

Rulemaking Comments

From: Greg Yuhas [gyuhas@berkeley.edu]
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Cc: 'Pat Goff'; 'Elsa Nimmo'
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Attachments: Part 37 Comments gpy.doc

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Dear Ms Gallagher

Attached please find our comments on the proposed 10 CFR Part 37.

The Juarez, Goiana and Mayapuri radioactive material dispersal incidents were caused by failure to comply with regulatory requirements for "Category 2" sources and resulted in minimal loss of life. Had the events all occurred in the United States, in a single year, the annualized risk of premature death would be a small fraction of the 1E-6 probability frequently used in establishing regulatory requirements.

The proposed Part 37 requirements should not apply to holders of Category 2 sources, particularly since the new requirements would not apply to the transshipment of Category 1 and 2 sources.

Thanks for the opportunity to provide comments.

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UC Berkeley would like to offer comments in response your questions concerning the following issues raised in your Proposed Part 37(RIN 3150-AI12, NRC-2008-0120):

Section II: (1) Item B5 of this document contains a request for comment on whether the reviewing official should be fingerprinted as part of the trustworthiness and reliability determination:

In developing comments on this issue, consider the following questions:

- (1) Does the reviewing official need to be fingerprinted and have a FBI criminal records check conducted?

No, if the current trustworthy and reliability reviewing (T&R) Official is a police officer recognized by a state or federal jurisdiction, or holds a security clearance issued by an U.S. government agency, they should not need an FBI check. For example: an individual granted a current Department of Defense "confidential" clearance to work in the personnel department at a military hospital should be permitted to continue to make T&R determinations under Part 37 as long they continue to satisfy the routine personal security questionnaire (PSQ) maintenance process.

- (2) Are the other aspects of the background investigation adequate to determine the trustworthiness and reliability of the reviewing official?

Yes, if the reviewing official has held a position of trust within the licensee's organization for more than the last three consecutive years, that person may have demonstrated their trustworthiness and reliability. For example: a Director of Human Resources may routinely determine the trustworthiness and reliability of new and existing employees and may be better qualified to make the T&R determination than the Radiation Safety Officer (RSO).

- (3) Are there other methods that could be used to ensure that the reviewing official is trustworthy and reliable?

Yes, a background investigation by a professional in the field, such as a police investigator, private security clearance contractor or human resource professional could do a better job than provided by the FBI criminal history records check because of the limit scope of the FBI check.

- (4) Does the requirement to fingerprint the reviewing official place too large of a burden on the licensee?

No, but it can create a stigma if a reviewing official nominee declines be fingerprinted for the FBI check.

(5) Do Agreement States have the necessary authority to conduct reviews of the nominated individual's criminal history record?

It is not clear if all Agreement State inspectors have been subject to the same FBI criminal history records check or fingerprinting requirements required of the reviewing official; therefore why should they be in a position to find a proposed reviewing official is trustworthy and reliable.

(2) Item B8 contains a request for comment on the elements of the background investigation; The NRC is specifically inviting comment on the elements of the background investigation.

Please consider the following questions in developing comments:

(1) Is a local criminal history review necessary in light of the requirement for a FBI criminal history records check?

No, the extent of the background investigation should be tied to the radiological risk. The regulatory authority granting the license should use published guidance if they believe it necessary to perform exceptional T&R reviews. It would be best if the regulatory authority performed its own reviews of license applicants or the reviewing official for those licensees granted authorization to possess Category 1 or perhaps 10XCategory 1 quantities.

(2) Does a credit history check provide valuable information for the determination of trustworthiness and reliability?

Yes, probably more than the FBI criminal history records check, however it is by no means adequate to detect persons with criminal intent.

(3) Do the Agreement States have the authority to require a credit history check as part of the background investigation?

Not in California.

(4) What are the appropriate elements of a background investigation and why are any suggested elements appropriate?

The existing framework provides an example of due diligence sufficient to make the public feel better, like taking your shoes off at the airport. However, would you grant a graduate student unescorted access to 1620 Ci of Am-241 power; given that might be on the order of 3 E11 Annual Limits on Intake (ALI) for non-stochastic effects? A better, but not absolute, approach might be to require more robust engineering controls and a "two person rule" for truly significant sources.

(5) Are the elements of the background investigation too subjective to be effective?

