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January 18, 2011

Ms. Cindy K. Bladey
Chief, Rules, Announcements, and Directives Branch
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Request for Public Comment on "Physical Protection of Byproduct Material; Proposed Rule" (75 FR 33902) and Draft Guidance Document (75 FR 40756); Docket Number NRC-2008-0120

Dear Ms. Bladey:

The American Association of Physicists in Medicine (AAPM)[1], appreciates the opportunity to provide both general and specific comments on the Commission's proposed rule and implementation guidance for Physical Protection of Byproduct Material, published in the Federal Register (FR) in June and July of 2010 (75 FR 33902 and 75 FR 40756). In addition to the points contained in this cover letter, Attachment 1 contains general comments and observations on the proposed rule and draft guidance and Attachment 2 provides specific comments for the staff's consideration. In providing these comments, we have also addressed the questions raised in the FR notices.

The FR notices provided proposed rule language and implementation guidance, for public comment, on a new 10 Code of Federal Regulations (CFR) Part 37 that would contain physical protection requirements for radioactive materials that meet the Category 1 or 2 quantity thresholds, as defined by the International Atomic Energy Agency and adopted by the Nuclear Regulatory Commission (NRC). We support the NRC's efforts to use rulemaking to codify necessary physical protection requirements, rather than continuing to rely on the previously

[1] The American Association of Physicists in Medicine's (AAPM) is the premier organization in medical physics; a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 7,500 medical physicists.

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issued security Orders. Given that current requirements were issued by orders, this is the medical community's first opportunity to comment on existing byproduct materials security requirements, some of which have been in effect since shortly after September 11, 2001, for Category 1 and 2 quantities of radioactive materials. As proposed, the rulemaking goes beyond the requirements in the existing orders. **AAPM believes that that NRC should limit the rulemaking to codifying the existing orders into regulation.**

On June 1 and 18, 2009, AAPM submitted comments on preliminary draft rule language to the NRC. At that time, there were significant concerns within the medical community regarding the practicality of some of the changes proposed in the new rule, which extend beyond those contained in previously issued and implemented NRC security orders or compatible Agreement State requirements. Many of the concerns identified at that time still remain applicable to the proposed rule and guidance and were emphasized during the two public meetings NRC conducted in September 2010.

We offer the following fundamental points for your consideration, which we elaborate on in the attachments to this letter:

- AAPM supports the general concept of physical security for radioactive materials to prevent the theft or illegal diversion of Category 1 and 2 quantities, and agrees with the NRC stated objective that the proposed rulemaking is to "provide reasonable assurance of preventing the theft or diversion of Category 1 and 2 quantities of radioactive material" (75 FR 33902).

- AAPM agrees with the NRC assessment that the current regulations and license orders assure that adequate security is in place for Category 1 and 2 byproduct materials (75 FR 33905). However, AAPM remains concerned that NRC appears to be adopting a "one size fits all approach" that is overly prescriptive and does not consider the relative risk and quantity of material possessed by the wide range licensees that would be subject to this rule.

- AAPM supports NRC's approach to terminate existing orders issued, coincident with the effective date of Part 37 (in each respective jurisdiction), to avoid potential confusion and non-compliance, as was experienced most recently with the 10 CFR Part 73 rulemaking to codify security Orders.

- AAPM acknowledges all medical licensees' efforts to implement and comply with the current Increased Controls License Orders (EA-05-090 and EA-07-305), which have required medical licensees expend significant financial and personnel resources. We believe that NRC has not demonstrated a need in the proposed rule to go beyond the requirements of existing orders nor the cost/benefit of doing so. AAPM is concerned with the exceptionally high resource estimate noted in the draft Regulatory Analysis for implementation of the proposed rule which indicates that "there are no quantifiable values (i.e. Benefits) associated with this rule" and the qualitative benefits identified are essentially identical to the regulatory program

in place today. AAPM believes that the Technical Basis for this and all proposed rules should be made available to the public for review.

