From: Lee Cox <lee.cox@ncmail.net>
To: Andrew Mauer <anm@nrc.gov>
Date: 9/28/05 4:47PM
Subject: NC Increased Controls

Andrew:
Thought you might be interested in how NC is approaching the new increased control mandate for licensees containing radioactive material quantities of concern. We started amending licenses this week. We also included in the information a database driven form entitled "Certification of Compliance Status" which must be returned to the Agency with supporting documentation. We have discovered that our licensees respond better to check boxes than decifering a bunch of regulatory language. Hopefully it will get us more timely return of the required information. The database also helps us with the monumental task of tracking due dates. Robin Haden was the author of this wonderful tool and database for us. It has been extremely useful in helping me process these amendments and getting out the orders. I have attached it for your convenience. You are welcome to pass this on to other folks if you find it helpful.
Lee

CC: Duncan White <adw@nrc.gov>, <sam9@nrc.gov>, Beverly Hall <Beverly.Hall@ncmail.net>, <PHL@nrc.gov>, Robin Haden <Robin.Haden@ncmail.net>, Mike A Kelly <Mike.A.Kelly@ncmail.net>

Mail Envelope Properties (433B013E.B4C : 17 : 52044)

Subject: NC Increased Controls
Creation Date: 9/28/05 4:46PM
From: Lee Cox <lee.cox@ncmail.net>

Created By: lee.cox@ncmail.net

Recipients
nrc.gov
owf1_po.OWFN_DO
ANM (Andrew Mauer)

nrc.gov
kp1_po.KP_DO
ADW CC (Duncan White)
SAM9 CC (Sheri Minnick)

nrc.gov
twf1_po.TWFN_DO
PHL CC (Paul Lohaus)

ncmail.net
Mike.A.Kelly CC (Mike A Kelly)
Robin.Haden CC (Robin Haden)
Beverly.Hall CC (Beverly Hall)

Post Office	Route
owf1_po.OWFN_DO	nrc.gov
kp1_po.KP_DO	nrc.gov
twf1_po.TWFN_DO	nrc.gov
	ncmail.net

Files	Size	Date & Time
MESSAGE	943	09/28/05 04:46PM
Attachment 3 Certification of Compliance.doc		122880
Attachment 2 -- Table.doc	54784	
Attachement 1 Increased Controls.doc		48640
Security_letter.doc	270848	
Mime.822	684649	

Options
Expiration Date: None
Priority: Standard
Reply Requested: No

Return Notification:	None
Concealed Subject:	No
Security:	Standard

From: Lee Cox <lee.cox@ncmail.net>
To: Andrew Mauer <anm@nrc.gov>
Date: 9/28/05 5:08PM
Subject: standard condition

Andrew,
Here is the standard condition. Sorry I misunderstood it was not already approved.
Lee

Mail Envelope Properties (433B0645.D1D : 7 : 52509)

Subject:	standard condition
Creation Date:	9/28/05 5:08PM
From:	Lee Cox <lee.cox@ncmail.net>
Created By:	lee.cox@ncmail.net

Recipients
nrc.gov
owf1_po.OWFN_DO
ANM (Andrew Mauer)

Post Office	**Route**
owf1_po.OWFN_DO	nrc.gov

Files	**Size**	**Date & Time**
MESSAGE	97	09/28/05 05:08PM
SECURE standard condition.doc		20480
Mime.822	29768	

Options

Expiration Date:	None
Priority:	Standard
Reply Requested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard

The licensee shall comply with the requirements described in the Agency letter dated [INSERT DATE] and attached document entitled "Increased Controls for Licensees that Possess Sources Containing Radioactive Materials Quantities of Concern." The licensee shall complete implementation of said requirements within 6 months from the issuance of the license amendment for 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 twenty-five (25) days after the implementation of the requirements of this condition, the licensee shall notify the Agency in writing that it has completed the requirements of this condition.

Administrative amendment in accordance with US Nuclear Regulatory Commission mandate requiring "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern".

NCDENR
North Carolina Department of Environment and Natural Resources
Division of Environmental Health
Radiation Protection Section

Michael F. Easley, Governor
Terry L. Pierce, Division Director

William G. Ross, Jr., Secretary
Beverly O. Hall, Section Chief

[DATE]

[RSO]
[Institution]
[Mailing Address]
[City, State, ZIP]

SUBJECT: Administrative Amendment No. XX to N.C. Radioactive Materials License No. XXX-XXXX-X and Increased Security Requirements

Dear :

The U.S. Nuclear Regulatory Commission (NRC) and North Carolina (an Agreement State) are in the process of implementing increased controls for licensees that possess certain radioactive materials in quantities of concern. The NRC has determined that additional requirements need to be implemented to supplement existing regulatory requirements in 10 CFR § 20.1801 - .1802 (rules similar to 15A NCAC 11 .1622). The increased controls are a matter of compatibility with NRC and must be implemented in a time frame desired by the NRC and with essentially identical content to those being used by NRC for its licensees.