No, a highly qualified reviewing official can use all the information to trigger additional questions or inquiry as necessary to better understand the situation. However, items 1, 5, 6, 7, 10 and 14 presented in Annex B of the implementation guidance may be considered medial information and protected from disclosure to the reviewing official.

(6) How much time does a licensee typically spend on conducting the background investigation for an individual?

About two hours now; perhaps 20 hours to satisfy the proposed requirements.

(3) Item C6 contains a request for comment on the protection of information; the NRC is specifically inviting comment on the requirement to protect security-related information.

Please consider the following questions in developing comments:

(1) Do the Agreement States have adequate authority to impose the information protection requirements in this proposed rule?

Yes, by existing Order.

(2) Can the Agreement States protect the information from disclosure in the event of a request under a State's Freedom of Information Act, or comparable State law?

Unknown

(3) Is the proposed rule adequate to protect the licensees' security plan and implementing procedures from unauthorized disclosure, are additional or different provisions necessary, or are the proposed requirements unnecessarily strict?

Yes, the rule is unnecessarily strict by requiring that persons having access to the security plan and procedures also be permitted unescorted access to the sources is inconsistent with ALARA and the need for enhanced control of the sources of concern. For example, a senior manager might be required to review and concur in the security plan since it involves a commitment of her resources or personnel, yet she may have no need for unescorted access to the actual sources. For the same reason, persons doing background checks should be "confidential employees" or T&R but not given access to the actual sources.

Access to the security plan should be limited and controlled to those T&R individuals having a need to know. However, many implementing procedures are necessary that will not include specific security measures designed to protect the sources. These procedures and forms, like how to apply for unescorted access, how to add people to Radiation Use Authorizations involving irradiators, records disposition, etc. should not be considered SGI-M.

(4) Should other information beyond the security plan and implementing procedures be protected under this proposed requirement?

No, only specific information describing structures, systems, components, response measures and lists of persons with unescorted access should be protected from public disclosure.

(5) Should the background investigation elements for determining whether an individual is trustworthy and reliable for access to the security information be the same as for determining access to category 1 and category 2 quantities of radioactive material (with the exception of fingerprinting)?

No

(4) Item C15 contains a request for comment on the need to notify the LLEA before working at a temporary jobsite; The NRC is specifically inviting comment on the requirement to contact the LLEA for work at a temporary jobsite.

Please consider the following questions in developing comments:

(1) Is there any benefit in requiring that the LLEA be notified of work at a temporary jobsite?

Yes, for Category 1.

(2) Should notifications be made by licensees for work at every temporary jobsite or only those where the licensee will be working for longer periods, such as the 7 day timeframe proposed in the rule?

Notifications for work involving Category 1 source at temporary job sites should be made for each activity.

(3) If notifications are required, is 7 days the appropriate threshold for notification of the LLEA or should there be a different threshold?

Seven days is adequate for Category 2 sources.

- (5) Will licensees be able to easily identify the LLEA with jurisdiction for temporary jobsites or does this impose an undue burden?

Yes , the LLEA can be easily determined however, training a new LLEA for a temporary jobsite could be problematic.

- (6) Are LLEAs interested in receiving these notifications?

Yes, campus police are committed to minimizing crime and protecting the safety of the campus population.

(5) Item C17 contains a request for comment on vehicle disabling requirements for mobile sources; The NRC is specifically requesting comment on this issue.

Please consider the following questions when developing comments on this issue:

- (1) Should relief from the vehicle disabling provisions be provided?

No

- (2) Have licensees experienced any problems in implementing this aspect of the Increased Controls?

No experience

- (3) Should there be an exemption written into the regulations or should licensees with overriding safety concerns be required to request an exemption from the regulations to obtain relief from the provision?

A blanket exemption for Category 2 sources should be in the regulations.

- (4) If an exemption is included in the regulations, should it be a blanket exemption or a specific exemption for the oil and gas industry?

A blanket exemption for category 2 sources should be in the regulations.

- (5) Does the disabling provision conflict with any Occupational Safety and Health Administration requirements or any State requirements?

Unknown

(6) item C19 contains a request for comment on the reporting requirements; the NRC is specifically requesting comment on the reporting requirements.

Please consider the following questions when developing comments on this issue.

(1) Are these the appropriate items and thresholds to be reported to the LLEA?

