PR 30,32,33,34,35,36,37,39,51,71 and 73
(75FR33901)

67

DOCKETED
USNRC

January 13, 2011 (4:45 pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

International Isotopes Inc.

January 13, 2011

Secretary
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville MD 20555-0001

Attn: Rulemaking and Adjudications Staff - *Rulemaking.Comments@nrc.gov*
Subject: Comments regarding the "Physical Protection of Byproduct Material; Proposed Rule" (75 FR 33902) and Draft Guidance Document (75 FR 40756); Docket Number NRC-2008-0120

Dear Secretary:

International Isotopes Inc. (INIS) is a small business licensed by the US Nuclear Regulatory Commission (NRC) that manufactures and distributes a wide array of products utilized in applications important to our national security, public safety, and in the treatment and diagnosis of diseases. A significant fraction of these products contain category 1 and category 2 quantities of radioactive material. In addition to manufacturing beneficial products; we recover and recycle cobalt-60 from expended sources that might otherwise have no disposal options.

Considering our product line, it is not surprising that we have kept ourselves engaged with the NRC in regards to the security category 1 and 2 quantities of materials. And while we may question the effectiveness of some of the additional security measures promulgated through the Orders we acknowledge our responsibility of compliance and we have expended a significant amount of resources ensuring we do so. The requirements of the Orders we find most challenging to comply with are the physical security requirements for materials in transit; primarily those regarding the transport of category 1 quantities of materials, commonly referred to as the RAMQC requirements. In these instances the burden of compliance with the RAMQC requirements is borne entirely by the licensee that offers the material for transport. The licensee however has very little control over the material once the material departs the licensee's facility. INIS ultimately expended a significant amount of resources and formed a motor carrier subsidiary, International Isotopes Transportation Services, to ensure compliance with the RAMQC requirements.

We appreciate the opportunity to provide comments on the Commission's proposed rule and implementation guidance that codifies these Orders. We also welcome the NRC's foresight in

4137 Commerce Circle, Idaho Falls, Idaho 83401
Phone: 208-524-5300, 800-699-3108 Fax: 208-424-1411
Website: www.intisoid.com

Template = SECY-067

DS10

preparing the draft implementation guidance in parallel with the proposed rule and the effort to engage with stakeholders through public meetings during the comment period.

While INIS supports codifying the previously issued security Orders into regulation through the Part 37 rulemaking, we are concerned with the estimated cost and lack of quantifiable benefit that is derived through the implementation of additional and more stringent security measures.

Based on INIS's experience implementing and complying with the previously issued security Orders, we urge the Commission to consider the following general comments as they develop the proposed rule.

- INIS has been absorbing the costs associated with implementing the requirements of these Orders as well as the costs associated with other security measures such as the National Source Tracking System and specific Import/Export licensing requirements. This monetary burden of compliance has required us to reduce the amount of resources allocated for other aspects of our business, and has made it very challenging for us to compete in the global market.
- INIS believes the authority to regulate the physical protection of category 1 and 2 quantities of material in transit (Subpart D of the Proposed Part 37 rule making) should not be relinquished to the Agreement States. While the adequacy and compatibility requirements of Agreement State programs would require the Agreement State regulations to be "essentially identical" to those contained in Subpart D of the proposed Part 37 rule; there are several instances where Agreement State regulations include requirements in addition to those found in the analogous NRC regulations. Agreement State regulations that go beyond those contained in Subpart D of the Proposed Part 37 rule could hinder interstate commerce and result in additional burden and expense to the licensees.
- Instead of taking a "one size fits all" approach, the NRC should consider dividing the proposed Part 37 rule into sub-parts based on the type of business and security risks commensurate with each type. Implementation guidance could be developed in an industry/risk specific manner similar to NUREG 1556.
- The NRC should include definitive criteria that disqualifies and individual from being granted unescorted access to category 1 and 2 quantities of materials. Alternately the NRC could develop a method similar to the Transportation Safety Administration's Transport Worker Identification Credential (TWIC^{TM}) program and undertake the task of authorizing unescorted access to category 1 and 2 quantities of materials.

I had the opportunity to attend the NRC sponsored workshop held this past September in Austin, Texas and found the workshop to be well organized and informative. I hope the NRC continues to engage with the stakeholders through the public meeting process as the proposed rule and implementation guide is further developed.

