



Blood Systems

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

August 23, 2010

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

ATTN: Rulemakings and Adjudications Staff
Docket ID: NRC-2008-0120

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USNRC

August 25, 2010 (1:00pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

To Whom It May Concern,

We appreciate the opportunity to provide comments on the Proposed Rule of Physical Protection of Byproduct Material published in the Federal Register, Vol. 75, No. 114 on June 15, 2010. We have the following comments on the proposed rule:

10 CFR 37.21(a)(3): By (insert date - 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 (insert the 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 specified in § 30.6.

Comment: We assume compliance with this part would be achieved by submitting a letter to the NRC or appropriate agreement state indicating we have successfully implemented an access authorization program. We would like to see clarification of this assumption in the law itself as it is vague as written and open to interpretation on what is required to comply with this part.

10 CFR 37.23(b)(2): Reviewing officials must be required to have unescorted access to category 1 or category 2 quantities of radioactive materials or access to safeguards information, if the licensee possesses safeguards information, as part of their job duties.

Comment: We do not understand the rationale for requiring the Reviewing Official to have unescorted access to the irradiator when, in many cases, they may never need it. If the intent is simply to have this person fingerprinted and background checked to undergo the same level of scrutiny as those who would be given unescorted access, we feel the regulation should be amended to state as much. There may be other requirements surrounding unescorted access that could be implemented in the future that may not apply to the Reviewing Official which could cause hardships for licensees at that time.

10 CFR 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.

Comment: Currently, it is not required for the Reviewing Official to have prior approval by the NRC. We feel the regulation should provide direction on how a licensee will know if an appointed Reviewing Official has been "approved".

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10 CFR 37.25(a)(6): Credit history evaluation. Licensees shall evaluate the full credit history of the individual who is applying for unescorted access authorization. A full credit history evaluation must include, but is not limited to, a review and evaluation of all of the information that is provided by a national credit-reporting agency about the individual's credit history. For individuals including foreign nationals and United States citizens who have resided outside the United States and do not have established credit history that covers at least the most recent 7 years in the United States, the licensee must document all attempts to obtain information regarding the individual's credit history and financial responsibility from some relevant entity located in that other country or countries;

Comment: We feel that credit history should not be a required element of the background investigation, especially in today's economic climate where many people are experiencing significant financial hardships due to loss of job or other reasons. Also, employees may not have much, if any credit history if they are young. The regulation provides no guidance on what is and is not acceptable. We feel employees could potentially interpret the requirement for a credit history as discriminatory.

10 CFR 37.25(a)(7): Criminal history review. 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;

Comment: We do not understand the purpose of obtaining criminal history records from local sources if a national background check is being performed. We suggest removing this requirement or providing an explanation as to why this check is necessary. Additionally, this information may be very difficult to obtain in many locales.

10 CFR 37.25(a)(8): Character and reputation determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this subpart must be limited to whether the individual has been and continues to be trustworthy and reliable;

Comment: This part is very subjective. The entire process of determining if an individual is trustworthy and reliable is essentially a character and reputation determination. We feel this part has little value and it could be perceived to be discriminatory by an employee if an adverse judgment is made as to their character and reputation.

10 CFR 37.25(a)(9): The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (e.g., seek references not supplied by the individual);

Comment: We feel this part is vague and do not understand how this would be accomplished.



10 CFR 37.25(a)(10): If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after 10 business days of the request, the licensee shall:

- (i) Document the refusal, unwillingness, or inability in the record of investigation; and
- (ii) Obtain a confirmation of employment, educational enrollment and attendance, or other form of engagement claimed by the individual from at least one alternate source that has not been previously used.

Comment: We feel there are many situations in which it would be impossible to obtain confirmation from an alternate source. For example, when trying to confirm employment, if the company where the employee claims to have worked is no longer in business, where else would we go to obtain confirmation?

10 CFR 37.43(a)(1): Each licensee subject to the requirements of this subpart shall develop a written security plan. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this subpart. The security plan must at a minimum:

Comment: We would like to know if the "written security plan" must be a separate document in addition to the Standard Operating Procedures (SOPs) that pertain to irradiator security. We feel it is acceptable for a set of written SOPs to constitute a "written security plan" and would like the regulation to confirm that.

10 CFR 37.45(a)(1)(viii): A request that the LLEA notify the licensee whenever the LLEA's response capabilities become degraded or it becomes incapable of providing a timely armed response; and

Comment: We do not feel there is value in making this request when we would have no way of knowing if the LLEA complied with it even if they agreed to the request. Also, what is the direction if a licensee is notified that the LLEA is not capable of responding?

10 CFR 37.45(a)(5): The licensee shall notify the appropriate NRC regional office listed in § 30.6(a)(2) of this chapter within three business days after the licensee becomes aware of any applicable state or local agency requirement that an initial response to an emergency involving radioactive materials must be provided by other than armed LLEA personnel.

Comment: We feel the NRC should coordinate with the states to be notified in these instances rather than placing the responsibility on the licensees.



Please contact Mark Georgescu at (480) 675-5643 if additional information is required.

Sincerely,

Mary Beth Bassett
Senior Vice President, Quality Management & Regulatory Affairs
Blood Systems, Inc.

PUBLIC SUBMISSION

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Physical Protection of Byproduct Material

Comment On: NRC-2008-0120-0038
Physical Protection of Byproduct Material

Document: NRC-2008-0120-DRAFT-0041
Comment on FR Doc # 2010-13319

Submitter Information

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Organization: Blood Systems, Inc.

General Comment

Please see the attached document for comments.

Attachments

NRC-2008-0120-DRAFT-0041.1: Comment on FR Doc # 2010-13319

Rulemaking Comments

From: Gallagher, Carol
Sent: Wednesday, August 25, 2010 9:31 AM
To: Rulemaking Comments
Subject: Comment on Physical Protection of Byproduct Material
Attachments: nrc-2008-0120-DRAFT-0041.pdf

Van,

Attached for docketing is a comment from Mary Beth Bassett on the above noted proposed rule (75 FR 33901) 3150-A112 that I received via the regulations.gov website on August 24, 2010.

Thanks,
Carol

Received: from HQCLSTR01.nrc.gov ([148.184.44.79]) by OWMS01.nrc.gov
([148.184.100.43]) with mapi; Wed, 25 Aug 2010 09:31:39 -0400
Content-Type: application/ms-tnef; name="winmail.dat"
Content-Transfer-Encoding: binary
From: "Gallagher, Carol" <Carol.Gallagher@nrc.gov>
To: Rulemaking Comments <Rulemaking.Comments@nrc.gov>
Date: Wed, 25 Aug 2010 09:31:01 -0400
Subject: Comment on Physical Protection of Byproduct Material
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X-MS-TNEF-Correlator:
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