No, NRC/FBI should be notified of any denial of request for unescorted access, for cause. This might be domestic intelligence information of interest to the FBI or Department of Homeland Security (DHS). The NRC/FBI should also be notified of activities determined to be suspect by LLEA such as reconnaissance or probing of T&R people for information specific to the sources for which they have been granted unescorted access.

(2) Are these the appropriate items and thresholds to be reported to the NRC?

See above

(3) Should suspicious activities be reported? If they are reported, what type of activities should be considered suspicious?

See above

(4) Is the timeframe for reporting appropriate?

No, an actual attempt or malevolent act should have a specific time stated. For example : Any actual attempt or malevolent act involving a Category 1 source shall be reported to the NRC Operations center within 15 minutes of the Incident Commander's determination that such act is in progress or has occurred. A similar report shall be made within one hour if the attempt or malevolent act involves a Category 2 source. Failure to set specific time limits will result in delay in implementing the Federal response framework.

(7) item D4 contains a request for comment on requiring license verification before transferring category 2 quantities of radioactive material.

In developing comments on this aspect, consider the following:

(1) Should there be a requirement for verification of the license for transfers of category 2 quantities of radioactive material or would it be acceptable to wait for the system being developed before requiring license verification for transfers of category 2 quantities of radioactive material?

It would be acceptable to wait because of the lesser radiological hazard associate with Category 2 sources.

(2) We are interested in how address verification might work for shipments to temporary job sites and the ability of both licensees and the Agreement States to comply with such a requirement. For example, would States be able to accommodate such requests with their current record systems?

The existing requirements in 10 CFR 30.41(d) should apply. The licensee should also require a copy of the shippers and carriers 10 CFR 37.41 (d) notification.

(3) We are also seeking comment on the frequency of the license verification. For example, should a licensee be required to check with the licensing agency for every transfer or would an annual check (or some other frequency) of the license be sufficient?

Every transfer should require verification.

(4) If an annual check is allowed, how would the transferring licensee know if a license has been modified since the last check and that the licensee is still authorized to receive the material?

The provision of 10 CFR 30.41 apply and the shipper should require a written statement signed by the receiving RSO attesting to the current amendment number and that the amount to be received will not exceed the their quantity limits or move them into an aggregate quantity 2 category at that use location. For example multiple radiography sources at one construction site.

(8) item D21 contains a request for comment on requiring an NRC-approved monitoring plan for the classification yard for rail shipment.

In developing comments on this aspect, consider the following questions:

(1) How could surveillance of the shipment be accomplished while in the classification yard?

No comment

(2) Would the classification yard allow an individual to accompany a shipment while the shipment is held in the classification yard?

No comment

(3) What precautions might be necessary from a personal safety standpoint?

No Comment

In addition, Section V of this document contains a request for comment on the compatibility designations for the proposed rule; The NRC invites

comment on the compatibility category designations in the proposed rule and suggests that commenters refer to Handbook 5.9 of Management Directive 5.9 for more information.

No comment

Section VI contains a request for comment on the use of plain language; The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used.

The 10 CFR 37.5 definition of Aggregated uses the term "sealed source". The use of "sealed source" lacks clarity and safety significance. It should be revised here and in Parts 30 and 70 as follows:

"Sealed source means any radioactive by-product material contained to minimize the spread of contamination in accordance with the presentation made in a Sealed Source and Device Registry certificate issued by the Nuclear Regulatory Commission, an Agreement State or the International Atomic Energy Agency, that is encased in a capsule designed to prevent leakage or escape of the byproduct material;

10 CFR 37.21 (b) uses the term "unreasonable risk." This term should be defined in 10 CFR 37. 5.

10 CFR 37.23 (e) (3) states in part: "The licensee shall document the basis for conducting whether or not there is reasonable assurance that an individual granted unescorted access to Category 1 or 2 quantities of radioactive material is trustworthy and reliable. "Reasonable assurance" is not defined in 10 CFR 37.5. The lack of clarity in this requirement will result in disputes with NRC inspection findings. For example, the reviewing official might check a box on a form stating: "Nothing in the background investigation and criminal history records check revealed any excessive: untruthfulness, unreliability, criminal convictions or extreme indebtedness therefore this person is consider trustworthy and reliable and is therefore granted unescorted access to the blood irradiator." The NRC inspector might be expecting documentation specific to the individual.

