



PR 37  
(73FR69590)

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DOCKETED  
USNRC

January 8, 2009 (4:00pm)

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

Henry H. Kramer, Ph.D., FACNP  
*Executive Director*

January 5, 2009

Ms. Annette L. Vietti-Cook, Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001  
ATTN: Rulemakings and Adjudications Staff

Subject: RIN 3150-A112 Comments on Preliminary Draft Language Part 37 Physical  
Protection of Byproduct Material

Dear Ms. Vietti-Cook,

These comments concerning the preliminary draft language for the physical protection of Category 1 and 2 materials while being transported to be contained in subpart D of the new Part 37 are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include manufacturers and shippers of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medical applications.

CORAR member companies have been subject to recently promulgated security regulations as well as the orders for implementing security measure enhancements and safeguarding sensitive information. CORAR understands and appreciates the need to ensure that radioactive materials are adequately secured from potential criminal or terrorist threats. Its member companies have taken necessary precautions, whether mandated by regulation or in a voluntary capacity as a result of internal risk assessment, to enhance the protections afforded to this material. At the same time we have come to appreciate that the resources required to implement and maintain security enhancement measures are also in demand to manufacture and distribute our products and to ensure that other radiation protection obligations are fulfilled.

CORAR believes the NRC is moving in the right direction by consolidating the various security enhancement Orders in the regulations by developing a new Part 37 to Title 10 of the Code of Regulations and appreciates the opportunity to provide the following comments and information concerning the topics for discussion in the NRC Request for Public Comments.

Template = SECY-067

SECY-02

## Comments to Preliminary Draft Language to Part 37 Physical Protection of Byproduct Material

### §37.3 Definitions

1. Include a definition for “Safe Haven” in §37.3 Definitions. In the context of this rule an appropriate definition may be: “A Safe Haven is a well lit and reasonably secure area such as a weigh station, military installation, law enforcement or fire department facility or interstate truck stop/travel center”.

Basis for change: The term safe haven is loosely defined by various agencies and states, in most cases the licensee will not be provided a list of approved safe havens and may not be granted access to safe havens such as military installations. If a list of safe havens isn't provided then the licensee at least has a definition to use as a guide when identifying safe havens.

2. Delete the term “readily” in the definition Lost or missing licensed material.

Basis for change: The term is subjective.

3. Strengthen the definition for the “No-later-than arrival time”. Consider language such as:

*No-later-than arrival time* means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time should not be more than 24 hours later than the estimated arrival time, and may be adjusted during transit to account for travel conditions. For export shipments of Category 2 quantities, the receiving facility may be considered the airport/customs of the receiving country.

Basis for change: The draft language does not include an enforceable parameter. The shipper and receiver could establish a no-later-than arrival time that an inspector feels is too long, a 24 hour maximum time should be adequate to account for normal delays in transit. The N-L-T arrival time should be adjustable once the shipment begins if weather conditions or vehicle breakdowns would result in the shipment to miss the original N-L-T. For export shipments of Category 2 quantities, the final transport to the end user is typically arranged by the final end user and not the shipper. As this takes place in other countries it is outside the jurisdiction of the NRC. In addition, the shipper is usually not aware of these arrangements and therefore can not readily determine final arrival at the end user facility.

### §37.99 Additional requirements for transfer of category 1 quantities of radioactive material.

1. Reword §37.99 (a) to read: “Before transferring category 1 quantities of radioactive material within the United States to a new licensee or location, the licensee transferring the material shall verify with the license issuing authority (NRC, DOE or Agreement State) that the transferee’s license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and verify that the delivery address of the transferee is valid.”

Basis for change: An NRC licensee should not be expected to consult directly with a foreign licensing agency the specific import/export licensing requirements ensures that the foreign licensing agency authorizes the transfer of category 1 material to the foreign licensee. Once a licensee and location is verified by the licensing agency then it should be considered valid so long as the license hasn't expired.

2. General comment §37.99 (a and b) – Would use of the National Source Tracking System Database fulfill the verification of delivery address and licensee authorization? If so then a statement as such should be included in §37.99 (a).

Basis for comment: The NSTS should take the place of this, otherwise we are dual reporting.