In addition to the fundamental comments provided above, comments specific to the proposed rule are provided in the attached enclosure.

Please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com if you have questions regarding these documents.

Sincerely,

John J. Miller, CHP
Radiation Safety Officer

JJM-2011-05

cc: Ms. Merri Horn

Comments on the Proposed Rule and Implementation Guidance for Part 37 Physical Protection of Byproduct Material in Category 1 and Category 2 Quantities

Comments Pertaining to Subpart A General Provisions

A1. The definition of *Aggregated* is unclear. Does the phrase "common physical barrier" used in the definition of the term apply to storage and/or transportation containers or to the area in which multiple sources are located? Recommend providing Q&A style clarification of the term Aggregated in Section §37.47 Security zones section of the Implementation Guide.

A2. The term "readily", as used in the definition of *Lost or missing licensed material* is subjective and would make compliance and enforcement of the reporting criteria established in §37.81 difficult. The definition should include some time frame to allow for an investigation; 8 hours after the no-later than arrival time seems reasonable.

A3. Clarify that the *No-later-than arrival time* applies to domestic transfers either within the definition of the term or in the implementation guide. There are far too many variables such as custom clearances and inspections associated with imports and exports.

A4. The 2 hour and 4 hour estimate for the N-L-T arrival time is unrealistic. Recommend revising the definition so that it is 24 hours past the estimated time of arrival.

A5. Clarify or delete the phrase "security is present" in the definition of *Safe Haven*. The NRC provides examples of what would qualify as a safe haven in the implementation guide so the phrase only adds confusion to the definition.

A6. Remove the sentence "The NRC expects safe havens to be identified and designated by the licensee based on discussions with appropriate State personnel" from paragraph A4 Section §37.75(a) of the implementation guide. Licensees have attempted to contact States in the past for a list of safe havens; these requests have been fruitless. The definition of safe haven is sufficient to allow the licensee to identify safe havens without contacting a representative of the State.

Comments Pertaining to Subpart B
Background Investigations and Access Authorization Program

B1. Delete paragraph §37.23(b)(2) in its entirety.

The Reviewing Official does not need unescorted access to perform their role of evaluating information obtained as part of the background investigation and subsequently making a determination of an individual's trustworthiness and reliability. Nothing is gained by requiring a reviewing official to have unescorted access to Category 1 and 2 materials or safeguards information.

B2. Recommend revising paragraph §37.23(b)(3) to allow a Reviewing Official to conduct T&R determination to authorize an individual as a Reviewing Official. This would give the licensee more flexibility in assigning individual duties.

B3. Recommend revising paragraph §37.23(b)(4) to include the Reviewing Officials ability to authorize access to safeguards information.

B4. Delete the phrase "or permit any individual to have unescorted access" from paragraph §37.23(b)(5). The phrase is not necessary; the T&R determination must be conducted before granting unescorted access so by preventing the Reviewing Official from performing a T&R determination also prevents the Reviewing Official from granting unescorted access to Category 1 or 2 quantities of material.

B5. Unless the NRC provides a list of disqualifying factors delete the term "disqualifying" from the paragraph §37.23(e)(2).

B6. Delete the requirement to maintain a list from paragraph §37.23(e)(3). There is no value to "maintaining a list" of individuals denied access and individuals approved access. The licensee may develop procedures on their own that generates a list or they may develop a badge system that indicates a person's level of access.

B7. Delete paragraph §37.23(h)(3) – there is no value to maintaining a list when complete documentation is required by §37.23(h)(1).

B8. Delete paragraph §37.25(a)(6) – Credit history evaluation. Unless the NRC provides disqualifying criteria that would be provided in a credit history report then the cost expended by the licensee in both time and money, and the intrusion into an employee's personal finances is not warranted. The other aspects of the background check are sufficient to make a T&R determination without the need to obtain a credit history report.

B9. Delete paragraph §37.25(a)(7) – Criminal history review. There is no justification in expending resources to conduct a 10 year local criminal history review when §37.25(a)(1) requires an FBI fingerprint based criminal history record check. The FBI criminal history would include anything of significance that a local criminal history check would indicate. A local criminal history check may have misdemeanor offenses and traffic violations that the FBI criminal history report may not contain, but these types of offenses are not even considered in Annex B of the implementation guide so how is the expense of conducting a 10 year local criminal history check justified? The cost and time expended by the licensee could be significant if an individual has lived in multiple jurisdictions over the previous 10 years.