10 CFR 37.23 (e) (3) states in part: "When a licensee determines that a person no longer requires unescorted access, the licensee shall immediately remove the person from the approved list..." "Immediately" is not defined in 10 CFR 37.5 and is not realistic for routine terminations such as student graduations, deaths, and terminations not based on a change in T&R status. The only justification for "immediate termination" would be for demonstrated unreliability that would result in withdrawal of the persons T&R status.

10 CFR 37.23 (f) (3) requires "procedures to ensure that persons who have been denied unescorted access authorization are not allowed access..." This item seems redundant. Typically, a person granted unescorted access is then provided keys or codes to the source. Why would you need a procedure to say that persons not found trustworthy and reliable shall not be provided key or codes to sources?

10 CFR 37.23 (h) (3) appears to require lists of those granted unescorted access, those denied unescorted access, and every change to these lists be maintained for 5 years. Given that the lists may be electronic, i.e. part of a database, it doesn't seem reasonable to keep a copy of each change for 5 years. Rather it would seem reasonable to ask that a list of all persons currently granted unescorted access be maintained (± a month) and that a list of all persons denied or removed from the unescorted access list be maintained (± a month) as long as the source is in the licensee's possession. Once a source requiring access controls pursuant to Part 37 is transferred the may dispose of those list after 5 years.

10 CFR Part 37.25 (a) (3) states: "Licensees shall verify the individuals' employment history for the most recent 10 years before the date of application." Given the lifespan of many employers, this language is too rigid. Consider, the licensee shall attempt to verify the individuals' employment history for the most recent 10 years before the date of application; unsuccessful attempts must be documented and considered by the reviewing official in making the unescorted access determination. This approach would allow verbatim compliance and recognizes that business fail and overseas employers may be impossible to contact.

10 CFR 37.25 (a) (4) and (5) also use "shall" in a way that may not permit verbatim compliance. Consider foreign graduate students or researchers. How does a licensee verify attendance at a community school in Myanmar or a militia in Djibouti.

10 CFR 37.25 (a) (6) Use of the terms "full credit history" and "must document all attempts to obtain information regarding the individual's credit history and financial responsibility" are too broad and inconsistent with the actual risk of Category 2 sources. A more realistic approach might be too only require the licensee to request a credit history report and to provide the reviewing official the report for consideration or a statement that a report was requested, but none was provided for Category 2 source access. It should be up to the reviewing official to decide if they have enough information to grant unescorted access to a Category 2 source without extraordinary investigative effort and documentation.

10 CFR 37.25 (a) (7) use of the terms "shall obtain from local criminal justice resources the criminal history records" and "must cover all residences of record for the 10-year period" are onerous and not possible for many foreign students

and researchers. Some provision must allow less than absolute compliance with these conditions.

10 CFR 37.27 (b) (1) states a licensee may not base a final determination to deny an individual unescorted access solely on the basis of information received from the FBI. This is inconsistent with the intent of the rule to protect the public from Category 1 and 2 radioactive sources. Since the FBI has statutory authority to spy on US citizens, and may take action in secret courts, how could a responsible licensee not use information provided by the FBI to restrict a terrorist from access to these sources?

10 CFR 37.29 (g) Have Agreement State employees that conduct security inspections been subject to the same or equivalent criteria expressed in Part 37? Are these inspectors obligated to present credentials indicating they are in compliance with this section? Licensee are obligated to provide unfettered access to Agreement State inspectors, however, licensee should be under no obligation to provide unescorted access to any inspectors.

10 CFR 37.33 use of: "shall evaluate all program performance objectives and requirements and shall ensure that its entire access program is reviewed at a frequency not to exceed 12 months" is onerous and unnecessary. Consider use of the sentence form 10 CFR 20.1101 (c) "The licensee shall periodically (at least annually) review the radiation protection program content and implementation."

10CFR37.43 (c)(1)(iv) Requires that each license shall conduct training on the appropriate response to security alarms. What is the appropriate response by an armed responder to someone running away with a Category 2 source? How about a Category 1 source? It would seem that Local Law Enforcement Agency (LLEA) could ask how should they respond to theft of a source when an unarmed individuals is absconding with the radioactive material? If the perpetrator holds the Category 2 Co-60 source up so as to exposed the responder, would it be consider self defense to shoot the perpetrator? I think not, but I do think the licensee should not be training the LLEA on rules of engagement.

