to actual testing of the component pursuant to the above referenced statement.

[2]3. In addition to the requirements adopted pursuant to subsection 1, a radiographic exposure device and associated equipment must comply with the following requirements:

(a) A licensee who uses a radiographic exposure device shall attach to the device a durable, legible and clearly visible label that includes:

(1) The chemical symbol and mass number of the radionuclide in the device;

(2) The measurement of activity and the date on which this activity was last measured;

(3) The model number and serial number of the sealed source;

(4) The name of the manufacturer of the sealed source; and

(5) The name, address and telephone number of the licensee.

(b) A radiographic exposure device intended for use as a Type B transport container must comply with the applicable requirements adopted pursuant to NAC 459.910.

(c) A radiographic exposure device and associated equipment may not be modified in any manner.

3. In addition to the requirements adopted pursuant to subsection 1 and the requirements set forth in subsection 2, a radiographic exposure device and any associated equipment that allow the source to be moved out of the device for routine operations must comply with the following requirements:

(a) The coupling between the source assembly and the control cable must be designed in such a manner as to prohibit:

(1) The source assembly from becoming disconnected if cranked outside the guide tube.

(2) The coupling from being unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(b) The radiographic exposure device must automatically secure the source assembly in the fully shielded position when it is cranked back into the radiographic exposure device. The release of the source assembly from the fully shielded position must require a deliberate operation on the radiographic exposure device.

(c) The fittings for outlets, the lock box and the fittings for drive cables on a radiographic exposure device must be equipped with safety plugs and covers. The safety plugs and covers must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(d) Each sealed source or source assembly must have attached to it or engraved upon it a durable, legible and visible label with the words "DANGER-RADIOACTIVE." The label must not interfere with the safe operation of the radiographic exposure device or the associated equipment.

(e) The guide tube must have passed the crushing tests for the control tube as specified in the American National Standards Institute, Inc., Standard N43.9-1991, and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

(f) A guide tube must be used when moving the source out of the radiographic exposure device.

(g) An exposure head or other similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.

(h) The connection between the guide tube and the exposure head must be able to withstand the tensile strength for control units specified in the American National Standards Institute, Inc., Standard N43.9-1991.

(i) A source changer must provide a system that ensures the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from the source assembly.

4. The provisions of this section apply to:

(a) Any radiographic exposure device and associated equipment that is manufactured on or after January 21, 1994; and

(b) Any radiographic exposure device and associated equipment that is used after January 10, 1996.

5. Notwithstanding subsection 1, equipment used in industrial radiographic operation need not comply with paragraph 6.6.2 of the Endurance Test in American National Standards Institute, Inc., Standard N43.9-1991, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

NAC 459.724 is hereby amended to read as follows:

459.724 Safety requirements for radiographers and radiographers' assistants.

1. A licensee's or registrant's operating and emergency procedures must include instructions in at least the following:

(a) The handling and use of sources of radiation to be employed so that no person is likely to be exposed to radiation doses in excess of the limits established in NAC 459.320 to 459.374, inclusive;

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for controlling access to radiographic areas;

(d) Methods and occasions for locking and securing sources of radiation;

(e) The monitoring of personnel and the use of personnel monitoring equipment;

(f) Transportation to field locations, including packing sources of radiation in the vehicles, posting vehicles and controlling sources of radiation during transportation;

(g) Minimizing the exposure of persons in the event of an accident;

(h) The procedure for notifying proper personnel in the event of an accident;

(i) The maintenance of records; and

(j) The inspection and maintenance of radiographic exposure devices, source changers, storage containers and radiation machines.

2. Except as otherwise provided in this subsection, a licensee or registrant shall not permit any person to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, the person wears a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter. An alarm ratemeter is not required to be worn for shielded-room radiography if other appropriate alarm or warning devices are used. Pocket dosimeters must have a range from zero to 200 milliroentgens and be recharged daily or at the start of each shift. Each film badge or thermoluminescent dosimeter must be assigned to and worn by only one person. Film badges and thermoluminescent dosimeters must be replaced at intervals not to exceed one month.

3. Pocket dosimeters must be read and exposures recorded daily. A person's film badge or thermoluminescent dosimeter must be immediately processed if his pocket dosimeter is discharged beyond its range. Reports received from the film badge or thermoluminescent dosimeter processor and records of the pocket dosimeter readings must be maintained for inspection by the division until it authorizes their disposal.

