



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

National Institutes of Health  
Bethesda, Maryland 20892  
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January 18, 2011

Secretary, US NRC  
Washington, DC 20555-0001  
Attn: Rulemakings and Adjudications Staff  
Ms. Merri Horn, FSME

DOCKETED  
USNRC  
January 19, 2011 (10:15 am)  
OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

Re: Request for Comments on Proposed Rule [Docket ID NRC-2008-0120].

Dear Ms. Horn,

The National Institutes of Health (NIH) appreciates this opportunity to review and provide input on the U.S. Nuclear Regulatory Commission's (NRC) proposed regulation on the Physical Protection of Byproduct Material published in the Federal Register on June 15, 2010 as Vol. 75, No. 114 [Docket ID NRC-2008-0120]. NIH submits these comments on behalf of the approximately 700 individuals who access and use category 1 and 2 quantities of radioactive material at the NIH. Below please find the excerpted proposed regulation, and the NIH applicable comment:

*37.21(a)(3) and 37.41(d) "By (30 days after the final rule is published in the Federal Register), each licensee that is authorized to possess a category 1 or category 2 quantity of radioactive material on (effective date of this rule) shall submit information concerning the licensee's compliance with the requirements of this subpart to the appropriate NRC regional office.*

NIH has identified 23 unique modifications that will need to be made to our RAMQC security program if the final rule is published as currently worded. We petition that 30 days implementation is not nearly sufficient time for these changes, some of which would require contract modifications and/or would be new enhancements. Note that the Draft Regulatory Analysis for the Proposed Rule (November 2009) referenced an implementation timeframe of 180 days, which is much more reasonable.

*37.23(b)(1) "The fingerprints of the nominated reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide finger printing services to the public, or commercial fingerprinting services authorized by a State to take fingerprints."*

NIH does not fit into any of these categories for purposes of the reviewing official's fingerprint submission. Previously, NIH had been granted approval under the Increased Controls Orders to collect and process fingerprints in-house for transmission to the FBI, due to our compliance with Homeland Security Presidential Directive # 12. This regulation appears to disallow such a practice. It may be more appropriate to exempt this restriction for licensees for whom 37.29 is applicable, and who possess a fully-accredited program, such as that at the NIH, to do its own collection and transmission of fingerprints to the FBI.

*37.23(b)(5) "Reviewing officials may not make any trustworthiness and reliability determinations or permit any individual to have unescorted access until they have been approved as a reviewing official by the NRC."*

NIH currently has an NRC-approved "T&R Official" as per the Increased Controls Order, and we intend for this same individual to serve as the reviewing official; if the same individual needs to re-apply for NRC approval to serve as a reviewing official, there will be a gap in processing new T&R

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applicants. This delay could be problematic for the volume of applicants processed at NIH (approximately 100/yr or 8+/month).

*37.23(c)(1) "Licensees may not initiate a background investigation without the informed and signed consent of the subject individual." "Licensees do not need to obtain signed consent from those individuals that have undergone a background investigation under the Fingerprint Orders." "A signed consent must be obtained prior to any reinvestigation."*

NIH conducts a background investigation on all badge-holders (employees, fellows, contractors, etc), the vast majority of whom have no intent of applying for T&R status for purposes of unescorted access to an irradiator. There is no opportunity, or it is a misplaced opportunity, to request an individual's signed consent under this regulation at the point of background investigation initiation; and there is no need to repeat the background investigation just because an individual later determines a need to request unescorted access to an irradiator. For purposes of those licensees who are exempt from fingerprinting, identification, criminal history records checks and other elements of background investigations per 37.29, the regulations contained within 37.23(c) should also be exempted.

*37.23(e)(3) "The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual granted unescorted access to category 1 or category 2 quantities of radioactive material is trustworthy and reliable."*

Does this mean that the licensee must document its basis for approval of T&R determination, as a written policy? The regulation should clarify the intent of its meaning, because an alternate interpretation could be that the licensee must document a rationale for each individual's T&R approval, as opposed to a generic basis for approval for all applicants.

*37.25(a)(5) ... "Before granting an individual unescorted access to category 1 or category 2 quantities of radioactive material, licensees shall complete a background investigation of the individual... The background investigation must include at a minimum ... military history verification. Licensees shall verify that the individual was in the military during the claimed period."*

NIH does not believe this contributes sufficient additional value to the T&R process, given the complex and difficult task this represents. Many T&R applicants are foreign nationals, and a verification of foreign military service is an extremely challenging proposition. In some countries, military service is a requirement of its citizens and so awareness or verification of a military history has little bearing on an individual's suitability for T&R approval. If, instead, the intent is to determine whether any falsehoods are knowingly provided by an applicant, the added task of military history verification is of modest value when opportunities for falsehoods are present in the form of educational background, employment history, etc.

