

From: "Larry C. Boschult" <LBOSCHULT@nvhd.state.nv.us>
To: "Andrew Mauer" <ANM@nrc.gov>
Date: 11/8/05 1:09PM
Subject: IC License Conditions

Here's is Nevada's submission for your review.

This is the web link we are providing to our licensees:

<http://health2k.state.nv.us/BHPS/rhs/RAM/IC.htm>

Thank you,

Larry Boschult <<mailto:%20lboschult@nvhd.state.nv.us>>

Radiological Staff Specialist

Nevada State Health Division

Radiological Health Section

1179 Fairview Drive, Ste 102

Carson City, NV 89701

775-687-5394 x 272

<http://health2k.state.nv.us/BHPS/rhs/RAM/>

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Subject: IC License Conditions
Creation Date: 11/8/05 1:08PM
From: "Larry C. Boschult" <LBOSCHULT@nvhd.state.nv.us>

Created By: LBOSCHULT@nvhd.state.nv.us

Recipients

nrc.gov
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MESSAGE	454	11/08/05 01:08PM
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NV IC license amendment.DOC		104960
Mime.822	179435	

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Concealed Subject: No
Security: Standard

November xx, 2005

Licensee

Re: Nevada Radioactive Material License No. xxxxxx

Dear Mr. xxxxxx:

The U.S. Nuclear Regulatory Commission (NRC) and its Agreement States are in the process of implementing increased controls for licensees that possess certain radioactive materials in quantities of concern. NRC has determined that additional requirements need to be implemented to supplement existing regulatory requirements in 10 CFR 20.1801-1802 (rules similar to NAC 459.3535.1):

The increased controls are a matter of compatibility with NRC and must be implemented in a time frame desired by the NRC and with essentially identical content to those being used by NRC for its licensees.

Your radioactive material license has been identified as authorizing possession of certain radioactive material in one of the affected categories. Therefore, in accordance with NAC 459.196.2, your license has been amended to require you to comply with the increased controls detailed in attachment 1. The table of radionuclides of concern (Table 1), is provided at attachment 2. Your newly amended license is provided at attachment 3. Within twenty-five (25) days of the date of this letter:

1. You shall notify this office:
 - (1) if you are unable to comply with any of the requirements in attachment 1,
 - (2) if compliance with any of the requirements is unnecessary because of your specific circumstances, or
 - (3) if implementation of any of the requirements would cause you to be in violation of the provisions of any regulation or your license. The notification shall provide your justification for seeking relief from or variation of any specific requirement.
2. If you consider that implementation of any of the requirements detailed in attachment 1 would adversely impact safe operation of your facility, you must notify this office, in writing, of the adverse safety impact, the basis for its determination that the requirement would have an adverse safety impact, and either a proposal for achieving the same objectives specified in the attachment 1-

requirement in question, or a schedule for modifying the facility to address the adverse safety condition. If neither approach is appropriate, you must supplement your response to paragraph 1 above to identify the condition as a requirement with which you cannot comply, with attendant justifications as required in paragraph 1 above.

3. You shall submit to this office a schedule for completion of each requirement detailed in attachment 1.

Responses to paragraphs 1-3, above, shall be submitted to the Nevada State Health Division, Radiological Health Section, 1179 Fairview Drive, Suite 102, Carson City, NV 89701. In addition, your response shall be marked as "Withhold from Public Disclosure Under NAC 459.236.6."

The Nevada State Health Division may, in writing, relax or rescind any of the above conditions upon your demonstration of good cause.

As provided by NAC 459.136, you have an opportunity to request a hearing to contest this action. In accordance with NAC 459.136, if you wish such a hearing to be convened, we must have your request to that effect, in writing, within 25 days of the date of this letter. Should you require assistance in addressing this letter, please contact our office at (775) 687-5394 x 272.

This amendment also changes the name of the Radiation Safety Officer as requested in your letter dated July 25, 2005. For ease of reference, the license is amended in its entirety. New and revised text is indicated in bold, underlined font.