4. Each pocket dosimeter must be checked at periods not to exceed 1 year for response to radiation. To be acceptable, a dosimeter must read within plus or minus 30 percent of the true radiation exposure.

5. Each alarm ratemeter must:

(a) Be inspected before the start of each shift to ensure that the alarm functions properly and can be heard;

(b) Be set to give the alarm at a level of radiation that is preset at 500 milliroentgens per hour;

(c) Require a deliberate action to change the preset alarm;

(d) Be calibrated at periods not to exceed 1 year for correct response to radiation; and

(e) Give an alarm within plus or minus 20 percent of the true rate of the radiation dose.

6. A licensee or registrant shall provide periodic training for radiographers and radiographer's assistants at least once each calendar year.

NAC 459.784 is hereby amended to read as follows:

459.784 Instructions to employees. All persons [working in or frequenting any portion of a restricted area] who in the course of employment are likely to receive in a year an occupational dose in excess of 100 millirems must:

1. Be informed of the storage, transfer or use of radioactive material or of radiation in that portion;

2. Be instructed in the problems of health protection associated with exposure to such radioactive material or radiation;

3. Be instructed in precautions or procedures to minimize exposure and in the purposes and functions of the protective devices which are provided;

4. Be [informed of and] instructed in, and required to comply with the provisions of NAC 459.010 to 459.794, inclusive, and licenses which pertain to the protection of personnel from any exposures to radiation or radioactive materials [occurring in those areas];

5. Be informed of their responsibility to report promptly to the licensee or registrant any condition which may cause or lead to a violation of NAC 459.010 to 459.794, inclusive, or licenses or any unnecessary exposure to radiation or radioactive material;

6. Be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

7. Be advised of the existence of exposure reports to radiation which workers may request pursuant to NAC 459.786[; and].

In determining those individuals subject to the requirements of this section, licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the work place.

[8. To the extent necessary, be instructed regarding the gravity of problems concerning radiological health protection in the restricted area.]

NAC 459.8165 is hereby amended to read as follows:

459.8165 Records of shipments.

1. After receipt and acceptance of a shipment of radioactive waste, the licensee shall record:

(a) The date of receipt and the condition of the packages of waste as received at the disposal facility;

(b) Any discrepancies between the materials listed on the manifest and those received;

(c) Any evidence of leaking or damaged packages or radiation, or levels of contamination in excess of the limits specified in the regulations of the United States Department of Transportation and the division; [and]

(d) A traceable shipment manifest number;

(e) A description of any engineered barrier or structural overpack provided for disposal of the waste;

(f) 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;

([d]g) The date of disposal of the waste and its location in the disposal area[.];and

(h) Any other information required by the division as a license condition. The licensee shall retain these records until the division transfers or terminates the license that authorizes the activities described in this section.

2. The licensee shall briefly describe any repackaging performed on the waste included in the shipment and any other information required to be kept by the division.

3. In addition to the other requirements of this section, 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--

(1) That required in NAC 459.823, with the exception of shipper and carrier telephone numbers and shipper and consignee certifications; and

(2) That information required in paragraph NAC 459.8165.1(a), (b), (c),(d) and 459.8165.2.

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

NAC 459.823 is hereby amended to read as follows:

459.823 Transfer for disposal and [S]shipping manifest.

[1. Each shipment of radioactive waste to a licensed broker or disposal area must be accompanied by a shipping manifest that contains the name, address and telephone number of both the person generating the waste and the person transporting the waste to the broker or disposal area.

2. The manifest must contain a statement which is as complete as is practicable and includes a physical description of the waste, its volume, the identity and quantity of radionuclides, the

total radioactivity and the principal chemical form. Any agent used for solidification of the waste must be specified.

3. Wastes containing more than 0.1 percent by weight of chelating agents must be identified and the percentage by weight of the chelating agent must be estimated.

4. The classification of the wastes as Class A, Class B or Class C must be clearly stated in the manifest.

5. The total quantity of the radionuclides H-3, C-14, Tc-99 and I-129 must be shown.

6. The manifest required by this section may be shipping papers which comply with the regulations of the United States Department of Transportation or Environmental Protection Agency or which fulfill the requirements of the recipient, as long as all the required information is included.