*37.25(a)(6) "Licensees shall evaluate the full credit history of the individual who is applying for unescorted access authorization."*

The NIH is adamantly opposed to a credit history evaluation for its T&R applicants based on our experiences in implementing an access control program in compliance with the Increased Controls Order of 2005. Initially, a "public trust level" background investigation (NACIC) was required of 500+ T&R applicants, which included a credit history evaluation. It created a significant uproar in a population that was comprised of mostly Ph.D. and M.D. applicants – in other words, a population that was not insignificantly in debt due to student loans and associated educational expenses. This single factor was the catalyst for increased distrust of the process and was the sole reason for

dozens of researchers to withdraw their irradiator access privileges. Due to the impact on the irradiator program, NIH chose to reduce its background investigation requirement to a NACI level, which no longer required a credit check but still fulfilled the specifics of the Increased Controls Orders. Should a credit check again be required, it would seem to imply that the Increased Controls Orders (which did not mandate such a check) were insufficient in their effectiveness. It also contradicts the NRC's own acknowledgement that an individual who has completed a NAC (let alone a NACI or NACIC) meets the requirements for T&R approval (37.29). In our current society, as more and more of our ability to control our finances is lost due to the economic downturn (i.e. not being able to pay one's bills in full each month), it becomes misplaced to tie our T&R status into our credit history. On the other hand, if the NRC's intent is to simply request a disclosure of outstanding significant debts, that is a different matter and NRC should consequently look to published federal guidance from the U.S. Office of Government Ethics on confidential financial disclosures. We contend that such a request would be far more palatable than a credit history evaluation.

*37.25(a)(7) "Reviewing officials shall obtain from local criminal justice resources the criminal history records of the individual who is applying for unescorted access authorization and evaluate the information to determine whether the individual has a record of local criminal activity that may adversely impact his or her trustworthiness and reliability. The scope of the applicant's local criminal history review must cover all residences of record for the 10-year period preceding the date of the application for unescorted access authorization."*

This seems to be a duplicative effort of the fingerprinting and FBI criminal history records check which is specified in 37.25(a)(1). There is not much explanation of the difference and the perceived need for both, if indeed they are different processes. For the many individuals who live in an area considered geographically separate from their area of employment, does the local criminal history review exclude their place of employment?

*37.25(c) "Licensees shall conduct a criminal history update and credit history reevaluation every 10 years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material."*

This suggests that only a criminal history records check (through the FBI or the local criminal justice resources?) and the dreaded credit history check is needed; it also implies that T&R is not sufficiently demonstrated by ten years' worth of the individual's irradiator access without an incident to prompt T&R revocation. The reinvestigation requirement seems overly draconian given that the OPM standard for background investigations only requires a reinvestigation at a level higher than even a NACIC – and in that case is prompted only every 15 years. Furthermore, there is insufficient information to determine whether the required 10-year reinvestigation is applicable to individuals for whom 37.29 applies. Once their approval is granted for unescorted access to category 1 or category 2 quantities of radioactive material under the conditions of 37.29, does 37.25(c) still apply? If it does, then is the 10-year reinvestigation triggered by the criminal history records check (fingerprinting date) or by the NAC (or higher) date?

*37.27(a)(1) "Licensees shall transmit all collected fingerprints to the Commission for transmission to the FBI."*

The narrowness of this regulation does not allow for licensees who possess a fully-accredited program, such as that at the NIH, to do its own collection and transmission of fingerprints to the FBI.

37.27(a)(4) *"Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material or access to safeguards information by another licensee, based upon a background investigation conducted under this subpart, the Fingerprint Orders, or part 73 of this chapter."*

There is a potential wide discrepancy in one licensee's basis for T&R approval and another licensee's. While the NIH is not opposed to the possibility of such a transfer of an individual's T&R status, we would seek greater harmony on this topic: either no T&R transfer is possible, or T&R transfer is allowed and therefore waives a second round of fingerprinting **and background investigation**.

37.29 *"Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials or other property"*

It is not clear whether the relief granted by this regulation may be extended to individuals who will serve as the licensee's reviewing official. A reviewing official may be given access to safeguards information as part of their job duties and not necessarily be required to have unescorted access to category 1 or category 2 quantities of radioactive materials [see 37.23(b)(2)], yet the relief granted by this regulation seems to only apply to individuals for whom unescorted access to category 1 or category 2 quantities of radioactive materials is sought.