10 CFR 37.45 LLEA coordination and notification seems to impose a significant administrative burden on the LLEA disproportionate to the product of the health consequences times the probability of occurrence for Category 2 sources. Given the low probability of an actual threat to sabotage or steal a Category 2 source, is this really the best use of LLEA resources? Would it be more efficient to inform/train only the LLEA involved when the billions we spend on intelligence indicate a credible threat? Why shouldn't the holder of a Category 1 source be obligated to pay for protecting its investment rather than the local tax payers?

10 CFR37.49 (a) (3) (C) (ii) requires weekly verification that the Category 2 material is still present. This is too prescriptive. What is the safety basis for

weekly as opposed to daily; monthly or every six months given the security area will be locked and alarmed.

10 CFR 37.51 (a) what is the technical basis to require operability and performance testing of intrusion alarms and communication systems every 3 months? Is this frequency supported by industry data or a probabilistic risk analysis (PRA) from the nuclear power industry?

10 CFR 37.57 requires reporting to NRC no later than 4 hours after the discovery of any actual theft or diversion, whereas §.81 requires reports with 1 hour of lost or missing material. Why is there a difference?

Section VIII contains a request for comment on the environmental assessment;

No comment

Section IX contains a request for comment on the information collection requirements;

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

No Comment

2. Is the estimate of burden accurate?

The current recharge rate for non-routine technical support is \$149/hr. The time estimated to update the security plan, procedures, agreements, training and audit program would be about 120 hr. The time to implement and maintain the plan, based on the existing inventory is about 200 hr/yr. The estimated cost to implement this change would be about 320 hr the first year or \$47,000. The cost to maintain the plan would be about \$30,000/year. The cost to dispose of two Category 2 sources in 2008 was \$81,000.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

No comment

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

No comment

Section X contains a request for comment on the draft regulatory analysis; The Commission requests public comment on the draft regulatory analysis. The analysis is available for inspection in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852. The analysis may also be viewed and downloaded electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> by searching for Docket Number NRC–2008–0120.

Section XI contains a request for comment on the impact of the proposed rule on small businesses. The NRC is seeking public comment on the potential impact of the proposed rule on small entities. The NRC particularly desires comment from licensees who qualify as small businesses, specifically as to how the proposed regulation will affect them and how the regulation may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety and common defense and security.

Comments on how the regulation could be modified to take into account the differing needs of small entities should specifically discuss–

(a) The size of the business and how the proposed regulation would result in a significant economic burden upon it as compared to a larger organization in the same business community;

Many Universities use small irradiators (Category 2). These irradiators are old reliable machines that have rarely been the target of abuse or diversion, other than occasional graffiti.

(b) How the proposed regulation could be further modified to take into account the business's differing needs or capabilities;

No Comment

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation was modified as suggested by the commenter;

If these comment were adopted, the program would better recognize the actual risk associated with Category 2 sources and provide more flexibility.

(d) How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations as opposed to providing special advantages to any individuals or groups; and

No comment

(e) How the proposed regulation, as modified, would still adequately protect the public health and safety and common defense and security.

The US census estimates that there are 310 million people in the United States. The Centers For Disease Control reports 438 thousand die each year as a result of smoking or exposure to second hand smoke. The US Department of Health and Human Services estimate that 300 thousand die from obesity each year. Health Grades report that 195 thousand die from hospital related mistakes each year. The National Highway Traffic Safety Association reports 37 thousand die in traffic accidents each year. There have been less than ten people die as a result of two major dispersals of Category 2 sources (300 Ci Co-60 in Juarez, Mexico and 1300 Ci of Cs-137 in the Goiania, Brazil Incident). The table below shows the annual risk of fatality from a Category 2 radioactive material dispersal device is between 10,000 and 100,000 times less likely than many other sources of premature death that the US population commonly accepts.

<i>Cause:</i>	<i>Annual deaths:</i>	<i>Risk:</i>
<i>Smoking</i>	<i>438,000</i>	<i>1.4 E-3</i>
<i>Obesity</i>	<i>300,000</i>	<i>9.8 E-4</i>
<i>Medical accident</i>	<i>195,000</i>	<i>6.3 E-4</i>
<i>Auto accidents</i>	<i>37,000</i>	<i>1.2 E-4</i>
<i>Radiological Dispersion</i>	<i>10</i>	<i>3.2 E-8</i>

The regulations proposed in Part 37 for Category 2 radioactive material should to be reconsider based on the actual safety significance of the threat.

*Greg Yuhas
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