

From: "Michael Snee" <Michael.Snee@odh.ohio.gov>
To: <ANM@NRC.GOV>
Date: 11/7/05 3:14PM
Subject: Ohio orders

Andrew,

Attached are the documents for your review.

Michael Snee

Ohio Department of Health

Bureau of Radiation Protection

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Subject: Ohio orders
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Files	Size	Date & Time
MESSAGE	609	11/07/05 03:13PM
TEXT.htm	2225	
ORDER.doc	51200	
FINAL INCREASED CONTROLS.doc		88576
license condition.doc	27648	
Mime.822	234688	

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ORDER AND NOTICE OF HEARING

Certain radioactive material licensees are authorized by the Department to possess certain quantities of radioactive material of concern. Rule 3701:1-38-17 of the Administrative Code requires licensees to secure, from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas. Rule 3701:1-38-17 of the Administrative Code also requires licensees to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Prior to the terrorist attacks of September 11, 2001, several national and international efforts were underway to address the potentially significant health and safety hazards posed by uncontrolled sources. These efforts recognized the need for increased control of high-risk radioactive materials to prevent inadvertent and intentional unauthorized access, primarily due to the potential health and safety hazards posed by the uncontrolled material. Following the attacks, it was recognized that these efforts should also include a heightened awareness and focus on the need to prevent intentional unauthorized access due to potential malicious acts. These efforts, such as the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct) concerning Category 1 and 2 sources, seek to increase the control over sources to prevent unintended radiation exposure and to prevent malicious acts.

A licensee's loss of control of high-risk radioactive sources, whether it is inadvertent or through a deliberate act, has a potential to result in significant adverse health impacts and could reasonably constitute a threat to the public health and safety. In this regard, I have determined that certain additional controls are required to be implemented by licensees to supplement existing regulatory requirements in Rule 3701:1-38-17 of the Administrative Code, to ensure adequate protection of, and minimize danger to, the public health and safety. Therefore, pursuant to rule 3701:1-40-16(C) of the Administrative Code as an additional term and condition of licensure, I am imposing the requirements set forth in Attachment A on radioactive materials licensees who possess, or have near term plans to possess, radioactive material quantities of concern. These requirements, which supplement existing regulatory requirements, will provide the Department with reasonable assurance that the public health and safety continues to be adequately protected and that danger to life and property will be minimized. These requirements will remain in effect until the Department amends its rules to require increased controls.

The Department recognizes that licensees may have already initiated many controls set forth in Attachment A in response to previously issued advisories or on their own. It is also recognized that some controls may not be possible or necessary at some sites, or may need to be tailored to accommodate the licensees' specific circumstances to achieve the intended objectives and avoid any unforeseen effect on the safe use and storage of the sealed sources.

To provide assurance that the licensees are implementing prudent measures to achieve a consistent level of control, all licensees who hold licenses issued by the Department authorizing possession of radioactive material quantities of concern, listed for IAEA Category 2 and as listed in Table 1, "Radionuclides of Concern," (Attachment A, Table 1), shall implement the requirements identified in Attachment A to this Order.

Accordingly, pursuant to section 3748.05(B)(5) of the Revised Code and rule 3701:1-40-16(C) of the Administrative Code, it is hereby ordered, effective upon receipt of a license amendment issued by the Department, that all licensees authorized to possess radioactive material quantities of concern shall comply with the requirements of this order as follows:

- A. 1. The licensee shall comply with the requirements described in Attachment A to this Order. The licensee shall complete implementation within six months of issuance of the license amendment, or the first day that radionuclides of concern at or above threshold limits, identified in Table 1, are possessed, whichever is later.
- B. 1. The licensee shall, within twenty five days of the date of issuance of the license amendment, notify the Department, (1) if it is unable to comply with any of the requirements described in Attachment A, (2) if compliance with any of the requirements is unnecessary in its specific circumstances, or (3) if implementation of any of the requirements would cause the licensee to be in violation of the provisions of any Department rules or its license. The notification shall provide the licensee's justification for seeking relief from or variation of any specific requirement.
2. If the licensee considers that implementation of any of the requirements described in Attachment A to this Order would adversely impact safe operation of the facility, the licensee must notify the Department, in writing, within twenty five days of issuance of the license amendment, of the adverse safety impact, the basis for its determination that the requirement has an adverse safety impact, and either a proposal for achieving the same objectives specified in the Attachment A requirement in question, or a schedule for modifying the facility to address the adverse safety condition. If neither approach is appropriate, the licensee must supplement its response to Condition B.1 of this Order to identify the condition as a requirement with which it cannot comply, with attendant justifications as required in Condition B.1.

- C. 1. The licensee shall, within twenty five days of the date of issuance of the license amendment, submit to the Department a schedule for completion of each requirement described in Attachment A.
- 2. The licensee shall report to the Department when they have achieved full compliance with the requirements described in Attachment A.
- D. Notwithstanding any provisions of the Department's rules to the contrary, all measures implemented or actions taken in response to this Order shall be maintained until the Department modifies its rules to reflect increased controls.

Upon receipt of a licensee's written application and for good cause shown, the Director may, in writing, modify or rescind any of the above terms and conditions.

Comment: 3701:1-40-16 is in terms of the director modifying terms and conditions, not the department. I think this needs to be director.

Licensee responses to Conditions B.1, B.2, C.1, and C.2 above shall be submitted to:

Ohio Department of Health
 Bureau of Radiation Protection
 Attn: Michael Snee
 246 North High Street
 Columbus, Ohio 43216

In addition, licensee's responses shall be marked as **"Withhold from Public Disclosure under Revised Code 149.433(A) & (B)"**.

In accordance with Chapter 119. of the Revised Code, you may appeal this order provided that you request a hearing within thirty days of the date of mailing of this order. At a hearing, you may appear in person, by your attorney, or may present your position, arguments, or contentions in writing. You may also present evidence and examine witnesses appearing for and against you. Corporations who wish to appeal must be represented by legal counsel. A request for hearing shall be directed to Lance D. Himes, Assistant Counsel, Office of General Counsel, 246 N. High Street, Columbus, Ohio 43215.

APPROVED: _____
 J. Nick Baird, MD
 Director of Health

DATE: _____

ATTACHMENT A

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 United States Nuclear Regulatory Commission (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 Ohio Department of Health, Bureau of Radiation Protection at (614) 644-2727.
- 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 Ohio Department of Health, Bureau of Radiation Protection at (614) 644-2727. 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 Ohio Department of Health, Bureau of Radiation Protection.

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 NRC¹, 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.

¹ Director, Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

2. Once the licensee has implemented the ASMs for the transportation of RAM QC, the notification requirements of IC 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 IC 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 IC 1.D., or the documented program required by IC 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.

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

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:
$$\left[\frac{\text{amount of radionuclide A}}{\text{quantity of concern of radionuclide A}} \right] + \left[\frac{\text{amount of radionuclide B}}{\text{quantity of concern of radionuclide B}} \right] + \text{etc.} \dots \geq 1$$

Guidance for Aggregation of Sources

The IAEA's source categorization methodology is 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: $(0.12 \div 0.2) + (0.18 \div 0.3) + (0.3 \div 0.6) = 0.6 + 0.6 + 0.5 = 1.5$. 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.

ATTACHMENT B

RADIOACTIVE MATERIALS LICENSE AMENDMENT

The licensee shall comply with the requirements described in the Ohio Department of Health 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 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 Ohio Department of Health in writing that it has completed the requirements of this condition.