Sincerely,

Karen K. Beckley, M.P.A., M.S.
Supervisor, Radiological Health Section
Bureau of Health Protection Services

- 4 Attachments
- 1. Increased Controls
- 2. Table 1
- 3. License Amendment
- 4. NAC 459 Regulatory References

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Attachment 1

INCREASED CONTROLS FOR LICENSEES THAT POSSESS SOURCES CONTAINING RADIOACTIVE MATERIAL QUANTITIES OF CONCERN

The purpose of the increased controls for radioactive sources is to enhance control of radioactive material in quantities greater than or equal to values described in Table 1, to reduce the risk of unauthorized use of radioactive materials, through access controls to aid prevention, and prompt detection, assessment, and response to mitigate potentially high consequences that would be detrimental to public health and safety. These increased controls for radioactive sources are established to delineate licensee responsibility to maintain control of licensed material and secure it from unauthorized removal or access. The following increased controls apply to licensees which, at any given time, possess radioactive sources greater than or equal to the quantities of concern of radioactive material defined in Table 1.

- IC 1. In order to ensure the safe handling, use, and control of licensed material in use and in storage each licensee shall control access at all times to radioactive material quantities of concern and devices containing such radioactive material (devices), and limit access to such radioactive material and devices to only approved individuals who require access to perform their duties.
- a. The licensee shall allow only trustworthy and reliable individuals, approved in writing by the licensee, to have unescorted access to radioactive material quantities of concern and devices. The licensee shall approve for unescorted access only those individuals with job duties that require access to such radioactive material and devices. Personnel who require access to such radioactive material and devices to perform a job duty, but who are not approved by the licensee for unescorted access, must be escorted by an approved individual.
 - b. For individuals employed by the licensee for three years or less, and for non-licensee personnel, such as physicians, physicists, house-keeping personnel, and security personnel under contract, trustworthiness and reliability shall be determined, at a minimum, by verifying employment history, education, and personal references. The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the employee (i.e., seeking references not supplied by the individual). For individuals employed by the licensee for longer than three years, trustworthiness and reliability shall be determined, at a minimum, by a review of the employees' employment history with the licensee.
 - c. Service providers shall be escorted unless determined to be trustworthy and reliable by an NRC-required background investigation as an employee of a manufacturing and distribution (M&D) licensee. Written verification attesting to or certifying the person's trustworthiness and reliability shall be obtained from the manufacturing and distribution licensee providing the service.

- d. The licensee shall document the basis for concluding that there is reasonable assurance that an individual granted unescorted access is trustworthy and reliable, and does not constitute an unreasonable risk for unauthorized use of radioactive material quantities of concern. The licensee shall maintain a list of persons approved for unescorted access to such radioactive material and devices by the licensee.

IC 2. In order to ensure the safe handling, use, and control of licensed material in use and in storage, each licensee shall have a documented program to monitor and immediately detect, assess, and respond to unauthorized access to radioactive material quantities of concern and devices. Enhanced monitoring shall be provided during periods of source delivery or shipment, where the delivery or shipment exceeds 100 times the Table 1 values.

- a. The licensee shall respond immediately to any actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices. The response shall include requesting assistance from a Local Law Enforcement Agency (LLEA).
- b. The licensee shall have a pre-arranged plan with LLEA for assistance in response to an actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices which is consistent in scope and timing with realistic potential vulnerability of the sources containing such radioactive material. The pre-arranged plan shall be updated when changes to the facility design or operation affect the potential vulnerability of the sources. Pre-arranged LLEA coordination is not required for temporary job sites.
- c. The licensee shall have a dependable means to transmit information between, and among, the various components used to detect and identify an unauthorized intrusion, to inform the assessor, and to summon the appropriate responder.
- d. After initiating appropriate response to any actual or attempted theft, sabotage, or diversion of radioactive material or of the devices, the licensee shall, as promptly as possible, notify the Radiological Health Section at (775) 687-5394.
- e. The licensee shall maintain documentation describing each instance of unauthorized access and any necessary corrective actions to prevent future instances of unauthorized access.

