

From: Ruth McBurney <Ruth.McBurney@dshs.state.tx.us>
To: "Andrew Mauer" <ANM@nrc.gov>, Pete Myers <Pete.Myers@dshs.state.tx.us>, Ruth McBurney <Ruth.McBurney@dshs.state.tx.us>
Date: 12/2/05 3:25PM
Subject: RE: FW: Security Letter, Table Attachment & Condition

I think that would be fine, since the other materials are also becoming publically available.

Ruth

-----Original Message-----

From: Andrew Mauer
To: Pete.Myers@dshs.state.tx.us; Ruth.McBurney@dshs.state.tx.us
Sent: 12/2/2005 1:43 PM
Subject: Re: FW: Security Letter, Table Attachment & Condition

Ruth/Pete,

The original documents developed by TX were marked OUO (consistent with direction at that time). Would you mind if we made these publically available, in a similar manner to submittals from the other Agreement States? Feel free to call me if you want to discuss.

Thanks, Andrew

>>> Pete Myers <Pete.Myers@dshs.state.tx.us> 08/02/05 11:00 AM >>>
Andrew, Jared, Steve ... FYI, "Tom" is our DSHS lawyer ... Pete.

-----Original Message-----

From: Ruth McBurney
Sent: Tuesday, August 02, 2005 9:52 AM
To: Pete Myers; Richard Ratliff
Subject: FW: Security Letter, Table Attachment & Condition

I just spoke with Tom--he suggested we use Section 552.101 of the Govt. Code (Open Records Act) as the citation in the letter. This is the exception provision of the Open Records Act for information that is "confidential by law". This would be overarching for the House Bill 9 provisions as well as any other laws (even federal and compatibility issues). I have made the change in the attached letter. Pete, could you pass this on to Jared, Andrew and Steve?

Thanks,
Ruth

-----Original Message-----

From: Pete Myers
Sent: Monday, August 01, 2005 4:07 PM
To: 'ANM@nrc.gov'
Cc: 'JWThompson@HealthyArkansas.com'; Ruth McBurney; 'Collins@iema.state.il.us'
Subject: Security Letter, Table Attachment & Condition

Andrew:

Attached.

Pete.

Peter H. Myers, Manager
Radioactive Material Licensing Group
Radiation Safety Licensing Branch
512-834-6688 ext 2209
512-834-6690 (fax)

NOTE: The Texas Department of Health (TDH) has merged with other agencies and is now part of the new Department of State Health Services (DSHS), resulting in the following e-mail address format change for all employees: firstname.lastname@dshs.state.tx.us.

Mail Envelope Properties (4390AD89.48B : 6 : 1163)

Subject: RE: FW: Security Letter, Table Attachment & Condition
Creation Date: 12/2/05 3:24PM
From: Ruth McBurney <Ruth.McBurney@dshs.state.tx.us>

Created By: Ruth.McBurney@dshs.state.tx.us

Recipients

nrc.gov

owf1_po.OWFN_DO
ANM (Andrew Mauer)

dshs.state.tx.us

Pete.Myers (Pete Myers)

Post Office

owf1_po.OWFN_DO

Route

nrc.gov

dshs.state.tx.us

Files

MESSAGE

Mime.822

Size

2056

3473

Date & Time

12/02/05 03:24PM

Options

Expiration Date:

None

Priority:

Standard

Reply Requested:

No

Return Notification:

None

Concealed Subject:

No

Security:

Standard

**TEXAS DEPARTMENT OF STATE HEALTH SERVICES**

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER

1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • <http://www.dshs.state.tx.us>

DATE

[LICENSEE NAME]
ATTN [RSO]
[LICENSEE ADDRESS]
[CITY] TX [ZIP]

Dear [RSO]:

The U.S. Nuclear Regulatory Commission (NRC) and its Agreement States are in the process of implementing additional protective measures for licensees that possess certain radioactive materials in quantities of concern. NRC has determined that certain protective measures are required to be implemented to supplement existing regulatory requirements in 10 CFR §§ 20.1801-1802 (rules similar to Title 25 Texas Administrative Code (TAC) §289.202(y). 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 Texas Health and Safety Code Chapter 401 and TAC §289.252(w)(2)(A)&(C), **your license has been amended to require you to comply with the additional security measures detailed in attachment 1.** Your newly amended license is provided at attachment 2. Within twenty-five (25) days of the date of this letter **[We use 30 days?]**:

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

[RSO]

<http://www.tdh.state.tx.us/radiation>
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[Date]

Page 2 of 2

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 Manager, Radioactive Material Licensing Group, Radiation Safety Licensing Branch, 1100 W. 49th Street, Austin, Texas 78756-3189. In addition, your response shall be marked as "Withhold from Public Disclosure Under **TX Government Code Section 552.101.**"

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

As provided by 25 TAC §289.205(c), you have an opportunity to request a hearing to contest this action. In accordance with 25 TAC §289.205(h), if you wish such a hearing to be convened, we must have your request to that effect, in writing, within 30 days of the date of this letter.