B10. Delete the requirement to include a credit history reevaluation from paragraph §37.25(c), Reinvestigations. Basis for the comment is the same as that provided for in comment B8.

B11. Revise the paragraph §37.33(a) 12 month program review frequency to when license authorizations change that warrant a change in the program or 36 months whichever is sooner. A 12 month review frequency for a program that should see little revision once it is put into place seems excessive. The benefit of conducting annual reviews of what should be a fairly static program would be minimal and justifying the cost of these reviews would be difficult. Non-conformities would most likely be discovered during the implementation of the program and corrected upon discovery.

Comments Pertaining to Subpart C
Physical Protection Requirements During Use

C1. Delete the phrase "without delay" from Paragraph §37.41(b) – General performance objective. The phrase is unrealistic during normal business hours. Unauthorized access whether actual or attempted would only be detected "without delay" if individuals were in the vicinity and could witness the access or attempt to access.

C2. Delete the phrase "an actual or attempted" from Paragraph §37.41(b) – General performance objective. After business hours an armed security system could detect (without delay) unauthorized access to an area that contained category 1 or 2 quantity of material but may not be able to detect an "attempt" to access the area. The attempt may have failed without compromising a security measure or triggering an alarm.

C3. Section §37.43 is very prescriptive. Many licensees will already have a security plan that has been reviewed by the NRC or an Agreement State. These earlier plans were written to demonstrate compliance with the security order(s) that the licensee had been issued. Revising security plans written to the Orders or developing new security plans will require a significant amount of the licensees' time and resources. Additionally these same licensees would have developed procedures to implement their security plans and they would have conducted training on these procedures and security plans. The proposed rule should allow a period of 120 days from the effective date of the rule for the licensees to transition from their current security plans, procedures and training. An additional 120 days should be given to licensees that may not have plans procedures and training in place.

C4. The phrase "security service provider employees" as used in paragraph §37.43(d)(4)(ii) is too general. It doesn't appear that the intent of the NRC was to require the §37.25(a) background checks on individuals that do not access the facility and simply monitor the facilities security system from an off-site location. Was the requirement intended to address security guard service employees that work on the licensees premises that contain category 1 and 2 quantities of materials?

C5. Recommend deleting paragraph §37.45(a)(1)(ii) and the 4th bullet from A5 of section §37.45(a) from the implementation guide. In many cases this information would be classified as SGI or SGI-M information and would require handling and control in accordance with §73.21. There appears to be little if any benefit in providing this information to the LLEA that would warrant the dissemination of SGI or SGI-M.

C6. Revise paragraph §37.45(a)(1)(vii) so that it is only required if the facility is not served by x911.

C7. Recommend deleting paragraph §37.45(a)(1)(viii) in its entirety as there is no prescribed action for the licensee to take if the LLEA response capability becomes diminished. The LLEA may not be willing to divulge such information.

C8. Recommend deleting paragraph §37.45(a)(1)(ix) in its entirety. There is no requirement to conduct drills and exercises with the LLEA. If the NRC intendeds to conduct security drills or exercises on a case-by-case basis then it would be more appropriate for the NRC to contact the affected LLEA and request their participation.

C9. Recommend deleting paragraph §37.45(b) in its entirety. The LLEA notification requirement for temporary job sites is not warranted if the job site is served by x911. If the licensee verifies x911 is unavailable at the temporary job site then the licensee should be required to document the contact information for the LLEA that has jurisdiction where the temporary job site is located. The back and forth formal notification does nothing but burden the licensee and the LLEA.

C10. Recommend including a provision in paragraph §37.47 that exempts the security zone requirements for category 1 or 2 quantities of material that are stored in casks or packages that require specialized equipment to move, open or access, if the equipment needed to access the material is unavailable.

C11. Recommend deleting the phrase "without delay" from paragraph §37.49(a) (1) basis is the same as that provided in comment C1.

C12. Add a 4th method; (D) "Security zone intrusion detection alarm" to §37.49(a) (3)(i).