IC 3. a. In order to ensure the safe handling, use, and control of licensed material in transportation for domestic highway and rail shipments by a carrier other than the licensee, for quantities that equal or exceed those in Table 1 but are less than 100 times Table 1 quantities, per consignment, the licensee shall:

- 1. Use carriers which:
 - A. Use package tracking systems,

- B. Implement methods to assure trustworthiness and reliability of drivers,
- C. Maintain constant control and/or surveillance during transit, and
- D. Have the capability for immediate communication to summon appropriate response or assistance.

The licensee shall verify and document that the carrier employs the measures listed above.

- 2. Contact the recipient to coordinate the expected arrival time of the shipment;
- 3. Confirm receipt of the shipment; and
- 4. Initiate an investigation to determine the location of the licensed material if the shipment does not arrive on or about the expected arrival time. When, through the course of the investigation, it is determined the shipment has become lost, stolen, or missing, the licensee shall immediately notify the Radiological Health Section at (775) 687-5394 or (775) 688-2830 (24 hour telephone number).

If, after 24 hours of investigating, the location of the material still cannot be determined, the radioactive material shall be deemed missing and the licensee shall immediately notify the Radiological Health Section at (775) 687-5394 or (775) 688-2830 (24 hour telephone number).

- b. For domestic highway and rail shipments, prior to shipping licensed radioactive material that exceeds 100 times the quantities in Table 1 per consignment, the licensee shall:
 - 1. Notify the NRC, Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, in writing, at least 90 days prior to the anticipated date of shipment. The NRC will issue the Order to implement the Additional Security Measures (ASMs) for the transportation of Radioactive Material Quantities of Concern (RAM QC). The licensee shall not ship this material until the ASMs for the transportation of RAM QC are implemented or the licensee is notified otherwise, in writing, by NRC.
 - 2. Once the licensee has implemented the ASMs for the transportation of RAM QC, the notification requirements of 3.b.1 shall not apply to future shipments of licensed radioactive material that exceed 100 times the Table 1 quantities. The licensee shall implement the ASMs for the transportation of RAM QC.
 - c. If a licensee employs an M&D licensee to take possession of the licensed radioactive material and ship it under its M&D license, the requirements of 3.a. and 3.b above shall not apply.
 - d. If the licensee is to receive radioactive material greater than or equal to the Table 1 quantities, per consignment, the licensee shall coordinate with the originating licensee to:
 - 1. Establish an expected time of delivery; and
 - 2. Confirm receipt of transferred radioactive material. If the material is not received at the expected time of delivery, notify the originating licensee and assist in any investigation.
- IC 4. In order to ensure the safe handling, use, and control of licensed material in use and in storage each licensee that possesses mobile or portable devices containing radioactive material in quantities greater than or equal to Table 1 values, shall:
- a. For portable devices, have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.
 - b. For mobile devices:

1. that are only moved outside of the facility (e.g., on a trailer), have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.
 2. that are only moved inside a facility, have a physical control that forms a tangible barrier to secure the material from unauthorized movement or removal when the device is not under direct control and constant surveillance by the licensee.
- c. For devices in or on a vehicle or trailer, licensees shall also utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee.

IC 5. The licensee shall retain documentation required by these increased controls for three years after they are no longer effective:

- a. The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years after the individual's employment ends.
- b. Each time the licensee revises the list of approved persons required by 1.d., or the documented program required by 2, the licensee shall retain the previous documentation for three years after the revision.
- c. The licensee shall retain documentation on each radioactive material carrier for three years after the licensee discontinues use of that particular carrier.
- d. The licensee shall retain documentation on shipment coordination, notifications, and investigations for three years after the shipment or investigation is completed.
- e. After the license is terminated or amended to reduce possession limits below the quantities of concern, the licensee shall retain all documentation required by these increased controls for three years.