7. The manifest must include a certificate by the generator of the waste or broker who processes, treats or repackages it that the transported materials are properly classified, described, packaged, marked and labeled and are in proper condition for transporting according to the applicable regulations of the United States Department of Transportation and the division.

8. An authorized representative of the generator or broker shall sign and date the manifest.]

Beginning August 31, 1998, a waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must:

1. Prepare a Manifest reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). NRC Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest. Licensees are not required to comply with the manifesting requirements of this section when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the ``waste generator'' or ``generator,'; or

(c) Radioactively contaminated material to a ``waste processor'' that becomes the processor's ``residual waste.''

2. The shipper of the radioactive waste, shall provide the following information on the uniform manifest:

(a) The name, facility address, and telephone number of the licensee shipping the waste;

(b) An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

(c) The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

3. The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

(a) The date of the waste shipment;

(b) The total number of packages/disposal containers;

(c) The total disposal volume and disposal weight in the shipment;

(d) The total radionuclide activity in the shipment;

(e) The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

(f) The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

4. The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

(a) An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

(b) A physical description of the disposal container, including the manufacturer and model of any high integrity container;

(c) The volume displaced by the disposal container;

(d) The gross weight of the disposal container, including the waste;

(e) For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

(f) A physical and chemical description of the waste;

(g) The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(h) The approximate volume of waste within a container;

(i) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

(j) The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

(k) The total radioactivity within each container; and

(l) For wastes consigned to a disposal facility, the classification of the waste pursuant to NAC 459.8265. Waste not meeting the structural stability requirements of NAC 459.8305 must be identified.

5. The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

(a) The approximate volume and weight of the waste;

(b) A physical and chemical description of the waste;

(c) The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

(d) For waste consigned to a disposal facility, the classification of the waste pursuant to NAC 459.8265. Waste not meeting the structural stability requirements of NAC 459.8305 must be identified;

(e) The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

(f) For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

6. The shipper of disposal containers enclosing mixtures of waste originating from different generators or mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators shall provide the following information regarding the waste shipment on the uniform manifest:

(a) For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

(b) For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

(1) The volume of waste within the disposal container;

(2) A physical and chemical description of the waste, including the solidification agent, if any;

(3) The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(4) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in NAC 459.8305; and

(5) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

7. Have an authorized representative certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the division. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

8. For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this section may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest. NRC Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained from the Information and Records Management Branch, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-7232.

9. Provide on the required EPA forms, information on hazardous, medical, or other waste, required to meet Environmental Protection Agency (EPA) regulations, as codified in 40 C.F.R. parts 259, 261 or elsewhere. The required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this section. Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information.

NAC 459.8235 is hereby amended to read as follows:

459.8235 Procedure for transfer to disposal area or broker.

1. Any licensee who [generates or] transfers radioactive waste to a land disposal [area] facility or to a [broker who collects prepackaged waste for shipment] licensed waste collector shall comply with all of the requirements of this section. Any licensee who [generates and] transfers waste to a [broker] licensed waste processor for processing, treatment or repackaging [before shipment] shall comply with the requirements of paragraphs (d) to (h), inclusive, of subsection 2.

2. A licensee shall:

(a) Prepare all wastes so that [they are in compliance with the permitted classes of waste and meet the requirements for physical form and packaging] the waste is classified according to NAC 459.8265 and meets the waste characteristics requirements in NAC 459.380 and 459.8305;

(b) Label each [package of waste] disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A, Class B or Class C waste, or greater then Class C waste, in accordance with NAC 459.8265;

(c) Conduct a program of inspection, including managerial evaluation of audits, to ensure that the wastes conform to permitted classes and the requirements for physical form and packaging;

(d) Prepare [shipping manifests] the NRC Uniform Low-Level Radioactive Waste Manifest which contains the required information and certifications;

(e) Forward a copy or electronically transfer the NRC Uniform Low-Level Radioactive Waste Manifest [of the manifest] to the intended [recipient] consignee [at the time of shipment, or deliver it to a broker at the time] so that the recipient of the manifest precedes the LLW shipment and/or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee and obtain acknowledgment of receipt of the shipment [from the broker or other recipient] consignee in the form of a signed copy of [the manifest] NRC Form 540;

(f) Include [a copy of the manifest] NRC Form 540 (and NRC Form 540A, if required), with the shipment;

(g) Retain a copy of [the manifest with] or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the required record of transfer of the licensed material as required in NAC 459.124; and

(h) [If] For any shipment or part of a shipment [has been accepted by a broker or a disposal area without returning an] for which acknowledgment of its receipt has not been received

within 20 days after the shipping date, conduct the required investigation in accordance with NAC 459.8255.