C13. Strike the term "calibration" from paragraph §37.51 and from any sub-paragraph. There are procedures to test and maintain these systems but the term calibration seems out of place.

C14. Revise paragraph §37.53(b) to allow credit for removing the key from the ignition and maintaining the key with the individual. A disabling device could add additional risks to the worker; for instance if the device fails the individual may become stranded, or it may slow emergency egress.

Comments Pertaining to Subpart D
General Provisions

D1. Delete the reference to the NRC's License Verification System from paragraphs §37.71(a) and (b), as the system does not yet exist.

D2. Recommend providing a mechanism in paragraphs §37.71(a) and (b) to relieve the licensee from conducting license verification if the licensee has verified the license and location for a previous shipment of category 1 or 2 quantities of material within the last 12 months.

D3. Recommend reducing the record retention requirement in §37.71(c) from 5 years to 3 years, consistent with the period currently required for the transfer of radioactive materials.

D4. Delete paragraphs §37.75(a)(2), including subparagraphs (i)-(v). The §37.77 advanced notification provided to the State by the licensee provides a sufficient amount of time for the State to contact the licensee if a revision to the route or additional State imposed controls, such as escorts are going to be implemented. Appendix A of the Regulatory Analysis indicates that there had been zero event notifications in the past 10 years regarding missing or lost material, suspicious activities, theft, or diversion of category 1 materials so how can additional coordination efforts that are not currently required by the Orders be justified.

Specifically in regards to §37.75(a)(2)(iii), the licensee would be unable to comply with the requirement to arrange for positional information sharing when required by the State. As written the States would be authorized to dictate which position tracking provider a carrier chooses to utilize, or the State could request that the carrier authorize the State to log into the tracking system utilized by the carrier, as there are licensing fees and data communication fees associated with tracking systems additional costs would be incurred. Unless the Federal government intends to develop and fund a single positional information tracking system the requirement of §37.71(a)(2)(iii) is unfeasible.

Specifically in regards to §37.75(a)(2)(v), safe havens – the proposed rule provides a definition for safe haven and the implementation guide provides examples of safe havens, the licensee and carrier are capable of determining safe havens along the route. Past experience has shown that requesting a State to identify safe havens has been fruitless.

D5. Recommend that the advanced notifications to the governor of a State or the governor's designee as required by §37.77 be made through the NRC's Operations Center. The licensee would simply provide the advanced notification to the NRC Operations center with a list of States affected. The NRC Operations center would then transmit the advanced notification to the affected States.

This would reduce the record retention and notification burden on the licensee and would ensure consistency in how the States receive notifications

D6. Provide an email address and fax number for the NRC point of contact receiving the notification in paragraph §37.77(a)(1).

D7. Recommend removing the §37.77(a)(2) option to mail in notifications or require that notifications not submitted by fax or email be sent via certified mail or delivery service.

D8. Recommend increasing the notification requirement in §37.77(a)(3) from 4 days to 7 days. Note the additional time would provide States with enough time to review and evaluate the details regarding the shipment and would preclude the need to conduct the pre-planning and coordination as required by §37.75(2). This advanced notification process has been in place and proven effective for the past 6 years.

D9. It is unclear what information the point of contact requested in §37.77(b)(7) should be able to provide. "Current shipping information" could imply that the point of contact should be a person accompanying the shipment. Or should the point of contact have information regarding the details of the notification.

D10. Change the phrase "movement control center" to "communication control center" in paragraph §37.79.

D11. Allow the licensee to provide current copies of normal and contingency procedures in lieu of training as required by §37.79(c)(2). It is not feasible to provide "appropriate training" to a group of individuals that the licensee has no control over.

Comments Pertaining to Draft Regulatory Analysis

RA1. There is no data provided to support the statement "Although significant costs are incurred as a result of the rule the qualitative benefits associated with the rule outweigh its cost" contained in Section 5. Decision Rationale. If there is evidence that suggests the security measures implemented through the current Orders are inadequate in the protection of public health and safety or common defense and security then this information should be presented in a technical basis document available to stakeholders.

RA2. In the current state of the economy it does not seem reasonable to propose rulemaking with an estimated $450 to $612 million cost that cannot be justified with a measured benefit. These costs coupled with the costs associated with other security related initiatives, such as the National Source Tracking System, could have a detrimental effect on the Industry, as well as the consumer.