37.29(i) *"Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials: Emergency response personnel who are responding to an emergency."*

We petition that emergency response personnel represent a category of a licensee's employment or liaison that, due to the extensive pre-planning, exercising, and frequent needs to access irradiator rooms absent an actual emergency (smoke detector checks, safety inspections of fire walls, assessment of and response to false alarms, etc.), should be permitted by virtue of their occupation to be automatically granted relief from fingerprinting, identification, criminal history records checks, and other elements of background investigations – without the clause that they be actively responding to an emergency.

37.29(m) *"Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials: Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to access to category 1 or category 2 quantities of radioactive materials."*

There exists a gap whereby this regulation does not cover self-employed service provider licensees who are small business owners, for example independent service technicians who are licensed to perform maintenance and repairs on sealed source irradiators. These individuals are qualified in a similar way for the applicability of 37.29, yet the wording of this regulation does not appear to extend to them.

37.43(c)(2) *"In determining those individuals who shall be trained on the security plan, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations"*

*involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material."*

The NRC should clarify the applicability of this regulation to individuals who have "assigned activities during authorized use". Is the intent to extend annual security plan training to all approved users and accessors? For NIH, this encompasses approximately 700 individuals! Should the NRC's intent be to extend annual security plan training simply to security-related personnel, then approved users and accessors may be excluded. Additionally, clarification is needed on the licensee's responsibility to extend annual security plan training to individuals who may be security-related personnel but not individuals within the licensee's control (outside LLEAs, for example, or non-licensee personnel).

*37.45(a)(1) "A licensee subject to this subpart shall provide information to and coordinate to the extent practicable with an LLEA for responding to threats to the licensee's facility, including any necessary armed response."*

The LLEA with whom NIH has coordinated has required us to file Non-Residential Burglary Alarm Registrations for each room in which an irradiator is housed (and to which they are expected to respond in the event of an alarm). The LLEA has furthermore clarified their position that an LLEA response is deemed false if no evidence of criminal activity is found, in which case a "False Alarm Notice" will be served, including penalties escalating up to \$4000 for requested LLEA responses that are judged to be false. This places the licensee in a very bad position to attempt compliance with this regulation and risk fines from the LLEA. There does not need to be evidence of criminal activity for the licensee to perceive a threat to their facility, and appropriately request LLEA response. NIH petitions that outreach be made to the LLEA community with the intent of clarifying NRC's expectations on this topic.

*37.45(a)(2) "The licensee shall notify the appropriate NRC regional office listed in 30.6(a)(2) of this chapter within three business days if: (i) The LLEA has not responded to the request for coordination within 60 days of the coordination request..."*

Notwithstanding the importance of relaying the information that a licensee may be left unsupported by an LLEA, it seems overly restrictive to place a 3-day required notification deadline of this on the licensee. It is sometimes difficult to know when day one of a coordination request is, especially if a licensee is reaching out to an LLEA without the benefit of a prior relationship, and/or if the coordination request is being made through administrative channels. The request may take several days to reach the right person within the LLEA, for example. The 3-day reporting deadline generates an added burden on the licensee to track the communication efforts with the LLEA in a manner that is not collaborative. We recommend that this regulation strike the notification deadline, as the wording loses no meaning without it. As NIH has learned through experience, absence of coordination response does not mean absence or denial of support.

*37.47(d) "For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide an approved individual to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities."*

It is not clear from this wording whether the regulation requires a physical presence for maintaining continuous surveillance, or whether the continuous surveillance may be by remote monitoring. Clarification would be appreciated. Furthermore, the wording implies that the **licensee** must provide an approved individual, and that an individual separately deemed T&R (for example, a

service technician as per 37.29(m)) may not be permitted to provide the continuous surveillance while working. Often, maintenance and other source servicing visits are conducted in teams of two or more T&R approved service providers. It seems short-sighted to not recognize the capability of such individuals to conduct themselves responsibly in matters related to source security, especially when intrusion detection systems may have been disabled and enhanced surveillance is already therefore provided by remote monitoring.

*37.49(d) "For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA."*

It would be appropriate to offer guidance here for LLEA first responders in reference to allowable radiation dose limits. There is conflicting guidance from ICRP, NCRP, EPA and NRC on this topic, and possibly most licensees are following the EPA's Protective Action Guidance of 25 rem whole body dose for life-saving actions and protection of large populations. While the NRC understandably cannot place a dose limit constraint on LLEA terrorist prevention responses, it would be helpful to have guidance on what to plan for, as part of LLEA training.