Your radioactive material license has been identified as authorizing possession of certain radioactive material in one of the affected categories. Therefore, in accordance with 15A NCAC 11 .0108(a), your license has been amended to require you to comply with the increased controls detailed in Attachment 1. The table of radionuclides of concern is provided as Attachment 2. A Certification of Compliance Status is provided as attachment 3. It shall be completed and returned to the Agency by **(DATE 25 days from the date of letter)**. Your newly amended license is enclosed which includes a new condition found in bold outlining specific implementation dates.

The Certification of Compliance Status (Attachment 3) shall be submitted to ***Manager, Radioactive Materials Branch, 1645 Mail Service Center, Raleigh, NC 27699-1645.*** In addition, your response shall be marked as **"Withhold from Public Disclosure Under N.C.G.S. 104E-9(a)(4)."**

The Radiation Protection Section, Radioactive Materials Branch may, in writing, relax or rescind any of the above conditions upon your demonstration of good cause.

As provided by N.C.G.S. 150B, you have an opportunity to request a hearing to contest this action. If you wish to appeal this action, your request must be in the form of a written petition, conforming to Chapter 150B of the North Carolina General Statutes. An original and one copy of the form prescribed by N.C. General Statutes §150-23, must be filed with:

The Office of Administrative Hearings
6714 Mail Service Center
Raleigh, North Carolina 27699-6714

A copy of the petition must also be served on the Department as follows:

Dan Oakley
Registered Agent and General Counsel
Department of Environment and Natural Resources
1601 Mail Service Center
Raleigh, North Carolina 27699-1601

Should you require assistance in addressing this letter, please contact either J. Marion Eaddy III, Health Physicist or me at (919) 571-4141.

Sincerely,

W. Lee Cox, III, Manager
Radioactive Materials Branch

jme

Attachments:
1. Increased Controls
2. Table 1
3. Certification of Compliance Status

Enclosure: Amended License

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

c. Service providers shall be escorted unless determined to be trustworthy and reliable by an NRC-required background investigation as an employee of a manufacturing and distribution (M&D) licensee. Written verification attesting to or certifying the person's trustworthiness and reliability shall be obtained from the manufacturing and distribution licensee providing the service.

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

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

a. The licensee shall respond immediately to any actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices. The response shall include requesting assistance from a Local Law Enforcement Agency (LLEA).

b. The licensee shall have a pre-arranged plan with LLEA for assistance in response to an actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices which is consistent in scope and timing with realistic potential vulnerability of the sources containing such radioactive material. The pre-arranged plan shall be updated when changes to the facility design or operation affect the potential vulnerability of the sources. Pre-arranged LLEA coordination is not required for temporary job sites.

c. The licensee shall have a dependable means to transmit information between, and among, the various components used to detect and identify an unauthorized intrusion, to inform the assessor, and to summon the appropriate responder.

d. After initiating appropriate response to any actual or attempted theft, sabotage, or diversion of radioactive material or of the devices, the licensee shall, as promptly as possible, notify the **N.C. RADIOACTIVE MATERIALS BRANCH at (919) 571-4141 during normal business hours or through the**

N.C. DIVISION OF EMERGENCY MANAGEMENT OPERATIONS CENTER at (800) 858-0368.

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 **N.C. RADIOACTIVE MATERIALS BRANCH at (919) 571-4141 during normal business hours or through the N.C. DIVISION OF EMERGENCY MANAGEMENT OPERATIONS CENTER at (800) 858-0368.**

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 or, for Agreement State licensees, the appropriate Agreement State regulatory agency.

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 material until the ASMs for the transportation of RAM QC are implemented or the licensee is notified otherwise, in writing, by NRC.

2. Once the licensee has implemented the ASMs for the transportation of RAM QC, the notification requirements of 3.b.1 shall not apply to future shipments of licensed radioactive material that exceed 100 times the Table 1 quantities. The licensee shall implement the ASMs for the transportation of RAM QC.

c. If a licensee employs an M&D licensee to take possession of the licensed radioactive material and ship it under its M&D license, the requirements of 3.a. and 3.b above shall not apply.

d. If the licensee is to receive radioactive material greater than or equal to the Table 1 quantities, per consignment, the licensee shall coordinate with the originating licensee to:

1. Establish an expected time of delivery; and

2. Confirm receipt of transferred radioactive material. If the material is not received at the expected time of delivery, notify the originating licensee and assist in any investigation.

---

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

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 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 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 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 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.pdf). The Code defines a three-tiered source categorization scheme. Category 1 corresponds to the largest source strength (greater then 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 collocated.