RA3. Based on our experience complying with the security Orders we feel the Regulatory Analysis cost estimates are significantly less than what could be expected. Specifically the costs associated with conducting background investigations and the resources expended in the planning, coordination and notifications associated with the shipments of category 1 quantities of materials do not reflect the actual burden of conducting these tasks under the current Orders.

RA4. The Regulatory Analysis does not address how harmonization between the NRC proposed rule and eventual Agreement State regulations will be assured; specifically in regards to the requirements contained in Subpart D Physical Protection in Transit. Inconsistencies between Agreement State transport security requirements could greatly hinder the ability to transport category 1 and 2 quantities of radioactive materials in commerce. Additional Agreement State requirements could also serves as barriers to transporting Category 1 and 2 quantities of materials through an Agreement State. It is also unclear if the NRC considered what fees Agreement States may impose to fund the cost of regulating the physical protection of material in transit. The State of Iowa currently has what Industry considers excessive fees to transport Category 1 quantities of materials through the state. It doesn't appear that potential Agreement State fees were considered in the overall cost estimate. The NRC should consider maintaining the Physical Protection in Transit security measures in Orders or alternately transferring this authority to the US Department of Transportation.

Rulemaking Comments

From: John Miller [jjmiller@intisoid.com]
Sent: Thursday, January 13, 2011 3:56 PM
To: Rulemaking Comments
Subject: Comments Proposed Rule Docket ID NRC-2008-0120
Attachments: JJM-2011-05_Part 37_Comments.pdf

Attached are comments to the Physical Protection of Byproduct Material; Proposed Rule

John J. Miller CHP
International Isotopes Inc
Phone: 208.524.5300
Mobile: 208.589.1580

Received: from mail2.nrc.gov (148.184.176.43) by TWMS01.nrc.gov
(148.184.200.145) with Microsoft SMTP Server id 8.2.247.2; Thu, 13 Jan 2011
16:00:01 -0500
X-Ironport-ID: mail2
X-SBRS: 5.3
X-MID: 32643433
X-fn: JJM-2011-05_Part 37_Comments.pdf
X-IronPort-Anti-Spam-Filtered: true
X-IronPort-Anti-Spam-Result:
AvwBACf2Lk1AGzhmmWdsb2JhbACCOpN/gSWEcYd+FQEBAQEBCAsKBxEkvHcCgwyCPgS
EaA
X-IronPort-AV: E=Sophos;i="4.60,319,1291611600";
d="pdf'?scan'208,217";a="32643433"
Received: from mail.gowesthosting.net ([64.27.56.102]) by mail2.nrc.gov with
ESMTP; 13 Jan 2011 16:00:00 -0500
Received: from jjmDynamite (65-121-78-186.dia.static.qwest.net
[65.121.78.186]) by mail.gowesthosting.net with SMTP; Thu, 13 Jan 2011
13:59:42 -0700
From: John Miller <jjmiller@intisoid.com>
To: <Rulemaking.Comments@nrc.gov>
Subject: Comments Proposed Rule Docket ID NRC-2008-0120
Date: Thu, 13 Jan 2011 13:56:14 -0700
Message-ID: <008701cbb364$513bdbd0$f3b39370$@com>
MIME-Version: 1.0
Content-Type: multipart/mixed;
boundary="----=_NextPart_000_0088_01CBB329.A4DD03D0"
X-Mailer: Microsoft Office Outlook 12.0
Thread-Index: AcuzZFDVE8fkcV7yTRaqsAlokVJ7RQ==
Content-Language: en-us
X-Declude-Sender: jjmiller@intisoid.com [65.121.78.186]
X-Declude-Spoolname: 74430741323.eml
X-Declude-RefID:
X-Declude-Note: Scanned by Declude 4.6.35 "http://www.declude.com/x-note.htm"
X-Declude-Scan: Outgoing Score [0] at 13:59:44 on 13 Jan 2011
X-Declude-Tests: Whitelisted
X-Country-Chain:
X-Declude-Code: 0
X-HELO: jjmDynamite
X-Identity: 65.121.78.186 | | nrc.gov
Return-Path: jjmiller@intisoid.com