- AAPM believes that the proposed Part 37 will impact medical licensees who have previously not been impacted by the Increased Controls License Orders based on their total possession limits as specified by license condition rather than their possession of single sources of Category 1 or 2 quantities. Educating and inspecting these new licensees will impact NRC and Agreement State staff resources, and could diminish their focus on ensuring security compliance for existing Category 1 and 2 sources.

- Consistent with the Energy Policy Act of 2005, continued stakeholder input and involvement in this area is essential and we request that the NRC allow substantive opportunities to engage industry over the next four years on the myriad of issues that the Congressionally mandated Radiation Source Protection and Security Task Force is addressing as we continue to work collectively toward our mutual safety and security objectives.

Should NRC proceed to promulgate the current proposed rule, NRC should consider conducting one or more additional public workshops prior to submitting the draft final rule and implementation guidance to the Commission for approval. The purpose would be to explain how the staff addressed and resolved the more major or controversial topics addressed in the public comments received, including comments from the Organization of Agreement States, which have been previously raised and rejected. The September 2008 workshop that NRC conducted on the Security and Continued Use of Cesium-137 Chloride sources could serve as an excellent model for such workshops.

AAPM recommends that NRC:

- Change the proposed Part 37 to implement the existing requirements contained in the Increased Controls License Orders to minimize confusion of implementing new requirements and to maintain the established security levels for Category 1 and 2 sources during this change from order requirements to regulations.

- AAPM recommends that NRC conduct two separate rulemakings. Specifically, codify the existing orders into the regulations and then work with stakeholders in a deliberative and constructive manner to determine, based on risk, which elements of the current proposed rule that go beyond the current orders should be incorporated into a subsequent more risk-informed and performance-based rulemaking and provide the justification for any additional requirements. AAPM recognizes that this may need to include changes in legislative authority, to develop the newly established Part 37 with a more risk-informed and performance-based model for security requirements for Category 1 and 2 quantities.

- Re-evaluate the additional requirement to conduct a credit history review. AAPM understands that this was discussed during the development of the requirements currently in place via the orders. Obviously it was determined that including a credit history review was not warranted since the orders did not include such a requirement. Since the time the orders

- have been in effect, we are not aware of any situations that have occurred that now warrant the inclusion of a credit history check.

- AAPM recommends that requirements for licensees who are authorized to posses but do not possess aggregated materials be spelled out separately to avoid confusion by a large set of previously unimpacted facilities.

Thank you for the opportunity to comment. Should you have any questions, please feel free to contact Lynne Fairobent at 301-209-3364 or lynne@aapm.org.

Sincerely,

J Anthony Seibert

J. Anthony Seibert, PhD, FAAPM, FACR

cc: Ms. Merri L. Horn, FSME/DILR/RB-B, NRC
Ms. Josephine M. Piccone, FSME/DILR, NRC

2 Attachments

Attachment 1
AAPM General Comments on the Proposed Rule and Implementation Guidance for 10 CFR Part 37 Physical Protection of Byproduct Material in Category 1 and Category 2 Quantities

1. Basis for Regulating Beyond the Orders

AAPM recognizes that a primary mission of the NRC is to ensure adequate protection of public heath and safety, common defense and security, and the environment, while enabling the use of radioactive materials for beneficial civilian purposes. Since the late 1990s, the NRC has repetitively stated that, in meeting its mission, its regulations, its inspection practices and enforcement actions would be risk based. For example, the NRC website states the "NRC's approach to physical protection is graded based on the significance of the material or facilities being protected."

AAPM questions the validity of this statement when the approach to this rulemaking appears to be that NRC is adopting a "one size fits all approach" that is overly prescriptive and does not consider the relative risk and quantity of material possessed by the wide range licensees that would be subject to this rule. The background section to the proposed rules (75FR33903) indicates that the NRC performed a vulnerability assessment prior to implementing the initial increased control (IC) Orders. AAPM understands that the NRC developed the existing performance-based security requirements based upon the results of vulnerability assessments (which identified gaps or vulnerabilities in security and considered the cost and effectiveness of enhancements) and consideration of the threat environment, among other things, such as efforts within the international community. These considerations formed the safety and security basis for the existing regulatory requirements, which were developed using a performance-based and graded approach based on the relative risk and quantity of material possessed by licensees. Upon careful review of the proposed rule and guidance and through attendance at the public workshops, it does not appear that additional vulnerability assessments have been performed or there was a change in the threat environment to warrant "enhancements."