IC 6. Detailed information generated by the licensee that describes the physical protection of radioactive material quantities of concern, is sensitive information and shall be protected from unauthorized disclosure.

- a. The licensee shall control access to its physical protection information to those persons who have an established need to know the information, and are considered to be trustworthy and reliable.
- b. The licensee shall develop, maintain and implement policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, its

physical protection information for radioactive material covered by these requirements. The policies and procedures shall include the following:

1. General performance requirement that each person who produces, receives, or acquires the licensee's sensitive information, protect the information from unauthorized disclosure,
2. Protection of sensitive information during use, storage, and transit,
3. Preparation, identification or marking, and transmission,
4. Access controls,
5. Destruction of documents,
6. Use of automatic data processing systems, and
7. Removal from the licensee's sensitive information category.

Attachment 2

Table 1: Radionuclides of Concern

Radionuclide	Quantity of Concern ¹ (TBq)	Quantity of Concern ² (Ci)
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above ³	See Footnote Below ⁴	

¹ The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

² The primary values used for compliance with this Order are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

³ Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

⁴ If several radionuclides are aggregated, the sum of the ratios of the activity of each source, i of radionuclide, n , $A_{(i,n)}$, to the quantity of concern for radionuclide n , $Q_{(n)}$, listed for that radionuclide equals or exceeds one. $[(\text{aggregated source activity for radionuclide A}) \div (\text{quantity of concern for radionuclide A})] + [(\text{aggregated source activity for radionuclide B}) \div (\text{quantity of concern for radionuclide B})] + \text{etc.} \geq 1$

Use the following method to determine which sources of radioactive material require increased controls (ICs):

- Include any single source equal to or greater than the quantity of concern in Table 1
- Include multiple collocated sources of the same radionuclide when the combined quantity equals or exceeds the quantity of concern
- For combinations of radionuclides, include multiple collocated sources of different radionuclides when the aggregate quantities satisfy the following unity rule: $[(\text{amount of radionuclide A}) \div (\text{quantity of concern of radionuclide A})] + [(\text{amount of radionuclide B}) \div (\text{quantity of concern of radionuclide B})] + \text{etc.} \dots \geq 1$

Guidance for Aggregation of Sources

NRC supports the use of the IAEA's source categorization methodology as defined in TECDOC-1344, "Categorization of Radioactive Sources," (July 2003) (see http://www-pub.iaea.org/MTCD/publications/PDF/te_1344_web.pdf) and as endorsed by the agency's Code of Conduct for the Safety and Security of Radioactive Sources, January 2004 (see <http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004.pdf>). The Code defines a three-tiered source categorization scheme. Category 1 corresponds to the largest source strength (equal to or greater than 100 times the quantity of concern values listed in Table 1.) and Category 3, the smallest (equal or exceeding one-tenth the quantity of concern values listed in Table 1.). Increased controls apply to sources that are equal to or greater than the quantity of concern values listed in Table 1, plus aggregations of smaller sources that are equal to or greater than the quantities in Table 1. Aggregation only applies to sources that are collocated.

Licensees who possess sources in total quantities that equal or exceed the Table 1 quantities are required to implement increased controls. Where there are many small (less than the quantity of concern values) collocated sources whose total aggregate activity equals or exceeds the Table 1 values, licensees are to implement increased controls.

Some source handling or storage activities may cover several buildings, or several locations within specific buildings. The question then becomes: When are sources considered collocated for purposes of aggregation? For purposes of the additional controls, sources are considered collocated if breaching a single barrier (e.g., a locked door at the entrance to a storage room) would allow access to the sources. Sources behind an outer barrier should be aggregated separately from those behind an inner barrier (e.g., a locked source safe inside the locked storage room). However, if both barriers are simultaneously open, then all sources within these two barriers are considered to be collocated. This logic should be continued for other barriers within or behind the inner barrier.