3. Delete §37.99 (c)

Basis for change: The transferor is already required to contact the licensing authority in §37.99 (a), the licensing authority should make the determination as to whether or not the transferee can receive the source. In addition the rule is unenforceable as written because it is subjective. “The transferor must verify with the transferee and the license issuing authority any unusual orders or changes that depart from historical patterns of ordering by an existing licensee customer. The transferor shall document the verification and keep a copy of the documentation as a record for 3 years”. Unless the US NRC’s defines the statement “any unusual orders or changes that depart from historical patterns” how would the licensee know when this rule goes into effect?

#### §37.101 Physical protection of category 1 and category 2 quantities of radioactive material during transit.

1. §37.101 (d) and (e) – Add to the end of each paragraph, “... during the domestic portion of the shipment”

Basis for addition: This clarifies that the physical protection requirements during transit pertain only to activities that occur in the US.

2. Add a paragraph to §37.101 that provides a mechanism for alternative methods of compliance as approved by the US NRC.

Basis for addition: There are instances, particularly at the Mexico Border where the carrier and communication requirements cannot be met.

#### §37.103 Preplanning and coordination of shipment of category 1 or 2 quantities of radioactive material

1. Recommend deleting §37.103(a)(2) in its entirety.

Basis- Preplanning a category 1 shipment with governor or governor’s designee would complicate the shipping logistics. Industry is very sensitive to the security concerns regarding category 1 shipments and has taken on a significant amount of responsibility in this regard. Industry believes and category 1 shipments conducted under the security order supports the notion that the advanced notification of the shipment would provide

sufficient time for the States to review the shipment and advise the licensee on any additional requirements or necessary changes in the route and schedule.

2. In addition to the recommendation to delete §37.103(a)(2) in its entirety Industry strongly opposes the requirement provided in §37.103(a)(2)(iii) - Arrange for positional information sharing when requested. This requirement should not be included in any of section of the proposed rule.

Basis: The language could be construed as meaning that a State should be able to log onto the carrier's tracking system. Taken in this context this requirement could provide a mechanism for a State to block the transport of Category 1 material through the state, if they cannot log onto the tracking system. There are several commercially available tracking systems available for licensees to choose from, a State should not dictate which system a carrier uses so that the carrier can "share" position information.

3. In addition to the recommendation to delete §37.103(a)(2) in its entirety, if the language of §37.103(a)(2)(iv) - Identify Highway Route Control Quantity shipments and safe havens, is retained in some part of the rule then clarification is necessary. Are safe havens only required for HRCQ shipments? Who is responsible for identifying safe havens, the State, the shipper or the carrier? If safe havens must be identified even if it is not an HRCQ shipment then separate HRCQ and safe havens into two separate paragraphs.

Basis: Language is confusing as written.

4. Delete §37.103(b)

Basis –Currently under the transport order, for Category 2 shipments the shipper is allowed to verify receipt by reviewing the carriers tracking system this, which shows that the shipment arrived at it destination. This has been effective and strongly recommend this option is retained. This allows for an efficient and documented method for verifying receipt of the majority of shipments. If it is required to manually follow up on each individual shipment, this will result in much more work and not any incremental gain, it also would not be "real time" due to delays in communication.

Not clear what is meant by "immediate notification" in para ( c), close of business of N-L-T as allowed by current order? This needs clearer definition and must take into account normal delays in communication.

5. Reword §37.103(c) that allows the licensee to utilize the NSTS database to read:

Each licensee who receives a shipment of a category 1 or category 2 quantity of radioactive material shall notify the shipping licensee of the arrival of the shipment at its destination. This notification may be made utilizing the NSTS database or other mechanism such as fax, phone or email.

Basis: For sources, the NSTS system will fulfill this requirements. Delete the term "immediately" or define the notification requirement as a period of time.

6. Add a documentation and retention requirement to §37.103

Basis for addition: Documentation and retention of the preplanning and coordination efforts should be required.

§37.105 Advance notification of shipment of category 1 quantities of radioactive material.

1. Revise the contact information list referenced in the opening paragraph that is available at <http://nrc-stp.ornl.gov/special/designee.pdf> to include a column for Part 37.

Basis: Ensures that the licensee is submitting a notification to the correct contact. Fax numbers and email addresses would be beneficial.