Nowhere in the Federal Register notice does the NRC state that the IC Orders were ineffective and/or provide any justification for the imposition of significant new requirements. In fact, under the question "why doesn't the NRC just keep the orders in effect?" (75FR33905). The NRC limits its response to an explanation that regulations are the most appropriate method for imposing long-term requirements, without addressing the significant substantive differences between the IC Orders and the proposed new regulations.

We believe the most efficient approach is for NRC to codify the existing orders into the regulations and then work with licensees in a deliberative and constructive manner to determine, based on risk, which elements of the proposed rule that go beyond the current orders should be incorporated into a subsequent, separate more risk-informed and performance based rulemaking. This two-part approach would be a major accomplishment for the NRC and would be consistent with NRC's "Principles of Good Regulation". In addition, this approach would reflect the Commission's Staff Requirements Memorandum (SRM) on the draft policy statement on the protection of Cesium-137 Chloride sources (SRM for COMSECY-09-0029) which states: "any additional efforts to enhance security for these sources should consider whether there are benefits of further risk reduction given the NRC's actions to date and the current threat environment." In addition, the draft Policy Statement that was approved by the Commission indicates that current security is adequate and states that current requirements are based on vulnerability assessments and follow the principles of the International Atomic Energy Agency Code of Conduct on the safety and security of sources.

AAPM notes that the NRC does not routinely share the technical basis for rulemakings with stakeholders. The NRC's website indicates that the staff was given permission from the Commission to share the technical basis for two rulemakings: "Unique Waste Streams" and "Options to Revise Radiation Protection Regulations." In light of the lack of a clear articulated basis for this significant rulemaking, we

believe that as a matter of practice, NRC should routinely share the technical basis for rulemaking with stakeholders. Providing the technical basis may have proven helpful for this proposed rulemaking.

2. Reviewing Official

The proposed rule modifies the process for assessing trustworthiness and reliability by employing a "reviewing official" concept. AAPM understands that the reviewing official who would make trustworthiness and reliability determinations for the licensee (usually human resources personnel) would be required to have access to radioactive materials and undergo a fingerprinting and criminal history records check by the Federal Bureau of Investigation (FBI). The responsible regulatory agency (NRC or the Agreement State) would be responsible for adjudicating the results and making a trustworthiness and reliability determination solely on the basis of fingerprints. This approach requires personnel who do not need access to radioactive materials to have access to radioactive materials and is contrary to the As Low as Reasonably Achievable principle required by 10 CFR Part 20. Moreover, it encourages licensees who appoint reviewing officials who do not have a real need for access to radioactive material in light of their positions to certify that they do to meet the legal basis for fingerprinting.

While we understand that the basis for this change is to ensure that someone conducts a check on the official making determinations in the company, fingerprinting alone is not a sufficient background investigation. Consequently, the proposed method of implementation does not equate to the comprehensive process in place today to assess trustworthiness and reliability, as the regulatory official only considers the fingerprint check, which does not contain sufficient information to approve an individual. AAPM recommends that NRC continue to seek legislative changes to require the reviewing official to be fingerprinted without requiring them to access materials and re-consider the completeness of the background check to be conducted by the NRC or Agreement States.

Alternatively, as discussed in the public meeting, NRC should consider working with the FBI to develop a program modeled off of the Centers for Disease Control and Prevention (CDC) Select Agent Program, where the Federal Government conducts and adjudicates background checks for individuals with access to select agents. This type of program would ensure nationwide consistency in the implementation of background checks, relieve the licensees of a significant financial burden and liability, reduce the burden on the Agreement States, and provide a simplified means of trustworthy and reliable individuals to move from one facility to another. This is an example of an area where licensees and the NRC could constructively work together through public meetings to find the most efficient and effective solution to address NRC's concern.