*37.51(a) "Each licensee subject to this subpart shall implement a maintenance, testing, and calibration program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition, are capable of performing their intended function when needed, and are inspected and tested for operability and performance at intervals not to exceed 3 months."*

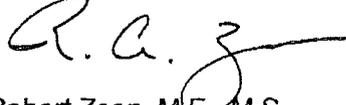
With multiple monitoring systems and physical security features on NIH irradiators, we believe that a quarterly inspection and testing schedule is excessive. Similar to the required leak test and safety inspection requirement for irradiators being conducted every six months, we suggest that six months is a more reasonable schedule for performing the security inspection. Note that the most recent NIH round of inspection and testing of intrusion alarms and associated systems required 40 man-hours to conduct, not including the subsequent follow-up of findings. Given that the alarms and associated systems are centrally-monitored, with 24/7 surveillance of their status, it is highly likely that any necessary maintenance to a security component would be abated well prior to a quarterly finding.

*37.57(b) "The licensee shall notify the LLEA upon discovery of any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material. As soon as possible but not later than 4 hours after notifying the LLEA, the licensee shall notify the NRC Operations Center."*

Additional clarification is needed on the "suspicious activities" described in Annex C. It is not uncommon to discover an unsuccessful attempted access to an irradiator room, and the individual's explanation given is perfectly reasonable – although may not be obtained until greater than four hours after the event. As long as the attempted access is unsuccessful (as the security system is designed to function), such an incident is not viewed as a possible theft, sabotage, or diversion of source material. Yet certain examples in Annex C seem to indicate these incidents are worthy of suspicious activity, warranting LLEA (immediate) and NRC (within 4 hours) notification. Furthermore, the requirement of NRC notification within four hours is certainly understandable for incidents under 37.57(a), but is excessive for incidents under 37.57(b). Our own assessment of the incident to determine its applicability to this regulation often exceeds four hours.

The NIH intends to follow the implementation of Part 37 very closely, and I appreciate the opportunity to provide these comments to you. Basic research needs are dependent upon access to category 1 and category 2 quantities of radioactive material (irradiators) and it would be a disservice to further complicate access to such a valuable tool to the NIH research mission.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. A. Zoon', with a long horizontal flourish extending to the right.

Robert Zoon, M.E., M.S.  
Radiation Safety Officer, NIH

cc: Dr. Michael Gottesman, Deputy Director for Intramural Research  
Dr. Alfred Johnson, Director, Office of Research Services  
Mr. William Cullen, Associate Director for Security and Emergency Response  
Dr. Ira Levin, Chair, Radiation Safety Committee  
Mr. Louis Klepitch, Director, Division of Physical Security Management  
Dr. Theresa Minter, Director, Division of Personnel Security and Access Control

## Rulemaking Comments

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**From:** Ribaldo, Cathy (NIH/OD/ORS) [E] [ribaudoc@ors.od.nih.gov]  
**Sent:** Wednesday, January 19, 2011 9:51 AM  
**To:** Rulemaking Comments  
**Cc:** Horn, Merri  
**Subject:** NRC-2008-0120 Comments on Proposed Rulemaking  
**Attachments:** NRC 2011 Comments Part 37.pdf

Please accept these comments on behalf of the National Institutes of Health (NIH), Department of Health and Human Services, for Docket ID NRC-2008-0120, Physical Protection of Byproduct Material.

Thank you,  
Cathy

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Received: from mail1.nrc.gov (148.184.176.41) by OWMS01.nrc.gov  
(148.184.100.43) with Microsoft SMTP Server id 8.2.247.2; Wed, 19 Jan 2011  
09:50:39 -0500

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Received: from NIHMLBXBB01.nih.gov ([156.40.71.51]) by NIHHTRC.nih.gov  
([156.40.71.74]) with mapi; Wed, 19 Jan 2011 09:50:34 -0500

From: "Ribaudoc, Cathy (NIH/OD/ORS) [E]" <ribaudoc@ors.od.nih.gov>

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Date: Wed, 19 Jan 2011 09:50:34 -0500

Subject: NRC-2008-0120 Comments on Proposed Rulemaking

Thread-Topic: NRC-2008-0120 Comments on Proposed Rulemaking

Thread-Index: Acu36Dm60o+DsL4LQUmi5O3lrGs8sA==

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X-MS-TNEF-Correlator:

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Content-Type: multipart/mixed;

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MIME-Version: 1.0

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