Licensees who possess sources in total quantities that 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 co-located for purposes of aggregation? For purposes of the additional controls, sources are considered co-located if breaching a single barrier (e.g., a locked door at the entrance to a storage room) would allow access to the sources. Sources behind an outer barrier should be aggregated separately from those behind an inner barrier (e.g., a locked source safe inside the locked storage room). However, if both barriers are simultaneously open, then all sources within these two barriers are considered to be collocated. This logic should be continued for other barriers within or behind the inner barrier.

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

> The room has the following sources outside the safes: Cf-252, 0.12 Tbq (3.2 Ci); Co-60, 0.18 TBq (4.9 Ci), and Pu-238, 0.3 Tbq (8.1 Ci). Application of the unity rule yields: $(0.12 \div 0.2) + (0.18 \div 0.3) + (0.3 \div 0.6) = 0.6 + 0.6 + 0.5 = 1.7$. Therefore, the sources would require increased controls.
>
> Shielded safe #1 has a 1.9 Tbq (51 Ci) Cs-137 source and a 0.8 Tbq (22 Ci) Am-241 source. In this case, the sources would require increased controls, regardless of location, because they each exceed the quantities in Table 1.
>
> Shielded safe #2 has two Ir-192 sources, each having an activity of 0.3 Tbq (8.1 Ci). In this case, the sources would not require increased controls while locked in the safe. The combined activity does not exceed the threshold quantity of 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.

NCDENR
North Carolina Department of Environment and Natural Resources

RADIATION PROTECTION SECTION
RADIOACTIVE MATERIALS BRANCH
Attachment 3

CERTIFICATION OF COMPLIANCE STATUS

(DRP USE ONLY)

INSTRUCTIONS: Completion and submittal of this form is required within 25 days of the date of the accompanying letter pursuant to 15A NCAC 11 .0108(a). Complete all appropriate sections of this form, using additional sheets as necessary. Item 9 MUST be completed on all certificates. Completion and submission of this certification does not relieve the licensee from other requirements associated with the terms of their license. Mail ONE original to: *Manager, Radioactive MaterialsBranch,1645 Mail Service Center, Raleigh, N.C., 27699-1645.* Mark responses as "Withhold from Public Disclosure under G.S. 104E-(9)(a)(4).

1. License No.: 2. Current Amendment No.: 3. Date of Letter: 9/29/2005
Response Due: _____

4. Licensee Name (on current license):

5. Physical Address:

CERTIFICATION

6. The Licensee and any individual executing this certification on behalf of the Licensee certify that *(check the most appropriate item below):*

☐ A. This facility can comply with all of the requirements in Attachment 1.
(Attach a schedule for completion of all requirements detailed in Attachment 1.)

☐ B. This facility is unable to comply with any/all of the requirements in Attachment 1.
(Attach a detailed explanation of the specific requirements with which the facility cannot comply and the reasons the facility is unable to comply, including a schedule of completion of those requirements with which the facility is able to comply.)

☐ C. It is unnecessary for this facility to comply with any/all of the requirements of Attachment 1 based on specific circumstances.
(Attach a detailed explanation of the specific requirements with which the facility believes it is unnecessary to comply and why is it unnecessary for this facility to comply, including a description of all special circumstances and a schedule of completion of those requirements with which the facility is able to comply.)

☐ D. The implementation of any/all of these requirements would cause this facility to be in violation of the provisions of the above referenced Radioactive Materials license.
(Attach a detailed explanation of the provisions of the license that will be violated with the implementation of the requirements, including the specific requirement and the provision that will be violated and a schedule of completion of those requirements not causing violation of the license.)

7. If, in the Licensee's judgment, the implementation of any of these requirements would adversely impact the safe operation of the facility, the Licensee must notify the Agency, in writing, of the following *(check A OR B, with B including either subitem i. or ii.)*

☐ A. Does not apply to this facility.

☐ B. A description of the adverse safety impact and the basis for that determination; **AND**

☐ i. **EITHER** a proposal for achieving the same objectives outlined in Attachment 1 **or** a schedule for modifying the facility to address the adverse safety condition; **OR**

☐ ii. If neither approach outlined in 7.B.i is appropriate, the facility's response to Question 6 shall be supplemented to include the identification of the requirement with which the facility cannot comply, complete with justifications.

8. Documentation Attached? ☐ Yes ☐ No Number of pages or attachments:

9. **The licensee, or any official executing this certificate on behalf of the licensee named in Item 1., certify that all information contained herein, including any supplements attached hereto, has been prepared in conformity with all applicable North Carolina Laws and Regulations and is true and correct to the best of our knowledge and belief.**

BY:

Signature of Certifying Official* Date Signed

Printed Name and Title of Certifying Official

Revised Sept. 2005

**NOTE: A certifying official is defined as (1) a member of upper management at the licensee's facility or (2) any person to whom the authority to sign for license amendments was granted by management during the application process.*