3. Credit history Reviews

It is unclear at this time whether Agreement States have the authority to require a credit history check. We believe the requirement for a credit history check is unjustified. It creates an additional cost for IC licensees who would now have to pay for a credit history. The proposed rule lacks criteria for making a determination on the credit history. To our knowledge, NRC has not provided a basis indicating that credit scores are a valid gauge of trustworthiness or reliability. This is especially true with the nation's current environmental climate. Thousands of citizens have lost jobs and are now unemployed, creating a significant impact on their credit scores. The economic climate and unemployment in this country have negatively impacted many citizens' credit histories, with no corresponding degradation of those individuals' trustworthiness or reliability. Also, there still do exist trustworthy American citizens who conduct business only in cash and may have limited credit history, if any. These situations are not indicators of a person's trustworthiness or reliability.

If NRC continues this requirement in the final rule, AAPM requests that NRC address how states laws which discriminate against employees due to credit history impacts this proposed requirement. A Google

search indicates that states that have and/or are considering laws covering this issue include Connecticut, Wisconsin, Hawaii, Illinois, Missouri, New York, Oregon, Washington and Texas.

4. Benefits not justified by the Costs

AAPM is concerned with the exceptionally high NRC resource estimates noted in the draft Regulatory Analysis for the proposed rule which indicates that "there are no quantifiable values (i.e. Benefits) associated with this rule" and the qualitative benefits identified are essentially identical to the regulatory program in place today - the no action alternative. Therefore, the proposed rule provides essentially no qualitative or quantitative benefit beyond current regulatory requirements, at an NRC estimated cost (difference between pre-order and main analysis) to licensees of approximately $0.5-0.7 billion. This is in addition to the approximately $0.5 billion NRC estimated costs borne by licensees for existing security requirements. These costs are all in addition to the $26 million that the National Nuclear Security Administration is spending to implement voluntary security enhancements at certain facilities. The very significant costs associated with these proposed additional requirements in combination with the lack of any apparent improvement to safety or security, adversely impacts licensees and ultimately the end consumers, who will face increased costs for many of the products and services they rely on which provide a direct and immediate benefit to public health and safety.

AAPM believes that the cost of complying with this rulemaking may cause medical facilities to rethink treatment options available. For example, facilities may decide to purchase CyberKnife instead of Gamma Knife simply to avoid the additional regulatory costs. This may unduly impact the access to treatment options in some parts of the country and to some patients. Many medical licensees cannot continue to absorb the costs associated with the cumulative effects of various source security requirements (e.g., security orders, National Source Tracking System and future license verification). This rulemaking does not consider the cumulative cost impacts or complying with all of these either in this rulemaking or to our knowledge in any regulatory action. The annual costs to implement all the requirements alone can exceed their annual license fees.

AAPM agrees with the following points made by the NRC's Advisory Committee on the Medical Use of Isotopes:

- "The ACMUI is concerned that costs of the proposed Part 37 regulations have not been adequately considered in determining reasonable security costs. Three cost options are presented in the NRC draft regulatory analysis for the proposed Part 37, but they do not seem to be fully developed to provide adequate justification that the proposed part 37 provides reasonable security.
    - It is not clear whether real licensee cost-to-date for implementing the Increased Controls License Orders were considered in cost calculations.
    - The number of individuals requiring trustworthiness and reliability assessments per licensee was 12. Was this estimate based on the overall number of licensees currently under the Increased Controls Orders, the number of trustworthiness and reliability officials reported to NRC, and the number of individuals who have completed the NRC FBI fingerprint background checks? This is a low estimate for the number of assessments for medical licensees, especially when considering the additional number of individuals needing trustworthiness and reliability assessments impacted by the proposed 10 CFR 37.43(d)(3). A major research medical licensee could have a few hundred individuals in their access authorization program.