Should you require assistance in addressing this letter, please call Mr. Pete Myers, Manager, Radioactive Material Licensing Group, at (512) 834-6688 extension 2209 (or e-mail Pete.Myers@tdh.state.tx.us).

Sincerely,

Ruth E. McBurney, CHP, Manager
Radiation Safety Licensing Branch
Regulatory Licensing Unit
Environmental and Consumer Safety Section
Division for Regulatory Services

3 Attachments

1. Increased Controls
2. Table 1
3. License Amendment

bcc: file

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

The purpose of the additional 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 malevolent 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 additional 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 additional controls apply to licensees who, 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

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Attachment 1- Page 3 of 5

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- 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 service.
- 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 malevolent use of radioactive material quantities of concern. The licensee shall maintain a list of persons approved for access to such radioactive material and device(s) 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 device(s), the licensee shall, as promptly as possible, notify DSHS at (512) 834-6688 ext 2022 during normal work hours; or (512) 458-7460 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

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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 DSHS at (512) 834-6688 ext 2022 during normal work hours; or (512) 458-7460 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 DSHS 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 NRC*, 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 this material until the ASMs for the transportation of RAM QC are implemented or 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.

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- * Director, Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555
- 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 **(because the M&D licensee will have to comply with equivalent requirements)**.
- 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.
- 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 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:

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- 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 security 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.
6. The licensee shall protect its sensitive information from unauthorized disclosure and control access to its sensitive information to those persons **for whom the licensee has** established the need-to-know the information, and are considered to be trustworthy and reliable. The licensees shall develop, maintain and implement policies and procedures for controlling access to, and proper handling and protection against unauthorized disclosure of, its sensitive information for radioactive material covered by these requirements.

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Table 1

Radionuclide	Minimum Quantity of Concern ¹ (TBq)	Minimum Quantity of Concern ¹ (Ci)
Am-241	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	0.6	16
Ra-226	0.4	10
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations	Unity ¹	

¹ The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity exceeds the quantity of concern. Radioactive materials are considered aggregated or co-located if breaching a common physical security barrier (e.g., a locked storage room door) would allow access to the material.

Use the following method to determine which sources of radioactive material require protective measures (PMs):

- ▶ 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: [(amount of nuclide A) ÷ (quantity of concern of nuclide A)] + [(amount of nuclide B) ÷ (quantity of concern for nuclide B)] + etc ... > 1

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

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Guidance for Aggregation of Sources

The 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 (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). PMs 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.

Licensees who possess sources in total quantities that exceed the Table 1 quantities are required to implement PMs. 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 PMs.

Some source handling or storage activities may cover several buildings, or several locations within specific buildings. The question then becomes: When are sources considered colocated for purposes of aggregation? For purposes of the PMs, sources are considered colocated 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 the 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 has 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 PMs. If the sources are distributed and shipped individually, PMs 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 0.75 Tbq (20 Ci) Ra-226 source. In this case, both sources would require PMs, because they exceed the quantities in Table 1. The Ra-226 source, although not licensed by the NRC, was colocated with an NRC licensed source and, therefore, would need to be similarly protected.

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 PMs. (Total activity = 0.4 Tbq (10 Ci)). They do not exceed the threshold quantity 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), 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 PMs for each location.

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TRC Form 12-1
08/04

Page 1 of 2



Department of State Health Services
RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER	AMENDMENT NUMBER
XXXXXXXXXX	XXXXXX

34. A. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material authorized by this license in accordance with statements, representations, and procedures contained in the following:

application dated August 29, 1995,
letters dated August 1, 1997, September 10, 1997, February 3, 1999, March 30, 2000,
September 8, 2000, October 25, 2000, January 25, 2001, October 23, 2002,
October 24, 2002, January 9, 2003, July 30, 2003, August 28, 2003, February 5, 2004,
and June 28, 2004.

Title 25 TAC §289 shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.

- B. The licensee shall comply with the requirements described in the DSHS letter dated () and attached document entitled "Additional 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 30 days after the implementation of the requirements of this condition, the licensee shall notify the Radiation Safety Licensing Branch in writing that it has completed the requirements of this condition.

ILP:ip

FOR THE DEPARTMENT OF STATE HEALTH SERVICES

Date

[Date When Issued]

J. Scott Kee, Chief
Medical and Academic Licensing Program