

From: "Cheryl Rogers" <rogerck@dhfs.state.wi.us>
To: <phl@nrc.gov>
Date: 9/13/05 10:07AM
Subject: FINAL Version-WI Letter and LC

Dear Paul and Andrew,
Attached is the FINAL version of WI's letter to licensees and license condition.
Cheryl

CC: <anm@nrc.gov>

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From: "Cheryl Rogers" <rogerck@dhfs.state.wi.us>

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Jim Doyle
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DIVISION OF PUBLIC HEALTH

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MADISON WI 53701-2659

608-267-4797
FAX: 608-267-3695
dhfs.wisconsin.gov

Date

Licensee Name
Attn:Contact Individual
Licensee Address
City WI Zip Code

Dear Contact Individual:

The U.S. Nuclear Regulatory Commission (NRC) and all 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 certain increased controls are required to be implemented to supplement existing regulatory requirements in 10 CFR 20.1801-1802 (similar to s. HFS 157.28(1)). The additional controls are a matter of compatibility with NRC and must be implemented in a time frame desired by the NRC Commissioners and consistent with that 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 Wisconsin State Statute ss. 254.31-45 and Chapter HFS 157 'Radiation Protection', **your license has been amended to require you to comply with the increased controls detailed in attachment 1.** Your newly amended license is provided as attachment 3.

Within twenty-five (25) days of the date of this letter, you are required to do the following:

1. Notify this office if (1) you are unable to comply with any of the requirements in attachment 1, (2) compliance with any of the requirements is unnecessary because of your specific circumstances, or (3) implementation of any of the requirements would cause you to be in violation of the provisions of any rule requirement 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. Submit to this office a schedule for completion of each requirement detailed in attachment 1.

Submit responses to paragraphs 1-3 above to the Wisconsin Department of Health and Family Services, Radioactive Materials Program, 1 West Wilson Street, P.O. Box 2659, Madison, WI 53701-2659. In addition, your response shall be marked as "Withhold From Public Disclosure Under s. 19.36 (1), WI Stats."

As provided by s. HFS 157.13 (16) (d), you may request a hearing to contest this action. If you wish such a hearing to be convened, we must receive your request to that effect, in writing, within 10 days of receipt of this letter.

The Department may, in writing, relax or rescind any of the above conditions upon demonstration by the licensee of good cause.

If you have any questions or wish to discuss implementation of the requirements, please contact Cheryl Rogers, Supervisor Radioactive Materials Program at (608) 266-8135 or email at rogerck@dhfs.state.wi.us or Jason Hunt, Nuclear Engineer Senior at (608) 266-9443 or email at huntjh@dhfs.state.wi.us.

Sincerely,

Paul Schmidt, Chief
Radiation Protection Section

Attachments

1. Increased Controls
2. Table 1 and Guidance for Aggregation of Sources
3. Amended License

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.

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 or distribution (M&D) licensee. Written verification attesting to or certifying the person's trustworthiness and reliability shall be obtained from the manufacturing/ distribution licensee providing the services.
 - d. The licensee shall document the basis for concluding that there is reasonable assurance 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

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licensee shall maintain a list of persons approved for unescorted access to such radioactive material and devices by the licensee.

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 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(s), the licensee shall as promptly as possible, notify the Department at (608) 267-4797 during normal work hours; or (608) 258-0099 after normal work hours.
 - e. The licensee shall maintain documentation describing each instance of unauthorized access and any necessary corrective actions to prevent future instances of unauthorized access.
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

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- 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 Department at (608) 267-4797 during normal work hours; or (608) 258-0099 after normal work hours. If after 24 hours of investigating, the location of the material still cannot be determined, the radioactive material is deemed missing and the licensee shall immediately notify the Department at the telephone numbers provided above.
- 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 U.S. Nuclear Regulatory Commission*, in writing, at least 90 days prior to the anticipated date of shipment. The NRC will issue the Order requiring implementation of Additional Security Measures (ASMs) for the transportation of Radioactive Material Quantities of Concern (RAM QC). The licensee shall not ship radioactive material until the ASMs for the transportation of RAM QC are implemented or notified otherwise, in writing, by the U.S. Nuclear Regulatory Commission.
 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 a 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:

* Director, Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

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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.
4. In order to ensure the safe handling, use and control of licensed material in use and in storage, each licensee which 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 radioactive 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.
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.

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- 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.
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.

TABLE 1: RADIONUCLIDES OF CONCERN

Radionuclide	Minimum Quantity of Concern ¹ (TBq)	Minimum 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	

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

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

³Radioactive 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.

⁴If 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 exceeds one. $[(\text{aggregated source activity for radionuclide A}) \div (\text{quantity of concern for radionuclide A})] + [(\text{aggregated source activity for radionuclide B}) \div (\text{quantity of concern for radionuclide B})] + \text{etc.} \dots \geq 1$

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

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

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Guidance for Aggregation of Sources

The U.S. Nuclear Regulatory Commission and the Department of Health and Family Services support the use of 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.web.pdf>). The Code defines a three-tiered source categorization scheme. Category 1 corresponds to the largest source strength (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 greater than the quantity of concern values listed in Table 1, plus aggregations of smaller sources that add up to greater than the quantities in Table 1. Aggregation only applies to sources that are co-located.

Licensee who possess sources in total quantities that exceed Table 1 quantities are required to implement increased controls. Where there are many small (less than the quantity of concern values) co-located sources whose total aggregate activity 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 co-located for purposes of aggregation? For purposes of the additional controls, sources are considered co-located if breaching a single security 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 a locked storage room). However, if both barriers are simultaneously open, then all sources within these two barriers are considered to be co-located. 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 as the following sources outside the safes: Cf-252, 0.12 TBq (0.3 Ci); Po-210, 0.36 TBq (10 Ci); and Pu-238, 0.3 TBq (8 Ci). Application of the unity rule yields: $(0.012 \div 0.2) + (0.36 \div 0.6) + (0.3 \div 0.6) = 0.06 + 0.6 + 0.5 = 1.2$. Therefore, the sources would require increased controls. If the sources are distributed and shipped individually, increased controls would not apply because they do not exceed the quantities in Table 1.

Shielded safe #1 has a 1.9 TBq (51 Ci) Cs-137 source and a 0.4 TBq (11 Ci) Co-60 source. In this case, both sources would require increased controls, because they exceed the quantities in Table 1.

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Shielded safe #2 has two Po-210 sources, each having an activity of 0.2 TBq (5 Ci). In this case, neither source would require increased controls. (total activity = 0.4 TBq (10 Ci). They do not exceed the threshold quantity of 0.6 TBq (20 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), licensee 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.

Additional Increased Controls - License Condition

30.	The licensee shall comply with the requirements described in the Department letter dated [Insert Date] and attached document entitled "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern." The licensee shall complete the 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 30 days after the implementation of the requirements of this condition, the licensee shall notify the Department in writing that it has completed the requirements of this condition.
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