- Option 1 of the cost analysis is inappropriate in its benefits/savings versus costs/burdens (draft regulatory analysis Exhibit 4-4) because it assumes no increased security efforts have been made. Instead, Option 1 should have considered the Increased Controls License Orders were in place with their existing qualitative security benefits similar to those listed in Option 2. An additional cost option determining the cost of implementing a new Part 37 with equivalent requirements as are in place with the Increased Controls License Orders would be helpful in this review.

- The ACMUI understands the need to quickly develop and implement the Increased Controls License Orders required the NRC to establish a one-size-fits all model for all types and uses of Category 1 and 2 sources. The ACMUI is concerned that the proposed Part 37 builds off of and expands the requirements of a one-size-fits all model.

- The ACMUI is concerned that the ultimate impact of the proposed Part 37 on medical licensees will be to increase the costs of diagnostic and therapeutic procedures, and further impede research and development of new medical procedures, that rely upon the use of Category 1 and 2 quantities of byproduct materials, ultimately denying patients access to essential medical care."

5. Regulatory Analysis Underestimates the Scope of Personnel Affected

We are concerned that the scope of the proposed rule is severely underestimated in the draft Regulatory Analysis. For example, the estimated costs assume an average of 10 individuals per facility and a total of 1,400 facilities will fall within the background investigation program. This estimate provides for 14,000 individuals subject to this program, however, NRC stated that as of April 2009, approximately 77,000 people have been fingerprinted for access to materials under the current Orders. In addition, it is unclear whether the regulatory analysis considered the cost impacts to all of the licensees the proposed rule is intended to cover such as byproduct, fuel cycle, research and test reactor, power reactor, decommissioning reactor, and source material licensees. Before finalizing the Regulatory Analysis the staff should conduct public meetings to discuss the document and receive insights from licensees on their perspectives on its content.

6. Local Law Enforcement Agencies (LLEA)

The proposed rule adds requirements regarding interactions with local law enforcement agencies (LLEA). There appears to be an unrealistic expectation or perception regarding LLEA coordination. It is inconceivable to believe that LLEA would ever notify a licensee that their response capabilities have become degraded, not only because that would appear to be an open invitation to the criminal sector, but also, if capabilities are degraded, logically LLEA would not have the capability to start calling IC licensees either. Many states have extensive experience dealing with natural disasters such as hurricanes or tornados. In these situations where there might be a temporary drain on local LLEA resources, there are plans in place for augmenting those capabilities. This requirement is not only unrealistic, but also unenforceable.

The proposed requirement that an IC licensee notify the regulatory agency if a LLEA declines to participate in coordination activities creates an unnecessary burden for the regulatory agencies that will now be required to notify the Department of Homeland Security or contact the LLEA directly to explain the importance of cooperating.

7. Implementation

AAPM concurs with the Nuclear Energy Institute's proposal that the effective date of the rule be 365 days after publication of the final rule, to allow sufficient time for implementation and minimize impacts to

safety and security. We also fully support the NRC's approach to terminate existing orders, coincident with the effective date (in each respective jurisdiction) of Part 37, to avoid potential confusion and non-compliance.

8. Continued Licensees Interaction is Necessary

Continued licensee input and involvement in this area is essential. Stakeholders have participated in the Nuclear Sector Coordinating Council, particularly through the Subcommittee on Radioisotopes (through the Department of Homeland Security) over the last several years and have made valuable contributions toward the security of radioactive materials. Recently, discussions within that forum have indicated that the key materials security issues going forward are being integrated into the Congressionally mandated Radiation Source Protection and Security Task Force. Therefore, we request that the NRC provide substantive opportunities to engage licensees over the next four years on the myriad of issues the Task Force is addressing as we continue to work collectively toward our mutual safety and security objectives.

Attachment 2
AAPM Specific Comments on the Proposed Rule and Implementation Guidance for 10 CFR Part 37 Physical Protection of Byproduct Material in Category 1 and Category 2 Quantities

Subpart A – General Provisions

§37.5 – Definitions

This section appears to be omitted from the guidance document. We recommend that all sections of the rule be included in the guidance document and commend NRC for the format of the document which is easy to use and should prove useful to licensees.