NAC 459.824 is hereby amended to read as follows:

459.824 Duties of [broker] waste collector who handles only prepackaged waste. Any [broker] waste collector who collects and handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the [licensee who generated it] shipper by returning a signed copy of [the manifest] NRC Form 540 within 1 week after receiving the waste.

2. Prepare a new shipping manifest to reflect consolidated shipments which [contains a listing or index of the details in the original manifests] meet the requirements of NAC 459.823 inclusive. [Copies of the original manifests must be a part of the new manifest unless the new manifest contains all the required information for each package. The broker shall certify that nothing has been done to the waste which would invalidate the certifications of the licensees who generated the waste.] The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

[3. Forward a copy of the new manifest to the operator of the disposal area at the time of shipment.

4. Include the new manifest with the shipment to the disposal area.

5. Retain a copy of the manifest with documentation of acknowledgment of receipt as the required record of transfer of licensed material, and retain information from the original manifests until disposition is authorized by the division.

6. If any shipment or part of a shipment has been accepted by a broker or a disposal area without acknowledgment of its receipt within 20 days after the shipping date, conduct the required investigation.]

3. Comply with the provisions of NAC 459.8235 2.(e), (f), (g), and (h).

4. Notify the shipper and the division listed when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

NAC 459.8245 is hereby amended to read as follows:

459.8245 Duties of [broker] waste processor who processes, treats or repackages wastes. Any broker who processes, treats or repackages wastes shall:

1. Acknowledge receipt of the waste from the [licensee who generated it] shipper by returning a signed copy of [the manifest] NRC Form 540 within 1 week after receipt of the waste;

2. Prepare a new shipping manifest which contains the required information and certificate, the preparation of which is acknowledgment that the [broker] waste-processor is responsible for [the waste] meeting the requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in NAC 459.823.6 inclusive;

3. Prepare all wastes so that [they are in compliance with the permitted classes of waste and meet the requirements for physical form and packaging] the waste is classified according to

NAC 459.8265 and meets the waste characteristics requirements in NAC 459.830 and 459.8305;

4. Label each package of waste to identify whether it is Class A, Class B or Class C waste, in accordance with NAC 459.8265;

5. Conduct a program of inspection, including managerial evaluation of audits, to ensure that the waste conforms to permitted classes and the requirements for physical form and packaging;

6. Forward a copy [of the new manifest to the operator of the disposal area, or deliver it to a broker at the time the waste is collected] or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either receipt of the manifest precedes the LLW shipment and/or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee, and obtain acknowledgment of receipt from the [operator or broker] in the form of a copy of [the manifest] NRC Form 540 signed by the [broker or operator] consignee;

7. Include [the new manifest] NRC Form 540 (and NRC Form 540A, if required) with the shipment;

8. Retain [copies of original manifests and new manifests with] a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the required record of transfer of licensed material as required by NAC 459.124; [and]

9. [If] For any shipment or part of a shipment [has been accepted by a broker or a disposal area without returning an] for which acknowledgment of its receipt has not been received within 20 days after the shipping date, conduct the required investigation in accordance with NAC 459.8255[.];and

10. Notify the shipper and the division listed when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

NAC 459.826 is hereby amended to read as follows:

459.826 Duties of operator of land disposal [area] facility.

An operator of a land disposal [area] facility shall:

1. Acknowledge receipt of the waste within 1 week after its receipt by returning a signed copy of [the shipping manifest] NRC Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator.

The returned copy or electronic transfer of the [manifest] NRC Form 540 must indicate any discrepancies between materials listed on the [manifest] NRC Form 540 and materials received.

2. Maintain copies of all completed manifests and electronically store the information required by NAC 459.8165 until the division authorizes their disposition.

3. Notify the shipper and the division when any shipment or part of a shipment has not arrived within [30] 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

4. Notify the division within 5 days after receipt of a shipment of any discrepancies between materials listed on the manifest and materials received.