The following example illustrates the point: A lockable room has sources stored in it. Inside the lockable room, there are two shielded safes with additional sources in them. Inventories are as follows:

The room has the following sources outside the safes: Cf-252, 0.12 TBq (3.2 Ci); Co-60, 0.18 TBq (4.9 Ci), and Pu-238, 0.3 TBq (8.1 Ci). Application of the unity rule yields: $(0.12 \div 0.2) + (0.18 \div 0.3) + (0.3 \div 0.6) = 0.6 + 0.6 + 0.5 = 1.7$. Therefore, the sources would require increased controls.

Shielded safe #1 has a 1.9 TBq (51 Ci) Cs-137 source and a 0.8 TBq (22 Ci) Am-241 source. In this case, the sources would require increased controls, regardless of location, because they each exceed the quantities in Table 1.

Shielded safe #2 has two Ir-192 sources, each having an activity of 0.3 TBq (8.1 Ci). In this case, the sources would not require increased controls while locked in the safe. The combined activity does not exceed the threshold quantity 0.8 TBq (22 Ci).

Because certain barriers may cease to exist during source handling operations (e.g., a storage location may be unlocked during periods of active source usage), licensees should, to the extent practicable, consider two modes of source usage — "operations" (active source usage) and "shutdown" (source storage mode). Whichever mode results in the greatest inventory (considering barrier status) would require increased controls for each location.

19.A. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. Nevada Administrative Code (NAC) 459 shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- 1.** Radiological Operating and Emergency Procedures dated **April 10, 2005**.
- 2.** Application dated December 10, 2004.
- 3.** Letter dated August 18, 2005, signed by William M. Ross.
- 4.** Letter dated September 15, 2005, from the Radiological Health Section.

B. The licensee shall comply with the requirements described in the Radiological Health Section letter dated October 18, 2005, and attached document entitled "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern." The licensee shall complete implementation of said requirements within 6 months from the issuance of the license amendment or the first day that radionuclides in quantities of concern are possessed at or above the limits specified in Table 1 of the attachment, whichever is later. Within 25 days after the implementation of the requirements of this condition, the licensee shall notify the Radiological Health Section in writing that it has completed the requirements of this condition.

October 18, 2005

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By _____
Karen K. Beckley, M.P.A., M.S.
Supervisor, Radiological Health Section
Bureau of Health Protection Services

Attachment 4

NAC 459 References

NAC 459.196 Issuance of specific licenses.

1. Upon a determination that an application meets the requirements of chapter 459 of NRS and the regulations of the Division, the Division will issue a specific license authorizing the proposed activity in a form and containing such conditions and limitations as it deems appropriate or necessary.

2. The Division may incorporate in any license at the time of issuance additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to NAC 459.180 to 459.314, inclusive, as it deems appropriate or necessary in order to:

- (a) Minimize danger to public health and safety or property;
- (b) Require such reports and the keeping of such records, and to provide for such inspections of activities under the licenses as may be appropriate or necessary; and
- (c) Prevent loss or theft of material subject to NAC 459.180 to 459.314, inclusive.

NAC 459.236 Specific licenses: Filing of application.

1. Applications for specific licenses must be filed on a form prescribed by the Division and accompanied by the appropriate fee as prescribed in NAC 459.310.

2. The Division may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Division to determine whether the application should be granted or denied or whether a license should be modified or revoked.

3. Each application must be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

4. An application for a license may include a request for a license authorizing one or more activities.

5. In his application, the applicant may incorporate by reference information contained in previous applications, statements or reports filed with the Division provided such references are clear and specific.

6. Applications and documents submitted to the Division may be made available for public inspection except that the Division may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

NAC 459.3525 Precautionary procedures: Control of licensed radioactive material and radiation machines in unrestricted areas and not in storage.

1. A licensee shall control and maintain constant surveillance of licensed radioactive material that is in an unrestricted area and that is not in storage or related to the care of a patient.

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