The definition of "aggregated" introduces the terms "common physical barrier" and "multiple sources of bulk material" which need clarification or their own definition to avoid potential compliance issues.

DOT removed "safe haven" terminology from its radioactive material transportation requirements several years ago because it was not implementable, in that, specific locations identified as potential "safe havens" were not allowing transport vehicles on site, e.g., military installations. We recommend that NRC work with the states to identify potential safe haven locations, in advance of the final rule and publish with the final rule a list of safe havens that have confirmed to the State their willingness to be listed as a "safe haven" for the purpose of this rule.

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. A definition alone is not adequate to ensure compliance with the rule; therefore, state coordination is needed to ensure intent meets practice. NRC should clearly define what "safe havens" are since many States do not recognize, identify, or acknowledge that they have such sites.

Delete the term "readily" in the definition of lost or missing licensed material since it is subjective and could lead to inadvertent non-compliance by licensees.

The definition of "No-later-than arrival time" (N-L-T) should allow a 24-hour maximum time which 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.

Subpart B – Background Investigations and Access Control Program

§37.21 – Personnel access authorization program requirements for category 1 or category 2 quantities of radioactive material

Paragraph (a)(3) states that the requirement of that section goes into effect 30 days after publication of the final rule. However, the Statements of Consideration provides that the rule does not go into effect until 270 days after publication. This discrepancy needs clarification. We recommend that the effective date be 365 days after publication of the final rule.

Paragraph (b) of this rule provides that the performance objective is to prevent an unreasonable risk to the public health and safety or the common defense and security. However, the Statements of Consideration indicates that the basis for this rule is health and safety and not common defense and security. If under the rule, findings must be made concerning a person's risk for the common defense and security, it is unclear whether this rule can be implemented under a public health and safety basis.

The proposed rule provides relief to the investigation element of the access authorization if an individual has an active Federal security clearance. This relief should be extended to include other aspects of the authorized individual process. For example, requiring NRC approval for someone with a Federal security clearance to be a reviewing official does not appear to provide an increased benefit (37.23(b)(4) and 37.23(b)(5)). In addition, requiring a controlled list of authorized individuals who have access to Category 1 and 2 materials is more restrictive than for facilities that manage classified material and does not provide increased benefit.

§37.23 – Access authorization program requirements

The proposed rule modifies the process for assessing trustworthiness and reliability by employing a "reviewing official" concept. AAPM understands that the reviewing official who would make trustworthiness and reliability determinations for the licensee (usually human resources personnel) would be required to have access to radioactive materials and undergo a fingerprinting and criminal history records check by the Federal Bureau of Investigations (FBI). The responsible regulatory agency would be responsible for adjudicating the results and making a trustworthiness and reliability determination solely on the basis of fingerprints. This approach requires personnel who do not need access to radioactive materials to have access to radioactive materials and is contrary to the As Low As Reasonably Achievable principle required by 10 CFR Part 20. Moreover, it encourages licensees who appoint reviewing officials who do not have a real need for access to radioactive material in light of their positions, to certify that they do to meet the legal basis for fingerprinting.

While we understand that the basis for this change is to ensure that someone conducts a check on the official making determinations in the company, fingerprinting alone is not a sufficient background investigation. Consequently, the proposed method of implementation does not equate to the comprehensive process in place today to assess trustworthiness and reliability, as the regulatory official only considers the fingerprint check, which does not contain sufficient information to approve an individual. AAPM recommends that NRC continue seek legislative changes to require the reviewing official to be fingerprinted without requiring them to access materials and re-consider the completeness of the background check.

Alternatively, as discussed in the public meeting, NRC should consider working with the FBI to develop a program modeled off of the Centers for Disease Control and Prevention (CDC) Select Agent Program, where the Federal Government conducts and adjudicates background checks for individuals with access to select agents. This type of program would ensure nationwide consistency in the implementation of background checks, relieve the licensees of a significant financial burden and liability, reduce the burden on the Agreement States, and provide a simplified means of trustworthy and reliable individuals to move from one facility to another. This is an example of an area where industry and the NRC could constructively work together through public meetings to find the most efficient and effective solution.