2. Clarify Paragraph §37.105(a)(3) to define “other means” – A notification delivered by any other means than mail, such as fax or email must reach the office of the governor or the governor's designee at least 4 days before transport of a shipment within or through the state.

Basis: Provides clarification, also provide fax number an email address for the NRC’s Director, Division of Security Policy, Office of Nuclear Security and Incident Response.

3. Add New Paragraph §37.105(b)(4) – The route the shipment will take through each State. Renumber remaining paragraphs of §37.105(b) accordingly.

Basis: Supports the requirement to provide the date and time the shipment is expected to enter each State along the “route” in the current §37.105(b)(4).

4. §37.105(c)(2) reword this paragraph to define “will not be met”, allow for alternative methods aside from a telephone call to revise a notification and require a notification in the event of a route change. Language such as:

“Notify affected States and the NRC’s Director, Division of Security Policy, Office of Nuclear Security and Incident Response of schedule delays in excess of 12 hours or changes in the route previously furnished to a governor or governor’s designee, in accordance with this section.

Basis: The current Order defines “will not be met” as 6 hours, Industry feels that this is rather restrictive for long haul shipments when you consider potential weather, road and traffic conditions. Under the Orders licensee’s typically make revisions using the same method as the original notification and this appears to work well. The proposed rule should utilize the lessons learned through the implementation of the Order.

5. On a general comment basis for this section, ensure that everything proposed is consistent with current requirements for HRCQ under Safeguards Information.

§ 37.107 Requirements for physical protection of category 1 and 2 quantities of radioactive material during shipment.

1. Add a paragraph §37.105(a)(2)(iv) – Shipments transported as *Exclusive Use*, in accordance with Title 49 Code of Federal Regulations Part 173.441 are exempted from the requirements of §37.105(a)(2)(i) and (iii).

Basis for the addition: Package tracking systems are necessary when a carrier handles multiple consignments on single vehicles and when packages traverse through delivery hubs. An exclusive use shipment removes the risk of lost or misdirected packages and

would provide the same level of control as a package tracking system. This would also give the licensee the ability to transport their own category 1 materials.

2. §37.107(a)(1)(i) – change terminology from “movement control centers” to “communication control centers”

Basis: Maintain consistency with previous Orders.

#### § 37.109 – Reporting of Events

1. §37.109(a) – Clarification needed into the term “immediately” and statement “determination that a shipment of category 1 radioactive material is lost or missing”. Can this be linked to the N-L-T delivery time? Should the licensee make an attempt to locate the shipment before considering it lost or missing.

Basis: Clarification is needed to ensure inappropriate notifications are not made.

2. §37.109(b) – Same clarification is needed as in (a) above. Provide some increment of time, i.e. 12 hrs to allow the licensee to locate the shipment before initially notifying the NRC.

Basis: Same as above.

Thank you for the opportunity to comment on this draft preliminary language. If you have any questions concerning these comments or would like additional explanation, please contact me at 314-795-6166

Sincerely,



Roy W. Brown  
Senior Director, Federal Affairs  
Council on Radionuclides and Radiopharmaceuticals

## Rulemaking Comments

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**From:** Carol Gallagher  
**Sent:** Thursday, January 08, 2009 10:45 AM  
**To:** Rulemaking Comments  
**Subject:** Comment letter on Draft Rule Language "Physical Protection of Byproduct Material"  
**Attachments:** NRC-2008-0120-DRAFT-0004[2].1.pdf

Attached for docketing is a comment letter on the above noted draft rule language (73 FR 69590) that I received via the Regulations.gov website on 1/5/09.

Carol

Received: from HQCLSTR01.nrc.gov ([148.184.44.76]) by OWMS01.nrc.gov  
([148.184.100.43]) with mapi; Thu, 8 Jan 2009 10:44:48 -0500  
Content-Type: application/ms-tnef; name="winmail.dat"  
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From: Carol Gallagher <Carol.Gallagher@nrc.gov>  
To: Rulemaking Comments <Rulemaking.Comments@nrc.gov>  
Date: Thu, 8 Jan 2009 10:44:47 -0500  
Subject: Comment letter on Draft Rule Language "Physical Protection of  
Byproduct Material"  
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