PR 30,31,32,33, 34,35,36,37,39,51,71, and 73
(75FR33901)

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Secretary

U.S. Nuclear Regulatory Commission

Washington D.C. 20555

Attention: Docket ID NRC-2008-0120, (Federal Register Volume 75, Number 14, June 15, 2010)

Re: Eli Lilly and Company Response to Docket NRC-2008-0120

Eli Lilly and Company, "Lilly," remains committed to the safe and secure use of radioactive materials under our control and appreciates the opportunity to comment on questions posed to licensees by the NRC and request clarification on portions of the proposed rule published in the June 15th Federal Register regarding Physical Protection of Byproduct Material.

Lilly submitted comments on the preliminary draft proposed rule language published November 19, 2008 in the Federal Register and appreciates the Commission's consideration of these comments as some changes were noted in the current proposed rulemaking. Portions of the current submittal are duplicative of Lilly's previous comments. In these instances, Lilly has attempted to provide additional information to substantiate our position or proposed specific regulatory alternatives for consideration.

As the Commission is undoubtedly aware, the terrorist threat precipitating this proposed rulemaking is an evolving one. This fact is well supported in a report titled "Assessing the Terrorist Threat"[1] released by the Bipartisan Policy Center on September 10, 2010. Statements from this report such as *"There seems no longer any clear profile of a terrorist"* and *"... America faces a dynamic threat that has diversified to a broad array of attacks..."* describe a diversified and evolving threat. Lilly respectfully submits that resources above and beyond those already invested for compliance with the increased control orders are not proportional to the real risk of occurrence of a radiological threat scenario given that it is only one of a widening array of plausible scenarios to be carried out by individuals with diversifying ethnic, economic, educational and social profiles.

Template = SECY-067

DS10

NRC Questions

Section II: (1)Item B8

NRC Question:

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

Lilly Response:

Lilly understands that completing a local criminal history review may reveal criminal activity not captured by FBI criminal history records, but the value of such information is speculative. Lilly's primary concern with the local criminal history review is language in the implementation guidance (page 55, answer A1) suggesting that such a review include a record of arrests. It is not Lilly's usual practice to review arrest data in the course of making employment decisions. Criminal history reviews are generally limited to convictions in order to avoid making character judgments based on unsubstantiated arrests. To this point, proposed 10 CFR 37.27 (6)(b)(1) does state that licensees may not base a final determination on *"(i) An arrest more than one year-old for which there is no information of the disposition of the case; or (ii) An arrest that resulted in dismissal of the charge or an acquittal,"* This criteria so severely limits the consideration of arrest data that its collection would seem to be more of a liability than an asset.

NRC Question:

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

Lilly Response:

No. It is not routine practice for Lilly to conduct employee credit history reviews. In fact, no corporate-wide process or evaluation criteria currently exist for such a review and would need to be created. Such efforts would be resource intensive, with little value realized given the inherent subjectivity of credit data and the notorious inaccuracy of credit histories (a 2004 US Public Interest Research Group, PIRG, study reported that 25% of credit history reports contain serious errors[2]). Also of concern is the growing number of states who have passed or are considering passing legislation restricting employer ability to obtain and use employee credit information (currently Illinois, Hawaii, Washington and Oregon have passed such legislation.)

Perhaps the most compelling argument against use of a credit history check is the Bipartisan

Policy Center's recently released report, "Assessing the Terrorist Threat[1]," which states "There seems no longer any clear profile of a terrorist." This in mind, it is difficult to imagine how credit history, particularly in the hands of radiation safety officers and/or human resources personnel can be reliably interpreted to predict malevolent intent.

NRC Question:

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

Lilly Response:

While Lilly does not agree outright that an individual's financial stability is a pertinent background investigation element (as is the stated intent of the credit history review per page 53 of the Implementation Guidance,) we would propose "SSN Validations" as a less subjective and more reliable alternative to credit history checks. Such screenings are commonly offered by verification services and can provide the following: 1) verification that a name matches a given SSN, 2) death records (if any) associated with the SSN, 3) confirmation of previous addresses, 4) cross checks with the OFAC and SDN Lists, and 5) bankruptcies, liens or judgments associated with the SSN. Such data would provide more precise and less subjective insight to an individual's financial stability.

NRC Question:

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

Lilly Response:

Yes, particularly in the hands of reviewing officials inexperienced in making determinations of the nature demanded by the proposed rulemaking. While some industries may be accustomed to associating an individual's background to a predisposition or likelihood to commit malicious acts, Lilly, (as we assume is the case for many in the research sector) is not. For this reason, we strongly recommend completion of the background check process by a centralized and experienced agency, and elaborate on this concept further in our response to question six below.

NRC Question:

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

Lilly Response:

While the time spent conducting the background check is not inconsequential (on the order of hours per individual, with extreme cases taking up to a week of dedicated effort,) Lilly suggests that the more pertinent question is how effective is it to rely on each licensee to develop and implement their own background check processes? Centralization of the background check process would realize efficiencies of magnitude, and ensure effective and consistent screening. For example, could the security clearance processes performed by the Defense Industrial Clearance Security Office (DISCO[3]) for the Departments of Defense, Energy, Justice and the Central Intelligence Agency be tailored to meet the proposed background check elements for category 1 and 2 quantities of radioactive material? This would appear to be a logistical and legislative possibility given that individuals with government security clearances granted by this agency are exempted per proposed 10 CFR 37.29 (k)(1)from a background investigation . Lilly would be willing to pay a reasonable fee for such services given that it would save resources required to develop our own program, decrease compliance liability and decrease employer liability in the event of an adverse determination.