§37.23(b) - This section specifically stipulates that fingerprints of the reviewing official "be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints." These three options seem arbitrarily restrictive. There does not appear to be a similar requirement concerning individuals fingerprinted for criminal history checks to grant unescorted access to Category 1 or 2 materials. For example, licensees subject to 10 CFR Part 73 have access authorization personnel perform fingerprinting at licensee facilities for background checks. In addition, the standards for approving a reviewing official are not clear since the regulatory agency will not be considering the full background investigation that the NRC has said, in the guidance for the proposed rule in 35.23, "is essential to ensure that individuals seeking unescorted access... are dependable in judgment, character, and performance such that ... does not

constitute an unreasonable risk to the public health and safety or common defense and security." Also, it is unclear who reviews the background information on the reviewing official that is collected pursuant to §37.23 (b)(1).

§37.23(b)(3) and (4) - The requirement that reviewing officials cannot approve other individuals to be reviewing officials seems arbitrary. The reviewing official can approve unescorted access to Category 1 and 2 quantities of radioactive material. Since the intent of Part 37 is to prevent theft or diversion of radioactive material, access to the material seems more important from a security perspective than the functions of a reviewing official. Once a reviewing official is approved by the NRC or an Agreement State, they should be authorized to make trustworthiness and reliability determinations. Excluding this function for additional reviewing officials is not justified. If the intent is to maintain a listing of approved reviewing officials, this can be accomplished without the stipulations in this proposed rule, and would be further enhanced by the CDC model described above.

§37.23(c)(1) – In light of the grandfathering provision of §37.25 (b), it is not clear why the 4th sentence raises the consent issue for persons who have already been subject to a background investigation under the fingerprint orders.

§37.23(e)(2) – The NRC should provide criteria on what constitutes "disqualifying" information or remove the term from this section.

§37.23(f) – For licensees subject to Part 73 with additional radioactive materials not covered by the Part 73 security plan, the procedures used for Part 73 background investigations, updating of background investigations, etc. should be considered adequate to meet the intent of Part 37.

§37.25 – Background Investigations

This rule is overly prescriptive and represents a significant increased burden to licensees without any apparent quantitative or qualitative benefit. This rule significantly expands the existing comprehensive background checks by adding verification of true identity, military history verification, local criminal history check, and a credit check. If the NRC proceeds with these additions and places the total responsibility on licensees, detailed adjudication criteria are necessary to implement a consistent national program. In addition, NRC should share with the Agreement States and licensees the specific and detailed adjudication criteria that it will use in approving reviewing officials.

We are very concerned with the credit checks required under the proposed rule as a gauge to assess trustworthiness and reliability. As other business sectors have experienced, credit check history results can have questionable accuracy. The degree of accuracy (or inaccuracy) coupled with the national economic climate where there are high unemployment rates and record numbers of home foreclosures, has negatively impacted many citizens' credit histories, without a corresponding degradation of trustworthiness and reliability. The increase in security added by this proposal is unclear.

Additional guidance is needed for the new requirement to check local criminal history records. For example, a person may live within the jurisdiction of multiple law enforcement agencies.

§37.33 – Access authorization program review

The annual access authorization review should be changed. A reasonable frequency would be 36 months, as this area is not expected to change very often.

Facilities utilizing Federal security clearances should be exempted from this section.

Subpart B – Annex A

The focus of this annex appears to be communication between the NRC and the individual nominated as a reviewing official. Information regarding communication between the NRC and the licensee or the individual and the licensee is not discussed. A licensee official, other than the individual nominated as a reviewing official, should be involved in these communications.

An individual is afforded 10 days to initiate an action challenging the results of an FBI criminal history records check. In consideration of holidays and weekends, we suggest revising this to 10 business days. Additionally, the licensee representative should initiate the challenging action at the request of the nominated individual.

