[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[Docket Nos: (Redacted), License Nos: (Redacted),

EA-05-090

In the Matter of all Licensees Authorized to Possess Radioactive Material Quantities of Concern, Order Imposing Increased Controls (Effective Immediately).

I

The Licensees identified in Attachment A[1] to this Order hold licenses issued in accordance with the Atomic Energy Act of 1954 by the U.S. Nuclear Regulatory Commission (NRC or Commission) and authorizing them to possess certain quantities of radioactive material of concern. Commission regulations at 10 CFR § 20.1801 require Licensees to secure, from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas. Commission regulations at 10 CFR § 20.1802 require Licensees to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

II

Prior to the terrorist attacks of September 11, 2001 (9/11), 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

[1] Attachment A contains sensitive information and will not be released to the public.

access, primarily due to the potential health and safety hazards posed by the uncontrolled material. Following 9/11, 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 be 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, the Commission has determined that certain additional controls are required to be implemented by Licensees to supplement existing regulatory requirements in 10 CFR § 20.1801 and 10 CFR § 20.1802, in order to ensure adequate protection of, and minimize danger to, the public health and safety. Therefore, the Commission is imposing the requirements set forth in Attachment B on radioactive materials licensees who possess, or have near term plans to possess, radionuclides of concern at or above threshold limits, identified in Table 1. These requirements, which supplement existing regulatory requirements, will provide the Commission with reasonable assurance that the public health and safety continues to be adequately protected. These requirements will remain in effect until the Commission modifies its regulations to reflect increased controls.

To effect nationwide implementation, these measures have been determined by the Commission to be an immediate mandatory Category "B" matter of compatibility for Agreement States. In parallel with the Commission's issuance of this Order, each Agreement State is

required to issue legally binding requirements to put essentially identical measures in place for licensees under their regulatory jurisdiction.

The Commission recognizes that Licensees may have already initiated many controls set forth in Attachment B to this Order 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 adverse effect on the safe use and storage of the sealed sources.

Although the additional controls implemented by the Licensees in response to the Safeguards and Threat Advisories have been adequate to provide reasonable assurance of adequate protection of public health and safety, the Commission concludes that additional controls must be imposed by an Order, consistent with the established regulatory framework.

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 NRC authorizing possession of radioactive material quantities of concern and as listed in Table 1, "Radionuclides of Concern," (Attachment B, Table 1), shall implement the requirements identified in Attachment B to this Order. In addition, pursuant to 10 CFR § 2.202, because of the potentially significant adverse health impacts associated with failure to control high risk radioactive sources, I find that the public health, safety, and interest require that this Order be effective immediately.

III

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR § 2.202, 10 CFR

Part 30, and 10 CFR Part 33, IT IS HEREBY ORDERED, **EFFECTIVE IMMEDIATELY**, THAT ALL LICENSEES IDENTIFIED IN ATTACHMENT A TO THIS ORDER SHALL COMPLY WITH THE REQUIREMENTS OF THIS ORDER AS FOLLOWS:

A. The Licensee shall comply with the requirements described in Attachment B to this Order. The Licensee shall complete implementation by June 2, 2006, or the first day that radionuclides of concern at or above threshold limits, identified in Table 1, are possessed, whichever occurs later.

B. 1. The Licensee shall in writing, within **twenty five (25) days** of the date of this Order, notify the Commission, (1) if it is unable to comply with any of the requirements described in Attachment B, (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 Commission regulation or its license. The notification shall provide the Licensee's justification for seeking relief from or variation of any specific requirement.

B. 2. If the Licensee considers that implementation of any of the requirements described in Attachment B to this Order would adversely impact safe operation of the facility, the Licensee must notify the Commission, in writing, within **twenty five (25) days** of this Order, 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 B 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 (25) days** of the date of this Order, submit to the Commission a schedule for completion of each requirement described in Attachment B.

C. 2. The Licensee shall report to the Commission when they have achieved full compliance with the requirements described in Attachment B.

D. Notwithstanding any provisions of the Commission's regulations to the contrary, all measures implemented or actions taken in response to this Order shall be maintained until the Commission modifies its regulations to reflect increased controls.

Licensee responses to Conditions B.1, B.2, C.1, and C.2 above shall be submitted to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. In addition, Licensee's responses shall be marked as "Withhold From Public disclosure Under 10 CFR 2.390."

The Director, Office of Nuclear Material Safety and Safeguards, may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

IV.

In accordance with 10 CFR § 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order, within **twenty five (25) days** of the date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time in which to submit an answer or request a hearing must be made in writing to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory

Commission, Washington, DC 20555, and include a statement of good cause for the extension. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, ATTN: Rulemakings and Adjudications Staff, Washington, DC 20555. Copies also shall be sent to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Materials Litigation and Enforcement at the same address, and to the Licensee if the answer or hearing request is by a person other than the Licensee. Because of possible disruptions in delivery of mail to United States Government offices, it is requested that answers and requests for hearing be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301-415-1101 or by e-mail to hearingdocket@nrc.gov and also to the Office of the General Counsel either by means of facsimile transmission to 301-415-3725 or by e-mail to OGCMailCenter@nrc.gov. If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR § 2.309(d) and (f).

If a hearing is requested by the Licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR § 2.202(c)(2)(i), the Licensee may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the

immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section III above shall be final **twenty five (25) days** from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section III shall be final when the extension expires if a hearing request has not been received. AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

Although this Order is not subject to the requirements of the Paperwork Reduction Act, there is nonetheless a clearance from the Office of Management and Budget, OMB approval number 3150-0002, that covers the information collections contained in the Order.

Dated this 9th day of May 2006

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Jack R. Strosnider, Director

Office of Nuclear Material Safety

and Safeguards

Attachments:

A. Increased Controls Licensee List (Not for Public Disclosure)

B. Increased Controls for Licensees That Possess Sources Containing Radioactive Material Quantities of Concern

Attachment A - Redacted

Attachment B

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

The purpose of the increased controls (IC) 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 a 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 NRC Operations Center at (301) 816-5100.

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 NRC Operations Center at (301) 816-5100. 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 NRC Operations Center at (301) 816-5100.

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[1], 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

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

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 exceeds 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 at the licensee's location 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 originator 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 originator 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.

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*, $\mathbf{A}_{(i,n)}$, to the quantity of concern for radionuclide *n*, $\mathbf{Q}_{(n)}$, listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) ÷ (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) ÷ (quantity of concern for radionuclide B)] + etc..... ≥ 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 <u>of the same radionuclide</u> when the combined quantity equals or exceeds the quantity of concern

- For combinations of radionuclides, include multiple collocated sources of <u>different radionuclides</u> when the aggregate quantities satisfy the following unity rule: [(amount of radionuclide A) ÷ (quantity of concern of radionuclide A)] + [(amount of radionuclide B) ÷ (quantity of concern of radionuclide B)] + etc.....$\geq$ 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_web.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 individual 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 ÷ 0.2) + (0.18 ÷ 0.3) + (0.3 ÷ 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.