Not only might this be more efficient, but a group such as DISCO is far more experienced in background investigations of the nature required by the proposed rulemaking than would be licensee personnel. As has been previously discussed, the Bipartisan Policy Committee's recent "Assessing the Terrorist Threat" report[1] well describes the complexity of profiling today's terrorist recruit and provides significant evidence warranting the involvement of experienced professionals in such determinations.

In addition to the above comments, Lilly requests clarification of the below proposed regulations

37.5 Definition: Background Investigation means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

Lilly clarification: We assume this definition of Background Investigation allows for provision of investigation elements to be outsourced by licensees to a third-party verification service, but seek confirmation of this interpretation.

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

Lilly clarification: Please clarify in the regulation how licensees will be informed that their reviewing official has been approved, the anticipated timeliness of such approval and how such approval will be

documented. Please also describe the controls that will be in place to protect the personal information provided to the NRC on behalf of the prospective reviewing official.

37.43 (a)(1) Each licensee subject to the requirements of this subpart shall develop a written security plan.

Lilly Clarification: Lilly currently maintains a high-level corporate security plan. It is our interpretation that the security plan referenced in proposed 37.43 is not required to apply exclusively to security of category 1 and 2 radioactive materials but can be an adaptation of a pre-existing site or corporate-wide plan as long as the 37.43 required elements are met. Please confirm or correct this interpretation.

37.43(d)(3) Before granting an individual access to the security plan or implementing procedures, licensees shall...(ii) Complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthy and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in 37.25(a)(2) through (a)(10.) The 37.25(a)(1) fingerprinting and criminal history records check requirements shall not be applied to those individuals who do not require unescorted access to category 1 or category 2 quantities of radioactive material.

Lilly interprets this requirement to mean that individuals, who by nature of their job position have knowledge of critical components of the security plan, would NOT be required to undergo background investigation unless they have access to the security plan document or any of its implementing SOPs. Examples of such individuals might be a security guard with access to an alarm-response schematic or an IT specialist who supports the IT system responsible for alerting security of adverse indicators in the area of category 1 or 2 radioactive sources. In each case the individual has knowledge of security plan components, but would NOT have access to the plan itself or implementing SOPs. Please clarify whether the background check requirements cited above would or would NOT be required for such individuals.

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...

Lilly Clarification: Lilly has procured the services of a third-party staffing agency to provide off-duty local law enforcement agents onsite at all times. These agents have full response and arrest capabilities (up to and including calling for LLEA reinforcements) while working at Lilly facilities on behalf of this third-party supplier. Will a written agreement with this third party service be acceptable to demonstrate compliance with the LLEA coordination requirements f 37.45?

37.45(a)(1)...The information provided to the LLEA must include...(viii) A request that the LLEA notify the licensee whenever the LLEA's response capabilities become incapable of providing a timely armed response

Lilly requests clarification of the rationale behind requiring the LLEA to notify licensees of compromised response capabilities. It would seem the LLEA is better equipped to arrange for alternative response capabilities than would be the licensee and that this would be an inherent part of their organizational framework. In the case of discretionary activities requiring LLEA support, such as source transportation, requiring advance notification of the LLEA by the licensee provides LLEA ample opportunity to disallow the planned activity if the LLEA is aware their resources will be constrained on any given day. In cases where resources are constrained due to unforeseen circumstances, one would assume LLEAs have contingency plans for such occasions which would be more reliable than expecting licensees to make alternative arrangements. Perhaps the requirement should simply be that the LLEA confirm it has such a contingency plan in case of compromised response capabilities.

Sources:

1) http://www.bipartisanpolicy.org/sites/default/files/NSPG%20Final%20Threat%20Assessment.pdf
2) http://www.uspirg.org/home/reports/report-archives/financial-privacy--security/financial-privacy--security/mistakes-do-happen-a-look-at-errors-in-consumer-credit-reports
3) http://www.clearancejobs.com/security_clearance_faq.pdf

Sincerely,

S. Elizabeth Kay

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Assistant Radiation Safety Officer
Eli Lilly and Company

PUBLIC SUBMISSION

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Physical Protection of Byproduct Material

Comment On: NRC-2008-0120-0070
Physical Protection of Byproduct Material; Extension of Comment Period

Document: NRC-2008-0120-DRAFT-0073
Comment on FR Doc # 2010-25397

Submitter Information

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Organization: Eli Lilly and Company
Government Agency Type: Federal

General Comment

See attached file(s)

Attachments

NRC-2008-0120-DRAFT-0073.1: Comment on FR Doc # 2010-25397

Rulemaking Comments

From: Gallagher, Carol
Sent: Monday, October 18, 2010 2:01 PM
To: Rulemaking Comments
Subject: Comment on Physical Protection of Byproduct Material
Attachments: NRC-2008-0120-DRAFT-0073.pdf

Van,

Attached for docketing is a comment letter from S. Elizabeth Kay on the above noted proposed rule (75 FR 33901) that I received via the regulations.gov website on 10/18/10.

Thanks,
Carol

Received: from HQCLSTR01.nrc.gov ([148.184.44.76]) by OWMS01.nrc.gov
([148.184.100.43]) with mapi; Mon, 18 Oct 2010 14:01:59 -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: Mon, 18 Oct 2010 14:01:08 -0400
Subject: Comment on Physical Protection of Byproduct Material
Thread-Topic: Comment on Physical Protection of Byproduct Material
Thread-Index: Actu7nDn+5mCwYMhT/q888iPChxwkQ==
Message-ID:
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<6F9E3C9DCAB9E448AAA49B8772A448C5469BF5B68E@HQCLSTR01.nrc.gov>
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