Subpart C – Physical Protection Requirements During Use

§37.41 – Security Program

The proposed rule places security requirements on licensees that do not possess but are authorized to possess Category 1 and 2 materials. It is unclear how the current requirements in this area are ineffective, since licensees must implement a full security program before they possess Category 1 and 2 quantities. This new approach is inconsistent and seems to place an undue burden on licensees. §37.41(a) would ensure that licensees implement a security program based on actual possession.

The proposed rule is overly prescriptive as it requires the development of a security plan and identifies the necessary information. Medical licensees under IC orders have already developed their security programs under current requirements, they have been inspected, and compliance has been verified. The benefits to safety and security for this requirement are unclear.

§37.43 – General security program requirements

The proposed rule indicates that refresher training is required "at a frequency not to exceed 12 months." Under this proposal, it would be our understanding that refresher training could be taken greater than 365 days from the previous training as long as it is taken within the same month of the succeeding year.

The proposed rule requires security programs to include a description of the environment, building or facility where radioactive material is stored or used. Many licensees use radioactive material in several different locations each day. Establishing and documenting a site specific security program (for sites that change daily such as pipeline locations) would require many companies to hire additional personnel and involve a significant amount of work without a commensurate improvement in security.

§37.45 – LLEA coordination and notification

The proposed rule adds requirements regarding interactions with local law enforcement agencies (LLEA). Coordination with LLEA was one of the most difficult areas to implement for the current security requirements and places responsibility on licensees for activities that they cannot control. This aspect of the proposed rule is not realistic and appears unenforceable. For example, it is not practical to expect that LLEA would notify a licensee that their response capabilities have become degraded and this provision should be removed. It is also unrealistic and unnecessary to require licensees to provide advance notification to LLEA of work at temporary jobsites. Simply put, there is insufficient information in the public domain to determine who the responsible LLEA is for a specific site (including overlapping jurisdictions for multiple LLEAs) and work at temporary jobsites often times requires that work be

required the same day as the licensee is notified. A three-day advance notification is unworkable and risks safety of critical oil and gas infrastructure if work is not initiated promptly, and many times the timeframe to complete the work in unknown at the outset. Licensees maintain communication abilities at temporary jobsites and call 911 in the event of an emergency – this is sufficient.

The goals and objectives of this section are admirable and an area where NRC should consider taking concerted efforts to engage law enforcement communities to improve situational awareness now, rather than waiting for feedback from licensees regarding potential LLEAs refusing to cooperate. NRC asked several questions in the FRN regarding benefits and periodicity for notifying LLEA of work at temporary jobsites, identification of the appropriate LLEA, and interest that LLEAs may have in receiving this information. Rather than asking industry to comment on this and speculate on these matters, NRC should consider an outreach campaign aimed at direct communications with these entities to better understand their perspectives regarding these issues.

§37.51 – Maintenance, testing, and calibration

It is unclear what more is expected of licensees with respect to calibration, beyond maintenance and testing. NRC should clarify what is expected for compliance with this section.

Subpart D – Physical Protection in Transit

Section § 37.75(a)(2)(i) needs clarification as the term "minimal delay" is ambiguous and subject to interpretation. Because of this ambiguity, there is little or no value added given the requirement to coordinate with local law enforcement. We propose that 37.75(a)(2)(i) at a minimum be clarified or potentially be deleted.

We recommend that the rule language or guidance relative to §37.75(b) & (c) be reworded to allow licensees to utilize the National Source Tracking System as a method to fulfill the notification requirement.

There appears to be an editorial error in section 37.75(d) which references 37.75(a)(1). The appropriate reference should be 37.75(b).

The proposal to include a "no-later-than" arrival time places a prescriptive requirement on licensees for activities outside of their control. Once a shipment is given to a carrier the routes and delays are the responsibility of the carrier. Licensees routinely monitor the status of shipments and notify both the carrier and the regulatory agency if a shipment does not arrive within a reasonable timeframe. The regulations should specify what is required and not how to achieve it; this will avoid making the system fail and unnecessarily subjecting the regulated community to essentially irrelevant non-compliances.